February 27, 2018

Subject: Proposal for the Review of Epidemiology Studies from the Open Literature Being Considered for a Basis for Regulatory Action

To: Office of Pesticide Program Managers

From: John D. Doherty, Ph.D.
(DABT: 1982-2017)
Email: Ex. 6

With regard to the situation that has developed over the past several years with chlorpyrifos that is mainly based on an epidemiology report from Columbia University, I would like to make the following proposal for reviewing epidemiology studies to minimize controversy in the future. Quite frankly, based on my rather rocky participation in the chlorpyrifos project until I was ordered to terminate all review work on this chemical, I rather strongly believe that the current situation could well have been prevented or at least minimized.

In particular, the review process in which an epidemiology study (or any study that appears in the open literature) needs to be standardized before any decision with regard to its use in the regulation of the chemical is deemed appropriate and necessary.

**A Call for the Standardization of the Review of an Epidemiology Report in the Open Literature – Production of the Record of Review (ROR)**

To achieve this end, I would like to introduce the following procedure:

The study needs to have a formal record of review (ROR) with a series of signatures of representatives for the several subdisciplines that are involved in the support of the conclusions of the study. In addition, a signature of a senior program official would be required. The roles of the several committees and individuals that would be signing the ROR are as follows:

1. ***Endpoint Evaluation Committee:*** Depending upon the lesion/condition claimed by the publication, the endpoint evaluation would be an expert committee in cancer, behavioral response, or other appropriate committee for interpretation of the significance of the lesion/condition. This evaluation should not be left to one individual.

This evaluation would limit its conclusions with regard to how well the character of the endpoint was assessed for and whether or not the data presented supports the increase in the lesion/condition reported. Some conclusion examples would be as follows:

The study supports the associated of *chemical* with an increase in lesion/condition.

There are problems with the identification of the lesion/condition to render a conclusion for an association between *chemical* and the lesion/condition unsupported. (Refer to pages --- of this ROR).

2. ***Statistical Evaluation Committee***: The sole role of the statistical evaluation is limited to determining if the statistical methods were/were not appropriate and adequately conducted to support the conclusion of the report. A committee of statisticians with expertise in epidemiological studies may need to be established for this evaluation. Although statisticians may disagree about the methods, it is problematic to have just one statistician make this decision. Some conclusion examples would be as follows:

The statistical methods were/were not appropriate and adequately conducted.

The statistical methods were appropriate but there was insufficient information available to determine if the statistics were adequately conducted and the study conclusions are not supported. (refer to pages --- of this ROR).

The statistical methods were in appropriate and the study conclusions are not supported. (Refer to pages ---- of this ROR).

***3. Exposure Assessment Committee:*** The role of the exposure assessment committee is limited to determining that the methodology used to determine the exposure of the cohort is adequate and appropriate. Some conclusion examples would be as follows:

The exposure of the individuals in the study cohort was adequate to support the association between *chemical* and lesion/conclusion.

There were serious problems with the assessment of the individuals in the cohort for exposure to *chemical* such that the conclusions of the study could not be supported. For example, some of the exposure information was obtained via telephone calls and relatives of the allegedly exposed person provided the information long after the exposure was alleged to occur. Refer to pages ---- of this ROR.

There was insufficient information to eliminate confounding factors such as simultaneous exposure to other chemicals to conclude that *chemical* is associated with lesion/condition.

***4. Analytical Chemistry Assessment Committee:*** The role of the analytical chemistry committee is limited to determining if the analytical techniques/methodology was appropriate and adequate for the study. Some conclusion examples would be as follows:

The methods of analysis were/were not appropriate and adequate to determine that *chemical* was associated with lesion/condition.

There were no analytical chemistry data presented in the report. (In this case, no committee review is needed by a qualified chemist should sign the document and if necessary make a statement as to why analytical chemistry data are/are not needed.



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[For the above assessments, it is important to have subdiscipline committees review the study so that the biases of just one reviewer are minimized.

***5. Animal Toxicity Assessor:*** A committee is not necessary for this evaluation since the hazard based on animal studies should already be established by committees. This assessor would normally be the person most responsible for reviewing the guideline studies (animal as well as mutagenicity). This assessor will also include studies from the open literature suggesting the association of the lesion with the chemical in animals. However, any publication supporting the association will need its own ROR signed by two qualified toxicologists. Their role is limited to determining if the lesion/condition is known to occur in laboratory animals and is some cases suggestive by *in vitro* studies. If the lesion/condition occurs in animals, it can support the epidemiological findings. If not, it does not automatically dismiss the epidemiological findings. Some conclusion examples would be as follows:

The lesion/condition has been demonstrated in the guideline study (or studies, name species) so that the conclusions associating *chemical* with lesion/condition are supported.

There is no evidence for the occurrence of lesion/condition associated with *chemical* in the guideline studies or in animal studies in the open literature.

Although there is no evidence for the occurrence of lesion/condition associated with *chemical* in the guideline studies, there is/are publication(s) reporting an association. Refer to pages --- of this DER.

***6. Senior Official:*** The senior official (needs to be determine if this is a Branch Chief, Program Director or Assistant administrator) has the final determination of deciding if the study demonstrates an association between *chemical* and the lesion/condition. Their conclusion must be inclusive of dismissing the significance of the objections of any of the five subdisciplines listed above. Some conclusion examples would be as follows:

There is near (or otherwise) unanimous agreement among the subdisciplines that *chemical* is associated with the lesion/condition in humans. Therefore, *chemical* is considered a direct cause of lesion/condition and the exposure data causing this lesion/condition can be used for risk assessment.

There were serious reservations from the assessors to preclude an association between *chemical* and lesion/condition. Therefore no further regulatory action is considered required at this time. Refer to pages --- of the ROR.

[There are many combinations of the conclusions of the individual subdisciplines that would allow the Senior Official to conclude that the study still demonstrates a plausible/probable association with the lesion condition. The Senior Official will have to justify their decision to conclude that there is a concern for an association in spite of the objections of the individual subdisciplies.] Example:

The association of *chemical* with the increased occurrence of lesion/condition was supported by the endpoint evaluator and the statistician and but not the exposure assessor or the animal toxicity



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assessor and there were no analytical data presented. However, overall, the study is considered to demonstrate an association between *chemical* and lesion/condition. The lesion/condition can be used for risk assessment at the exposure levels reported. Refer to pages ---- of this ROR for a more detailed discussion to support the association of *chemical* with lesion/condition and justification for minimizing the deficiencies in the exposure assessment.

The reservations of both the exposure assessor and the analytical chemistry assessor preclude establishing an association of between *chemical* and lesion/condition in spite of the conclusions of the endpoint evaluator and the statistician. Refer to pages --- of this ROR.

## The ROR Product:

The ROR would include separate sections for detailed commentary of each of the five assessment committees or individual assessors listed above. These sections should clearly demonstrate that the committee/assessors independently reviewed the study (or provided their input) without influence of others. Once the first five committee/assessors finish their respective sections, they meet together with the Senior Official to discuss their findings and conclusions. The Senior Official then makes the overall decision but may consult with others as needed. Ultimately, the decision may go to an SAP for confirmation.

The cover page of the ROR will have a table where the first row identifies the study, authors, affiliations, location and duration of the observation period. The actual study publication will be appended to the ROR. This table will have rows for the names and signatures identifying each of the five subdisciplines and the Senior Official with the first column identify the individual in type, the persons signature and date signed and in the second column, their conclusion as indicated above. An additional row for the conclusions of a SAP review would also be present in the table. The first column would identify the SAP chairman, the date of the review. The second column would state in a few sentences the recommendation of the SAP and the reference to where the SAP report can be found.

Note: In some cases there may be more than one person from each subdiscipline that reviews the report. Separate names and signatures as well as conclusions would then be incorporated into the table.

## Purpose:

The purpose of this procedure is to assure that responsible persons for each of the critical subdisciplines independently review the study in terms of their expertise. Rather than have the publication be accepted by one individual based on the study's face value, the public can see that experts in appropriate subdisciplines evaluated the study.



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The Senior Official is something of a referee that eventually decides on the significance of the study after taking into consideration the inputs from the subdisciplines that may differ in the relative importance or acceptability of the study for regulatory purposes. The Senior Official and the subdiscipline committees own the decision are responsible for defending it.

If industry objects to the conclusions, they can address the conclusions of the Senior Official and the subdisciplines that supported the Senior Officials decisions.

Similarly, if concerned groups object to the conclusions again they will need to address the conclusions of the subdisciplines and the Senior Official.

Therefore the decisions in the resulting ROR should be transparent. The current system renders too much power to individuals who can profit by making career projects for themselves based on the face value of the publication.

I am well aware that a publication in the open literature associating a chemical with a lesion/condition in an epidemiological study is going to be controversial. However, preparing a ROR for such studies with the several subdisciplines all contributing to the Agency's determination of the conclusions in the report will greatly help to minimize controversies. Industry and/or the public can see right away why the Agency made its decisions with regard to the study and protection of public health.

The ROR is not a final conclusion of the study (no documents in EPA should be considered final) and as new information is generated, the ROR can be updated and the recommendations for use (or otherwise) can be adjusted as appropriate. The ROR will also be presenting data or other deficiencies that the authors of the publication can address.

I am looking forward to receiving any comments on this proposal.

email: Ex. 6

**Proposed Cover Letter to Potential Copper Clinical Trial Expert Panel Reviewers**

January 15, 2018

Dear Reviewers:

In 2008, the U.S. Environmental Protection Agency (EPA) Antimicrobials Division (AD) approved public health registrations for "Antimicrobial Copper Alloys" (EPA Reg. Nos. 82012-1 to -6), which are solid, metallic materials containing 60%-99.9% copper. These engineering materials are used to manufacture a variety of touch surfaces in healthcare facilities, community buildings, and homes.[1] The labeling of Antimicrobial Copper Alloys was carefully crafted to ensure that users were well-informed about the proper role of the product as a supplement to – but not a replacement for – routine cleaning and sanitizing programs.

At the time of registration, EPA approved claims for Antimicrobial Copper Alloys based on laboratory data showing that the materials continuously kill over 99.9% of bacteria, including E. coli, MRSA, and VRE, within two hours of contact.[2] Prior to registration, EPA required the registrant, the Copper Development Association (CDA), to conduct outreach to experts in the infection control community.[3] The input received noted that antimicrobial copper could provide a public health benefit as a supplement to existing infection control measures, and included a recommendation to conduct clinical trials to demonstrate the efficacy of the product outside of the laboratory in helping to reduce bioburden and the rate of infection.

Subsequently, the U.S. Department of Defense (DoD) launched an effort to study the antimicrobial properties of copper alloys. DoD funded a multi-site clinical trial of antimicrobial copper use in intensive care units (ICUs) at three facilities: Medical University of South Carolina; Memorial Sloan-Kettering Cancer Center; and Ralph H. Johnson Veterans Administration Medical Center. In conducting the studies, microbial burden was measured on high touch surfaces in patient rooms for 43 months. At month 23, half of the rooms were outfitted with components made from EPA-registered Antimicrobial Copper Alloy materials. After two years of measuring microbial burden on the copper and control surfaces, patient data were collected from July 12, 2010 to June 14, 2011 to investigate the impact on infection rates. During the study period, each facility followed pre-existing infection control measures and cleaning protocols.

Results of the clinical trials were peer-reviewed and published in 2012-2013. The researchers reported a greater than 80% reduction in the level of microbes present on components made from Antimicrobial Copper Alloys (*e.g.*, bedrails, IV poles, *etc.*) deployed in outfitted

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1 A copy of the currently registered label for Antimicrobial Copper Alloys Group I is attached (similar labels are registered for Groups II-VI).

2 The currently approved claims are specified on the attached registered label for Antimicrobial Copper Alloys Group I.

3 Outreach was directed to the Association for Professionals in Infection Control and Epidemiology ("APIC"), the American Society for Healthcare Environmental Services ("ASHES"), and a leading expert in the field, Dr. William Rutala from the University of North Carolina-Chapel Hill, among others.

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hospital ICU rooms over the study period. The researchers also identified a 58% reduction in the number of infections acquired by patients in these rooms.

In order to assist the agency in reviewing proposed claims for Antimicrobial Copper Alloys based on the DoD clinical trials (a copy of the proposed claims is included in the supporting materials), EPA is seeking expert review of the clinical data. Included in this package are information on the clinical study, the raw data from the study, and other supporting background materials provided by CDA, as well as charge questions designed to help you and EPA develop a complete understanding of the clinical study under review, and how that data relates to the proposed microbial burden and infection reduction claims that EPA will consider for antimicrobial copper products.

Thank you for your assistance in this matter.

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TSCA
NEW CHEMICALS
COALITION

**TSCA New Chemicals Coalition[1] Position Statement Concerning the Consultation with OSHA Required by New TSCA and EPA Adoption of Restrictions to Address Workplace Exposures**
**December 2017**

## I. ISSUES TO BE RESOLVED

The TSCA that was originally enacted in 1976 was comprehensively restructured and revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA). New TSCA generally requires EPA to issue an order under Section 5(e) governing the manufacture, processing, distribution, use, or disposal of a new chemical substance whenever EPA makes a determination under Section 5(a)(3)(B). EPA is directed to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance … to the extent necessary to protect against an unreasonable risk of injury to health or the environment." As part of this determination, EPA must consider risks "to a potentially exposed or susceptible subpopulation" that EPA deems relevant, which typically will include workers who are occupationally exposed to the new substance during the manufacture, processing, or use of the substance.

While EPA may issue an order under new TSCA Section 5(e) that contains prohibitions or restrictions intended to address workplace exposure, new TSCA Section 5(f)(5) requires that, prior to doing so, "[t]o the extent practicable, [EPA] shall consult with the Assistant Secretary of Labor for Occupational Safety and Health…." This required consultation with the U.S. Occupational Safety and Health Administration (OSHA) is vital as it both acknowledges a role for EPA concerning workplace exposures and explicitly recognizes OSHA's primary responsibility for protecting worker safety and health. TSCA NCC believes that the clear intent of the consultation provision is to require that EPA, before deciding to implement separate TSCA action, will jointly evaluate the contemplated regulatory approach with OSHA, thereby assuring that EPA adequately considers OSHA's established regulatory programs and avoids conflicts or confusion in addressing and mitigating worker exposure risks to a new chemical substance. Section 5(f)(5) addresses the need for consultations "prior to adopting *any* prohibition or other restriction" (emphasis added). Without such ongoing consultations, TSCA NCC believes that EPA's adoption of restrictions for a new chemical to

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[1] The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the new TSCA and to work collaboratively with the U.S. Environmental Protection Agency (EPA) to address these issues.



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address workplace exposures that are also regulated by OSHA would inevitably increase the potential for conflicts concerning -- or material differences in interpretation -- of these parallel requirements.

The value of coordination was recognized in a 1981 Memorandum of Understanding (MOU) between EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), a predecessor of the current EPA Office of Chemical Safety and Pollution Prevention (OSCPP) (attached). The MOU included provisions relating to sharing of information and joint participation in reviews and regulatory determinations on new chemicals presenting an occupational concern as well as sharing of confidential business information (CBI).

Section 4(b)(1) of the Occupational Safety and Health (OSH) Act, which addresses preemption of OSHA's regulatory authority in certain instances, states: "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies … exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." An MOU entered into by EPA and OSHA on February 13, 1991, affirms that OSHA retains principal "broad authority" to regulate workplace exposures to chemicals, while "EPA responsibilities include the protection of public health and the environment." The comprehensive OSHA Field Operations Manual (FOM) (2016), in explicitly addressing the effect of this preemption provision, observes that the only group of workers for whom OSHA regulation is considered to be preempted by EPA authority are farmworkers and pesticide applicators directly exposed to pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for which the worker protection measures in the EPA-approved label instructions preempt OSHA. While changes in the regulatory landscape may change the scope of preemption as well, as the FOM notes, how it is delineated can be a complex determination. It would be inappropriate for EPA to presume that it has been afforded broad authority under TSCA Section 5(e) to make independent regulatory decisions affecting areas that have been in OSHA's domain for decades.

TSCA NCC's reading of the effect of Section 5(f)(5) does not suggest that Congress, in amending TSCA, intended to supplant OSHA's regulatory authority over workers exposed to any chemical substance that is "new" for TSCA purposes. For this reason, it would be prudent to minimize the likelihood that EPA's regulatory activities affecting occupational exposures to new chemicals may be construed to preempt OSHA's authority to regulate exposures of those same workers. TSCA NCC believes that a robust consultation process that assures that EPA does not unnecessarily encroach on OSHA regulation should suffice to prevent any unintended preemption. Furthermore, TSCA NCC believes that the existing 1991 MOU



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(and, as appropriate, the 1981 MOU) should be updated to clarify the effect of TSCA statutory changes, including orders and rules concerning workplace exposures for new chemical substances issued by EPA under new TSCA. Such a revision would also be an appropriate response by EPA to the directive in TSCA Section 26(*l*)(1) that EPA, within two years of enactment, develop any policies, procedures, and guidance that are determined to be necessary to carry out the amendments.

## II. OSHA REGULATION OF OCCUPATIONAL EXPOSURE TO NEW CHEMICALS

OSHA has in place an extensive regulatory scheme, as well as enforcement mechanisms, governing chemical exposure in the workplace. OSHA's longstanding policy preference is to minimize workplace exposures to chemicals through engineering and process controls, which it may specify in substance-specific standards. In those circumstances where personal protective equipment (PPE) is needed to further limit worker exposure, OSHA has adopted PPE regulations; those for General Industry are found at 29 C.F.R. Part 1910, Subpart I. Section 1910.132 describes the current OSHA standards generally applicable to PPE and provides a framework for determining whether an employer has complied with those standards, while, as discussed below, respiratory protection specifically is addressed in Section 1910.134.

In a workplace inspection, OSHA's Certified Safety and Health Official (CSHO) makes the determination whether the employer has selected the particular PPE that is necessary to protect employees from identified hazards. An employer that fails to select adequate PPE generally is subject to a citation for violating 29 C.F.R. § 1910.132(d)(1)(i) unless a provision specific to the type of PPE involved applies instead. If an employer has not provided a written certification that a hazard assessment has been conducted, the inspector is directed to cite the employer for violating 29 C.F.R. § 1910.132(d)(2). If no specific PPE standard applies to the working conditions involved, or does not fully address a workplace hazard, the OSH Act's General Duty clause in Section 5(a) nonetheless requires the protection of the affected employees.

The OSH Act's General Duty clause requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm; it also requires every employer to comply with the occupational safety and health standards and all rules, regulations, and orders issued under the OSH Act. Thus, the General Duty clause adds a broad safety net and also underscores the workplace-centric nature of the OSH Act and of the intertwined responsibilities of both OSHA and individual employers in meeting specific occupational health and safety objectives. It is TSCA NCC's view that the



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General Duty clause requires employers to implement measures to prevent or to mitigate chemical exposures that may present a risk, including instances where the potential risk is identified as part of EPA's review of a new chemical substance and not fully addressed through OSHA's regulations.

OSHA also has issued detailed regulatory provisions addressing respiratory protection in the workplace; respiratory protection is disfavored as a matter of policy whenever engineering or process controls will suffice to limit occupational exposure. Respiratory protection in the form of PPE nonetheless is of particular importance for limiting chemical exposures, and is addressed both in 29 C.F.R. Subpart I at § 1910.134, as well as in various substance-specific 29 C.F.R. Part 1910 standards. The regulatory standard requires use of respirators where they are needed to protect employees from exposures to air contaminants above an exposure limit, or where they are otherwise necessary to protect employee health.

The standard places a range of responsibilities on employers as to the written respiratory protection program that must be in place, including procedures for respirator selection, use, fit, testing, cleaning, maintenance and repair; training in use and hazards; and medical evaluations of employees who use them, among other program elements. The employer is required to select and provide an appropriate respirator (National Institute for Occupational Safety and Health (NIOSH) certified) based on the respiratory hazard(s) present in the workplace, as well as workplace and user factors that affect respiratory performance and reliability. The assessment of workplace-specific hazards is a key prerequisite to the choice of the appropriate respirator; an employer who fails to assess those respiratory hazards and to select respiratory protection suitable for the purpose intended is subject to a citation for violating 29 C.F.R. § 1910.134(a)(2). Likewise, unless a substance-specific standard applies, an inspector can cite an employer for failing to provide the type of respirator needed for the substance and level of exposure involved as required under 29 C.F.R. § 1910.134(d).

TSCA NCC's review of the relevant materials does not suggest that, in enacting new TSCA, Congress intended to alter the scope of the effect of these OSHA requirements. Absent any such indication, TSCA NCC believes that the OSHA regulatory structure, including but not limited to its approach to workplace- and employee-specific PPE requirements, continues to apply where a "new" chemical substance under TSCA is involved.



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## III. RECONCILING EPA'S OBLIGATION TO PROTECT AND EPA'S OBLIGATION TO CONSULT

Although EPA has an obligation to formulate and to adopt TSCA Section 5(e) orders that include measures to protect workers from exposure to new chemical substances, this duty only applies "to the extent necessary to protect against an unreasonable risk." When this duty is viewed in juxtaposition with the mandatory consultation requirement in new TSCA Section 5(f)(5), it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme, including the General Duty clause, and to adopt additional restrictions or prohibitions only when they are needed to protect against unreasonable risk.

Given the robust nature of the existing OSHA regulatory program, the proper role for EPA should be to provide hazard identification and risk assessment information that OSHA and affected employers can utilize in selecting appropriate PPE, including respiratory protection measures. For example, EPA can provide its hazard, exposure, and risk assessment information on a specific new chemical to OSHA and to the notifier, which will assist OSHA and affected employers in selecting the respiratory protection equipment and other PPE needed to comply with OSHA's regulations in 29 C.F.R. §§ 1910.134 and 1910.132. In TSCA NCC's view, when OSHA and the notifier receive EPA's hazard, exposure, and risk assessment for a new chemical substance, these materials must be considered by all employers who manufacture, process, distribute, or use the chemical in satisfying their obligation to provide a safe working environment. EPA could also make its new chemical hazard assessments more widely available, for example, by including them in its ChemView system. The chemical identity (where non-CBI), new chemical case number, and the accession number and generic name for CBI chemicals can also be included. In the case of commenced CBI new chemicals, EPA could make its appropriately sanitized hazard assessment available in responding to a *bona fide* request to ensure that future manufacturers are aware of its assessment. To ensure that this occurs, EPA could amend its *bona fide* procedures at 40 C.F.R. § 720.25 to include this step.

EPA can utilize specific restrictions in TSCA Section 5(e) consent orders to mitigate workplace exposure, but this authority is also less pervasive in nature than OSHA's broad authority to control occupational exposures. The same is true of EPA's use of Section 5(a)(2) significant new use rules (SNUR) to extend the requirements to entities beyond the notifier. Such approaches do not provide the same breadth of protection and the ongoing compliance responsibilities on the employer afforded by the OSH Act and OSHA's implementing measures. TSCA NCC believes that careful ongoing consultation with OSHA, as required under new TSCA, along with a full appreciation of the scope and effect of the OSH Act



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and OSHA's implementing measures, is essential to ensure adequate protection of all workers while also assuring that EPA only adopts separate restrictions in consent orders to the "extent necessary" to protect against an unreasonable risk.

On balance, TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Even when the measures in question merely replicate what the applicant itself has suggested in a proposed Safety Data Sheet (SDS), such prescriptive orders have a variety of significant disadvantages. Such orders ignore OSHA's established expertise and the robust existing regulatory program, risk creating disputes over whether the EPA action has preempted OSHA's general authority to protect the involved workers, will inevitably lead to conflicts with or disputes over interpretation of parallel OSHA requirements, and may have applicability that is significantly limited by jurisdictional factors. It merits noting, as well, that OSHA does not give its approval or sign-off to the recommendations contained in SDSs and that recommendations in Section 8 of an SDS as to PPE are by no means determinative from a compliance standpoint. OSHA relies as well on its own considerable expertise, on the degree to which any industry consensus standards may be relevant, and on the impact of site- or employee-specific circumstances. For all of these reasons, TSCA NCC also believes that it is of paramount importance that to meet its obligation under Section 5(f)(5), EPA promptly should create a mechanism for the necessary ongoing consultations with OSHA. TSCA NCC further recommends that EPA act swiftly to meet its responsibilities under Section 26(*l*)(1) and commence discussions with OSHA that will lead to an update of existing MOUs to delineate clearly each agency's role in regulating exposure to new chemical substances given the changes in new TSCA.

For the reasons elaborated above, TSCA NCC is of the view that for many, if not most, of the new chemicals for which EPA has proposed workplace restrictions under TSCA, the OSH Act and OSHA's regulatory program, once EPA has informed OSHA and the notifier of its occupational risk assessment, will be sufficient to ensure workplace protection and thereby make any unreasonable risk to workers "not likely." Section 5(e) requirements to restrict workplace exposures should be reserved for those instances where EPA has determined, after consultation with OSHA, that the OSH Act and OSHA's regulatory program are not sufficient to protect against unreasonable risk from workplace exposures and that TSCA action therefore meets the "extent necessary" requirement. To the extent that EPA proceeds as recommended by TSCA NCC and relies on the OSH Act and OSHA's regulatory program, this will also have the benefit of reducing EPA's administrative burden currently spent in negotiating consent orders and promulgating SNURs for occupational concerns. Such a change in approach could also allow



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EPA to focus these regulatory resources on the potential risks to the environment and the general population -- areas that do not present the same level of overlapping authority and duplicative requirements as exist for workplace exposures.

Attachment



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- **Information Date:** 01/19/1981
- **Agreement Agency:** The Office of Pesticides and Toxic Substances and U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES,
U.S. ENVIRONMENTAL PROTECTION AGENCY
AND THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR
FOR

- GENERAL COOPERATION

- SHARING OF CONFIDENTIAL BUSINESS INFORMATION

- OSHA-EPA COOPERATION IN THE TSCA PREMANUFACTURE NOTIFICATION PROGRAM

- TRANSFER OF EPA INFORMATION ON SUBSTANTIAL RISK NOTICES

I. GENERAL WORKING AGREEMENT

This Memorandum of Understanding establishes a general working relationship between the Occupational Safety and Health Administration, U.S. Department of Labor, and the Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, regarding matters having or potentially having an effect on the activities and responsibilities of the two agencies.

II. COORDINATION

To achieve the coordination desired by both EPA AND OSHA, each agency hereby designates a coordinating office. The coordinating office for the Office of Pesticides and Toxic Substances (OPTS) will be the Office of Toxics Integration (OTI); for the Occupational Safety and Health Administration (OSHA), the Division of Interagency Programs. These offices shall serve as the initial communication link between the two agencies. Future specific agreements will be made by the program offices of OSHA and EPA's Office of Toxic Substances. Parts A, B and C below are directed at specific areas of coordination for sharing of confidential business information, OSHA's cooperation in the OPTS premanufacture notification program, and referral to OSHA of TSCA section 8(e) notices.

In carrying out their respective responsibilities, OPTS and OSHA will, to the extent practicable, consult and exchange information with each other through the coordinating offices. Specifically they will:

(1) Coordinate programs, including the development of standards, to avoid duplication of effort, to assist in setting priorities, and share information and research;

(2) When appropriate, consider the development of joint regulatory efforts. If no joint efforts are possible, both agencies will coordinate the development of any regulations concerning occupational exposure to new chemicals, to the extent feasible;

(3) Exchange information and report on general enforcement matters and on particular situations of common concern to each agency;

(4) Make every effort to achieve uniformity of approach in long-range planning;

(5) Obtain legal and policy positions on statutory authority regarding the extent to which the other agency can remedy a particular condition or matter that may be within the regulatory purview of the agencies;

(6) Use communication systems available to both agencies for educational services to the public about safety and health topics.

A. Confidential Business Information Exchange

PURPOSE:

This section allows OSHA to have access to confidential business information (CBI) submitted to EPA under the Toxic Substances Control Act (TSCA). OSHA will use this information to assist in fulfilling its duty to protect worker health under the Occupational Safety and Health Act of 1970.

SCOPE:

OSHA is permitted access to all confidential business information submitted to EPA under TSCA. When OSHA requests transfer of specific CBI, a justification of the need for access will be submitted through the OSHA Document Control Office (DCO) to any DCO in OPTS. OSHA will treat all such information in accordance with the Memorandum of Understanding. When OPTS initiates the transfer of CBI, a justification of OSHA's need for access should be prepared by the appropriate EPA program official and submitted to an OPTS DCO prior to the transfer of any documents containing confidential business information. The appropriate OPTS DCO must approve the justification prior to transfer of CBI.

PROVISIONS:

(1) OSHA will protect information received from EPA under this agreement by following the procedures set forth in its "OSHA TSCA Confidential Business Information Security Manual." The procedures have been approved by EPA's Inspector General's Office, and they meet or exceed the requirements of EPA's own "TSCA Confidential Business Information Security Manual."

(2) OSHA agrees that it will not release or transfer TSCA confidential business information outside of OSHA without the prior approval of EPA.

(3) OSHA will normally return confidential documents to EPA within one year, but with approval by the OPTS Document Control Officer, will be granted extensions. In addition, with approval of the OPTS Document Control Officer, OSHA may destroy the documents according to the requirements of the EPA TSCA Security Manual instead of returning them to EPA.

(4) OSHA personnel will be made aware of the possible criminal liabilities that may result from unauthorized release of CBI and will sign the TSCA-Federal non-EPA employee confidentiality agreement (Appendix 14).

(5) The Information Control Branch of the Management Support Division of OPTS (EPA) will provide initial CBI training to appropriate OSHA staff.

(6) A physical inspection of OSHA's security facilities will be made by EPA. No exchange of TSCA CBI will be made until such facilities are found to be satisfactory. There will be future periodic inspections of OSHA's security program by EPA.

(7) Following inspection and approval of OSHA's security facilities, a Federal Register notice will be published announcing this agreement and will provide the required ten days of notice, covering all future sharing of data under this section, pursuant to section 2.209 of EPA's regulations on confidentiality of business information, 40 CFR Part 2, Subpart B.

B. Premanufacture Notification (PMN) Data Exchange Procedure

PURPOSE:

This section deals with the exchange of PMN data between OSHA and OPTS. PMNs can provide information about possible worker exposure to new chemicals before they are produced on a large scale, enabling both OSHA and OPTS to discuss any possible hazards to exposed worker populations and, if necessary, coordinate action on these chemicals.

SCOPE:

OSHA and OPTS will work to assure that complete and timely notification is made concerning PMNs which may involve or affect occupational exposures to chemical hazards, and also to assure necessary coordination between OPTS and OSHA, including joint review of selected PMNs. This will permit OPTS to have the benefit of OSHA expertise in assessing occupational exposure risks, and will alert OSHA to possible chemical threats to worker health.

PROVISIONS:

To assure the above conditions are met, the following procedures are established:

(1) Contacts with OSHA concerning PMNs will be initiated by the Notice Manager for a particular PMN or by OTI through the designated individual in the OSHA Division of Interagency Programs. This individual will receive all data and information from EPA and be responsible for the response from OSHA. This individual shall coordinate the OSHA response or refer the EPA Notice Manager to the appropriate OSHA staff.

(2a) In order to assure that OSHA is informed of the status of EPA actions on PMNs, EPA's Chemical Control Division (CCD) will forward to the OSHA representative, as available, a copy of EPA's weekly PMN report. OSHA will use the report to identify PMNs of potential concern about which OSHA has not been contacted by OTI or the Notice Manager.

(2b) If the occupational exposure to a chemical is a concern during initial review, the Notice Manager or OTI will notify OSHA. EPA may request OSHA data concerning the chemical or its analogue or may refer the PMN to OSHA for information or consideration if no TSCA action is to be taken.

(2c) If a PMN for which there is concern regarding potential occupational exposure, goes into a more detailed review, the Notice Manager or OTI will notify OSHA. During the detailed review, Chemical Control Division may request technical assistance from OSHA to aid in EPA's assessment of the PMN and invite OSHA to participate in the work group.

(3) During the development of any regulatory action on a PMN for which occupational exposure is of concern, CCD will consult with OSHA. OSHA may be asked to participate in the detailed review work group for the PNM to assist in development of regulatory options. At that time, OPTS will provide OSHA with copies of documents generated by the OPTS initial review which describe the problem. As a member of this group the OSHA staff may be involved in reviewing draft regulatory actions and will be provided with a copy of the package which enters the EPA official rulemaking and clearance process.

(4) EPA will notify OSHA representatives of the final action taken by EPA on any PMN where occupational exposure is a concern.

C. Notices of Substantial Risk

PURPOSE:

This section provides a mechanism for EPA to provide OSHA with information submitted by industry under section 8(e) of TSCA, Notices of Substantial Risk.

SCOPE:

Section 8(e) of TSCA requires that any person who manufactures, processes, or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the substance of mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA.

For each 8(e) notice received, the OPTS Chemical Hazard Information Branch (CHIB) prepares a status report. CHIB will, by this agreement, refer to OSHA any 8(e) notices in connection with which CHIB identifies an occupational exposure of concern. OTI will coordinate any necessary follow-up work with OSHA, such as plans for further evaluation or discussion of regulatory action.

III. AUTHORITY

The Office of Pesticides and Toxic Substances enters into this agreement under the authority of Sections 9 and 14 of the Toxic Substances Control Act (15 USC 2601, et seq.). Section 9 of TSCA requires certain coordination of actions taken under TSCA with actions taken under other Federal laws. Section 14 of TSCA provides that confidential business information may be disclosed to any officer or employee of the United States in connection with the official duties of such officer or employee under any law for the protection of health or the environment.

The Occupational Safety and Health Administration enters into this agreement under authority of the Occupational Safety and Health Act of 1970 (29 USC 651, et seq.), Section 7(c)(1). That section allows the Secretary of Labor to "use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement...."

IV. PERIOD OF AGREEMENT

This Memorandum of Understanding shall continue in effect unless modified by mutual assent of the parties or terminated by either party upon a 30-day advance written notice to the other party.

This Memorandum does not preclude the parties from entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.

Nothing in this agreement is intended to diminish or otherwise affect the authority of either agency to carry out its respective statutory functions.

This Memorandum will become effective on the date of the last signature.

Marilyn C. Bracken
Associate Assistant Administrator
for Toxics Integration

Warren R. Muir
Deputy Assistant Administrator
for Toxics Substances

TSCA
NEW CHEMICALS
COALITION

December 1, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the amended Toxic Substances Control Act (TSCA) and to work collaboratively with you and your team to address them. Thank you for the opportunity to meet on November 16; we appreciate the discussion that we had.

One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes that the U.S. Environmental Protection Agency (EPA) needs to implement an appropriately robust and ongoing consultation process with OSHA "prior to adopting any prohibition or other restriction" per TSCA Section 5(f)(5) that addresses occupational exposure issues. We believe that such a procedure is needed to ensure that EPA's adoption of restrictions fully considers and avoids conflicts with OSHA's established regulatory programs in addressing and mitigating worker exposure risks to new chemical substances, a result Congress seemed to intend in amending TSCA.

Picking up on a point raised in our meeting, we note for your information that EPA's *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*,[1] requires that the notification include, among others:

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[1] Available at https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.

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- A description of each specific worker activity during which workers may be exposed to the new chemical substance. Activities must be described even if workers wear protective equipment. The SDSs indicating recommended protective equipment should be submitted as part of Hazard Information in Part I, Section C, subsection 3 of the notice form.
- Information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance (*i.e.*, type of gloves, type of goggles, National Institute for Occupational Safety and Health (NIOSH)-certified 21c respirator, NIOSH-certified 19c respirator, closed containment system, nitrogen blanket, and related measures).
- Information on the physical form of the new chemical, the maximum number of workers exposed, and the maximum duration of exposure in hours/day and days/year.

The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical reviews, EPA staff will have access to available understanding concerning occupational exposures to the new chemical and the engineering controls or personal protective equipment (PPE) that the notifier believes is needed to protect workers, and on which the notifier will be regulated under OSHA.

As discussed in more depth in the attached paper, the TSCA NCC does not believe that EPA's approach under TSCA adequately appreciates and recognizes the significance and effect of OSHA's statutory authorities and extensive regulatory scheme, as well as its enforcement mechanisms, governing workplace chemical exposures, including to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants



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above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the Occupational Safety and Health (OSH) Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty requirement is, as you recognize, particularly relevant to new chemicals given the limited information that is often available.

We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making determinations and taking required actions, Congress included the OSHA consultation provision at Section 5(f)(5) to ensure that EPA's regulation of new chemicals did not create or result in conflicts with requirements implemented by OSHA.

Although EPA has an obligation to review and make determinations regarding worker exposure issues and to formulate and adopt TSCA Section 5(e) actions that include measures to protect workers, this duty applies "to the extent necessary to protect against an unreasonable risk." When this duty is juxtaposed with the mandatory consultation requirement, it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme and to adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks not otherwise addressed.

Accordingly, the proper role for EPA should be to provide hazard identification and risk assessment information to the new chemical notifier and to OSHA to make these parties fully aware of EPA's assessment and its identified occupational concerns, if any. Once informed of EPA's assessment, the employer will be known to have information that must be considered in selecting respiratory protection and other PPE needed to comply with OSHA's broadly applicable regulations and with the General Duty clause requirement that employers provide a safe working environment. By the same token, once OSHA has been informed of EPA's



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assessment, it will be in a position to enforce its regulations and to ensure that the General Duty clause requirements are being satisfied.

For these reasons, and others elaborated in the attachment, the TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Instead, the TSCA NCC recommends the following approach if EPA identifies a workplace-specific risk concern:

1. EPA should consult with OSHA on the workplace risk concern.

2. EPA should inform the notifier of its assessment and concerns.

3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA, as well as OSHA's established expertise and robust existing regulatory program, to ensure worker protection.

Failure to follow a procedure as outlined above risks creating disputes over whether EPA's action preempted or created conflicts with OSHA's general authority and its regulations.

The TSCA NCC recognizes that the approach being advocated is at odds with EPA's longstanding practice in assessing and regulating new chemicals. Nonetheless, for the reasons provided above and elaborated in the attachment, TSCA NCC believes that EPA's prior and current approach is mistaken in that it does not give due recognition to OSHA's authorities and regulations and their role in ensuring a workplace free from recognized or potential occupational hazards. We believe that a modification in EPA's approach is necessary, given the changes in amended TSCA, including the OSHA consultation requirement. While EPA may have believed that, whenever an OSHA Permissible Exposure Limit (PEL) (or similar enforceable limit) is not in place, there is no enforceable requirement for companies to protect their workers from new chemical exposures, this belief is mistaken; and, as explained in this communication, does not have a basis in law or policy. Quite to the contrary, once EPA has informed the notifier and OSHA of its hazard and risk assessments, it has had the effect of triggering and setting in motion the existing regulatory requirements on employers to protect workers from recognized or likely occupational harms. Thus, any belief by EPA that, in the



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absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

Put another way, EPA's current practice under amended TSCA to equate any potential health hazard to represent an unreasonable and unmanaged risk to potentially exposed workers represents a misreading of the broadly applicable and pervasive regime that is implemented and enforced based on the OSH Act and OSHA's regulations and policies. On the contrary, once appropriately informed of EPA's concerns, any employer having a commercial relationship to the notifier must be made aware of and must consider EPA's assessment conclusions and respond appropriately to meet their obligation to protect workers and provide for a safe workplace. Furthermore, the fact that OSHA has also been informed of EPA's concerns puts to rest any questions about the level of information and the hazard, exposure, and risk assessments that the notifier and affiliated employers have access to, and establishes a factual written record that can be considered during any OSHA inspections or enforcement actions.

The TSCA NCC believes that for many, if not most, new chemicals for which EPA has proposed workplace restrictions under new TSCA, once EPA has informed OSHA and the notifier of its occupational risk assessment, that will be sufficient to ensure adequate workplace protection and to make any unreasonable risk to workers "not likely." Having made such a determination regarding occupational risks, EPA should proceed to meet its obligations to assess and determine other exposure risks, such as to the environment and general population, and to take the steps required depending on the final determination. Such a change in EPA's approach would avoid the issues associated with overlapping authority and imposing duplicative, if not conflicting, requirements for workplace exposures while also allowing EPA to focus its regulatory resources on other potential risks that are not subject to the overarching and comprehensive requirements that otherwise apply in the workplace.



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We hope you find these comments helpful. We would be pleased to discuss them with you and your staff in more detail prior to the **December 6, 2017**, public workshop if that is of interest.

Sincerely,

Kathleen M. Roberts

Attachment
cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)
Kevin W. McLean, Esquire (w/attachment) (via e-mail)
Brian P. Grant, Esquire (w/attachment) (via e-mail)

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(09/24/02 - Revised)
(07/18/17-Revised)[1]

# Defined Formats Proposal: Increased Efficiency and Reduced Costs in the Submission and Review of Pesticide Studies

J.D. Doherty, Ph.D., D.A.B.T. (primary author)
William Irwin, Ph.D., D.A.B.T. (secondary contributor)

**Executive Summary**

**This proposal defines a system to *improve efficiency* and to reduce taxpayer costs in the review of the toxicity, chemistry, fate and exposure studies submitted in support of the registration of pesticides to the Office of Pesticide Programs of the Environmental Protection Agency. This Defined Formats approach can save OPP $ millions/year in staff and contract work expenses derived from the taxpayers. Since the format was first proposed in the mid 1990's, OPP could have saved over $50 million in contract and staff expenses across all the disciplines. The Defined Formats system simply allows the pesticide companies to write the pesticide draft study analysis from the full study reports which are then reviewed by the EPA, saving taxpayer money and greatly speeding up the registration process. The pesticide companies are the experts on the study results and it would be much more efficient if they wrote the evaluation analysis and the EPA simply reviewed the evaluations for accuracy. The Defined Formats would better allow the EPA to meet the deadlines and obligations of FIFRA, FQPA and PRIA, for increased protection of children at decreased cost to the taxpayers. The Defined Formats approach to company data evaluation has applications in other offices across the Agency for further savings to the taxpayers. The computer technology to support this proposal has been available for decades.**

## I. Introduction

In this proposed system, the OPP reviewers will still retain all authority and responsibility to classify the study, identify study deficiencies, identify all responses to treatment, write a discussion on their interpretation of the data and write the executive summary. The purpose of this proposal:

-Increase the efficiency and decrease the taxpayer expense of assessing pesticide studies

[1]Previous versions have been prepared since approximately 1992. Modifications in this current version have been made partly in response to comments by various OPP staff.

across all disciplines in OPP (toxicology, chemistry, fate, exposure, etc)

- Utilize the reviewers' time more *efficiently* so that more quality time is spent actually analyzing the data and better supporting the Food Quality Protection Act (FQPA, unamiously approved by Congress) to protect children's health.

-Provide a more balanced product that assures that all customers including the public that the peer review committees considered both the study author's conclusions and the EPA reviewer's conclusions and is supported by the FIFRA statute.

-Provide a more useful product for other government agencies that utilize OPP's reviews of pesticide toxicity data such as WHO, CALEPA and Canada.

-Improve the OPP ability to meet PRIA deadlines, often missed in the current review system.

-Provide an assurance against the "cut and paste" plagiarism promoted by the current OPP system.

This proposal provides that the *study authors* complete *specifically defined supplements or formats that will be designed by the Office of Pesticide Programs (OPP) staff* and toxicologists from other governmental agencies that contain the facts of the study including the methods and materials and obvious responses to treatment in the test animals. The formats present the facts of the study and not the interpretation of the study for regulatory purposes.

The basic tenet that justifies this proposal has been valid for many years. FIFRA clearly states that the burden of proof for a pesticide's safety is on the registrant. The registrant is therefore obligated to provide a document that can be used for the Agency's purposes that does not have to be rewritten at government expense of time and resources. The pesticide company has already written the full study reports and they are the experts on the information, it is easy for them to write the summary Data Evaluation Records (DERs) from the full study documents. The Defined Formats approach requires that the full study report have a defined format which would make it much faster to write the draft study DERs. The Defined Formats system could speed up the pesticide registration process by up to one year if the EPA was not responsible for this step in the process. The EPA would still have the authority to revise the draft DERs to meet their policies.

The conduction and review of toxicity studies are a means to an end. It is the *quality of the study* that satisfies the data requirement, characterizes the toxicity of the chemical and drives a meaningful risk assessment. The quality of the study is related to the design, preparation, conduction and reporting at the laboratory and by the people who performed the study (often the

pesticide companies/registrants). The proposed supplements are a form of reporting the study. A DER prepared by OPP/HED staff or its contractors, no matter how well polished with fancy outlines and tables, does not improve the quality or render added value to the study. Having contractors write DERs actually gives the HED reviewers two documents to review for each study and decreases efficiency.

## II. **Factors that Justify a Consideration of this Proposal.**

1. Conduction of the study and the generation of toxicity data.

Since the current 870 series study protocols are so specifically designed to meet a particular guideline, there should be no need to copy over the methods and materials for each study review, except for deviations that may invalidate the study. Such information related to the particular properties of the test chemical, the test animals used and the procedures used for all analyses and tissue preparation are better presented directly by the study author or the pesticide company, they are the experts in the study results and conduct.

Toxicity studies consist of the generation of data that is gathered by direct observation such as clinical signs, assessment of the behavioral parameters in neurotoxicity studies, counting of fetuses and their visible malformations in developmental toxicity studies and necropsy. In the case of direct observations, when the event occurs, only the observer can record it and note its severity and duration. The reviewer cannot change the data and observations made by direct observations. Again, this information is best reported in the evaluation record (DER) directly by the laboratory or the pesticide company for the toxicity, chemistry, fate and exposure studies.

In the case of data such as hematology, clinical chemistry and urinalysis that are mostly generated by modern and highly sophisticated analytical instrumentation, there is nothing the reviewer can do to change the readings as presented in the study report. The reviewer's responsibility is to be able to identify inconsistencies in the data that would suggest something is wrong with the instrumentation that may have given a false result or to spot other indications of possible error.

In the case of histopathology data, the pathologist reading the slide has total control of the observation and diagnosis. The OPP toxicology reviewers cannot see what is on the slides. Any question regarding the pathology diagnosis in the report has to be directed to OPP's consulting pathologists. The reviewer can look for consistency in the gross pathology and histopathology reports but this should not require that the reviewer copy over the study report tables. Also, when gross necropsy tables are prepared, the current DER does not provide that an animal by animal comparison with the histopathology be provided.

Another compelling reason for having the study author or company prepare the data in a defined format is when the study author is a specialist in some particularly narrow field

of toxicology. Only such specialists can best present the data with the tissue slides, chromatograms and hard data directly available to them, not provided to the EPA with the full study reports.

2. The study authors already identify the critical responses to the pesticides and indicate responses that may be related to treatment but in their opinion do not relate to treatment.

The EPA reviewer needs to spend time trying to identify responses to treatment not already indicated by the study author. Any subtle responses that a EPA reviewer identifies that are not already indicated by the study authors are controversial and require resolution of their significance by peer review groups. The HED reviewers need to spend quality time to make a case that these subtle responses are indeed significant, rather than spending large amounts of time simply transcribing information into study DERs.

3. The OPP Peer Review Committees and Risk Assessors and other governmental review groups have emerged as the principal customers of the reviews of toxicity studies.

The 1995 and later 2001 versions of the Data Evaluation Record (DER) formats were specifically designed to meet the needs of the various OPP peer review committees. OPP has committed to harmonize its reviews so that they can also be used by other governmental regulatory groups such as CALEPA, Canada and WHO. These groups are now very important customers of EPA's reviews of pesticide toxicity studies. Thus, a product that produces a first hand account of the study in the format that will be a part of the review product as well as OPP/HED reviewer's interpretation that would result from this proposal better suits the needs of its principal customers. For example, they can directly compare the facts presented by the study author and the EPA reviewer.

4. The current system of DER production does not provide an assurance against "cut and paste".

Completing the DER as per the current instructions requires the reviewer to include the methods and materials and the obvious responses to treatment. All of this information is routinely taken from the full study report and incorporated verbatim into the OPP DER, which could much easier be done by the company. In the current system there is no way for someone reading the DER to tell if the information entered in the table are the same as from the study author's data tables or if the conclusions entered by the reviewer are the same as the study author's. The proposed defined formats system clearly indicates what was provided by the study author and what the EPA reviewer contributed. Thus, the defined formats system provides a better assurance that the OPP review was not cut and pasted.

5. OPP scientists are customers too.

In the Total Quality Management (TQM) paradigm, customer satisfaction is the driving force. The products submitted to customers are supposed to satisfy their needs. OPP

scientists provide products in the form of reviews for their customers such as the Peer Review Committees. The OPP toxicologists, chemists, physicists and exposure scientists are also customers of the products that are submitted to them for review. It stands to reason that they can ask for products that more efficiently satisfy their needs.

6. Study audits.

The most appropriate way to demonstrate that study discrepancies have occurred in a study would be to audit that study on site. The OPP reviewers would still have the authority to request a study audit if there is a reasonable suspicion of study discrepancies.

## III. **The Roles of the Study Author and Reviewer.**

The roles of the study author and toxicology reviewer (either an OPP staff or a contractor) would be as follows:

Study Author. The study author completes the study and prepares and submits the entire study*. The study author also prepares defined formats DERs as a supplement that strictly follows prescribed instructions as provided by OPP scientists for describing certain specific factual aspects of the methods and materials used, certain factual data that demonstrate the proficiency of the study (i.e. survival or pregnancy rate etc depending on the study type) and the effects of the test material. The obvious responses to treatment include those parameters that are statistically significant in the treatment groups as well as those parameters that the study author believes to be treatment related. The NOAEL and LOAEL as determined by the study author for each of several investigational parameter groups would be presented in the Table of Concurrence/Non-Concurrence (see below).

[*Note: The Formats as designed by the HED scientists can eventually be incorporated as the study report so that the author does not have to prepare two documents.]

OPP Reviewer. The OPP reviewers would first review the study report, ascertain that the study is valid and identify all study deficiencies (if any) as well as identify the responses to treatment using the summary tables and the raw data. The reviewers then ascertain that the supplements contain all the necessary methods and materials parameters and that the obvious and suspected effects of the test material are consistently presented.

OPP reviewers should be trained to know what to assess, expect from and interpret in a toxicity study. *Thus, a good review depends on the work habits of the individual reviewer.* Trained reviewers should welcome this proposal because it frees them from simply transcribing the mundane aspects of the study and allows them to use their judgment and expertise more efficiently. This proposal raises the level of professionalism of OPP's science reviewers.

If the reviewer identifies an effect of the test material that was not identified by the study author, the reviewer can enter these data in a Table in the reviewer's discussion Another item that can be included in appendixes are reanalysis of the data by statistical methods not already used by the study author if the alternate statistical analysis renders a different interpretation.

The reviewer then completes a Table of Concurrence and Non-Concurrence in which the many parameter groups of a study are listed in one column, the study author's conclusion in the second and the reviewer's statement as to whether or not they concur with the study author. The design of the Table of Concurrence and Non-Concurrence would be different for each guideline study type to assure that all of the key parameter groups were addressed.

The reviewer then prepares a Discussion section. The discussion of the study is where the reviewer interprets the data for regulatory purposes. The Table of Concurrence/Non-Concurrence will have paragraph reference numbers to refer the reader to the relevant section of the discussion to explain why there was differing opinions.

The reviewer then prepares an executive summary.

The reviewer then assembles the Record of Review (RR)[2] as follows.

| Item | Preparation |
|---|---|
| Cover Page | EPA Reviewer |
| Executive Summary | EPA Reviewer |
| Classification statement | EPA Reviewer |
| Methods and Materials Supplement | Study Author* |
| Results Supplement | Study Author* |
| Table of concurrence/non-concurrence | EPA Reviewer |
| Discussion (study deficiencies and comments) | EPA Reviewer |
| Appendix (if required) | EPA Reviewer |

*Included only after having been verified by the EPA Reviewer.

## IV. **Principal Advantages of the Proposal**

1. A more thorough assessment of the study would result.

The reviewer would be spending a larger portion of the review time challenging and assessing the entries made in the supplements provided by the study author as well as identifying omissions by the study author. If the study author/company prepared the draft DERs

[2]The term Record of Review (RR) would replace the term DER to distinguish the two products.

more effort could be devoted by OPP scientists evaluating mechanistic evaluations, fulfilling FQPA statute obligations and meeting PRIA deadlines. The current procedure of preparing DERs requires the reviewers to follow specific outlines that are time consuming and require much polishing and creation of data tables showing the obvious results of the study and rewriting the methods and materials sections—unnecessary and wasteful effort by OPP staff. The current procedure just transcribes the study report information at taxpayer expense. The time spent polishing the DER as they are now prepared would be better spent assessing and interpreting the actual raw data of the study to fulfill FQPA and PRIA statutes. The current OPP system of pesticide study review takes at least 2 years. The proposed Defined Formats approach could speed up pesticide registrations by one year.

2. The public has a better assurance that the EPA reviewer (or its contractor) did not "cut and paste" to produce the DER.

Since the defined format supplements are clearly indicated as being provided by the study author (see section below on logistics and mechanisms) and the other sections are clearly indicated as being authored by the EPA reviewer, the public knows where all of the information in the Record of Review originated. The public can judge what both the study author and reviewer contributed to the Record of Review.

3. The table of Concurrence/Non-Concurrence provides both a source to indicate that the EPA reviewer takes responsibility for each phrase of the study and a source to indicate where there are differences between the study author and the EPA reviewer. Thus, this Defined Formats approach is transparent and EPA scientists and review committees still retain the final authority of the study conclusions.

Since the EPA reviewer must commit to concur or otherwise with the several phrases of the study, the reviewer must assess the data to satisfy themselves that the data support the author's conclusion (concur) or the conclusion that the reviewer decides (non-concurrence). When the EPA reviewer does concur, the necessary data would already be in the supplement provided by the study author. When the EPA reviewers do not concur, the reviewer would be making a separate data table to illustrate the points and this table would be in either the discussion section or an appendix.

In this Defined Formats system, the peer reviewers as well as other governmental review groups and the public can see immediately where the reviewer and the study author did not agree and can formulate their own conclusion by assessing both data evaluations as provided by the author and EPA reviewer.

4. A first hand account of the study methods and materials and results would be presented to the Peer Review Committees.

In the Defined Formats, the study author whom wrote the DER/supplements

would be providing a first hand account of the study methods, materials and results to maximize DER accuracy to the various Peer Review groups. The current system of preparing DERs conveys a second hand account of the study and only the reviewer's viewpoint in selecting data for the tables conveying the information. In the defined formats proposal, the various customers of the product are assured that the viewpoints of both the company and EPA scientist are considered for transparency.

In the Defined Formats approach, there will be less mis-transcription errors by the EPA reviewers simply transcribing copying numbers from the full study reports which occurs in the present system.

5. The proposed system is "market driven" to produce thorough supplements by the study authors and reviews by OPP scientists.

Pesticide testing is a competitive business. A study laboratory or pesticide company would strive to prepare thorough supplements that require a minimum of critical comments made by the EPA, to protect the integrity and reputation of their laboratory/company. The laboratories that are owned by the companies/registrants would also be pressured to produce quality studies and reports that are not rejected by the Agency because this would reduce the delays in having their products registered.

The system is also "market driven" for the EPA reviewers. The EPA reviewers would not want some other reviewer or reviewer groups to identify a response to treatment or study deficiency that they did not recognize. Thus, the EPA reviewers would be conscientious in completing the review to fully identify and assess the impact of study deficiencies as well as identify subtle responses to treatment and explain why these responses should be considered as potential risk findings. The EPA reviewers would also not want to magnify a trivial response to treatment.

6. The products sent to the peer review groups would be more uniform for all studies.

Since the Defined Formats will be rigidly designed, the EPA peer reviewers will see products that are more uniform, thus more efficient to review and meet PRIA deadlines.

7. The Record of Review would be more useful to other regulatory agencies.

In many cases, the reviews of all studies for pesticides produced by EPA are sent to other regulatory Agencies in states within the USA or to other countries such as Canada or to the WHO. When the reviews include the defined format supplements, the other regulatory scientists can readily see the conclusions of the study author and the conclusions of the EPA reviewer, as well as the indications of study commentaries as indicated by the EPA reviewer. Thus, when the Record of Review contains the defined formats supplements, the other regulatory

groups can resolve to their own standards the differences in conclusions between the study author and the EPA reviewer.

8. Savings in time, labor, tax money, paper and other supplies.

DERs are typically 5-15 pages but some are 40 or more pages long. Several drafts of each DER are often made. The current system amounts to much use of time, labor, paper and other supplies at the taxpayer expense. Since the study authors are already preparing the methods and materials sections as well as results in their reports, they are the experts on the study, thus they can more efficiently prepare the supplements using less time and paper than an EPA reviewer would expend.

## V. **Logistics and mechanistics of the proposal.**

1. Identifying the contributions from the study author and EPA reviewer.

In order to identify the contributions that were provided by the study author, it is proposed that the supplements will be submitted in a form that cannot be altered by EPA staff such as on watermarked paper or unalterable electronic disks. The contributions made by the EPA reviewer will be on paper with an identifying header.

2. Compatibility with the proposed electronic submission of data.

The defined formats proposal is entirely compatible with proposed electronic submission of toxicity data. The electronic submissions are useful for extracting data for independent analysis by alternate methods and this will be very useful in the proposed system for review of toxicity studies.

## VI. Conclusions

**The Defined Formats system would increase the efficiency of pesticide study reviews in all disciplines, potentially saving OPP and other EPA offices $ millions each year in contractor expenses. The Defined Formats would better allow OPP to meet FIFRA, FQPA and PRIA obligations for improved protection of children.**

Sample Table of Concurrence and Non-Concurrence. For a Chronic feeding Study

| Parameter | Study Author's Conclusion | OPP Reviewer's Conclusion[2] |
|---|---|---|
| Analytical Report | N/A[1] (Only the reviewer may comment on this in this table.) | -Report Adequate<br>OR<br>-Report not adequate. Needs homogeneity data refer to item 1 of discussion. |
| Statistical Methods | N/A | -Statistical methods adequate.<br>OR<br>-Inappropriate statistical methods used refer to item 2 of discussion. |
| Clinical signs and mortality. | NOAEL and LOAEL = 100 and 200 ppm. Tremors. At 600 ppm deaths. | -Concur with study authors<br>-NOAEL and LOAEL = 50 and 100 ppm, respectively. Tremors in 6 males considered significant and adverse. |
| Body Weight and Food Consumption | NOAEL and LOAEL = 100 and 200 ppm. | -Concur with study authors |
| Hematology | NOAEL and LOAEL = 200 and 600 ppm. Decreases in leucocytes. | -Concur with study authors |
| Clinical Chemistry | NOAEL and LOAEL = 200 and 600 ppm. Increases in ASAT and LDH. | -Concur with study authors |
| Urinalysis | NOAEL and LOAEL > 600 ppm. | -Concur with study authors |
| Organ Weights | NOAEL and LOAEL = 200 and 600 ppm. | -Concur with study authors |
| Pathology | NOAEL and LOAEL = 200 and 600 ppm. Liver hypertrophy. | -Concur with study authors<br>-Kidney data needs re-evaluation, refer to item 6 in discussion. |
| Carcinogenicity | Positive for liver tumors. | -Concur with study authors<br>-Positive for liver tumors and brain tumors, refer to item 7 of discussion and Table 3 below. |
| Overall NOAEL and LOAEL | 100 and 200 ppm based on tremors. | -Concur with study authors<br>-50 and 100 ppm based on tremors. |
| Study Classification | N/A | STUDY ACCEPTABLE (870.xxxx) for regulatory purposes<br>OR<br>PENDING. Needs reassessment of the kidney histopathology. |

[1] N/A means that the study author will not be making entries for this parameter.
[2] Sample entries that the reviewer would be making. In some cases more than one sample is presented for illustrating how this table would be completed by the reviewer.

# Dr. William Irwin, DABT, ERT

Ex. 6

Email : Ex. 6
Tel :

Skilled Interdisciplinary Scientist

Toxicologist--Biochemist/Molecular Biologist--Chemist--Physical Scientist

## EXPERIENCE SUMMARY:

---Diplomat of the American Board of Toxicology (DABT Certification)
---European Registered Toxicologist (ERT Board Certification)
---Currently a GS-14 toxicologist as US EPA Structure Activity Team committee co-chair (detail)
---Chair of US EPA Hazard and Risk Assessment Tech Team committee
---Expert in analog identification, read across and structure-activity relationships (SAR)
---Member of the OPP SAR read across team for 6 years (Residues Of Concern Knowledge team)
---Regularly advise senior OPPT managers in read across and toxicology topics
---Developed tools for read across endeavours (dermal & GI absorption, surfactancy calculators)
---Developed and lead the Qualitative Risk Assessment Strategies team
---Given briefings to division directors, office director and the Assistant Administrator
---Given multiple presentations at public meetings representing the Agency (SOT, ACS)
---Written several Technical Directives for contracting work projects
---Worked on the team that developed 4 new Chemical Categories (Lung Effects Project)
---High Quality Work: Published in *Nature, PNAS, JBC, Arch. Tox.*, Book Chapters
---My Independent Initiatives Vital to Project Successes
---Very Motivated and Very Innovative
---Very Independent, but Also a Team Player
---Work at the Leading Edge of Fields
---PhD in Biochemistry/Molecular Biology
---Experience at US EPA, Pfizer, Cerep, Lipton, GSK,
---Biotech Senior Scientist equivalent to a GS14
---Hazard Characterization, Exposure Models & Risk Assessment for Chemicals
---4.5 Years Postdoctoral Research in BioPhysics lab: Muscular Dystrophy, Mitochondrial Disease
---BS in Chemistry, Physics, Mathematics
---U.S. Patent (1st Author)
---Mitochondrial Research Expert
---Muscle Research Expert
---Research Has Led to Clinical Trials
---In vitro Assay Consultant
---Process and Product Design
---Research in Italy, England, Croatia, USA
---Primary and Tumor Cell Assay Experience
---Biotech Sales & Marketing
---Research in Pharmaceutical, Toxicology, Food, Photographic, Protein Folding Areas
---Research in Biotech, Purification and Environmental Areas
---High Content Screening (HCS) Microscopy Assay Expert
---HTS Assay Design Expert (Biological, Chemical, Physical)
---Teaching Experience in Biochemistry, Toxicology, Chemistry & Physics
---In vivo Tumor Models and Animal Surgery
---Toxicology Presentation with Professor Don Fox (*C&D Toxicology* Author)
---4 Book Chapters (In vitro toxicology, endocrine-repro & development, protein folding)
---Toxicology Journal Editor & Scientific Integrity Experience
---QSAR and Risk Assessment Review Committee
---US EPA Innovation Award (Lung Toxicity Project toxicology lead)
--- Policy Contributions, Risk Assessment Forum, OECD LLNA Sensitization Committee

## Position Qualifications and Education:

I have sufficient college credits to qualify for Chemist, Biochemist, Physical Scientist, Biologist and Toxicologist. I am currently a co-chair of the read across Structure Activity Team, the perfect combination of skills for this SAR position. No other candidate may have degrees in all of the listed

**categories (biology, toxicology, physical science, chemistry). I was on the OPP QSAR read across team (ROCKS) for 6 years and studied SAR for years in the pharmaceutical industry, thus I may be the most experience candidate for this SAR position. I have developed tools for read across in RAD, such as the dermal absorption project guidance, dermal absorption calculator and the surfactancy/solubility calculator. I developed and led the Qualitative Risk Assessment Strategies team and presented this project at the 2017 ACS meeting. I was the toxicology lead for Lung Effects Project, which developed four new Chemical Categories in OPPT and received an Innovation Award. I have written several Technical Directives for contracting work. I have given presentations on read across topics. I have briefed and advised senior management at the Director, Office Director and Assistant Administrator levels in the Agency. I worked for 4 years in the pharmaceutical industry with Pharmacology experience. I performed research on a muscular dystrophy therapy that later had successful clinical trials, so my combination of skills have been validated in the health sciences in practical terms.**

**Senior Scientist: I was a senior scientist toxicologist in industry with people reporting to me, equivalent to a GS-14 senior scientist. I have certified for multiple GS14 positions previously (i.e. certification scores up to 98). I am currently a GS-14 senior scientist as the SAT SAR co-chair in RAD in OPPT (detail).**

**Toxicology: >78 credit hours in biochemical toxicology research during PhD, 13 years professional experience as a toxicologist (Pfizer, GSK, Cellumen, US EPA), DABT board certification in toxicology, Book chapter on endocrine/developmental/reproductive toxicity of organotins, In Vitro and mitochondrial toxicology expert, Toxicology journal editor, seminars, etc. Applications of thermodynamics to toxicology SOT presentation with Dr. Don Fox (*C&D Toxicology* author). In vivo project on tumorigenesis of pesticide acetylaminofluorene *(PNAS* paper). I participated in a Scientific Advisory Panel on the pyrethroids. Toxicology assays patent. I gave 7 presentations to represent the US EPA at SOT meetings. Drug cumulative work in pharma. OECD LLNA sensitization validation committee, US EPA Risk Assessment Forum, designed 10 ToxCAST assays, Co-chair of the US EPA Hazard and Risk Assessment Tech Team, Innovation Award for the US EPA Lung Toxicity Project as the toxicology lead, US EPA Focus committee member, US EPA Structure Activity committee**

**Toxicology Experience: Endocrine disruption, Immunotoxicity, Cancer models, Myotoxicity, Blood Cell Toxicity, In vitro models, Hepatoxicity, Pharma models, Mitochondrial toxicity, Imaging toxicology, Dermal sensitization, Lung toxicology**

**Biochemistry-Biology-Health Sciences: PhD in biochemistry/molecular biology from the Sanford School of Medicine. Biochemistry is critical to Mechanism Of Action investigations. Animal surgery and physiology experience. My muscular dystrophy research was published in the prestigious journal *Nature*. The research led to a therapy with successful clinical trials which validated my health sciences qualifications.**

**Chemistry: BS degree in analytical chemistry, >40 credit hours, worked as a research chemist for ~9 years with duties such as product/process development, chemical testing, assay development and water treatment/testing roles. I developed products for the pharmaceutical, medical and food technology industries. I developed P-Chem models for dermal exposure of chemicals and environmental fate.**

**Physical Science: 35 credit hours in physics-engineering-electronics (24 credits needed for a major), taught electronics laboratory, performed physical testing methods in industry (viscosity, polarimetry hysteresis, solubility, Soxlet fat content, moisture content, etc). Physical-chemistry analysis for Quantitative Structural Activity Relationship modeling.**

**Mathematics-Computer Science: 29 credit hours, Integral and differential calculus, Statistical Design of Experiments training, graphical data analysis skills, computer programming and design of computer circuits.**

**Pharmacology:** **I worked in the pharmaceutical industry for ~4 years, thus I learned the pharmacology of many drugs and pesticides (equivalent experience to a degree) based on experiments both in vivo and in vitro. I tested hundreds of drugs and chemicals for on-target effects and adverse effects with in vitro toxicity assays.**

**Volunteer Work:** **SOT educational outreach program volunteer, Chemistry tutor, agricultural extension agent volunteer, volunteer farm worker for low income people, chemistry lab instructor, electronics lab instructor, biochemistry lab instructor, ROCKS committee, RARC committee, Scientific Integrity Committee, HED Tox Study Group presenter, RAD template committee, CAPHRA Pyrethroid Committee and Scientific Advisory Panel Committee, Overseas muscle disease project for 4 years (lead to a successful human clinical trial), COOP volunteer (EPA continuity of operations project)**

| Risk Assessment Factor | William Irwin, PhD, DABT, ERT Qualifications |
|---|---|
| Leadership | Co-Chair of the US EPA Hazard and Risk Assessment Committee, Currently a GS-14 co-chair of the US EPA Structure Activity Team committee (detail); Supervised & Mentored many associates at Lipton, US EPA (HED, RAD), Pfizer, GSK, Cellumen (Chem., Tox., Biochem.); Briefed Lipton General Manager, Assistant Administrator, Deputy Assistant Administrator, Office Director and R&D Director on projects; Toxicology lead for the Lung Toxicity Project (Innovation Award); First Author *Nature* Paper (12 authors team, only 3 years), Risk Assessor, Acting Branch Chief, Mentored & Taught Environmental Chemistry & Biochemistry & Physics Laboratory, Independent: Initiated Pivotal Projects with little Supervision, Developed P-Chem model for exposure; Senior Scientist Toxicologist in Biotech equivalent to a GS14 (>2 years): Designed main company product, Patents 1st Author, supervised staff; Designed 10 ToxCAST Assays; Participated in a Scientific Advisory Panel on the pyrethroids; Designed Tox Imaging Assays (12 authors team paper, widely used assays, only 3 years), Overseas Muscular Dystrophy Therapy Team-- Successful Clinical Trials, 1st author on Nature paper, First Pyrethroid Hazard Model to ToxSAC, Industry Meetings, Tox Study Group Instruction, First Protocol to ToxSAC, Seminar on Mitochondrial Toxicity, Two Seminars on In Vitro Toxicology, Represented EPA in 7 SOT and one ACS Presentations, Book chapter on pesticide endocrine disruption, Maturity, Risk Assessment Forum, OECD Dermal Sensitization Assay Validation Team, Qualitative risk assessment team leader |
| Policy Contributions | **Pyrethroid Scientific Advisory Panel Committee**<br>**Inhalation Policy Contributions**<br>**Dermal Policy Contributions**<br>**Gastro-Intestinal Policy Contributions**<br>**Quantitative Structural Analysis Relationship Contributions**<br>**Structural Alerts Policy Contributions**<br>**Immunotoxicity Policy Contributions**<br>**In Vitro Policy Contributions**<br>**US EPA ToxCAST Assay Contributions**<br>**Qualitative Risk Assessment Strategies** |
| Teamwork | HazRATT and SAT Committees co-chair; ROCKS QSAR Committee, RARC risk assessment committee, ToxSAC every meeting, CAPHRA team, Pyrethroids/Inhalation, Tox21, COOP, Inerts, Defibrillator team, EOGRTS reproduction study, Assisted other branches, Mitochondrial Tox resource, Scientific Integrity Committee, Risk Assessment Forum, OECD LLNA Validation Team, Document review and QC |

| | |
|---|---|
| **Interdisciplinary Analytical Research** | Designed Physical & Chemical Analytical Assays as a research chemist (Process & Production Plant Experiments $20,000/day at times), Muscular Dystrophy Research (Biochemistry, Toxicology, Pharmacology & Physiology),<br>Tox Assay Validation, ISO "9000" QC/QA, Imaging Tox Assays (biochemistry, optics, toxicology) |
| **Toxicology** | Toxicologist, DABT Board Certification (peer status), Pharma, Biotech, Regulatory Tox Experience<br>>78 Tox Research credits during PhD, Clinical Chemistry, Tested Pesticides in Pharma, In Vitro Tox<br>(Pesticide & Invertebrate Tox Models: rotenone, antimycin & cyanide), Bradford-Hill Analysis |
| **Chemistry** | Chemistry Degree (44 Credits), ROCKS Member, Taught Environmental Chemistry Lab<br>Research Chemist for ~9 years, Know DEEM Software, Water Treatment Expertise, QSAR |
| **Physical Science** | Physics Degree (35 Credits, with electronics research & engineering), Taught Physics Laboratory |
| **Pharmacology** | Pharma Experience at Pfizer & GSK pharmaceuticals, Tox And App. Pharm. Journal Editing |
| **Exposure Modeling** | Developed P-Chem model to explain pesticide transfer from collars to fur to hand to mouth based on physics, biochemistry & chemistry partitioning & experience as a research chemist (RD Award). Lived on Farm 22 years: Used many herbicides, insecticides, fungicides, Physics & Chemistry degree gives understanding of important exposure factors (vapor pressure, mp, bp, viscosity, surface tension, partition coefficients, pKa, solubility, diffusion, charge, etc) |
| **Biochemistry/Molecular Biology-MOA Knowledge** | PhD in Biochemistry/Molecular Biology, MOA at molecular level skills, Taught Biochem Lab, Regularly review pesticide biochemistry papers for senior staff |
| **Physiology** | Muscular Dystrophy Research, Surgery in animals |
| **Mathematics, Data Analysis & Modeling** | Mathematics Minor, Statistical Design of Experiments Course, "BMD" Calculations in pharma |
| **Cancer Research** | Cancer Postdoc research on herbicide Acetylaminofluorene in vivo published in *PNAS,* Cancer presentation at SOT |
| **Writing & Presentation Skills** | *Nature* paper (first author), papers in *PNAS, JBC, Arch. Tox*, Repro. & Dev. Toxicology Chapter, Two in vitro toxicology book chapters, protein folding book chapter, Papers cited over 1000 times, Journal Editing (*JBC, TAAP*, etc), Risk Assessments, Over 52 Seminars in 4 Countries (USA; London, Sandwich England; Zagreb, Vodice |
| **In Vitro & Tox21 Skills** | Designed & Adapted Assays >10 years, Patents, In Vitro toxicology review articles, Assays implemented into ToxCAST |
| **Training** | I have helped train and mentor the newer toxicologists at Cellumen, Pfizer, GSK, US EPA (HED, RAD). I have supervised multiple research associates over the years, such as when I was a senior scientist in industry. I also participated in the student mentoring programs at the SOT meetings. My *Nature* paper has been cited over 359 times and led to other disease investigations. My imaging toxicology paper has been cited over 423 times and widely implemented and copied. |
| **Honors** | DABT Toxicology Certification, European Registered Toxicologist (ERT board certification); Physics Honor Society , Mathematics Honor Society; US EPA Innovation Award; US EPA Bronze Medal |

**Experience:**

My mitochondrial research published in *Nature* led to successful clinical trials for a muscular dystrophy therapy. I have a very powerful skills set to be a versatile scientist with my toxicology background, research chemist work, and physics/mathematics degrees plus my direct experience with chemical exposure on a farm. Very few people possess my mix of skill. I have demonstrated teamwork, high productivity, quality assurance and customer service at several jobs, as demonstrated by my past bonus awards. I have skills in data analysis, developing new methods, teamwork and instruction on technical matters. I also have experience in hazard characterization, exposure and risk assessment of chemicals, plus quality control methods.

In my past experience, I have planned and performed scientific investigations, developed new methods or adapted existing methods and validated these models, then implemented them in practical applications. I have originated projects and led them in my previous experience. I have developed interdisciplinary analytical procedures in toxicology, physics and chemistry areas. I have performed environmental sampling and testing to determine the exposure to waste products of industry. I have excellent analysis and problem solving skills, from the most advanced toxicology models in pharma. Obviously, I have pharmacology experience from working at Pfizer and GSK pharmaceuticals in the Safety Sciences Department (Toxicology/Pharmacology). At Pfizer, my main focus was developing advanced in vitro toxicology assays similar to the Tox21 initiative. At GSK my focus was antimicrobial compound research. I have presented many toxicology seminars in scientific meetings

to various stakeholders in industry and the public, thus I appreciate the needs of various viewpoints. I have published my research in outstanding journals such as *Nature Genetics,* thus I have excellent communication skills. At Lipton, I was deeply involved in the ISO quality assurance (QA) implementation.

A versatile scientist absolutely needs degrees in the multiple disciplines to perform at the higher levels, which is an interdisciplinary endeavor, with a PhD degree preferred. My background in toxicology from pharma provides excellent experience in the most advanced toxicology models in the world, an exceptional education for hazard characterization and risk assessment of chemicals/pesticides. My DABT board certification confirms that I am at the top of my field in toxicology, as evaluated by my peer toxicologists. I have a BS degree in Chemistry and functioned at a high level as a research chemist for about 9 years for Lipton. Thus, I well comprehend the chemistry aspects of hazard identification, also supported by my work on the US EPA ROCKS QSAR and Risk Assessment committees. I lived on a farm for 22 years, so I well understand the exposure aspect (ORE) of occupational chemical use, having directly applied pesticides many times myself. I also have a degree in Physics, and interpreting the physical properties of chemicals is crucial to interpreting their exposure potential (solubility, viscosity, melting point, hydrophobicity, surface tension, etc) and I have performed many of these physical tests myself. My environmental testing and water purification experience also aids my understanding of exposure to hazardous materials from industry. I have a PhD in Biochemistry/Molecular Biology which is very valuable in determining the mechanism of toxicity of chemicals (i.e. MOA), often the result of enzymatic inhibition or receptor binding or damage at the molecular level. Biochemistry is a strong bridging discipline between toxicology and residue chemistry. My mathematics minor is very valuable in complex calculations, advanced modeling, and statistical analysis. My supervisor at Lipton was a statistical modeler and I was taught statistical design of experiments techniques. I have considerable experience in computer programming which can aid modeling projects.

I have >10 years experience developing in vitro toxicology assays and analysis. My experience with toxicology from pharma is very valuable, since some chemicals are also drugs or have the same mechanism of toxicity. Some pharma companies also make chemicals, so understanding their methods is important. I am continually seeking knowledge and science information, as demonstrated by my continued meeting attendance, presentations and publications. My memberships in the Physics Honor Society, Society of Toxicology, Diplomat of the American Board of Toxicology and Mathematics Honor Society demonstrate my consistent quest for excellence. I have taught in Chemistry, Biochemistry, Physics and Toxicology settings.

**Introduction** I have over 10 years experience with product and assay development, with over 10 years experience in the pharmaceutical-related industry. I have worked for the US EPA, Pfizer, Cerep, Lipton, and GSK in product and assay development (risk & toxicology/pharmacology departments). I have a BS in Analytical Chemistry, with other degrees in Physics and Mathematics. I also have a PhD in Biochemistry, with 4.5 years post-doctoral experience (mostly toxicology/pharmacology research). I am a Diplomat of the American Board of Toxicology, a certification confirming mastery of the specialty.

I strive for excellence and my recent evaluations have been "exceeds expectations" or "outstanding". I am a very motivated person, with papers in excellent journals such as ***Nature Genetics*** (first author) and ***PNAS***. My ***Nature Genetics*** paper was central to our laboratory getting a $1.4 million grant subsequently and it was listed as one of the top research advances of the year by ***Neurology Today***. This work was also a pivotal one in both the fields of mitochondrial and muscular dystrophy research that has led to successful human clinical trials. I am an expert in High Content Screening imaging and mitochondrial research.

My independent initiatives have been pivotal to make my previous projects successful. I work well in a team format, but I also work very well independently. I have demonstrated leadership roles. I have very good problem-solving skills and I have initiated new projects at previous pharmaceutical companies. I have excellent oral and written communications skills. I have presented my research at international meetings. I have good equipment repair skills. I have experience with HCS and HTS laboratory automation. I have supervisory skills experience. I have experience with patents, new product development and process development.

I have over 10 years work in product development and I have a great deal of experience in this area. I have provided a great deal of input into products for my past companies (technically and as a market viewpoint). I even supervised implementing new processes that I designed into the production facilities. I am extremely practical in business matters as they apply to research.

Research expenditures (time and money) need to be focused on products that will make profit for the company. Research decisions need to be market driven and based on what the customers will purchase, so that the company can prosper. As a manager, I am demanding, but fair. I have always met my goals and I often exceed them. I obtained the prestigious Highly Skilled Migrant Programme UK Visa while working for Pfizer.

**Summary:** Risk assessments for pesticides experience, Toxicologist, PhD in Biochemistry, Nature & PNAS publications, >10 years post-graduate experience as a scientist, 14 years industrial research experience, 4.5 years postdoctoral research experience, toxicology experience at US EPA, Pfizer, Cerep, and GSK (toxicology/pharmacology), BS degrees in Chemistry and Physics/Mathematics, experience with many different types of assays (chemical, biochemical and physical), product development and production plant implementation experience, fluorescence microscopy assay expertise, High Content Screening, Macrolide biochemistry, GSK work experience, Muscle Research experience, Mitochondria research experience, Statistically Designed Experiments, Computer Programming, US Patent as first author, Lipton experience, Interests/knowledge in Diabetes and Transplantation, Environmental testing, "ISO9000" skills, SDS-PAGE, Immuno-Assays, Graduate School GPA=3.9, EpiSuite QSAR Chemical Modeling Software, ICCVAM, Journal Editing experience, DABT Certification, PBPK, Process Chemist experience, Highly Skilled Migrant Programme UK Visa, Senior Scientist in biotech

**Work Experience:**

**Toxicologist, US Enviromental Protection Agency (US EPA): 8 Years August 2, 2009-Present.** Work involved writing and reviewing hazard characterizations and risk assessments for herbicides, fungicides, insecticides, and toxic substances to protect the environment and the general public. Duties also involved critically reviewing tox studies or protocols, writing data evaluation records, presenting tox research at SOT meetings, interacting with the press, participating in QSAR evaluations and providing scientific guidance to in vitro tox assay development, as well as mitochondrial-based studies. I also am a member

of the ROCKS committee, which evaluates the structural properties of chemicals and residues in plants/animals. I was a co-author on a 20-page book chapter reviewing organotin toxicity and its reproduction/developmental/endocrine disruption effects. My farm experience with many chemicals, chemistry, toxicology and physics backgrounds provide unique insights into the needs of the consumers, public, wildlife and manufacturers. I received an award for developing a physical chemistry model of exposure. I am also on the Risk Assessment Review Committee (RARC) which has the final evaluation of EPA risk assessments. I participated in a Scientific Advisory Panel on the pyrethroids. Presented 6 times at SOT: mitochondrial toxins, organotin endocrine model, neurotoxicity signs, toxicology application of thermodynamics, organelle imaging toxicology, cancer biology models. Dermal, inhalation and gastro-intestinal policy work, as well as toxicity structural alerts and qualitative risk assessment strategies. OECD dermal sensitization assay validation team. Risk Assessment Forum. HazRATT committee co-chair. Lung Toxicity Project toxicology lead (Innovation Award). Focus risk assessment committee, Structure Activity QSAR committee, Mentoring and training new staff

**Cellular Toxicologist-Senior Scientist Cellumen, Inc.:** 2.5 Years Nov. 1, 2006-March, 2009, Research involved developing new test assays using advanced HCS imaging technology to assess drug toxicity and mechanism of action, representing company in booth at trade shows and overseeing collaborations with partner companies. Primary and tumor cell isolation/propagation for use in assay development. I developed and patented a panel of assays which was the major revenue producer for the company and was a senior level-researcher that contributed to major research decisions and policies in the company. I supervised my own research associate, as well as co-supervised several others. Research also yielded a publication on cellular systems biology and a US patent (first author). Trained and mentored staff, wrote SOPs, set policies, and QC of data. Laid off due to economic recession.

**Toxicology Assay Consultant, GSK Pharmaceuticals 9 Months HTS Lab (Pliva Site, Zagreb, Croatia): Feb. 1, 2006-Oct. 15, 2006** Research involved developing new test assays to assess drug toxicity and cellular action (mostly antimicrobials and antibiotics) utilizing fluorescence plate readers, FACS and fluorescence microscopy. Research into alternate macrolide pharmaceutical applications, immunotoxicity assays, mitochondrial assays and effects on cells at the sub-cellular level were also performed. I supervised two research associates in the HTS laboratory. Research yielded two review articles on tox assay development guidance. I left when offered Cellumen position back in the USA.

**Cellular and Biochemical Toxicologist, Pfizer Pharmaceuticals 3 Years, Sandwich Site (Kent England, Dec. 2002-Dec. 2005).** Research involved developing new test assays to assess drug toxicity utilizing fluorescence microscopy and High Content Screening technology in the Safety Sciences/Pharmacology department and in collaboration with Cerep and the University of Padova, Italy. The first year of research was in Padova, Italy at the University developing muscle tox assays and the remaining two years were in Sandwich, England at the Pfizer Global Research Centre (supervised by SRG with Cerep funding). Research also involved optimizing High Content Screening microscopy technology for mechanism of action and toxicology studies for drug discovery. Supervision and training of 3 junior lab members was also involved. Research yielded a high-impact 25-page paper on HCS applications in toxicology with impressive concordance to human toxicity which has been highly cited (Arch. Tox. 2006, cited 423 times). Many types of compounds were evaluated on the system such as antibiotics, medications, pesticides, solvents, household chemicals, etc. The research was involved with animal reduction, refinement and replacement (the 3 R's and ICCVAM projects). I started this research while still in Italy during postdoctoral study (one year overlap period). Completed three full contracts and went to GSK.

**Research Chemist, Lipton/Kind & Knox, Inc./DGF Stoess/Gelita 9 Years** Chemist in research and development laboratory. Research involved test method development and experiments/troubleshooting in the production facilities. Other work involved developing new products and improving existing products derived from collagen for the pharmaceutical, photographic and food industries. Implementing new technology, up-scaling laboratory research into the production facilities, and supervising laboratory interns was also performed. Kind & Knox is a division of DGF Stoess, the largest producer of medical-grade collagen and collagen-derived protein products in the world (previously owned by Lipton/Unilever). I made presentations to the general manager.

I have "ISO9000" QA/QC skills, as well as statistical designed experiments experience. I have excellent skills of adapting quickly and determining which components of a process are critical and to find solutions to improve both efficiency and quality. I worked as a process scientist in a development laboratory, transferring laboratory models into practical implementation on a large scale. I also have extensive experience in water treatment, purification and testing. I left to complete a PhD program.

***Post Doctoral Study, Paolo Bernardi Laboratory*** 2 Years **(University of Padova, Italy, Department of Biochemistry and Pathology):** June 15, 1999-June 2001. Supported by Telethon Fellowship/Grant #1141 ("**Mitochondria as Targets of Pharmaceutical Intervention in Muscle Disease**"). Research involved the study of anesthetics and extra-cellular matrix protein knockout on skeletal muscle as models of muscular dystrophy. The study of the mitochondrial permeability transition/apoptosis in intact muscle cells, fibroblasts and hepatocytes was performed. The calcein-release method and the cytochrome c release immunoassay were used to monitor the permeability transition in intact cells (normal vs cancerous), utilizing fluorescence microsopy and confocal microscopy, respectively. Calcium measurement techniques/signaling (cytosolic and mitochondrial) were also performed in collaboration with the Tullio Pozzan laboratory. Most of the research was in toxicology areas.

***Research yielded a ***Proceedings of the National Academy of Sciences*** article on an epigenetic carcinogen and a *Journal of Biological Chemistry* publication on anesthetic myotoxicity.

***Post Doctoral Study, Paolo Bonaldo Laboratory*** 2 Years **(Department of Histology, Microbiology and Medical Biotechnologies, University of Padova)** June 2001-Dec. 2003. Supported by Telethon Grant #1201 ("**Study Of Bethlem Myopathy Using Collagen 6 Knockout Mice As An Animal Model**"). Research involved the study and histology of collagen VI knockout mice in as a model of Bethlem/Ullrich Muscular Dystrophies. The mitochondrial permeability transition in intact muscle cells was monitored using TMRM fluorescence assays by fluorescence microscopy and confocal microscopy. Calcium signal transduction and calcium measurement techniques were also performed. Also, started performing research for Pfizer while still in Italy during my postdoctoral study.

***Research yielded a ***Nature Genetics*** publication with myself as a first author and listed in *Neurology Today* as one of the top research advances of 2003. *This research led to successful human clinical trials for a muscular dystrophy therapy, methods replicated for other diseases and cited 359 times..*

***Effluent Water Monitoring Consultant*** **4 Months (IBP Inc., Iowa, Kansas, Texas)** Collected samples of production plant effluents at various locations and waste water lagoons and tested them in the laboratory for industrial waste products that could adversely affect the environment.

**Skills**: Toxicology risk assessment and data analysis, QSAR, ICCVAM, COOP disaster team, Fluorescence and confocal microscopy, High Content Screening microscopy, HPLC skills, Problem-solving skills, Calcium testing, Protein purification/chemistry, Polymer chemistry, Affinity and Ion exchange chromatography, A wide range of chemical and physical testing assays, Primary cell isolation and culture (hepatocytes, skeletal muscle, fibroblasts, cardiac myocytes, etc.), Electrophoresis, Western blotting, Electronic and mechanical equipment repair skills, Equipment modification skills, Mitochondrial and permeability transition expertise, Mitochondria isolation/testing (heart, liver, kidney, muscle, invertebrates, etc.), Metabolism biochemistry and biochemical assays, Enzyme kinetics, Interests in structure/function relationships of compounds on biological systems, Computer skills and programming, Statistical designed experiments, Animal surgery, Invertebrate tox models, Biochemistry laboratory teaching, Research intern supervision, Team project research, Excellent English language skills, "ISO9000" skills (QA/TQM), Macrolide biochemistry, Muscle research experience, New Product development, Process development, Computer skills (Excel, Word, PowerPoint, programming, etc.), Company Representative at trade show booth, Scored very high on PA Forensic Scientist exam and the Environmental position exam, Environmental Chemistry laboratory instructor, Defibrillator/First Aid, ToxSAC experience, Basic & Applied Myology Board Member, Highly Skilled Migrant Program UK Visa

**Specialized Training:**

**High Content Screening Imaging Microscopy Training** (3 weeks) Course covered in-depth the theory and practical applications of simultaneous, multi-probe fluorescence microscopy in research and medicine. Cellomics, Inc. Pittsburgh, Pennsylvania, 2003 (updated in 2005)

**Ion Exchange Chromatography/Technology Course** (3 Days) Course covered applications and theory of advanced ion exchange purification and separation methods in industry and research. The focus was on the purification of drinking water from hazardous materials. Illinois Water Treatment Co., Dearborn, Illinois

**Membrane Separation/Purification and Filtration Technology Course** (3 Days) Course covered applications and theory of advanced membrane separation/purification/filtration technology in industry and medicine. Chicago, Illinois.

**Statistical Design of Experiments (T.J. Lipton, Inc.)** Course covered the basics of designing statistically optimized experiments and data interpretation

**ISO Quality Systems** Covered the essentials of "ISO9000" type of quality systems implementation and auditing procedures

**US Patents Workshop (MIC, 3 Days)** Course covered the fundamentals of US patent concepts and applications

**EpiSuite QSAR Chemical Modelling Course** Structure analysis relationships software, US EPA, 2009

**Toxicology Study Groups** US EPA 2009-2010 and 2017

**Physiologically Based Pharmacokinetic (PBPK) Models in Risk Assessment** SOT Meeting, 2011

**Grant Writing Workshop**

**Advanced Writing Training** US EPA, 2011

**Risk Assessment Training** US EPA, 2011

**Neurotoxicity Assessment Training** US EPA 2012

**NIST Standards Workshop** NIST 2013

**Alternative In Vitro Toxicology Testing for the 21st Century** SOT Workshop, 2012

**NIH Nanomaterials Workshop** NIH, 2013

**Practical Applications of Emerging Scientific Tools, ASCCT Symposium** NIH, 2013

**Adverse Outcome Pathways Workshop** NIH 2014

**Primary Mitochondrial Disorders Workshop** NIH 2014

**OECD QSAR Toolbox Training** June 2017

**Alternative Methods Toxicology Workshop** IIVS July 2017

**Education**:

***Bachelor of Science Degree*** ***(Morningside College)***
Major: ***Chemistry*** Minors: ***Physics, Mathematics***
Undergraduate Research involved interfacing normal laboratory equipment to computers. I was a laboratory instructor for an Environmental Chemistry class and an Electronics (Physics) class.

***PhD Degree: Biochemistry and Molecular Biology (Sanford School of Medicine, GPA=3.9)***
Doctoral research involved developing methods to protect vital tissues from hypoxia (i.e. transplantation conditions) or conditions of exposure to toxins. In particular, our laboratory sought to protect mitochondrial integrity and tissue/cell viability during conditions of hypoxia/transplantation, mitochondrial inhibition, toxic insults or stress. Most experiments involved toxicology, metabolism or pharmacology research (>78 credit hours in toxicology research). Other projects during the doctoral program involved invertebrate toxicity models, protein folding/chaperone/collagen synthesis enzyme biochemistry and ethanol metabolism enzyme kinetics (i.e. aldehyde dehydrogenase).

***Research yielded a *Biochemical Biophysical Research Communications* article on the toxicity of aldehydes and a book chapter publication ***Prolyl Hydroxylase, Protein Disulfide Isomerase and Other Structurally Related Proteins.***

UNIVERSITY OF
SOUTH DAKOTA
SANFORD SCHOOL OF MEDICINE

October 16, 2012

Ms. Brittany J. Jones
Human Resources Specialist
U. S. Environmental Protection Agency
Human Resources Management Division—Branch A
Research Triangle Park, North Carolina 27711

Dear Ms. Jones: RE: William A. Irwin, PhD, DABT

Dr. William Irwin has asked that I write regarding his application for a position with your organization. Will earned his Ph.D. in our Department of Biochemistry and Molecular Biology in 1999. I was chair of the department and a member of Will's dissertation committee. The title of Will's dissertation was the "An Investigation into the Protective Mechanisms of Fructose on Hepatocytes During Hypoxia". This work focused on the impact of a variety of mitochondrial toxins that induce hypoxia in mammalian hepatocytes. Cyanide, rotenone and antimycin A, all government-regulated pesticides, damage hepatocyte mitochondria which results in hepatocyte death and ultimately liver failure. Will demonstrated that fructose can protect hepatocyte mitochondria from toxin damage, thereby preventing hepatocyte death. Will's research approaches and methods were the tools of biochemical toxicology. The identification of fructose's protection from the toxic effects of these compounds is applied toxicology.

If I can provide additional information, please do not hesitate to contact me.

Sincerely yours,

Ronald Lindahl, Ph.D.
Executive Dean

**Patents:** **"Cellular Systems Biology Assays to Assess Human Toxicity Potential Utilizing Primary Rat Hepatocytes"** (William Irwin, Larry Vernetti, Kate Johnston), Filed in USA and Europe (pending)

**Publications:**

Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P., **"Mitochondrial Dysfunction and Apoptosis in Myopathic Mice with Collagen VI Deficiency"** (2003) *Nature Genetics* Vol. 35 (No. 4): 367-371

See also commentaries about this article:
Rizzuto, R. **The Collagen-Mitochondria Connection** (2003) *Nature Genetics* Vol. 35 (No. 4): 300-301
**From the Editor's Desk (2004)** Matrix Biology Vol. 22: 519-520
**Editors' Picks: Top Research Advances From 2003** (2004) *Neurology Today* Vol.4 (No. 1): 5-6
Hayworth, J. **"Mitochondria Play a Role in Disease (Biochemist William Irwin)"** *Sioux City Journal (2003)*
Hayworth, J. **"Scientist Irwin Takes Studies To Italy"** *Sioux City Journal (2003)*

Kloehn, P., Soriano, M., Irwin, W., Penzo, D., Scorrano, L., Bitsch, A., Neumann, H-G., Bernardi, P. **"Early Resistance to Cell Death and to Onset of the Mitochondrial Permeability Transition During Hepatocarcinogenesis With 2-Acetylaminofluorene"** (2003). ***Proceedings of the National Academy of Sciences*** Vol. 100 (No. 17): 10014-10019

Irwin, W., Jelic, D., Antolovic, R. **"Biomarkers for Drug Discovery: Important Aspects of *in vitro* Assay Design for HTS and HCS Bioassays" (2006)** *CROATICA CHEMICA ACTA **81** (1): 51-59*

Vernetti, L., Irwin, W., Guiliano, K., Gough, A., Johnston, K., Taylor, D. **"Cellular Systems Biology Applied to Pre-Clinical Safety Testing"** *Drug Efficacy, Safety, and Biologics Discovery: Emerging Technologies and Tools (Wiley & Sons, 2008)*

Irwin, W., Jelic, D., Antolovic, R. **"Bio-Assays for Drug Safety and Mechanism Assessment: Design, Precautions and Integration"** ("Medicinal Chemistry in Drug Discovery", July 2009)

Doherty, J., Irwin, W., **"Organo-Tins: Reproductive and Developmental Effects in Mammals",** US EPA sponsored, Manuscript published in the book "Reproductive and Developmental Toxicology", Elsevier, February 2011

Irwin, W., Fontaine, E., Penzo, D., Bernardi, P., **"Bupivacaine Myotoxicity Is Mediated By Mitochondria"** (2002). *Journal of Biological Chemistry* Vol. 277(No. 14): 12221-12227.

Irwin, W., Gaspers, L., Thomas, J., **"Inhibition of the Mitochondrial Permeability Transition by Aldehydes"** (2002). *Biochemical Biophysical Research Communications* Vol. 291 (No. 2): 215-219

Noiva, R., Onodera, S., Schwaller,M., Irwin,W. **"The Peptide Binding Site of Protein Disulfide Isomerase"** pp. 369-395. In *Prolyl Hydroxylase, Protein Disulfide Isomerase and Other Structurally Related Proteins (1998)*, Editor Norberto Guzman, Marcel Dekker, Inc. New York

O'Brien, P., Irwin, W., Diaz, D., Howard-Cofield, E., Bernardi, P., et al **"High Concordance of Drug-Induced Human Hepatotoxicity With in vitro Cyto-Toxicity Measured in a Novel Cell-Based Model Using High Content Screening" (2006).** *Archives of Toxicology:* 2006 Sep;80(9):580-604

Slaughter, M., Hougham, C., Hitchcock, J., Potter, A., Brain, P., Irwin, W., **"A Medium-Throughput, Sensitive *in vitro* Screen for Chronic Cyto-Toxicity Assessment of Nucleoside Analogues"**, Manuscript in preparation

Irwin, W., Gaspers, L., Thomas, J., **"Fructose Protects Hepatocytes During Hypoxia or Toxin Exposure by Inhibition of the Mitochondrial Permeability Transition".** Manuscript in preparation

**Affiliations**: ***American Board of Toxicology (ABT), Society of Toxicology (SOT), Physics Honor Society, Mathematics Honor Society, American Chemical Society, ABT Standards of Knowledge Committee, SOT National Capital Area Chapter, SOT In Vitro Toxicology Specialty Section***

**Languages:** English (fluent), Italian (essential), Spanish (basic), Croatian (basic)

**Invited Seminars:**

American Chemical Society Annual Meeting (August, 2017), **"Qualitative Risk Assessment Strategies"**

US EPA (October, 2016), **"Critical Aspects of In Vitro Assay Design, Analysis and Integration"**

SOT Meeting (March, 2015), **Ask An Expert Program: "In Vitro Toxicology Assay Design"**

SOT Meeting (March, 2014), **Ask An Expert Program: "Mitochondrial Toxicology"**

US EPA (Oct. 2, 2012), **"Important Aspects of In Vitro Assay Design and Interpretation"**

US EPA (May 25, 2010), **"Mitochondrial Toxicities and Interactions With Other Organelles"**

Notre Dame School of Medicine (May 29, 2009) **"Organelle Pathologies in Disease States"**

Stem Cell Research Center, University of Pittsburgh (Feb. 9, 2009) **"Mitochondrial and SR Pathologies in Muscular Dystrophy"**

Croatian Society of Biochemistry Annual Meeting (Oct. 3, 2006, Vodice, Croatia), **"High Content Screening Imaging Applications in Toxicology and Pharmaceutical Discovery"**

Becton Dickinson (August, 2006) **"High Concordance of HCS-Based Toxicity Assays With Human Drug Toxicity"**

Cellumen, Inc. (August, 2006) **"High Content Screening Applications in Drug Discovery Programs"**

Cellomics, Inc. (August, 2006), **"Human Drug Toxicity Concordance With High Content Screening In Vitro Assays"**

University of Iowa Medical School (Aug. 10, 2006) **"Mitochondrial Research: Experimental Design, Assay Precautions and Data Interpretation"**

University of Iowa Medical School (Aug. 9, 2006) **"High Content Screening Fluorescence Microscopy Applications in Medical Research"**

University of Iowa Medical School (K. Campbell sponsor, Aug. 9, 2006) **"In Vivo and In Vitro Characterization of the Collagen VI Knockout Mouse Model of Muscular Dystrophy"**

Croatian Genetic Society, (May 17, 2006, Zagreb, Croatia) **"Use of Macrolides as Discovery Tools in Medical Research: Muscular Dystrophy Applications"**

Pfizer Pharmaceuticals, Safety Sciences (October 24, 2005, Sandwich, England) "**Organelle Pathologies in Muscle Disease"**

High Content Screening Conference (October 19, 2005, Le Meridien, London, England) "**Predicting Drug-Induced Hepatotoxicity With in vitro Cyto-Toxicity Assays: High Content Screening Methods"**

Croatian Society of Biochemistry and Molecular Biology (September 2005, Zagreb, Croatia) "**The Unexpected Organelle Pathology in Collagen VI Deficiency Muscular Dystrophies"**

Pfizer Pharmaceuticals (March 2005, Sandwich, Kent, England) "**The Role of Mitochondria in Carcinogenesis"**

Sanford School of Medicine (February 28, 2005) "**The Unexpected Organelle Pathologies in Collagen VI Deficiency Muscular Dystrophies"**

Pfizer Pharmaceuticals (May 2004, Sandwich, Kent, England) "**High Content Screening Multi-Channel Fluorescence Microscopy Applications in Toxicology"**

Pfizer Pharmaceuticals (March 2004, Sandwich, Kent, England) "**Important Biochemical and Metabolic Considerations in Muscle Diseases and Their Therapies"**

Pfizer Pharamaceuticals (November 2003, Sandwich, Kent, England) **"Mitochondrial Membrane Potential Measurement Applications in Toxicology, Techniques and Precautions"**

University of Padova, School of Medicine (October 2003, Padova, Italy) "**High-Content Screening Methods: Utilizing Coherent Multi-Probe Fluorescence Microscopy to Monitor Simultaneous Sub-cellular Events"**

Pfizer Pharmaceuticals (May 15, 2003, Sandwich, Kent, England) **"Anesthetic Toxicology: Calcium And Mitochondrial Roles In Muscle Pathology"**

Padova Foundation of Organ Transplantation (March 20, 2003, Padova, Italy) **"Organ Transplantation: Important Metabolic and Biochemical Considerations"**

Sanford School of Medicine (September 28, 2001): **"An Animal Model of Human Bethlem Myopathy: Muscle Characterization of Collagen VI Knockout Mice"**

NovaSite Pharmaceuticals (September 21, 2001, San Diego, California,): **"Muscle Characterization of Collagen VI Knockout Mice: An Animal Model of Human Bethlem Myopathy"**

University of Colorado, Health Sciences Center (December, 1999, Denver, Colorado): **"Fructose and Glyceraldehyde Protection of Hepatocytes During Hypoxia Is Mediated by Mitochondria"**

University of North Carolina (December 1999, Chapel Hill, North Carolina): **"Fructose Protects Hepatocytes During Hypoxia by Inhibition of the Mitochondrial Permeability Transition"**

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DGF Stoess, Inc. (February, 1993, Sioux City, Iowa) "**The Biochemistry of Collagen Proteins and Implications in Various Pathologies"**

Sanford School of Medicine (January 1993): **"Collagen Biochemistry in Health and Disease"**

**Seminars:**

London School of Hygiene and Tropical Medicine (May 22, 2009) **"High Throughput Screening Assay Applications in Tropical Disease Research"**

Toxicology 2003 Conference (Dec. 9 2003, London, England) **Predicting Drug-Induced Human Hepatotoxicity With In Vitro Cytotoxicity Assays**

University of Padova, Department of Medical Biotechnology (May 2003, Padova, Italy): **"Collagen VI, Calcium and Mitochondrial Roles In Bethlem Myopathy"**

University of Padova, Department of Microbiology (December 2002, Padova, Italy): **"Important Metabolic Considerations in Muscle Diseases for Therapeutic Intervention"**

University of Padova, Department of Histology (May 2002, Padova, Italy): **"An Animal Model of Human Bethlem Myopathy: Characterization of the Pathological Defects in the Skeletal Muscles of Collagen VI Knockout Mice"**

University of Padova, Department of Biomedical Sciences (July 2001, Padova, Italy) **"Ullrich Muscular Dystrophy Is Caused By Mutations In The Collagen VI Genes"**

University of Padova, Department of Medical Biotechnology (May 2001, Padova, Italy): **"The Role of Mitochondria in Muscle Cell Death"**

University of Padova, Department of Biomedical Sciences (March 2000) **"HIV-1 Mediates Apoptosis By Its Proteins Inducing The Mitochondrial Permeability Transition"**

University of Padova, Department of Biomedical Sciences (September 1999, Padova, Italy): **"Fructose Protects Liver During Hypoxia By Its Metabolite Glyceraldehyde Protection of Mitochondrial Function"**

Sanford School of Medicine (June 1999): **"An Investigation Into the Protective Mechanisms of Fructose To The Liver During Hypoxia"**

Sanford Medical School, Department of Biochemistry and Molecular Biology (January 1998): **"Membrane Transporters That Lack Protein Components"**

Sanford School of Medicine (October 1997): **"Artificially-Gated Pores: Designer Pore Applications in Cancer Chemotherapy, Cryopreservation and Biosensors"**

Sanford School of Medicine (January 1997): **"Immunophilins: Protein Folding Roles in Signal Transduction, Vision, Secretion and AIDS"**

Sanford School of Medicine (December 1996): **"Prion Proteins and Disease"**

Sanford School of Medicine (March 1996): **"Gerontogenes, Diet, Free Radicals and Aging: Factors That Affect the Lifespan of an Organism"**

Sanford School of Medicine (October 1995): **"The Involvement of Mitochondria in Cell Life and Programmed Cell Death"**

Sanford School of Medicine (May 1995): **"How Does Fructose Protect Liver Tissue From Hypoxia?"**

Sanford School of Medicine (October 1994): **"The Role of Mitochondria in Ischemia-Reperfusion Injury"**

Sanford School of Medicine (April 1994): **"Investigation Into the Role of the Protein Disulfide Isomerase Subunits in Prolyl Hydroxylase Activity"**

**Meetings Presentations:**

American Chemical Society Annual Meeting (August 2017): **"Adverse outcome pathways- a mechanistic approach for future risk assessments"**

American Chemical Society Annual Meeting (August 2017): **"In vitro metabolomics as alternative testing strategy for predicting adverse outcome pathways of the exposome"**

Mitochondrial Health Meeting (June 2017, Arlington, VA) Poster Presented: **"Mitochondrial Involvement in Carcinogenesis"**

Society of Toxicology Meeting (March 2017, Baltimore MD) Poster Presented: **"Mitochondrial Roles in Tumorigenesis"**

Mitochondrial Biology Symposium (NIH, Bethesda, MD, May 19-20, 2016) Poster Presented: **"Oranelle Imaging Toxicology: Utilizing Coherent Multi-Probe Fluorescence Microscopy to Monitor Mitochondrial Health and Other Simultaneous Sub-cellular Events"**

Future Tox III, Society of Toxicology Meeting (November 2015, Crystal City, VA) Poster Presented: **"Utilizing Coherent Multi-Probe Fluorescence Microscopy to Monitor Simultaneous Sub-cellular Events"**

Society of Toxicology Meeting (March 2015, San Diego, CA) Poster Presented: **"Organelle Imaging Toxicology"**

Society of Toxicology Meeting (March 2014, Phoenix, AZ) Poster Presented with Professor Don Fox: **"Compound-Induced Bioenergetics Alterations: Relevance to Pathophysiology"**

Society of Toxicology Meeting (March 2012, San Francisco, CA) Poster Presented: **"Functional Observational Battery in Perspective"**

Society of Toxicology Meeting (March 2011, Washington, DC) Poster Presented: **"Organotin Toxicology: A Novel Mitochondrial Nernst Model"**

Society of Toxicology Meeting (March 2010, Salt Lake City) Poster Presented: **"The Role of Mitochondria In Toxicology"**

World Pharmaceutical Congress (May 2008, Philadelphia) **Represented Cellumen, Inc at trade booth**

High Content Analysis 2007 (Jan. 2007, San Francisco) **Represented Cellumen, Inc. at trade booth**

Croatian Biophysics Congress (September 2006 Rovinj, Croatia) Poster Presented: **"Non-Radioactive Fluorescence-Based Cell Quantitation Assay Development"**

Society For Biomolecular Screening Meeting (September 2005, Geneva, Switzerland) Poster Presented: **"An In Vitro Oxidative Stress Biomarker Assay For Drug Toxicity Screening"**

Telethon Convention (2005, Salsomaggiore Terme, Italy) Poster Presented: **"Therapeutic Intervention in Muscular Dystrophy Targeting Mitochondria"** Bernardi, P., Irwin, W., Angelin, A., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bonaldo, P.

New R&D Opportunities Forum (December 9, 2004, Sandwich, England) Poster Presented *Poster Presented:* **Low-Dose Enhancement Drug Responses in In Vitro Toxicity Assays: Detecting and Modelling Hormesis Effects of Drugs**

Ethical Innovation in the Laboratory (Sept. 21, 2004, Sandwich, England) *Poster Presented*: **Utilizing In Vitro, Human Tumor Cell Line-Based Fluorescence Microscopy Screening Assays (High Content Screening) to Reduce Animal Testing in Drug Safety Assessments.** The intent was to refine, reduce and replace animal testing (the 3 R's) with advanced in vitro toxicology models and ICCVAM initiatives.

Biomarkers Forum (April 29, 2004, Sandwich, England) *Poster Presented*: **Evaluation of Fluorescence Microscopy-Based In Vitro Safety Assays (High Content Screening) For Predicting Drug Toxicity in Humans**

Telethon Convention (2004, Italy) Poster Presented: **"Mitochondrial Intervention in Muscle Disease"** Bernardi, P., Irwin, W., Angelin, A., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bonaldo, P.

Group Italian Bioenergetics Biophysics Congress (2003, San Daniele, Italy) *Oral Presentation*: **"Lack Of Collagen VI Causes Mitochondrial Dysfunction And Calcium Dysregulation In Skeletal Muscle"** Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Telethon Convention (2003, Italy) Poster Presented: **"Study of the Mitochondrial Pathogenesis of Bethlem Myopathy Using COL6A1 Knockout Mice as an Animal Model"."** Bernardi, P., Irwin, W., Angelin, A., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bonaldo, P.

Group Italian Bioenergetics Biophysics Congress (2001, Ancona, Italy) *Oral Presentation*: **"An Animal Model of Human Bethlem Myopathy: Characterization of the Pathological Defects in the Skeletal Muscles of COL6A1 Knockout Mice"** Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Group Italian Bioenergetics Biophysics Congress (2000, Friuli, Italy) *Oral Presentation*: **"Mitochondria in Muscle Cell Death by Bupivacaine"** Irwin, W., Fontaine, E., Bernardi, P.

South Dakota Academy of Sciences Congress (1996, Rapid City, South Dakota) *Oral Presentation*: **"Fructose and Its Metabolite D-Glyceraldehyde Protect Hepatocytes During Hypoxia"**

South Dakota Academy of Sciences Congress (1995, Madison, South Dakota) *Oral Presentation*: **"Investigation Into the Protective Mechanism of Fructose During Hypoxia"**

Keystone Symposia: Mitochondria and Pathogenesis (2002, Keystone USA). Poster Presented: **"Mitochondrial Dysfunction in Muscle Fibers From Collagen VI Null Mice"**. Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Telethon Convention (2002, Riva del Garda, Italy) Poster Presented: **"Study of the Pathogenesis of Bethlem Myopathy Using COL6A1 Knockout Mice as an Animal Model"**. Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Columbaro, M., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Group Italian Bioenergetics Biophysics Congress (2001, Ancona, Italy) Poster Presented: **"Mitochondrial Changes During Chronic Feeding With the Hepatocarcinogen Acetylaminofluorene"**. Klohn, P., Soriano, M., Irwin, W., ., Bitsch, A., Neumann, H-G., Bernardi, P.

Telethon Convention (2001, Riva del Garda, Italy) Poster Presented: **"Study of the Pathogenesis of Bethlem Myopathy Using COL6A1 Knockout Mice as an Animal Model"**. Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Telethon Convention (2001, Riva del Garda, Italy) Poster Presented: **"Mitochondria as Targets of Pharmaceutical Intervention in Muscle Cell Death"** Irwin, W., Fontaine, E., Penzo, D., Bernardi, P.

Group Italian Bioenergetics Biophysics Congress (2000, Friuli, Italy) Poster Presented: **"Modulation of the Mitochondrial Permeability Transition at the P Site"**. Kloehn, P., Soriano, M., Irwin, W., Bitsch, A., Neumann, H-G., Bernardi, P.

Frontiers of Mitochondrial Research Congress (2000, Albany, USA) Poster Presented: **"The Role of Mitochondria in Muscle Cell Death"** Irwin, W., Fontaine, E., Penzo, D., Bernardi, P.

Telethon Convention (2000, Rimini, Italy) Poster Presented: **"Study of the Pathogenesis of Bethlem Myopathy Using COL6A1 Knockout Mice as an Animal Model"**. Irwin, W., Bergamin, N., Sabatelli, P., Merlini, L., Megighian, A., Reggiani, C., Braghetta, P., Volpin, D., Bressan, G.M., Bernardi, P., Bonaldo, P.

Telethon Convention (2000, Rimini, Italy) Poster Presented: **"Therapeutic Intervention in Muscle Cell Death By Mitochondrial Modulation"** Irwin, W., Fontaine, E., Bernardi, P.

Telethon Convention (1999, Rimini, Italy) Poster Presented: **"Mitochondria as Targets of Pharmaceutical Intervention in Muscle Cell Death"** Irwin, W., Fontaine, E.,., Bernardi, P.

Frontiers of Mitochondrial Research Congress (September 1998, Albany, USA) Poster Presented: **"Fructose Protects Hepatocytes During Hypoxia by Inhibition of the Mitochondrial Permeability Transition"** Irwin, W., Thomas, J.

American Society of Biochemistry and Molecular Biology Meeting (August 1997, San Francisco, USA) Poster Presented: **"Fructose Protection of Hepatocytes During Hypoxia and the Mitochondrial Permeability Transition"** Irwin, W., Thomas, J.

American Society of Biochemistry and Molecular Biology Meeting (1996, New Orleans, USA) Poster Presented: **"Protection of Hepatocytes by Fructose During Hypoxia"** Irwin, W., Thomas, J.

Mary Manibusan, Senior Managing Toxicologist
1150 Connecticut Ave., NW
Washington, DC
20005
(202) 772-4926
mmanibusan@exponent.com

Dear Sir or Madam, December 13, 2015

It is my great pleasure to recommend Dr. William Irwin for a position with your company. I had the honor of hiring Dr. Irwin into the USEPA Office of Pesticide Programs when I had served as the Chief of the Toxicology and Epidemiology Branch. As a new hire, I immediately recognized Dr. Irwin's potential as a key contributor and future leader of the Office of Pesticide Programs.

During the years that followed, Dr. Irwin has not only met my expectations, but exceeded them at many different levels. He has been a key contributor to the pyrethroid FIFRA Scientific Advisory Panel meetings due to his direct experience in Pharma with sodium channels; this is an important project for the Agency. As a technical reviewer, he has served as a member of the Residue Of Concern Knowledge based Subcommittee, Quantitative Structure Activity Relationship and Risk Assessment Review Committee and has performed the many functions of a highly skilled and experienced risk assessor.

The Office of Pesticide Programs has some challenging chemicals, including Chlorpyrifos, Amitraz, Dicamba and Dr. Irwin has contributed to these excellent assessments. In total, he has given six unique presentations at SOT representing HED, served as a representative on the Scientific Integrity Committee and wrote a chapter on organotin pesticide endocrine disruption in a development and reproduction book.

Dr. Irwin has a unique background that includes a PhD in Biochemistry and ideal experience for mode of action investigations. I highly recommend Dr. Irwin for a technical leadership position within your company and organization.

Sincerely,

Mary Manibusan, Former Director of the Endocrine Disruptor Screening Program

December 1, 2015

To Whom It May Concern:

I am writing this letter of reference for Dr. William Irwin. Dr. Irwin is currently employed by the Health Effects Division of EPA's Office of Chemical Safety and Pollution Prevention and works in the capacity of toxicologist. In his current position, Dr. Irwin has made many contributions to the agency. A few of his notable achievements are listed below:

- Mitochondrial toxicology expert (models validated in clinical trials)
- In vitro toxicology expert (assays implemented into ToxCAST)
- Editor of a toxicology journal -DABT board certification in toxicology
- Key contributor to the pyrethroid Science Advisory Panel due to experience with sodium channels, an important project for the agency
- Member of the several HED peer review committees
- Served as lead toxicologist on several complex pesticide active ingredients
- Gave 5 presentations at SOT representing HED
- Served as representative on the Scientific Integrity Committee
- Wrote a book chapter on organotin pesticide endocrine disruption

William is a valuable member of HED. Although I am not his first –line supervisor, I am aware of his contributions to the organization. As his Division Director, I see William as a highly intelligent individual with scientific expertise in toxicology. William is a dedicated and hard-working scientist who often put his personal life on hold to work on issues of scientific importance.
Dr. Irwin holds himself and those around him to high standards, and takes great care in his work. Perhaps most importantly, William is a curious and creative scientist who likes to investigate new approaches and methods. He is very proficient with technology and his cell biology training, specifically in mitochondrial function, was very valuable to much of his work in HED.
Based on all the above factors, I recommend Dr. Irwin for a scientific position.

Sincerely,

Dana Vogel,
Director, Health Effects Division, OPP/OCSPP/USEPA

Raymond J. Kent, Ph.D.
Senior Scientist
U.S. Environmental Protection Agency
Washington, D.C., 20460

Dear Sir or Madam,

It is my privilege to write a general letter of recommendation for Dr. William Irwin, DABT. I have known and worked with Dr. Irwin since he joined the EPA in 2009. He has a bachelor's degree in chemistry and a Ph.D. in biochemistry (as I do) and I have relied on him for many years for his depth of knowledge in matters of chemistry and biochemistry. In addition, his extensive scientific knowledge and expertise extend well beyond chemistry, especially in the area of pharmacology and toxicology, providing invaluable scientific support for the regulation of pesticides.

Among Will's various assignments at EPA, he is lead toxicologist for a number of high profile and complex chemicals such as chlorpyrifos, dicamba and amitraz. Based on his background and prior experience in sodium channel research, Will provides critical technical input to the pyrethroid class of insecticides. At the EPA's Office of Pesticide Programs, he is member of a variety of key committees including a toxicology scientific advisory committee (ToxSAC), a risk assessment advisory committee (RARC) and a committee that defines pesticide residues of concern (ROCKS). Apart from Will's current work in the OPP, Will's prior work on designing and implementing in vitro methods for high throughput and high content screening is utilized in the Agency's ToxCast program.

As a scientific professional in the field of toxicology, Will is board certified as a Diplomate of the American Board of Toxicology, has given multiple presentations to the Society of Toxicology while at the Agency and is an editor of a toxicology journal.

Will is highly respected by his colleagues. At the EPA, he can always be counted on to go the extra mile to ensure a robust scientific basis for regulatory action.

I am confident Will would be a great asset to your organization.

Sincerely,

Raymond J. Kent, Ph.D.
Telephone: Ex. 6

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# Mitochondrial dysfunction and apoptosis in myopathic mice with collagen VI deficiency

William A Irwin[1,2,6], Natascha Bergamin[1,6], Patrizia Sabatelli[3], Carlo Reggiani[4], Aram Megighian[4], Luciano Merlini[5], Paola Braghetta[1], Marta Columbaro[5], Dino Volpin[1], Giorgio M Bressan[1], Paolo Bernardi[2] & Paolo Bonaldo[1]

**Collagen VI is an extracellular matrix protein that forms a microfilamentous network in skeletal muscles and other organs[1–3]. Inherited mutations in genes encoding collagen VI in humans cause two muscle diseases, Bethlem myopathy and Ullrich congenital muscular dystrophy[4,5]. We previously generated collagen VI–deficient (*Col6a1*$^{-/-}$) mice and showed that they have a muscle phenotype that strongly resembles Bethlem myopathy[6]. The pathophysiological defects and mechanisms leading to the myopathic disorder were not known. Here we show that *Col6a1*$^{-/-}$ muscles have a loss of contractile strength associated with ultrastructural alterations of sarcoplasmic reticulum (SR) and mitochondria and spontaneous apoptosis. We found a latent mitochondrial dysfunction in myofibers of *Col6a1*$^{-/-}$ mice on incubation with the selective $F_1F_O$-ATPase inhibitor oligomycin, which caused mitochondrial depolarization, $Ca^{2+}$ deregulation and increased apoptosis. These defects were reversible, as they could be normalized by plating *Col6a1*$^{-/-}$ myofibers on collagen VI or by addition of cyclosporin A (CsA), the inhibitor of mitochondrial permeability transition pore (PTP). Treatment of *Col6a1*$^{-/-}$ mice with CsA rescued the muscle ultrastructural defects and markedly decreased the number of apoptotic nuclei *in vivo*. These findings indicate that collagen VI myopathies have an unexpected mitochondrial pathogenesis that could be exploited for therapeutic intervention.**

Mechanical measurements showed that isolated *Col6a1*$^{-/-}$ muscles had less tension development (**Fig. 1**). Loss of contractile strength was most prominent in diaphragm, which is the most affected muscle[6], but was also detected in flexor digitorum brevis (FDB) and other hindlimb muscles (data not shown). In diaphragm strips, isometric tetanic tension was significantly lower (**Fig. 1a**). Twitch tension was even more reduced and relaxation time was prolonged (**Fig. 1b–d**), suggesting an abnormal SR function with less $Ca^{2+}$ released on stimulation or less effective $Ca^{2+}$ uptake during relaxation[7]. The decrease in tension development was not due to variations in fiber excitability (**Supplementary Table 1** online) or to changes in fiber type composition (data not shown). The decreased contractile strength of *Col6a1*$^{-/-}$ muscles was confirmed by mechanical measurements on single skinned fibers during maximal activation (**Fig. 1e**). We detected structural alterations and irregular shape in about one-third of the skinned *Col6a1*$^{-/-}$ fibers (**Fig. 1f**). These partially damaged fibers were never found in wild-type samples and developed significantly less tension than apparently healthy *Col6a1*$^{-/-}$ fibers (**Fig. 1g**). Taken together with the presence of Evans blue–positive fibers[6], this finding suggests that collagen VI–deficient muscles contain differently affected fibers that might represent various steps of the dystrophic process.

Electron microscopic analysis identified ultrastructural defects in various *Col6a1*$^{-/-}$ muscles. About 30% of fibers had structural alterations of mitochondria and SR (**Fig. 2b**). Mitochondria had abnormal cristae with tubular shape and altered matrix density associated with the presence of dense bodies (**Fig. 2d,e**). We observed marked dilations in SR, especially at the level of triadic system (**Fig. 2g**), but sarcomeres, sarcolemma and basal lamina appeared normal. We detected myonuclei with the typical hallmarks of apoptosis in *Col6a1*$^{-/-}$ fibers with organelle alterations (**Fig. 2i**). None of these defects were present in wild-type muscles (**Fig. 2a,c,f,h**).

We investigated mitochondrial function in cultured FDB myofibers. Mitochondrial transmembrane potential ($\varnothing\psi_m$) was monitored by tetramethylrhodamine methyl ester (TMRM), a fluorescent probe that accumulates in polarized mitochondria and is released when $\varnothing\psi_m$ decreases[8]. When measured for 1 h in standard conditions, the absolute TMRM fluorescence showed no significant differences between *Col6a1*$^{-/-}$ and wild-type fibers, indicating that $\varnothing\psi_m$ levels were the same. But a mitochondrial dysfunction of *Col6a1*$^{-/-}$ fibers could have been masked by the ATP synthase operating in a reverse mode, maintaining $\varnothing\psi_m$ during the experiment[9]. To test this hypothesis, we incubated the fibers with oligomycin, an inhibitor of mitochondrial $F_1F_O$-ATP synthase that is widely used to investigate mitochondrial function in cultured cells[9–11]. As expected, addition of oligomycin to wild-type fibers did not cause immediate $\varnothing\psi_m$ changes, and mitochondrial depolarization proceeded at slow rates even after extensive incubation (**Fig. 3a**). We observed fast mitochondrial depolarization in wild-type fibers only after addition of the protonophore carbonylcyanide-*p*-trifluoromethoxyphenyl hydrazone (FCCP). In contrast, addition of oligomycin to the *Col6a1*$^{-/-}$ fibers quickly caused marked mitochondrial depolarization (**Fig. 3a,b**). Depolarization was fast, proceeding at a rate

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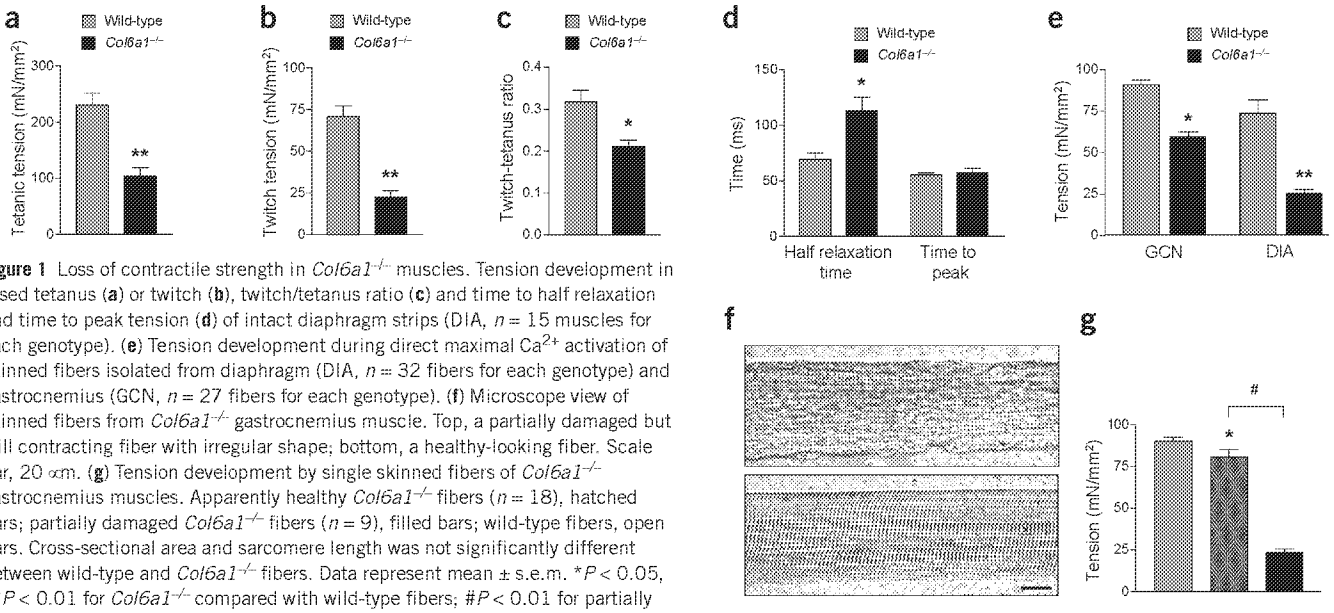


**Figure 1** Loss of contractile strength in *Col6a1*$^{-/-}$ muscles. Tension development in fused tetanus (**a**) or twitch (**b**), twitch/tetanus ratio (**c**) and time to half relaxation and time to peak tension (**d**) of intact diaphragm strips (DIA, $n = 15$ muscles for each genotype). (**e**) Tension development during direct maximal $Ca^{2+}$ activation of skinned fibers isolated from diaphragm (DIA, $n = 32$ fibers for each genotype) and gastrocnemius (GCN, $n = 27$ fibers for each genotype). (**f**) Microscope view of skinned fibers from *Col6a1*$^{-/-}$ gastrocnemius muscle. Top, a partially damaged but still contracting fiber with irregular shape; bottom, a healthy-looking fiber. Scale bar, 20 μm. (**g**) Tension development by single skinned fibers of *Col6a1*$^{-/-}$ gastrocnemius muscles. Apparently healthy *Col6a1*$^{-/-}$ fibers ($n = 18$), hatched bars; partially damaged *Col6a1*$^{-/-}$ fibers ($n = 9$), filled bars; wild-type fibers, open bars. Cross-sectional area and sarcomere length was not significantly different between wild-type and *Col6a1*$^{-/-}$ fibers. Data represent mean ± s.e.m. $^{*}P < 0.05$, $^{**}P < 0.01$ for *Col6a1*$^{-/-}$ compared with wild-type fibers; $\#P < 0.01$ for partially damaged *Col6a1*$^{-/-}$ fibers compared with apparently healthy *Col6a1*$^{-/-}$ fibers.

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comparable to that observed in wild-type fibers treated with FCCP, indicating that *Col6a1*$^{-/-}$ mitochondria were very permeable to protons.

Under various pathological conditions, mitochondria undergo a large increase in inner membrane permeability due to opening of the PTP. This process depends on mitochondrial $Ca^{2+}$ accumulation and leads to mitochondrial depolarization and other modifications that may trigger apoptosis[12]. Treatment with the PTP inhibitor CsA (**Fig. 3c**) or with the membrane-permeant $Ca^{2+}$ chelator BAPTA-AM (**Fig. 3d**) greatly improved the $\varnothing\psi_m$ response to oligomycin in *Col6a1*$^{-/-}$ fibers, but cyclosporin H (CsH), an analog that does not inhibit PTP[13], was ineffective (**Fig. 3c**). The $\varnothing\psi_m$ changes in *Col6a1*$^{-/-}$ fibers also normalized when we plated the fibers on collagen VI, indicating that the abnormal mitochondrial response to oligomycin is the result of a reversible alteration (**Fig. 3d**). These experiments indicate that the mitochondrial dysfunction unmasked by oligomycin in *Col6a1*$^{-/-}$ fibers involves PTP opening.

Increased PTP opening may alter the dynamics of intracellular $Ca^{2+}$ fluxes[14,15]. Therefore, we monitored the resting $[Ca^{2+}]_c$ of FDB fibers with Fura-2 (ref. 16; **Fig. 4**). Basal $[Ca^{2+}]_c$ levels in wild-type and *Col6a1*$^{-/-}$ fibers were not significantly different when measured in standard conditions (data not shown) or in the presence of 20 mM extracellular $Ca^{2+}$ (**Fig. 4a**). Addition of oligomycin caused a marked

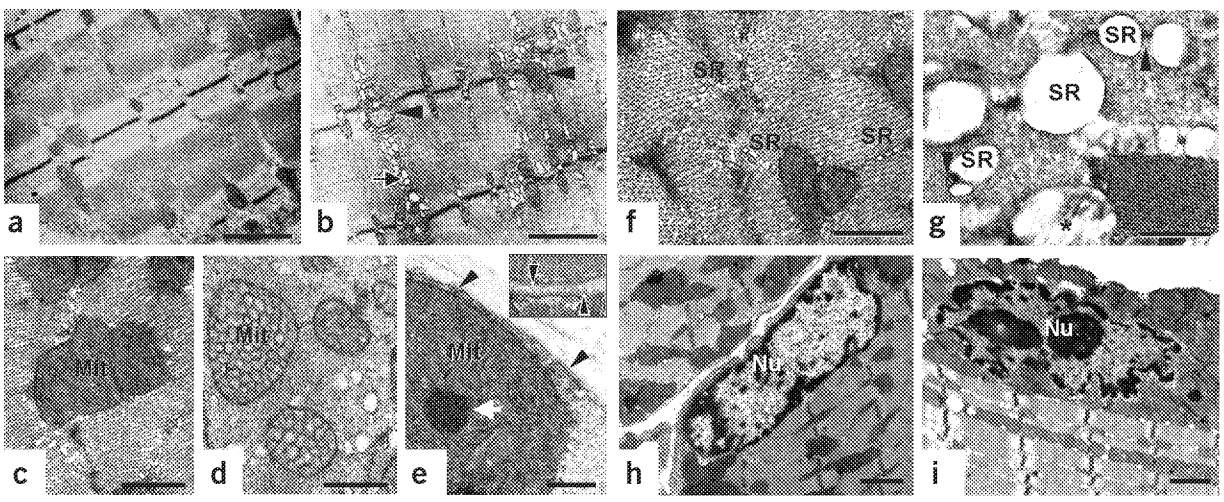


**Figure 2** Ultrastructural defects in collagen VI–deficient muscles. Electron micrographs of diaphragm and FDB muscles from wild-type (**a**,**c**,**f**,**h**) and *Col6a1*$^{-/-}$ (**b**,**d**,**e**,**g**,**i**) mice. (**a**,**b**) Low-power view of FDB longitudinal sections showing alterations in SR (arrows) and mitochondria (arrowheads) in *Col6a1*$^{-/-}$ fibers. Myofibrillar network is comparable in *Col6a1*$^{-/-}$ and wild-type mice. (**c**–**e**) High-power view of diaphragm transverse sections showing abnormal mitochondria (Mit) with altered cristae and dense bodies (white arrow) in *Col6a1*$^{-/-}$ fibers. Sarcolemma and basal lamina appear normal (arrowheads and inset in **e**). (**f**,**g**) High-power view of the triadic system showing dilation of the terminal cisternae of SR and normal T-tubules (arrowheads) in *Col6a1*$^{-/-}$ fibers. Swelling is visible in some *Col6a1*$^{-/-}$ mitochondria (asterisk). (**h**,**i**) Peripheral chromatin condensation and irregular shape characteristic of apoptosis are detected in *Col6a1*$^{-/-}$ myonuclei (Nu). Scale bars: **a**,**b**,**h**,**i**, 1 μm; **c**–**g**, 0.5 μm.



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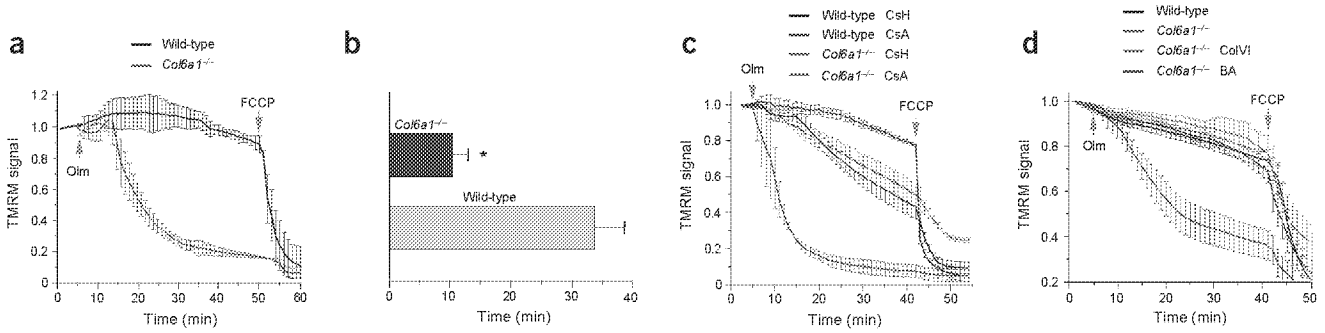


**Figure 3** Altered mitochondrial response to oligomycin in collagen VI–deficient myofibers. FDB muscle fibers were loaded with TMRM (20 nM) for 10 min at 37 °C. TMRM accumulates in mitochondria that maintain $\Delta\psi_m$. Oligomycin (Olm, 5 ∝M) and the protonophore FCCP (5 ∝M) were added at the indicated time points. (**a**) Measurement of $\Delta\psi_m$ in *Col6a1*$^{-/-}$ and wild-type fibers incubated with oligomycin. (**b**) Statistical analysis of the time required for a 20% decrease of the TMRM signal after addition of oligomycin in *Col6a1*$^{-/-}$ (five experiments) and wild-type (four experiments) fibers. (**c**) Effect of the PTP inhibitor CsA (2 ∝M). CsH (4 ∝M), an analog that does not inhibit PTP, was used as a control. CsA or CsH was added at $t = 0$. (**d**) Effect of the intracellular $Ca^{2+}$ chelator BAPTA-AM and of collagen VI. Where indicated, BAPTA-AM (BA, 5 ∝M) was added 15 min before the experiment or fibers were cultured on a substrate of collagen VI (ColVI) instead of laminin. Neither treatment changed the response of wild-type fibers (data not shown). Data represent mean ± s.e.m., $n = 2$–6 fibers for each time point and all results were confirmed in two or more independent experiments. $^*P < 0.01$ for *Col6a1*$^{-/-}$ compared with wild-type fibers.

increase of $[Ca^{2+}]_c$ in *Col6a1*$^{-/-}$ but not wild-type fibers (**Fig. 4b,c**). As for mitochondrial depolarization, the $[Ca^{2+}]_c$ response of *Col6a1*$^{-/-}$ fibers was normalized by plating on collagen VI (**Fig. 4b**). To investigate the mechanisms of oligomycin-dependent $[Ca^{2+}]_c$ increase, we incubated *Col6a1*$^{-/-}$ myofibers with EGTA and various $Ca^{2+}$ channel antagonists (**Fig. 4d**). The $[Ca^{2+}]_c$ increase was still detected in nominally $Ca^{2+}$-free buffer or in the presence of sarcolemmal voltage-dependent $Ca^{2+}$ channel antagonists, such as verapamil, but it was completely prevented by dantrolene, a specific inhibitor of the SR $Ca^{2+}$ release channels[17] (**Fig. 4d**). CsA, but not CsH, delayed and reduced the oligomycin-dependent $[Ca^{2+}]_c$ increase (data not shown). These data indicate that SR and PTP are involved in the abnormal $[Ca^{2+}]_c$ response of *Col6a1*$^{-/-}$ fibers to oligomycin, in keeping with the mutual regulatory role of mitochondria and SR for $Ca^{2+}$ handling in excitation-contraction coupling[18].

We evaluated the occurrence of DNA strand breaks and detected TUNEL-positive (apoptotic) nuclei in both *Col6a1*$^{-/-}$ muscles and cultured *Col6a1*$^{-/-}$ FDB fibers, but not in the corresponding wild-type samples (**Fig. 5a,b**). *Col6a1*$^{-/-}$ fibers had approximately seven times more apoptotic nuclei than wild-type samples (**Fig. 5c**). Addition of oligomycin increased the fraction of apoptotic nuclei and caused a significant decrease of the total number of myonuclei in *Col6a1*$^{-/-}$ fibers; both events were prevented by CsA (**Fig. 5c,d** and **Supplementary Table 2** online). As adjacent fiber segments are controlled by individual nuclei[19], progressive depletion of *Col6a1*$^{-/-}$ myonuclei may contribute to muscle fiber loss and dystrophic processes.

To test whether PTP has a crucial role in the pathogenesis of the myopathy *in vivo*, we subjected wild-type and *Col6a1*$^{-/-}$ mice to intraperitoneal injection of 5 mg CsA per kg body weight every 12 h. We chose this dose and frequency of CsA treatment on the basis of *in vivo* experiments in which PTP inhibition was estimated from the calcium retention capacity of liver mitochondria[20] (M. E. Soriano and P. Bernardi, unpublished data). After 4 d of CsA treatment, we observed substantially fewer apoptotic nuclei in both diaphragm sec-

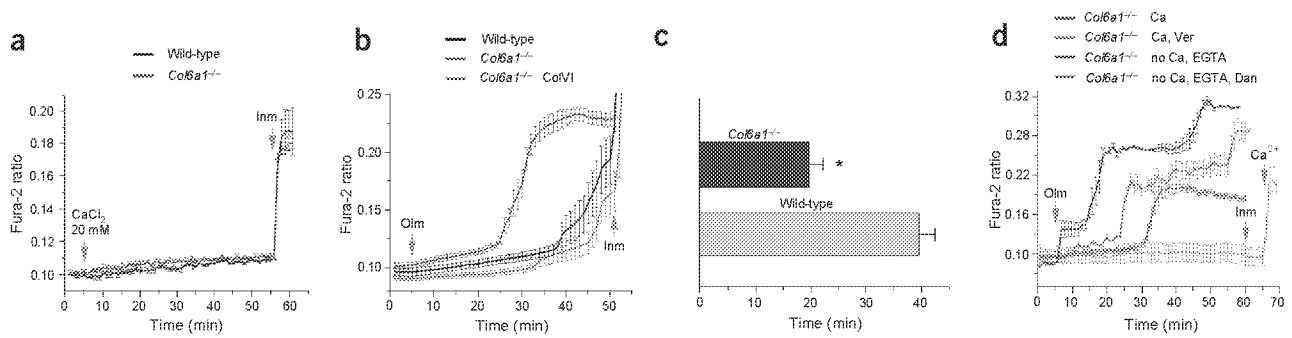


**Figure 4** Altered $[Ca^{2+}]_c$ response to oligomycin in collagen VI–deficient myofibers. FDB muscle fibers were loaded with Fura-2/AM (5 ∝M) for 20 min at 37 °C. The ratio of emission signals after excitation at 340 nm and 380 nm (Fura-2 ratio) increases with $Ca^{2+}$ levels. Oligomycin (Olm, 5 ∝M) and ionomycin (Inm, 5 ∝M) were added where indicated. (**a**) Measurement of $[Ca^{2+}]_c$ in *Col6a1*$^{-/-}$ and wild-type fibers using oligomycin-free Tyrode buffer supplemented with 20 mM $CaCl_2$. (**b**) Measurement of $[Ca^{2+}]_c$ in *Col6a1*$^{-/-}$ and wild-type fibers incubated with oligomycin and effect of collagen VI addition. Where indicated, fibers were cultured on a substrate of collagen VI (ColVI) instead of laminin. Collagen VI addition had no effect on wild-type fibers (data not shown). (**c**) Statistical analysis of the time required for a 50% increase of Fura-2 signal after addition of oligomycin in *Col6a1*$^{-/-}$ (nine experiments) and wild-type (six experiments) fibers. (**d**) Effect of EGTA, verapamil and dantrolene. Verapamil (Ver, 150 ∝M), dantrolene (Dan, 100 ∝M) or EGTA (5 mM) was added at $t = 0$ in standard Tyrode buffer (Ca) or in Tyrode buffer without $CaCl_2$ (no Ca). $CaCl_2$ ($Ca^{2+}$, 10 mM) was added at the end of the experiment as a control. Data represent mean ± s.e.m., $n = 2$–6 fibers for each time point and all results were confirmed in two or more independent experiments. $^*P < 0.01$ for *Col6a1*$^{-/-}$ compared with wild-type fibers.

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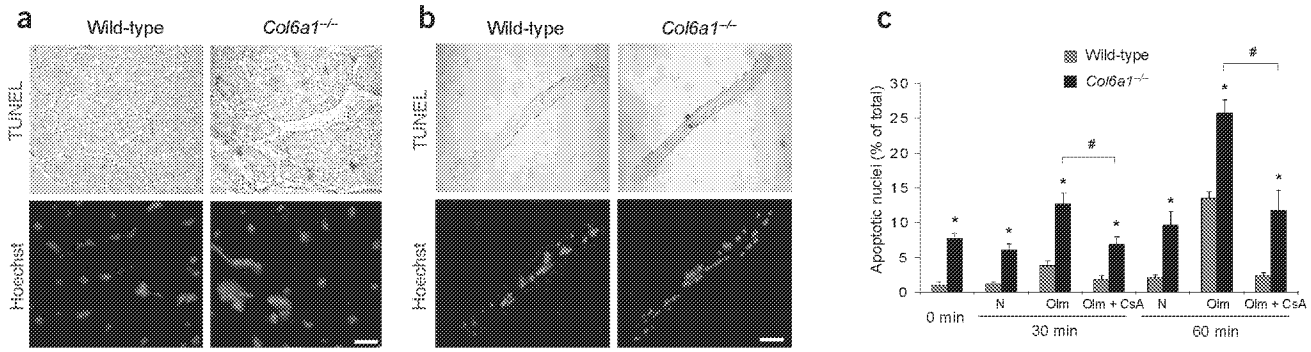


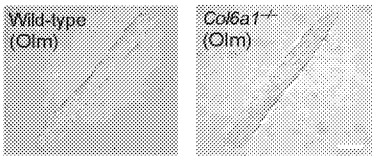
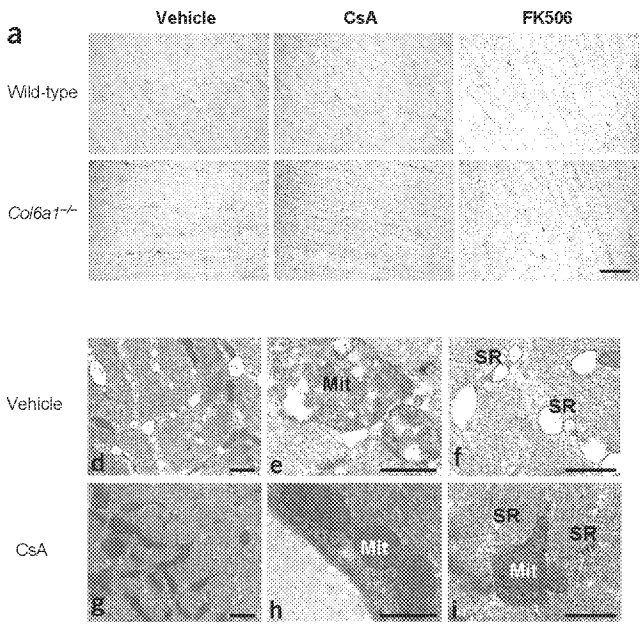




**Figure 5** Nuclear apoptosis in histological sections and cultured fibers from *Col6a1*$^{-/-}$ muscles. TUNEL staining of diaphragm (**a**) and of fiber cultures from FDB muscle (**b**). Hoechst-stained sections are shown below the corresponding TUNEL pictures. Several TUNEL-positive nuclei, labeled in red, are present in *Col6a1*$^{-/-}$ but not in wild-type fibers. (**c**) Frequency of TUNEL-positive nuclei in cultured fibers from *Col6a1*$^{-/-}$ and wild-type FDB muscles. Fibers were cultured for the indicated times in Tyrode buffer with no additions (–), in the presence of 5 μM oligomycin (Olm) or in the presence of 5 μM oligomycin and 2 μM CsA (Olm + CsA). Data represent mean ± s.e.m. of three independent experiments, $n$ = 40–130 fibers. (**d**) Hoechst staining showing a prominent example of myonuclear loss in *Col6a1*$^{-/-}$ fibers after oligomycin addition. Scale bars: **a**, 50 μm; **b**,**d**, 10 μm. *$P$ < 0.01 for *Col6a1*$^{-/-}$ compared with wild-type fibers; #$P$ < 0.01 for *Col6a1*$^{-/-}$ (Olm + CsA) compared with *Col6a1*$^{-/-}$ (Olm) fibers.

tions (**Fig. 6a**,**b**) and isolated FDB fibers of *Col6a1*$^{-/-}$ mice (**Fig. 6c**). Occurrence of PTP inhibition *in vivo* was confirmed by measurements of the calcium retention capacity of isolated mitochondria, which was always higher in mice treated with CsA (data not shown). We also treated mice with FK506, which inhibits calcineurin but not PTP[13]. FK506 increased rather than decreased the incidence of apoptotic nuclei in both wild-type and *Col6a1*$^{-/-}$ mice (**Fig. 6a–c**). When compared with diaphragm fibers from *Col6a1*$^{-/-}$ mice treated with vehicle (**Fig. 6d–f**), those from *Col6a1*$^{-/-}$ mice treated with CsA recovered considerably from the ultrastructural defects, as both mitochondrial and SR abnormalities disappeared (**Fig. 6g–i**). Rescue was virtually complete; we detected a small residual SR dilation in 1 of 300 fibers examined for diaphragm and 9 of 300 fibers for FDB muscle.

Our results identify an unexpected mitochondrial pathogenesis in collagen VI deficiency. The key issue is the mechanism leading to mitochondrial defects and apoptosis. $Ca^{2+}$ overload has been proposed as an early event in certain muscular dystrophies[21], and one possibility is that slight increases of sarcolemmal $Ca^{2+}$ influx in collagen VI–deficient fibers might result in intracellular $Ca^{2+}$ overload, eventually causing PTP opening and apoptosis. Our results suggest that this may not be the case, because $[Ca^{2+}]_c$ levels were indistinguishable in wild-type and *Col6a1*$^{-/-}$ fibers, even at 20 mM extracellular $Ca^{2+}$, and because addition of dantrolene or CsA, but not verapamil, ameliorated oligomycin-dependent $Ca^{2+}$ deregulation. Another possibility is suggested by the interaction of collagen VI with integrins and other cell surface receptors[2,3]. Collagen VI prevents



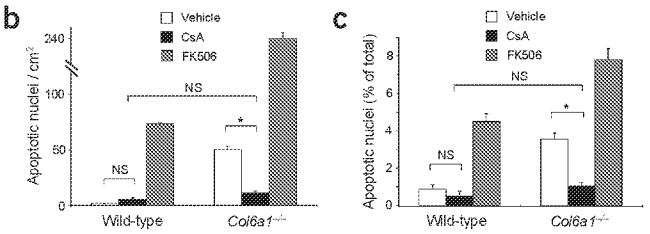




**Figure 6** *In vivo* administration of CsA prevents nuclear apoptosis and ultrastructural defects in collagen VI–deficient muscles. (**a**) TUNEL staining of diaphragm from wild-type and *Col6a1*$^{-/-}$ mice treated with CsA, FK506 or vehicle alone. (**b**,**c**) Quantification of TUNEL-positive nuclei in diaphragm sections (**b**) and cultured FDB myofibers (**c**) from wild-type and *Col6a1*$^{-/-}$ mice treated with CsA, FK506 or vehicle. (**d–i**) Electron micrographs of diaphragm transverse sections from *Col6a1*$^{-/-}$ mice treated with CsA (lower panels) or vehicle (upper panels). Low-power view (**d**,**g**) shows a marked recovery of the ultrastructural defects in mice treated with CsA. Mitochondria (Mit) and SR of *Col6a1*$^{-/-}$ mice treated with CsA are morphologically normal and similar to wild-type (compare **h**,**i** with **Fig. 2c**,**f**). Extensive alterations in mitochondria and SR are detected in *Col6a1*$^{-/-}$ mice treated with vehicle, similar to untreated *Col6a1*$^{-/-}$ mice (compare **e**,**f** with **Fig.2d**,**g**). Scale bars: **a**, 50 μm; **d–i**, 0.5 μm. *$P$ < 0.01 for *Col6a1*$^{-/-}$ mice treated with CsA compared with *Col6a1*$^{-/-}$ mice treated with vehicle; NS, not significant ($P$ > 0.05).

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apoptosis of fibroblasts when integrin-matrix interactions are perturbed or serum is withdrawn[22,23]. Notably, addition of collagen VI to fibroblasts causes downregulation of Bax[23], a proapoptotic protein that triggers PTP opening[12]. Lack of collagen VI might cause mitochondrial dysfunction and increased PTP opening through an abnormal engagement of integrins, in keeping with the recent finding that integrin-mediated signaling regulates mitochondrial function[24]. Increased PTP opening would alter $Ca^{2+}$ handling by SR[15], cause $Ca^{2+}$ deregulation with further increase of the PTP open time and thus set in motion a self-amplifying loop eventually leading to structural defects of both mitochondria and SR. Our finding that the structural alterations and apoptotic defects of *Col6a1*$^{-/-}$ muscles *in vivo* can be rescued by CsA through a mitochondrial mechanism may open the way to a pharmacological treatment for Bethlem myopathy and Ullrich congenital muscular dystrophy.

## METHODS

**Mice.** We backcrossed *Col6a1*$^{+/-}$ mice in a mixed 129/Sv × C57BL/6J background[6] into C57BL/6J strain for eight generations. We obtained data by comparing sex-matched, 8–32-wk-old *Col6a1*$^{-/-}$ mice with the corresponding wild-type littermates. Mouse procedures were approved by the ethics committee of the University of Padova.

**Drug treatment *in vivo*.** We injected wild-type and *Col6a1*$^{-/-}$ mice intraperitoneally every 12 h for 4 d with CsA (Novartis, 5 mg per kg body weight; $n = 8$), FK506 (Fujisawa, 2.5 mg per kg body weight; $n = 4$) or vehicle (olive oil; $n = 8$).

**Muscle mechanics and electrophysiology.** We dissected FDB, extensor digitorum longus and diaphragm strips from wild-type ($n = 20$) and *Col6a1*$^{-/-}$ ($n = 15$) mice and recorded twitches and tetani as described[25]. We isolated single myofibers from diaphragm and gastrocnemius muscles, chemically skinned them as described[25] and measured the tension during maximal isometric activation (pCa = 4.5, T = 20 °C, sarcomere length = 2.75 ∝m). We recorded resting and action membrane potentials intracellularly as described[26].

**Transmission electron microscopy.** We longitudinally stretched diaphragm and FDB muscles from wild-type ($n = 7$) and *Col6a1*$^{-/-}$ ($n = 7$) mice on wax, fixed them with 2.5% glutaraldehyde in phosphate buffer 0.1 M (pH 7.4) and embedded them in Epon E812 resin. We observed ultrathin sections, stained with uranyl acetate and lead citrate, in a Philips EM400 electron microscope at 100 kV.

**Isolation and culture of skeletal myofibers.** We isolated fibers from FDB muscles of wild-type ($n = 33$) and *Col6a1*$^{-/-}$ ($n = 28$) mice as described[8]. We plated intact myofibers onto glass coverslips coated with mouse EHS laminin (3 ∝g cm$^{-2}$) or collagen VI (15 ∝g cm$^{-2}$) and cultured them in Dulbecco's modified Eagle medium containing 10% fetal calf serum for 16–40 h before starting the experiment. Only apparently healthy fibers (*i.e.*, fibers without structural alterations and not stained by Evans blue) adhered to the coverslips.

**$\varnothing\psi_m$ and $[Ca^{2+}]_c$ assay.** We placed FDB myofiber cultures in 1 ml glucose-free Tyrode buffer and loaded them with appropriate probes. We used TMRM (Molecular Probes, 20 nM) to monitor $\varnothing\psi_m$ as described[8] and Fura-2/AM (Sigma, 5 ∝M) to monitor $[Ca^{2+}]_c$ according to established procedures[16]. We used oligomycin, CsA, FCCP, ionomycin, dantrolene, verapamil (all Sigma), CsH (a gift from Novartis) or BAPTA-AM (Molecular Probes) at the indicated times and concentrations. Imaging was done with a Zeiss Axiovert epi-fluorescence microscope. We analyzed data with the MetaFluor Imaging software.

**TUNEL.** We prepared 7-∝m-thick sections of muscles from wild-type ($n = 6$) and *Col6a1*$^{-/-}$ ($n = 6$) mice after formalin fixation and paraffin embedding. We fixed FDB fiber cultures in 50% acetone/50% methanol. TUNEL was done using the ApopTag *in situ* apoptosis detection kit (Intergen). We stained samples with peroxidase-diaminobenzidine to detect TUNEL-positive nuclei and counterstained them with Hoechst 33258 (Sigma) to mark all nuclei. We determined the numbers of total and TUNEL-positive nuclei in randomly selected fibers using a Zeiss Axioplan microscope.

**Statistical analysis.** Data are expressed as mean ± s.e.m. We analyzed data with the unpaired Student's *t*-test. Values with $P < 0.05$ were considered significant.

*Note: Supplementary information is available on the Nature Genetics website.*

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COMPETING INTERESTS STATEMENT
The authors declare that they have no competing financial interests.

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# Early resistance to cell death and to onset of the mitochondrial permeability transition during hepatocarcinogenesis with 2-acetylaminofluorene

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**A hallmark of tumorigenesis is resistance to apoptosis. To explore whether resistance to cell death precedes tumor formation, we have studied the short-term effects of the hepatocarcinogen 2-acetylaminofluorene (AAF) on liver mitochondria, on hepatocytes, and on the response to bacterial endotoxin lipopolysaccharide (LPS) in albino Wistar rats. We show that after as early as two weeks of AAF feeding liver mitochondria developed an increased resistance to opening of the permeability transition pore (PTP), an inner membrane channel that is involved in various forms of cell death. Consistent with a mitochondrial adaptive response *in vivo*, (*i*) AAF feeding increased the expression of BCL-2 in mitochondria, and (*ii*) hepatocytes isolated from AAF-fed rats became resistant to PTP-dependent depolarization, cytochrome *c* release, and cell death, which were instead observed in hepatocytes from rats fed a control diet. AAF-fed rats were fully protected from the hepatotoxic effects of the injection of 20–30 μg of LPS plus 700 mg of D-galactosamine (D-GalN) × kg$^{-1}$ of body weight, a treatment that in control rats readily caused a large increase of terminal deoxynucleotidyltransferase-mediated dUTP nick end labeling-positive cells in liver cryosections and release of alanine and aspartate aminotransferase into the bloodstream. Treatment with LPS and D-GalN triggered cleavage of BID, a BCL-2 family member, in the livers of both control- and AAF-fed animals, whereas caspase 3 was cleaved only in control-fed animals, indicating that the mitochondrial proapoptotic pathway had been selectively suppressed during AAF feeding. Phenotypic reversion was observed after stopping the carcinogenic diet. These results underscore a key role of mitochondria in apoptosis and demonstrate that regulation of the mitochondrial PTP is altered early during AAF carcinogenesis, which matches, and possibly causes, the increased resistance of hepatocytes to death stimuli *in vivo*. Both events precede tumor formation, suggesting that suppression of apoptosis may contribute to the selection of a resistant phenotype, eventually increasing the probability of cell progression to the transformed state.**

The role of mitochondria in cell death is being increasingly recognized (1). Mitochondrial dysfunction due to a permeability transition can precipitate a bioenergetic crisis with ATP depletion and $Ca^{2+}$ dysregulation (2–4). On the other hand, mitochondria can release proteins that cause cell death through both caspase-dependent and caspase-independent mechanisms (5–9). Release of these apoptogenic factors is modulated by members of the BCL-2 family of proteins in a way that is consistent with their role in apoptosis. Antiapoptotic members inhibit (8, 10, 11) whereas proapoptotic members favor the release (12–16) in a process that is initiated by insertion of truncated BID in the outer mitochondrial membrane (17–19) and/or by the mitochondrial permeability transition (8, 16, 20–22). Defects of apoptosis are critical to both tumorigenesis and drug resistance (23). An involvement of mitochondria in the resistance of cancer cells to apoptosis is supported by many *in vitro* studies (24), but whether this holds true *in vivo* remains to be established.

The early formation of drug-resistant hepatocytes during feeding with the hepatocarcinogen 2-acetylaminofluorene (AAF) is well documented (25), but the basis for resistance and its potential role in tumorigenesis remain obscure. Metabolic activation of AAF is a prerequisite for the manifestation of both genotoxic and nongenotoxic effects (26). Previous work has shown that 2-nitrosofluorene, a metabolite of AAF, undergoes redox cycling after reduction by the mitochondrial respiratory chain (27) and is able to trigger opening of the permeability transition pore (PTP) (28). Yet, liver mitochondria isolated from rats fed with AAF were strikingly resistant to PTP opening well before the animals developed liver cancer, leading Neumann and Coworkers to propose that mitochondrial adaptation may play a role in the selection of resistant hepatocytes (28).

The present study was designed to investigate whether mitochondrial resistance is matched by an early inhibition of cell death regulation *ex vivo* and *in vivo*. We confirmed that within 2 weeks of feeding with a diet containing 0.01–0.04% (wt/wt) AAF, liver mitochondria developed an increased resistance to opening of the PTP (28). Consistent with a mitochondrial adaptive response *in vivo*, hepatocytes isolated from AAF-fed rats became resistant to PTP-dependent depolarization, cytochrome *c* release, and cell death. AAF-fed rats were fully protected from the hepatotoxic effects of the injection of *Escherichia coli* lipopolysaccharide (LPS) plus D-galactosamine (D-GalN) (29), a treatment that in control rats readily caused a large increase of terminal deoxynucleotidyltransferase-mediated dUTP nick end labeling (TUNEL)-positive cells in liver cryosections and release of alanine and aspartate aminotransferase into the bloodstream. Treatment with LPS plus D-GalN caused BID cleavage irrespective of AAF feeding, whereas caspase 3 was cleaved only in animals fed a control diet. These results demonstrate that mitochondrial adaptation is an early effect of AAF feeding, which is likely to cause the increased resistance of hepatocytes to death stimuli *in vivo*.

## Materials and Methods

**Chemicals and Antibodies.** LPS from *E. coli* serotype O111:B4, D-GalN hydrochloride, collagenase type IV, collagen type I, valinomycin, and AAF were purchased from Sigma. Calcium-green-5N and tetramethylrhodamine methyl ester (TMRM)

Abbreviations: AAF, 2-acetylaminofluorene; D-GalN, D-galactosamine; LPS, lipopolysaccharide of *Escherichia coli*; PTP, permeability transition pore; TMRM, tetramethylrhodamine methyl ester; TNF, tumor necrosis factor; TUNEL, terminal deoxynucleotidyltransferase-mediated dUTP nick end-labeling.

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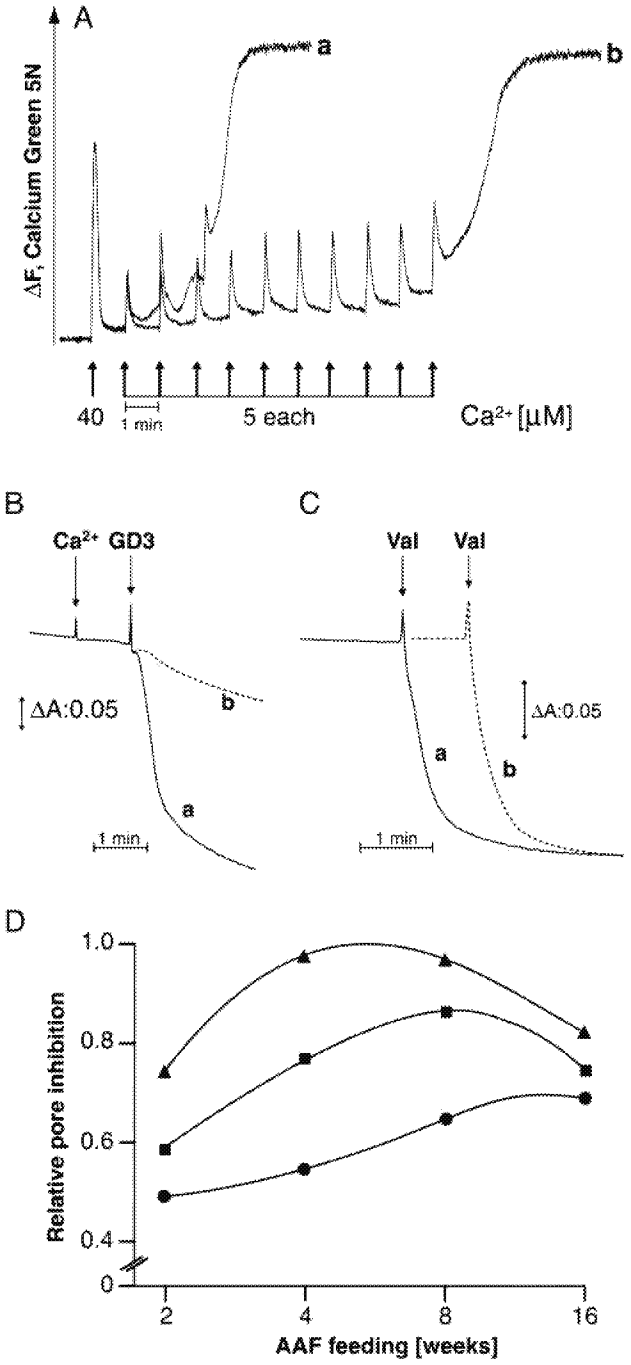


**Fig. 1.** Effect of AAF feeding on mitochondrial $Ca^{2+}$ loading capacity and on PTP-dependent and valinomycin-dependent swelling. The incubation medium contained 200 mM sucrose, 10 mM Tris–Mops, 5 mM succinate/Tris, 1 mM $P_i$/Tris, 10 $\mu$M EGTA/Tris, and 2 $\mu$M rotenone. Final volume was 2 ml, pH 7.4, 25°C. All experiments were started by the addition (not shown) of 0.4 mg $\times$ $ml^{-1}$ liver mitochondria prepared from rats fed either a control diet (traces a in all panels) or a diet containing 0.04% AAF (traces b in all panels) for 3–4 weeks. (*A*) The medium was supplemented with 1 $\mu$M calcium-green-5N, and the indicated concentrations of $Ca^{2+}$ were added at the time points marked by arrows. (*B*) Where indicated 50 $\mu$M $Ca^{2+}$ and 40 $\mu$M GD3 ganglioside were added. (*C*) The medium was supplemented with 1 mM KCl, and 1 $\mu$M valinomycin (Val) was added where indicated by the arrows. These experiments are representative of 10–45 replicates each. PTP adaptation (i.e., increased resistance to PTP opening relative to controls in protocols similar to those of *B*) was observed in mitochondria isolated from 45 of 50 AAF-fed animals. (*D*) Male Wistar rats were fed a diet containing 0.04% (▲), 0.02% (■), or 0.01% (●) AAF. At the indicated time points, rats were killed and liver mitochondria were isolated. Osmotic swelling of mitochondria (1 mg $\times$ $ml^{-1}$) was determined as shown in *B*, except that the concentration of $P_i$/Tris was 15 mM and the $Ca^{2+}$ addition, which was sufficient to trigger mitochondrial swelling in the control mitochondria, was 80 $\mu$M. Data are expressed as inhibition of swelling rates, where 0 is the rate of control mitochondria (corresponding to $\Delta A/\Delta t$ values of 249 $\pm$ 9, 201 $\pm$ 34, 210 $\pm$ 82, and 232 $\pm$ 64 $\times$ $10^{-3}$ $\times$ $min^{-1}$ for mitochondria from weeks 2, 4, 8, and 16, respectively) and 1 is the inhibition observed in the presence of 120 nM cyclosporin A (corresponding to $\Delta A/\Delta t$ values of 4 $\pm$ 2, 3 $\pm$ 2, 1 $\pm$ 1, and 10 $\pm$ 4 $\times$ $10^{-3}$ $\times$ $min^{-1}$ for mitochondria from weeks 2, 4, 8, and 16, respectively). The rate of swelling was determined by linear regression of the $A_{540}$ versus time diagram. Data represent mean values of four animals, and curves were fitted by interpolation. Standard deviations were omitted for clarity and did not exceed 0.1. Swelling rates for mitochondria from AAF-fed animals were significantly different from control values for all time points ($P <$ 0.001, Student's *t* test).

were purchased from Molecular Probes. The mouse IgG1 antibody directed against BCL-2 was purchased from Transduction Laboratories (Lexington, KY). A rabbit polyclonal antiserum raised against the core subunit 2 (Core-2) of the mitochondrial $bc_1$ complex was kindly provided by Hermann Schägger. Antibodies against cytochrome *c* (clone 6H2.B4) and BID were from PharMingen, the antibody against cleaved caspase 3 was from Cell Signaling (CELBIO, Milan), and the antibody against actin was from Sigma. The rabbit polyclonal antibody raised against the rat $bc_1$ complex and the GD3 ganglioside were generous gifts of Roberto Bisson and Fidia Research Laboratories (Abano Terme, Italy), respectively.

**Animals.** Male albino Wistar rats (180–200 g) had free access to a standard diet (Altromin 1324, Altrogge, Lage/Lippe, Germany) or standard diet supplemented with 0.01–0.04% AAF. *In vivo* treatment was essential because concentrations up to 1 mM AAF had no effects on the PTP and on respiration when added directly to isolated mitochondria (results not shown). Animals were kept under controlled conditions of temperature and humidity on a 12-h light/12-h dark cycle. With the exception of Fig. 1*D*, experiments on mitochondria, hepatocytes, or living animals were carried out after 3–4 weeks of feeding with AAF or control diet. At this time point, mitochondrial PTP resistance was already significant (see Fig. 1*D*), whereas toxic effects of AAF-feeding were not apparent as assessed by monitoring the body weight, which did not show a significant difference relative to control animals (30). All preparations and treatments were always carried out in parallel for the two sets of feeding conditions.

**Assays on Isolated Mitochondria.** Rat liver mitochondria were isolated as described (27). Mitochondrial volume changes were determined from absorbance changes at 540 nm with an Aminco DW2000 spectrophotometer (SLM, Urbana, IL). The $Ca^{2+}$ retention capacity of mitochondrial preparations was assessed fluorimetrically in the presence of the $Ca^{2+}$ indicator calcium-green-5N with a Perkin–Elmer LS50B spectrofluorimeter exactly as described (31). All instruments were equipped with magnetic stirring and thermostatic control. The incubation conditions are specified in the figure legends.

**Western Blot Analysis.** For the experiments of Fig. 2, rat liver mitochondria were lysed in a buffer containing 50 mM NaF, 40 mM sodium pyrophosphate, 20 mM Tris·HCl (pH 8.0), 10 mM EGTA, 5 mM $MgCl_2$, 1% Triton X-100, 0.5% sodium deoxycholate, 0.1% SDS, 1 mM phenylmethylsulfonyl fluoride, 20 $\mu$g $\times$ $ml^{-1}$ aprotinin, and 20 $\mu$g $\times$ $ml^{-1}$ leupeptin for 1 h at 4°C, and the lysates were cleared by centrifugation at 14,000 $\times$ *g* for 10 min at 4°C. For the experiment of Fig. 4*E*, liver homogenates were extracted with 0.3 M mannitol/5 mM Tris–Mops (pH 7.4)/4 mM $KH_2PO_4$/1 mM EGTA/2 mM phenylmethylsulfonyl

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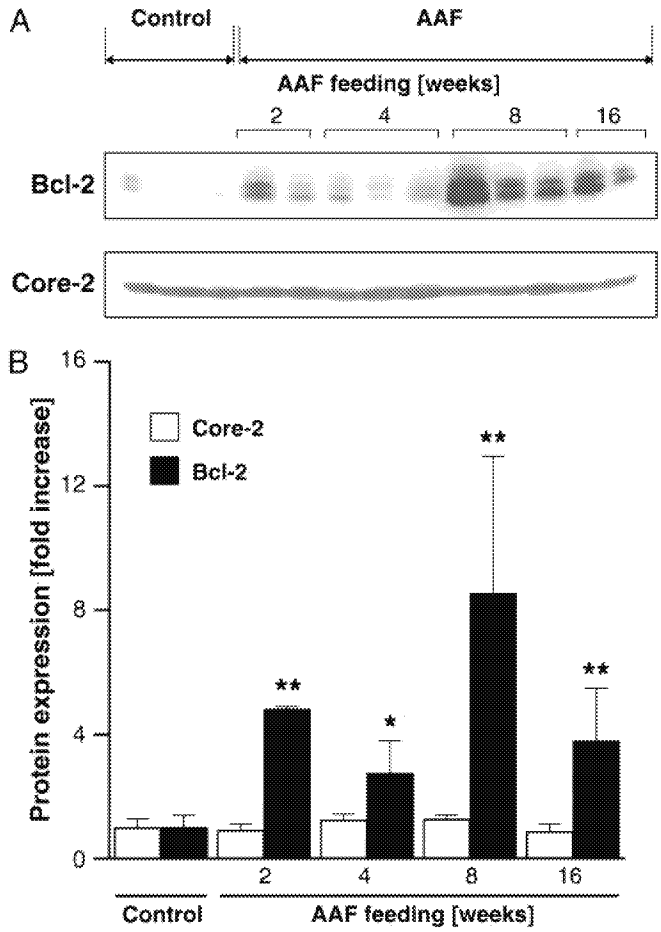


Fig. 2. Effect of AAF feeding on mitochondrial BCL-2 expression. (*A*) The levels of expression of BCL-2 and of complex III subunit Core-2 were determined by Western blotting of isolated mitochondrial proteins with antibodies against BCL-2 and Core-2. Animals were fed either a control diet or a diet containing 0.02% AAF for the indicated length of time, and each lane was loaded with mitochondrial proteins from one individual animal. (*B*) Protein expression levels were quantified as described in *Materials and Methods*, and the levels of expression were normalized to control values. Data represent mean values ± SD of three to five animals for each condition.

fluoride/10 $\mu g \times ml^{-1}$ aprotinin/1% Nonidet P-40 for 30 min at 4°C, and the lysates were centrifuged at 90,000 × *g* in a Beckman L7-55 ultracentrifuge. The extracts were diluted with 2× Laemmli gel sample buffer and boiled for 3 min. Identical protein amounts were separated by SDS/PAGE, electroblotted onto Immobilon-P poly(vinylidene difluoride) membranes (Millipore), and incubated with the antibodies as specified in the figure legends. For the experiments of Fig. 2, blots were scanned with the TLC Scanner 3 (Camag, Berlin) and quantified with the manufacturer's software, CATS 4.04.

**Preparation of Hepatocytes.** Hepatocytes were isolated by collagenase perfusion essentially as described by Berry and Friend (32). Hepatocytes were purified through a 40% (vol/vol) Percoll/Krebs–Henseleit Hepes buffer solution and rinsed free of Percoll with M199 medium supplemented with 24.7 mM Hepes and 25 mM bicarbonate (pH 7.2). Hepatocyte integrity was assessed by trypan blue exclusion and found to be always >85%. Cells were plated in six-well tissue culture plates coated with 0.01% (wt/vol) collagen type I ($5 \times 10^5$ cells per well). The culture medium was M199 supplemented with 5% heat-inactivated FBS, 100 units $\times ml^{-1}$ penicillin, 100 $\mu g \times ml^{-1}$ streptomycin, 200 nM dexamethasone, 1 nM insulin, 12.5 mM Hepes, and 25 mM bicarbonate (final pH 7.2). After 16 h the culture medium was replaced by serum-free M199 medium supplemented with 100 units $\times ml^{-1}$ penicillin, 100 $\mu g \times ml^{-1}$ streptomycin, 12.5 mM Hepes, and 25 mM bicarbonate (pH 7.2), and the experiments were carried out as further described in the following paragraph.

**Experiments with Isolated Hepatocytes.** The mitochondrial membrane potential was assessed by epifluorescence microscopy based on the mitochondrial accumulation of TMRM. Briefly, hepatocytes were preincubated with 20 nM TMRM and 1.8 $\mu M$ cyclosporin H in Hanks' balanced salt solution (HBSS) containing $Ca^{2+}$ and $Mg^{2+}$ (pH 7.4) for 20 min at 37°C, and changes of mitochondrial TMRM fluorescence were monitored with the Olympus IMT-2 inverted epifluorescence microscope equipped with a cooled charge-coupled device (CCD) camera exactly as described (33). The distribution of cytochrome *c* was determined exactly as described in ref. 34. Cell death was determined based on staining with propidium iodide. Cells were washed three times with HBSS, incubated with 2 $\mu M$ propidium iodide in HBSS for 20 min, rinsed, and immediately analyzed with the Olympus IMT-2 epifluorescence microscope.

**Treatment with LPS and D-GalN.** Rats were treated with a single i.p. injection of 20–30 $\mu g$ of LPS plus 700 mg of D-GalN $\times kg^{-1}$ of body weight. After 8 h blood samples were withdrawn from the tail vein, animals were killed by cervical dislocation, and livers were isolated for TUNEL. The TUNEL reaction was carried out on 10 $\mu m$-thick liver cryosections with an *in situ* cell death detection kit (Roche Molecular Biochemicals, Milan). Sections preincubated for 30 min with 5 $\mu g \times ml^{-1}$ DNase I (GIBCO/BRL) served as positive controls. An aliquot of serum was used to determine the concentration of tumor necrosis factor (TNF)-$\alpha$, whereas the remainder was stored at −80°C until determination of serum enzymes was performed. TNF-$\alpha$ was determined by using a rat TNF-$\alpha$ immunoassay (Quantikine M, R & D Systems) according to the manufacturer's instructions. Serum levels of alanine aminotransferase and aspartate aminotransferase were determined according to standard procedures.

**Statistical Procedures.** Paired, two-tailed Student's *t* test was used to determine the statistical significance of differences between sample mean. $P < 0.05$ and $P < 0.01$ are denoted with one or two asterisks, respectively.

## Results

In the experiments of Fig. 1*A*, we tested the mitochondrial $Ca^{2+}$-retention capacity, a sensitive measure of the propensity of mitochondria to open the PTP after $Ca^{2+}$ uptake. Mitochondria from animals fed a control diet accumulated ≈125 nmol of $Ca^{2+}$ per mg of protein before PTP opening, which can be identified by release of the accumulated $Ca^{2+}$ (trace a). Mitochondria isolated from rats fed a diet containing 0.04% AAF for 3 weeks were more resistant, in that nearly twice as much $Ca^{2+}$ was needed to trigger opening of the PTP (trace b). Mitochondria from AAF-fed rats became more resistant to other PTP-inducing stimuli. Fig. 1*B* shows that after the uptake of 100 nmol of $Ca^{2+}$ per mg of protein (a load that was not sufficient to cause PTP opening *per se*), addition of GD3 ganglioside readily caused swelling of mitochondria from control rats (trace a). As expected of a PTP-dependent event, swelling was fully inhibited by cyclosporin A (results not shown, but see ref. 35). No swelling was observed after addition of GD3 ganglioside to mitochondria from AAF-fed rats (trace b). Similar results were obtained when mitochondria were treated with other PTP-inducing agents (acetoacetate, arachidonic acid, diamide, menadione, 2-nitrosofluorene, or uncoupler; results not shown). In contrast,



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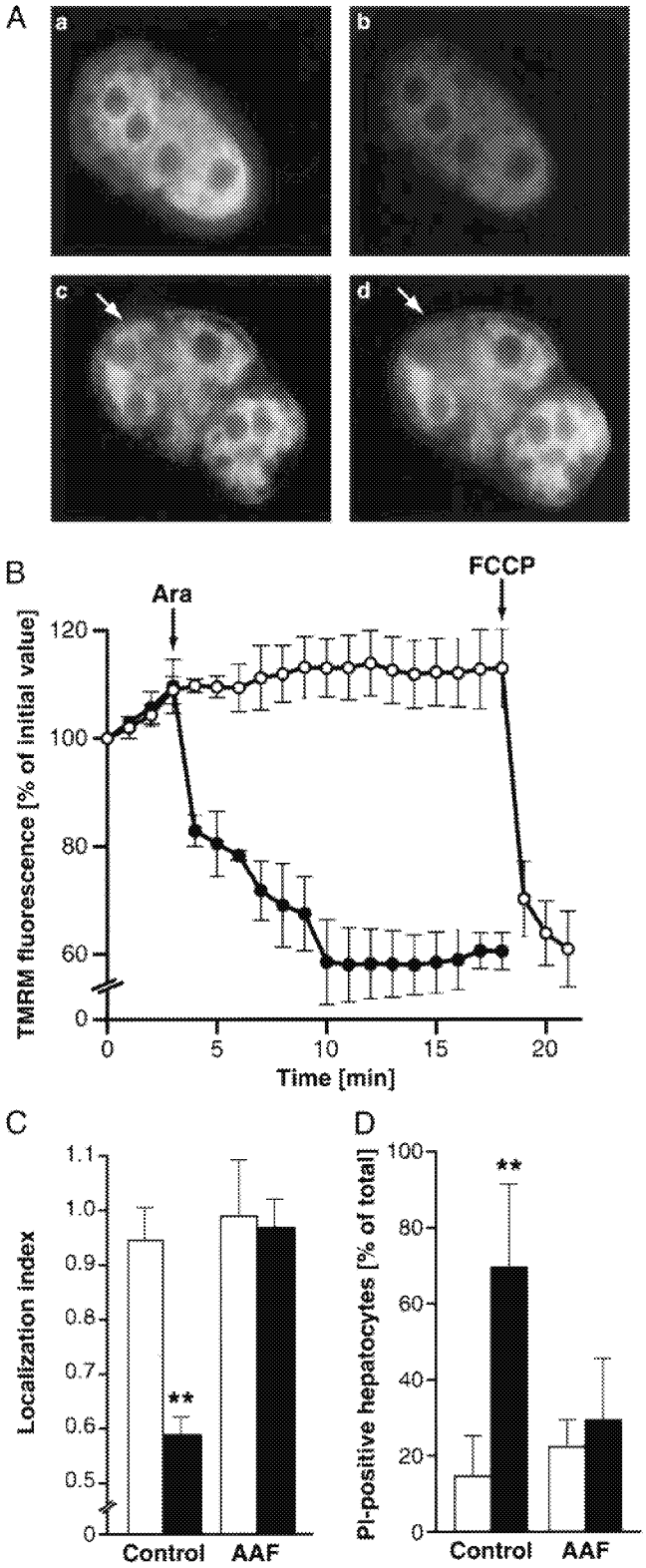


Fig. 3. Effect of AAF feeding on PTP-dependent mitochondrial depolarization, cytochrome *c* release, and cell survival after treatment of primary cultures of hepatocytes with arachidonic acid. Hepatocytes were isolated by collagenase perfusion as described in *Materials and Methods* from rats fed either a control diet or a diet containing 0.04% AAF for 4 weeks, and kept 24 h in the $CO_2$ incubator. (*A*) Hepatocytes were loaded for 20 min with 20 nM TMRM and transferred to the microscope stage. Shown are fluorescence images (magnification ×400) of hepatocytes from control (*a* and *b*) and AAF-fed animals (*c* and *d*) before (*a* and *c*) and 15 min after the addition of 200 μM arachidonic acid (*b* and *d*). (*B*) Time course of the mitochondrial fluorescence changes after the addition of 200 μM arachidonic acid (Ara) in hepatocytes from control (●) and AAF-fed (○) rats. Values (normalized to the initial fluorescence) report the mean fluorescence ± SD as determined in four independent determinations on the same preparations of hepatocytes and are representative of four separate experiments. Where indicated, 1 μM carbonyl cyanide *p*-trifluoromethoxyphenylhydrazone (FCCP) was added. (*C* and *D*) Two hundred micromolar arachidonic acid or vehicle was added to the hepatocytes, and the incubation was continued for a further 30 min [a time point at which the cytochrome *c* distribution was determined (*C*)] or 60 min [a time point at which nuclear staining with propidium iodide was determined (*D*)]. For both *C* and *D*, addition of vehicle or 200 μM arachidonic acid is denoted by open and filled bars, respectively. A lower localization index corresponds to a more diffuse distribution of cytochrome *c* relative to the $bc_1$ complex; see ref. 34 for details. Values refer to the mean ± SD of four independent determinations on the same preparations of hepatocytes and are representative of three (cytochrome *c*) or four (propidium iodide) separate experiments.

PTP-independent mitochondrial swelling by the addition of the $K^+$ ionophore valinomycin (Fig. 1*C*) caused an identical absorbance decrease in mitochondria from control and AAF-fed animals (traces a and b, respectively). Half-maximal PTP inhibition was already detectable after 2 weeks of treatment with the lowest AAF dose (0.01%) and reached a peak between 4 and 8 weeks (Fig. 1*D*). The inhibitory effect was transient, a decrease being detected with all AAF doses between 8 and 16 weeks of treatment, i.e., a time period that is characterized by a marked increase of focal lesions *in vivo* (30, 36). PTP resistance was matched by expression of mitochondrial BCL-2, which increased with the same time course as PTP adaptation (Fig. 2 *A* and *B*).

We next studied the responses of the PTP *in situ* in primary cultures of hepatocytes prepared from control and AAF-fed rats. In the experiments of Fig. 3*A*, hepatocytes were challenged with 200 μM arachidonic acid, a cytotoxic concentration (21, 37) that readily caused mitochondrial depolarization as measured by the release of intramitochondrial TMRM in hepatocytes from rats fed a control diet (*b*, compare with *a*). A striking resistance to mitochondrial depolarization was observed in hepatocytes prepared from AAF-fed rats (*d*, compare with *c*). The vast majority, but not all, hepatocytes from AAF-fed rats were resistant to arachidonic acid-induced mitochondrial depolarization. Indeed, the hepatocyte marked by the arrow in *c* and *d* underwent a mitochondrial depolarization that was indistinguishable from that of hepatocytes prepared from control animals. In Fig. 3*B*, the time course of the fluorescence changes induced by arachidonic acid in the two populations of hepatocytes is compared, confirming resistance to PTP opening *in situ* in hepatocytes prepared from AAF-fed rats. Control hepatocytes treated with arachidonic acid readily released mitochondrial cytochrome *c* (Fig. 3*C*) and became positive for nuclear staining with propidium iodide (Fig. 3*D*), whereas hepatocytes from AAF-fed rats retained cytochrome *c* in the mitochondrial compartment and remained impermeable to propidium iodide (Fig. 3 *C* and *D*, respectively).

To test whether AAF-feeding also conferred resistance to liver cytotoxic stimuli *in vivo*, we injected rats with a single bolus of LPS plus D-GalN, a well established protocol to induce acute hepatotoxicity through TNF-α release (29, 38). After 8 h of treatment with 20 μg of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight, liver cryosections revealed a sizeable number of TUNEL-positive hepatocytes in control but not in AAF-fed animals (Fig. 4*A b* and *e*, respectively). TUNEL positivity in control rats correlated with a significant number of apoptotic bodies in hematoxylin/eosin-stained slices, which were rarely detectable in slices from AAF-fed animals (data not shown). Inflammation, a frequent event in control rats that is indicated by lymphocyte infiltration of liver parenchyma, was absent in

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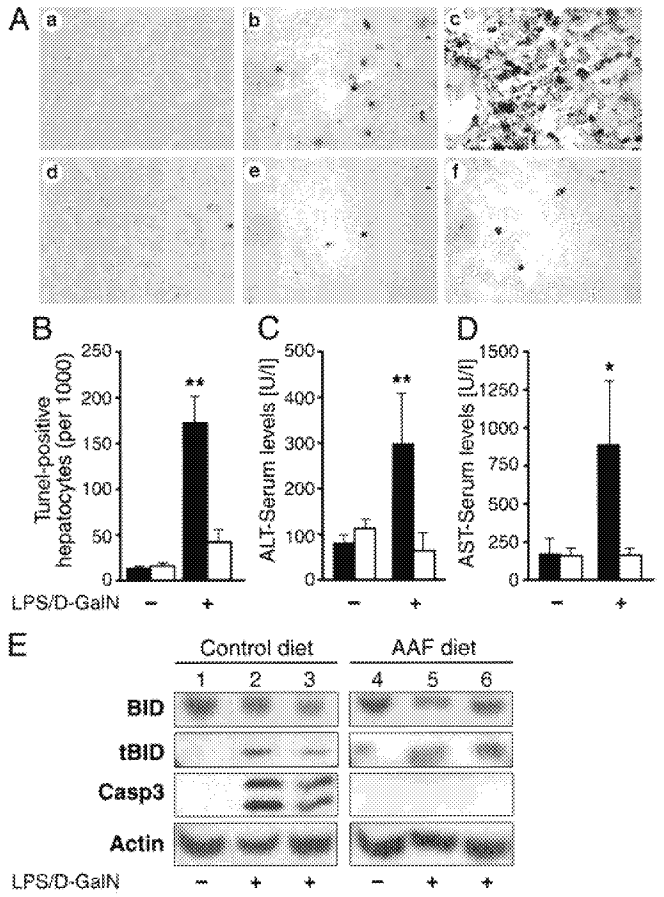


**Fig. 4.** Effect of AAF feeding on liver TUNEL staining, serum enzyme release, and BID and caspase 3 cleavage after treatment with LPS plus D-GalN *in vivo*. Rats fed a control diet or a diet containing 0.04% AAF for 3 weeks were treated with a single i.p. injection of vehicle (isotonic saline) or with LPS plus D-GalN. After 8 h blood was withdrawn from the tail vein to determine plasma levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST). Extracts from liver homogenates and liver cryosections were prepared and analyzed by Western blotting and TUNEL staining, respectively (see *Materials and Methods* for details). (*A*) Magnifications of ×50 of TUNEL-stained cryosections from control animals (*a–c*) and AAF-fed animals (*d–f*) treated with saline (*a* and *d*), or with 20 $\mu$g of LPS (*b* and *e*) or 30 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight (*c* and *f*). (*B*) Percentage of TUNEL-positive hepatocytes in control (filled bars) or AAF-fed (open bars) animals after treatment with saline (−) or 20 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight (+). For each condition nuclear labeling was determined from 20 high-power fields, which corresponds to a total of ≈1,200–1,500 hepatocytes. Error bars denote the SD of six (treatment with LPS plus D-GalN) or four (treatment with saline) independent experiments. (*C* and *D*) Plasma levels of ALT and AST, respectively, in animals treated with a control diet (filled bars) or AAF diet (open bars) after injection of saline (−) or 20 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight (+). Error bars denote the SD of five independent experiments. (*E*) Western blot analysis of BID, truncated BID (tBID), cleaved caspase (Casp) 3, and actin in liver extracts from control-fed (lanes 1–3) and AAF-fed (lanes 4–6) animals; samples in lanes 1 and 4 were from animals treated with saline, whereas samples in lanes 2, 3, 5, and 6 were prepared 8 h after treatment with 20 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight. The same blot was sequentially probed with all antibodies after stripping, and exposure times were adjusted to the intensity of the signals.

AAF-fed rats (data not shown). We also treated one pair of rats with 30 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight, a dose that caused diffuse hepatonecrosis in the control (Fig. 4*Ac*) but not in the AAF-fed animal (Fig. 4*Af*). The graph of Fig. 4*B* documents the protection obtained in AAF-fed rats challenged with 20 $\mu$g of LPS plus 700 mg of D-GalN × $kg^{-1}$ of body weight. We measured the changes of TNF-$\alpha$ after the addition of the same amounts of LPS plus D-GalN in five AAF-fed and five control-fed rats. The peak TNF-$\alpha$ serum levels displayed the following changes (fold increase over the basal level): 9.1 ± 4.8 for the group of control-fed animals; and 9.1 ± 2.9 for the AAF-fed animals. The results obtained with TUNEL staining were consistent with serum alanine and aspartate aminotransferase levels measured 8 h after administration of LPS plus D-GalN (Fig. 4 *C* and *D*). Apical caspases were activated in both control and AAF-fed rats, as shown by cleavage of BID to truncated BID (tBID), whereas caspase 3 was cleaved only in control-fed animals (Fig. 4*E*). Note that a small amount of tBID could be detected in AAF-fed animals even in the absence of LPS plus D-GalN. Thus, resistance to LPS cytotoxicity is downstream of BID cleavage.

To investigate whether discontinuation of the AAF diet would reverse the inhibition of the permeability transition, a group of four animals was fed a diet containing 0.04% AAF for 4 weeks, followed by control diet for a further 12 weeks. Measurements of PTP opening at this time indicated that inhibition of the permeability transition had been relieved by 80% in protocols identical to those described in Fig. 1*D*, and the animals regained sensitivity to hepatotoxicity after injection of LPS plus D-GalN (data not shown).

## Discussion

An involvement of the mitochondrial permeability transition in the regulation of cell death has been demonstrated in several *in vitro* systems (39), but remains to be established *in vivo*, where evidence is limited to animal models of stroke (40, 41). In the present study we addressed the question of whether an increased resistance to PTP opening plays a role in carcinogenesis in a rat liver model.

We confirmed that mitochondria isolated from livers of AAF-fed rats are strikingly resistant to $Ca^{2+}$-dependent PTP opening well before the clonal expansion of focal lesions (28). Adaptation appears to be specific for the PTP, because the response of liver mitochondria from AAF-adapted rats is indistinguishable from that of control mitochondria when valinomycin-dependent $K^+$ uptake rather than PTP opening is used to induce swelling. These findings demonstrate that inhibition of swelling does not depend on mitochondrial structural constraints or on differences in formation of the proton electrochemical gradient, issues that had not been addressed in previous studies.

Increased resistance to PTP opening was matched, and possibly caused, by an increased mitochondrial expression of BCL-2. This is at apparent variance with a previous study on mitochondria from transgenic mice overexpressing BCL-2 in the liver, where no difference in PTP opening could be detected despite *in vivo* resistance to hepatotoxicity by anti-Fas antibodies (42). We note that the increased PTP resistance to $Ca^{2+}$ is not an all-or-nothing event (Fig. 1) that can therefore be missed in protocols based on a single, large $Ca^{2+}$ load (42), and that our data are in keeping with results obtained in neural cell lines where BCL-2 overexpression promoted an increased mitochondrial $Ca^{2+}$ retention capacity (43).

PTP adaptation can also be detected in primary cultures of hepatocytes challenged with arachidonic acid, a potent inducer of cell death through the PTP (21). We assume that resistance to pore opening is an adaptation to reactive species generated by AAF metabolism in the liver. These species include 2-nitrosofluorene, which drains electrons from the respiratory chain at the level of the $bc_1$ complex, undergoes redox cycling with production of superoxide anion, and is a potent inducer of PTP opening (27, 28, 44). We think that up-regulation of BCL-2 may be a response to the increased oxidative stress (45), which would cause inhibition of the PTP and result in a decreased propensity to the release of cytochrome *c* and other apoptogenic factors (8).



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It is remarkable that the opposite phenotype, i.e., an increased sensitivity to PTP opening *ex vivo* and increased liver apoptoses were observed in the $Sod2^{+/-}$ mice, which have a decreased ability to cope with oxidative stress (46). Our demonstration that AAF feeding induces an early resistance to the otherwise hepatotoxic treatment with LPS plus D-GalN clearly indicates that an anti-apoptotic response is initiated by AAF *in vivo*. Feeding with AAF did not affect the TNF-$\alpha$ response to LPS plus D-GalN and the formation of tBID, which depends on activation of apical caspases, but it did completely prevent the activation of caspase 3. These data indicate that in this model of hepatotoxicity cell death strictly depends on the mitochondrial pathway, and that the latter is selectively suppressed by AAF feeding.

The ability to evade apoptosis is an essential hallmark of both tumorigenesis and drug resistance (23), and the early appearance of hepatocytes resistant to apoptosis during AAF carcinogenesis may substantially promote the accumulation of mutations. The inhibition of cell demise would in turn interfere with the DNA damage response pathways, leading to the accumulation of unrepaired DNA lesions, genomic instability, and malignant progression (47, 48). In other words, the selection of resistant cells would represent a tumor-promoting property of AAF, and our data indicate that resistance is established through an epigenetic rather than a mutagenic process. First, resistance was observed before the clonal expansion of preneoplastic cells (30), suggesting that cells acquire resistance to cell death stimuli before the selection of critical mutations in genes of growth-regulating proteins, and before their transformation into autonomously growing cancer cells (49). Second, increased resistance was fully reversible after returning to the control diet, a feature that is characteristic of epigenetic processes, whereas a phenotype generated by mutations is presumed to be irreversible (50, 51).

In summary, our results support a sequence of events in which the chronic challenge to the liver by AAF metabolites triggers epigenetic responses that include mitochondrial PTP adaptation. The benefit of resistance to AAF toxicity would be outweighed by the persistence of mutated cells, eventually resulting in the formation of tumors. It will be interesting to identify the relevant changes by comparing the protein expression profiles of liver mitochondria from control and AAF-fed rats.

We thank Dr. Martina Zaninotto (Department of Laboratory Medicine, Padua University Hospital) for the determination of serum enzymes, Prof. Hermann Schägger for generously providing Core-2 antibody, and Ray Young for expert help with graphics. This work is in partial fulfillment of the requirements for the Ph.D. degree of M.E.S. It was supported in part by grants from the Ministero per l'Università e la Ricerca Scientifica e Tecnologica "I mitocondri nella fisiopatologia cellulare: meccanismi patogenetici e sintesi chimica di nuovi farmaci," the Associazione Italiana per la Ricerca sul Cancro, and the Armenise-Harvard Foundation (to P.B.). W.I. was supported by a Fellowship from Telethon-Italy (Grant 1141 to P.B.). P.-C.K. gratefully acknowledges the Deutscher Akademischer Austauschdienst (DAAD), the Forschungszentrum Karlsruhe, and the Armenise-Harvard foundation for support during his visits to Padua.

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TSCA
NEW CHEMICALS
COALITION

January 23, 2018

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of company representatives that have identified specific issues related to new chemical review at the U.S. Environmental Protection Agency (EPA) under amended TSCA. The TSCA NCC was formed to work collaboratively with you and others at EPA to resolve these issues while still achieving mandated deadlines and timely chemical reviews.

We are well aware of and grateful for EPA staff's efforts to address the backlog of premanufacture notices (PMN) that initially resulted after new TSCA was enacted. As we stated during the December 6, 2017, EPA workshop, we are alarmed that EPA's review of PMNs considered since TSCA was amended has resulted in "not likely" determinations for only ten percent of the notifications submitted. This contrasts sharply with the >80 percent that were dropped without regulation under old TSCA. While we recognize and understand EPA's obligation under new TSCA to make determinations and take necessary actions, we do not agree with the implication that the vast majority of PMNs were under-regulated under old TSCA. We believe that EPA's current practice of imposing restrictions may be inappropriate and, in many cases, is based on a review process that lacks transparency and on legal and/or scientific principles that are, for the most part, entirely unspecified. This lack of clarity has inspired regulatory results that to us seem anomalous.

For example, there are six process steps and/or meetings that are part of EPA's review of a PMN -- (1) Chemistry Review and Search Strategy (CRSS); (2) Structure Activity

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Team (SAT); (3) Engineering and Exposure Assessments; (4) Focus meeting; (5) Risk Assessment Division (RAD) Disposition meeting; and (6) Division Directors meeting. We believe it would be helpful to confirm that in each of these steps the appropriate parameters and interpretations for "reasonably foreseen" conditions of use are identified so that they can be applied consistently. These criteria should not be subject to change between steps or applied differently by EPA staff or managers. A request from EPA senior management to new chemical review staff to describe the reasonably foreseen conditions of use of a particular chemical should be quickly and easily answerable, and the same answer should be provided at all points during the review process. Similarly, the review process should be based on a clear and consistent understanding of what is considered a reasonably foreseeable (as opposed to any foreseeable) use, and that understanding should be consistently applied during the review process.

Within the SAT, it would be helpful to obtain a better understanding on whether staff at this step in the PMN review process might conclude "insufficient information" exists and, if so, how staff makes "low/moderate/high" calls for health and ecotoxicity concerns. We believe that any default exposure/release assumptions that are applied should be compiled, shared, and reviewed to ensure all such assumptions have been appropriately peer or expert reviewed. Furthermore, we have noticed a number of cases in which information provided in a submission was ignored or missed or in which assessors made errors in the information input to EPA models. While we recognize the resource constraints that EPA is operating under, such errors exacerbate the problem, requiring additional effort for EPA reviewers to rerun models and revise the various reports. This problem may be a result of or compounded by the organization of assessment teams that do not provide for redundancy of expertise.

Recognizing that amended TSCA states that any "unreasonable risk" should be managed "to the extent necessary," EPA new chemical review staff should be able to explain clearly exactly how any proposed management action satisfies the "to the extent necessary" standard, but does not exceed it. EPA should also be able to provide documentation of coordination with the U.S. Occupational Safety and Health Administration (OSHA) for any proposed workplace exposure control measures, as required under TSCA Section 5(f)(5).

We offer these as illustrative examples of the types of issues TSCA NCC wishes to explore with EPA. We believe our members are well suited to share with EPA other examples that merit discussion and believe that our collective experience with the new Section 5 process,

and thoughts and observations on it, will assist EPA in developing a robust, transparent, and legally defensible process.

The TSCA NCC membership appreciates that you are aware of concerns on the high percentage of regulated new chemicals and will be reviewing new chemical assessment decisions for the time being. We offer below several questions as potential discussion starters between you and the PMN review staff.

- At each step in the PMN process, how are reasonably foreseen uses identified and differentiated from "any possible" conditions of use?
- How much of a driver are reasonably foreseen uses in precluding "not likely" determinations?
- How and on what basis does the SAT make its low/moderate/high hazard calls? What is the role of uncertainty in these judgments?
- Under what circumstances would EPA make a "not likely" determination if SAT makes a moderate or high hazard call?
- What role do chemical analogs pay within the SAT deliberations? How does SAT assess the appropriateness of analogs?
- How do the number of SAT low/moderate/high calls post amended TSCA compare with prior statistics?
- Is there a summary of default assumptions used for exposure/release estimations?
- What kinds of risks are attributed to chemicals with insufficient information?

- If testing is proposed, how are elements of Section 4 (tiered testing, animal welfare issues) considered and incorporated?

- If workplace exposure controls are required, how did the required coordination with OSHA occur?

- If restrictions are proposed, how are those assessed to be "to the extent necessary"?

Thank you for your consideration of these suggestions. We hope you find them helpful.

Sincerely,

Kathleen M. Roberts

cc: Nancy B. Beck, Ph.D., DABT (via e-mail)

TSCA
NEW CHEMICALS
COALITION

January 19, 2018

Via Docket Submission

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: TSCA NCC Comments on EPA New Chemicals Review Process Documents; Docket Number EPA-HQ-OPPT-2017-0585

Dear Sir or Madam:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)[1] offers these comments in response to the U.S. Environmental Protection Agency's (EPA) request for comment on its process for reviewing new chemical substances under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (82 Fed. Reg. 51415 (Nov. 6, 2017)). The input below builds on the oral comments made on behalf of the TSCA NCC during the December 6, 2017, EPA workshop.

EPA prepared three separate documents for discussion at the December 6, 2017, workshop: (1) Points to Consider When Preparing TSCA New Chemical Notifications; (2) New Chemicals Decision-Making Framework; and (3) New Chemicals Decision Guidelines Manual. The TSCA NCC is particularly pleased that EPA issued the second two documents that we believe make significant strides in providing transparency to new chemical submitters on how EPA assesses and reaches decisions on new chemical notifications. As the TSCA NCC noted to EPA before the December 6, 2017, workshop, while the information elements in the Points to Consider document are important, the identification of this information without more explanation does not provide the clarity, transparency, and understanding that affected companies need regarding EPA assessment and regulatory approaches under amended TSCA. Beyond knowing *what* to report in a submission, stakeholders need to understand *why* the information is needed by EPA assessors and *how* that information will be used by EPA and incorporated into a new chemical risk evaluation.

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[1] The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under amended TSCA and work collaboratively with EPA and other stakeholders to address them.



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We offer below specific feedback on the three documents.

**Points to Consider When Preparing TSCA New Chemical Notifications**

TSCA NCC members appreciate EPA's efforts in preparing the Points to Consider document. The document will assist submitters in preparing new chemical notifications that meet the requirements under Section 5 and facilitate EPA's review of the submission by ensuring that the information received accurately and completely reflects the intended manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance. Below we identify additional considerations or revised text that we believe will strengthen the utility of this document for new chemical notifiers.

**Section II:** The TSCA NCC recommends that the section be expanded to include a discussion on analogs for notified chemicals. Specifically, EPA should provide guidance for submitters to consider in explaining and scientifically justifying the basis for any proposed analogs. This will provide EPA staff with clear indications as to why the submitter believes that EPA should consider and apply the analog in review of the new chemical. The TSCA NCC also recommends that EPA provide specific justification when EPA disagrees with the submitter's suggestion of analogs.

**Section III, Part D, Subpart i - Human Health Hazard/Toxicity:** The TSCA NCC urges EPA to expand on the language related to information needed for chemical substances that may be potentially respirable. In the document, EPA recommends that submitters consider whether information on the particle or droplet size may assist in EPA's assessment of respirability. We believe EPA should also consider other factors that could assist in its determination of respirability, such as viscosity and vapor pressure for liquids.

The TSCA NCC also suggests that an additional consideration be added in this section related to the potential for absorption, relevant or anticipated routes of exposure, and metabolic potential of the new chemical.

EPA should revise its bullet point that currently reads, "Justification for consideration of the analog for the endpoint(s) identified (e.g., similarity of structure, physical chemistry, toxicological data, as applicable)," to "Scientific justification for consideration of the analog for the endpoint(s) identified (e.g., similarity of structure, physical chemistry, toxicological data, metabolism, as applicable)."

The TSCA NCC urges EPA to consider the conclusions of other competent authorities, rather than relying solely on full studies on the analogs, and suggests that the guidance reflect this point.

**Section III, Part D, Subpart ii – Environmental Fate:** EPA should provide additional clarification on the two approaches offered for estimating fate parameters: (1) modeling and (2) use of physical-chemical properties. EPA should elaborate on and explain the difference between the two approaches and the reliability of information generated, particularly when a new chemical is not suitable for modeling.

**Section III, Part D, Subpart iii – Aquatic (Environmental) Hazard/Toxicity:** In its discussion regarding the use of the Ecological Structure Activity Relationships (ECOSAR) Predictive Model, EPA should provide clarity as to when the model should be used. The text could be interpreted to mean that EPA will use ECOSAR regardless of data included in the new chemical submission.

EPA should specify under what circumstances EPA will give preference to a ten-fold acute-to-chronic extrapolation or an ECOSAR predicted value in its derivation of chronic toxicity values for this endpoint. If EPA will default to whichever is more conservative, there is little incentive for submitters to perform aquatic toxicity testing.

EPA states that, as a general rule, it will consider that an organic new chemical substance has a low hazard if the log $K_{ow}$ is greater than 8. EPA should specify whether it will use measured melting point, water solubility, or other measured physical-chemical data to improve the estimate of $K_{ow}$. EPA should also include examples of when this general rule would not apply. The TSCA NCC notes a number of circumstances when EPA assessors have excluded measured properties in the modeling calculations.

In the document, EPA explains that it may consider environmental aquatic hazard to be low for a specific toxicity endpoint value (96-h fish $LC_{50}$), if that value is greater than ten times the measured water solubility value or the measured water solubility value is less than 1 microgram/liter (< 1 part per billion). EPA should clarify that this also applies in the case of an ECOSAR estimate.

EPA notes that "information" related to environmental hazards for both short-term (acute) and long-term (chronic) exposures should be included in a new chemical submission. EPA should clarify whether ECOSAR estimates would be sufficient for this purpose.

EPA suggests that notifiers provide information on the percent of amine-nitrogen content for all relevant chemical substances (*e.g.*, polycationic polymers). The TSCA NCC

notes that EPA chemists routinely calculate this number. Rather than simply submitting the percent amine-nitrogen, the notifier could provide EPA with insight as to the limits of amine nitrogen intended or necessary for the functional use of the notified chemical.

EPA should revise the bullet point, "Provide justification for consideration of the analog for the endpoint(s) identified," to read, "Provide scientific justification for consideration of the analog for the endpoint(s) identified.

**Section III, Part E:** The TSCA NCC notes that potentially exposed or susceptible subpopulations are not mentioned in this section, which focused on exposure assessments.

**Section IV, Part B:** In its discussion of chronic aquatic risk, EPA should provide clarification that the conservative criterion for potential chronic risk should not apply if it is known that the number of consecutive days for exceedance is lower than 20 (batch process).

**Section VII, Part ii – Additional Information and Training:** The TSCA NCC urges EPA to continue the Sustainable Futures program, and consider expanding it so that more parties can receive the training. We believe that stakeholders benefit greatly from this program and wish to see it utilized more robustly.

**Input on New Chemicals Decision-Making Framework**

The TSCA NCC applauds EPA in providing this document as part of the public review and comment on its new chemical review process. The Framework allows stakeholders to understand better EPA's approach in decision making for new chemical notices and is a solid first step in EPA's efforts to clarify its policies and procedures under new Section 5. Transparency and predictability are vital for a well-functioning New Chemicals Program, for submitters, for stakeholders, and for program efficiency. We provide below some thoughts and suggestions to strengthen the Framework document and EPA approaches.

**Introduction:** EPA should refrain from stating that the Lautenberg Act amendments require it to make affirmative determinations on Section 5 notices, as the term "affirmative" does not appear in the statute. The sentence in the EPA Framework document that currently reads, "The Lautenberg Act amendments to TSCA require that EPA make affirmative determinations on premanufacture notices received under section 5," should be revised to read, "The Lautenberg Act amendments to TSCA require that EPA make determinations on notices received under section 5."

**Footnote 3:** The TSCA NCC supports the EPA statement that a reasoned evaluation will be able to shape hazard and exposure characterizations into either a quantitative or robust qualitative characterization of risk. We are concerned, however, with the statement, "This suggests that the level of uncertainty in a reasoned evaluation to inform a 'not likely' determination could be greater than that in an evaluation to inform a 'presents' determination." In our view, this could be read to mean that EPA will use the qualitative approach to support a "likely to present" determination but will be unable to do so for a "not likely to present" determination. The TSCA NCC suggests that EPA modify the language to state that in EPA's view the statutory language requires a greater degree of certainty for EPA to make a "presents unreasonable risk" finding.

**Overall Framework:** EPA references workplace practices and exposure controls as part of its consideration of conditions of use for a notified new chemical substance. The TSCA NCC reminds EPA of the points articulated in the TSCA NCC's December 1, 2017, letter to Jeffery Morris (EPA) regarding workplace exposure controls and regulations under the Occupational Safety and Health (OSH) Act. As stated in the Framework document, EPA should rely on the information provided by the submitter in a safety data sheet (SDS) on recommended personal protective equipment (PPE) and/or engineering controls to protect workers from potential exposure and incorporate those factors into the intended condition of use determination for the new chemical substance. Furthermore, EPA should recognize that the Occupational Safety and Health Administration (OSHA) has the statutory authority and extensive regulatory scheme, as well as its enforcement mechanisms, to govern workplace chemical exposures, including exposure to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place, including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the OSH Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty

requirement is particularly relevant to new chemicals given the limited information that is often available.

If the PPE and engineering controls are considered as part of the conditions of use, they should also be considered in EPA's decision regarding imposition of risk management requirements. We remind EPA that, as discussed in the referenced letter, under TSCA Section 5(f)(5), it is required to consult with OSHA before requiring workplace protections under Sections 5(e) and (f). EPA can inform the submitter and OSHA of its hazard assessment and EPA's views on exposure limits and PPE and EPA can publish such information (for example, using its ChemView database), and point to such information using an Inventory Flag so that other manufacturers or processors are aware of EPA's concerns and address those concerns in their own workplace safety assessments. We believe that absent extraordinary circumstances, EPA should rely on OSHA's pervasive and established requirements and enforcement mechanisms to ensure workplace protections for new chemicals. It is frequently the case that the new substance is less hazardous than an existing substance it is intended to replace. If two substances both require gloves, goggles, and a particular respirator to ensure a safe workplace, but one has a Section 5(e) order and/or a significant new use rule (SNUR) requiring such protection and the other applies these workplace protections based on the General Duty clause and OSHA's regulations, there is little to be gained, and much to be lost by the unequal TSCA regulatory burden that disfavors the safer new chemical alternative. We look forward to further discussion with EPA on the points raised in our letter.

The TSCA NCC supports the Framework document statement that identification of "reasonably foreseen conditions of use will be fact- or knowledge-specific: that is it will be based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission" and that EPA "should try to minimize speculation when identifying reasonably foreseen conditions of use." Additional language that clarifies that "reasonably foreseen" is not the same as "any imaginable" condition of use should be included.

The TSCA NCC also supports the proposed approach to address concerns with reasonably foreseen conditions of use, but not the intended conditions of use as described in a submission, through the use of SNURs. The TSCA NCC is aware that some non-governmental organizations (NGO) have raised concerns with this approach but the TSCA NCC does not believe these concerns are valid. The concept that persons using a chemical would be unknown to EPA and therefore unable to have enforcement applied is ill-conceived. Parties using a chemical are required to have an SDS and provide to an inspector upon request, which would trigger any questions as appropriate. While testing cannot be imposed via a non-order SNUR as it can via a SNUR based on an order, EPA can and does discuss testing needs in SNURs and if there is a need to impose testing, EPA has that authority under Section 4. Like consent orders, SNURs can be reopened if EPA comes to understand new toxicity or risk issues. SNURs apply

to all parties using the chemical in question, whereas consent orders only apply to the signatories and a SNUR is typically written to have the same binding effect on a premanufacture notice (PMN) that a Section 5(e) consent order can. The TSCA NCC notes that in its "non-order SNUR" approach, EPA does not make its final determination until the SNUR is published in final, so non-exempt commercial activity is prohibited until the SNUR is in place.

**"Not Likely to Present Unreasonable Risk" Section:** The TSCA NCC is concerned that EPA does not explicitly mention the role of analog information in making a "not likely to present unreasonable risk" decision. Analog information is clearly identified as a consideration in an EPA determination of "presents unreasonable risk." The TSCA NCC believes that analog data can and should be relied on for either "presents" or "not likely to present" determinations, but suggests that this section be expanded to include how analog data can support a "not likely to present unreasonable risk" decision.

**"Insufficient Information to Permit a Reasoned Evaluation" Section:** The TSCA NCC notes that determinations under Section 5(a)(3)(B)(i) are based on health and environmental effects. As such, EPA should delete reference to "exposure potential" in the discussion of data adequacy.

Furthermore, the TSCA NCC reminds EPA of the need to develop information that will be needed to inform decisions on prioritizations of existing chemicals. In the event EPA determines that it has insufficient information to permit a reasoned evaluation of a new chemical substance, but close analogs of that substance are active in commerce, EPA could consider testing on the category, cluster, or class of substances, rather than simply placing the testing burden on the new chemical. This approach reduces the "bias" against new chemicals and builds off of EPA's previous efforts to develop categories, such as the category evaluations conducted under the High Production Volume (HPV) Chemicals Challenge.

**Additional Thoughts and Comments:** EPA should expand the Framework to include discussion on Section 5 exemptions.

EPA should provide stakeholders with assurance that "reasonably foreseen" conditions of use do not equate to "any possible conditions of use." As noted in the TSCA NCC oral comments from the December 6, 2017, workshop, EPA appears to be proposing regulation for every substance for which EPA has identified a hazard other than low hazard for both health and the environment. Such a "hazard-based" approach cannot possibly be the correct interpretation of TSCA as reformed; otherwise Congress would have not left the risk-based standard in place for the "not likely" determination in the TSCA amendments.

EPA should provide more clarity on the level of certainty needed on hazards and conditions of use for EPA to reach a "not likely" determination.

While the TSCA NCC understands and appreciates that each new chemical submission is unique and requires its own evaluation, EPA should strive to include additional case studies or examples in the Framework document.

As noted in the TSCA NCC oral comments at the December 6, 2017, workshop, and as discussed in written communications with EPA, the TSCA NCC recommends that EPA provide written guidance on the use, applicability, and legal effect of the "polymer flags" that are being used by EPA in the case of a PMN for a polymer that meets the polymer exemption criteria.

**Outline for New Chemicals Decision Guidelines Manual**

As requested, the TSCA NCC is providing input on sections that should be added to the outline for the New Chemicals Decision Guidelines Manual, as well as other suggested edits.

**Section 1.6 - Affirmative Determinations, Risk Management and Regulatory Options:**

- Delete the term "affirmative" as it does not appear in the statute.
- Add "OSHA Consultation Section 5(f)(5)."
- Add "Section 5(h) Exemptions."

**Section 7.0.2 - Testing Strategies:**

- Add "and Adverse Outcome Pathway Information."

**Section 7.1 - Development of New Categories:**

- Revise to two separate units: (1) "Updating of Existing Categories" and (2) "Development of New Categories."

**Section 8.0.2 - Selection and Use of Analogs:**

- Revise title to read "Selection and Use of Analogs and SAR Analysis."

**Section 8.2.3 - Use of Models:**

- Revise title to read "Use of Models and SAR Analysis."

**Section 8.2.4 - Selection and Use of Analogs:**

- Revise title to read "Selection, Scientific Justification, and Use of Analogs and SAR (QSAR and SAR) Models."

**Section 9 - Environmental Fate:**

- Include a section, "Overview of Environmental Fate."

**Section 10 - Chemical and Biotechnology Exposure Assessment:**

- The TSCA NCC believes this section needs more depth and explanation.
- Add "Overview of the Exposure Assessment Process."
- Add "Human Exposure Assessment."
- Add "Occupational Exposure Assessment."
- Add "Relationship to OSHA Hazard Communication, SDS, and General Duty."
- Add "General Population and Consumer Exposure Assessment."
- Add "Potentially Exposed Subpopulations."
- Add "Susceptible Subpopulations."
- Add "Environmental Exposure Assessment."

**Section 11 - Exposure-Based Policy for Chemicals:**

- Add "Overview."
- Add new section -- "Role of Section 26 Sound Science Provisions" before current Section 12.

**Section 14 - Risk Management:**

- Add "Section 5(f)(5) OSHA Consultation."
- Exemptions.

**Section 14.2 - Statutory Determinations:**

- Revise to read "Statutory Determinations, Regulatory Actions, and SNURS on PMNs."

**Appendix A - Chemical Categories:**

- Revise to two separate appendices: (1) "Existing Chemical Categories" and (2) "Guidance/methodology to formulate and use categories."

The TSCA NCC looks forward to continuing to work with EPA to strengthen the Section 5 program. Thank you for the opportunity to provide these comments.

Sincerely,

Kathleen M. Roberts
TSCA NCC Manager

TSCA
NEW CHEMICALS
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January 23, 2018

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) submits this letter as a follow up to its December 1, 2017, letter related to the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5) (copy appended).

**Approach for Communication of Workplace Exposure Concerns with New Chemical Notifier**

As discussed in the December 1, 2017, letter, and our other engagements with the U.S. Environmental Protection Agency (EPA), the TSCA NCC believes that EPA needs to implement an appropriately robust and ongoing consultation process with OSHA "prior to adopting any prohibition or other restriction" per TSCA Section 5(f)(5) that addresses occupational exposure issues. Should EPA identify new chemical risk concerns related to worker exposure issues in a premanufacture notice (PMN), EPA should evaluate the adequacy of the existing OSHA regulatory obligations and adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks that are not otherwise addressed. Given the mandate to consult with OSHA, the proper role for EPA should be to provide hazard identification and risk assessment information to the PMN submitter, to OSHA, and to other potential manufacturers, importers, or processors to make these parties fully aware of EPA's assessment and its identified occupational concerns, if any. Once informed of EPA's assessment, the PMN submitter will be known to have information that must be considered in selecting respiratory protection and other personal protective equipment (PPE) needed to comply with OSHA's broadly applicable regulations and with the General Duty clause requirement that



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employers provide a safe working environment. By the same token, the TSCA NCC believes that once OSHA has been informed of EPA's assessment, it will be in a position to ensure that the General Duty clause requirements are being satisfied.

**Suggested Approach for Communication of Workplace Exposure Concerns with Other Potential Manufacturers/Importers/Processors**

The TSCA NCC understands that in addition to communicating potential workplace exposure concerns to the PMN submitter, EPA must also have a mechanism to inform other potential manufacturers, importers, and/or processors of EPA's identified risk concern and the specific workplace exposure controls recommended by EPA to address that concern, including quantitative and qualitative exposure limits and suggested PPE.

The TSCA NCC proposed that this communication need can be addressed easily by using EPA's Inventory "flags." We know that before engaging in manufacturing, importing, or processing, a company must check the TSCA Inventory to confirm the subject chemical is listed on the Inventory and is active. EPA flags Inventory listings to indicate the existence of rules or other status. For example, the "T" flag indicates that the substance is subject to a test rule. An entity is thereby informed that a test rule has been promulgated and can research the terms of that rule. By flagging the subject chemical in the Inventory with a flag indicating workplace exposure concerns with a "W," EPA would appropriately inform the potential manufacturer, importer, or processor that a workplace exposure control issue has been identified and must be considered in the manufacturer, importer, or processor's OSHA compliance program. EPA can publish information concerning its occupational risk concerns and identified workplace exposure controls in a separate location, such as in the *Federal Register* or on EPA's ChemView database. Thus, the Inventory flag informs the potential manufacturer, importer, or processor that EPA has identified workplace risk concerns and the *Federal Register* or ChemView database can provide details on the concerns and the controls recommended by EPA.

As noted above and as EPA staff will recognize, this proposal for notification to potential manufacturers, importers, or processors builds off of existing EPA approaches. EPA already uses a number of Inventory flags to inform potential manufacturers, importers, or processors of critical information needed to comply with TSCA. For example, EPA uses Inventory flags to inform stakeholders of the existence of Section 5(e) or 5(f) orders, significant new use rules (SNUR), Section 6 rules, and Section 4 test rules. The flags apply to substances listed on both the public and confidential portion of the Inventory. As with the TSCA NCC

proposal for workplace control flags, the current EPA flags do not indicate the specific details on the TSCA action, but require the manufacturer, importer, or processor to find those details in ChemView, the *Federal Register,* or the Code of Federal Regulations.

By building off of the existing Inventory flag approach, this proposal will be easy for TSCA stakeholders to understand and implement. Such an approach would also assist in identifying cases where OSHA may want to raise questions concerning compliance with its regulations and the general duty clause.

We hope you find this additional input helpful. We will be contacting your office soon to set up a meeting with you and your staff to discuss these ideas as well as our thoughts related to the use of polymer flags for listing of exempt polymers on the Inventory.

Sincerely,

Kathleen M. Roberts

Attachment
cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)
Brian P. Grant, Esquire (w/attachment) (via e-mail)

TSCA
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December 1, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the amended Toxic Substances Control Act (TSCA) and to work collaboratively with you and your team to address them. Thank you for the opportunity to meet on November 16; we appreciate the discussion that we had.

One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes that the U.S. Environmental Protection Agency (EPA) needs to implement an appropriately robust and ongoing consultation process with OSHA "prior to adopting any prohibition or other restriction" per TSCA Section 5(f)(5) that addresses occupational exposure issues. We believe that such a procedure is needed to ensure that EPA's adoption of restrictions fully considers and avoids conflicts with OSHA's established regulatory programs in addressing and mitigating worker exposure risks to new chemical substances, a result Congress seemed to intend in amending TSCA.

Picking up on a point raised in our meeting, we note for your information that EPA's *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*,[1] requires that the notification include, among others:

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[1] Available at https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.

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- A description of each specific worker activity during which workers may be exposed to the new chemical substance. Activities must be described even if workers wear protective equipment. The SDSs indicating recommended protective equipment should be submitted as part of Hazard Information in Part I, Section C, subsection 3 of the notice form.
- Information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance (*i.e.*, type of gloves, type of goggles, National Institute for Occupational Safety and Health (NIOSH)-certified 21c respirator, NIOSH-certified 19c respirator, closed containment system, nitrogen blanket, and related measures).
- Information on the physical form of the new chemical, the maximum number of workers exposed, and the maximum duration of exposure in hours/day and days/year.

The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical reviews, EPA staff will have access to available understanding concerning occupational exposures to the new chemical and the engineering controls or personal protective equipment (PPE) that the notifier believes is needed to protect workers, and on which the notifier will be regulated under OSHA.

As discussed in more depth in the attached paper, the TSCA NCC does not believe that EPA's approach under TSCA adequately appreciates and recognizes the significance and effect of OSHA's statutory authorities and extensive regulatory scheme, as well as its enforcement mechanisms, governing workplace chemical exposures, including to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants



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above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the Occupational Safety and Health (OSH) Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty requirement is, as you recognize, particularly relevant to new chemicals given the limited information that is often available.

We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making determinations and taking required actions, Congress included the OSHA consultation provision at Section 5(f)(5) to ensure that EPA's regulation of new chemicals did not create or result in conflicts with requirements implemented by OSHA.

Although EPA has an obligation to review and make determinations regarding worker exposure issues and to formulate and adopt TSCA Section 5(e) actions that include measures to protect workers, this duty applies "to the extent necessary to protect against an unreasonable risk." When this duty is juxtaposed with the mandatory consultation requirement, it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme and to adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks not otherwise addressed.

Accordingly, the proper role for EPA should be to provide hazard identification and risk assessment information to the new chemical notifier and to OSHA to make these parties fully aware of EPA's assessment and its identified occupational concerns, if any. Once informed of EPA's assessment, the employer will be known to have information that must be considered in selecting respiratory protection and other PPE needed to comply with OSHA's broadly applicable regulations and with the General Duty clause requirement that employers provide a safe working environment. By the same token, once OSHA has been informed of EPA's



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assessment, it will be in a position to enforce its regulations and to ensure that the General Duty clause requirements are being satisfied.

For these reasons, and others elaborated in the attachment, the TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Instead, the TSCA NCC recommends the following approach if EPA identifies a workplace-specific risk concern:

1. EPA should consult with OSHA on the workplace risk concern.

2. EPA should inform the notifier of its assessment and concerns.

3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA, as well as OSHA's established expertise and robust existing regulatory program, to ensure worker protection.

Failure to follow a procedure as outlined above risks creating disputes over whether EPA's action preempted or created conflicts with OSHA's general authority and its regulations.

The TSCA NCC recognizes that the approach being advocated is at odds with EPA's longstanding practice in assessing and regulating new chemicals. Nonetheless, for the reasons provided above and elaborated in the attachment, TSCA NCC believes that EPA's prior and current approach is mistaken in that it does not give due recognition to OSHA's authorities and regulations and their role in ensuring a workplace free from recognized or potential occupational hazards. We believe that a modification in EPA's approach is necessary, given the changes in amended TSCA, including the OSHA consultation requirement. While EPA may have believed that, whenever an OSHA Permissible Exposure Limit (PEL) (or similar enforceable limit) is not in place, there is no enforceable requirement for companies to protect their workers from new chemical exposures, this belief is mistaken; and, as explained in this communication, does not have a basis in law or policy. Quite to the contrary, once EPA has informed the notifier and OSHA of its hazard and risk assessments, it has had the effect of triggering and setting in motion the existing regulatory requirements on employers to protect workers from recognized or likely occupational harms. Thus, any belief by EPA that, in the



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absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

Put another way, EPA's current practice under amended TSCA to equate any potential health hazard to represent an unreasonable and unmanaged risk to potentially exposed workers represents a misreading of the broadly applicable and pervasive regime that is implemented and enforced based on the OSH Act and OSHA's regulations and policies. On the contrary, once appropriately informed of EPA's concerns, any employer having a commercial relationship to the notifier must be made aware of and must consider EPA's assessment conclusions and respond appropriately to meet their obligation to protect workers and provide for a safe workplace. Furthermore, the fact that OSHA has also been informed of EPA's concerns puts to rest any questions about the level of information and the hazard, exposure, and risk assessments that the notifier and affiliated employers have access to, and establishes a factual written record that can be considered during any OSHA inspections or enforcement actions.

The TSCA NCC believes that for many, if not most, new chemicals for which EPA has proposed workplace restrictions under new TSCA, once EPA has informed OSHA and the notifier of its occupational risk assessment, that will be sufficient to ensure adequate workplace protection and to make any unreasonable risk to workers "not likely." Having made such a determination regarding occupational risks, EPA should proceed to meet its obligations to assess and determine other exposure risks, such as to the environment and general population, and to take the steps required depending on the final determination. Such a change in EPA's approach would avoid the issues associated with overlapping authority and imposing duplicative, if not conflicting, requirements for workplace exposures while also allowing EPA to focus its regulatory resources on other potential risks that are not subject to the overarching and comprehensive requirements that otherwise apply in the workplace.



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We hope you find these comments helpful. We would be pleased to discuss them with you and your staff in more detail prior to the **December 6, 2017**, public workshop if that is of interest.

Sincerely,

Kathleen M. Roberts

Attachment
cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)
Kevin W. McLean, Esquire (w/attachment) (via e-mail)
Brian P. Grant, Esquire (w/attachment) (via e-mail)

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TSCA
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**TSCA New Chemicals Coalition[1] Position Statement Concerning the Consultation with OSHA Required by New TSCA and EPA Adoption of Restrictions to Address Workplace Exposures**
**December 2017**

## I. ISSUES TO BE RESOLVED

The TSCA that was originally enacted in 1976 was comprehensively restructured and revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (new TSCA). New TSCA generally requires EPA to issue an order under Section 5(e) governing the manufacture, processing, distribution, use, or disposal of a new chemical substance whenever EPA makes a determination under Section 5(a)(3)(B). EPA is directed to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance … to the extent necessary to protect against an unreasonable risk of injury to health or the environment." As part of this determination, EPA must consider risks "to a potentially exposed or susceptible subpopulation" that EPA deems relevant, which typically will include workers who are occupationally exposed to the new substance during the manufacture, processing, or use of the substance.

While EPA may issue an order under new TSCA Section 5(e) that contains prohibitions or restrictions intended to address workplace exposure, new TSCA Section 5(f)(5) requires that, prior to doing so, "[t]o the extent practicable, [EPA] shall consult with the Assistant Secretary of Labor for Occupational Safety and Health…." This required consultation with the U.S. Occupational Safety and Health Administration (OSHA) is vital as it both acknowledges a role for EPA concerning workplace exposures and explicitly recognizes OSHA's primary responsibility for protecting worker safety and health. TSCA NCC believes that the clear intent of the consultation provision is to require that EPA, before deciding to implement separate TSCA action, will jointly evaluate the contemplated regulatory approach with OSHA, thereby assuring that EPA adequately considers OSHA's established regulatory programs and avoids conflicts or confusion in addressing and mitigating worker exposure risks to a new chemical substance. Section 5(f)(5) addresses the need for consultations "prior to adopting *any* prohibition or other restriction" (emphasis added). Without such ongoing consultations, TSCA NCC believes that EPA's adoption of restrictions for a new chemical to

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[1] The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) is a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the new TSCA and to work collaboratively with the U.S. Environmental Protection Agency (EPA) to address these issues.



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address workplace exposures that are also regulated by OSHA would inevitably increase the potential for conflicts concerning -- or material differences in interpretation -- of these parallel requirements.

The value of coordination was recognized in a 1981 Memorandum of Understanding (MOU) between EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS), a predecessor of the current EPA Office of Chemical Safety and Pollution Prevention (OSCPP) (attached). The MOU included provisions relating to sharing of information and joint participation in reviews and regulatory determinations on new chemicals presenting an occupational concern as well as sharing of confidential business information (CBI).

Section 4(b)(1) of the Occupational Safety and Health (OSH) Act, which addresses preemption of OSHA's regulatory authority in certain instances, states: "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies … exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." An MOU entered into by EPA and OSHA on February 13, 1991, affirms that OSHA retains principal "broad authority" to regulate workplace exposures to chemicals, while "EPA responsibilities include the protection of public health and the environment." The comprehensive OSHA Field Operations Manual (FOM) (2016), in explicitly addressing the effect of this preemption provision, observes that the only group of workers for whom OSHA regulation is considered to be preempted by EPA authority are farmworkers and pesticide applicators directly exposed to pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for which the worker protection measures in the EPA-approved label instructions preempt OSHA. While changes in the regulatory landscape may change the scope of preemption as well, as the FOM notes, how it is delineated can be a complex determination. It would be inappropriate for EPA to presume that it has been afforded broad authority under TSCA Section 5(e) to make independent regulatory decisions affecting areas that have been in OSHA's domain for decades.

TSCA NCC's reading of the effect of Section 5(f)(5) does not suggest that Congress, in amending TSCA, intended to supplant OSHA's regulatory authority over workers exposed to any chemical substance that is "new" for TSCA purposes. For this reason, it would be prudent to minimize the likelihood that EPA's regulatory activities affecting occupational exposures to new chemicals may be construed to preempt OSHA's authority to regulate exposures of those same workers. TSCA NCC believes that a robust consultation process that assures that EPA does not unnecessarily encroach on OSHA regulation should suffice to prevent any unintended preemption. Furthermore, TSCA NCC believes that the existing 1991 MOU



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(and, as appropriate, the 1981 MOU) should be updated to clarify the effect of TSCA statutory changes, including orders and rules concerning workplace exposures for new chemical substances issued by EPA under new TSCA. Such a revision would also be an appropriate response by EPA to the directive in TSCA Section 26(*l*)(1) that EPA, within two years of enactment, develop any policies, procedures, and guidance that are determined to be necessary to carry out the amendments.

## II. OSHA REGULATION OF OCCUPATIONAL EXPOSURE TO NEW CHEMICALS

OSHA has in place an extensive regulatory scheme, as well as enforcement mechanisms, governing chemical exposure in the workplace. OSHA's longstanding policy preference is to minimize workplace exposures to chemicals through engineering and process controls, which it may specify in substance-specific standards. In those circumstances where personal protective equipment (PPE) is needed to further limit worker exposure, OSHA has adopted PPE regulations; those for General Industry are found at 29 C.F.R. Part 1910, Subpart I. Section 1910.132 describes the current OSHA standards generally applicable to PPE and provides a framework for determining whether an employer has complied with those standards, while, as discussed below, respiratory protection specifically is addressed in Section 1910.134.

In a workplace inspection, OSHA's Certified Safety and Health Official (CSHO) makes the determination whether the employer has selected the particular PPE that is necessary to protect employees from identified hazards. An employer that fails to select adequate PPE generally is subject to a citation for violating 29 C.F.R. § 1910.132(d)(1)(i) unless a provision specific to the type of PPE involved applies instead. If an employer has not provided a written certification that a hazard assessment has been conducted, the inspector is directed to cite the employer for violating 29 C.F.R. § 1910.132(d)(2). If no specific PPE standard applies to the working conditions involved, or does not fully address a workplace hazard, the OSH Act's General Duty clause in Section 5(a) nonetheless requires the protection of the affected employees.

The OSH Act's General Duty clause requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm; it also requires every employer to comply with the occupational safety and health standards and all rules, regulations, and orders issued under the OSH Act. Thus, the General Duty clause adds a broad safety net and also underscores the workplace-centric nature of the OSH Act and of the intertwined responsibilities of both OSHA and individual employers in meeting specific occupational health and safety objectives. It is TSCA NCC's view that the



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General Duty clause requires employers to implement measures to prevent or to mitigate chemical exposures that may present a risk, including instances where the potential risk is identified as part of EPA's review of a new chemical substance and not fully addressed through OSHA's regulations.

OSHA also has issued detailed regulatory provisions addressing respiratory protection in the workplace; respiratory protection is disfavored as a matter of policy whenever engineering or process controls will suffice to limit occupational exposure. Respiratory protection in the form of PPE nonetheless is of particular importance for limiting chemical exposures, and is addressed both in 29 C.F.R. Subpart I at § 1910.134, as well as in various substance-specific 29 C.F.R. Part 1910 standards. The regulatory standard requires use of respirators where they are needed to protect employees from exposures to air contaminants above an exposure limit, or where they are otherwise necessary to protect employee health.

The standard places a range of responsibilities on employers as to the written respiratory protection program that must be in place, including procedures for respirator selection, use, fit, testing, cleaning, maintenance and repair; training in use and hazards; and medical evaluations of employees who use them, among other program elements. The employer is required to select and provide an appropriate respirator (National Institute for Occupational Safety and Health (NIOSH) certified) based on the respiratory hazard(s) present in the workplace, as well as workplace and user factors that affect respiratory performance and reliability. The assessment of workplace-specific hazards is a key prerequisite to the choice of the appropriate respirator; an employer who fails to assess those respiratory hazards and to select respiratory protection suitable for the purpose intended is subject to a citation for violating 29 C.F.R. § 1910.134(a)(2). Likewise, unless a substance-specific standard applies, an inspector can cite an employer for failing to provide the type of respirator needed for the substance and level of exposure involved as required under 29 C.F.R. § 1910.134(d).

TSCA NCC's review of the relevant materials does not suggest that, in enacting new TSCA, Congress intended to alter the scope of the effect of these OSHA requirements. Absent any such indication, TSCA NCC believes that the OSHA regulatory structure, including but not limited to its approach to workplace- and employee-specific PPE requirements, continues to apply where a "new" chemical substance under TSCA is involved.



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## III. RECONCILING EPA'S OBLIGATION TO PROTECT AND EPA'S OBLIGATION TO CONSULT

Although EPA has an obligation to formulate and to adopt TSCA Section 5(e) orders that include measures to protect workers from exposure to new chemical substances, this duty only applies "to the extent necessary to protect against an unreasonable risk." When this duty is viewed in juxtaposition with the mandatory consultation requirement in new TSCA Section 5(f)(5), it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme, including the General Duty clause, and to adopt additional restrictions or prohibitions only when they are needed to protect against unreasonable risk.

Given the robust nature of the existing OSHA regulatory program, the proper role for EPA should be to provide hazard identification and risk assessment information that OSHA and affected employers can utilize in selecting appropriate PPE, including respiratory protection measures. For example, EPA can provide its hazard, exposure, and risk assessment information on a specific new chemical to OSHA and to the notifier, which will assist OSHA and affected employers in selecting the respiratory protection equipment and other PPE needed to comply with OSHA's regulations in 29 C.F.R. §§ 1910.134 and 1910.132. In TSCA NCC's view, when OSHA and the notifier receive EPA's hazard, exposure, and risk assessment for a new chemical substance, these materials must be considered by all employers who manufacture, process, distribute, or use the chemical in satisfying their obligation to provide a safe working environment. EPA could also make its new chemical hazard assessments more widely available, for example, by including them in its ChemView system. The chemical identity (where non-CBI), new chemical case number, and the accession number and generic name for CBI chemicals can also be included. In the case of commenced CBI new chemicals, EPA could make its appropriately sanitized hazard assessment available in responding to a *bona fide* request to ensure that future manufacturers are aware of its assessment. To ensure that this occurs, EPA could amend its *bona fide* procedures at 40 C.F.R. § 720.25 to include this step.

EPA can utilize specific restrictions in TSCA Section 5(e) consent orders to mitigate workplace exposure, but this authority is also less pervasive in nature than OSHA's broad authority to control occupational exposures. The same is true of EPA's use of Section 5(a)(2) significant new use rules (SNUR) to extend the requirements to entities beyond the notifier. Such approaches do not provide the same breadth of protection and the ongoing compliance responsibilities on the employer afforded by the OSH Act and OSHA's implementing measures. TSCA NCC believes that careful ongoing consultation with OSHA, as required under new TSCA, along with a full appreciation of the scope and effect of the OSH Act



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and OSHA's implementing measures, is essential to ensure adequate protection of all workers while also assuring that EPA only adopts separate restrictions in consent orders to the "extent necessary" to protect against an unreasonable risk.

On balance, TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Even when the measures in question merely replicate what the applicant itself has suggested in a proposed Safety Data Sheet (SDS), such prescriptive orders have a variety of significant disadvantages. Such orders ignore OSHA's established expertise and the robust existing regulatory program, risk creating disputes over whether the EPA action has preempted OSHA's general authority to protect the involved workers, will inevitably lead to conflicts with or disputes over interpretation of parallel OSHA requirements, and may have applicability that is significantly limited by jurisdictional factors. It merits noting, as well, that OSHA does not give its approval or sign-off to the recommendations contained in SDSs and that recommendations in Section 8 of an SDS as to PPE are by no means determinative from a compliance standpoint. OSHA relies as well on its own considerable expertise, on the degree to which any industry consensus standards may be relevant, and on the impact of site- or employee-specific circumstances. For all of these reasons, TSCA NCC also believes that it is of paramount importance that to meet its obligation under Section 5(f)(5), EPA promptly should create a mechanism for the necessary ongoing consultations with OSHA. TSCA NCC further recommends that EPA act swiftly to meet its responsibilities under Section 26(*l*)(1) and commence discussions with OSHA that will lead to an update of existing MOUs to delineate clearly each agency's role in regulating exposure to new chemical substances given the changes in new TSCA.

For the reasons elaborated above, TSCA NCC is of the view that for many, if not most, of the new chemicals for which EPA has proposed workplace restrictions under TSCA, the OSH Act and OSHA's regulatory program, once EPA has informed OSHA and the notifier of its occupational risk assessment, will be sufficient to ensure workplace protection and thereby make any unreasonable risk to workers "not likely." Section 5(e) requirements to restrict workplace exposures should be reserved for those instances where EPA has determined, after consultation with OSHA, that the OSH Act and OSHA's regulatory program are not sufficient to protect against unreasonable risk from workplace exposures and that TSCA action therefore meets the "extent necessary" requirement. To the extent that EPA proceeds as recommended by TSCA NCC and relies on the OSH Act and OSHA's regulatory program, this will also have the benefit of reducing EPA's administrative burden currently spent in negotiating consent orders and promulgating SNURs for occupational concerns. Such a change in approach could also allow



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EPA to focus these regulatory resources on the potential risks to the environment and the general population -- areas that do not present the same level of overlapping authority and duplicative requirements as exist for workplace exposures.

Attachment



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- **Information Date:** 01/19/1981
- **Agreement Agency:** The Office of Pesticides and Toxic Substances and U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES,
U.S. ENVIRONMENTAL PROTECTION AGENCY
AND THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR
FOR

- GENERAL COOPERATION

- SHARING OF CONFIDENTIAL BUSINESS INFORMATION

- OSHA-EPA COOPERATION IN THE TSCA PREMANUFACTURE NOTIFICATION PROGRAM

- TRANSFER OF EPA INFORMATION ON SUBSTANTIAL RISK NOTICES

I. GENERAL WORKING AGREEMENT

This Memorandum of Understanding establishes a general working relationship between the Occupational Safety and Health Administration, U.S. Department of Labor, and the Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, regarding matters having or potentially having an effect on the activities and responsibilities of the two agencies.

II. COORDINATION

To achieve the coordination desired by both EPA AND OSHA, each agency hereby designates a coordinating office. The coordinating office for the Office of Pesticides and Toxic Substances (OPTS) will be the Office of Toxics Integration (OTI); for the Occupational Safety and Health Administration (OSHA), the Division of Interagency Programs. These offices shall serve as the initial communication link between the two agencies. Future specific agreements will be made by the program offices of OSHA and EPA's Office of Toxic Substances. Parts A, B and C below are directed at specific areas of coordination for sharing of confidential business information, OSHA's cooperation in the OPTS premanufacture notification program, and referral to OSHA of TSCA section 8(e) notices.

In carrying out their respective responsibilities, OPTS and OSHA will, to the extent practicable, consult and exchange information with each other through the coordinating offices. Specifically they will:

(1) Coordinate programs, including the development of standards, to avoid duplication of effort, to assist in setting priorities, and share information and research;

(2) When appropriate, consider the development of joint regulatory efforts. If no joint efforts are possible, both agencies will coordinate the development of any regulations concerning occupational exposure to new chemicals, to the extent feasible;

(3) Exchange information and report on general enforcement matters and on particular situations of common concern to each agency;

(4) Make every effort to achieve uniformity of approach in long-range planning;

(5) Obtain legal and policy positions on statutory authority regarding the extent to which the other agency can remedy a particular condition or matter that may be within the regulatory purview of the agencies;

(6) Use communication systems available to both agencies for educational services to the public about safety and health topics.

A. Confidential Business Information Exchange

PURPOSE:

This section allows OSHA to have access to confidential business information (CBI) submitted to EPA under the Toxic Substances Control Act (TSCA). OSHA will use this information to assist in fulfilling its duty to protect worker health under the Occupational Safety and Health Act of 1970.

SCOPE:

OSHA is permitted access to all confidential business information submitted to EPA under TSCA. When OSHA requests transfer of specific CBI, a justification of the need for access will be submitted through the OSHA Document Control Office (DCO) to any DCO in OPTS. OSHA will treat all such information in accordance with the Memorandum of Understanding. When OPTS initiates the transfer of CBI, a justification of OSHA's need for access should be prepared by the appropriate EPA program official and submitted to an OPTS DCO prior to the transfer of any documents containing confidential business information. The appropriate OPTS DCO must approve the justification prior to transfer of CBI.

PROVISIONS:

(1) OSHA will protect information received from EPA under this agreement by following the procedures set forth in its "OSHA TSCA Confidential Business Information Security Manual." The procedures have been approved by EPA's Inspector General's Office, and they meet or exceed the requirements of EPA's own "TSCA Confidential Business Information Security Manual."

(2) OSHA agrees that it will not release or transfer TSCA confidential business information outside of OSHA without the prior approval of EPA.

(3) OSHA will normally return confidential documents to EPA within one year, but with approval by the OPTS Document Control Officer, will be granted extensions. In addition, with approval of the OPTS Document Control Officer, OSHA may destroy the documents according to the requirements of the EPA TSCA Security Manual instead of returning them to EPA.

(4) OSHA personnel will be made aware of the possible criminal liabilities that may result from unauthorized release of CBI and will sign the TSCA-Federal non-EPA employee confidentiality agreement (Appendix 14).

(5) The Information Control Branch of the Management Support Division of OPTS (EPA) will provide initial CBI training to appropriate OSHA staff.

(6) A physical inspection of OSHA's security facilities will be made by EPA. No exchange of TSCA CBI will be made until such facilities are found to be satisfactory. There will be future periodic inspections of OSHA's security program by EPA.

(7) Following inspection and approval of OSHA's security facilities, a Federal Register notice will be published announcing this agreement and will provide the required ten days of notice, covering all future sharing of data under this section, pursuant to section 2.209 of EPA's regulations on confidentiality of business information, 40 CFR Part 2, Subpart B.

B. Premanufacture Notification (PMN) Data Exchange Procedure

PURPOSE:

This section deals with the exchange of PMN data between OSHA and OPTS. PMNs can provide information about possible worker exposure to new chemicals before they are produced on a large scale, enabling both OSHA and OPTS to discuss any possible hazards to exposed worker populations and, if necessary, coordinate action on these chemicals.

SCOPE:

OSHA and OPTS will work to assure that complete and timely notification is made concerning PMNs which may involve or affect occupational exposures to chemical hazards, and also to assure necessary coordination between OPTS and OSHA, including joint review of selected PMNs. This will permit OPTS to have the benefit of OSHA expertise in assessing occupational exposure risks, and will alert OSHA to possible chemical threats to worker health.

PROVISIONS:

To assure the above conditions are met, the following procedures are established:

(1) Contacts with OSHA concerning PMNs will be initiated by the Notice Manager for a particular PMN or by OTI through the designated individual in the OSHA Division of Interagency Programs. This individual will receive all data and information from EPA and be responsible for the response from OSHA. This individual shall coordinate the OSHA response or refer the EPA Notice Manager to the appropriate OSHA staff.

(2a) In order to assure that OSHA is informed of the status of EPA actions on PMNs, EPA's Chemical Control Division (CCD) will forward to the OSHA representative, as available, a copy of EPA's weekly PMN report. OSHA will use the report to identify PMNs of potential concern about which OSHA has not been contacted by OTI or the Notice Manager.

(2b) If the occupational exposure to a chemical is a concern during initial review, the Notice Manager or OTI will notify OSHA. EPA may request OSHA data concerning the chemical or its analogue or may refer the PMN to OSHA for information or consideration if no TSCA action is to be taken.

(2c) If a PMN for which there is concern regarding potential occupational exposure, goes into a more detailed review, the Notice Manager or OTI will notify OSHA. During the detailed review, Chemical Control Division may request technical assistance from OSHA to aid in EPA's assessment of the PMN and invite OSHA to participate in the work group.

(3) During the development of any regulatory action on a PMN for which occupational exposure is of concern, CCD will consult with OSHA. OSHA may be asked to participate in the detailed review work group for the PNM to assist in development of regulatory options. At that time, OPTS will provide OSHA with copies of documents generated by the OPTS initial review which describe the problem. As a member of this group the OSHA staff may be involved in reviewing draft regulatory actions and will be provided with a copy of the package which enters the EPA official rulemaking and clearance process.

(4) EPA will notify OSHA representatives of the final action taken by EPA on any PMN where occupational exposure is a concern.

C. Notices of Substantial Risk

PURPOSE:

This section provides a mechanism for EPA to provide OSHA with information submitted by industry under section 8(e) of TSCA, Notices of Substantial Risk.

SCOPE:

Section 8(e) of TSCA requires that any person who manufactures, processes, or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the substance of mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA.

For each 8(e) notice received, the OPTS Chemical Hazard Information Branch (CHIB) prepares a status report. CHIB will, by this agreement, refer to OSHA any 8(e) notices in connection with which CHIB identifies an occupational exposure of concern. OTI will coordinate any necessary follow-up work with OSHA, such as plans for further evaluation or discussion of regulatory action.

III. AUTHORITY

The Office of Pesticides and Toxic Substances enters into this agreement under the authority of Sections 9 and 14 of the Toxic Substances Control Act (15 USC 2601, et seq.). Section 9 of TSCA requires certain coordination of actions taken under TSCA with actions taken under other Federal laws. Section 14 of TSCA provides that confidential business information may be disclosed to any officer or employee of the United States in connection with the official duties of such officer or employee under any law for the protection of health or the environment.

The Occupational Safety and Health Administration enters into this agreement under authority of the Occupational Safety and Health Act of 1970 (29 USC 651, et seq.), Section 7(c)(1). That section allows the Secretary of Labor to "use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement...."

IV. PERIOD OF AGREEMENT

This Memorandum of Understanding shall continue in effect unless modified by mutual assent of the parties or terminated by either party upon a 30-day advance written notice to the other party.

This Memorandum does not preclude the parties from entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.

Nothing in this agreement is intended to diminish or otherwise affect the authority of either agency to carry out its respective statutory functions.

This Memorandum will become effective on the date of the last signature.

Marilyn C. Bracken
Associate Assistant Administrator
for Toxics Integration

Warren R. Muir
Deputy Assistant Administrator
for Toxics Substances

October 18, 2017

Via email: Beck.Nancy@epa.gov

Ms. ***Nancy B. Beck***
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: ***§770.4(b) Rulemaking Petitions for Exemptions***

Ms. Beck:

The American Home Furnishings Alliance (AHFA) welcomes the opportunity to discuss the petition process[1] outlined in the 'Formaldehyde Emission Standards for Composite Wood Products.' As detailed in our written comments[2], AHFA has held the long-standing belief that EPA was granted broad discretion by Congress to exempt certain laminated products from the definition of hardwood plywood[3].

AHFA submitted to the docket three definitive studies that clearly demonstrate that the value-added process of finishing further reduces the emission characteristics of an already certified composite wood product by, at a minimum, 80%[4]. The conclusion of the data contained in the studies submitted to EPA, clearly supports the fact, that when a compliant composite wood core is veneered and finished, the emissions profile is further reduced beyond that of the already compliant panel.

AHFA has read the language of the rule, both in the preamble and at §770.4(b) and would like to better understand the petition process. AHFA believes the data request as stipulated in the section titled ***'Rulemaking Petitions for Exemption'***[5], has been adequately addressed and respectfully asks that EPA publish a proposed rule in the Federal Register exempting the intermediate laminated product produced by fabricators as a component part of a finished good. It is understood that this component part is not a commodity and is not offered

[1] §770.4(b)(1-3)
[2] EPA-HQ-OPPT-2012-0018-0616
[3] Section 601(a)(3)(C)((i)((I)&(II)
[4] EPA-HQ-OPPT-2012-0018-0562
[5] §770.4(b)(2)

for sale to consumers. The data already submitted is representative of how the consumer will interface with the component part produced using a compliant composite wood product (CWP) and takes advantage of the value-added process of finishing which is proven to further reduce the emission profile of a compliant CWP platform.

The CARB ATCM exempts the intermediate laminated product based on the understanding that the component part stays in the control of the fabricator and is not offered for sale as a commodity to the consumer. AHFA strongly urges EPA to harmonize with the CARB ATCM, using their legislative discretion, to also exempt this component part from the definition of hardwood plywood. AHFA and its members have already put in place compliance systems for the CARB ATCM and understand that you must start with a compliant CWP platform and be able to produce verifiable documentation if asked during an enforcement evaluation of the finished good.

If after reviewing the data and in consideration of the proposed rule, EPA determines the data lacking, AFHA respectfully asks EPA to outline what additional data needs to be submitted and outline the specific process of the petition process during our meeting. It is critical that we expedite this matter and bring a positive resolution to the exemption request.

AHFA has a long-standing history of working with EPA on this rule and welcomes the opportunity to walk through the petition process and adequately address the exemption of the intermediate laminated product from the definition of hardwood plywood. It has always been understood that this is a 'raw board' standard and AHFA members are committed to sourcing compliant CWP platforms. As demonstrated, if you start with a compliant CWP platform to produce a component part of a finished good, the value-added process of finishing provides an additional measure of emissions reduction, thereby reducing the potential exposure to the consumer. This is a 'win-win' for the agency, the U.S. consumer, and the U.S. based furniture industry.

Sincerely,

Bill Perdue
VP Regulatory Affairs
AHFA
336-881-1017
bperdue@ahfa.us

c.c: Erik Winchester

# Draft Agenda

**GC Symposium / WDC**
***Managing Change in a New Environment: Strategies and Solutions***

**Thursday, October 26 @ 12:00 noon —to Friday, October 27 @ 1:00 pm**

**Thursday / October 26 – 3.75 CLE hours**

12:00 pm – 1:00 pm – Lunch

1:00 – 2:00 pm (1 hour)Chemical Industry M&A Consolidation Outlook – 2017 Year in Review & Outlook 2018

- Tony Kuhel, Partner / Thompson Hine
- **Alain Harfouche** , Chemicals Investment Banking, **KeyBanc Capital Markets**
- Laurens Dalmijn – General Counsel / IMCD Group

2:00 – 3:45 pm (1 hour & 45 minutes) Regulatory Outlook for the Trump Administration

- EPA/TSCA 40 min
  - Jim Jones – CSPA (TSCA)
  - Robert Helminiak, Managing Director , Government Relations / SOCMA
- Trade – Overall and NAFTA renegotiations – 35 min
  - Samir Varma, Partner / Thompson Hine
  - Steven Goldberg – BASF
- Corporate Tax Reform - 30 min
  - Erick Gustafson, Global head of Government Relations, Marsh McLennan Companies

Break 3:45 – 4:00 pm (15 minutes)

4:00 – 5:00 pm (1 hour) ***Congressman Bill Johnson– Regulatory update: A view from the Hill***

6:30 pm Dinner

**Friday / October 27 – 3.5 hours CLE**

8:00 – 8:30 am – Breakfast

8:30 – 9:30 am. Hot Topics (1 hour)– short presentations (Trump Impact Seminar topics)

- Government Contracts – Tom Mason, Partner / Thompson Hine; Ray McCann & Chip Purcell - Thompson Hine (20 min)
- Immigration – Sarah Flannery, Partner / Thompson Hine (20 min)
- EPA – Nancy Beck (Tentative) (20 min)

9:30 – 10:30 am (1 hour)Cyber Trends & Risks, What You need to Know ! (Panel Discussion) Roy Hadley Moderator, Partner / Thompson Hine

- After the breach – crisis communication –Scott Sobel, KGlobal
- Threat identification/response – TBD
- Cyber insurance –TBD

10:30 – 10:45 Break (15 minutes)

10:45 – 11:15 am (1/2 hour) BTI report – Tim Coughlin, Partner / Thompson Hine

11:15 am – 12:15 pm (1 hour) Crisis Management in the Era of Entitlement, Transparency & Trump / Disaster Focus – Gene Grabowski, Director / K Global

12:15 – 1:00 Lunch
Adjourn

Total CLE – 7.25 Hours

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# Chemical Data Reporting (CDR) Inorganic Byproducts Meeting
# Negotiated Rulemaking Committee
# September 13-14, 2017
### Ronald Reagan Building and International Trade Center
### Oceanic Suite, 1300 Pennsylvania Ave NW, Washington, DC 20004

## *Meeting Summary (10/10/17 - Approved by Committee)*

This document summarizes discussions held during the September 13-14 Chemical Data Reporting (CDR) Inorganic Byproducts Negotiated Rulemaking Committee Meeting. It provides a general summary of key discussion points, but does not attempt to describe specific views of all Committee Members. It also does not attempt to summarize input from previous meetings or describe the details of proposals. See the August 16-17, 2017 summary for initial input on proposals and the handouts for more information, which are available on the Byproducts Committee website or in the docket (EPA-HQ-OPPT-2016-0597).

**Meeting Objectives**

- Present and discuss updated proposals
- Develop a package of recommendations that Committee Members can tentatively agree on which they can take back to their constituents for feedback and approval and finally approve at the October 25-26th Committee Meeting
- Outline next steps and roles and responsibilities of Committee Members to refine draft recommendations and obtain constituent input before the October Committee meeting

**Meeting Agenda**

September 13, 2017

- Welcome, Introductions and Agenda Review
- Overview of Updated Proposals and Discussion and Background Presentations (see summary of meeting below)
- Caucus Discussions

September 14, 2017

- Caucus Discussions
- Cross-Caucus Package Working Group
- Caucus Discussions
- Caucus Report Out
- Next Steps

**Action Items**

- Amy D Kyle, representing the Sierra Club and CA Communities Against Toxics, will provide clarification comments on the August 16-17, 2017 meeting summary. The Committee tentatively approved the meeting summary, assuming Amy's comments do not change the content of the summary.
- EPA will review Burn as Fuel guidance, especially related to organic and inorganic mixtures (e.g., page 2-5 of CDR 2016 Instructions for Reporting).
- Committee Members will provide any comments on the September meeting summary by October 4, 2017. If written feedback is not provided, approval is assumed.
- EPA will provide notification through a Federal Register notice that the Committee has completed its deliberations without consensus recommendations. EPA will provide more detailed next steps to the Committee, including how and when to submit any individual Stakeholder Reports to be added to the public docket.
- EPA will begin the process of closing out the FACA Committee by the end of October / early November.



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061_00040511-00001

**Handouts** (The * indicates new materials provided at the meeting and not sent in advance.)

- Agenda
- Meeting Summary from Aug 16-17, 2017 Meeting
- Committee Contact List (slightly updated)
- Form U
- Exemptions Proposal
- Option of Reporting via Categories Proposal
- Modified Processing and Use Reporting (Form U Part III Data) Proposal
- * Slightly updated Part III Table
- Modernize Data System under TSCA
- * Approach E – Limit Reporting for Site-Specific Catalyst Recycling
- * Approach F – Limit Reporting for Reuse of Inorganic Byproducts
- * EPA Data Analysis on Subset of Metal Compounds Reported to TRI and under CDR
- * Small Business Administration Office of Advocacy Presentation
- * Negotiated Rulemaking Mandate from TSCA Section 8(a)(6)
- * Guidance from correspondence between EPA and USWAG that describes how manufacturers and recyclers have to report if they are putting materials into a product (e.g., fly ash byproduct being used in potting soil)

## Summary of the Meeting

### Agenda Review and Meeting Summary Approval

Amy D Kyle, representing Sierra Club and CA Communities Against Toxics, requested additional time to provide clarification comments on the August 16-17, 2017 meeting summary (dated September 6, 2017). The Committee tentatively approved the meeting summary, assuming Amy's comments do not change the content of the summary. Other issues, including a review of the mandate and scope of the Committee raised in previous meetings, were also discussed.

### Review and Refining of Potential Approaches

The Committee reviewed proposals for six topics identified at the August meeting for further development and as potential components of a package agreement. Five of the proposals were discussed among members of Working Groups between the August and September meetings. Working Groups discussed proposals and provided feedback and ideas to lead authors. Working Groups did not strive to come to a consensus on the content of each of the proposals. They recommended that all of them be brought back to the full Committee for its consideration. The proposal to Modernize Data Systems under TSCA was developed by Amy Kyle, representing Sierra Club and CA Communities Against Toxics. The Committee decided that this draft would be distributed to all members for review.

The proposals addressed issues related to:

- Exemptions
- Option of Reporting via Categories
- Modified Reporting of Processing and Use Reporting (Form U Part III Data)
- Approach E - Limit Reporting for Site-Specific Catalyst Recycling
- Approach F - Limit Reporting for Reuse of Inorganic Byproducts
- Modernize Data Systems under TSCA

The Committee discussed questions of clarification and shared initial perspectives on strengths/merits and considerations/concerns on each of the proposals. In some cases, additional ideas or suggestions for modifications were shared. This discussion is captured in the "Presentations on Approaches and Feedback from Committee Members" section below. Note that Approach E was not shared until the night before the Committee

Meeting and Approach F was shared at the meeting, so Members had very limited time to review the proposal prior to its discussion at the Committee Meeting and to consider what changes or refinements might be needed.

**Other Background Presentations**
EPA provided an overview of its data analysis on a subset of metal compounds reported to both the Toxics Release Inventory (TRI) and CDR and thought to be inorganic byproducts under CDR. The Small Business Administration (SBA) Office of Advocacy presented an overview of Regulatory Flexibility Act processes required if a Proposed Rule would have a significant economic impact on a substantial number of small entities. This discussion is captured in the "Background Presentations" section below.

**Caucus Discussions to Review Proposals**
Prior to this Committee Meeting, it was clear to Process Working Group Members and the facilitators that Committee Members were not likely to be able to support all of the suggested components of a proposal if they had to agree on them individually. Therefore, Committee Members were encouraged to consider the development of a package agreement in which the sum of a combination of trade-offs on different components of proposals that Committee Members valued differently would adequately satisfy the interests of individual Committee Members, their caucuses and the Committee as a whole. The Process Working Group and the facilitators believed that a package agreement, which included integrative solutions to address the range of Committee Members' interests, would be more likely to result in a consensus that all could support, or at a minimum, not oppose.

Committee members formed and met in four caucus groups: 1) EPA; 2) states; 3) environmental/public health and tribes; and 4) industry. EPA also provided technical and policy information to the caucus groups, as requested. Each caucus reviewed the proposals and discussed where they agreed with the proposals, where they could agree with modifications, and where they had significant concerns. They also discussed whether they wanted to create a Cross-Caucus Package Working Group, a smaller mixed-interest group composed of representatives from each of the caucuses, to develop and assemble a potential package to be presented back to the Committee as a whole, and if so, who would represent each caucus. The Process Working Group and facilitators recommended this approach, as they believed it would be easier for a small group to negotiate a package, rather than have the Committee do it as a large group.

**Proposed Package**
All caucuses agreed to participate in a Cross-Caucus Package Working Group. The mandate of this working group was to develop a package that it believed would be acceptable to all Committee Members and their caucuses. It would be brought back to the full Committee for its consideration.

The Cross-Caucus Package Working Group representatives shared what each of the caucuses thought should be included in a package. The Working Group identified potentially common elements. They included:

- **Exemptions** – Maintain and clarify existing exemptions with improved EPA Guidance to address identified concerns and ensure they are being properly applied. For example, EPA could clarify that the "soil enrichment" exemption only applies to "disposal", reportable under TRI, but does not apply where the inorganic byproduct is incorporated into a product for sale (e.g., potting soil). EPA could clarify the scope of the burning as a fuel exemption, as applied to inorganic byproducts. Since limited information is available, EPA could also require one-time reporting to determine who is currently using the exemptions and under what circumstances or conditions.

- **Option to Report via Categories** – Include this component in the package if it was important to industry. This approach was developed to streamline and simplify reporting and address industry concerns regarding difficulties in precisely identifying chemical constituents in byproducts. Committee Members from the EPA, tribes, states and environmental/ public health were willing to continue to

explore incorporating it. It was not, however, clear that all industry representatives saw value in this option.

- **Modified Reporting of Processing and Use Information (Form U Part III)** – Incorporate the proposal. This option was identified as an approach to limit reporting and reduce reporting burdens by simplifying and reducing the data reported on Form U. Industry recommended removing the "land application" and "burned as a fuel" checkboxes in the directly used section because those uses were exempted. This change would need to be further discussed, as it could eliminate information about practices that are of potential environmental concern and important for tracking inorganic byproducts under TSCA.

- **Address situations in which a chemical reaction occurs to form a different chemical or molecular form of the initial inorganic component chemical** – Explore other methods to address this reporting burden. At the August 16-17 meeting, only industry members were willing to continue to explore Approach B - Expand Commercial Use Exemption, so this option had not been carried forward for further development (see August meeting summary). In addition, Approach B was not raised for further consideration during the Exemptions Working Group meetings. Only industry discussed Approach B in their caucus.

  The Cross-Caucus Approach B discussion triggered other ideas to address the burden of reporting. Because these were being discussed for the first time, the members of this Working Group agreed that if they were to be pursued, additional time would be needed to review and respond to concepts. Some of the options considered included:
  - One-time reporting by all byproduct manufacturers/recyclers during the next CDR reporting. Industry would only have to report in the future if there was a distinguishable change. Discussion to define "distinguishable change" would be needed. One idea to define "distinguishable change" is a change in the production range, potentially with consolidated ranges. More details would be needed to ensure industry did not have to continuously closely track changes in byproducts, which would limit the impact on reducing the reporting burden. More details are also needed to ensure that there would not be a broad loss of data and substantive changes would be adequately captured.
  - Another option was for industry to separately pursue the processing/use information of 'low current interest' partial exemption (711.6.B.2). This is a process that is currently available, where industry petitions EPA to partially exempt their chemical from reporting. EPA must respond within 120 days and then go through a rulemaking process to add chemicals to the partial exemption list. Some groups raised concerns about data loss, especially if any exemptions under this option were not sufficiently limited in scope. Others noted that, for chemicals covered by Approach B, they would expect there to be little reduction in burden because of the limited processing of the byproducts.

- **Limit Reporting for Site-Specific Catalyst Recycling (Approach E)** – Explore this approach for on-site recycling/regeneration of intermediates where there is minimal risk of exposure. EPA and the environmental/ public health representatives were not willing to consider cases in which a catalyst is regenerated at a different site and returned to the site of byproduct manufacture for further use or processing because this scenario would still include additional pathways of exposure during handling and transportation to a different site. Industry raised the point that since manufacturing, transportation and regeneration take place in closed systems; the only potential for exposure would be accidental release. Industry noted that limiting this component to on-site would not significantly reduce the burden of reporting, since less than 5% of catalysts are recycled on-site.

- **Modernize TSCA Data Systems (Approach G)** – Incorporate the proposal. All caucus groups seemed to support this approach describing how EPA should consider how to simplify reporting, make it more efficient and to make data more accessible and user friendly. The Committee acknowledged that the proposal was beyond the specific scope of the Committee's mandate, but agreed that a statement could still be incorporated.

- **Reuse of Inorganic Byproducts (Approach F)** - Most Working Group Members recommended that this proposal be considered as part of the broader CDR Revisions Rule because it impacts both inorganics and organics. Industry and one state felt that aspects of this option could warrant further discussion in the context of inorganic byproducts, though several issues would need to be addressed. One key issue is how to identify and define, or chemically characterize, isolated intermediaries. Working Group Members identified that this proposal would need the following refinements:
    - Clarity on requirements for how to determine and ensure that byproducts are chemically identical to the original process inputs.
    - Clearer definitions (e.g., closed loop systems and isolation).
    - Requirements for storage and handling (e.g., methods and duration).
    - More detailed examples to enable EPA to conduct its analysis. It might necessary for EPA to be more restrictive at first and then reduce reporting further once staff learn more.

The Cross-Caucus Package Working Group included the following representatives:

- EPA: Lynn Vendinello
- EPA: Susan Sharkey
- States: John Gilkeson
- States: Mark Smith
- Natural Resources Defense Council (NRDC): David Lennett
- WE ACT for Environmental Justice: Adrienne Hollis
- American Chemistry Council (ACC): Karyn Schmidt
- American Fuel and Petrochemical Manufacturers (AFPM): Jim Cooper
- Association Connecting Electronics Industries (IPC): Bret Bruhn
- North American Metals Council (NAMC): Kathleen Roberts

If the Committee agreed on the package developed by the Cross-Caucus Working Group, or the proposed package with additional refinements, its members would be expected to outline and address remaining questions, make appropriate revisions and take it to their constituents for their consideration and input. This input would be used to refine the final package, which would be submitted to and approved by the Committee at its final meeting on October 25-26, 2017. One member suggested that a "final" package should be completed by October 6, 2017 in order for members to provide enough time to obtain feedback from their constituents before the final October meeting.

**Caucus Discussions to Determine if/how to Proceed**

Following the discussions of the Cross-Caucus Working Group, Committee Members returned to their caucus groups. They reviewed the proposed package and discussed whether their caucuses could support, or, at a minimum "live with", the package. Committee Members were encouraged to consider their best alternative to a negotiated agreement through the Negotiated Rulemaking process when making this decision.

**Determination Whether to Proceed with Negotiations**

The full Committee reconvened in a public session and reported out on their caucus discussions. Industry Committee Members reported that they could not support the package proposal because they believed the package "did not sufficiently meet the mandate of reducing burden". Additionally, the industry Committee Members did not believe that further discussions would help the Committee reach consensus. The environmental/ public health, states, tribes and EPA were willing to continue refining the outlined package developed by the Cross-Caucus Package Working Group, including new proposals identified during its

discussions. They believed that the package did reduce burden for industry, while providing adequate data for EPA and others to identify conditions of use, prioritization, conduct risk assessments and other needed analysis under the Revised TSCA, retained a science-based approach, and addressed state concerns about state pre-emption and access to CBI. EPA acknowledged that while the package did reduce burden, it might not reduce burden to the same extent for all industry members, as there are different needs across sectors. EPA also acknowledged that even though the Committee was unable to come to a consensus agreement, the process was very informative and will support EPA as it determines next steps.

**Next Steps Related to Drafting a Committee Report**

The industry caucus requested that no Committee Report should be developed or written. The industry caucus argued that a Committee Report should not be developed unless the full Committee agreed that this was appropriate.

Other Committee Members wanted to document the progress the Committee made in a Committee Report with the opportunity for Committee Members to provide Stakeholder Reports as appendices. This would allow the investments made in the discussions to provide some lasting benefit and not be lost. Several members noted that the preparation of a Committee Report had been discussed at length during the early sessions of the Committee. They referred to the following language in the Operating Protocol.

> **Section 4.3**
> Following the provisions of the Negotiated Rulemaking Act (f) Report of Committee, "If the committee does not reach a consensus on a proposed rule, the committee may transmit to the agency a report specifying any areas in which the committee reached a consensus. The committee may include in a report any other information, recommendations, or materials that the committee considers appropriate. Any committee member may include as an addendum to the report additional information, recommendations, or materials."
>
> **Section 3.3**
> The Facilitators will draft a Final Committee Report detailing the deliberations of the Committee and its outcomes. The Final Report will be prepared regardless of whether any agreements are reached and will include content requested by Committee Members. The Final Committee Report will be circulated among Committee Members for review, comment and concurrence on language used to describe the outcome of the Committee's deliberations.

Environmental and public heath and state members argued that the intent during Operating Protocol discussions was to always have a Committee Report with an opportunity for members to add their perspectives via Stakeholder Reports as appendices, if they chose to do so. They noted that this was the agreed upon approach instead of considering alternative options for decision making such as voting. EPA clarified after the meeting that Section 3.3 is focused on the Facilitator's Final Committee Report, which is different than the Final Committee Report referenced in section 4.3. The facilitators will develop a report for EPA to document the overall process.

The final resolution of this issue at the end of the meeting was that EPA will inform the public via a Federal Register Notice that the Committee's negotiations concluded without a consensus agreement. No formal Committee Report will be shared with the public. However, Committee Members or groups of Committee Members can provide Stakeholder Reports that will be added to the public docket. EPA will send a deadline for receipt of Stakeholder Report, likely by end of October 2017.

**Public Comments**

No observers requested to make comments during the public comment periods.

## Presentations on Approaches and Feedback from Committee Members

This section of the Meeting Summary describes feedback on proposals shared at the August 16-17th, 2017 Committee Meeting (see summary for initial feedback) that were refined by Working Groups and presented to the full Committee at its September meeting. Most updated proposals were shared before the meeting, and are available on the docket (EPA-HQ-OPPT-2016-0597). This summary does not describe the proposals, but instead describes the discussion at the meeting, including clarification notes and additional strengths/merits and concerns/considerations.

**Exemptions Proposal**

David Lennett, Natural Resources Defense Council (NRDC), shared the updated proposal. There was considerable discussion and disagreement regarding this issue (see August 16-17 Meeting Summary).

*Clarification Notes*

**Burn as a Fuel**

- The Committee discussed whether the "Burn as a Fuel" exemption is being used for inorganic byproducts. Some members believed that industry would only burn inorganic byproducts for disposal purposes via incineration. In this case the inorganic byproduct would not have a commercial purpose and CDR reporting would not be required. Other members noted that inorganic byproducts could be sent to boilers or other applications, and commercial intent could be determined by the BTU value or subsequent commercial use of post combustion byproduct materials.
- Inorganics do not burn. Generally, putting inorganics into a combustion process will cause them to be released into the air, usually increasing likelihood of exposure. Alternately, they may be captured in air pollution control processes.
- The Committee discussed whether the current guidance on organic and inorganic mixtures is sufficient. Guidance in the CDR 2016 Instructions for Reporting page 2-5 states that if manufacturers or recyclers burn organic/ inorganic mixtures and dispose of whatever remains they can take the exemption. If, however, they burn an organic/inorganic mixture as a fuel and reuse the inorganic residuals for a commercial purpose, they must report. The guidance does not address the combustion of inorganic byproducts where the sole purpose of burning the inorganic byproducts (and anything else in the fuel) is to generate power. After further discussion, EPA agreed to look more closely at guidance to determine if disposal and recycling need to be more closely aligned.
- The oil and gas industry uses this exemption. They send sludge to boilers and use this organic and inorganic mixture as a fuel, though the inorganics do not burn.
- The rationale for removing the exemption only for inorganic byproducts is that there is no fuel value for inorganics.
- Other regulations such as the Clean Air Act, or state and local authorities, may require air emission/pollution control devices and emissions monitoring that would control the environmental impacts of such burning. However, the extent to which all the burning is adequately controlled could not be determined without the CDR data. There is no link between the TSCA regulatory reporting exemption for 'burning as a fuel' and CAA permit/regulatory information. It is unclear whether all potential air toxics emissions would be addressed or whether all combustion facilities using the material would be adequately regulated.

**Disposal as Waste**

- EPA provided a copy of relevant guidance that describes how manufacturers and recyclers have to report if they are putting materials into a product (e.g., fly ash byproduct being used in potting soil).
- EPA should be able to use information from TRI reporting to clarify land application issues unless it is used in a product (e.g., potting soil), as TRI does not cover use as a product. Others were concerned that TRI does not provide adequate information; it provides general quantities disposed

of, not those used as "soil enrichment". Materials reported under TRI as going to 'land treatment' or 'disposal' are different from TSCA byproducts exempt from reporting that go to 'enriching soil'. There are significant discrepancies between TRI and TSCA data, it is not clear how many of the facilities and substances included in the CDR are also covered by TRI reporting, and one set of data cannot serve as a proxy for the other.

- There are no inorganics within the Persistent Bioaccumulative Toxic (PBT) chemicals EPA will be moving forward with. However, there are additional PBTs identified in the Great Lakes Binational Toxics Reduction Strategy, Appendix I, including compounds of lead, mercury, cadmium, and tin. Additional ones may be identified in the future. Some members recommended that EPA could incorporate limits on highly problematic inorganics like mercury and lead.
- There is a potential for vegetative uptake in addition to other forms of bioaccumulation of potentially toxic metals when substances are applied to land. To address this requires different metrics from what are used typically to describe bioaccumulation.

**Component Extraction by Physical Means**

- Two initial options are removing the exemption or utilizing one-time reporting, as outlined in the proposal.
- The recycler who is extracting a component substance would check a check box that says, "source material comes from a byproduct". (See Part III proposal.)

***Strengths/ Merits***

- If an exemption does not make sense or is not scientifically defensible then it should be removed. Burning inorganic byproducts could have significant environmental impacts if not done in an appropriate way.
- Under the revised TSCA, EPA should be identifying conditions of use for the inorganic byproduct regardless of how it has been extracted from the original mixture.
- Information should be reported via CDR (and not exempt) if it is not adequately covered by another program.

***Concerns/ Considerations***

- Maintaining the 'burn as a fuel' exemption could cause releases to the air, encourage the combustion of materials with little or no fuel value, or lead to confusion and noncompliance liabilities.
- If exemptions are to be addressed in the future, this could be done via the CDR Revisions Rule or other efforts that are broader than inorganic byproducts. EPA would like to minimize specific regulatory changes for inorganic byproducts if they may impact other areas.
- Manufacturers may choose to dispose of an inorganic byproduct instead of recycling it in order to avoid having to continuously track and assure that they are accurately reported, especially when working with chemicals that are not hazardous. The cost/burden of reporting the substance may be higher than the commercial value of the reused/recycled inorganic byproduct, and there is a potential for enforcement penalties when reporting has unintentionally not been accurate. EPA pointed out that the analysis provided in the May information public meeting demonstrated that a large amount of material was being recycled.

**Option of Reporting via Categories Proposal**

Susan Sharkey, U.S. Environmental Protection Agency, shared the updated proposal.

***Clarification Notes***

- The purpose of this proposal is to reduce burden for manufacturers when it is difficult to precisely characterize a byproduct stream. It would allow a company to report without detailing exact components and variations of quantities.
- Manufacturers would have the choice to report information on inorganic byproducts either as listed on the TSCA Inventory or broader categories, to be determined, of inorganic byproducts. The category

approach would only be used for CDR inorganic byproduct reporting, and would not exempt industry from reporting in other parts of TSCA.

- The Working Group recommended using the definitions for "inorganic" from the IUR Regulations and "byproduct" from 40 CFR 704.3, referenced by 40 CFR 711.3. They also clarified the definition of recycled, reprocessed and reused.
- EPA used the periodic table to describe which chemical substances might benefit most from a category reporting approach. They include transition metals in columns 3-12 for which it is more difficult to determine chemical structure because they have multiple valences and variability in bonds and therefore multiple possible compounds within a complex mixture typical for a byproduct. Readily identifiable chemicals/compounds from columns 1-2 are more likely to report via the CAS number because they are easier to identify. Discussion is needed on what categories would be included.
- More discussion is needed on how to evaluate whether a byproduct would meet the reporting threshold. Initial options described in the proposal are to determine the threshold based on: 1) total volume of the byproduct stream and 2) the volume of each category in the byproduct stream.
- Initial ideas for adding/subtracting categories in the future are included in the proposal. More discussion is needed to refine an approach.

***Strengths/ Merits***

- Category reporting could relieve the burden of having to identify specific components and amounts of a byproduct stream, such as impurities or components that are in small amounts. This is especially the case when reporting on a mixture.
- Category reporting would help address industry concerns regarding the potential for enforcement penalties when reporting has unintentionally not been accurate.

***Concerns/ Considerations***

- The proposal does not offer burden reduction for reporting UVCBs (which are narrower than the proposed categories). Manufacturers will still need to ensure that future chemicals are properly identified on the TSCA Inventory through Section 5 reporting.
- It is still complicated to determine chemical substances in the byproduct stream, and whether the threshold is met.
- If the threshold is determined by each chemical component then it could lead to more reporting. The overall byproduct production volume may be small enough that reporting is not required, but individual component chemical categories could meet the threshold. It would still be difficult to determine the percentage of each of the category components.

**Modified Reporting of Processing and Use Reporting (Form U Part III Data) Proposal**

Susan Sharkey, U.S. Environmental Protection Agency, shared the updated proposal.

***Clarification Notes***

- When determining which reporting elements to keep and remove, EPA considered typical data received and its value. The reporting response for "workers likely to be exposed" is often not known or reasonably ascertainable since this information depends on knowledge of downstream operations and their uses of inorganic byproducts.
- Companies that manufacture a byproduct have to check one of the Part III check boxes. If the substance were used at the same site, the information such as number of workers exposed would likely be the same as in Part II.
- Pulling out copper from a copper compound is an example of when the "consumed in the manufacture of a chemical substance" check box would be used.
- Consumer and commercial are combined within the "directly used and incorporated into a product and other options" because it's too difficult to separate them. The person reporting may not know how the product will be used downstream. Many products fit both categories (e.g., cleaners can be used both in

residential and commercial settings). If this is the case, EPA could assume that the combined category represents consumer uses for risk prioritization purposes, in the absence of information to the contrary.
- It's unlikely that EPA will be able to eliminate additional reporting elements. However, there may be ways to modify details such as combining sectors.
- The provided sectors are what is currently included in CDR guidance. However, EPA is in the process of considering modifying the sectors to be more aligned with other typical forms of chemical data collection.
- Appendix D: 2016 CDR inorganics with recycle box checked – reporting "processing as a reactant" was included to demonstrate confusion from reporters on how to properly complete this section. EPA expected this to be primarily intermediates and therefore restrictive reporting. The solution is improved guidance.

***Strengths/ Merits***
- Industry members noted that it is helpful to eliminate the "number of workers" and "number of commercial workers reasonably likely to be exposed". The quality of the data may be limited for far downstream uses.
- It retains the data needed on consumer uses of products resulting in potential widespread exposures.

***Concerns/ Considerations***
- The approach still requires tracking of products.
- While it may be true that many products can be used in both commercial and consumer settings, most products can be distinguished as being primarily for one or the other.

**Limit Reporting for Site-Specific Catalyst Recycling Proposal (Approach E)**
Jim Cooper, American Fuel and Petrochemical Manufacturers (AFPM) provided an updated description of this approach. Approach E limits reporting for catalyst recycling, when as an inorganic byproduct that is recycled, reused, or reprocessed either at the site of byproduct manufacture or at a different site, when returned to the site of byproduct manufacture for further use or processing.

***Clarification Notes***
- "Spent catalysts" have multiple meanings. For acid catalysts "spent" means the catalyst needs to be regenerated and for metal catalysts it means it can no longer be regenerated. The flow chart was updated to reflect this.
- Catalysts are chemical compounds that are only used to facilitate the production of other compounds. Catalysts are used in a repetitive process.
- The process to regenerate catalysts typically happens within a closed system, including closed storage. The risk profile does not change, even if the catalyst is sent to another site, since the same regeneration process is used.
- The term "closed loop" needs to be defined. Jim Cooper referred to closed loop as a process that occurs in one facility or related facility in a closed system during processing. The only time a catalyst is released is if there is an accident. Other Committee Members noted that processing at another site is not closed loop, nor are there storage restrictions ensuring true closed loop management.
- There were some minor changes to the flow chart presented, based on current CDR processes. If the catalyst is regenerated onsite, the box should read "catalyst and intermediates formed during regeneration exempt under CDR". If the regeneration of spent catalyst does not cause a chemical change to form a different chemical substance then the box should read "not reportable under CDR".
- There were some inconsistencies with the text proposal, which raised questions regarding the terms of the proposal. For example, one time reporting is no longer included in the proposal.
- While this proposal may only impact a subset of industry, it reduces reporting burden significantly.

**Limit Reporting for Reuse of Inorganic Byproducts Proposal (Approach F)**
Jay Willis, Portland Cement Association, provided updated descriptions of this approach. Approach F limits reporting for inorganic byproducts that are isolated from a process and later reintroduced into that same process.

**Clarification**

- This proposal exempts reporting of an isolated byproduct reintroduced into a manufacturing process to make a final product, if it is chemically indistinguishable from the raw materials or final product. Limited reporting would only be allowed for on-site activities.
- It is estimated that 95% of the byproducts that would be impacted by this proposal are non-isolated within a closed loop. More clarity is needed on how "closed loop" is defined.

***Strengths/ Merits***

- This approach limits reporting and eliminates double counting, which will result in better information for EPA.

***Concerns/ Considerations***

- There could be exposures during storage or transport such as air dust, which could be significant due to large volumes of chemical substances. The stored chemical substances could also get mixed with impurities and could create additional exposure pathways.
- Need to clarify what "chemically indistinguishable" means and how this is demonstrated. Byproducts contaminated or enriched with various impurities would not be chemically identical but could be, depending on analytical methods employed, chemically indistinguishable.
- Depending upon how "chemically indistinguishable" is defined, the exemption could apply to intermediates significantly more toxic than the feedstock they are replacing. For example, pollution control residues could be considered "chemically indistinguishable", even though such residues could contain much higher concentrations of toxic metals than the comparable feedstock materials.
- If the materials are exempt from reporting, CDR would not provide necessary data on the onsite reuses of the chemicals and the potential resulting exposures.

***Ideas/ Suggestions Modifications***

- Specific examples are needed to more fully understand the applicability of this approach.
- A more detailed review of EPA policies is needed to clarify the differences between isolated and non-isolated intermediates. Additional information may be needed on whether isolated processes could result in greater exposures than non-isolated processes.
- Some Committee Members described that exposures may be quite different and requested exploration of an alternative approach that would provide data to assure that exposures are the same and provide guidance when they are different.
- Consider a reduced reporting requirement rather than a full exemption.
- This approach may be more relevant within the broader CDR Revisions Rule, as it is really about intermediates that could be inorganic or organic.

**Statement on Modernizing TSCA Data System**
Amy Kyle, representing the Sierra Club and CA Communities Against Toxics, described this recommendation on how to modernize agency data collection and reporting.

***Clarification Notes***

- The proposed statement goes beyond inorganic byproducts and is relevant for broader TSCA reporting requirements.
- The key points in the proposal are standard practice for creating information systems.
- It helps everyone when data is understandable to all audiences.
- The costs of sharing data are completely different than they were decades ago.

*Strengths/ Merits*

- Opportunity for more accessible information from EPA data programs.
- Interoperability could be significant to streamline reporting across programs.

## Other Background Presentations

**Data on Metal Compounds Reported to TRI and CDR as Byproducts**

Maria Doa, Director of EPA's Chemical Control Division, presented results of EPA's data analysis. EPA conducted a crosswalk of byproducts reported under TRI and CDR in order to gauge production volume of byproducts within various metal compound categories. This serves as an indicator of information that could be lost if manufacturers do not report on inorganic byproducts that are recycled, reused or reprocessed through CDR. The data demonstrated significant non-overlap between TRI and CDR, indicating that considerable data could be lost if CDR reporting were significantly limited.

**Small Business Interests Presentation**

Tayyaba Waqar, Assistant Chief Counsel for Environmental Policy, Small Business Administration Office of Advocacy, presented an overview of Regulatory Flexibility Act (RFA) processes that are required if the Proposed Rule would have a "significant economic impact" on a "substantial number of small entities". Under RFA, if EPA determines that there is not a significant impact, it can certify it and no further analysis is required. If there is a projected impact (both positive and negative), SBA's view is that EPA needs to convene a SBREFA panel and conduct a regulatory flexibility analysis to determine what further considerations/steps are required.

The purpose of the presentation was to identify whether small business interests were being represented by Committee Members, and to aid EPA and SBA with any necessary later determination regarding whether negotiated rulemaking process could be used instead of, or as a supplement to, any required actions under RFA. See the presentation slides for more information.

*Clarification Notes*

- There is no specific definition for "significant economic impact" as it depends on the industry. Some potential approaches are comparing the annual compliance cost to a small business to its revenue and/or considering profits and cash flow. EPA has a chart and guidance for how to determine this.
- EPA has the option to submit a waiver that indicates that the Negotiated Rulemaking considered small business interests. The Committee does include members who represent small businesses, either as an individual company or by association.

## Participants

**Committee Members**

- US Environmental Protection Agency (EPA): Susan Sharkey, Lynn Vendinello and Jonah Richmond (Designated Federal Officer)
- Environmental Council of the States (ECOS): Mark Smith, Massachusetts Department of Environmental Protection (Mass DEP); John Gilkeson, Minnesota Pollution Control Agency (MPCA);
- National Tribal Toxics Council (NTTC): Kristin K'eit, Zender Enivronmental Heath and Research
- Earthworks: Aaron Mintzes (not present day 2 afternoon)
- National Pollution Prevention Roundtable (NPPR): Rick Reibstein (day 1)
- Natural Resources Defense Council (NRDC): David Lennett
- Sierra Club and CA Communities Against Toxics: Amy Kyle
- WE ACT for Environmental Justice: Adrienne Hollis
- American Chemistry Council (ACC): Karyn Schmidt, ACC and Schuyler Pulleyn, The Chemours Company FC, LLC (day 1)
- American Coal Ash Association (ACAA): Danny Gray, Charah, LLC
- American Fuel and Petrochemical (AFPM): Jim Cooper, AFPM and David Dunlap, Koch Companies Public Sector, LLC
- American Petroleum Institute (API): Uni Blake and Derek Swick, API
- Association Connecting Electronics Industries (IPC), Fern Abrams, IPC and Bret Bruhn, TTM Technologies
- Guardian Industries: Mark Duvall, Beveridge & Diamond, PC and James Riley, Guardian Industries Corp.
- Institute of Scrap Recycling Industries (ISRI): David Wagger, ISRI
- North American Metals Council (NAMC): Kathleen Roberts, NAMC (day 2)
- Phibro-Tech, Inc.: Dwight Glover, Phibro-Tech, Inc. (not present day 2 afternoon)
- Portland Cement Association: Jay Willis, Titan America, LLC
- Steel Industry: Joseph Green, Kelley Drye & Warren, LLP
- Utility Solid Waste Activities Group (USWAG): Maggie Fawel, Venable, LLP (day 1)

**Facilitators**

- Chris Moore, CDR Associates
- Laura Sneeringer, Consensus Building Institute

**Speakers and Observers**

- American Coal Ash Association (ACAA): Thomas Adams (day 1), Tom Schmaltz (Headwaters Resources/ ACAA Consultant)
- API Consultant: Stephen Bowes
- Bloomberg BNA: Pat Rizzuto (day 2)
- Consumer Specialty Products Association (CSPA): Nicholas Georges
- Eastern Research Group (ERG): Dan-Tam Nguyen (day 1), Sean Layton (day 2)
- EPA: Kent Anapolle, Maria Doa (day 1), Stephanie Griffin, Franklyn Hall (day 1), Niva Kramek, Doyoung Lee (day 1), Tanya Mottley, Laura Nielsen, Barry Parker, Mel Peffers, Tom Smith, James Tyree, Eric Wilber, Kazumi Yamada, Liang Zhang (day 2)
- Inside EPA Insider News: Dave Reynolds (day 2)
- International Precious Metals Institute (IPMI): Michael Riess
- Portland Cement Association: Louis Baer
- Specialty Graphic Imaging Association (SGIA): Allison Lundy
- Small Business Administration-Advocacy: Tayyaba Waqar
- Roland Halstead
- Aisha Samples

October 30, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the New Chemicals Coalition (NCC), a group of over 20 company representatives that have come together to identify new chemical notification issues under the amended Toxic Substances Control Act (TSCA) and to work collaboratively with you and your team to address them. We wish again to thank you and your colleagues for your tireless efforts to implement amended TSCA. We appreciate all that you do.

The NCC is aware that the U.S. Environmental Protection Agency (EPA) intends soon to issue updated guidance material to assist stakeholders in developing Section 5 submissions. We further understand that the document is focused on identifying required information elements and approaches that will facilitate EPA review of such submissions. This guidance material, referred to as the "Points to Consider When Preparing TSCA New Chemicals Notification" (Points to Consider document), is expected to be available for public comment in **November 2017**.

The NCC strongly supports EPA's efforts to identify information elements that TSCA notifiers should consider in preparing their chemical notifications. The identification of this information without more explanation, however, does not provide the clarity, transparency, and understanding that affected companies need regarding EPA assessment and regulatory approaches under amended TSCA. Beyond knowing *what* to report in a submission, stakeholders need to understand *why* the information is needed by EPA assessors and *how* that information will be used by EPA and incorporated into a new chemical risk evaluation. Without this information, the lack of certainty regarding the EPA process will adversely impact investment, stifle innovation, and deny the regulated community of a clearer understanding of how EPA is actually implementing the new law as it relates to new chemical review. To achieve this objective of greater transparency, NCC strongly urges EPA either to expand the Points to Consider document to provide details on its policies, procedures, and guidance related to new chemical notifications, risk assessments, and risk management, or to agree to develop additional



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policies, procedures, and guidance material relevant to carrying out the requirements under amended Section 5. We provide specific areas of interest, and our suggested solutions, below.

**Expanded Points to Consider Document Could Fulfill a Portion of Section 26 Requirements**

TSCA Section 26(*l*)(1) requires that, by June 2018 (two years after enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act),

> ...the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments of this [Act] made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

New TSCA reflects significant amendments to Section 5, including the critically important requirement that EPA make a formal determination on notified chemicals. By expanding the Points to Consider document to include information on the policies and procedures it uses in making Section 5(a)(3) determinations, EPA could fulfill some of Congress's expectations under Section 26 as it relates to Section 5 policies, procedures, and guidance. If EPA elects not to expand the Points to Consider document, it should be prepared to explain how it intends to meet the requirements under Section 26(*l*)(1) within the mandated timeframe.

**Guidance Needed on EPA Policy Interpretation and Application of TSCA Terms**

In addition to enumerating specific types and categories of information that EPA needs to consider under Section 5, EPA also needs to provide each submitter and other TSCA stakeholders with a policy context within which EPA will interpret and apply key terms that are new to the TSCA lexicon and a critical part of the new chemical assessment and risk management process. The past 16 months has demonstrated that EPA's implementation of these terms has had a dramatic impact on its decisions and actions, impacts far beyond what stakeholders envisioned in reading the new law. In particular, to fulfill EPA's commitment to transparency, EPA needs to provide the submitters and other stakeholders much greater detail on its policy interpretation and application of terms, particularly as they apply to decisions related to additional testing or specific restrictions, for the following in a Section 5 review:

- Insufficient information (Section 5(a)(3)(B)(i));
- Not likely to present an unreasonable risk (Section 5(a)(3)(C));

- Reasonably foreseen (Section 3(4)); and

- To the extent necessary to protect against an unreasonable risk (Section 5(e)(1)(A)).

A lack of both clarity and context as to these pivotal terms is in no one's best interests. Providing more policy context regarding these terms will allow greater transparency, and likely diminish the time and resources EPA expends in processing notifications during the review process. If the submitter understands better how EPA will interpret and apply these terms within the submitter's particular notification, the submitter's point of reference will be more closely aligned with EPA's need for the information. This will allow notifiers to be better positioned to develop a notification that proactively addresses EPA inquiries. Otherwise, notifiers remain in limbo regarding not understanding the basis for EPA's determination. Both the notifier and EPA staff spend unnecessary time, resources, and money in back and forth communications.

**Guidance Should Include Needed Updates on Chemical Categories**

As further articulated in the July 26, 2017, letter to you from Bergeson & Campbell, P.C. (B&C®) (appended), it is vital that EPA develop, refine, and update the new chemicals categories and their associated documents. The Points to Consider document should, at a minimum, explain the role of these documents and how EPA uses them in its assessment processes under amended TSCA. This explanation is essential to inform more effectively how EPA decisions will be made as such on category members and in the context of the Section 26 sound science requirements under the amended TSCA and, of course, to satisfy EPA's fundamental obligations to explain decisions that compromise final agency action from a perspective of TSCA and the Administrative Procedure Act.

The chemical category documents need to be updated (many are decades old) regarding human health issues and expanded to provide submitters with further understanding on read-across and hazard characterization issues. Similarly, EPA needs to expand upon the points included under Section 4(h) concerning reduction of testing on vertebrates, and upon what stakeholders should consider in preparing their submissions. Alternatively, if EPA believes that certain new chemical categories are no longer useful or relevant, the categories and associated documents for them should be withdrawn. The Points to Consider document is an excellent opportunity for EPA to initiate this process by releasing for public comment newly revised category documents such as those concerning the four lung toxicity categories that were discussed in our July letter. We urge EPA to work toward guidance that is functionally equivalent to that developed under the Organization for Economic Cooperation and Development (OECD) category guidance to ensure consistency and predictability.

The documents also need to provide insight into EPA's category approaches on physical state and use applications. EPA should share publicly an overview as to how it assesses potential risks associated with the physical state of a new chemical substance and its listed use applications within a category context. The Points to Consider document should highlight, for example, if and when new chemical substances that are solids might be subject to inhalation testing requirements or what testing should be expected for new chemical substances that may be used in spray applications and if there is an exit ramp option for such testing depending on particle size or workplace exposure controls. If there are specific use applications that result in automatic concerns requiring additional scrutiny or automatic restrictions, EPA should include such information in the Points to Consider document. Additionally, EPA should also provide guidance as to what language should be included in a premanufacture notifications (PMN) to ensure EPA that such use applications will not occur.

We also stress the need to include in the updated chemicals categories document a robust overview of a tiered testing strategy (as required by Section 4(a)(4)) that clearly adheres to the basic principle of applying what is learned in one tier to what might eventually be needed to determine category membership and to meet a regulatory requirement. The tiering strategy needs to include "exit" decision points for each testing tier based on information requirements for the category, *i.e.*, individual test outcomes should consider the context of what we know about the toxicity and characteristics of category members, exposure considerations, and associated risk management.

**Guidance Should Address Impacts to Sustainable Futures**

As EPA knows well, many industry stakeholders rely on the training and tools provided under the EPA Sustainable Futures program to prepare and pre-review new chemical notifications prior to submission. Because Sustainable Futures tools allow chemical developers to use the same risk-screening models that EPA relies on for new chemicals evaluations, companies utilizing the tools, and particularly those companies that have received Sustainable Futures program training or that rely on Sustainable Futures assessments prepared by experts, should know better what the outcome of an EPA assessment will be. It is unclear to NCC members whether the EPA assessment process under amended TSCA and its use of the models and approaches included in the Sustainable Futures program have changed. Stakeholders need to be aware if there have been changes in EPA's acceptance of Sustainable Futures assessments as well as modifications in the modeling used, uncertainty factors applied within those models, or assumptions made. The Points to Consider document should include information on how EPA intends to maintain the Sustainable Futures program and highlight any altered approaches it will use in its reliance on the Sustainable Futures approaches and models provided. In particular, we remind EPA of the statement on its website that "[c]ompanies that take the training and graduate

from Sustainable Futures become eligible for an expedited EPA premanufacture review" (https://www.epa.gov/sustainable-futures).

**EPA Should Provide Greater Explanation of Polymer Flags Used with Certain New Chemicals**

The Points to Consider document should include an overview as to how EPA will assess and approach PMNs submitted for polymers that are intended to be manufactured in a way that meets the polymer exemption at 40 C.F.R. § 723.250. We are aware that EPA, following its review of relevant PMN cases, has previously taken the approach of using a polymer flag as a way to limit how such polymers could be made based on EPA's assessment. While the NCC supports this innovative approach and commends EPA's efforts to avoid the resort to such unnecessary regulatory actions, as a consent order and/or Significant New Use Rule (SNUR) that might otherwise have been needed to achieve the same end, we also note the need for EPA to develop and provide guidance explaining the purpose of the flag and its effect. Such flags seem to be distinctly different from other Inventory flags that merely indicate some status (*e.g.*, XU = exempt from the Chemical Data Reporting rule, S = proposed or final SNUR), but do not otherwise restrict the identity of the substance or how such a substance is manufactured. The Polymer Exemption Flag seems to operate more like a substance definition, which, in association with the substance name, make up the formal identity for TSCA purposes. Given the role and impact of these flags, it is incumbent on EPA to provide this explanation and understanding.

**EPA Should Consider Alternative Naming Approaches for Polymers and UVCBs**

In addition to the Polymer Exemption Flag approach noted above, EPA should consider similar approaches that provide appropriate and much needed flexibility to EPA in meeting the legal and timing requirements under Section 5(a), while speeding up commercial innovation and the introduction of other low-concern polymers that would not otherwise meet the polymer exemption criteria. For example, EPA could rely on a polymer name, perhaps with the addition of a definition, to limit the polymers that can be made based on a given name to a subcategory of the possible polymers that meets low-concern criteria or otherwise satisfies criteria EPA has developed. This approach is based on EPA's polymer guidance, which states:

> An Inventory listing for each polymer describes a category of possible chemicals that would fit that substance name, instead of just representing a single molecular structure'' and can vary within that listing in molecular weight and composition (e.g., the ratios or the order of reaction of the starting monomers; Toxics

> Substances Control Act Inventory Representation for Polymeric Substances (1995)).

Dividing the large "polymer" category into subcategories allows EPA to limit the forms of the polymer that can be manufactured under that subcategory identity, thereby providing strong protection with minimal EPA resources and without the need for a TSCA Section 5(e) order or Section 5(a)(2) SNUR.

This naming scheme could also be applied more broadly to substances with Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB). Such approaches also would speed commercial innovation via the introduction of low hazard substances, while at the same time avoiding the impacts of unnecessary regulatory impediments to the supply chain, providing strong, Section 5 protection against substances that do not meet the low-concern criteria, and reducing the burdens on EPA and manufacturers associated with developing consent orders or SNURs.

**Guidance Should Explain How Mandated Consultation Process with OSHA Will Occur**

Based on completed and ongoing new chemical assessments, it is evident that EPA is focused on the need to apply appropriate workplace exposure controls for new chemicals. The Points to Consider document should articulate exactly how EPA will implement the requirements in Section 5(f)(5), which states:

> (5) WORKPLACE EXPOSURES – To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

The EPA guidance should explain the steps taken by EPA to meet this requirement for ongoing consultations with the Occupational Safety and Health Administration (OSHA) and how it has satisfied the "prior to adopting any prohibition or other restrictions relating to…workplace exposures" provision. The guidance should further explain EPA's thinking as to why regulation using TSCA authority in addition to the obligations imposed by OSHA if a Safety Data Sheet specifies the necessary protections is required to maintain no unreasonable risk in the workplace.

* * * * *

We hope you find these comments helpful. We would be pleased to discuss them with you and your staff in more detail prior to the anticipated **December 2017** public workshop if that is of interest.

Sincerely,

Kathleen M. Roberts

Attachment
cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)
Kevin W. McLean, Esquire (w/attachment) (via e-mail)
Brian P. Grant, Esquire (w/attachment) (via e-mail)

Lynn L. Bergeson
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BERGESON & CAMPBELL PC

July 26, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director, OPPT, OCSPP
Office of Pollution Prevention and Toxics
Ronald Reagan Bldg. and International Trade Center
Room 71184
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Dear Jeffery:

Thank you for sharing with us the recent new drafts of four new chemicals categories with a focus on human health: Polymer Lung Overload; Polycationic Substances (Cationic Binding); Waterproofing Agents; and General Surfactants. We appreciate the effort by the U.S. Environmental Protection Agency (EPA) to upgrade and update the category documents and encourage continued activity in this area. We offer technical comments on the documents (appended) and encourage EPA to engage in a broader effort to solicit public comments. We recognize the critical role that the new chemicals categories have played in the implementation of the New Chemicals Program over time, however, we believe there is a need to further develop and refine these documents to inform more effectively decisions in the context of the science requirements under the amended Toxic Substances Control Act (TSCA).

The new chemicals categories prior to the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) were regarded primarily as a risk management tool to alert submitters to classes of new chemicals that were identified by EPA as being of concern. The write-ups for the most part consist of generic descriptions of potential environmental and/or human health hazards. The substance of these categories is closer to a structural alert than to a category like those developed in the Organization for Economic Cooperation and Development (OECD) program. The New Chemicals Program category documents do not provide the kind of understanding needed to inform submitters of read-across and hazard characterization issues that should be considered in submitting relevant information on a new chemical. This difference between the (traditional) new chemicals categories and categories developed under the OECD grouping programs is not always apparent to premanufacture notification (PMN) submitters. The latter categories are better models but require additional effort to design and build and the recent drafts hint at movement in this direction. Many of the new chemicals category documents are also quite dated, particularly with regard to human health issues, and are in need of update. This could be done over time and provide opportunities for public review and commenting and peer review as indicated.


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Given the changes in new TSCA, current versions of the new chemicals category documents do not provide the kind of understanding needed to inform submitters of category definitions and boundaries, read-across, and hazard/exposure/risk characterization issues and information needs that should be considered in submitting relevant information on new chemicals. The New Chemicals Program category documents also need to evolve to better align with the sound science provisions in Section 26. A goal of the New Chemicals Program could be to develop new chemical categories that are functionally equivalent to those developed under the OECD's category guidance. We note that the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) also uses categories based on the OECD guidance.

Our comments attempt to examine the category documents under the guidance of the Section 26 science standards. A topic that we feel the need to highlight is the inclusion of tiered testing strategies in these documents. The tiered testing approach illustrated in the recent categories does not conform to the basic principle of relating what is learned from each testing tier to what is eventually needed to determine category membership and to meet a regulatory requirement. The tiering strategy needs to include "exit" decision points for each testing tier based on information requirements for the category, *i.e.*, individual test outcomes need to consider the context of what we know about the toxicity and characteristics of category members, exposure considerations, and associated risk management.

We hope you find these comments helpful. We would be pleased to discuss them with your technical staff in more detail if that is of interest.

Sincerely,

Lynn L. Bergeson

Attachments
cc: Nancy B. Beck, Ph.D., DABT (w/attachments) (via e-mail)

**Initial Comments on Polymer Lung Overload New Chemicals Category**

**Definition**

This category includes a variety of poorly soluble polymers, and specifically insoluble/non-water absorbing ("non-swellable") high molecular weight materials typically formed through a free-radical polymerization process. Included are branched and linear polymers, as well as copolymers produced by random, block, graft, or other techniques. Crosslinked polymers are included in the category, but crosslinking is not necessary for inclusion.

The high molecular weight polymers included in this category are otherwise considered non-toxic and this characteristic should be included in the category boundaries discussed below. The hazard concerns for the category are limited to the effects on the lung as a result of inhaling respirable poorly soluble particles. The toxicity information that supports this category consists exclusively of inhalation studies in rodents. No epidemiological studies are cited. A title more reflective of the scope of the category should be considered as well. For example, Respirable Poorly Soluble Polymers is a better description of the category than the current title that highlights an experimental design outcome.

**Section 26 Standards**

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information:* Yes, to a point. The hazard concerns require better framing that includes a pragmatic discussion of the lung overload condition and its implications in realistic human exposure scenarios.

(h)(2)—*Relevance of Information:* As above.

(h)(3)—*Clarity and Completeness:* The document makes use of available public information on these chemicals and provides an arrow rationale for the category. Lung overload is a controversial subject that should be discussed in the context of a mode of action.

(h)(4)—*Variability and Uncertainty:* Needs a better description. There are some questions about the relevance of animal inhalation data to characterize effects in humans (lung overload).

(h)(5)—*Independent Verification or Peer Review:* The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review. At a minimum, and considering the important role of category documents in guiding testing decisions by the U.S. Environmental Protection Agency (EPA) and premanufacture


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notification (PMN) submitters, a public comment period could prove valuable in increasing clarity, completeness, and better understanding of the tiered testing strategy.

**Boundaries**

Polymers must be respirable and poorly soluble in water. No molecular weight requirements specified. The boundaries should note that the polymers that fit the category are otherwise non-toxic.

**General Testing Strategy**

The purpose of a tiered strategy is to generate information to inform subsequent steps and then to determine the need to proceed to the next step or not. Tier 1, as discussed below, does not operate as a mechanism to determine the need for higher tier testing. The approach as currently framed appears to consider only moving on to the next tier, which defeats the purpose of a tiered testing strategy.

**Tier 1**

Physicochemical Characterization: Particle size distribution and biosolubility testing. The strategy indicates that if respirable and poorly soluble particles can be generated, proceed to Tier 2. If the studies are negative, there is still a requirement to determine if Tier 2 is needed. It is not explained why, if the chemical is not found to meet the terms of the category (respirable and poorly soluble), there is still a need to determine if higher tier testing is required. This seems to violate a basic principle of tiering where early tier results inform as to the need for higher tiers. As mentioned above, a public comment period could prove a resource to increased clarity, completeness, and understanding of the approach.

**Tier 2**

A series of inhalation studies in rats with durations ranging from 4 hours to 28 days.

**Tier 3**

90-Day Inhalation Study: Based on results of the 90-day inhalation study, a 2-year inhalation bioassay in rats may be warranted.

The *in vivo* tiering is reasonable; as discussed above, there are questions about the role and effect of the first tier. The 2-year cancer bioassay seems excessive considering there is no epidemiological or other (animal) evidence of cancer associated with exposure to these

polymers, including in occupational settings. EPA acknowledges this point in the category document but notes that poorly soluble inorganic particulates have been shown to be carcinogenic in the rat. As discussed below, this is a scientifically controversial area.

The proposed *in vivo* studies involve inhalation tests of various durations utilizing the rat. The adverse effects under consideration for the category range from pulmonary inflammation to tumor formation. The latter effect, which is associated with poorly soluble particulates, does not reflect the interspecies comparative studies that show fundamental differences in the toxicokinetics -- particle disposition, retention, and clearance -- of inhaled particles between rats and non-human primates and humans, nor does it reflect the fact that the lung tumor response is unique to the rat and not observed in other species similarly exposed. Building on the initial work that contributed to the understanding of lung overload (https://www.ncbi.nlm.nih.gov/pubmed/10715616), a s cientific consensus emerged in recent years that, because of unique and substantial differences in toxicokinetics and toxicodynamics, rat lung tumor data generated under overload conditions are not considered appropriate for hazard/risk assessment of exposed human populations (http://www.sciencedirect.com/science/article/pii/S0300483X1630292X). A recent action from EPA in the diesel exhaust risk assessment (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=29060) illustrates this understanding:

> Although high-exposure chronic rat inhalation studies show a significant lung cancer response, this is not thought predictive of a human hazard at lower environmental exposures. The rat response is considered to result from an overload of particles in the lung resulting from the high exposure, and such an overload is not expected to occur in humans at environmental exposures.

The use of the rat as an inhalation model to determine lung toxicity for this category is appropriate since it represents a sensitive test species and consequently the results obtained afford an extra margin of protection. T he proposed cancer bioassay, particularly with the rat model, is not a reasonable inclusion in the test strategy. The cancer question for respirable poorly soluble polymers should be evaluated on a case-by-case basis considering the weight of the scientific evidence.

**Initial Comments on Polycationic Substances New Chemicals Category**

The operational use of a new chemicals category is to identify hazard concerns for a particular group of chemicals and corresponding toxicity or other testing to provide information to address concerns.

**Definition**

Any polymer or substance with multiple functional groups bearing positive charges at physiologically relevant pH is a member of this class. Positive charges may be dissociable (*e.g.*, amine salts) or non-dissociable (*e.g.*, quaternary ammonium cations). Such structures include polyamines, polyquaternary ammonium, polyurea-amines, polyamide-amines, and polyguanidine compounds.

The definition is relatively open-ended and it is unclear what other substance(s) may be considered part of this category. The definition also lacks any indicator of minimum size or molecular weight (MW). For example, a simply alkyl polyamine such as tetraethylene pentamine (TEPA) would seemingly be included.

The toxicity information that supports the category is derived from epidemiological, animal testing and *in vitro* studies on polymeric amines/amides. A potential mode of action for these chemicals is proposed that highlights the critical role of charge density, MW, and molecular conformation in the expression of toxicity. The identified polycationic polymers that form the basis for this category have MWs around 20,000 and higher.

To the extent that lower MW polycationic chemicals (*e.g.*, MW<1,000) are considered part of this category, their inclusion would be inconsistent with the available toxicity and mode of action information. Lower MW polyamine/amides have been shown to produce predominantly irritation upon dermal and/or ocular exposure in test animals. Irritation becomes the prevalent adverse effect linked to exposure of low(er) MW polyamine/amides. The proposed mechanism of cytoxicity for high MW polycationic polymers involves the initial electrostatic interaction of the polycationinc polymer with the negatively charged cell membrane. This interaction neutralizes cell membrane charge over the area of contact. This condition weakens the membrane structure that eventually leads to leakage and a more permeable membrane. A low(er) MW polycationic substance would experience a similar but more localized interaction short of the impact associated with higher MW polycationc polymers.

A separate argument against a low MW polyamine/amide belonging to this category is the postulated mode of action for the polyamine/amides in the epidemiological studies that require certain MW, charge density, and conformation characteristics not present in the former. In addition, a lower MW would facilitate absorption of a polyamine/amide by the cell and the toxicity observed would be associated with intracellular interactions rather than the postulated membrane effects associated with the category.


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**Section 26 Standards**

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The scientific information and methodologies are consistent with the intended use of the information; the description of the rodent inhalation exposure protocols fall short of the standard.

(h)(2)—R*elevance of Information*: T he toxicity information is relevant for making decisions about these polycationic polymers.

(h)(3)—*Clarity and Completeness*: The document makes use of available public information on these chemicals and provides a reasonable rationale for the category.

(h)(4)—*Variability and Uncertainty*: T he U.S. Environmental Protection Agency (EPA) discloses the limitations of the available animal testing information. There are few adequate animal studies and some are short on experimental details. Other studies cited were conducted by intratracheal instillation, which are useful as confirmatory of the hazard concern but not very helpful for hazard and risk characterization.

(h)(5)—*Independent Verification or Peer Review*: The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review. At a minimum, and considering the important role of category documents in guiding testing decisions by EPA and premanufacture notification (PMN) submitters, a public comment period could prove valuable in increasing clarity, completeness, and understanding of the tiered testing strategy.

**Boundaries**

Polymers must be water soluble or water-dispersible. N o MW requirements are specified. Although the Definition section includes the requirement for multiple positive charges at physiologically relevant pH, this point is not included in the discussion of boundaries.

**Proposed Testing Strategy**

EPA identifies a series of tests that, although not explicitly stated, partly relate to a determination whether a chemical should be included in the category.

The initial recommendations address the physicochemical characterization of the polymer. This is followed by a set of three *in vitro* tests for Cytotoxicity and Dermal Irritation. The two cytoxicity tests identify the purpose as generating data to predict the starting doses for rodent acute oral systemic toxicity assays and along the way provide a qualitative description of the cytoxicity potential of the test substance. The document does not discuss how PMN submitters and EPA should consider and use the results of the *in vitro* tests, thus it is not clear what role they play in the tiering.

The *in vitro* dermal irritation test is a standard Organization for Economic Cooperation and Development (OECD) test guideline. It is not clear what role the test plays in the polycationic substances category tiering strategy. The polymers that were the subjects of the epidemiological reports are described by the authors as not irritating. Does this suggest that evidence of irritation in this test provides a basis or a partial basis for questioning whether the category applies to a given new chemical? For polyamine/amide chemicals, irritation potential generally decreases as MW increases. This is one of the issues about potentially extending the category to low MW polycations. Low MW polycations (*e.g.*, polyamines such as TEPA) are irritants and this feature tends to drive their toxicity.

**General Testing Strategy**

Tier 1 -- Use physical-chemical properties to characterize lung exposure/binding potential

- Charge density in milliEquivalents/gram or functional group equivalent weight or % amine nitrogen. It would be useful to specify use of physiologically relevant pH in conducting the test.

- Particle Size Distribution or Aerosolized Droplet Size (OECD TG 110 or OPPTS 830.7520).

As discussed in the document, this tier is driven by respirability without also specifying that polycationic character at physiologically relevant pH must be shown.

Tier 2 -- Proposed *In Vivo* Studies

- Step 1: OECD Acute TG 403 featuring rats exposed for 4 hours and observed for 2 weeks (< 2000 mg/m$^3$, proceed to step 2).

- Step 2: Five-day study to address toxicity progression (substantial decrease in the Point of Departure (POD) over time relative to the acute study, proceed to step 3).

- Step 3: OECD TG 412 ( 28-day inhalation study in rats with 14-day recovery period).

EPA concludes that 28-day inhalation studies are adequate to characterize the toxicity of polycationic substances based on the appearance of lung effects in the available studies.

The purpose of a tiered strategy is to generate information to inform subsequent steps and determine the need to proceed to the next step or not. There is a need for better guidance from EPA if it intends to use the results of the initial physiochemical, *in vitro,* and *in vivo* tests. For example, what happens if a polycationic substance is not respirable or shows low cytoxicity in the identified *in vitro* assays? Similar questions can be raised about outcomes of other early toxicity tests. The process as currently framed appears to consider only moving on to the next tiered step resulting in a "tiered strategy" that then devolves into a fixed set of tests that should be implemented regardless of intermediary outcomes. A more descriptive tiered strategy should include information requirements that would inform decisions about proceeding to the next tier or exiting the process. As mentioned above, a public comment period could prove a resource to increased clarity, completeness, and understanding of the approach.

## Initial Comments on Waterproofing Agents New Chemicals Category

### Definition

Any compound that is applied to a solid surface (*e.g.*, carpets, clothing, fabrics, leather, wood, paper packaging, ceramic tiles, concrete, masonry, flooring) to confer or enhance repellency or resistance to water, grease, or stains is considered to be a member of this category. Of particular focus are chemicals used in consumer spray products, which may be applied without the presence of personal protective equipment.

This category includes a range of chemical functionalities with the unifying characteristic being that they bind to surfaces and confer water repellence to the coated area. T he toxicity information that supports this category includes human observations, animal studies, and *in vitro* information.

### Section 26 Standards

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The scientific information and methodologies are consistent with the intended use of the information.

(h)(2)—*Relevance of Information*: T he toxicity information is relevant for making decisions about waterproofing agents.

(h)(3)—*Clarity and Completeness*: T he document makes effective use of available public information on these chemicals and provides a reasonable rationale for the category.

(h)(4)—*Variability and Uncertainty*: V ariability and uncertainty in experimental outcomes are discussed briefly.

(h)(5)—*Independent Verification or Peer Review*: The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review.

### Boundaries

No boundaries are identified for this category.


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**General Testing Strategy**

**Tier 1**

Physicochemical Characterization: Particle size distribution or aerosolized droplet size; surface tension increases.

**Tier 2**

Similar inhalation battery to other inhalation categories that culminate with a 28-day inhalation study. The supporting data section notes that the Organization for Economic Cooperation and Development (OECD) 403 four-hour inhalation exposure with some modifications may be adequate for a comparative assessment of waterproofing agents.

The testing strategy identifies *in vitro* methods that have shown promise as tools for the hazard screening of waterproofing agents.

## Initial Comments on General Surfactants New Chemicals Category

### Definition

Includes anionic, cationic, and nonionic surfactants.

**Anionic Surfactants:** Any molecular structure with a net negative charge and having surfactant activity is a m ember of this category. The category includes, for example, alkyl sulfonates, alkylbenzene sulfonates, alkyl silicic acids, alkyl phosphates, alkyl carboxylic acids, or combinations of these anionic groups, *e.g.*, alkyl sulfonate with carboxylic acid substitutions.

**Cationic Surfactants:** Any cationic surfactant is a member of this category, for example: didecyldimethyl ammonium chloride (DDAC).

**Nonionic Surfactants:** Any neutral structure having surfactant activity (*e.g.*, Triton-X 100) is considered a member of this category.

This category shares several design features with the Waterproofing Agents category, including a range of different functionalities that show surfactant properties. The toxicity information that supports this category includes human observations, animal studies, and *in vitro* data from studies conducted with nonionic and anionic surfactants. An unstated assumption is that ionic character is not relevant for the expression of toxicity by surfactants.

### Section 26 Standards

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The limited scientific information and methodologies are consistent with the intended use of the information.

(h)(2)—*Relevance of Information*: T he toxicity information is relevant for making decisions about waterproofing agents.

(h)(3)—*Clarity and Completeness*: The document makes use of limited public information on these chemicals and provides a reasonable rationale for the category. No data included for cationic surfactants.

(h)(4)—*Variability and Uncertainty*: Variability and uncertainty in experimental outcomes are discussed briefly.

(h)(5)—*Independent Verification or Peer Review*: he information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review.


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**Boundaries**

No boundaries are identified for this category.

**General Testing Strategy**

The proposed inhalation battery (Organization for Economic Cooperation and Development (OECD) 403 progressing to OECD 412) for surfactants is the same as for the other inhalation categories.

The testing strategy identifies *in vitro* methods that have shown promise as tools for the hazard screening of surfactants.

BERGESON & CAMPBELL PC

# The Effect of TSCA Reform on New and Existing Chemicals: EPA Review, Regulation, and Testing Requirements

## TSCA: Best Practices in Toxicology, Risk, and Chemical Management Strategies Fall 2017 Symposium
## October 13, 2017

Richard E. Engler, Ph.D.
Bergeson & Campbell, P.C.
Washington, D.C.
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# Key Provisions

- Section 4 -- Testing
  - New order authority
  - Use tiered testing
  - Minimize vertebrate testing
- Section 5 -- New Chemicals
  - Must make determinations
  - Must take regulatory action if potential for risk
- Section 6 -- Existing Chemicals
  - Must undertake prioritization, risk evaluation, risk management
  - Tight deadlines

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## Key Terms

- Unreasonable risk
- Conditions of use
- Reasonably foreseeable
- Potentially exposed and susceptible subpopulations (PESS)
- Not likely to present
- Sound science

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## Challenges

- No phase-in -- Effective immediately; policies, processes, and interpretation are still in flux
- Many short deadlines for rulemaking
- Brain drain – The U.S. Environmental Protection Agency (EPA) had been losing and continues to lose senior staff to retirements
- Staff shortages -- Between hiring freeze and retirements, staff is stretched thin; EPA using "details" (temporary internal transfers) to fill the gaps
- Funding for contract support -- Expanding capacity of contracts takes time

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# Existing Chemicals Issues

- Stakeholders must take care not to pre-judge outcomes
- EPA will have to require testing to fill gaps on existing chemicals
- Prioritization and risk evaluation are resource intensive
  - If EPA cannot demonstrate low priority with sufficient information, must designate as high priority
- Blurred lines between commercial and consumer use -- many "professional-grade" products available to consumers
- Recognize that while in-place substances may contribute to exposure, the Toxic Substances Control Act (TSCA) may not be the best mechanism to protect against exposures
- TSCA does not have authority to regulate non-TSCA uses

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## Expected Changes

- More consent orders (CO) and more Significant New Use Rules (SNUR)
- More testing, especially on existing chemicals

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## Unexpected Changes

- >90% new chemicals regulated
- Polymer eligible for the Polymer Exemption being regulated
- New chemicals bias worsened
- 90-day clock "reset"

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## Inhalation Categories

- Surfactant default exposure limit of about $10^{-5}$ mg/m$^3$, or about two sprays from a spray bottle
- Water-proofing of lungs
- Lung overload (due to high molecular weight polymers)
- Cationic binding to lung tissue

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Notes:
All known categories prior to Lautenberg; EPA routinely identified the potential hazard
EPA says it has “insufficient information”, but does not exercise testing authority over existing chemicals
EPA spent 6 months doing a literature search, but did not search data in OPP
EPA’s initial finding is insufficient information; upfront inhalation testing;
now require APF 1000 or APF of 50 after break-through testing
If the surfactants on the SCIL were submitted without test data, EPA would require APF 1000 respiratory protection (full-face supplied air)

## Common EPA Responses

- If low/low -- Not likely to present unreasonable risk; otherwise, 5e/SNUR
- Most common PESS: Workers
- Most common regulatory outcome: Required personal protective equipment (PPE); limits to water releases

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## Examples of Flawed Risk Evaluations

- Mist concentrations equivalent of 16 L/m$^3$
- Vapor concentration above the vapor pressure
- Number of containers emptied corresponding to 250,000 kg in a Low Volume Exemption (LVE)

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Notes:
Submitters need to scrutinize risk evaluations

## COs and SNURs

- SNURs are a “black mark” in the market
- Until more existing chemicals have SNUR-like burden (testing, restrictions, recordkeeping), many customers (especially unsophisticated far down the supply chain) will avoid CO/SNUR substances

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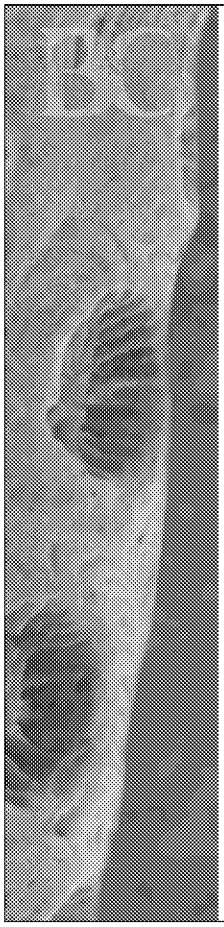



## Creative Solutions

- Exempt polymer flag
- Non-order SNURs

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Notes:

Non-order SNURs as now envisioned require that EPA promulgate the SNUR, then EPA makes non-likely finding, after which submitter may commence

## Suggestions for Submitters

- Detailed release and exposure data
- Duplicate key information, make it less likely an assessor will miss it
  - Key information in the premanufacture notification (PMN) form, not just attachments
- Equipment cleaning and maintenance
- Specify medium of release
- Specify treatment method -- "appropriate WWT" is not enough
- Pollution Prevention (P2) statements
- Learn Sustainable Futures (SF) tools; use them before submitting
- Request prenotice review meeting to identify weaknesses

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## Suggestions for EPA

- Can SNURs focus on critical portions of supply chain?
- Issue test orders related to inhalation categories -- spread the burden among new and existing chemical manufacturers
- Must improve the quality and consistency of assessments
- Prepare new chemical review reports to be ready to send upon request
- Points to Consider must be more than just what to put in a PMN
  - Provide insight into EPA's thinking and EPA's approaches to hazard, exposure, and risk assessments
  - Explain role of P2 statements/risk reduction

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# Questions for Stakeholders

- Is EPA required to regulate for PPE?
  - Can PPE be reasonably assumed to be a "condition of use" in an industrial setting?
  - Can PPE be reasonably assumed if there are other reasons to use PPE?
- If EPA is not required to regulate for PPE, are COs/SNURs for PPE the best use of EPA's resources?
- Is skin or eye irritation an "unreasonable risk" that requires EPA to regulate?
- Is corrosion an endpoint that requires a SNUR? Is a clear warning sufficient?
- What is "reasonably foreseeable"? Is it the same as "someone could"?
- How likely is "not likely"?
- Does it make sense to require confirmatory testing for substances with high aquatic toxicity?
- Should there be a stakeholder group in which these and other issues can be discussed to provide EPA input?

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## Closing Thoughts

- Cooperation among stakeholders is vital to get TSCA implementation right
- EPA needs to exercise its test authority for existing chemicals
  - Even the playing field between new and existing chemicals
- Submitters must provide more complete data set
  - Identify potential analogs
- Have some patience

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# Thank You

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August 10, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Request for Continued Stay of Nanoscale Materials Reporting Rule

Dear Dr. Morris:

We write to renew our collective request that the U.S. Environmental Protection Agency (EPA) continue to stay the effective date of the January 12, 2017, final rule, "*Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*,"[1] which is now scheduled to expire on August 14, 2017,[2] until six months from issuance of the promised guidance. The reasons for our request are set forth below.

The purpose of the May 12, 2017, *Federal Register* notice was to stay the rule pending the issuance of guidance. Unfortunately, the promised guidance has not yet been issued in final form. A substantial number of thoughtful comments and detailed questions were submitted on the draft guidance. Our collective hope was that EPA's consideration of these comments and questions would result in a more user-friendly document that provided more meaningful guidance than merely repeating the instructions in the rule and addressed specific gaps that the rule did not acknowledge. The draft guidance did not, for example, address such fundamental matters as how to characterize changes to surface area and whether the one percent reporting threshold applies both to intentionally and unintentionally produced nanoscale particles.

In its May 12, 2017, notice, EPA noted the "complex issues regarding [the] reporting requirements of the rule."[3] We agree with this statement. The lack of EPA guidance on how to

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1 82 Fed. Reg. 3641 (Jan. 12, 2017).

2 82 Fed. Reg. 22088 (May 12, 2017).

3 *Id.*

address these complex issues is of significant concern, given our deep and abiding interest in ensuring that EPA's rule elicits the quality information it needs to fulfill its mission. Several industry sectors are specifically looking to the guidance for instructions on threshold issues such as how to determine the reporting status of their materials. For example, guidance on intentionality, surface area, surface treatment, the definition of a solid, physical-chemical property test protocols, and the appropriate starting material for making the seven standard deviation determinations is sought to make these reports. These and other examples can be found in the docket that contains the comments submitted by our respective associations, copies of which are appended here for your convenience.

Because the nanoscale materials reporting rule becomes immediately effective for new commercial introductions of nanomaterials, including by processors unfamiliar with this extensive level of reporting, we ask that EPA issue the final guidance and extend the effective date of the rule. Additional time is much needed to allow companies an opportunity to study the guidance and to assess their compliance obligations.

Given the potential for compliance issues to arise if the final rule and EPA's interpretative guidance of it are not well understood, EPA must ensure that the final interpretative guidance is released well in advance of the commencement of the reporting period. We note also, as many commenters on this rule predicted, the timing of this reporting over the next year will significantly overlap with the new industry reporting requirements under the final Toxic Substances Control Act (TSCA) Inventory notification (active-inactive) rule.[4] Manufacturers and importers must report to EPA, within 180 days of the rule's publication in the *Federal Register,* existing chemicals listed on the Inventory that are not already deemed active. The nanoscale materials reporting rule and the TSCA Inventory notification rule are important rulemakings. We are certain EPA shares our interest in ensuring that regulated entities are able to provide the most meaningful information possible in response to each, and this is best accomplished by delaying the effective date of the nanoscale materials reporting rule as outlined above.

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4 EPA published a pre-publication version of the final rule on June 22, 2017. EPA, *Federal Register Notice: TSCA Inventory Notification (Active-Inactive) Requirements*, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/federal-register-notice-tsca-inventory-notification.

Accordingly, for all the reasons noted above, the organizations listed below respectfully request that EPA consider the significant resources it is asking industry to commit in responding to the nanoscale materials reporting rule, acknowledge that the guidance is urgently needed, and extend the stay of the effective date of the rule until six months from the issuance of the final guidance. Thank you for your consideration of our request.

Sincerely,

John DiLoreto
Executive Director
Nanotechnology Coalition

John W. Hilbert III
Nanomanufacturing Association

Jay West
Senior Director, Chemical Products and Technology Division
Nanotechnology Panel of the American Chemistry Council

Vincent Caprio
Executive Director
NanoBusiness Commercialization Association

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Lawrence E. Culleen
Counsel to the Chemical Users Coalition

Timothy A. Brown, Esq.
Vice President, Regulatory Counsel & International Affairs
Consumer Specialty Products Association

Attachments
cc: The Honorable E. Scott Pruitt (w/attachments) (via e-mail)
Ms. Wendy Cleland-Hamnett (w/attachments) (via e-mail)
Nancy B. Beck, Ph.D. (w/attachments) (via e-mail)

**Nanotechnology Coalition**

Submitted electronically via regulations.gov

June 15, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment; EPA-HQ-OPPT-2010-0572

Dear Sir or Madam:

On behalf of the Nanotechnology Coalition, I thank you for the opportunity to submit comments to the U.S. Environmental Protection Agency (EPA) *Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment,* published in the Federal Register on May 16, 2017 (Docket EPA-HQ-OPPT-2010-0572).

We thank EPA for acknowledging the concerns of the companies that are most significantly impacted by the rule and for delaying its implementation until August while the Agency prepares to issue final reporting Guidance. While we appreciate the Guidance, as currently written it does little to clarify many of the definitions used by EPA that remain unclear, it provides confusing responses to questions submitted by stakeholders, and in some respects the Guidance raises additional areas of uncertainty regarding reporting requirements delineated in the rule. Our specific concerns with the final rule are noted in our comments submitted on May 15, 2017, appended and incorporated by reference here. For example, in the final rule EPA states "...**Because not all enhanced properties are unique or novel properties, EPA replaced the word enhanced with novel in section C.5. of the reporting form**....", yet in the Guidance document the Agency has resurrected this term in response to Q&A 3 in a way that causes confusion and is contrary to the principles of physics.

**Recommendation**

Although EPA has extended the implementation date from May 12, 2017 to August 14, 2017, the effective date of the rule should be extended further to address the many unresolved questions regarding the reporting requirement. EPA has delayed the effective date and/or compliance date of several significant rules in the recent past precisely to ensure the regulated community is equipped with the appropriate guidance to implement new regulatory requirements and/or to reduce

"compliance burdens" and to "help prevent disruptions to supply chains." *See* EPA Extends Compliance Date for Formaldehyde Emissions Standards, 82 Federal Register 23735 (May 24, 2017); EPA Delays Implementation of Agricultural Worker Protection Standard, May 11, 2017, letter from Acting Assistant Administrator Wendy Cleland-Hamnett to National Association of State Departments of Agriculture; and EPA delays Effective Date of Risk Management Program, 82 Federal Register 27133 (June 14, 2017).

We share EPA's desire for accurate information to inform EPA's judgment regarding the manufacture and process of nanoscale materials, but believe the final rule and draft reporting Guidance lack sufficient clarity to elicit accurate, quality information necessary to achieve this goal. We urge EPA to delay the effective date of the final reporting rule until EPA revises, re-proposes, and re-issues the final rule along the lines of many comments EPA received on May 15, 2017, and re-issues the reporting Guidance. Only these actions will enable EPA to obtain the information it needs to effectuate Congress' statutory goals underlying TSCA Section 8 in a way that does not impose unnecessary reporting burdens on regulated entities or disrupt supply chains.

Sincerely,

John DiLoreto
Executive Director
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johnd@nanoreg.net

## Nanotechnology Coalition

Submitted electronically via regulations.gov

May 15, 2017

Sarah Rees, Ph.D.
Director, Office of Regulatory Policy and Management
Office of Policy
1200 Pennsylvania Avenue NW
Mail Code 1803A
Washington, DC 20460

Re: Evaluation of Existing Regulations; EPA-HQ-OA-2017-0190

Dear Dr. Rees:

On behalf of the Nanotechnology Coalition, I thank you for the opportunity to submit comments to the Environmental Protection Agency (EPA) in response to Executive Order 13777, *Enforcing the Regulatory Reform Agenda*. These comments focus on EPA's final rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements,* published in the Federal Register on January 12, 2017 (Docket EPA-HQ-OPPT-2010-0572).

We thank EPA for hearing the concerns of the companies who need to comply with the rule and delaying its implementation until August while the Agency develops it guidance for reporting. The Nanotechnology Coalition is composed of nanomaterial producers, users and other stakeholders that focus on environmental, health, and safety issues to promote the safe development of nanomaterials, communicate industry positions to regulatory agencies, address standards and definitions in nanotechnology, and promote development of nanotechnology stewardship programs.

Nanotechnology, the science of understanding and harnessing the properties of materials that occurs at the nanoscale — about 100,000 times smaller than the width of a human hair — is leading to revolutionary new materials, devices, and structures that are improving human health, creating jobs, and strengthening our national defense. Companies of all sizes, including start-ups and small and mid-sized entrepreneurial companies, engaged in the manufacture, use, or sale of products enhanced by nanotechnology innovations have steadily moved nanoscale materials from the laboratory to the marketplace. Nanotechnology is now enabling

or enhancing products in a variety of sectors, including clothing, electronics, clean energy technologies, and automobiles.

With the continuation of scientific innovation through significant corporate and academic R&D investment, nanotechnology is poised to greatly improve how we diagnose and treat disease, enable comfortable garments that protect our troops from biological and chemical threats, improve existing consumer products in virtually every industrial sector, and provide innovative medicines and medical devices. Despite no evidence of specific hazards related to nanomaterials, the new regulation will necessitate unnecessary and costly reporting and recordkeeping requirements which will have the effect of discouraging new market entrants, and correspondingly reduce job creation and stifle technological innovation.

The referenced reporting tool is not required by the statute and the decision to develop the rule was wholly within EPA's discretion under TSCA §8. Below are several specific examples of regulatory overreach in the rule which will have a negative effect on the continued growth of the nanotechnology industry and particularly small businesses.

**Unnecessary and Unlawful Moratorium on Manufacturing/Processing of Existing Chemicals**

The final rule is unclear with regard to when manufacturing may commence for new nanoscale materials, due to the new requirement to submit reports at least 135 days prior to commencing manufacturing or processing an existing chemical. While the final rule helps clarify that TSCA requirements for a Premanufacture Notice at least 90 days prior to manufacturing will apply to new chemicals instead, this is only works to exempt the PMN submitter from this rule. All of the submitter's processor customers also will need to file duplicative reports under this rule. Many companies are confused as to when manufacturing may commence. Many manufacturers continue to believe that reporting on nanoscale materials must occur 135 days before initiation of manufacturing operations. The 135-day pre-manufacturing and pre-processing reporting requirement (§704.20(f)(2)) is contrary to TSCA for several reasons:

1. ***No Authority Under TSCA §8 to Prohibit Manufacturing or Processing.*** TSCA §8(a)(1) authorizes the Agency to require companies to keep records and submit reports, but it does not contemplate, or authorize EPA to impose, even a temporary moratorium on the manufacture or processing of existing chemicals. Despite comments from the EPA regarding when manufacturing may be initiated, the 135-day advance notice requirement still functions as a practical manufacturing bar if a company will face one-time or daily "late" reporting penalties if it begins to manufacture or process before the expiration of the 135-day period. In addition, the explanation EPA provided for why additional time is needed to implement a 135-day requirement has created additional uncertainty. EPA states that it will evaluate whether the activity requires regulation. Most companies will not want to go into production without a full and clear understanding of their regulatory requirements up front. Indeed, the explanation only confirms that the pre-manufacture or processing rule is

effectively a SNUR for nanoscale chemicals promulgated without meeting the TSCA Section 5(a) criteria for proposing a SNUR.

2. ***Duplicative Reporting.*** *Contrary to TSCA §8(a)(2)*, the rule makes no provision to avoid duplicative and unnecessary reporting that will arise from the 135-day notice requirement (e.g., from every new processor customer of a single manufacturer of a reportable substance and new manufacturers and processors of nanoscale materials that have been through the PMN risk review with a different submitter since 2005).

3. ***Reporting Period Contrary to TSCA §5(a)(1), (2).*** The TSCA §5 significant new use rule (SNUR) provisions specify the only circumstances (and procedures) for imposing temporary moratoria on the manufacture or processing of existing chemicals to allow for EPA risk review. EPA has no authority under TSCA § 8 either (i) to ignore the TSCA §5 significant new use notice selection criteria and procedures (§5(a)(2)) in choosing reportable substances subject to the moratorium, or (ii) to extend the statutory review period for existing chemicals subject to a properly promulgated SNUR from 90 to 135 days.

4. ***Arbitrary Class Selection.*** The rule lacks factual predicate or a rational basis to justify singling out and imposing the perpetual 135-day manufacturing/processing moratoria on an entire class of materials (i.e., nanoscale materials). The rule states that EPA has made no risk or exposure based finding with respect to nanomaterials as a class. Instead, the intent is to obtain reporting now and for all future users, for any material that presents even an innocuous size-related property unrelated to risk (e.g., change in color) on the unsupported theory that innocuous size-related properties "likely" are accompanied by changes in other properties that are relevant to risk. There is no legal basis upon which to regulate either the particular class of materials chosen for regulation, or for the particular regulation imposed (moratorium on manufacturing/processing) in this manner.

5. ***Arbitrary Applicability Determination Criteria.*** The rule provides no factual predicate or other rational basis to explain how and why EPA selected the particular applicability criteria it chose to propose to define a reportable chemical substance or distinguish among "discrete" physical forms. EPA does not explain how these criteria effectuate the agency's objectives for the data collection or why they are needed to understand the nature of the reportable substances. The rule's technical criteria also are arbitrary because some of them do not even apply for characterizing certain reportable substances, a fact that is not acknowledged by the proposal. The absence of designated test methods for particular technical applicability criteria will lead to inconsistent and arbitrary results. Although some recommendations were made in the final rule, these are voluntary and will not measurably improve the arbitrary nature of the data the agency may receive as a result.

6. ***Unfair Status for New Substances versus Existing Substances.*** The rule as proposed does not explicitly require testing for existing materials, while new substances must have a

minimum physical and chemical testing requirement. This creates an unfair preference for existing substances and inherently a potential under reporting for existing chemical substances.

**Costs that Exceed Benefits**

1. ***§8(a) Does Not Authorize Compelled Product Testing.*** EPA expects manufacturers to obtain and report all available information from customers in order to determine compliance with the rule. The public record on this rulemaking documents several valid reasons why not all of the physical-chemical data specified in the rule is routinely collected by companies. If manufacturers are unable to obtain the needed information, many companies may feel compelled to do costly new product testing to determine whether their respective materials triggered the rule's highly technical reporting applicability criteria (particularly for "discrete substances"); however, TSCA §8 does not authorize EPA to compel such product testing. Applicability determinations for the same material by different persons made with and without the indicated test data will be inconsistent with each other and lead to arbitrary reporting results (as will determinations for the same materials based on data from different test methods for the same endpoint).

2. **Cost Estimate of Reporting Grossly Understated.** EPA's assessment of the reporting burden estimates 140 hours for each nanoscale material to be reported, while providing no explanation for the cost estimate. However, the agency has provided no estimate of the cost of testing to determine if each nanoscale material meets the requirement for reporting. The testing costs alone can be in the tens of thousands of dollars for each material and given the confusing requirements for what constitutes a 'discrete form of a chemical substance' in the nanoscale, industry will spend far more than the EPA estimate. For example, nanoscale materials can easily be modified to meet a broad range of performance characteristics which will require testing on materials with each small variation in size. A company manufacturing a carbon nanotube 50 nanometers in length may make the same nanotube in lengths of 60, 70, 80, or 90 nanometers just to allow manufacturers to vary performance depending on the final product use. Under this rule the company will be required to determine if these changes resulted from a change in process and whether the change in the size of the particle is seven standard deviations in difference from the mean measured value or if any property has changed to a similar degree. The perceived need to make these determinations will cause companies to feel they must test or simply report on each and every size carbon nanotube it manufactures. The alternative is that EPA is placing these companies in the position of failing to provide requested information to a federal government agency -- a position no responsible company wants to be in. There is the further complication that all of these substances will be classified by CAS Number with nothing to allow the Agency to determine whether these present different hazards from each other or are they different from those reported by another manufacturer (importer). The consequence of this lack of

identifier is that users reviewing the reporting will not be able to verify that the substance they have used has been reported or not.

3. **Impact on U.S. Manufacturers.** If allowed to go into effect this regulation will have significant financial impacts on U.S. manufacturers and processors of nanoscale materials including:

   - The creation of unwarranted regulatory costs and commercial stigma;
   - Manufacturing of innovated materials and products will be hindered in terms of time and cost;
   - Unnecessary or duplicative reporting by a group of companies (processors) with little or no experience in filling out EPA's extensive premanufacture notification forms and who will not have all of the information EPA is seeking;
   - Creation of an unwarranted economic burden on impacted small businesses, the number of which is grossly underestimated in the rule; and
   - Provides significant economic burden on legacy industries such as inks, paints, coatings, pigments, plastics, and rubber.

**Summary**

***Arbitrary Rule/Regulation*** -- The finalized rule lacks factual predicate or a rational basis to justify singling out and imposing on an entire class of materials, without regard to risk, the perpetual 135-day manufacturing/processing reporting requirement. There is a commercial moratoria element to this requirement, whether or not the agency intended this to be the case. The rule is holding nanoscale materials to a higher standard of reporting than any other existing materials.

***135-day Reporting Requirement*** – Despite the current 90-day review requirement for Premanufacture Notice (PMN) new chemical submissions under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA has made a gross presumption that companies have the intent to manufacture or process at least 135 days before manufacturing or processing nanoscale materials and requires this intent to be reported. The reasoning behind this presumption is not factually supported. The agency acknowledged this when it added an abbreviated 30 day reporting period to the final rule. As a result, the rule establishes a "double standard" for reporting that penalizes more prepared companies who have to wait longer to commercialize a substance that is already in U.S. commerce and being sold by its competitors.

**Reportable Nanoscale Forms of Chemical Substances** – The rule is based upon ambiguous and/or subjective applicability criteria the regulation creates arbitrary results in who reports and what is reported.



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061_00042000-00011

**Cost** – Due to confusion about what reporting is required under the rule, manufacturers will be required to perform costly eligibility analyses that will likely involve testing nanoscale materials. Higher regulatory costs prior to initiating manufacturing operations contribute to higher product introduction costs which negatively impact the introduction of new products into the marketplace.

The Coalition agrees there is value in EPA seeking information on nanoscale materials. EPA must not stretch the boundaries of the statute and common sense in doing so. It would be useful for the Agency to more specifically explain how it would establish that the information it seeks can be correlated with the identification of a potential risk. Instead, EPA seeks information without regard to quality, value, or cost. The rule places an undue economic burden on U.S. companies at the forefront of innovation that already has broad-based consumer benefits across a wide range of industry sectors.

**Recommendation**

EPA has several options. Based on the foregoing, we are grateful that EPA has chosen to suspend the effective date of the rule, presumably until such time as the foregoing issues have been addressed and EPA issues suitable guidance and/or amendments or clarifications. Although the Agency has extended the implementation date from May 12, 2017 to August 14, 2017, the rule should be made effective no earlier than one year from the issuance of such final guidance and/or clarification. If EPA is unable or unwilling to pursue this option, EPA should withdraw the final rule. We appreciate EPA's need for information, but there is a better, more efficient way to obtain such information. Starting over is our preferred alternative if EPA is unwilling to address the issues described above.

Sincerely,

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June 15, 2017

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Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements

Dear Mr. Morris:

On behalf of our client, the Nanomanufacturing Association (NMA), the enclosed questions are provided for consideration by the Environmental Protection Agency (EPA) concerning the implementation of the final rule entitled Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.[1]

NMA appreciates the opportunity to provide EPA with questions regarding the final rule for which NMA hopes to gain additional clarity. NMA respectfully requests that EPA provide answers to these questions in a response to NMA, and consider the inclusion of these topics as part of the guidance document that is currently out for public comment.[2]

Respectfully Submitted,

Martha E. Marrapese

cc: Maria Doa, Ph.D., Director, Chemical Control Division (CCD), OPPT
Raymond J. Alwood, CCD, OPPT

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1 82 Fed. Reg. 3641 (January 12, 2017).
2 82 Fed. Reg. 22452 (May 16, 2017) (Docket No. EPA–HQ–OPPT–2010–0572).

14114695.1

**Nanomanufacturing Association**

**Questions for EPA Concerning Implementation of the Final Rule "Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements (40 C.F.R. § 704.20)**

1. Definition of Solid

a. In a suspension of a liquid in a liquid, particles in the 1 – 100 nm range are not solids for purposes of this rule provided they are 1) formed in suspension, 2) not separated, and 3) are droplets which are not stable in shape when suspended in the liquid matrix at 25°C at atmospheric pressure. Does EPA agree with this assessment?

b. Is a pigment purchased in the form of a paste a solid if the aggregate or agglomerate particle size of the pigment in the paste is less than 100 nm?

c. If a liquid mixture contains pliable solid particles that are < 100 nm and composed of a natural, oily or greasy heat-sensitive substance (i.e., a wax), consisting of hydrocarbons or esters of fatty acids that are insoluble in water but soluble in nonpolar organic solvents; are these particles considered a solid for purposes of this rule?

d. What if particles < 100 nm in the liquid matrix are liquid forms of paraffin, originating from petroleum and used in paper coating, as insulation, in crayons, and in medicinal preparations?

e. In a case in which the starting ingredients are liquids, a reaction takes place and polymer molecules are formed. Please address whether the solid definition is or can be met in the following cases:

i. The physical form of the polymers formed from these liquids is not clearly a solid.

ii. The physical form of the polymers formed are polymeric chains with no specific structure that are bound in a droplet.

iii. The polymers formed are heavier liquids in a suspension of a liquid.

f. Please address if the following examples meet the definition of a solid for this rule: a solid particle < 100 nm at 25 C with irregular shape such as carbon black or carbon nanotubes when added to a liquid mixture?

2. Unique and Novel Properties

a. How does one determine if the "nano" portion of the substance has unique properties compared to the "non-nano" portion, especially for products that have been made the same way for decades? What is the standard or baseline EPA recommends that companies use?

b. Can EPA confirm that if particles < 100 nm are present at < 1% by weight in a mixture the chemical substance is not reportable, even if it contributes a unique and novel property to the mixture?

c. Does the threshold (1%) apply to exempt incidentally produced particles that are < 100 nm in a pigment from having to report even if they provide an intentional and known unique and novel function?

d. Does the 1% threshold apply to both intentionally and unintentionally produced nanoscale particles?

e. If a polymeric coating contains particles of a chemical substance that are solid at 25° C and between 1 – 100 nm, and these particles only contribute to matrix compatibility and homogeneous distribution, which is the same function the chemical substance performs at larger particle sizes, is the coating reportable?

f. If a solid raw material has particles of the same substance which exist in a range of particle sizes, which may include some in the nanoscale, but which do not behave differently and cannot be separated from the other particles of larger size, is the material reportable?

g. If a solid raw material has a range of particle sizes (all the same substance) which includes > 1 % below 100 nm but which do not behave differently (do not exhibit a unique and novel property) is the material an RCS under this rule?

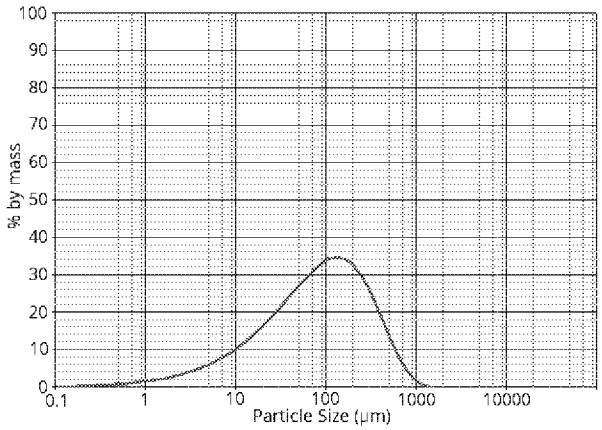
h. Carbon black may be produced at the nanoscale size, however the color is not unique or novel. If it can be purchased in different size ranges, should a downstream processor assume that there are different properties associated with each size which requires separate reports?

i. Does the fact that an RCS is encapsulated in a film during end use change the reporting obligation of processors and manufacturers upstream?

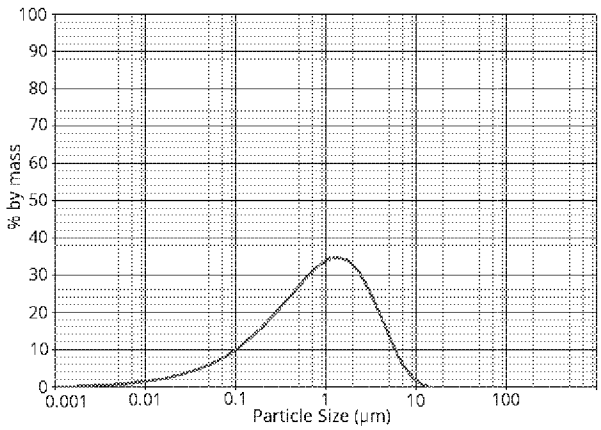
j. If a solid raw material has a range of particle sizes (all the same substance), which may include some in the nanoscale—but which do not behave differently (do not exhibit a unique and novel property) and cannot be separated from the other particles of non-nanoscale size—is the material a reportable chemical substance under this rule?

k. There are two particle size distributions, Distribution A and Distribution B, shown below. Distribution A has less than 1% by weight of solid particles < 100 nm (therefore not an RCS under the rule) and Distribution B has more than 1% by weight of solid particles < 100 nm. Both sets of particles are able to form a colloid (specifically a sol, which is solid particles in a liquid medium). Is a determination that both are able to form a colloid sufficient to conclude that Distribution B would not be a reportable chemical substance under the rule since its ability to form a colloid is not a unique and novel property?

Distribution A




Distribution B




l. If Distribution A was unable to form a colloid (sol) due to its larger particles and Distribution B could form a colloid (sol), then would Distribution B be an RCS?

m. If a pigment that is present as solid particles of < 100 nm in a paste causes the paste to blend more homogenously does it need to be reported? What if the pigment in this size range contributes to a more vibrant shade of the same color? What if the pigment in this size range causes the paste to become transparent? What performance properties are not unique and novel for a pigment in this size range to exhibit? Does the intensity of the color imparted by the pigment have to exactly match the shade imparted at larger particle sizes or is it sufficient to disqualify a pigment if they all impart red?

3. <u>Discrete Forms</u>

a. The rule says a discrete form is "A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture." If an additive is used in paint or coatings, is that a "different coating" and a discrete form? How does this language about coated particles apply to importers?

b. EPA's draft guidance includes references to surface treatments although the final rule only refers to coatings. Please address the following scenarios:

i. Silane is deposited on the surface of a silica particle that is < 100 nm. The silane is present as regions over a majority of the particle but it is not uniformly distributed over the entire surface of the particle. The silane chemistry is later modified but the manner in which it is deposited is the same.

ii. A covalently bound surface coating on a solid particle of < 100 nm is modified.

iii. EPA guidance indicates the adsorption to a particle is considered a mixture (not a reaction required to be notified as a new chemical under Section 5). A liquid mixture of nanoparticles contains a dispersing agent to prevent agglomeration. The dispersant is a polymer that is adsorbed onto the nanoparticle surface without forming covalent bonds. The polymer allows the nanoparticles to be compatible in the coating matrix and to ensure homogeneous distribution.

iv. If the coating on the surface is held by van de Wall forces, is this simply a mixture or does a change in the coating require a new report?

v. Does a change in a coating that forms a shell around a particle which is not covalently bound to the particle core require reporting?

c. If the rule does not require testing, and data are not available on the properties specified in the rule to distinguish discrete forms, should companies report all dispersions with coated nanoparticles?

d. Would EPA confirm that simply placing an RCS in a different suspension would not constitute a new "coating" for the nanomaterial if there were no strong bonds that made the (solid) coating a stable component of the nanomaterial?

e. Would EPA confirm that what is targeted by the shape criterion for reporting is whether or not changes in shape that are stable are altered? We understand the rule to mean that stable variations in shape may need to be separately reported as discrete forms of a RCS.

f. When determining whether the seven standard deviation degree of change is met, what is the standard material that companies should use as the starting point from which to gauge the degree of change? If a chemical substance identified by the same CASRN has at least 30 different ratios to vary performance, which one should be used to make this comparison?

4. Filing mechanics

a. Since both manufactures and processors are required to report under this rule, are manufacturers and importers allowed to support the processor notifications by their customers? Can a reference number be assigned to each report to allow the manufacture to submit information on behalf of their customers and for customers to reference in their submissions?

b. Company X is the manufacturer of Chemical Substance Y, a reportable chemical substance (RCS). Chemical Substance Y is not listed on the TSCA Inventory and no exemption from premanufacture notification (PMN) applies (i.e., it is a new chemical substance). Is Company X only required to file a PMN? Does Company X need to file a section 8(a) report? Assuming the PMN clears EPA review and a notice of commencement (NOC) is filed, what are the section 8(a) reporting obligations of the manufacturer's downstream customers who process the chemical? Does the answer change if they use the chemical for a use that is the same as the non-nanomaterial form of the chemical?

c. Company X forms the intent 6 months in advance to replace the resin in the coating. What does Company X have to report? What if Company X replaces the biocide or stabilizer in the coating less than 135 days before commercialization?

d. Due to continued confusion over the definition of "reasonably ascertainable," can EPA add the Chemical Data Reporting (CDR) guidance on "reasonably ascertainable" as an addendum to EPA's recently issued guidance on the nanomaterial reporting rule?

5. Testing Protocols

a. If analytical techniques are not being recommended by EPA, how will EPA be able to compare data derived from the use of different analytical methods for example with respect to particle size?

b. We are not required to measure substances in order to determine reportability. If analytical techniques for a particular chemical substance do not exist for the properties identified in the rule, can we conclude on this basis that a reportable substance determination cannot made and we do not need to report?

c. How can a person determine particle morphology for substances where the particles are not separated from a mixture such as when they are part of a liquid?

American Chemistry Council | Nanotechnology Panel

June 15, 2017

**Submitted via regulations.gov and email (Alwood.Jim@epa.gov)**

Mr. Jim Alwood
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

**Re: Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment (Docket EPA-HQ-OOPT-2010-0572)**

Dear Mr. Alwood:

The Nanotechnology Panel of the American Chemistry Council (the Panel)[1] is pleased to provide the attached comments on the U.S. Environmental Protection Agency's (EPA) "Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce" (Draft Guidance).[2] The Panel trusts that EPA will find our comments to be helpful in further developing the Draft Guidance to better clarify EPA's expectations for manufacturers and processors of nanoscale materials who may have reporting obligations under EPA's reporting and recordkeeping rule for nanoscale materials.[3]

The Panel's main objective is to promote the safe and responsible development of nanotechnology, and we recognize EPA's role in ensuring the appropriate oversight of nanomaterials. To clarify reporting requirements, the Panel submitted a set of questions to EPA that we hoped EPA would address when preparing the Draft Guidance. However, after reviewing the Draft Guidance, the Panel continues to seek further clarity on the original request in addition to new questions emerging from review of the Draft Guidance. Our comments are attached.

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[1] Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Cabot Corporation, Chemours, DuPont, Evonik Corporation, and Procter & Gamble.
[2] U.S. EPA. *Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce.* May 2017. Available at https://www.epa.gov/sites/production/files/2017-05/documents/draft_nano_section_8a_guidance_5_15_17_for_docket_clean_002.pdf.
[3] 40 C.F.R. § 704.20.

*The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $801 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*

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The Panel believes that EPA must further elaborate and clarify its expectations for reporting so the regulated community can understand its obligation clearly. Without significant additional clarifications and refinements of the scope and key concepts such as "unique and novel properties," "processing," "soluble substances," and "detailed information," the Panel is concerned that the reporting and recordkeeping rule will be perceived as confusing, subjective, and arbitrary.

The Panel recognizes the challenge that the EPA is facing and appreciates the opportunity to comment. We would welcome further dialogue with EPA on this matter. Please do not hesitate to contact me if you have any questions (Jay_West@americanchemistry.com; 202-249-6407).

Sincerely,

Jay West

Senior Director, Chemical Products and Technology Division
ACC Nanotechnology Panel

**ATTACHMENT. Comments on the "Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce" (Draft Guidance).**

Questions previously submitted by the Panel to EPA after the finalization of the rule are presented below in *italics*. The Panel's comments on the Draft Guidance are not italicized.

1. *EPA has not clearly addressed how surface-treated substances should be reported.*
   a. *There is disagreement within industry as to the meaning of "coatings". Please clarify: Some interpret "coatings" as full encapsulation of a particle (e.g., a core particle with a complete shell around it). Others interpret "coating" as a discontinuous/random surface treatment of a particle.*

      Panel Comment: EPA partially clarifies this question in the Draft Guidance when it says, "The term coating in the rule describes surface treating or coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all the other intrinsic characteristics of the reportable chemical substance remain the same."[4] This answer implies that the term "coating" refers generally to manipulations via surface chemistry. This terminology needs to be clarified, as it is our understanding that the scientific community generally refers to coatings as continuous films on a surface (i.e., encapsulation), whereas surface treatments are more patchy.

      Due to the breadth of the inferred response, the Panel requests further clarity from EPA on whether the coating terminology refers to both chemically attached and physically attached coatings.

   b. *EPA has not clarified how surface-treated particles that are regarded as statutory mixtures under EPA's guidance should be reported. Based on EPA's response to comments, we understand that the "change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all of the other intrinsic characteristics of the reportable chemical substance remain the same."[5] The substrate particle is the reportable substance, correct? Where would information about the surface treatment be reported, if at all? If the substrate particle is the reportable substance, the final coated/ surface treated particle is not considered a reportable chemical, correct?*

      Panel Comment: The Panel does not feel that this question is addressed adequately in the Draft Guidance. At question 9 EPA says, "Mixtures are not reportable under this rule, however the components of any mixture that contains reportable chemical substances subject to the rule would be reported."[6] One possible interpretation of this statement is

[4] U.S. EPA, *supra* note 2, at 3.
[5] U.S. EPA. *Response to Comments to the Proposed Rule, Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.* December 27, 2016. Docket # EPA-HQ-OPPT-2010-0572. Page 48.
[6] U.S. EPA, *supra* note 2, at 3.

that for a nanomaterial that is a statutory mixture, the substrate particle should be reported, and the surface treatment is not reportable unless it is independently reportable.

EPA should address this question directly. Surface-treated particles that are regarded as mixtures are not uncommon. The Panel suggests that a reasonable approach would be to report only the substrate particle for surface-treated nanomaterials considered to be statutory mixtures under TSCA. For surface-treated nanomaterials that are not considered to be statutory mixtures under TSCA, each surface-treated nanomaterial would be reported according to the clarifications EPA provides to the Panel's question 1 above.

c. *There are questions regarding whether surface-treated particles should be regarded as having "unique and novel" properties due to size. The behavior of the particle is determined by the chemistry of the surface treatment, which is predictable. Furthermore, the surface treatments would behave the same way regardless of the size of the substrate particle.*

   Panel Comment: The Draft Guidance does not address this question directly. EPA states, "The rule does not require that every chemical substance coated or surface treated with another chemical substance be reported. However, any type of engineering including surface treatment of a chemical substance that results in a reportable chemical substance triggers a reporting requirement."[7] One could infer from those sentences that the reporting status of surface-treated particles depends on the fulfillment of the "unique and novel property" criterion and the chemically-bound criterion. However, the Panel remains concerned that what constitutes a "unique and novel property" is still vague and requires further clarification from EPA. Further concerns about the "unique and novel property" interpretation are articulated in many of our comments below.

d. *If a reportable substance is surface treated, is it automatically reportable as a new "discrete form"? How should the seven standards of deviation test apply?*

   Panel Comment: EPA has not answered this question. Since mixtures are excluded, it is assumed that only chemically bound surface treatments would result in a reportable discrete form. However, how different do these surface treatments need to be? When is a surface treatment sufficiently similar to another that it does not require additional reporting? If the distribution of a surface treatment on a surface changes, but the percent composition remains constant, is that considered equivalent? Does the seven standards of deviation test apply? With respect to which measurand (e.g., mass, coverage, thickness, speciation) should the seven standards of deviation test apply, if any?

2. *EPA's definition of "unique and novel" does not resolve questions regarding properties, such as surface area or thermal conductivity, that vary predictably and continuously with size.*

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[7] *Id.*

a. *Does EPA consider these continuously scaling properties to be "unique and novel"? What about size itself?*

Panel Comment: EPA does not address this question directly. One possible interpretation from the Draft Guidance is that continuously scaling properties can be "unique and novel" simply because they are "different from properties at sizes greater than 100 nanometers and those properties are the reason why the chemical substance is manufactured in that form or size."[8] However, the Draft Guidance also says that "[n]ot all enhanced properties are unique or novel."[9] The Panel agrees that enhanced properties are not necessarily unique and novel, and EPA should make this distinction clearer.

The Panel recommends that the EPA apply terminology agreed upon in standards communities as much as possible to clarify their intentions. For example, the International Organization for Standardization (ISO) Technical Committee on Nanotechnologies (TC 229) uses two different terms to describe changes in properties facilitated by nanoscale size: "Nano-enhanced" (ISO/TS 8004-1:2015(en), 2.16) and "Nano-enabled" (ISO/TS 8004-1:2015(en), 2.15). Definitions of those terms are publicly available through ISO's online browsing platform (http://www.iso.org/obp) and are as follows:

> **2.15. nano-enabled:** exhibiting function or performance only possible with nanotechnology (2.3)
>
> **2.16. nano-enhanced:** exhibiting function or performance intensified or improved by nanotechnology (2.3)
>
> **2.3. Nanotechnology:** application of scientific knowledge to manipulate and control matter predominantly in the nanoscale (2.1) to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules, or extrapolation from larger sizes of the same material.
> Note 1 to entry: Manipulation and control includes material synthesis.

Do "unique and novel properties" pertain to "nano-enabled" properties? The Panel requests that EPA clarify the degree to which its thinking regarding the difference between "unique and novel properties" and "enhanced properties" aligns with existing definitions established by ISO.

The Panel notes that EPA has not answered definitively the question about whether size itself is a "unique and novel property." The Panel does not consider size itself a "unique and novel property." For example, if particle size is changed to the nanoscale to make dispensing easier or to facilitate the removal of larger contaminants, is that considered "unique and novel" for the purposes of establishing a reporting requirement? The Panel

[8] *Id.* at 1.
[9] *Id.* at 2.

does not believe these examples (and there could be more) illustrate "unique and novel properties."

b. *If the desirable property is particles that are small enough such that they do not interfere with visual clarity of materials, would this be considered "unique and novel" under the rule?*

Panel Comment: EPA has not addressed this question directly in the Draft Guidance. The Panel notes that EPA's definition of "unique and novel properties" indicates that the properties "vary from those associated with other forms or sizes of the same chemical substance," which the Panel interprets to mean that if the same chemical substance of a larger particle size distribution exhibits the same property, then the nanoscale material is not a reportable substance.

Following this logic, the Panel notes that many materials are transparent when formed into macroscopic bodies like glass panes or macroscopic films. Yet the common form of the material may have a particle size half the wavelength of light (i.e., >100 nm), such that it is no longer transparent due to light scattering from the particle surface. When the same material is taken to the nanoscale, it becomes transparent again. Thus, transparency should not be considered a "unique and novel property."

c. *What about color? Some substances like carbon black (and some pigments) are always produced at the nanoscale, yet do not have "unique and novel" properties due to size. Many processors use carbon black as a colorant, and the color of carbon black is not due to its size; it is an intrinsic property. Can it therefore be excluded from reporting?*

Panel Comment: EPA has not addressed this question clearly. At question 3, EPA says, "engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties." However, at question 11, EPA says, "organic and inorganic pigments…are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique and novel properties that are not exhibited by other forms or sizes of the same chemical substance." In our reading, these two statements concerning pigments do not align, and the Panel requests further clarity.

3. *Industry needs EPA to provide more clarity on the reporting expectation for "detailed information on methods of manufacturing or processing."[10] For discrete form(s), what "detailed information"? Does a standard/precedent exist under TSCA?*

Panel Comment: This question is not addressed in the Draft Guidance, and the Panel requests clarification.

[10] 40 CFR § 704.20(d)(7).

4. *EPA says that chemical substances that are manufactured or processed in a nanoscale form for the purposes of being sold to others for use as a component of a mixture, encapsulated material, or composite are subject to reporting. EPA further states that those substances do not require separate reporting for their incorporation.*
   a. *Doesn't the "unique and novel" properties criterion and the tests for determining a discrete form also apply in terms of determining whether either material is reportable? Shouldn't the sentence above say "discrete forms of a reportable substance"?*

      Panel Comment: The Draft Guidance sufficiently clarifies that the "unique and novel" property criterion always applies. However, the Draft Guidance does not address the second part of our question regarding the other tests for identifying a reportable discrete form.

   b. *Is the entity doing the incorporation required to report if that entity does not manufacture the substance and information is neither available nor reasonably ascertainable?*

      Panel Comment: EPA indicates in question 6 that each processor needs to report its activities under the rule.[11] In question 14, EPA also seems to indicate if the supplier does not have or supply information indicating the substance is reportable, then the processor is not required to report.[12] However, it remains unclear when the act of incorporation is considered "processing" under the rule. Some intended uses of nanomaterials are simply for incorporation into another mixture or chemical substance. In question 14 EPA states, "Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule."[13] What is considered a "formulation"?

5. *Some companies may manufacture/import substances with differing surface areas. The aggregate sizes of some grades may be larger than 100 nanometers, and others may have an aggregate size between 1-100 nm. Differing surface area is a reason that these grades are manufactured/imported. In this circumstance, does surface area meet the definition of a "unique and novel property" such that grades having aggregate sizes of 1-100 nm may be reportable under the final rule?*

   Panel Comment: EPA has not addressed this question directly. The Panel notes that materials with aggregate sizes above 100 nm may have identical surface areas to materials less than 100 nm. Does that indicate that surface area does not meet the definition of "unique and novel property"? The Panel requests further clarity.

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[11] U.S. EPA, *supra* note 2, at 3.
[12] *Id.* at 5.
[13] *Id.* at 6.

6. *EPA should clarify its definition of "processing" for the purpose of this rule. There is considerable confusion regarding which activities would require reporting under the rule, based on EPA's responses to comments. The ACC Nanotechnology Panel recommends that the scope of the term "processing" in this rule should be consistent with EPA's use of this term in other areas of TSCA, such as SNURs and CDR. For example, formulation, repackaging, and processing substances into articles would all be considered processing activities subject to reporting. However, some are reading the following EPA responses to comments as establishing a narrower definition that would exclude activities such as blending a raw material into a formulation without "changing" it.*
    a. *Comment 22: "Most of the activities described by commenters for exemption would only require reporting for a reportable chemical substance before it is incorporated into a formulated product or polymer matrix. Reporting would not be required by persons who use the formulated product or polymer matrix."*[14]
    b. *Comment 32: "Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report."*[15]

    Panel Comment: The Draft Guidance does not answer this question. The Panel requests further clarity on the definition of the terms "processing" and "formulation," including clarification of any changes to existing TSCA policy and TSCA guidance that EPA intends to apply to the nanoscale material reporting rule.

7. *Regarding the "reasonably ascertainable" standard, in the final CDR rule, EPA states clearly:*

    *"[S]ubmitters are not required to conduct a new or additional customer survey (i.e., to pose a comprehensive set of identical questions to multiple customers) under this standard. If particular information cannot be derived or reasonably estimated from the information available to the company without conducting further customer surveys, it is not 'known to or reasonably ascertainable' to the submitter for purposes of the CDR."*[16]

    *However, in comment 3 of the nanomaterial rule Federal Register notice,*[17] *EPA seems to expect processors to conduct supplier surveys as part of meeting the "reasonably ascertainable" standard. This expectation seems inconsistent with the standard established for the CDR. EPA should reconcile what appears to be a contradiction in forthcoming guidance.*

    Panel Comment: The Panel appreciates the clear reference to existing definitions of "known or reasonably ascertainable" in question 21 and the clear expectation in question 14 that processors should contact their suppliers to request information to understand and fulfill potential reporting obligations.

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[14] U.S. EPA, *supra* note 5, at 17.
[15] *Id.* at 25.
[16] 76 Fed. Reg. 50829 (August 16, 2011).
[17] 82 Fed. Reg. 3646 (January 12, 2017).

The Panel notes that question 21 repeats the CDR standard that "reasonably ascertainable" does not require customer surveys. The Panel's interpretation is that the same standard applies to processors with regard to supplier surveys. In that regard, if a supplier fails to provide a response, has the processor met its obligation? Does EPA also expect that processors conduct and document in-depth literature searches if the material supplier fails to provide information?

8. *Some companies may manufacture and sell products in aqueous dispersion. The particle size in solution would be within the range (including any agglomerates) specified in the rule, but the commercial product itself is never sold or used as a solid (i.e., evaporated or otherwise dried). In this circumstance, does the manufacturer have to report under the rule?*

   Panel Comment: This question is not addressed directly in the Draft Guidance. Are particles in suspension that are never handled in solid form reportable? The Panel would appreciate EPA's clarification.

9. *When is the electronic reporting tool going to be available? Will EPA develop user guidance for the new CDR reporting module?*

   Panel Comment: This question is not addressed in the Draft Guidance, and the Panel requests further information.

In addition, the Panel requests clarification on the following questions and issues that emerged during review the Draft Guidance.

1. Aggregates and Agglomerates. Although EPA indicates that aggregates and agglomerates larger than 100 nm are not reportable, further clarity on whether the terms "aggregates" "agglomerates" includes heterostructures (heteroagglomerates and heteroaggregates) would be useful. Are the terms "aggregates" and "agglomerates" specific to the chemical substance in question, or do the terms more broadly apply to mixtures of particles of different chemical substances that come together to form larger structures?

2. Data Utility and Transparency. EPA has been clear that the rules promulgated under TSCA Section 8(a) do not require the generation of new information (i.e., testing). EPA has also acknowledged that information received will not be standardized across reporting entities. It is assumed that this information will be applied, in part, for decision-making purposes. EPA also notes that non-confidential information under the rule will be made available in ChemView. Given that many of the parameters provided represent extrinsic properties (i.e. zeta potential), the Panel continues to have significant concerns about the utility of the data EPA will receive. Will EPA provide further guidance on how the data will be used and on its preferred fit-for-purpose methods? Will ChemView contain disclaimer language to note that the data were not necessarily produced in accordance with a globally recognized standard or test method? The Panel strongly recommends such disclaimer language to dissuade misrepresentation and, in the worst case, misuse of the data. Other federal agencies, states,

and foreign governments rely on information and data from EPA to inform their own chemical regulatory processes, and we therefore believe accuracy and context are essential.

3. Seven Standard Deviations. With regard to changes in particle size that may trigger a new reportable substance, one consideration (among others) is "a size variation in the man particle size that is greater than 7 times the standard deviation of the mean particle size."[18] For the properties to which changes are to be considered, the final language is not clear on the measure of central tendency.[19] The Panel assumes the measure of central tendency is also the man. However, the Panel does seek clarification on whether the standard deviations are around the sample mean or the population mean.

4. "And" or "Or." In the *Federal Register* notice for the final rule,[20] the accompanying question and answer document,[21] and the Draft Guidance, the phrases "unique **and** novel" and "unique **or** novel" (emphases added) are used to describe "properties." The Panel would like clarification as to which of the phrases is the correct, consistent, and intended language from EPA. The use of "and" versus "or" could potentially be a deciding factor in determining whether a nanoscale material is a reportable substance.

[18] 40 C.F.R. § 704.20(a), part (i)(B) of the definition of "Discrete form of a reportable chemical substance."
[19] *Id.*, part (i)(C).
[20] 82 Fed. Reg. 3641 (January 12, 2017).
[21] U.S. EPA, *supra* note 5.

May 12, 2017

Via Electronic Submission

Sarah Rees, Ph.D.
Director, Office of Regulatory Policy and Management
Office of Policy
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1803A
Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-OA-2017-0190

Dear Dr. Rees:

We are writing on behalf of the NanoBusiness Commercialization Association (NanoBCA) in response to the U.S. Environmental Protection Agency's (EPA) request for input on regulations that may be appropriate for repeal, replacement, or modification. 82 Fed. Reg. 17793 (Apr. 13, 2017). EPA's request for comment is derivative of Executive Order 13777, *Enforcing the Regulatory Reform Agenda,* which seeks to establish a "federal policy to 'alleviate unnecessary regulatory burdens' on the American people." We are pleased to provide this information.

NanoBCA is the world's first nonprofit association focused on the commercialization of nanotechnologies. NanoBCA is dedicated to creating an informed and responsible commercial environment that nurtures research and innovation in nanotechnology, promotes the tech-transfer of nanotechnologies from academia to industry, encourages private capital investments in nanotechnology companies, and helps its member companies bring innovative nanotechnology products to the market.

We write to express our concerns with EPA's January 12, 2017, final rule, *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements.* 82 Fed. Reg. 3641. As noted in our extensive comments on the proposed reporting rule, NanoBCA believes that the adoption of uniform recordkeeping and reporting requirements for nanoscale chemical substances could create a more level playing field, assuring that no individual company or group of companies is burdened with the responsibility to submit information on nanoscale chemical substances on behalf of an entire segment of the nanotechnology sector, and providing EPA with meaningful information to assist it in discharging its Toxic Substances Control Act (TSCA) responsibilities. In addition, if EPA had more useful, comprehensive, and accurate information concerning the nature and properties of nanoscale chemical substances, this could favorably and efficiently address unwarranted



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concerns that have been raised concerning the health and environmental effects of the products of nanotechnology, and promote more balanced and scientifically informed risk assessment and risk mitigation decisions.

Unfortunately, the final reporting rule includes many of the same legal deficiencies noted in our comments. This includes the inherent structural problem that EPA has no authority under TSCA Section 8(a) to require manufacturers or processors to make the measurements needed to implement any definition of a reportable chemical substance based on data on the size of particles, aggregates, or agglomerates. The definition of a chemical substance under TSCA is based on molecular identity, not size. The definition of a reportable chemical substance in the final rule is inherently subjective and, thus, confusing and unenforceable. Further, whether a chemical substance is deemed reportable under the final rule depends in large part on the technical method used to characterize particle size. This means that the measured results can be expected to vary widely depending upon the technical method used, calling into question the utility, reliability, and regulatory value of these results.

We also expressed concern with the requirement to report information on nanoscale chemical substances 135 days before commencing manufacture or processing, and note that this requirement has no legitimate legal basis. Notwithstanding our objection, and over the objections of many other commenters, this requirement has been retained, albeit modestly amended in the final rule.

Finally, NanoBCA remains concerned with the excessive reporting burden the rule imposes on regulated entities, particularly smaller businesses which reflect a substantial portion of NanoBCA's membership. Given the vagaries in the final rule, and the lack of clarity as to what must be reported and by when, the actual reporting burden on the regulated community will be significantly higher than EPA estimated.

For all the reasons noted above, in our comments, and consistent with the comments submitted by many others, NanoBCA urges EPA to suspend the effectiveness of the rule beyond the August 14, 2017, date, suspend the reporting deadline of May 12, 2018, address and resolve the many problems with the final rule as outlined briefly above, issue the guidance on the revised final rule that EPA committed to issue, and require reporting no earlier than one year from the date EPA actually issues guidance on the revised final rule. If EPA is unable or unwilling to agree to these measures, EPA should withdraw the final rule and essentially start over. We appreciate EPA's need for information, but there is a better, more efficient way to obtain such information, and starting over is the preferred alternative if EPA is unwilling to address the many issues industry has carefully identified with the final rule.

Thank you for providing an opportunity to bring this important matter to EPA's attention.

Sincerely,

Lynn L. Bergeson

ARNOLD & PORTER KAYE SCHOLER

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June 15, 2017

Mr. Jim Alwood
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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
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Re: Comments of the Chemical Users' Coalition on the Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce; Notice of Availability and Request for Comment; EPA–HQ–OPPT–2010–0572; 82 Fed. Reg. 22452 (May 16, 2017)

Dear ~~Mr. Alwood~~ Jim:

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide the following comments on the Agency's draft guidance[1] on the final TSCA Section 8(a) rule establishing reporting and recordkeeping requirements for certain chemical substances manufactured or processed at the nanoscale.[2]

The CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[3] The CUC appreciates the need to protect human health and the environment while fostering the pursuit of technological innovation, two goals that can and must be made compatible if our society is to achieve sustainable economic development. Aligning these goals is particularly important in the area of chemical management policy, since chemistry underlies all aspects of manufacturing, and all products are made from chemicals. Our comments are offered with a view toward reducing the reporting burden on chemical manufacturers and processors without undercutting EPA's ability to collect the information it needs to identify nanomaterials in commerce and to gather existing information and data that might enhance the Agency's ability to characterize risks.

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[1] *Draft Guidance for Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials; Notice of Availability and Request for Comment*, EPA–HQ–OPPT–2010–0572; 82 Fed. Reg. 22452 (May 16, 2017).
[2] Final Rule: *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*, 82 Fed. Reg. 3641 (Jan. 12, 2017).
[3] The members of CUC are Intel Corporation, Procter & Gamble Company, American Honda Motor Corporation, Lockheed Martin Corporation, HP Incorporated, IBM Company, The Boeing Company, General Electric Company, and Airbus S.A.S.



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061_00042000-00032

Below, we offer comments concerning EPA's answers to specific questions in the draft guidance. We also are providing the attached redlined version of the draft guidance that reflects certain suggested changes that are self-explanatory.

**Question 1**

The answer to this question states that if, upon manufacture, a primary particle "almost immediately" forms aggregates and agglomerates that are larger than 100 nanometers (nm), that particle would not constitute a reportable chemical substance "unless the manufacturer was making a form of carbon black consisting solely of those primary particles that exhibit size-dependent properties." It is not clear why the Agency's draft answer addresses carbon black, since the question posed does not refer to carbon black. The reference to carbon black implies the substance is an example of a substance or a primary particle that does NOT aggregate or agglomerate "almost immediately" upon manufacture, and therefore would be a reportable chemical substance. We recommend EPA clarify the answer or delete the reference to carbon black entirely to avoid confusion, as indicated in the attached mark-up. Otherwise, then the Agency should explain why carbon black should be treated differently from other nanomaterials for purposes of this question and answer and the example provided.

**Question 3**

The first three sentences of the Agency's draft answer appear to indicate that an "enhanced property" is one which is only improved or strengthened when a substance is manufactured in a size range of 1-100 nm in at least one dimension, whereas a "unique and novel" property is a property that is exhibited only when a substance is manufactured in that size range. That makes sense. The last two sentences, however, create confusion as they imply that whether a property is "enhanced" or "unique and novel" depends upon the proportion of particles that are within the size range of 1-100 nm in at least one dimension. That does not make sense in light of the rest of EPA's draft reply. We recommend that EPA further edit the draft response and include an example along the following lines:

> If, for example, a pigment exhibits a specific property (e.g., adding blue tones to a resin) in all size ranges, but the blue tones are more apparent when the pigment particles are in the size range of 1-100 nm in at least one dimension, that would be an "enhanced" property. If the blue tones are apparent only when the pigment particles are in the size range of 1-100 nm in at least one dimension, that would be a "unique and novel" property.

**Question 5**

We agree with the Agency's reply that the final Section 8(a) rule does not require reporting on the basis of whether a use of a previously reported substance is new. Reporting for the 8(a) rule is determined by whether the substance in question represents a discrete form of a substance that also meets the criteria of being a reportable substance. The Agency's draft answer therefore is correct in saying that the Section 8 rule imposes no obligation to report a new use of a chemical substance that has been reported as a new chemical or reported previously under the Section 8(a) rule. On the attached mark-up, we are suggesting some changes to this answer to clarify that new uses of a chemical substance do not determine whether the chemical substance must be reported pursuant to this rule.

**Question 6**

The answer to this question states: "If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor also is required to report." As the CUC explained in CUC's August 5, 2015 comments on the proposed rule, requiring processors to report will result in duplicative reporting that is unlikely to provide significant new information to EPA. At minimum, processors should not be required to provide information that already has been provided by a manufacturer. Instead, processors should be expected to report only information that is unique to their operations and uses of the chemical substance (e.g., exposure and release information), and only to the extent the information is known or reasonably ascertainable by the processors. That would be consistent with Section 8(e) of TSCA, which does not require manufacturers/processors to report "substantial risk" information if the company has knowledge that the Agency already has been "adequately informed" of the information. CUC encourages EPA to consider amending the regulation to provide a mechanism whereby processors can confer with their suppliers and determine whether the supplier intends to submit information pursuant to the rule which would make a report from the processor duplicative.

**Question 7**

EPA should provide guidance on the method(s) and criteria that should be used to determine whether a chemical substance will disassociate completely in water to form ions smaller than 1 nm. That is necessary because dissolution is a dynamic process that is not only dependent upon a particle's chemical and surface properties, as well as size, but is also impacted by the surrounding media. Therefore, different approaches have the potential to produce very different results.

**Question 8**

The Agency's draft answer is not responsive to the question being asked. The question asks how a person is expected to determine whether a particle is, for example, a rod, wire, or needle. The answer provided in EPA's draft guidance addresses the question of when a change in shape results in a new reportable chemical substance. To answer the question asked, EPA should adopt and provide reference to the relevant definitions promulgated by the International Organization on Standardization, such as ISO/TS 80004-2:2015 (Nanotechnologies -- Vocabulary -- Part 2: Nano-objects), which defines terms such as nanofiber and nanorod.

**Question 9**

On the attached mark-up, we suggest changes to clarify that only those components of a mixture that meet the criteria for a "reportable chemical substance" need to be reported pursuant to the final Section 8(a) rule.

**Question 10**

Question 10 attempts to highlight the challenges in identifying forms of reportable chemical substance that might be "discrete" due to a coating. The answer is not responsive to the question, and is confusing in a number of respects.

First, the question asks why coated nanomaterials are treated differently than mixtures, but the answer does not say anything about mixtures.

Second, the preamble to the final rule describes three circumstances that can give rise to a "discrete form" of a reportable chemical substance. The third circumstance is expressed as: "forms of a reportable chemical substance that are coated with different chemical substances would be considered discrete forms for each chemical coating." 82 Fed. Reg. at 3644. That makes sense. The final rule, however, uses different language. The rule says that a "discrete" form occurs when "(iii) A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture." That description makes no sense, and could be read to mean that a reportable chemical substance must be coated with two different substances in order to be a "discrete" form. We do not believe that is what EPA intends.

Third, the answer says that a "change in coating makes . . . a discrete form . . . even if all of the other intrinsic characteristics of the reportable chemical substance remain the same." The next sentence then states that "[c]oating or surface treating a nanoscale material results in a

nanoscale material with different properties." That implies that coating or surface treating a nanoscale material always changes the intrinsic properties of the nanoscale material." Those two sentences are inconsistent.

Finally, the final rule and the answer fail to recognize that "coating" is not necessarily the same as "surface treating." EPA should re-examine this question and answer, and revise the answer to respond to the question.

**Question 11**

The answer states that "[i]n order to be a reportable chemical substance, the chemical must . . . be a *particle* in the size range of 1-100 nm." [Emphasis added.] The answer also implicitly acknowledges that monomers, polymers, colloids, pigments and dyes generally will not be reportable chemical substances. That is because polymers, pigments and dyes generally are not "particles" within the meaning of the rule, as they are not "minute piece[s] of matter with defined physical boundaries." EPA should clarify that monomers, polymers, colloids, pigments and dyes will be reportable chemical substances only if they are manufactured in a form with at least one dimension in the size range of 1-100 nm and exhibit a unique and novel property, and such property is a reason that the chemical substance is manufactured or processed in that form.

The last sentence of the Agency's draft answer is internally inconsistent and confusing. It says that "[l]arge molecules and ligands . . . that *do not meet* the definition do not need to be reported . . . unless they *meet* the definition." [Emphasis added.] EPA should either delete this sentence or revise it as we have recommended in the attached mark-up of the draft Guidance.

**Question 13**

EPA should reverse the order of the information provided in this draft answer. Because EPA states in the last paragraph that the Agency "considers most forms of carbon nanotubes [CNTs] as new chemical substances", CUC recommends making clear that the first question a CNT manufacturer or processor should ask is whether the CNT is a "new" chemical or the processing activity would be a "significant new use" that must be reported in the context of a PMN or SNUN. If the answer to that question is "yes", then the manufacturer "only needs to submit a new chemical [or new use] notification under TSCA." 82 Fed. Reg. at 3649.

If the CNT is not a "new" chemical, and a SNUN is not needed, then the next step is to determine whether the CNT is a reportable chemical substance. If the answer to that question is "yes", then and only then do the dates and deadlines discussed in the first paragraph of the answer come into play.

We note that EPA has not referenced in the draft guidance the 2008 memorandum, "TSCA Inventory Status of Nanoscale Substances – General Approach", https://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf (accessed on June 9, 2017). If that memorandum still is in effect, it should be referenced in the answer to Question 13.

**Question 14**

The guidance provided in the answer to Question 14 is similar, but not identical to, the guidance provided on the meaning of "reasonably ascertainable" in the context of the Chemical Data Reporting rule. To avoid confusion, instead of paraphrasing that guidance, EPA should simply refer the reader, and provide hyperlinks, to the definitions and guidance provided for the CDR.

As currently described, EPA's paraphrasing of the guidance provided for the CDR misstates the efforts processors must take to create or collect information from external sources, such as suppliers and customers. Specifically, the Agency's draft answer to Question 14 states:

> If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, **it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable to processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have.**

(emphasis added). This suggests an obligation to affirmatively ask suppliers for information that the processor does not otherwise have and to collect reportable information from suppliers (i.e., to create and collect information that is new to the processor).

Such an obligation is inconsistent with the definition of "known or reasonably ascertainable" in 40 CFR 704.3, which refers only to information in a company's possession and control ("all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know"). Processors do not possess or control information held by its supplier, and therefore requiring

processors to both create new information by surveying upstream suppliers and then to collect that information from upstream suppliers overstates a processor's obligations to fulfil its reporting obligations under Section 8(a).

This conclusion is supported by EPA's prior guidance for the CDR on these points where EPA stated explicitly that there is no such obligation:

> EPA would like furthermore to clarify that submitters are not required to conduct a new or additional customer survey (i.e., to pose a comprehensive set of identical questions to multiple customers) under this standard. **If particular information cannot be derived or reasonably estimated from the information available to the company without conducting further customer surveys, it is not "known to or reasonably ascertainable" to the submitter for purposes of the CDR.** However, to the extent that customer surveys are already in the submitter's possession or control, and to the extent that reasonable efforts to analyze or derive information from already-available customer surveys may inform processing and use information that is reported, the information is generally "known to or reasonably ascertainable."

76 Federal Register 50816, 50829-30 (August 16, 2011) (emphasis added). EPA should therefore revise Question 14 to either refer explicitly to the guidance for the CDR or to remove any suggestions that processors must create and collect from upstream suppliers information that the processor does not currently know nor possess and control.

**Question 16**

The answer states that "*Once a chemical substance has been incorporated into an article*, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting." That could be read to mean that a person who purchases a reportable chemical substance solely for purposes of incorporating it into an article has a reporting obligation up until the time that the substance is incorporated into the article. EPA should provide further clarity and include in the final guidance specific examples of when a person who purchases a reportable chemical substance for purposes of incorporating it into an article is strictly a "user" of the substance who has no obligations under the Section 8(a) rule in contrast to a person who is a "processor" with reporting obligations under the final rule.

**Question 17**

The last sentence of the answer states: "EPA expects that in most cases such information will be in the company's possession or reasonably ascertainable." It is not clear what information EPA is referring to in that sentence. EPA should delete the sentence (as shown in the attached mark-up) or provide clarification and the basis for that expectation, especially since the question strongly implies that such information on critical physical-chemical properties might not be readily available. As the CUC explained in our August 5, 2015 comments on the proposed rule, methods for determining zeta potential, surface area, dispersion stability and surface reactivity of nanoscale materials have not been standardized, and no analytical methodologies have been approved by EPA. We recommend EPA simply delete the final sentence of the draft answer.

**Questions 21 through 23**

As with Question 14, we recommend that EPA simply refer the reader to the definitions and guidance provided for the CDR.

**Question 24**

A reportable chemical substance might be used to manufacture a consumer product, but not be present in the consumer product. EPA should confirm that a company need not provide information about a consumer product if it does not contain the reportable chemical substance.

To make it easier for companies to report use information, EPA should recommend that companies refer to the use tables and codes used for the CDR.[4]

**Question 25**

The answer to this question states: "[I]f a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation . . . to wait 135 days after reporting to manufacture or process." The final rule, however, clearly states that a report must be submitted:

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[4] Codes appear in the Agency's 2016 Instructions for TSCA Chemical Data Reporting, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, June 23, 2016. https://www.epa.gov/sites/production/files/2016-05/documents/instructions_for_reporting_2016_tsca_cdr_13may2016.pdf

> [A]t least 135 days *before* commencing manufacture or processing . . . except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.

40 CFR 704.20(f)(2)(emphasis added).

CUC remains concerned that an EPA enforcement official might construe the rule to require that a person *must* wait either the full 135 days or at a minimum 30 days after reporting before commencing manufacture or processing. EPA should issue a technical amendment to the pertinent passage in the rule to conform the text of 704.20(f)(2) to the understanding expressed in the draft answer to this question.

To help companies determine whether they have a "discrete" form of a nanomaterial, EPA also should refer in the final version to this draft answer to the 2008 memorandum, "TSCA Inventory Status of Nanoscale Substances – General Approach", https://www.epa.gov/sites/production/files/2015-10/documents/nmsp-inventorypaper2008.pdf (accessed on June 9, 2017).

**Question 26**

This answer states that "updating with new information is not required unless [a] change in manufacture or processing creates a new discrete form of a reportable chemical substance." If a new discrete form is created, CUC interprets the final rule to require a separate report to be filed for each new discrete form of a reportable chemical substance, as opposed to filing an update to a previous submission under the rule. We recommend EPA clarify its response.

**Question 32**

The draft answer to this question is similar to the answer to Question16, in that this answer implies that a person who purchases a reportable chemical substance solely for purposes of incorporating it into an article has some type of reporting obligation covering activities that occur prior to the point at which the substance is incorporated into the article. CUC requests EPA provide greater clarity and provide examples of activities in the context of manufacturing an article that constitute solely on site "use" of a reportable chemical (for which reporting is not required) versus those activities that constitute "processing" of a substance prior to its incorporation into a finished article.

**Question 35**

This draft answer is incomplete. Before determining whether a substance is subject to the reporting rule, the manufacturer or processor should first determine whether the substance is a chemical substance within the meaning of TSCA; then determine whether the substance is subject to any reporting exemptions; and then determine whether the substance is on the Inventory or is a "new" chemical substance for which a PMN might be required. Depending upon the answers to those questions, the manufacturer/processor might or might not need to determine whether the chemical substance is a reportable chemical substance that is subject to the rule.

We also note that the answer refers to "the last principal reporting year." The term "Principal reporting year" is not used in the rule or elsewhere in the guidance. EPA should delete that term from the draft answer as recommend in the attached mark-up.

**Question 37**

This answer states: "In order to manufacture (including import) or process a chemical substance for a non-exempt commercial purpose, it must be: on the TSCA Inventory, a naturally occurring chemical substance, . . . or excluded by TSCA Section 3(2)(b). The draft answer requires clarification; the attached mark-up provides suggested edits to address the confusing portions of the draft sentence. EPA should add a reference to the need to submit a request to search the Confidential Inventory, and note there are exemptions from TSCA reporting requirements that could explain why a substance might not be listed on the Inventory (e.g., the polymer and LVE exemptions). EPA also should reiterate that if a PMN must be submitted for a new chemical substance, that substance need not be reported pursuant to the final Section 8(a) rule.

**Question 38**

EPA should reference its interpretation of the substantiation requirements that was published in January. *Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)*, 82 Fed. Reg. 6524 (Jan. 19, 2017).

**Comments on Reporting Form**

The version of the reporting Form appearing in the Agency's docket for the final rule is labeled "draft"; CUC request this be clarified. If the Form appearing in the docket is not yet "final", the CUC offers these additional comments on the draft Form:

- The draft Form in the docket fails to capture whether the submitter is reporting as a manufacturer/importer or a processor (or both) and should be amended to capture this information.
- The draft Form looks like the PMN Reporting Form, which was designed to serve a different purpose than Section 8(a) information gathering. The Form could be simplified considerably to focus more explicitly (and solely) on gathering the information items set forth in the final regulation at 40 CFR §724.20(d)(1) – (11).
- The final Form should provide a check box or other simple method for designating when an information item is not being supplied because it is "not known to or reasonably ascertainable" by the entity completing the Form. Such a check box could be positioned near the boxes provided throughout the draft Form for asserting CBI claims.

**Conclusion**

As our comments and those of other commenters indicate, the draft guidance will be unlikely to anticipate and provide answers to all of the potential questions that will arise as manufacturers and processors seek to comply with the rule and complete the reporting form when necessary. CUC recommends it is more appropriate for EPA to focus its limited resources on making entities who are unfamiliar with TSCA aware of the final regulation and providing assistance to manufacturers and processors seeking to comply, as opposed to emphasizing rigorous enforcement efforts -- especially where the requirements of the rule might be misunderstood or easily misinterpreted. Doing so will reduce disincentives to reporting and help to ensure EPA achieves its stated goals for the final rule: to "assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale, informed by available scientific, technical and economic evidence … on a case-by-case basis without a presumption of either harm or safety…".[5]

[5] *See* Final Rule at 3642.

ARNOLD & PORTER
KAYE SCHOLER



The CUC appreciates your consideration of these comments. If you have any questions relating to these comments, please feel free to contact me.

Sincerely,

Lawrence E. Culleen
Counsel to the Chemical Users Coalition

Enclosure -- Mark-up EPA draft guidance document

# Mark-up

# EPA draft guidance document

# Draft Guidance on EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce

## What Chemicals are Reportable?

**Question 1: My company manufactures a nanoscale material in the form of primary particles less than 100 nanometers in the reactor system but almost immediately due to ~~V~~van van der Waall forces forms aggregates and agglomerates with particle sizes far greater than 100 nanometers(nm). Are these types of nanostructured materials with particle sizes greater than 100 nm considered reportable chemical substances under this rule?**

No. The definition of a reportable chemical substance under this rule is a combination of particle size and unique and novel properties. For the example given in the question, the form consisting of primary particles at "creation" would not meet the definition of a reportable chemical substance, unless the manufacturer was making a form ~~of carbon black~~ consisting solely of those primary particles that exhibit size dependent properties. Because in the example the particle size of the aggregates and agglomerates is greater than 100 nm, that form ~~of carbon black~~ as manufactured is not a reportable chemical substance.

**Question 2: Can you describe what is considered a reportable chemical substance? Is there some way to differentiate between genuinely new nanoscale materials in commerce and traditional products?**

Under this rule, a reportable chemical substance is a solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that is manufactured or processed to exhibit unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates, and agglomerates, measured by weight are in the size range of 1–100 nm in at least one dimension.

The rule also includes a definition of unique and novel properties. Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance that are not in the size range of 1-100 nm in at least one dimension, and such properties are a reason that the chemical substance is manufactured or processed in that form or size. For purposes of this rule, EPA defined unique and novel properties to include an element of intent, meaning that those properties are the reason why the chemical substance is manufactured in that form or size. In order to be reportable it is not sufficient that a chemical substance contains particles in the size range of 1-100 nanometers in at least one dimension; it must also have a size-dependent property different from properties at sizes greater than 100 nanometers in all dimensions, and those properties are the reason that the chemical substance is manufactured or processed in that form or size.

Intentionally manufacturing or processing nanoscale gold so that it exhibits a red or purple color instead of a yellow color is an example of a unique or novel optical property seen at the nanoscale. Such a change would likely result in changes of other properties, such as specific

surface area, which can result in different health and safety impacts. Unique and novel properties which impact performance generally cannot be isolated from concurrent changes in properties that impact biological systems. Some nanostructured materials are stronger or have different magnetic properties compared to other forms or sizes of the same material. Others are better at conducting heat or electricity. They may become more chemically reactive or reflect light better or change color as their size or structure is altered. A property is novel when it is different from the properties associated with other forms or sizes of the same chemical substance. As noted on www.nano.gov, when particle sizes of solid matter in the visible scale are compared to what can be seen in a regular optical microscope, there is little difference in the properties of the particles. But when particles are created with dimensions of about 1–100 nanometers in at least one dimension, the materials' properties can change significantly from those at larger scales.

**Question 3: What is the difference between enhanced properties and unique and novel properties?**

Enhanced properties are generally described as increased reactivity or surface area when particle size decreases. While reactivity and surface area increase, there is often little difference in the intrinsic properties of the particles in ranges above 100 nanometers. When particles are created with dimensions in the 1–100 nanometer range, the materials' properties can change significantly from those at larger scales. Not all enhanced properties are unique or novel. For example, grinding or engineering pigments for better performance which results only in incidental amounts of particles between 1-100 nm would not constitute a nanoscale material with unique or novel properties. Grinding or engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties.

**Question 4: To what objects and collections of objects does the 1-100 nm measurement apply? In other words, does that mean any form with particles 1-100 nm or does that include aggregates and agglomerates greater than 100 nm but based on primary particles less than 100 nm?**

Chemical substances required to be reported would include any form with more than 1% by weight of particles 1-100 nm in at least one dimension, but would not include aggregates or agglomerates greater than 100 nm in all dimensions even if they contain primary particles less than 100 nm in at least one dimension.

**Question 5: If a reportable chemical substance is reported as a new chemical for one use but later has a different use from the one reported, would this require reporting under this rule?**

Because this rule is one-time reporting of nanoscale forms of chemical substances in commerce, new uses of reportable chemical substances that have been reported previously pursuant to this rule or were previously reported on or after January 5, 2005 as a new chemical, do not ~~require additional reporting~~need to be reported under this Ssection 8(a) reporting requirement. However, if ~~under the new use the~~a person manufactures or processes a new discrete form of the reportable

chemical substance, then that person would be required to report under this rule. Note that there may be notification requirements unrelated to this Section 8(a) reporting rule if a company manufactures or processes the chemical substance for a use that is subject to a significant new use rule (SNUR) for the chemical substance.

**Question 6: Is "reporting for mixtures" notifier-specific or substance-specific. For example, if a manufacturer reports and sells to 10 processors, does each processor report?**

Reporting for mixtures is not required, but you must report each individual reportable chemical substance in a mixture. Any reportable chemical substance that is incorporated into a mixture or substrate would require reporting for manufacturing or processing of that chemical substance. If a manufacturer sells a mixture containing a reportable chemical substance to multiple processors, then each processor is also required to report based upon known or reasonable ascertainable data provided by the manufacturer.

**Question 7: Please clarify the criterion to exclude chemical substances that dissociate completely in water to form ions that are smaller than 1 nm. How fast or what is the rate of dissociation?**

The rate of dissociation or how fast that dissociation occurs in water does not affect which chemicals are excluded. If the chemical substance completely dissociates to form ions smaller than 1 nm it is not a reportable chemical substance.

**Question 8: What are the criteria to discern one shape from another shape? How would manufacturers and processors distinguish between the different morphologies identified in the rule as for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum?**

A different morphology would be any change in the shape of particles. Different morphology does not include random shape changes or natural variation in shapes of particles that are not definitive and that occur in a continuum. Some nanoscale materials are engineered to give all the particles a certain morphology or shape. The change in shape needs to be a specifically engineered change in the shape of particles of a nanoscale material, to effect a change and form a unique or novel property for a chemical substance in the particle size range of 1-100 nm in at least one dimension.

**Question 9: Are mixtures ever reportable under the rule?**

Mixtures are not reportable under this rule, however ~~the~~ any components of ~~any~~ mixture that ~~contains~~meet the definition of a "reportable chemical substances" ~~subject to the rule~~ would be reported. If you manufacture (including import) or process chemical substances as part of a mixture, you would evaluate each chemical substance in the mixture against the requirements of this rule. ~~for each chemical substance in the mixture~~.

**Question 10: Why are coated nanomaterials defined separately from chemical mixtures? What does the rule mean by coating? There are cases where discrete nanomaterials are**

**surface treated (commonly coated with polymeric substances) in a similar fashion as defined for chemical mixtures.**

The term coating in the rule describes surface treating or coating of a reportable chemical substance with another chemical substance. The change in coating makes it a discrete form of a reportable chemical substance subject to reporting even if all of the other intrinsic characteristics of the reportable chemical substance remain the same. Coating or surface treating a nanoscale material results in a nanoscale material with different properties. The rule does not require that every chemical substance coated or surface treated with another chemical substance be reported. However, any type of engineering including surface treatment of a chemical substance that results in a reportable chemical substance triggers a reporting requirement.

**~~Comment~~ Question 11: Is it EPA's intention to require reporting on large molecules within the size range of 1 – 100 nm, which are not normally considered to be nanoscale materials (for example, monomers, polymers, colloids, organic and inorganic pigments and dyes, polymer dispersions, etc.)? Are polymers or metals attached to ligands which are larger than 1 nm in size also considered a nanoscale material for reporting?**

In order to be a reportable chemical substance, the chemical must not only be a particle in the size range of 1-100 nanometers in at least one dimension, it also~~.~~ ~~It~~ must ~~also~~ have a unique or novel property (i.e., ~~which is~~ ~~any~~ size-dependent property that varies from those associated with other forms or sizes of the same chemical substance), and such property is a reason that the chemical substance is manufactured or processed in that form. While these categories of large molecules are not exempt per se, monomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique or novel properties that are not exhibited by other forms or sizes of the same chemical substance. Large molecules and chemicals attached to ligands greater than 1 nm that do not meet the definition do not need to be reported unless they meet the definition of a reportable chemical substance.

**Who is Required to Report?**

**Question 12: My company manufactures ink/toner products and is planning to import ~~their~~ our products, which include a chemical substance with particle sizes of 1-100 nm in at least one dimension, used as a pigment and/or additive in toner and ink cartridges. Is my company required to report even though the chemical substance is incorporated into a formulation that is not manufactured or processed in the United States?**

Under TSCA, the definition of manufacture is not limited to domestic manufacture; the definition of manufacture includes import. This includes importing a chemical substance as part of a formulation. The chemicals in the formulation are subject to any manufacturing reporting requirements under TSCA including the reporting and recordkeeping rule for chemical substances that are nanoscale materials. If the chemical substance is imported in a form that meets the definition of a reportable chemical substance, the importer of the toner must report under 40 CFR 704.20.

**Question 13: My company is currently processing carbon nanotubes for research and development (R&D). Within the next few years there is a probability that we will be selling products containing the carbon nanotubes. At that point, we would not be exempt from this reporting requirement. Would it be proactive for us to report to the EPA now, even though we are still in the R&D phase, or should we wait until we are processing for production?**

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule. The rule will become effective on August 14, 2017. By August 14, 2018 you would need to report any non-exempt processing of a reportable chemical substance that occurred before August 14, 2017. If you begin non-exempt processing of a reportable chemical substance after August 14, 2017 you would need to report at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except if you have not formed an intent to manufacture or process at least 135 days before commencing such manufacture (including import) or processing, in which case the information must be filed within 30 days of the formation of such an intent. You are the best judge on when to report to meet the requirement of reporting 135 days before processing a reportable chemical substance or within 30 of forming an intent to manufacture or process.

You will also need to determine if the carbon nanotubes you are processing meet the definition of a reportable chemical substance. Not all carbon nanotubes contain particles less than 100 nm although most of them would be described as having unique and novel properties.

EPA considers most forms of carbon nanotubes as new chemical substances (See 73 FR 64946) Are you importing the carbon nanotubes or purchasing the carbon nanotubes from a domestic supplier? Can your supplier confirm they are on the TSCA Inventory? If you cannot confirm they are on the TSCA Inventory, then apart from this Ssection 8(a) reporting rule you may also need to submit a pre-manufacture notice (PMN) under TSCA Ssection 5 for the carbon nanotubes if you are the importer of record or your domestic supplier may need to submit a PMN. You can learn whether your nanotubes are on the TSCA Inventory by submitting a *bona fide* request to EPA pursuant to procedures in 40 CFR 720.25.

**Question 14: What is required of processors that do not know about the particle size and other characteristics of formulations they process or use?**

Reporting of information under the rule is required only to the extent that information is known or reasonably ascertainable. This standard applies both to the extent of an entity's obligation to determine whether it is required to report, and to the extent of information any entity is required to report. If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable to processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have. Their supplier is not required to provide any additional

information to the processor but might provide other supporting information, for example, whether their supplier has reported or intends to report the chemical substance under this rule. If the supplier provides information indicating that the substance is not reportable or if the processor lacks any other means of reasonably ascertaining whether the substance is reportable, the processor does not need to perform tests to determine whether the substance is reportable. Information developed in the normal course of business or that the processor chooses to develop must also be used. The processor may want to document the steps they took to determine if reporting was required.

If the information provided by the supplier indicates that reporting is required, the processor is required to report information that is known or reasonably ascertainable, which may include information obtained from the supplier. This would include situations where the processor may not know the exact chemical identity or some of its physical properties. Companies that purchase formulations from a manufacturer/processor located in the US but do not change or modify those formulations and only use them are not considered processors and are not required to report under the rule. Importers that purchase formulations that contain reportable substances from a source outside of the US are considered to be the same as manufacturers and are required to report under the rule even if they do not change or modify those formulations and only use the formulation.

The obligations imposed by the reasonably ascertainable standard are discussed more fully in the Chemical Data Reporting final rule, 76 FR 50816, 50829 (August 16, 2011).

**Question 15: Is a processor of a reportable chemical substance submitted as a PMN required to report?**

Only persons who submitted the Ssection 5 submission after January 1, 2005 are exempt from reporting. Other manufacturers and processors would still be required to report.

**Question 16: Where in the supply chain must a ~~nanoscale material~~ reportable chemical substance be reported: at every point in the supply chain, or only at the point of manufacture? Would this include incorporation into articles and substrates?**

Each manufacturer and processor in the supply chain must report known or reasonably ascertainable information on the reportable chemical substance. Once a reportable chemical substance has been incorporated into an article, no further reporting is required as persons that manufacture or process chemical substances as part of articles are exempt from reporting.

**Question 17: The physical properties that define discrete forms of a reportable chemical substance sometime cannot reliably be measured and the rule appears to require companies to conduct tests on these or other physical-chemical properties to determine whether they must report. Many of these tests are not commonly performed.**

Testing is not required under a TSCA Ssection 8(a) rule. While manufacturers and processors are not required to test for the properties identified in the definition of discrete forms of a reportable chemical substance, they are still required to determine their compliance obligations

under the rule based upon information that is in their possession or which is reasonably ascertainable. If information within a company's possession or that is reasonably ascertainable does not demonstrate that the company is manufacturing or processing a discrete form of a reportable chemical substance, there is no obligation to report. ~~EPA expects that in most cases such information will be in the company's possession or reasonably ascertainable.~~

**Question 18: If a company manufactures or processes a reportable chemical substance solely for export is the company subject to the reporting requirements?**

Yes. Persons who manufacture or process reportable chemical substances solely for export are subject to the reporting requirements. TSCA Section 12(b) exemptions for export do not apply to Section 8(a) rules. Note, however, that the processing and use information is restricted to domestic activities, i.e., within the customs territory of the United States.

**Question 19: Are importers of a reportable chemical substance required to report under the rule?**

Yes. The definition of "manufacture" under Section 3(9) of TSCA includes import.

**What Information is to be Reported?**

**Question 20: Can you clarify whether manufacturers and processors who are only required to report available or reasonably ascertainable information need to develop information to comply with the rule.**

Manufacturers and processors are not required to conduct testing or develop information under this rule. However, they are required to report information that is known or reasonably ascertainable.

**Question 21: Please provide further clarification on the scope of what would be required under the "known to or reasonably ascertainable by" reporting standard. How would this reporting standard apply to manufacturing, processing and use information?**

The term "known to or reasonably ascertainable by" is defined at 40 CFR 704.3. It means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." Under the "known to" portion of the standard, a submitter must therefore ascertain what they know about the manufacturing, processing and use of a chemical substance it manufactures (including imports) or processes, without confining its inquiry to what is known to managerial and supervisory employees. A submitter would also be expected to review other information which the manufacturer (including importer) or processor may have in its possession. This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The

standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

Inquiry under the "reasonably ascertainable" portion of standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Note however, that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be "reasonably ascertainable" to the submitter. Thus there is not a need to conduct new customer surveys for purposes of reporting under the rule. As described above, however, existing customer survey data may nevertheless be "known to" the organization.

**Question 22: What are some examples of types of information that are considered to be in a person's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know?**

Information could be possessed by employees or other agents of the company reporting under the rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance. This information includes knowledge gained through discussions, symposia, and technical publications. Other examples include:

- Files maintained by the submitter or employees in the submitter's company, such as marketing studies, sales reports, or customer surveys;
- Information contained in standard references, such as MSDSs, that contain use information or concentrations of chemical substances in mixtures; and
- Identification numbers from the Chemical Abstracts Service (CAS) and from Dun & Bradstreet.

**Question 23: A company manufactures or processes chemical substances but often does not know how these chemical substances are used by downstream customers. Does EPA intend for submitters to send questions to customers requesting information about downstream uses?**

It depends on what is meant by sending "questions to customers." Submitters need not send out a comprehensive set of identical questions to multiple customers in order to fulfill the reporting standard. That is, they need not conduct a new survey of their customers. However, one way of fulfilling the reporting standard might involve limited" inquiries outside the organization (e.g., contacting a major customer or examining that customer's public website) to fill in gaps in the submitter's knowledge, where the submitter's current knowledge is less than what a "reasonable person similarly situated might be expected to possess, control, or know." See 40 CFR 704.3.

**Question 24: All of a company's products are used to make commercial products through various process steps by different manufacturers. Should the company provide information about consumer uses even if its reportable chemical substance is not the end use product?**

Yes, provided that the~~. If~~ reportable ~~the~~ chemical substance is ~~used~~present in a~~the~~ consumer product~~,~~ and the ~~company would still report the~~ information ~~if it~~ is known to or reasonably

ascertainable by the company, even if the company does not manufacture the ~~end-use item~~consumer product. The information provided on the reporting form about downstream use is associated with the processing and use of reportable chemical substances and typically relates to processing or use that is outside of the manufacturing, importing, or processing site, unless, of course, the manufacturer, importer, or processor also processes or uses the reportable chemical substance.

Information on subsequent industrial users and processors and on commercial and consumer uses of the reportable chemical substance would be reported on the reporting form to the extent the information is known to or reasonably ascertainable by the manufacturer (includes import) or processor of the subject chemical substance. A company which is a manufacturer or processor must report information about the distribution and use of the chemical substance that is known to or reasonably ascertainable by the company. To the extent the information is not known or reasonably ascertainable, the company may report NKRA (i.e., "not known or reasonably ascertainable").

**When is Reporting Required?**

**Question 25: Please clarify how the 135-day reporting requirement for new discrete forms would work. For example, can commercialization begin after notification to EPA or after 135 days after notification to EPA?**

The 135-day period is not a formal review-period that prohibits manufacture before the end of the 135-day period. Rather, based on EPA's experience with the PMN reviews in the new chemicals program, EPA believes that in most cases companies have the requisite intent to manufacture or process a reportable chemical substance at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent. However, if a company does not form the requisite intent 135 days ahead of time, the company must report within 30 days of the formation of such an intent. Moreover, if a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation upon the company to wait 135 days after reporting to manufacture or process.

**Question 26: Is there a mechanism or requirement to update any new information if there is a change in manufacture, processing or use after the initial reporting of a reportable chemical substance?**

Because this rule only requires one-time reporting, updating with new information is not required unless the change in manufacture or processing creates a new discrete form of a reportable chemical substance.

**Question 27: Can EPA clarify if the exemptions for new chemicals reported since January 1, 2005 and the Nanoscale Materials Stewardship Program (NMSP) would exempt information that has changed since the original reporting?**

For a reportable chemical substance that was submitted as a new chemical substance under Ssection 5 of TSCA or as part of the NMSP, no updated information would need to be reported unless a manufacturing or processing change resulted in a new discrete form of the reportable chemical substance.

**Question 28: What is the criterion for distinguishing new processing methods for a nanoscale material from existing methods? What would constitute a process change that would require filing a new report?**

The type of process change is not the criterion; it is the intent of the process change. Any manufacturing or processing change that is intended to change particle size and properties would be a process change that could require new reporting.

**General Questions**

**Question 29: The reporting rule was published in the Federal Register on January 12, 2017. When does this rule become law?**

On May 12, 2017, EPA published a Federal Register notice extending the effective date of the rule 90 days; the rule will become effective on August 14, 2017.

**Question 30: Is there a minimum production volume below which no reporting is required, such as 10 or 100 kg?**

There is no exemption based on production volume or reporting threshold based on production volume.

**Question 31: (a) Is research and development exempt from reporting under the rule? (b) Can you define small quantities? (c) Can companies sell research and development quantities for profit? (d) Is reporting required if the core commercial activity of a company is research and development?**

(a) Yes. As described in 40 CFR part 704.5(e), a person who manufactures (including imports), processes, or proposes to manufacture or process a substance subject to reporting under this rule only in small quantities solely for research and development is exempt from the reporting requirements of the rule.

(b) Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") is defined in 40 CFR part 704.3 to mean quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(c) Yes. The exemption may apply even if a company sells research and development quantities for a profit.

(d) The research and development exemption applies to use for which the specific chemical substance is manufactured. It is irrelevant whether the main commercial activity of the company is research and development or industrial sales or use.

**Question 32: Are articles exempt from reporting under this rule?**

As described in 40 CFR 704.5(a), a person who imports, processes, or proposes to import or process a reportable chemical substance subject to this rule solely as part of an article is exempt from the reporting requirements of this part with regard to that substance. Manufacturers (including importers) or processors of a reportable chemical substance that is incorporated into an article would be required to report any required information for activities before the chemical substance is incorporated into the article. An article is defined in 40 CFR 704.3 as manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

**Question 33: Can imported metal powders ever be considered "articles" regardless of their end use?**

No. Powders cannot be considered articles. The definition of article includes the statement that "fluids and particles are not considered articles regardless of shape or design".

**Question 34: Is the purpose of the rule to compile an inventory of nanoscale material chemical substances in commerce?**

No. The purpose of the rule is to collect information on the manufacture (including importation); processing; and industrial, commercial, and consumer uses of certain chemical substances that are nanoscale materials. This rule will allow EPA to obtain basic data from those that manufacture or process existing nanomaterials made from substances that are on the TSCA Inventory. EPA will use information gathered through this rule to inform the Agency's understanding about the manufacture, processing and use of nanoscale substances and to determine if any further action under TSCA, including additional information collection, is needed in specific instances.

**Question 35: How do I determine my reporting requirements?**

Carefully review the regulations located at 40 CFR 704.20 to determine your reporting requirements. You should consider the following three steps to determine whether you are required to report for each chemical substance that you domestically manufactured (including imported) into the United States~~ since the last principal reporting year~~:

o Step I: Is your chemical substance subject to the reporting rule?

o Step II: Are you a manufacturer (including importer) or processor who is required to report?

o Step III: What information must you report?

**Question 36: Must a submitter conduct new chemical analyses to report information?**
No. The regulation does not require submitters to perform new chemical analyses. The information required by the rule is limited to information that is "known to or reasonably ascertainable." This standard is applicable to all information reported in accordance with 40 CFR 704.20.

**Question 37: What should a company do if it determines that it manufactures or processes a chemical substance that is not included on the TSCA Inventory?**

In order for a person to report a substance that it manufactures (including imports) or processes a ~~chemical substance~~ for a non-exempt commercial purpose, the substance~~it~~ must be~~:~~ on the TSCA Inventory~~, a naturally occurring chemical substance as defined by TSCA (see 40 CFR 710.1(b)), or excluded by TSCA Section 3(2)(B)*~~. You can visit Substance Registry Services to determine whether your chemical substance is on the TSCA Inventory. If your chemical substance is not on the TSCA Inventory, you may need to submit a PMN to the new chemicals program. Please see EPA's PMN Requirement flowchart to determine if a notice must be submitted to the Agency prior to manufacture (including import). You can also phone the TSCA Hotline at (202)-554-1404 for assistance.

For a chemical substance that is not on the TSCA Inventory, a naturally occurring chemical substance as defined by TSCA, or exempted in TSCA Section 3(2)(B)), a person must submit a notice as per 40 CFR 720.22(a)(1) prior to manufacture (including import).

If a person is manufacturing (including importing) a substance which is not on the TSCA Inventory and has not provided the required notice to EPA, each day of such manufacture or importation is a violation of Section 5 of TSCA and could subject the person to enforcement action. If a person finds that it has or may have manufactured or imported a chemical substance in violation of TSCA, contact the Agency at the following address: https://www.epa.gov/compliance/epas-edisclosure.

Significant reductions in penalties may be given to persons who voluntarily disclose such information. Note, however, that continued manufacture, (including importation) or use of such chemical substances remains in violation per Section 15 of TSCA, even after a person has contacted EPA, until the requirements of TSCA Section 5 have been met. These reporting requirements are distinct from the requirements at 40 CFR 704.20.

**Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide; any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.*

**Question 38: If a company manufactures a reportable chemical substance for a non-TSCA use, is the company required to report under 40 CFR 704.20?**

Substances exempted in TSCA Section 3(2)(B) need not be reported. Substances exempted in TSCA Section 3(2)(B) include: any pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act, when manufactured, processed, or distributed in commerce for use as a pesticide (but see Question 39 below regarding intermediates in the manufacture of an active ingredient in a pesticide); any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material as such terms are defined in the Atomic Energy Act of 1954; and, any article the sale of which is subject to the tax imposed by Section 4181 of the Internal Revenue Code.

**Question 39. A company manufactures Chemical C. Its customers use Chemical C for a variety of uses including as an intermediate in the manufacture of a chemical substance to be used as a pesticide active ingredient. Pesticides are exempt from regulation by TSCA. Does the company need to report industrial processing and use data for this chemical substance?**

Yes. The manufacture of a chemical substance that is a pesticide intermediate is manufacture under TSCA.

**Question 40: If a company manufactures or processes a reportable chemical substance which may be used for purposes regulated by TSCA and also for uses which are excluded from regulation under TSCA Section 3(2)(B), should the entire quantity that the company manufactures or processes be reported in the submission?**

No. Report the manufactured or processed quantity intended for the TSCA use and do not report the quantity that is exempt from TSCA in Section 3(2)(B).

**Question 41: Are small manufacturers and processors exempt from reporting requirements of the rule?**

Yes. A small manufacturer or processor is defined in the rule as any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million.

**Question 42: What role does the technical contact play?**

The technical contact is the person whom EPA may contact for clarification of the information in a submission. The technical contact should be a person who can answer questions about the reported chemical substance(s). Typically, a person located at the manufacturing or processing site is best able to answer such questions. However, companies may use their discretion in selecting a technical contact or multiple technical contacts. Submitters should consider, in

selecting the technical contact, that EPA may have follow-up questions about a submission one or more years after the submission date. The technical contact need not be the person who signs the certification statement.

**Confidentiality**

**Question 43: What are the restrictions on submitting confidential information under the rule?**

Information submitted under the rule may be claimed as confidential at the time it is submitted. Submitters must provide upfront substantiation of confidentiality claims for processing and use information as well as for confidentiality claims for site or chemical identity. See EPA guidance on asserting confidentiality claims at https://www.epa.gov/tsca-cbi.

**Question 44: What must generally be considered in making a claim of confidentiality under TSCA?**

EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B and 40 CFR 704.20(h). The Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that for all claims for protection for any confidential information made with this submission the submitter certify they have:
(i) taken reasonable measures to protect the confidentiality of the information;
(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to my competitive position; and
(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 15 U.S.C. 2613(c).

Kitchen Cabinet Manufacturers Association ™

By email to beck.nancy@epa.gov

July 6, 2017

Dr. Nancy B. Beck (7401M)
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

**Re: Formaldehyde in Composite Wood Products – Non-Complying Lots Provision**

Dear Dr. Beck:

On behalf of the Kitchen Cabinet Manufacturers Association (KCMA), I am writing to request that EPA issue a formal guidance document on the non-complying lot provision of the Formaldehyde Emission Standards for Composite Wood Products, 81 Fed. Reg. 89674 (Dec. 12, 2017) (the "Rule").

The key provision, 40 C.F.R. § 770.22(f), requires that downstream entities, i.e., fabricators, importers, distributors, and retailers, notify their customers when they have distributed composite wood products belonging to non-complying lots. Section 770.22(f) merely makes general references to "composite wood products," and it is unclear whether the provision is applicable even when the downstream entities distribute component parts and finished goods, rather than panels. In a recent FAQ, EPA indicated that it is not applicable in that circumstance. KCMA appreciates this, but other provisions in the Rule provide a reasonable reading to the contrary. Given the potential conflict between the regulatory language and the FAQ, KCMA requests EPA to take more formal action to cement its position in the FAQ that paragraph (f) does not apply to component parts and finished goods.

Non-complying lots are composite wood products for which test results show that the products exceeded the applicable formaldehyde emission standards under the Rule.[1] Such composite wood products should not be certified and may not be sold, supplied, or offered for sale in the United States in a way inconsistent with section 770.22.[2] The 2013 proposed rule did not address the situation where a non-complying lot had been shipped to customers, because under the proposal composite wood products could not be shipped until after receipt of test

[1] See 40 C.F.R. § 770.3 (definition of "non-complying lot").
[2] 40 C.F.R. § 770.22(a).

results showing them to be in compliance with the applicable emission standards.[3] In the final rule, however, EPA established a notification system in section 770.22 requiring that panel producers and downstream entities notify their customers if composite wood products have already entered into commerce but are subsequently identified as belonging to non-complying lots.

Section 770.22 notifications have two components: Paragraph (d)(1) governs panel producer notifications; paragraph (f) governs downstream entity notifications. KCMA's concern is with paragraph (f), which states:

> Fabricators, importers, distributors, or retailers who are notified that they have received composite wood products belonging to a non-complying lot and who have further distributed the composite wood products are responsible for notifying the purchasers of the composite wood products in accordance with paragraph (d)(1) of this section.

This language only refers to "composite wood products" without any qualification. However, generally, the Rule regulates three forms of products: panels, component parts, and finished goods. The Rule defines "component wood products" without specific reference to any of the three products:

> *Composite wood product* means hardwood plywood made with a veneer or composite core, medium-density fiberboard, and particleboard.[4]

Important for our discussion here, section 770.22(f) does not mention panels. Thus, a permissible inference is that the term "component wood product," which section 770.22(f) uses, is not equivalent or limited to panels. Instead, component parts and finished goods might also be in scope. This inference is supported by the fact that the Rule has a separate definition for "panel":

> *Panel* means a thin (usually less than two inches thick), flat, usually rectangular piece of particleboard, medium-density fiberboard or hardwood plywood. Embossing or imparting of an irregular surface on the composite wood products by the original panel producer during pressing does not remove the product from this definition. Cutting a panel into smaller pieces, without additional fabrication, does not make the panel into a component part or finished good. This does not include items made for the purpose of research and development, provided such items are not sold, supplied, or offered for sale.[5]

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[3] The 2013 proposed rule would require that panel producers retain the lots of panels before the testing results are available. Thus, no notification would be required. EPA changed the compliance burden in the final rule by permitting panel producers to ship their panels downstream before test results became available, thus necessitating the notifications. See 78 Fed Reg. 34820, 34834-35 (June 10, 2013); 81 Fed. Reg. 89674, 89704 (Dec. 12, 2016).
[4] 40 C.F.R. § 770.3.
[5] Id.

The possible broad construction of "composite wood products" leads to the concern for fabricators: It would be extremely disruptive of the downstream supply chain if component parts and finished goods that are fabricated from non-complying lots of panels also were to trigger notification obligations. When fabricators receive notification from their panel suppliers that a shipment of panels failed an emissions test, those panels almost certainly no long exist as such. Instead, they will almost always have already been converted into component parts or finished goods. Unfortunately, affected component parts or finished goods are not easily trackable. Nor will it be meaningful for paragraph (f) to cover component parts or finished goods. In contrast to panels, testing of component parts or finished goods is not feasible. Also, formaldehyde emissions may have well diminished to acceptable levels by the time a composite wood product reaches the fabrication stage. Therefore, paragraph (f) should not apply to the distribution of component parts or finished goods by fabricators and others in the supply chain.

EPA agrees with this conclusion and issued an FAQ document on June 7, 2016 to clarify its position.[6] FAQ 18, addressing the meaning of "composite wood products" in the downstream entity notification context, states:

> 18. As a fabricator, distributor, importer, or retailer, what are my responsibilities if I have been supplied panels that are determined to have come from a non-complying lot, but I have already fabricated or incorporated them into a component part or finished good?
>
> The non-complying lots provision in 40 CFR § 770.22 only refers to composite wood products in the form of panels, meaning that only affected panels are subject to the requirements of that section. The non-complying lot provisions do not apply beyond when non-complying panels have been incorporated into component parts or finished goods; thus, in that scenario, there is no requirement for you to notify downstream entities in the supply.

EPA also stated:

> NOTE: The following three questions [i.e. Questions 16 through 18] apply only to composite wood panels. Panels that have been incorporated into component parts or finished goods are not subject to the requirements discussed in these questions.

KCMA appreciates these statements in the FAQs. However, we request more formal documentation of the position. While EPA's position in the FAQs is reasonable and should be followed, the language in the Rule itself permits alternative construction.

The term "composite wood panels" has confusing references in the Rule and, in multiple provisions, suggests a position contrary to that in the FAQs. For example, in some provisions, EPA clearly intended for the term "composite wood products" to encompass panels, component parts, and finished goods alike:

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[6] The FAQs are available at https://www.epa.gov/formaldehyde/regulated-stakeholder-questions-and-answers-epas-rule-implement-formaldehyde-standards.

> *Stockpiling* means manufacturing or purchasing **composite wood products, whether in the form of panels or incorporated into component parts or finished goods**, between July 7, 2010 and June 12, 2017 at an average rate at least 20% greater than the average rate of manufacture or purchase during the 2009 calendar year for the purpose of circumventing the emission standards and other requirements of this subpart.[7]
>
> The sale of stockpiled inventory of **composite wood products, whether in the form of panels or incorporated into component parts or finished goods**, is prohibited after December 12, 2017.[8]
>
> After December 12, 2017, only certified **composite wood products, whether in the form of panels or incorporated into component parts or finished goods**, are permitted to be sold, supplied, offered for sale, or manufactured (including imported) in the United States, unless the product is specifically exempted by this part.[9]
>
> Importers, fabricators, distributors, and retailers must take reasonable precautions to ensure that **the composite wood products** they sell, supply, offer for sale, or hold for sale, **whether in the form of panels, component parts, or finished goods**, comply with the emission standards and other requirements of this subpart.[10]

A similar statement also appeared in the preamble to the final rule:

> As proposed, in order to document compliance, the importer or fabricator would have to obtain from the supplier records identifying the panel producer(s) that produced the composite wood products and the dates that the composite wood products were manufactured and purchased from the panel producer(s), as well as bills of lading or invoices that include a written affirmation from the supplier that **the composite wood products, whether in the form of panels or incorporated into component parts or finished goods**, are compliant with this subpart.[11]

EPA apparently recognized that some requirements may attach differently to different types of products. It acknowledged the need for clarification of the regulatory scope in certain contexts. The preamble stated:

> EPA has also clarified throughout the regulatory text whether particular provisions apply to panels, component parts, or finished goods, or all three.[12]

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[7] Id. (emphasis added).
[8] 40 C.F.R. § 770.12(a) (emphasis added).
[9] 40 C.F.R. § 770.15(a) (emphasis added).
[10] 40 C.F.R. § 770.30(a) (emphasis added).
[11] 81 Fed. Reg. 89674, 89708 (emphasis added). A similar statement appears at p. 89709.
[12] 81 Fed. Reg. at 89678-79.

One such case is in the stockpiling provision. There, EPA proposed a good solution to assign obligations specific to certain products—it qualified "composite wood products" by product type:

> To determine whether stockpiling has occurred, the rate of manufacture or purchase is measured as follows:
> (1) For **composite wood products in the form of panels**, the rate is measured in terms of square footage of panels produced.
> (2) For **composite wood products incorporated into component parts or finished goods**, the rate is measured in terms of the square footage of composite wood product panels purchased for the purpose of incorporating them into component parts or finished goods.[13]

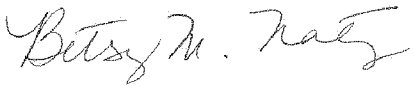
Section 770.22(f) has no corresponding limitation. In the FAQs, EPA expressed its intent that only panels are included. Ideally, the term "composite wood products" in section 770.22(f) would be expressly limited to panels. Unfortunately, it is not; EPA did not use the limiting phrase "in the form of panels" or its equivalent anywhere in section 770.22. Consequently, it could be argued in the future that, because EPA did not take a similar approach in section 770.22(f) as it did for the stockpiling provision, EPA intended to impose downstream notification requirements on distribution of component parts and finished goods that contain panels from non-complying lots. The FAQs may be helpful to rebut such an argument, but a more formal guidance document would be even more effective.

Thus, KCMA requests that EPA prepare a formal guidance document to cement its position in the FAQs—that section 770.22(f) does not apply to distribution of component parts or finished goods. That is a sound policy position. EPA has already made a helpful effort to establish it. The position is vulnerable only because the regulatory language is unclear. A more controlling and authoritative measure to permanently lock in that position will protect EPA from potential challenges, provide regulatory certainty to KCMA and its members, and serve well the implementation of the non-complying lot provision and the Rule in general.

[13] 40 C.F.R. § 770.12(b) (emphasis added).

Thank you for your consideration of this request. Please feel free to contact me with questions or comments. I may be reached at (703) 264-1690, bnatz@kcma.org.

Sincerely,



Betsy Natz, CEO
Kitchen Cabinet Manufacturers Association

cc: Erik Winchester (7404T)
winchester.erik@epa.gov

E. SCOTT PRUITT
ADMINISTRATOR

July 3, 2017

Mr. James R. Barbee
Director
Nevada Department of Agriculture
405 South 21st Street
Sparks, Nevada 89431

SUBJECT: **NOTICE OF DISAPPROVAL**
SLN No. NV170003 – General Hydroponics Prevasyn (EPA Reg. No. 91865-1)
SLN No. NV170004 – General Hydroponics Exile (EPA Reg. No. 91865-2)
SLN No. NV170005 – General Hydroponics Defguard (EPA Reg. No. 91865-3)
SLN No. NV170006 – General Hydroponics Azamax (EPA Reg. No. 91865-4)

Dear Mr. Barbee:

On April 5, 2017, the Nevada Department of Agriculture issued Special Local Need registrations under Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act as amended, to Hawthorne Hydroponics LLC d/b/a General Hydroponics. These state registrations, submitted to the U.S. Environmental Protection Agency by Jian (Jim) Zhang of NDA, were issued for the application of the following chemicals: capsicum oleoresin extract, garlic oil and soybean oil (NV170003), potassium salts of fatty acids (NV170004), *Bacillus amyloliquefaciens* strain D747 (NV170005) and azadirachtin (NV170006) to control various insect pests, mites and/or diseases on cannabis. The aforementioned chemicals are not registered by the EPA for use on cannabis. On June 22, 2017, the agency sent the NDA a Notice of Intent to Disapprove the four SLN registrations. On June 29, 2017, the NDA consulted with the agency about the SLN registrations.

**Decision:** The EPA concludes that SLN Nos. NV170003, NV170004, NV170005 and NV170006 are disapproved, effective immediately, for the reasons provided below.

**Reasons for Disapproval:** During the consultation on June 29, 2017, the NDA expressed their interest in pesticide use for the marijuana industry in Nevada. However, pursuant to FIFRA section 24(c), the EPA's regulations pertaining to state registrations of pesticides to meet special local needs state that "the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have . . . a similar

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use pattern . . .." 40 C.F.R. § 162.154(a)(1). The regulations define "similar use pattern" to mean "a use of a pesticide product . . . which is [among other things] substantially the same as the federally registered use." 40 C.F.R. § 162.151. Under federal law, cultivation (along with sale and use) of cannabis is generally unlawful as a schedule I controlled substance under the Controlled Substances Act.[1] The EPA finds that the general illegality of cannabis cultivation makes pesticide use on cannabis a fundamentally different use pattern.

The Administrator may disapprove a different use pattern "on any reasonable grounds." Here, in accordance with 40 C.F.R. section 162.154, the Administrator has determined disapproval is reasonable because the EPA does not believe that Congress intended the process under section 24(c) of FIFRA to be used for the purpose of facilitating activities that are generally in violation of federal law. While the EPA believes that it is not required to consider the general cost-benefit standard applicable to FIFRA registrations when disapproving a registration that is inextricably linked with violations of federal law, application of the cost-benefit standard would not yield a different result – any economic, social or environmental costs associated with pesticide use on cannabis would not be reasonable or justified in light of the fact that such use is in furtherance of an illegal act. The EPA has reviewed the SLN registrations submitted by the state and has not identified any significant risks associated with the SLN registrations; the EPA would not have been inclined to disapprove these registrations were cultivation and sale of marijuana generally lawful in the United States.

**Disposition of Existing Stocks:** The disapprovals of SLN Nos. NV170003, NV170004, NV170005 and NV170006 are effective immediately. You must take steps to halt any further sale or distribution of products under these SLN registrations. For uses subject to the disapproval, distribution or sale of existing stocks of all disapproved products listed above is prohibited. Sale or distribution of the EPA-registered products is still permitted, as long as the products are still properly labeled and the SLN labeling does not accompany the product.

Per 40 CFR § 162.154(c), a notice of the disapproval of these SLN registrations will be published in the Federal Register. However, this disapproval is effective immediately, as of the date of this letter.

If you have any questions, please contact Nancy Beck at (202) 564-2910 or beck.nancy@epa.gov.

Respectfully yours,

E. Scott Pruitt

Cc: Jian (Jim) Zhang, Nevada Department of Agriculture
Alexis Strauss, Acting Regional Administrator, EPA Region 9

[1] Marihuana, an older spelling of marijuana, and tetrahydrocannabinols are listed under schedule I in 21 U.S.C section 812(c).

# Identification and Comparison of Solvents and Paint Removers as Alternatives to Methylene Chloride in Paint Removal Applications

**R&D, W. M. Barr**
March 21, 2017

## ABSTRACT

This study compares the paint removing performance of methylene chloride to 22 solvents currently used in non-methylene chloride paint removers or solvents proposed as an alternative to methylene chloride by chemical manufacturers. The paint stripping performance of three methylene chloride paint removers was then compared to 26 non-methylene chloride paint removers and five experimental formulas using alternative methylene chloride chemistry. The solvents and paint removers were tested on 1 month and 1 year aged wood panels treated with multiple layers of an oil-based alkyd paint, a solvent-borne epoxy paint and OEM automotive coating. For chemically resistant oil-based alkyd, solvent-born epoxy paints and OEM automotive coatings, only methylene chloride based paint removers were determined to be effective.


## BACKGROUND

Methylene chloride has been the preferred solvent for use in paint removers for seventy years. Before methylene chloride was introduced, most paint removers consisted of a mixture of benzene and other volatile solvents such as methanol, acetone, and methyl ethyl ketone. Paint removers formulated with these volatile solvents are extremely flammable and the flammability of these paint removers resulted in fires causing injury and deaths. The benzene based removers were rapidly replaced with the methylene chloride paint removers because methylene chloride paint removers can be formulated to be non-flammable and are effective in removing multiple layers of paint. The physical characteristics give the methylene chloride molecule the ability to quickly penetrate multiple layers and to soften or dissolve chemically resistant coatings. Methylene chloride does not deplete the ozone layer and is considered to make negligible contributions to smog formation, the green-house effect and acid rain. Like other organic solvents, methylene chloride can be harmful to human health if used improperly.

### Consumer Use of Paint Removers

Most consumers use paint removers for refinishing antique furniture, or woodworking's (doors, frames, moldings, etc.) in older houses. Many of these items have been painted, and repainted many times over the years. This results in items having multiple layers of paint containing different chemistry types and a different degree of difficulty from being removed. Paint removers are also used in the auto body repair industry to help with vehicle restoration.

### Effect of Paint Chemistry and Age of Paint

There is a range of paint types that a consumer can encounter when paint stripping. The main paint chemistries that can be encountered include latex, urethane, 1-part epoxy, 2-part epoxy, enamel (alkyd type), lacquer, varnish, and shellac based paint. In recent times, latex paint has taken over the painting industry as the paint technology of choice. This paint is relatively easy to remove with paint strippers, but is also a paint technology that people will not frequently encounter as they are stripping older items. Historically, enamel alkyd based paint have been the most prevalently used paint technology. The resin used in alkyd paint dries by an oxidation reaction with oxygen from the air after the solvents has evaporated from the paint. The oxidation reaction irreversibly cross-links the polymers hardening the alkyd resin making it very difficult to remove. The alkyd paint continues to form cross-linking bonds as the paint ages making older painted items even harder to strip. 2-part epoxy paint is by far the most difficult paint technology to remove. It is frequently used in industrial settings. For this reason, the

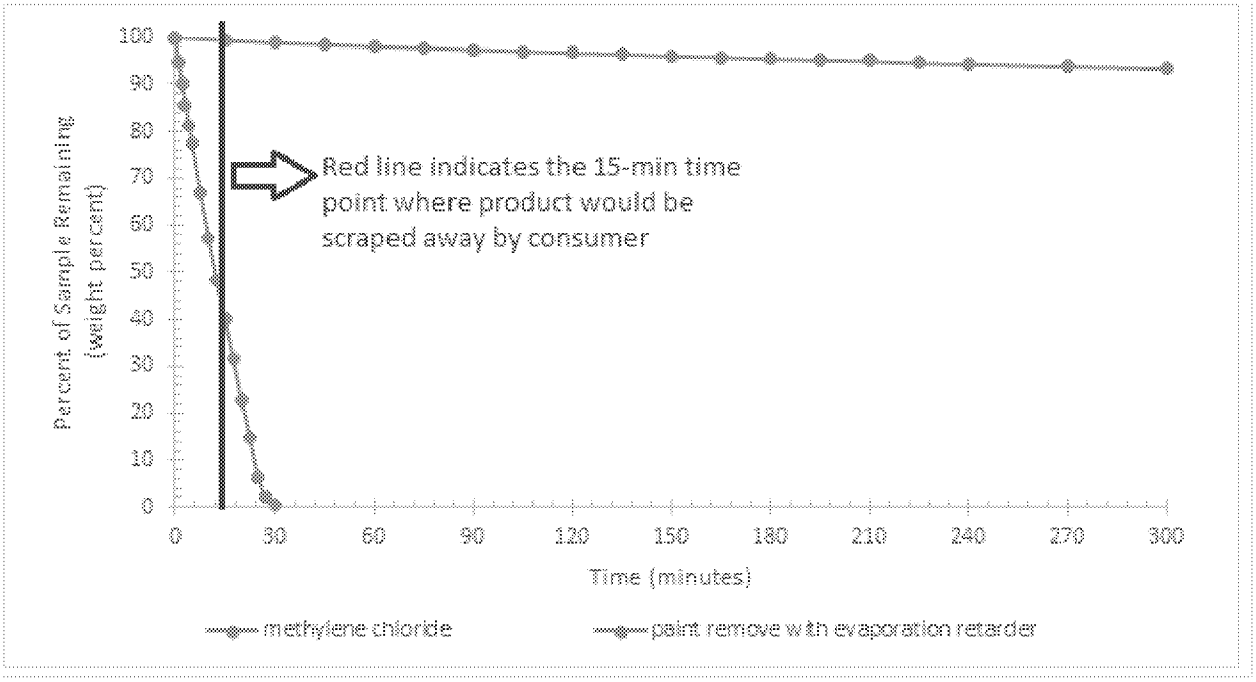
experimental studies outlined in this report will focus on the removal of alkyd, 2-part epoxy paint, and OEM automotive coatings.

**Basics of Paint Remover Formulation**

A chemical paint remover is composed of a mixture of solvents, additives and sometimes an activator. To be an effective paint remover, the solvent must be able to penetrate multiple layers of paint and have solubility to cause the paint to swell which breaks the bond of the paint to the substrate. The movement of the solvent from the paint remover to the paint layer is call diffusion and is the result of the random kinetic movement of the solvent. The rate of diffusion of is affected by the size of the solvent molecule (molar volume) and the polarity of the molecule. Smaller, nonpolar molecules will have a higher diffusion rate into the coating than molecules that are larger or more polar. The more effective replacements for methylene chloride will be molecules with the following general characteristics, small polar or halogenated molecules, five-member cyclic rings or six-member aromatic rings. These types of molecules are generally flammable and will also have health and safety risks.

Additives, such as surfactants, thickeners and paraffin wax are added to modify the physical properties of the paint remover. Surfactants improves the wetting of the surface by the paint remover and permits the use of water for clean-up after the paint has been stripped. Thickeners are added to allow the paint removers to cling to vertical surfaces. To reduce the evaporation of methylene chloride and other solvents in the paint remover, paraffin wax is added. Paraffin wax reduces the evaporation of the solvents by forming a physical barrier between the paint remover and air. The weight loss of methylene chloride over a period of five hours was compared to the weight loss of a paint remover containing more than 60% methylene chloride and an evaporation retarder with the results shown in **Figure 1.** Approximately 20 grams of methylene chloride and 20 grams of the paint remover were placed in separate containers and the weight of the sample remaining was determined at timed intervals. After 30 minutes, only 0.5% of the straight methylene chloride remained in the container. The result of the study showed that evaporation retarder is effective in reducing the evaporation rate of methylene chloride from the paint remover. As shown in **Figure 1**, 98.9% of the paint remover remained after 30 minutes and 93.5% remained after five hours. Since the methylene chloride based paint remover (containing evaporation retardant) is effective after 15 minutes from application, the amount of methylene chloride released into the atmosphere during this time is minimal, minimizing the inhalation risk to the product user. At 15 min, only 0.6% of the methylene chloride based paint stripper formula has evaporated.

**Figure 1.** Comparison of weight loss of methylene chloride to a methylene chloride paint remover formulated with an evaporation retarder at 70°F. At 15 min, only 0.6% of the methylene chloride based paint stripper formula has evaporated.




To increase the performance of the paint remover, an acid or a base is sometimes added as an activator. The activator is thought to disrupt the bond between the substrate and the paint and weaken or break the chemical or physical bonds in the polymer that is used in the paint. Formic acid, ammonium hydroxide and ethanolamine are common activators used in paint removers.

To establish the performance criteria of methylene chloride based paint removers, the label copies from different manufactures were evaluated for consumer benefits. The three most important criteria include:

A. Fast removal of the coating, starts working within 15 minutes.
B. Removal of many types of coatings including oil-based and epoxy paints for architectural coatings and factory applied OEM automotive paints
C. Removal of multiple layer of coatings

Other criterial considered in the evaluation of the paint remover includes the cost of the paint remove and the VOC content of the paint remover. The VOC content of paint removers is limited to 50 % by weight. When considering viability of a paint remover it must be considered that the paints to be removed are generally older and more chemically resistant than many paints available today. While water-based latex paints are widely available and chemically easily removed, they were not nearly as common 30 or more years ago. Furthermore, there are coatings in common use today that are

considered more chemically resistant than water-based latex paints. Once again, this study focuses on the more difficult, chemically resistant oil-based alkyd and solvent-born two-part epoxy paints.

## MATERIALS AND METHODS

The procedure used to test the performance of the solvents and paint removers is based on a modification of the ASTM D-6189 (2003) test method (Standard Practice for Evaluating the Efficiency of Chemical Removers for Organic Coatings). Modification of the procedure included using 12 x 8 inch panels instead of 12 x 12 inch panels and the panels were treated with five coats of the oil-based alkyd paint instead of three coats as described in the panel preparation procedure in the ASTM D-6189 test method. Painted panels aged 1 month were used for screening experiments and painted panels aged 1 year were used for final efficacy validation. The solvents and paint removers were applied to the panel using a pipette instead of following manufactures directions for application as called for in the ASTM test method. During the paint removal step, scrapping was performed using moderate force with a plastic paint scrapper.

**Solvent Selection –** The solvents used in this study were selected from solvents currently used in non-methylene chloride paint removers, solvents recommended as methylene chloride replacements by chemical manufacturers, and the EPA Exempt VOC Solvents list. Technical grade samples of the solvents were obtained and used in this study's experimental formulations without further purification.

**Paint Remover Selection** – The paint removers used in this study were purchased from hardware stores or from suppliers on the internet. Composition and the flash point of the paint removers based on information found in the Material Safety Data Sheets (MSDS) are listed in **Appendix A.** All paint removers were used as is in the experiments.

**Experimental Paint Removers** – Based on the results of the solvents screening testing, two alternative methylene chloride solvents were identified as having some paint remover potential. These solvents were formulated into paint removers that meet the 50 wt% VOC requirements. Three other experimental formulas based on solvent chemistry utilized by paint removers on the market today were also formulated into experimental paint removers with the VOC content less than 50 wt%. These experimental paint removers are listed below:

A. a solvent based remover based on toluene, methanol, and acetone
B. a solvent based remover based on 1,2 trans-dichloroethylene, methanol, and acetone
C. a solvent based remover based on 1,3-dioxolane, methanol, and acetone
D. an emulsion based on benzyl alcohol
E. an emulsion based on dibasic esters (DBE)

**Paint Selection -** Oil-based alkyd paint was selected to be used since it has historically been the most predominantly used paint technology and consumers are typically stripping older items which contains multiple layers of this type of paint. Two-part component epoxy paint was also selected because it is the most difficult paint technology to remove and is frequently used in industry applications. The paints used were purchased from a local hardware or paint stores. The paints purchased for this study are listed in Table 1 along with numbers of layers of paint used on the test panel. Only one type of paint was used for each test panel.

**Table 1**. List of paint, paint type and number of coatings used in study

| Paint | Paint Type | Number of Coatings |
|---|---|---|
| Rust-Oleum Professional High Performance Protective Enamel Exterior Gloss | Oil-based alkyd paint | 5 |
| Sherwin Williams Macropoxy 646 | Two component oil-based epoxy paint | 3 |

**1 Month Aged Panel Preparation Procedure –** Sanded birch plywood (4 ft. x 4 ft. x ½ in.) was cut into approximately 12 x 8 inch panels. A four-inch multi-purpose paint roller was used to apply the coats of the designated paint to the birch panels as determined in Table 1. Each layer of paint was dried for four hours at ambient conditions and then was placed in a laboratory oven at 50°C overnight. Each layer of paint was tinted to a different color to increase the visibility of the paint layers. The color schematic went as follows: Blue = color of 1$^{st}$ paint layer applied, White = color of 2$^{nd}$ paint layer applied, Green = color of 3$^{rd}$ paint layer applied, Yellow = color of 4$^{th}$ paint layer applied, Red= last paint layer applied. After the red coat of paint was applied, the panels were then aged for 30 days at 50°C in the laboratory. The test panels were then stored at ambient conditions until needed for the stripping test.

**1 Year Aged Panels-** Painted panels aged for 1 month/30 days are only good for giving directional data on the efficacy of a paint stripper. These 1 month aged panels are typically used by the formulation chemist to quickly screen new chemistries to see if they have the potential of becoming an efficacious paint remover. The reality is that consumers are trying to remove multiple layers of paint off items that are many years old. As mentioned in the introduction, alkyd paint types get harder to remove over time due to their chemistry. True efficacy validation of a paint remover requires it to be tested on Alkyd painted boards that have been allowed to age for at least 1 year. These boards were initially prepared in the same manner as the 1 month aged boards, but were allowed to sit at ambient conditions for up to a year prior to testing.

**Automotive Panel Preparation** – The hood from a 2006 Chevrolet Impala SS was purchased in good condition with the factory paint intact. The hood was cleaned with a damp cloth and used in testing without further modifications. The original paint was used on the hood, so the paint job during removal testing was at least 9 years old. The age of this paint is not as of great importance due to the chemistry being stable over time in comparison to the Alkyd paint which continues to react and get stronger.

**Neat Solvent Screening** – Neat solvent screening was done on 1 month aged boards to generate directional efficacy data on chemicals that might be promising to be incorporated in a paint remover formula. A grid is marked on the panel with masking tape creating test cells approximately 1 ½ in. x 1 ½ in. for the stripping trials. Each cell was labeled with the name of the solvent to be tested and the duration time of the test. A C31 Large Commercial Sponge from 3M was cut to approximately sized 1 ½ in. x 1 ½ in. x ¼ in. pieces were placed on each test cell to control evaporation and retain the solvent to the test area. For each sample, 2 ml of solvent was applied to the sponge and a timer is started. Additional solvent was added to the sponges as needed to ensure that the solvent remained in contact with the surface of the test panel. At the timed intervals, the test area was scraped using a plastic scraper and evaluated for the effects on the coatings and the number of layers of paint removed.

**Experimental Paint Remover Screening and Validation –** Experimental paint remover formulas were tested on 1 month aged boards to get directional efficacy data in comparison to a commercialized paint remover competitive set. This process helps weed out underperforming formulas prior to testing on valuable 1 year aged boards. This same experiment was then repeated on 1 year aged alkyd painted boards to validate the true efficacy of the experimental and commercially available paint removers. A grid was marked on the panel with masking tape to create test cells of approximately 1 ½ in. x 1 ½ in. dimensions. Each cell was labeled with the name of the solvent to be tested and the time duration of the test. Approximately 2 ml of the paint remover was applied to the cell and a timer is started. At timed intervals, the test area was scraped using a plastic scraper and judged for the effects on the coating and the numbers of layers of paint removed.

## Results

**Neat Solvent Screening** – Neat solvent experiments were done on 1 month aged painted boards for the sole purpose of getting directional efficacy data to drive future non-methylene chloride formulation development. The results comparing the performance of methylene chloride to the 22-alternate solvents selected are listed in Table 2. The performance was evaluated after 15 minutes, 30 minutes and 1 hour with number of layers of paint removed and the effect of the solvent on the paint noted. Methylene chloride performed the best removing all five layers of oil-based alkyd paint and two layers of the two-component oil-based epoxy paint in 15 minutes. Trans-1,2-dichloroethylene and 1,3-dioxolane were identified as the best performing alternate solvent removing all five layers of the oil-based alkyd paint in 30 minutes. After 1 hour, 1,3-dioxolane removed two layers of the two-component oil-base epoxy paint, however, trans-1,2-dichloroethylene failed to remove any layers of the epoxy paint after an hour. Results from this experiment helped drive decisions on which chemicals could be used in new experimental paint removal formulas that did not utilize methylene chloride.

**Table 2.** Neat solvent experiments were done on 1 month aged painted boards for the sole purpose of

| Chemical (Neat) | Alkyd (5 Layers) | | | Epoxy (3 Layers) | | |
|---|---|---|---|---|---|---|
| | 15 min | 30 min | 1 hrs | 15 min | 30 min | 1 hrs |
| methylene chloride | 5 | 5 | 5 | 2 | 2 | 2 |
| trans-1,2 dichloroethylene | 5 | 5 | 5 | | | |
| 1,3 dioxolane | 5 | 5 | 5 | | | 2 |
| n-methyl-2-pyrrolidone | | 5 | 5 | | | |
| acetone | 5 | 5 | 5 | | | |
| dimethoxymethane (methylal) | | 5 | 5 | | | |
| n-butyl propionate | | | 5 | | | |
| dimethyl sulfoxide (DMSO) | | | 4 | | | |
| dimethyl carbonate | | | | | | |
| benzyl methyl ether | | | | | | |
| TOC (2,5,7,10 tetraoxaundecane) | | | | | | |
| 3-methoxy-3-methyl-1-butyl acetate (MMB-AC) | | | | | | |
| Steposol MET-10U | | | | | | |
| PCBTF/Oxsol 100 | | | | | | |
| 3-methoxy-3-methyl-1-butanol (MMB) | | | | | | |
| Eastman Omnia (butyl-3-hydroxybutyrate) | | | | | | |
| benzyl alcohol | | | | | | |
| dibasic esters (LVP) | | | | | | |
| dibutoxymethane (butylal) | | | | | | |
| propylene carbonate | | | | | | |
| Elevance Clean 1200 | | | | | | |
| soya methyl ester | | | | | | |
| glyercol formal | | | | | | |

| | |
|---|---|
| no effect on coating | |
| slight softening of paint but no removal with plastic scraper | |
| paint has softened requiring effort to remove with plastic scraper | |
| paint has blistered with all layers paint removed with plastic scraper | |

getting directional efficacy data to drive future formulation development. Results of solvent testing showing the layers of oil-based alkyd and two component oil- based epoxy removed.

The performance of trans-1,2-dichloroethylene and 1,3-dioxolane in removing OEM automotive paint was then compared to methylene chloride and three solvents n-methyl-2-pyrrolidone, benzyl alcohol and DBE currently used in commercially available non-methylene chloride paint removes with the results listed in **Table 3.** The performance of the solvents was evaluated after 15 minutes, 30 minutes, 1 hour and 4 hours with number of layers of paint removed and the effect of the solvent on the paint noted in **Table 3.** Once again methylene chloride performed the best by removed the clear and color coat in fifteen minutes. Trans-1,2-dichloroethylene and 1,3-dioxolane removed the clear and color coat after 30 minutes while NMP, benzyl alcohol and DBE had no effect on the paint after four hours. None the neat solvents, including methylene chloride, stripped all layers of the automotive coating including the primer. Only a formulated paint remover would remove all layers of an automotive coating.

**Table 3.** Results of solvent testing showing the layers of OEM automotive paint removed.

| Chemical (Neat) | Automotive Coating | | | |
|---|---|---|---|---|
| | 15 min | 30 min | 1 hrs. | 4 hrs. |
| methylene chloride | | | | |
| trans-1,2 dichloroethylene | | | | |
| 1,3 dioxolane | | | | |
| n-methyl-2-pyrrolidone | | | | |
| benzyl alcohol | | | | |
| dibasic esters (LVP) | | | | |

| | |
|---|---|
| No effect | |
| Stripped clear coat and top coat | |
| Stripped clear coat, top coat and base coat | |

## Experimental Formula Paint Remover Screening on 1 month Aged Boards

Experimental paint remover formulas were tested on 1 month aged boards to get directional efficacy data in comparison to a commercialized paint remover competitive set. This process helps weed out underperforming formulas prior to testing on valuable 1 year aged boards. Test results comparing the performance of three methylene chloride paint removers to 5 experimental formulas and 26 commercial non-methylene chloride paint removers on one month aged boards are presented in **Table 4**. The panels used in this experiment were evaluated after 5 minutes, 15 minutes, 30 minutes, 1 hour and 4 hours with the numbers of layers of paint stripped by the paint remover recorded. For test panels

painted with oil-based alkyd paint, two of the three methylene chloride paint removers, Klean Strip Aircraft Remover and Klean Strip Premium Stripper, stripped all five layers of the alkyd paint after five minutes. The third paint remover, Klean Strip Strip-X, contains less methylene chloride and took 15 minutes to strip the five layers of the alkyd paint. Experimental Formulas A, B, and C were also able to strip all five layers of the oil-based alkyd paint in 15 minutes. Experimental Formula A was formulated with toluene, methanol and acetone. Experimental Formulas B and C contained the two alternate solvents identified in the alternated solvent study and were formulated with 1,2 trans-dichloroethylene, methanol, and acetone and 1,3-dioxolane, methanol, and acetone. Experimental Formula D based on a benzyl alcohol emulsion and Experimental Formula E based on a DBE emulsion failed to strip any layers of the alkyd paint after four hours. Fifteen of the twenty-six commercial non-methylene chloride paint removers tested stripped all layers of alkyd paint in four hours. Eight of sixteen paint removers that stripped the alkyd paint were formulated with NMP. Five of the sixteen paint removers were formulated for professionals to remove automotive or aircraft coatings were based a blend of solvents and high levels of an activator. The remaining two formulas were based on dimethyl sulfoxide (DMSO) or caustic.

For the panels painted with the two-component oil-based epoxy paint, two of the three methylene chloride paint removers, Klean Strip Aircraft Remover and Klean Strip Premium Stripper, stripped two layers of the epoxy paint after 15 minutes. The third paint remover, Klean Strip Strip-X which contains less methylene chloride, took four hours to remove two layers of the epoxy paint. The experimental and

**Table 4.** Results of paint remover screening showing the layers of oil-based alkyd and two-component oil-based epoxy removed on 1 month aged panels. Promising experimental formulations from this test were later validated on 1 year aged panels with competition.

| Company | Paint Remover | Ingredients (MSDS) | Retail Cost (gallon) | Alkyd (5 Layers) | | | | | Epoxy (3 Layers) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5 min | 15 min | 30 min | 1 hrs | 4 hrs | 15 min | 30 min | 1 hrs | 4 hrs |
| W. M. Barr | Klean-Strip Aircraft Remover | methylene chloride/methanol/Tall oil/ammonium hydroxide/xylene | $27.99 | 5 | 5 | 5 | 5 | 5 | 2 | 2 | 2 | 2 |
| | Klean-Strip Premium Stripper | methylene chloride/methanol/Stoddard solvent | $22.98 | 5 | 5 | 5 | 5 | 5 | 2 | 2 | 2 | 2 |
| | Klean-Strip Strip-X Stripper | methylene chloride/methanol/toluene/acetone/xylene | $18.97 | | 5 | 5 | 5 | 5 | | | | 2 |
| | Citristrip Safer Paint & Varnish Stripping Gel | NMP/DBE | $39.94 | | | | 5 | 5 | | | | |
| | Experimental Formula A | toluene/acetone/methanol | $23.88* | | 5 | 5 | 5 | 5 | | | | |
| | Experimental Formula B | 1,2 trans dichloroethylene/acetone/methanol | $42.97* | | 5 | 5 | 5 | 5 | | | | |
| | Experimental Formula C | 1,3 dioxolane/acetone/methanol | $31.55* | | 5 | 5 | 5 | 5 | | | | |
| | Experimental Formula D | benzyl alcohol emulsion | $39.96* | | | | | | | | | |
| | Experimental Formula E | DBE emulsion | $34.00* | | | | | | | | | |
| Dumond | Peel Away 1 | calcium hydroxide/magnesium hydroxide/sodium hydroxide/water | $68.30 | | | 1 | 3 | 5 | | | | |
| | Peel Away 5 Soy Based | benzyl alcohol/NMP/soya methyl ester/DBE/water | $78.12 | | | | | 5 | | | | |
| | Peel Away 7 | benzyl alcohol/NMP/DBE/water | $90.15 | | | | | | | | | |
| | Smart Strip | water/benzyl alcohol/water | $50.59 | | | | | | | | | |
| | Smart Strip Pro | water/benzyl alcohol/formic acid/water | $77.74 | | | | | | | | | |
| Ecoprocote | EcoFast HD Heavy Duty Paint Stripper | NMP/soy methyl ester/water | $54.99 | | | | | | | | | |
| EZ Strip | EZ Strip Paint and Varnish Stripper | DBE/triethyl phosphate/water | $38.98 | | | | | | | | | |
| Franmar | Soy-Gel Paint and Urethane Remover | NMP/DBE/soy ester/water | $81.20 | | | | | 5 | | | | |
| Motsenbocker | Lift Off Paint and Varnish Remover | acetone/2-butoxyethanol/DBE/water | $49.94 | | | | | | | | | |
| Packaging Service Co. | Crown Paint Strip Next | DBE/DMSO/water | $47.92 | | | | | 5 | | | | |
| PPG | DuraPrep 200 Coating Remover (Gel) | benzyl alcohol\solvent naphtha/2-aminoethanol/nonylphenol, branched ethoxylated | $41.34 | | | | | 5 | | | | |
| | DuraPrep 240 Industrial Coating Remover (Gel) | benzyl alcohol/hydrogen proxide/solvent naphtha/glycollic acid/malic acid/barium bis(dinonylnaphthalenesuphonate)/amines, coco alkyl, ethoxylated | $40.75 | | | | | 5 | | | | |
| | DuraPrep Prep 400 Overspray Remover | benzyl alcohol/petroleum distillates/glycolic acid/quaternary ammonium compounds/hydrogen proxide/water | $127.60 | | | | | 5 | | | | |
| Solvent Kleene | D-Zolve 1012 Powder Coating Remover (immersion tank) | alkyl methyl ester/potassium hydroxide/cyclic amide/water | Not Available | | 1 | 2 | 2 | 5 | | | | |
| | D-Zolve 15-33R (aircraft) | alkyl methyl ester/petroleum naphtha/benzyl alcohol/methyl phenyl ether/water | Not Available | | | | | 5 | | | | |
| Sunnyside | Multi-Strip Professional Paint Remover | DBE/NMP/formic acid/water | $49.97 | | | | | 5 | | | | |
| | Ready Strip Pro | DBE/NMP/formic acid/water | $39.97 | | | | | | | | | |
| | Ready Strip Safer Paint & Varnish Remover | DBE/NMP/formic acid/water | $34.71 | | | | | | | | | |
| | Ready-Strip Spray | NMP/DBE/monoethanolamine/water | $39.92 | | | | | | | | | |
| | Ultri-Strip | DBE/NMP/formic acid/water | $66.85 | | | | | 5 | | | | |
| This Stuff Works, Inc. | TSW2 Multi-Master | NMP/DBE/water | $99.95 | | | | | 5 | | | | |
| | TSW2G Multi-Master (Gel) | NMP/DBE/water | $99.95 | | | | | 5 | | | | |
| | TSW3G (GEL) Mason-Master | potassium hydroxide/butyl cellosolve/water | $85.00 | | | 1 | 1 | 4 | | | | |
| | TSW9 Plasti-Master | DBE/proprietary surfactant/water | $99.95 | | | | | | | | | |
| Zinsser | Magic Strip Citrus-Action | NMP/DBE/d-limonene/water | $84.32 | | | | | 5 | | | | |

| | |
|---|---|
| no layers of paint were removed with plastic paint scraper | |
| paint has softened requiring effort to remove with plastic scraper | |
| paint has blistered with all layers of paint removed with plastic scraper | |

* Estimated retail price of experimental formulas based on formula, packaging, and manufacturing costs.

the commercial paint removers failed to strip any layers of the epoxy paint at 15 and 30 minutes, 1 hour and four hours.

Since the experimental formulas A, B, and C showed comparable efficacy on the 1 month aged alkyd painted board in comparison to the methylene chloride containing formulas they were allowed to advance onto the validation test done on a 1 year aged alkyd painted board.

**Final Efficacy Validation of Experimental Formulations vs Competition on 1 Year Aged Boards**

As shown in the results in Table 5, Klean Strip Premium Stripper took 15 minutes to remove all layers of paint on a 1 year aged panel but only 5 minutes on the newer 1 month aged panel. The alternate paint removers also required more time to strip all layers of the alkyd paint on the aged panels. The time to strip all layers increased to an hour compared to 30 minutes for the Experimental Formulas A, B, and C. Crown Safer Paint Strip stripped all layers of paint after 24 hours on the new panels but failed to remove any layers of paint on the 1 year aged panels. See **Appendix B** for a visual of 1 month and 1 year aged panels used in this validation test. The difference in results between the 1 month aged panels in Table 4 and Table 5 is due to the inconsistencies of how Alkyd paint cures over a month time. Experiments done in Table 4 were done with one month boards created on different time periods than used in table 5. As the alkyd painted panels age, the alkyd resin continues to crosslink making the paint more difficult to strip. More consistent results are obtained using alkyd painted panels which are aged for at least one year. 1 month aged panels are used strictly for directional feedback and should not be used to validate the final efficacy of a paint remover.

**Table 5.** Validation results of paint remover testing done on panels aged 1 month to 1 year. Since Alkyd paint continues to bond and get harder to remove over time, 1 year aged paint boards are more realistic on what the consumer will experience while paint stripping. Klean-strip Premium Stripper methylene chloride based stripper is far superior to the current competitive set on the market. New experimental formulas are extremely flammable and do not perform as fast as current methylene chloride formulations. The difference in results between the 1 month aged panels in Table 4 and Table 5 is due to the inconsistencies of how Alkyd paint cures over a month time. As the alkyd painted panels age, the alkyd resin continues to crosslink making the paint more difficult to strip. More consistent results are obtained alkyd painted panels which are aged for at least one year. 1 month aged panels are used strictly for directional feedback.

| Paint Remover | Ingredients (MSDS) | Month Old Panel - Alkyd (5 Layers) | | | | | | Year Old Panel - Alkyd (5 Layers) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 5 min | 15 min | 30 min | 1 hrs | 4 hrs | 24 hrs | 5 min | 15 min | 30 min | 1 hrs | 4 hrs | 24 hrs |
| Klean-Strip Premium Stripper | methylene chloride/methanol/Stoddard solvent | 5 | 5 | 5 | 5 | | | | 5 | 5 | 5 | | |
| Klean-Strip Strip-X Stripper | methylene chloride/methanol/toluene/acetone/xylene | | 1 | 5 | 5 | | | | | 5 | 5 | | |
| Experimental Formula A | toluene/acetone/methanol | | 1 | 5 | 5 | | | | | | 5 | | |
| Experimental Formula B | 1,2 trans dichloroethylene/acetone/methanol | | | 5 | 5 | | | | | | 5 | | |
| Experimental Formula C | 1,3 dioxolane/acetone/methanol | | 1 | 5 | 5 | | | | | | 5 | | |
| Citristrip Safer Paint & Varnish Stripping Gel | NMP/DBE | | | | | 5 | 5 | | | | | 5 | 5 |
| Peel Away 1 | calcium hydroxide/magnesium hydroxide/sodium hydroxide | | | | | 3 | 5 | | | | | 5 | 5 |
| Smart Strip | water/benzyl alcohol | | | | | | 5 | | | | | | 5 |
| Smart Strip Pro | water/benzyl alcohol/formic acid | | | 1 | 1 | 1 | 5 | | | | | | 5 |
| EZ Strip Paint and Varnish Stripper | DBE/triethyl phosphate | | | | | | | | | | | | |
| Lift Off Paint and Varnish Remover | acetone/2-butoxyethanol/DBE | | | | | | | | | | | | |
| Crown Safer Paint Strip | DBE/DMSO | | | | | | 5 | | | | | | |

| | |
|---|---|
| no layers of paint were removed with plastic paint scraper | |
| paint has softened requiring effort to remove with plastic scraper | |
| paint has blistered with all layers of paint removed with plastic scraper | |

Test results comparing the performance of three methylene chloride paint removers to five experimental formulas and five commercial non-methylene chloride paint removers on an OEM automotive coating are listed in Table 6. The five commercial non-methylene chloride paint removers were formulated to remove automotive or aircraft coatings containing a blend of solvents and an activator. The effects on automotive coating was evaluated after 15, and 30 minutes, 1 hour and 4 hours. Only one of the paint removers tested, Klean Strip Aircraft Remover, stripped all layers of the OEM automotive coating. Klean Strip Aircraft Remover stripped the clear, color and base coat in 15 minutes and continued to strip all layers at 4 hours without drying. Klean Strip Aircraft Remover is formulated to remove automotive coatings containing methylene chloride and the activator ammonium hydroxide. Klean Strip Premium Stripper and Klean Strip Strip-X, removed the clear and color coat after 15 minutes but did not strip the primer coat after four hours. Klean Strip Premium Stripper and Klean Strip-X are methylene chloride paint removers but do not contain an activator. Experimental Formulas A, B, and C were also able to strip the clear and color coat after 15 minutes but failed to strip the primer coat after 4 hours. Experimental Formulas D and E failed to strip the automotive coating after four hours. D-Zolve 15-33R rom Solvent Kleene was the only commercial non-methylene chloride paint remover tested that stripped the automotive coating. D-Zolve 15-33R is a paint remover designed to remove aircraft coatings and took four hours to remove the clear and color coats.

**Table 6.** Results of paint remover testing on an OEM Automotive Coating.

| Company | Paint Remover | Ingredients (MSDS) | Automotive Coating | | | |
|---|---|---|---|---|---|---|
| | | | 15 min | 30 min | 1 hrs | 4 hrs |
| W.M. Barr | Klean-Strip Aircraft Remover | methylene chloride/methanol/Tall oil/ammonium hydroxide/xylene | | | | |
| | Klean-Strip Premium Stripper | methylene chloride/methanol/Stoddard solvent | | | | |
| | Klean-Strip Strip-X Stripper | methylene chloride/methanol/toluene/nonyl phenol ethoxylate/acetone/xylene | | | | |
| | Citristrip Safer Paint & Varnish Stripping Gel | NMP/DBE | | | | |
| | Experimental Formula A | toluene/acetone/methanol | | | | |
| | Experimental Formula B | 1,2 trans dichloroethylene/acetone/methanol | | | | |
| | Experimental Formula C | 1,3 dioxolane/acetone/methanol | | | | |
| | Experimental Formula D | benzyl alcohol emulsion | | | | |
| | Experimental Formula E | DBE emulsion | | | | |
| PPG | DuraPrep 200 Coating Remover (Gel) | benzyl alcohol\solvent naphtha/2-aminoethanol/nonylphenol, branched ethoxylated | | | | |
| | DuraPrep 240 Industrial Coating Remover (Gel) | benzyl alcohol/hydrogen proxide/solvent naphtha/glycollic acid/malic acid/barium bis(dinonylnaphthalenesuphonate)/amines, coco alkyl, ethoxylated | | | | |
| | DuraPrep Prep 400 Overspray Remover | benzyl alcohol/petroleum distillates/glycolic acid/quaternary ammonium compounds/hydrogen proxide | | | | |
| Solvent Kleene | D-Zolve 1012 Powder Coating Remover (immersion tank) | alkyl methyl ester/potassium hydroxide/cydic amide | | | | |
| | D-Zolve 15-33R (aircraft) | alkyl methyl ester/petroleum naphtha/benzyl alcohol/methyl phenyl ether | | | | |

| | |
|---|---|
| No effect | |
| Stripped clear coat and top coat | |
| Stripped clear coat, top coat and base coat | |

## Conclusion

The performance of methylene chloride was compared to 22 alternate solvents selected as possible replacements for methylene chloride in paint removers. Testing was conducted on three types of paints using wood panels painted with an oil-based alkyd paint, wood panels paint with a two-component oil-based epoxy paint and an OEM automotive coating. Trans-1,2-dichloroethylene and 1,3-dioxolane were

identified as the best performing alternate solvent tested. However, based on the results from this study, none of the alternative solvents tested were determined to be an adequate replacement for methylene chloride.

Based on the results of the solvents screening testing, two solvents, trans-1,2-dichloroethylene and 1,3-dioxolane were selected as having some paint remover potential and were formulated into paint removers that met the 50 wt% VOC limit for paint removers. Three other experimental formulas were also formulated based on a toluene, methanol and acetone formula, a benzyl alcohol emulsion formula and a DBE emulsion formula. Three methylene chloride paint removers were then compared to the five-experimental formula and 26 commercially available non-methylene chloride paint removers. Based on the results of the paint remover study, none of the experimental formulas or the 26 non-methylene chloride paint removers were determined to be an adequate replacement for methylene chloride paint removers. Performance of the experimental formulas based on trans-1,2-dichloroethylene and 1,3-dioxolane was determined to be no better than the experimental formula based on toluene, methanol and acetone.

Methylene chloride has been the preferred for use in paint removers for seventy. Consumers expect that paint removers to be able to remove many types of coatings, remove multiple layers of the coating and to start working within 15 minutes and quickly remove the coating. To be an effective paint remover, the solvent must be able to penetrate multiple layers of paint and have solubility to cause the paint to swell which breaks the bond of the paint to the substrate. The size of the solvent molecule and the polarity of the molecule affects rate the solvent penetrates the coating. The movement of the solvent from the paint remover to the paint layer is call diffusion and is the result of the random kinetic movement of the solvent molecules. Smaller, nonpolar molecules will have a higher diffusion rate into the coating than molecules that are larger or more polar. The more effective replacements for methylene chloride will be molecules with the following general characteristics, small polar or halogenated molecules, five-member cyclic rings or six-member aromatic rings. Unlike methylene chloride, these types of molecules are most likely flammable and possibly will have a significant threat to health and safety.

**Appendix A.** Composition of Paint Removers and Flash Point as Listed in Material Safety Data Sheets

| Company | Paint Remover | Ingredients (MSDS) | | | Flash Point |
|---|---|---|---|---|---|
| | | Chemical Name | CAS Number | Weight % | |
| W. M. Barr | Klean Strip Aircraft Remover | methylene chloride | 75-09-2 | 60 – 100 | no flash to boiling |
| | | methanol | 67-56-1 | 5 – 10 | |
| | | ammonium hydroxide | 1336-21-6 | < 5 | |
| | | xylene | 1330-20-7 | < 5 | |
| | | hydrotreated light distillate (petroleum) | 64742-47-8 | < 5 | |
| | | fatty acid soap | 68132-50-3 | < 5 | |
| | | ethylbenzene | 100-41-4 | < 3 | |
| | Klean Strip Premium Stripper | methylene chloride | 75-09-2 | 60 – 100 | no flash to boiling |
| | | methanol | 67-56-1 | 10 – 20 | |
| | | Stoddard Solvent | 8052-41-2 | < 5 | |
| | Klean Strip Strip-X Stripper | methylene chloride | 75-09-2 | 30 – 40 | 30°F |
| | | methanol | 67-56-1 | 15 – 26 | |
| | | acetone | 67-64-1 | < 10 | |
| | | xylene | 1330-20-7 | < 10 | |
| | | toluene | 108-88-3 | < 10 | |
| | | ethylbenzene | 100-41-4 | < 5 | |
| | | ethyl alcohol | 64-17-5 | < 5 | |
| | | isopropyl alcohol | 67-63-0 | < 5 | |
| | Citristrip Stripping Gel | n-methyl-2-pyrrolidone | 872-50-4 | 30 – 60 | >200°F |
| | | dimethyl adipate | 627-93-0 | 10 – 30 | |
| | | dimethyl glutarate | 1119-40-0 | 10 – 20 | |
| | Experimental Formula A | acetone | 67-64-1 | 40 – 50 | 0°F |
| | | toluene | 108-88-3 | 40 – 50 | |
| | | methanol | 67-56-1 | < 10 | |
| | Experimental Formula B | acetone | 67-64-1 | 40 – 50 | 0°F |
| | | trans-1,2-dichloroethylene | 646-06-0 | 40 – 50 | |
| | | methanol | 67-56-1 | < 10 | |
| | Experimental Formula C | acetone | 67-64-1 | 45 – 55 | 0°F |
| | | 1,3-dioxolane | 646-06-0 | 40 – 50 | |
| | | methanol | 67-56-1 | < 10 | |
| | Experimental Formula D | benzyl alcohol | 100-51-6 | 20 - 40 | no flash to boiling |
| | | alcohol ethoxylate (alcohols, c9-11, ethoxylated) | 68439-46-3 | < 5 | |
| | Experimental Formula E | water | 7732-15-5 | 40 – 60 | no flash to boiling |
| | | dimethyl adipate | 627-93-0 | 10 – 30 | |
| | | dimethyl glutarate | 1119-40-0 | 10 – 20 | |
| | | starch | 9005-25-8 | 5 – 20 | |
| | | alcohol ethoxylate (alcohols, C9-11, ethoxylated) | 68439-46-3 | <5 | |

| Company | Paint Remover | Ingredients (MSDS) | | | Flash Point |
|---|---|---|---|---|---|
| | | Chemical Name | CAS Number | Weight % | |
| Dumond | Peel Away 1 | calcium hydroxide | 1305-62-0 | 21 | none |
| | | magnesium hydroxide | 1309-42-8 | 16 | |
| | | sodium hydroxide | 1310-73-2 | 9 | |
| | Peel Away 5 Soy Based | benzyl alcohol | 100-51-6 | 20 – 50 | > 200°F |
| | | n-methyl-2-pyrrolidone | 872-50-4 | 25 – 35 | |
| | | fatty acid methyl ester | 67784-80-9 | 15 – 20 | |
| | | alpha-(4-nonylphenyl)-omega-hydroxy-poly(oxy-1,2,ethanediyl) branched | 127087-0 | < 3 | |
| | | dimethyl glutarate | 1119-40-0 | 25 – 35 | |
| | | dimethyl adipate | 627-93-0 | | |
| | Peel Away 7 | benzyl alcohol | 100-51-6 | 20 – 40 | > 200°F |
| | | n-methyl-2-pyrrolidone | 872-50-4 | 10 – 20 | |
| | | alpha-(4-nonylphenyl)-omega-hydroxy-poly(oxy-1,2,ethanediyl) branched | 127087-0 | < 2 | |
| | | dimethyl glutarate | 1119-40-0 | 25 – 35 | |
| | | dimethyl adipate | 627-93-0 | | |
| | Smart Strip | water | 7732-18-5 | 40 – 60 | none |
| | | benzyl alcohol | 100-51-6 | 30 – 50 | |
| | | titanium dioxide | 13463-67-7 | 1 - 5 | |
| | Smart Strip Pro | water | 7732-18-5 | 40 – 60 | none |
| | | benzyl alcohol | 100-51-6 | 30 – 50 | |
| | | titanium dioxide | 13463-67-7 | 1 – 5 | |
| | | formic acid | 64-18-6 | 1 – 5 | |
| Ecoprocote | EcoFast HD Heavy Duty Paint Stripper | water | 7732-18-5 | Trade Secret | non-flammable |
| | | benzyl alcohol | 100-51-6 | Trade Secret | |
| | | Bio-Based Emulsion | Non-Hazardous | Trade Secret | |
| | | Solvent-Free Thickeners | Non-Hazardous | < 1 | |
| | | Solvent-Free Surfactants | Non-Hazardous | 1 – 5 | |
| EZ Strip | EZ Strip Paint and Varnish Stripper | dimethyl adipate | 627-93-0 | 3 – 7 | not listed |
| | | dimethyl succinate | 106-65-0 | 5 – 10 | |
| | | dimethyl glutarate | 1119-40-0 | 10 – 30 | |
| | | triethyl phosphate | 78-40-0 | 3 – 7 | |
| Frammar | Soy-Gel Paint and Varnish Stripper | n-methyl-2-pyrrolidone | 872-50-4 | 41 | > 200°F |
| | | dimethyl adipate | 627-93-0 | 40 – 45 | |
| | | dimethyl glutarate | 1119-40-0 | | |
| | | soy ester | 67781-80-9 | 15 – 20 | |
| | | Proprietary Thickening and Surfactant Blend | Proprietary | 1 – 5 | |
| Motsenbocker | Lift Off Paint and Varnish Remover | acetone | 67-64-1 | < 10 | not listed |
| | | 2-butoxy ethanol | 111-76-2 | Not Listed | |
| | | dimethyl adipate | 627-93-0 | Not Listed | |
| | | dimethyl succinate | 106-65-0 | Not Listed | |
| | | dimethyl glutarate | 1119-40-0 | Not Listed | |

| Company | Paint Remover | Ingredients (MSDS) | | | Flash Point |
|---|---|---|---|---|---|
| | | Chemical Name | CAS Number | Weight % | |
| Packaging Services Co | Crown Paint Strip Next | dimethyl sulfoxide | 67-68-5 | 20 – 25 | 160°F |
| | | dimethyl glutarate | 1119-40-0 | 45 – 45 | |
| | | dimethyl succinate | 106-65-0 | 10 – 20 | |
| | | dimethyl adipate | 627-93-0 | 5 – 15 | |
| | | alcohol ethoxylate surfactant | Not Listed | 0 – 1 | |
| PPG | DuraPrep 200 Coating Remover | benzyl alcohol | 100-51-6 | 15 – 40 | 221°F |
| | | solvent naphtha (petroleum), light aromatic | 64742-95-6 | 1 – 5 | |
| | | 2-aminoethanol | 141-43-5 | 1 – 5 | |
| | | nonylphenol, branched, ethoxylated | 68412-54-4 | 0.1 – 1 | |
| | DuraPrep 240 Industrial Coating Remover | benzyl alcohol | 100-51-6 | 15 – 40 | 178°F |
| | | hydrogen peroxide | 7722-84-1 | 5 – 10 | |
| | | solvent naphtha (petroleum), heavy aromatic | 64742-94-5 | 3 – 7 | |
| | | barium bis(dinonyl-naphthalenesulphonate) | 25619-56-1 | 0.1 – 1 | |
| | | amines, coco alkyl, ethoxylated | 61791-14-8 | 0.1 – 1 | |
| | DuraPrep Prep 400 Overspray Remover | 2-(methoxymethylethoxy) propanol | 34590-94-8 | 30 – 60 | 203°F |
| | | dimethyl sulfoxide | 67-68-5 | 7 – 13 | |
| | | dimethyl glutarate | 1119-40-0 | 5 – 10 | |
| | | benzyl alcohol | 100-51-6 | 5 – 10 | |
| Solvent Kleene | D-Zolve 1012 Power Coating Remover | alkyl methyl ester | Proprietary | Trade Secret | 170°F |
| | | potassium hydroxide | 1310-58-3 | 2 – 5 | |
| | | cyclic amide | 72-50-4 | 5 – 30 | |
| Sunnyside | Multi-Strip Professional Paint Remover | n-methyl-2-pyrrolidone | 872-50-4 | 15 – 35 | 203°F |
| | | dimethyl glutarate | 1119-40-0 | 20 – 35 | |
| | | dimethyl adipate | 627-93-0 | 5 – 10 | |
| | | dimethyl succinate | 106-65-0 | 5 – 15 | |
| | | formic acid | 64-18-6 | 1 – 2 | |
| | | non-hazardous components | N/A | 20 – 40 | |
| | Ready Strip Pro | benzyl alcohol | 100-51-6 | 20 – 35 | 205°F |
| | | n-methyl-2-pyrrolidone | 872-50-4 | 5 – 15 | |
| | | formic acid | 64-18-6 | 2 – 15 | |
| | | non-hazardous components | N/A | 50 – 65 | |
| | Ready Strip Safer Paint & Varnish Remover | benzyl alcohol | 100-51-6 | 20 – 35 | 205°F |
| | | n-methyl-2-pyrrolidone | 872-50-4 | 5 – 15 | |
| | | formic acid | 64-18-6 | 2 – 15 | |
| | | non-hazardous components | N/A | 50 – 65 | |
| | Ready Strip Spray | n-methyl-2-pyrrolidone | 872-50-4 | 35 – 50 | 205°F |
| | | dimethyl glutarate | 1119-40-0 | 20 – 35 | |
| | | dimethyl adipate | 627-93-0 | 5 – 20 | |
| | | dimethyl succinate | 106-65-0 | 3 – 5 | |
| | | monoethanolamine | 141-43-5 | 1 – 3 | |
| | | isopropanolamine mixture | 78-96-6 | 2 - 5 | |
| | | | 110-97-4 | | |
| | | | 122-20-3 | | |
| | | non-hazardous components | N/A | 45 – 50 | |

| Company | Paint Remover | Ingredients (MSDS) | | | Flash Point |
|---|---|---|---|---|---|
| | | Chemical Name | CAS Number | Weight % | |
| Sunnyside | Ready Strip Spray | n-methyl-2-pyrrolidone | 872-50-4 | 35 – 50 | 205°F |
| | | dimethyl glutarate | 1119-40-0 | 20 – 35 | |
| | | dimethyl adipate | 627-93-0 | 5 – 20 | |
| | | dimethyl succinate | 106-65-0 | 3 – 5 | |
| | | monoethanolamine | 141-43-5 | 1 – 3 | |
| | | isopropanolamine mixture | 78-96-6 | 2 - 5 | |
| | | | 110-97-4 | | |
| | | | 122-20-3 | | |
| | | non-hazardous components | N/A | 45 – 50 | |
| | Ultra-Strip | n-methyl-2-pyrrolidone | 872-50-4 | 35 – 50 | >200°F |
| | | dimethyl glutarate | 119-40-0 | 20 – 35 | |
| | | dimethyl adipate | 627-93-0 | 5 – 20 | |
| | | dimethyl succinate | 106-65-0 | 3 – 5 | |
| | | formic acid | 64-18-6 | 1 – 2 | |
| | | non-hazardous components | N/A | 5 – 35 | |
| This Stuff Works, Inc | TSW2 Multi-Master | n-methyl-2-pyrrolidone | 872-50-4 | Trade Secret | >212°F |
| | | dimethyl glutarate | 1119-40-0 | Trade Secret | |
| | | dimethyl adipate | 627-93-0 | Trade Secret | |
| | TSW2G Multi-Master (Gel) | n-methyl-2-pyrrolidone | 872-50-4 | Trade Secret | >212°F |
| | | dimethyl glutarate | 1119-40-0 | Trade Secret | |
| | | dimethyl adipate | 627-93-0 | Trade Secret | |
| | TSW3G (Gel) Mason-Master | potassium hydroxide | 1310-58-3 | Trade Secret | non-flammable |
| | | butyl cellosolve | 11-76-2 | Trade Secret | |
| | TSW9 Plasti-Master | dimethyl glutarate | 1119-40-0 | Trade Secret | >212°F |
| | | dimethyl adipate | 627-93-0 | Trade Secret | |
| | | proprietary surfactant | Trade Secret | Trade Secret | |
| Zinsser | Magic Strip Citrus-Action | n-methyl-2-pyrrolidone | 872-50-4 | 25 – 50 | >199°F |
| | | dimethyl glutarate | 1119-40-0 | 25 – 50 | |
| | | dimethyl adipate | 627-93-0 | 2.5 – 10 | |
| | | dimethyl succinate | 106-65-0 | 2.5 – 10 | |
| | | monoethanolamine | 141-43-5 | 2.5 – 10 | |
| | | d-limonene | 5989-27-5 | 1.0 – 2.5 | |

**Appendix B:** Photographs comparing test results on new and aged panels painted with an oil-based alkyd paint.

**Figure 1.** Results of stripping screening test on a new panel **(1-month-aged)** painted with an oil-based alkyd paint. **Column 1** is Klean Strip Premium (methylene chloride based), **Column 2** is Strip-X methylene chloride based (lower level), **Column 3** is an experimental formula containing toluene, **Column 4** is an experimental formula containing trans-1,2-dichloroethylene, **Column 5** is an experimental formula containing 1,3-dioxolane and **Column 6** is Citrus strip (contains NMP and DBE). Blue = 1st paint layer applied, White = 2nd paint layer applied, Green = 3rd paint layer applied, Yellow = 4th paint layer applied, Red= last paint layer applied. Seeing Red = no layers of paint were stripped.

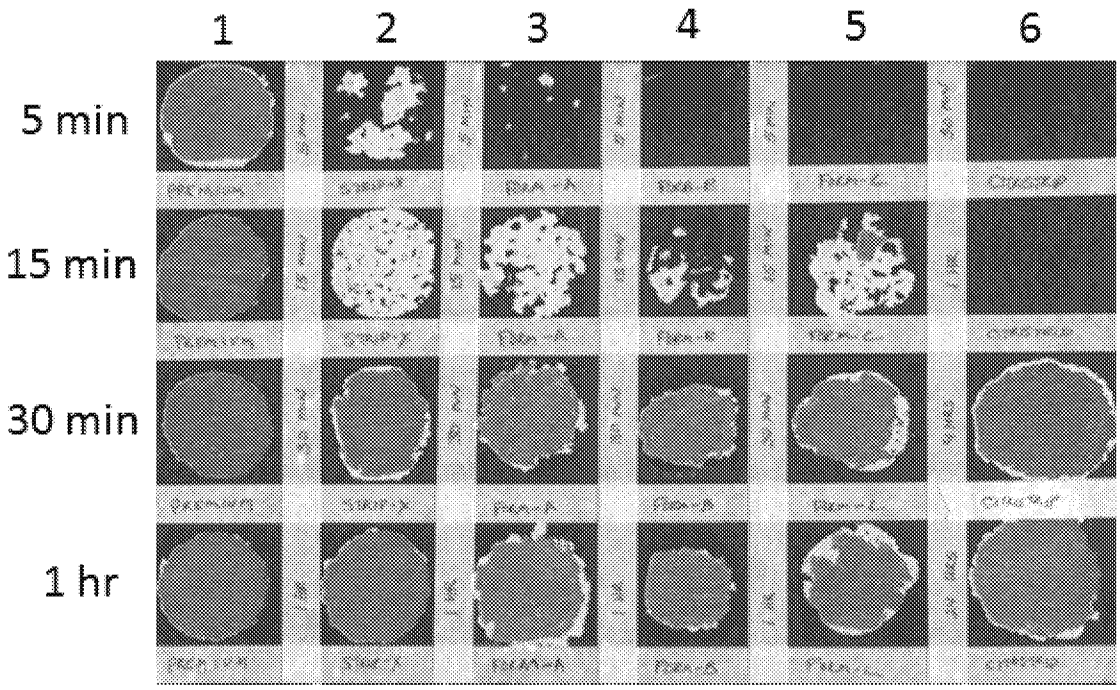


**Figure 2**. Results of stripping validation test on an aged panel **(1-year-aged)** painted with an oil-based alkyd paint. **Column 1** is Klean Strip Premium (methylene chloride based), **Column 2** is Strip-X methylene chloride based (lower level), **Column 3** is an experimental formula containing toluene, **Column 4** is an experimental formula containing trans-1,2-dichloroethylene, **Column 5** is an experimental formula containing 1,3-dioxolane and **Column 6** is Citrus strip (contains NMP and DBE). Blue = 1st paint layer applied, White = 2nd paint layer applied, Green = 3rd paint layer applied, Yellow = 4th paint layer applied, Red= last paint layer applied. Seeing Red = no layers of paint were stripped.

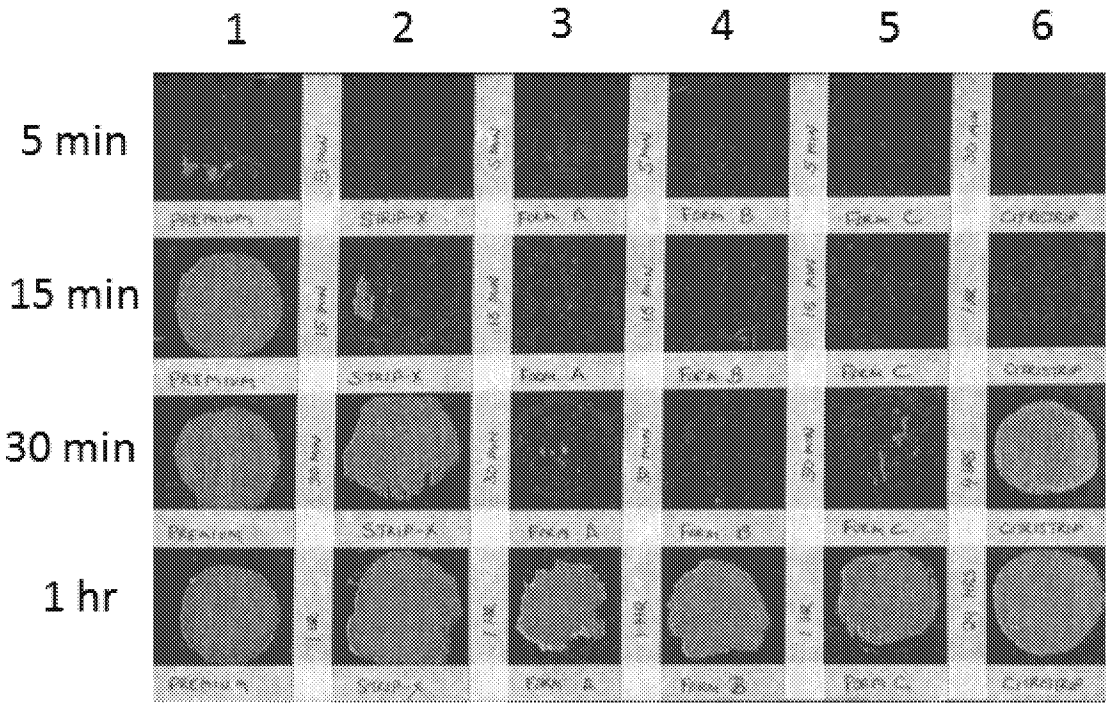


**Figure 3.** Results of stripping screening test on a new panel **(1-month-aged)** painted with an oil-based alkyd paint**. Column 1** is Peel Away 1 (caustic based), **Column 2** is Smart Strip (benzyl alcohol based), **Column 3** is Smart Strip Pro (benzyl alcohol based with formic acid), **Column 4** is EZ strip (DBE and triethyl phosphate), **Column 5** Lift Off (acetone and 2-butoxy ethanol and DBE based) and **Column 6** is Safer Paint Strip (DMSO and DBE based). Blue = 1st paint layer applied, White = 2nd paint layer applied, Green = 3rd paint layer applied, Yellow = 4th paint layer applied, Red= last paint layer applied. Seeing Red = no layers of paint were stripped. ** Ingredients of competitive products cited from MSDS and/or GC analysis.

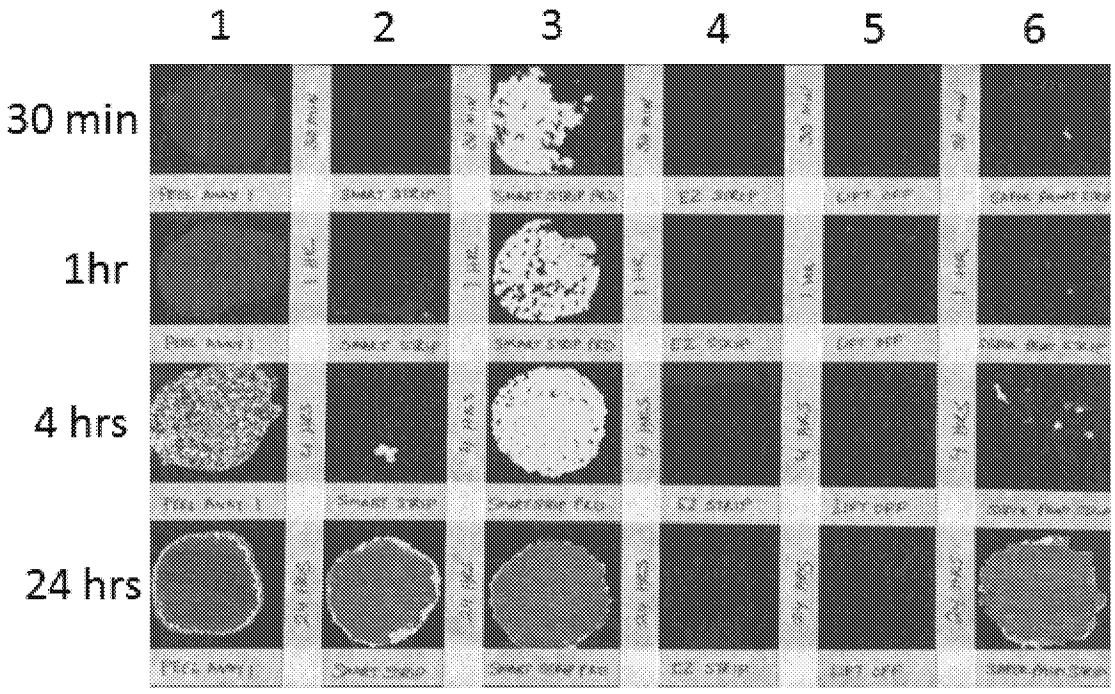
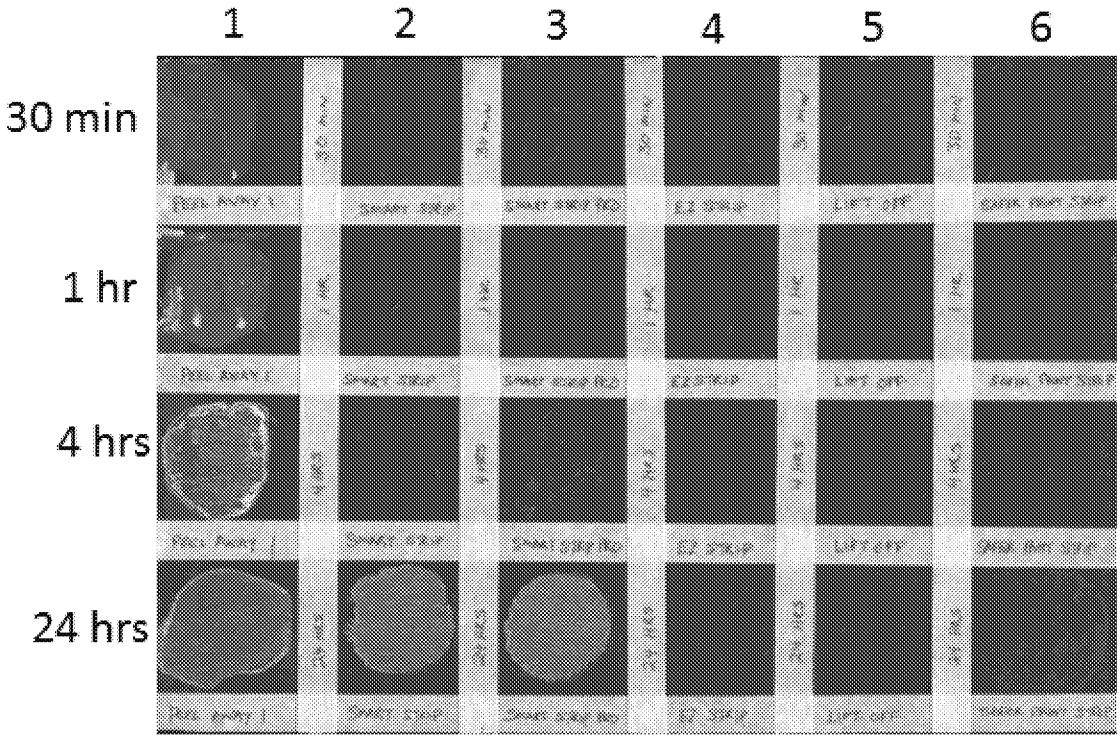


**Figure 4**. Results of stripping validation test on an aged panel **(1-year-aged)** painted with an oil-based alkyd paint. **Column 1** is Peel Away 1 (caustic based), **Column 2** is Smart Strip (benzyl alcohol based), **Column 3** is Smart Strip Pro (benzyl alcohol based with formic acid), **Column 4** is EZ strip (DBE and triethyl phosphate), **Column 5** Lift Off (acetone and 2-butoxy ethanol and DBE based) and **Column 6** is Safer Paint Strip (DMSO and DBE based). Blue = 1st paint layer applied, White = 2nd paint layer applied, Green = 3rd paint layer applied, Yellow = 4th paint layer applied, Red= last paint layer applied. Seeing Red = no layers of paint were stripped. ** Ingredients of competitive products cited from MSDS and/or GC analysis.



## Authors

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BERGESON & CAMPBELL PC

July 26, 2017

Via E-Mail

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Dear Jeffery:

Thank you for sharing with us the recent new drafts of four new chemicals categories with a focus on human health: Polymer Lung Overload; Polycationic Substances (Cationic Binding); Waterproofing Agents; and General Surfactants. We appreciate the effort by the U.S. Environmental Protection Agency (EPA) to upgrade and update the category documents and encourage continued activity in this area. We offer technical comments on the documents (appended) and encourage EPA to engage in a broader effort to solicit public comments. We recognize the critical role that the new chemicals categories have played in the implementation of the New Chemicals Program over time, however, we believe there is a need to further develop and refine these documents to inform more effectively decisions in the context of the science requirements under the amended Toxic Substances Control Act (TSCA).

The new chemicals categories prior to the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) were regarded primarily as a risk management tool to alert submitters to classes of new chemicals that were identified by EPA as being of concern. The write-ups for the most part consist of generic descriptions of potential environmental and/or human health hazards. The substance of these categories is closer to a structural alert than to a category like those developed in the Organization for Economic Cooperation and Development (OECD) program. The New Chemicals Program category documents do not provide the kind of understanding needed to inform submitters of read-across and hazard characterization issues that should be considered in submitting relevant information on a new chemical. This difference between the (traditional) new chemicals categories and categories developed under the OECD grouping programs is not always apparent to premanufacture notification (PMN) submitters. The latter categories are better models but require additional effort to design and build and the recent drafts hint at movement in this direction. Many of the new chemicals category documents are also quite dated, particularly with regard to human health issues, and are in need of update. This could be done over time and provide opportunities for public review and commenting and peer review as indicated.


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Given the changes in new TSCA, current versions of the new chemicals category documents do not provide the kind of understanding needed to inform submitters of category definitions and boundaries, read-across, and hazard/exposure/risk characterization issues and information needs that should be considered in submitting relevant information on new chemicals. The New Chemicals Program category documents also need to evolve to better align with the sound science provisions in Section 26. A goal of the New Chemicals Program could be to develop new chemical categories that are functionally equivalent to those developed under the OECD's category guidance. We note that the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) also uses categories based on the OECD guidance.

Our comments attempt to examine the category documents under the guidance of the Section 26 science standards. A topic that we feel the need to highlight is the inclusion of tiered testing strategies in these documents. The tiered testing approach illustrated in the recent categories does not conform to the basic principle of relating what is learned from each testing tier to what is eventually needed to determine category membership and to meet a regulatory requirement. The tiering strategy needs to include "exit" decision points for each testing tier based on information requirements for the category, *i.e.*, individual test outcomes need to consider the context of what we know about the toxicity and characteristics of category members, exposure considerations, and associated risk management.

We hope you find these comments helpful. We would be pleased to discuss them with your technical staff in more detail if that is of interest.

Sincerely,

Lynn L. Bergeson

Attachments
cc: Nancy B. Beck, Ph.D., DABT (w/attachments) (via e-mail)

**Initial Comments on Polymer Lung Overload New Chemicals Category**

**Definition**

This category includes a variety of poorly soluble polymers, and specifically insoluble/non-water absorbing ("non-swellable") high molecular weight materials typically formed through a free-radical polymerization process. Included are branched and linear polymers, as well as copolymers produced by random, block, graft, or other techniques. Crosslinked polymers are included in the category, but crosslinking is not necessary for inclusion.

The high molecular weight polymers included in this category are otherwise considered non-toxic and this characteristic should be included in the category boundaries discussed below. The hazard concerns for the category are limited to the effects on the lung as a result of inhaling respirable poorly soluble particles. The toxicity information that supports this category consists exclusively of inhalation studies in rodents. No epidemiological studies are cited. A title more reflective of the scope of the category should be considered as well. For example, Respirable Poorly Soluble Polymers is a better description of the category than the current title that highlights an experimental design outcome.

**Section 26 Standards**

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information:* Yes, to a point. The hazard concerns require better framing that includes a pragmatic discussion of the lung overload condition and its implications in realistic human exposure scenarios.

(h)(2)—*Relevance of Information:* As above.

(h)(3)—*Clarity and Completeness:* The document makes use of available public information on these chemicals and provides a narrow rationale for the category. Lung overload is a controversial subject that should be discussed in the context of a mode of action.

(h)(4)—*Variability and Uncertainty:* Needs a better description. There are some questions about the relevance of animal inhalation data to characterize effects in humans (lung overload).

(h)(5)—*Independent Verification or Peer Review:* The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review. At a minimum, and considering the important role of category documents in guiding testing decisions by the U.S. Environmental Protection Agency (EPA) and premanufacture


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notification (PMN) submitters, a public comment period could prove valuable in increasing clarity, completeness, and better understanding of the tiered testing strategy.

**Boundaries**

Polymers must be respirable and poorly soluble in water. No molecular weight requirements specified. The boundaries should note that the polymers that fit the category are otherwise non-toxic.

**General Testing Strategy**

The purpose of a tiered strategy is to generate information to inform subsequent steps and then to determine the need to proceed to the next step or not. Tier 1, as discussed below, does not operate as a mechanism to determine the need for higher tier testing. The approach as currently framed appears to consider only moving on to the next tier, which defeats the purpose of a tiered testing strategy.

**Tier 1**

Physicochemical Characterization: Particle size distribution and biosolubility testing. The strategy indicates that if respirable and poorly soluble particles can be generated, proceed to Tier 2. If the studies are negative, there is still a requirement to determine if Tier 2 is needed. It is not explained why, if the chemical is not found to meet the terms of the category (respirable and poorly soluble), there is still a need to determine if higher tier testing is required. This seems to violate a basic principle of tiering where early tier results inform as to the need for higher tiers. As mentioned above, a public comment period could prove a resource to increased clarity, completeness, and understanding of the approach.

**Tier 2**

A series of inhalation studies in rats with durations ranging from 4 hours to 28 days.

**Tier 3**

90-Day Inhalation Study: Based on results of the 90-day inhalation study, a 2-year inhalation bioassay in rats may be warranted.

The *in vivo* tiering is reasonable; as discussed above, there are questions about the role and effect of the first tier. The 2-year cancer bioassay seems excessive considering there is no epidemiological or other (animal) evidence of cancer associated with exposure to these

polymers, including in occupational settings. EPA acknowledges this point in the category document but notes that poorly soluble inorganic particulates have been shown to be carcinogenic in the rat. As discussed below, this is a scientifically controversial area.

The proposed *in vivo* studies involve inhalation tests of various durations utilizing the rat. The adverse effects under consideration for the category range from pulmonary inflammation to tumor formation. The latter effect, which is associated with poorly soluble particulates, does not reflect the interspecies comparative studies that show fundamental differences in the toxicokinetics -- particle disposition, retention, and clearance -- of inhaled particles between rats and non-human primates and humans, nor does it reflect the fact that the lung tumor response is unique to the rat and not observed in other species similarly exposed. Building on the initial work that contributed to the understanding of lung overload (https://www.ncbi.nlm.nih.gov/pubmed/10715616), a s cientific consensus emerged in recent years that, because of unique and substantial differences in toxicokinetics and toxicodynamics, rat lung tumor data generated under overload conditions are not considered appropriate for hazard/risk assessment of exposed human populations (http://www.sciencedirect.com/science/article/pii/S0300483X1630292X). A recent action from EPA in the diesel exhaust risk assessment (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=29060) illustrates this understanding:

> Although high-exposure chronic rat inhalation studies show a significant lung cancer response, this is not thought predictive of a human hazard at lower environmental exposures. The rat response is considered to result from an overload of particles in the lung resulting from the high exposure, and such an overload is not expected to occur in humans at environmental exposures.

The use of the rat as an inhalation model to determine lung toxicity for this category is appropriate since it represents a sensitive test species and consequently the results obtained afford an extra margin of protection. T he proposed cancer bioassay, particularly with the rat model, is not a reasonable inclusion in the test strategy. The cancer question for respirable poorly soluble polymers should be evaluated on a case-by-case basis considering the weight of the scientific evidence.

**Initial Comments on Polycationic Substances New Chemicals Category**

The operational use of a new chemicals category is to identify hazard concerns for a particular group of chemicals and corresponding toxicity or other testing to provide information to address concerns.

**Definition**

Any polymer or substance with multiple functional groups bearing positive charges at physiologically relevant pH is a member of this class. Positive charges may be dissociable (*e.g.*, amine salts) or non-dissociable (*e.g.*, quaternary ammonium cations). Such structures include polyamines, polyquaternary ammonium, polyurea-amines, polyamide-amines, and polyguanidine compounds.

The definition is relatively open-ended and it is unclear what other substance(s) may be considered part of this category. The definition also lacks any indicator of minimum size or molecular weight (MW). For example, a simply alkyl polyamine such as tetraethylene pentamine (TEPA) would seemingly be included.

The toxicity information that supports the category is derived from epidemiological, animal testing and *in vitro* studies on polymeric amines/amides. A potential mode of action for these chemicals is proposed that highlights the critical role of charge density, MW, and molecular conformation in the expression of toxicity. The identified polycationic polymers that form the basis for this category have MWs around 20,000 and higher.

To the extent that lower MW polycationic chemicals (*e.g.*, MW<1,000) are considered part of this category, their inclusion would be inconsistent with the available toxicity and mode of action information. Lower MW polyamine/amides have been shown to produce predominantly irritation upon dermal and/or ocular exposure in test animals. Irritation becomes the prevalent adverse effect linked to exposure of low(er) MW polyamine/amides. The proposed mechanism of cytoxicity for high MW polycationic polymers involves the initial electrostatic interaction of the polycationinc polymer with the negatively charged cell membrane. This interaction neutralizes cell membrane charge over the area of contact. This condition weakens the membrane structure that eventually leads to leakage and a more permeable membrane. A low(er) MW polycationic substance would experience a similar but more localized interaction short of the impact associated with higher MW polycationc polymers.

A separate argument against a low MW polyamine/amide belonging to this category is the postulated mode of action for the polyamine/amides in the epidemiological studies that require certain MW, charge density, and conformation characteristics not present in the former. In addition, a lower MW would facilitate absorption of a polyamine/amide by the cell and the toxicity observed would be associated with intracellular interactions rather than the postulated membrane effects associated with the category.


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**Section 26 Standards**

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The scientific information and methodologies are consistent with the intended use of the information; the description of the rodent inhalation exposure protocols fall short of the standard.

(h)(2)—R*elevance of Information*: T he toxicity information is relevant for making decisions about these polycationic polymers.

(h)(3)—*Clarity and Completeness*: The document makes use of available public information on these chemicals and provides a reasonable rationale for the category.

(h)(4)—*Variability and Uncertainty*: T he U.S. Environmental Protection Agency (EPA) discloses the limitations of the available animal testing information. There are few adequate animal studies and some are short on experimental details. Other studies cited were conducted by intratracheal instillation, which are useful as confirmatory of the hazard concern but not very helpful for hazard and risk characterization.

(h)(5)—*Independent Verification or Peer Review*: The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review. At a minimum, and considering the important role of category documents in guiding testing decisions by EPA and premanufacture notification (PMN) submitters, a public comment period could prove valuable in increasing clarity, completeness, and understanding of the tiered testing strategy.

**Boundaries**

Polymers must be water soluble or water-dispersible. N o MW requirements are specified. Although the Definition section includes the requirement for multiple positive charges at physiologically relevant pH, this point is not included in the discussion of boundaries.

**Proposed Testing Strategy**

EPA identifies a series of tests that, although not explicitly stated, partly relate to a determination whether a chemical should be included in the category.

The initial recommendations address the physicochemical characterization of the polymer. This is followed by a set of three *in vitro* tests for Cytotoxicity and Dermal Irritation. The two cytoxicity tests identify the purpose as generating data to predict the starting doses for rodent acute oral systemic toxicity assays and along the way provide a qualitative description of the cytoxicity potential of the test substance. The document does not discuss how PMN submitters and EPA should consider and use the results of the *in vitro* tests, thus it is not clear what role they play in the tiering.

The *in vitro* dermal irritation test is a standard Organization for Economic Cooperation and Development (OECD) test guideline. It is not clear what role the test plays in the polycationic substances category tiering strategy. The polymers that were the subjects of the epidemiological reports are described by the authors as not irritating. Does this suggest that evidence of irritation in this test provides a basis or a partial basis for questioning whether the category applies to a given new chemical? For polyamine/amide chemicals, irritation potential generally decreases as MW increases. This is one of the issues about potentially extending the category to low MW polycations. Low MW polycations (*e.g.*, polyamines such as TEPA) are irritants and this feature tends to drive their toxicity.

**General Testing Strategy**

Tier 1 -- Use physical-chemical properties to characterize lung exposure/binding potential

- Charge density in milliEquivalents/gram or functional group equivalent weight or % amine nitrogen. It would be useful to specify use of physiologically relevant pH in conducting the test.

- Particle Size Distribution or Aerosolized Droplet Size (OECD TG 110 or OPPTS 830.7520).

As discussed in the document, this tier is driven by respirability without also specifying that polycationic character at physiologically relevant pH must be shown.

Tier 2 -- Proposed *In Vivo* Studies

- Step 1: OECD Acute TG 403 featuring rats exposed for 4 hours and observed for 2 weeks (< 2000 mg/m$^3$, proceed to step 2).

- Step 2: Five-day study to address toxicity progression (substantial decrease in the Point of Departure (POD) over time relative to the acute study, proceed to step 3).

- Step 3: OECD TG 412 ( 28-day inhalation study in rats with 14-day recovery period).

EPA concludes that 28-day inhalation studies are adequate to characterize the toxicity of polycationic substances based on the appearance of lung effects in the available studies.

The purpose of a tiered strategy is to generate information to inform subsequent steps and determine the need to proceed to the next step or not. There is a need for better guidance from EPA if it intends to use the results of the initial physiochemical, *in vitro,* and *in vivo* tests. For example, what happens if a polycationic substance is not respirable or shows low cytoxicity in the identified *in vitro* assays? Similar questions can be raised about outcomes of other early toxicity tests. The process as currently framed appears to consider only moving on to the next tiered step resulting in a "tiered strategy" that then devolves into a fixed set of tests that should be implemented regardless of intermediary outcomes. A more descriptive tiered strategy should include information requirements that would inform decisions about proceeding to the next tier or exiting the process. As mentioned above, a public comment period could prove a resource to increased clarity, completeness, and understanding of the approach.

## Initial Comments on Waterproofing Agents New Chemicals Category

### Definition

Any compound that is applied to a solid surface (*e.g.*, carpets, clothing, fabrics, leather, wood, paper packaging, ceramic tiles, concrete, masonry, flooring) to confer or enhance repellency or resistance to water, grease, or stains is considered to be a member of this category. Of particular focus are chemicals used in consumer spray products, which may be applied without the presence of personal protective equipment.

This category includes a range of chemical functionalities with the unifying characteristic being that they bind to surfaces and confer water repellence to the coated area. T he toxicity information that supports this category includes human observations, animal studies, and *in vitro* information.

### Section 26 Standards

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The scientific information and methodologies are consistent with the intended use of the information.

(h)(2)—*Relevance of Information*: T he toxicity information is relevant for making decisions about waterproofing agents.

(h)(3)—*Clarity and Completeness*: T he document makes effective use of available public information on these chemicals and provides a reasonable rationale for the category.

(h)(4)—*Variability and Uncertainty*: Variability and uncertainty in experimental outcomes are discussed briefly.

(h)(5)—*Independent Verification or Peer Review*: The information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review.

### Boundaries

No boundaries are identified for this category.


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**General Testing Strategy**

**Tier 1**

Physicochemical Characterization: Particle size distribution or aerosolized droplet size; surface tension increases.

**Tier 2**

Similar inhalation battery to other inhalation categories that culminate with a 28-day inhalation study. The supporting data section notes that the Organization for Economic Cooperation and Development (OECD) 403 four-hour inhalation exposure with some modifications may be adequate for a comparative assessment of waterproofing agents.

The testing strategy identifies *in vitro* methods that have shown promise as tools for the hazard screening of waterproofing agents.

# Initial Comments on General Surfactants New Chemicals Category

## Definition

Includes anionic, cationic, and nonionic surfactants.

**Anionic Surfactants:** Any molecular structure with a net negative charge and having surfactant activity is a m ember of this category. The category includes, for example, alkyl sulfonates, alkylbenzene sulfonates, alkyl silicic acids, alkyl phosphates, alkyl carboxylic acids, or combinations of these anionic groups, *e.g.*, alkyl sulfonate with carboxylic acid substitutions.

**Cationic Surfactants:** Any cationic surfactant is a member of this category, for example: didecyldimethyl ammonium chloride (DDAC).

**Nonionic Surfactants:** Any neutral structure having surfactant activity (*e.g.*, Triton-X 100) is considered a member of this category.

This category shares several design features with the Waterproofing Agents category, including a range of different functionalities that show surfactant properties. The toxicity information that supports this category includes human observations, animal studies, and *in vitro* data from studies conducted with nonionic and anionic surfactants. An unstated assumption is that ionic character is not relevant for the expression of toxicity by surfactants.

## Section 26 Standards

(h)(1)—*The scientific information, protocols, methodologies are reasonable and consistent with the intended use of the information*: The limited scientific information and methodologies are consistent with the intended use of the information.

(h)(2)—*Relevance of Information*: T he toxicity information is relevant for making decisions about waterproofing agents.

(h)(3)—*Clarity and Completeness*: The document makes use of limited public information on these chemicals and provides a reasonable rationale for the category. No data included for cationic surfactants.

(h)(4)—*Variability and Uncertainty*: Variability and uncertainty in experimental outcomes are discussed briefly.

(h)(5)—*Independent Verification or Peer Review*: he information to support the category was obtained from the scientific literature. The testing strategy includes test methods that have been subjected to peer review in different forums. The category document itself has not received peer review.


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**Boundaries**

No boundaries are identified for this category.

**General Testing Strategy**

The proposed inhalation battery (Organization for Economic Cooperation and Development (OECD) 403 progressing to OECD 412) for surfactants is the same as for the other inhalation categories.

The testing strategy identifies *in vitro* methods that have shown promise as tools for the hazard screening of surfactants.

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June 28, 2017

Via E-Mail

Nancy B. Beck, Ph.D.
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Nancy:

I wanted to thank you personally for your participation in yesterday's *TSCA Reform: One Year Later* program sponsored by Bergeson & Campbell, P.C. and the Environmental Defense Fund and hosted by the Milken Institute School of Public Health at George Washington University and the Environmental Law Institute. Many people remarked to me how clear and compelling your remarks were, and how elegantly you responded to some of the questions and issues presented.

We believe the program achieved its intended goal -- to bring stakeholders together to celebrate the reform of TSCA, and to discuss its ongoing implementation. We could only achieve this goal with your participation and others from the U.S. Environmental Protection Agency, and we greatly appreciate your generous contribution of time, energy, intellectual rigor, and devotion to TSCA.

Thanks again.

Sincerely,

Lynn L. Bergeson

2200 Pennsylvania Avenue, NW, Suite 100W
Washington, DC 20037-1701
phone: 202.557.3800
fax: 202.557.3836
www.lawbc.com

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Milken Institute School of Public Health
THE GEORGE WASHINGTON UNIVERSITY

ENVIRONMENTAL LAW INSTITUTE

# TSCA Reform -- One Year Later

**Co-Hosted by: Environmental Law Institute &**
**George Washington University Milken Institute School of Public Health**

**June 27, 2017**

**950 New Hampshire Ave, NW, 7th Floor**
**Washington, DC 20052**

8:00-9:00 Registration

9:00-9:30 **Welcome and Overview of Forum**

Lynn R. Goldman, M.D., M.S., M.P.H.
Michael and Lori Milken Dean, Milken Institute School of Public Health;
Professor of Environmental and Occupational Health

9:30 – 10:15 **Keynote Discussion: "Reflections on the Passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act"**

Hon. John Shimkus
U.S. Representative, 15th District of Illinois

Hon. Tom Udall *(invited)*
U.S. Senator, New Mexico

10:15 – 10:30 **Coffee Break**

10:30 – 12:00 **Plenary Panel: "TSCA Implementation: Where Are We?"**

Lynn L. Bergeson
Managing Partner, Bergeson & Campbell PC

Dimitri J. Karakitsos
Partner, Holland & Knight

Wendy Cleland-Hammett
Acting Assistant Administrator, EPA Office of Chemical Safety and Pollution Prevention

James J. Jones
Former Acting Assistant Administrator, EPA Office of Chemical Safety and Pollution Prevention

12:00 - 1:00 **Lunch Break**

DRAFT

Milken Institute School of Public Health
THE GEORGE WASHINGTON UNIVERSITY

ENVIRONMENTAL LAW INSTITUTE

1:00 – 1:30 **Luncheon Keynote**

Bonnie Englebardt Lautenberg

1:30 – 3:00 **Guided Discussion: "Science Policy Issues"**

**Facilitators:**

Nancy B. Beck, Ph.D., D.A.B.T., *(invited)*
Deputy Assistant Administrator, EPA Office of Chemical Safety and Pollution Prevention

Bob Diderich
Head of Division, Environment, Health & Safety,
Organisation for Economic Cooperation Development

Lynn R. Goldman, M.D., M.S., M.P.H.
Michael and Lori Milken Dean, Milken Institute School of Public Health;
Professor of Environmental and Occupational Health

Richard A. Denison, Ph.D.
Lead Senior Scientist, Environmental Defense Fund

3:00 - 4:30 **Guided Discussion: "Regulatory & Policy Issues"**

**Facilitators:**

Charles Auer,
Senior Policy and Regulatory Advisor, Bergeson & Campbell PC

Lawrence E. Culleen,
Partner, Arnold & Porter Kaye Scholer LLP

Benjamin E. Dunham
Senior Policy Advisor, Holland & Knight LLP

Jeffrey Morris, Ph.D.
Director, EPA Office of Pollution Prevention and Toxics

Robert M. Sussman,
Counsel, Safer Chemicals, Healthy Families

4:30 – 4:45 **Concluding Remarks and Adjournment**

Scott Fulton
President, Environmental Law Institute

DRAFT

Lynn L. Bergeson
phone: 202.557.3801
lbergeson@lawbc.com

BERGESON & CAMPBELL PC

June 14, 2017

Via E-Mail

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Avenue, N.W.
Washington, D.C. 20002

Dear Dr. Beck:

Thank you for visiting with Charlie Auer, Rich Engler, and me on Tuesday. We greatly enjoyed our discussion, welcomed the opportunity to visit briefly on topics of shared interest, and appreciate your devoting time to our discussion.

To memorialize briefly a few of the many topics we touched upon, we took the liberty of noting them below, in no particular order. We would be pleased to continue our discussion, after June, as your schedule permits.

**Open a Docket to Submit TSCA "Fixes" --** As we discussed, many stakeholders are thinking hard about creative solutions to some Toxic Substances Control Act (TSCA) implementation challenges. To ensure stakeholders know that the U.S. Environmental Protection Agency (EPA) is solicitous of suggestions and proposed solutions, it may wish to open a docket to house all such suggestions. A docket, the opening of which would be noted in the *Federal Register* and on EPA's website, would provide a convenient and transparent means for allowing stakeholders to review and consider suggestions, build upon them, and jump-start the development of other solutions based on docket submissions. As an example of such TSCA fixes, we briefly reviewed the paper we developed on the "Use of the Chemical Name in Managing New Chemical Polymers." The paper has been provided to Dr. Jeff Morris and others in the Office of Pollution Prevention and Toxics (OPPT).

**Establish a TSCA FACA Committee --** The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) sunset years ago after the non-governmental organization community elected to withdraw. We have suggested to the Office of Chemical Safety and Pollution Prevention leadership many times over the past three years resuming a Federal Advisory Committee Act (FACA) committee focused on TSCA regulatory, policy, and program implementation issues. We renew that request here. Such a committee would operate in parallel to and complement the Science Advisory Committee on Chemicals. The Pesticide Program Dialogue Committee has been an enormously successful mechanism to identify, discuss, and resolve issues of concern to the pesticide community. There is every reason to

believe a similar FACA committee would be effective in addressing TSCA issues, especially in light of Lautenberg. While we appreciate EPA's investment of time in public hearings, they seldom provide the venue needed for thoughtful, reflective discourse on complicated issues, such as the meaning of key statutory terms (*e.g.*, "not likely," "reasonably foreseeable"). A FACA committee would provide such a venue and ensure continuity of consideration on an on-going basis.

**Attend Focus and Other New Chemicals Meetings** -- We encouraged that you make an effort to drop in, without advance notice, on the key meetings that occur with regularity during the new chemicals process to get a flavor of the nature and the level of the discussion. The list could include both technical and regulatory meetings. The former includes both initial (Chemistry Review and Search Strategy (CRSS), Structure Activity Team (SAT), and Focus) and late stage meetings while the latter includes the Options meeting and the Division Directors meeting. We believe this would be a very useful and informative use of your time. You might also find it useful to review examples of the reports produced after these meetings to get a sense of how the discussion is captured and documented. We appreciate how busy you are, but there is no substitute for the real-time experience this opportunity would provide.

**Ensure Legal Review of All Consent Orders** -- As we discussed, the EPA consent order template may need reviewing by legal counsel. We suggest that all consent orders be reviewed by counsel as a matter of routine.

**15-Day Review Period** -- Jeff Morris' PowerPoint indicates that EPA is dispensing with the "action letter" approach and sending consent orders directly to submitters and requesting a response within 15 days. We suggested to you that requiring a response within 15 days is not possible without also providing submitters a substantive and meaningful summary of the basis of EPA's risk issues. EPA must provide a sound science justification for its determination; justification should include the Focus, CRSS, SAT, engineering/exposure, and reports developed after the Focus meeting (*e.g.*, during Standard Review). The reports would be sanitized of any non-submitter confidential business information (CBI) (*e.g.*, information on premanufacture notification analogs), but can provide critical visibility into EPA's hazard, exposure, and risk assessments of the new chemical substance. We suggest that OPPT work over time to improve the clarity and transparency of the reports, which are cryptic given their current focus almost exclusively on an internal audience. Reports can also be redesigned to make it easier to sanitize information that is CBI to the submitter. Another suggestion is that EPA, after promulgation of the fees rule, adopt the practice of timely providing submitters with copies of reports on all cases as a matter of routine.

**New Chemical Category Documents** -- We also briefly discussed the lung toxicity category documents that we recently received and indicated that we planned to submit comments. We encouraged that EPA consider an effort to update and improve the documents on

relevant categories and to provide an informal public review step. Many of the other categories in the OPPT Chemical Categories document are quite dated. Given new TSCA, the documents play a more significant role in EPA's determinations and testing strategy; reviewing, updating, and including discussion of the tiering strategy for testing will be important in meeting the sound science provisions in Section 26.

Sincerely,

Lynn L. Bergeson
Charles M. Auer
Richard E. Engler, Ph.D.

Lynn L. Bergeson
phone: 202.557.3801
lbergeson@lawbc.com

BERGESON & CAMPBELL PC

June 25, 2018

Via E-Mail

Nancy B. Beck, Ph.D.
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Nancy:

Thank you for participating in the Bloomberg "Chemical Policy Summit -- TSCA at 2: An Update on Implementation and Hot Topics" webinar today. We are especially appreciative of your participating remotely from your hotel in North Dakota. Your summary of the U.S. Environmental Protection Agency's recent implementation measures was excellent and the audience was very fortunate to hear these developments directly from you. We are grateful to you for being so generous with your time and commitment to excellence.

Sincerely,

Lynn L. Bergeson

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 27, 2012

Lynn L. Bergeson
Bergeson & Campbell PC
2200 Pennsylvania Avenue NW, Suite 100W
Washington, DC 20037-1701

Dear Ms. Bergeson:

I am writing to provide notice that the cancellation of "group 2" uses, the sod farm, golf course, and highway rights of way uses identified in the September 30, 2009, Federal Register (74 FR 50187) (FRL-8437-7) (2009 Notice) cannot be finalized, and the existing stocks provisions for all remaining products containing the organic arsenical monosodium methanearsonate (MSMA) will be corrected in a Federal Register notice to be published in the near future.

In the cancellation order of the 2009 Notice registrants would have been prohibited from selling and distributing products containing MSMA for use on sod farms, golf courses, and highway rights of way, after December 31, 2012. Persons other than registrants would have been prohibited from selling and distributing products containing MSMA for use on sod farms, golf courses, and highway rights of way, after June 30, 2013 and after December 31, 2013 use of products containing MSMA labeled for all uses, except cotton would have been prohibited.

Pursuant to paragraph 6 of the Agreement in Principle to Implement the Organic Arsenicals Reregistration Eligibility Decision dated January 16, 2009, if EPA fails to provide a written determination by December 31, 2012, based on the Agency's consideration of recommendations of the peer review body, whether EPA believes that the science on the mode of action issue has changed sufficiently to warrant a continuation of golf course, sod farms or highway rights of way uses of MSMA, the effective date for the deletion of these uses will be extended until the required written determination has been provided. The deadlines for the sale, distribution and use of existing stocks labeled for these uses will be extended by an equivalent period. Because EPA will not provide a written determination by December 31, 2012, the group 2 uses will not be deleted as of December 31, 2012 and will be extended until the required written determination has been provided.

Paragraph 3 of the Agreement in Principle provided that EPA would convene a public meeting of either the Agency's Scientific Advisory Board, the Scientific Advisory Panel, or both to evaluate any new data on the mode of action of inorganic arsenicals, and the cancellation request and existing stocks provision of the 2009 Notice were conditioned upon the timely completion of the

peer review process. In light of a Congressional directive to have the National Academy of Sciences (NAS) look at the mode of action for carcinogenic effects by inorganic arsenic, EPA and the arsenic registrants recently agreed to modify Paragraph 3 of the Agreement to include the NAS as a third potential peer review body, one of which must hold a public meeting on the mode of action before the cancellations can be finalized. As noted in my letter to you dated September 14, 2012, it is EPA's current intention to undertake the peer review contemplated by the Agreement in Principle by relying upon the NRC/NAS review. EPA will notify registrants should this intention change in the future.

Based on the above information and how it affects the current registration status of the Group 2 uses, registrants may submit label amendments to remove the restrictions regarding use of the product on sod farms, golf courses, and highway rights of way after December 31, 2013, from the product labels.

If you have any questions, please do not hesitate to contact Tom Myers of my staff at myers.tom@epa.gov or (703) 308-8589.

Sincerely yours,

Richard P. Keigwin, Jr.

Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 14 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Lynn L. Bergeson
Bergeson & Campbell PC
2200 Pennsylvania Avenue NW, Suite 100W
Washington, DC 20037-1701

Dear Ms. Bergeson:

We received your letter dated August 16, 2012, seeking clarification of the terms of the Agreement in Principle to Implement the Organic Arsenicals Reregistration Eligibility Decision (RED) dated January 16, 2009.

As noted in your letter, the parties have agreed to modify Paragraph 3 of the Agreement to include the NRC/National Academy of Sciences (NAS) as a potential peer review body. The Agreement as modified would provide three potential peer review bodies: NAS, the Science Advisory Board (SAB) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). It is currently EPA's intention to undertake the peer review contemplated in Paragraph 3 by relying upon the NRC/NAS review (as opposed to the SAB/SAP review noted in the Agreement) as the scientific peer review of the mode of action. Should this intention change in the future, EPA will notify the registrants.

The registration of Group II uses (as identified in Attachment A to the Agreement) will be extended until EPA responds to any peer review body's report on the mode of action, as explained in Paragraph 6 of the Agreement.

Once the timeframe for the NAS review is publicly available, EPA will send a follow-up letter to you regarding that timeframe.

If you have any questions, please do not hesitate to contact me via telephone (703-305-7618) or via e-mail (keigwin.richard@epa.gov).

Sincerely yours,

Richard P Keigwin, Jr

Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs

Lynn L. Bergeson
phone: 202.557.3801
lbergeson@lawbc.com

BERGESON & CAMPBELL PC

August 16, 2012

Via E-Mail

Steven P. Bradbury, Ph.D.
Director, Office of Pesticide Programs
United States Environmental Protection Agency
MC: 7507P
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: January 16, 2009, Agreement between OAPTF and EPA

Dear Dr. Bradbury:

The Organic Arsenical Products Task Force (OAPTF) writes to seek clarification from the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) of the terms of the Agreement in Principle to Implement the Organic Arsenicals Reregistration Eligibility Decision (RED) dated January 16, 2009. Paragraph 3 of the Agreement calls for EPA to provide an opportunity to have new scientific information on the mode of action for carcinogenic effects by inorganic arsenic peer reviewed by the EPA Science Advisory Board (SAB) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) or the SAP in the first half of 2012.

We understand that more recent events have overtaken the literal meaning of that provision in the Agreement. Specifically, the House-Senate Conference Report for EPA's 2012 Appropriations measure directs EPA to request a National Research Council (NRC) review of the Integrated Risk Information System (IRIS) cancer and noncancer assessments for inorganic arsenic. The parties agree to modify the Agreement to include the NRC/National Academy of Sciences (NAS) as a potential peer review body. We understand that the NRC/NAS contract with EPA to undertake this review is now in place and that OPP is currently planning to rely upon the NRC/NAS review (as opposed to the SAB/SAP review noted in the Agreement) as the scientific peer review of the mode of action contemplated under the Agreement. Should this intention change in the future, EPA will notify the registrants. Under the terms of the contract between NRC/NAS and EPA, the project duration is expected to last 41 months, contingent upon the public release of the IRIS assessment by EPA at least 15 months before the contract date end.

We further understand that the registration of Group II uses (as identified in Attachment A to the Agreement) will be extended until after the peer review is completed.

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2200 Pennsylvania Avenue, NW, Suite 100W
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Please confirm that the Task Force's understanding of the interpretation of the Agreement as set forth above is accurate. Thank you for your attention to this matter.

Sincerely,

Lynn L. Bergeson

Business Roundtable

300 New Jersey Avenue, NW
Suite 800
Washington, DC 20001

Telephone 202.872.1260
Facsimile 202.466.3509
Website brt.org

May 15, 2018

The Honorable Andrew R. Wheeler
Deputy Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Jamie Dimon
JPMorgan Chase & Co.
Chairman

Mark S. Sutton
International Paper Company
Chair, Energy and
Environment Committee

Joshua Bolten
President & CEO

Dear Deputy Administrator Wheeler:

On behalf of Business Roundtable, it is my pleasure to invite you to meet with the Business Roundtable Energy and Environment Committee on Wednesday, June 6 from 9:00 a.m. to 9:45 a.m. ET. The meeting will take place at the Business Roundtable offices in Washington, DC.

If you are able to join us, we would like you to provide opening comments for up to 10 minutes, followed by 30 minutes of discussion.

Business Roundtable CEOs lead America's largest companies and represent a variety of economic sectors, from manufacturing to financial services, from energy production to health care. The Energy and Environment Committee is particularly focused on those regulations which will have significant economic consequences and broad cross-sectoral impact, such as the regulation of surface ozone levels and "New Source Review". However, individual CEOs may also be interested in regulations that impact their particular industries.

We hope you will join us on June 6. Please contact Matt Sonnesyn of the Business Roundtable staff (msonnesyn@brt.org) if you have any questions and to confirm your attendance.

Sincerely,

Mark S. Sutton
Chairman and CEO
International Paper Company
Chair, Energy and Environment Committee
Business Roundtable

**To:** Charmley, William[charmley.william@epa.gov]
**Cc:** Spears, Matthew[spears.matthew@epa.gov]
**From:** Berry Steve
**Sent:** Tue 3/28/2017 11:56:48 AM
**Subject:** FW: Fitzgerald Gliders
Pete 579 sign.JPG
Service.JPG
Engine options.JPG

Volvo Trucks

Hi Bill

Hope you're well.

No loss of enthusiasm by glider manufacturers at the Mid-America Truck Show.

Steve

**From:** Nash Jay
**Sent:** Monday, March 27, 2017 5:18 PM
**To:** Berry Steve; McKenna David; Alt Susan; Miller Jonathan; Alec Zacaroli (alec.zacaroli@haynesboone.com); Fasnacht Robert; Istenes Raymond; Anderson Rick (ey)
**Subject:** Fitzgerald Gliders

All,

I wanted to let you know that Fitzgerald had a larger than normal presence at Mid America last week. They have expanded their booth from just Fitzgerald gliders, to now include Fitzgerald Peterbilt (dealership), Fitzgerald Truck Parts, & Fitzgerald Collision & Repair. I've attached several notable pics regarding the gliders.

Additionally, Daimler Gliders also had a booth similar to past years with 3 trucks in it. I have pics of that as well if you're interested.

Please let me know if you have any questions or need anything else.

Thanks!

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To: Cullen, Angela[cullen.angela@epa.gov]
Cc: Moulis, Charles[moulis.charles@epa.gov]; Charmley, William[charmley.william@epa.gov]
From: Berry Steve
Sent: Wed 9/6/2017 11:48:58 AM
Subject: RE: Steve's voice-mail on possible tractor test program

Hi Angela

Looks like we'll be able to provide at least one glider, more if you have time to test. A Volvo test article as well, if you don't already have "modern product" data for comparative purposes.

Two good places to start:

1) Test program: UDDS? Chassis dyno operation at RMC points? GHG 55/65/ARB transient?

2) Scheduling: Soonest you can test? How long should we plan for each truck to be in Ann Arbor?

I can be available for a discussion before 9, between 10 and 12, and between 2 and 5. (All Eastern times). I'll try to tie in Jeff Marley as well.

Steve

Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061_00259402-00002

From: Berry Steve
Sent: Friday, September 08, 2017 11:08 AM
To: Cullen, Angela (cullen.angela@epa.gov); Marley Jeffrey
Subject: glider request

Angela, Jeff

I finally reached the dealer this morning. He sounded very cooperative, but was a bit taken aback by the 5 week request. He was expecting a couple of days. But he didn't say it was impossible just yet. I agreed to outline the request; please review what I wrote here and get back to me ASAP with your OK so I can send.

Steve

---

Hi Tim Ex. 6 - Personal Privacy

Good to talk to you this morning. Here's how we might shape up this request, from an "ideal" perspective. We'll compromise from there, as we know there are limitations in what can be done.

**VEHICLE PREFERENCE**

- Two vehicles, built in 2016 or 2017.



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061_00259402-00003

•□□□□□□□ Vehicle types: One "western style", and one more modern aero design.

•□□□□□□□ Engine types: One "Fitzgerald rebuild" – this is typically a Detroit Diesel, and should have a Fitzgerald ID plate, including Fitzgerald serial number, on the cold side of the engine. The second can be a remanufactured engine, from DD or CAT, but we prefer to stay away from Cummins. One of these engines should be without EGR, and the second with EGR if such a glider exists.

Any combination of the above "specs" is acceptable (doesn't matter which engine in which chassis, ...).

After those two vehicles are tested, EPA spoke about a high mileage unit, so in the range of 400,000 miles or so. But let's hold that request for now and discuss later.

**SCHEDULE**

EPA said that ideally they'd like to have the two vehicles simultaneously for 5 weeks, but they recognized that this could be impractical or too costly. If this is too unreasonable to even approach the customer, then let's say the first vehicle for two weeks, and then the second for two weeks on the heels of the first. (I'm sure that 3 weeks each is a better situation for them, so if that's possible...and let's see about cost). EPA is ready to start as early as Sept 18, so as close to that date as reasonable. The trucks should be delivered to their facility in Ann Arbor.

**COST**

Please give me an idea of what sort of charges we'll be incurring. This may curtail our ambition somewhat.

Again, what we've outlined is ideal, but we'll take what you can deliver. No problem. Really appreciate the support, and look forward to hearing back from you.

Steve Berry

**To:** Cullen, Angela[cullen.angela@epa.gov]
**Cc:** Marley Jeffrey[jeff.marley@volvo.com]; Alt Susan[susan.alt@volvo.com]
**From:** Berry Steve
**Sent:** Tue 9/12/2017 9:34:31 PM
**Subject:** FW: glider request

Hi Angela

Keeping you posted....

Steve

**From:** Tim Schimmel[mailto:tim.schimmel@mktruck.com]
**Sent:** Tuesday, September 12, 2017 5:32 PM
**To:** Berry Steve
**Subject:** Re: glider request

I will be meeting with the customer on Friday. Should have more details then.

Sent from my iPhone

On Sep 12, 2017, at 5:25 PM, Berry Steve <steve.berry@volvo.com> wrote:

Hi Tim Ex. 6 - Personal Privacy

I believe you said you'd be preoccupied this week with a truck show, but did your first contacts give you the sense that we could work something out next week?

Thanks if you have an update,

Steve Berry

**From:** Berry Steve
**Sent:** Friday, September 08, 2017 1:59 PM
**To:** 'tim.schimmel@mktruck.com'
**Subject:** RE: glider request

Hi Tim Ex. 6 - Personal Privacy

**To:** Cullen, Angela[cullen.angela@epa.gov]
**From:** Berry Steve
**Sent:** Tue 9/26/2017 5:30:47 PM
**Subject:** RE: Vehicle for Testing

Hi Angela

Thanks for copying me. Does EPA plan to request (from Fitzgerald) a copy of the Tennessee tech report? Seems appropriate to do so.

Steve

**From:** Cullen, Angela [mailto:cullen.angela@epa.gov]
**Sent:** Tuesday, September 26, 2017 1:23 PM
**To:** timsohimmel@mktruck.com
**Cc:** Berry Steve
**Subject:** Vehicle for Testing

Dear Tim Ex. 6 - Personal Privacy

Steve Berry has indicated that you will be working with us to test a glider.

First, thank you for all of the coordination and willingness to work with us to test the vehicle. We truly appreciate it.

My understanding from Steve is that the vehicle will be delivered to our lab on Monday, October 2. EPA's National Vehicle and Fuel Emissions Lab building is located at 2565 Plymouth Road in Ann Arbor. The building is enclosed by an iron gate. When the vehicle arrives, please pull over to the right and the guards will ask you who you are here to see. Please let them know that you are here to deliver a vehicle for testing and request that they contact Garrett Brown, Maria Peralta, or Connie Hart (in that order). The guards have been notified and will be expecting you. Wait for them to lower the vehicle barrier. Ensure the vehicle barrier has been lowered and the light is green before proceeding. The guards and/or Garrett will then direct you to where to

To: Cullen, Angela[cullen.angela@epa.gov];
tim.schimmel@mktruck.com[tim.schimmel@mktruck.com]
From: Berry Steve
Sent: Tue 10/10/2017 2:20:54 PM
Subject: Glider #2

Hi

Angela: What's the sooncst you anticipatc to bc ready for glider #2?

Tim: Any prospects?

Stcvc

This email message and any attachments may contain confidential information and may be privileged. If you are not the intended recipient or otherwise not authorized to receive this message, you are prohibited to use, copy, disclose or take any action based on this email or any information contained herein. If you are not the intended recipient, please advise the sender immediately by replying to this email and permanently delete this message and any attachments from your system.

To: Cullen, Angela[cullen.angela@epa.gov]
From: Berry Steve
Sent: Thur 10/19/2017 2:38:25 AM
Subject: Re: Glider #2 .

Angela
Tim is struggling to secure glider #2, ao we reached out to other dealers earlier this week
Steve

On Oct 18, 2017, at 4:15 PM, Tim Schimmel <tim.schimmel@nikitruck.com> wrote:

Let me see if I can get a driver there. Probably be back at you in the morning.


Tim Schimmel | New Truck Sales Manager

<image002.jpg>

Ex. 6 Personal Privacy

8800 Byron Commerce Dr Byron Center, MI 49315

main 616.583.2100 | direct 616.583.3000

mobile 616.438.1264 fax 616.583.3070

tim.schimmel@nikitruck.com

nikitruckcenters.com

We really appreciate your help with this.

Thank you,

Angela

**From:** Berry Steve [mailto:steve.berry@volvo.com]
**Sent:** Friday, October 20, 2017 10:19 AM
**To:** Cullen, Angela <cullen.angela@epa.gov>
**Subject:** FW: 2nd Glider

Hi Angela

Glider #2 ! Not a remanufactured engine as we had targeted, but another Fitzgerald rebuild.

Move forward?

**From:** Tim Schimmel [mailto:TPetsonmilPrivatrack.com]
**Sent:** Friday, October 20, 2017 9:37 AM
**To:** Berry Steve
**Cc:** Alt Susan
**Subject:** 2nd Glider

Fitzgerald Glider w 30,000 miles

2017 579 Pete Aero. Just released this year as a aero glider.

Detroit 12.7 500 Fitzgerald Rebuild.

10 speed

Next Friday I can pick it up.

**To:** Millett, John[Millett.John@epa.gov]
**From:** Dunham, Sarah
**Sent:** Fri 10/27/2017 7:21:18 PM
**Subject:** RE: EPA Glider Testing

Thanks—I'll defer to you on responding to Liz based on whoever responds and what the response is—sorry I got a little separate with my note

**From:** Millett, John
**Sent:** Friday, October 27, 2017 3:10 PM
**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Dunham, Sarah <Dunham.Sarah@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Grantham, Nancy <Grantham.Nancy@epa.gov>; Hewitt, James <hewitt.james@epa.gov>
**Subject:** RE: EPA Glider Testing

Thanks, checking with the program.

**From:** Bowman, Liz
**Sent:** Friday, October 27, 2017 3:09 PM
**To:** Dunham, Sarah <Dunham.Sarah@epa.gov>; Millett, John <Millett.John@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Grantham, Nancy <Grantham.Nancy@epa.gov>; Hewitt, James <hewitt.james@epa.gov>
**Subject:** EPA Glider Testing

Do any of you know about "EPA staff conducting their own testing of glider kits at an EPA facility"? This is the first I have heard about it, but the Washington Post is asking, so hoping to provide more information here.

Thank you,

Liz Bowman

U.S. Environmental Protection Agency (EPA)

**To:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]; Lewis, Josh[Lewis.Josh@epa.gov]
**Cc:** Dominguez, Alexander[dominguez.alexander@epa.gov]
**From:** Dunham, Sarah
**Sent:** Fri 10/27/2017 7:40:34 PM
**Subject:** RE: Gliders

We're checking.

-----Original Message-----
From: Gunasekara, Mandy
Sent: Friday, October 27, 2017 3:39 PM
To: Dunham, Sarah <Dunham.Sarah@epa.gov>; Lewis, Josh <Lewis.Josh@epa.gov>
Cc: Dominguez, Alexander <dominguez.alexander@epa.gov>
Subject: Gliders

We got a press question asking whether OTAQ is doing emissions testing on gliders? Have we before or are we in the process?

Sent from my iPhone

**To:** Charmley, William[charmley.william@epa.gov]
**Cc:** Berry Steve[steve.berry@volvo.com]
**From:** Alt Susan
**Sent:** Tue 10/31/2017 12:25:00 PM
**Subject:** response for the EPA Letter/Gliders
SAccounting17101309520.pdf
NT&E letter to Hon. Scott Pruitt, 10.14.pdf
GATR-Letter.pdf
Glider Vehicles.pdf
Glider Issue.pdf
doc20171030153037.pdf

MISSING

Hi Bill,

I was copied on a response you sent to Terry Dotson, the owner of Worldwide Equipment dealer group (with dealerships in KY, OH, SC, TN, WV and VA) on a letter he sent to Administrator Pruitt.

I wanted to be sure you had seen some of the letters also sent with the same message from other dealer groups (copied here) as I am not sure any of these other groups got a response from your office (other than an email acknowledgment of receipt from Erik Baptist).

Some of the letters are attached, and the groups' locations show the pervasiveness of the Glider sales across America:

- TEC Equipment with dealerships in CA, WA, OR, NV, and AZ…over 1,200 employees
- Nuss Trucks with dealerships in MN, WI
- GATR Trucks with dealerships in MN, IA…275 employees
- RDO Truck Centers with dealerships in NE, ND
- VoMack Trucks with dealerships in IN, KY and IL…even lists some of the companies they have lost sales to gliders

Thanks, Susan

**To:** Charmley, William[charmley.william@epa.gov]
**From:** Matthew Spears
**Sent:** Thur 11/9/2017 11:28:36 PM
**Subject:** Gliders

Hi Bill,

Thanks for the quick reply. I'm optimistic that EMA as a whole is coming together on this issue too. Jed might have shared with you that we're already drafting comments that we'll eventually share with our members for consensus building, when the time is right.

I read the NPRM today, and I'll be following up with EMA's attorneys here because there are legal arguments in the NPRM that confuse my engineering mind. I don't follow the argument in *3. Glider kits*. Regardless of what eventually gets installed into a glider kit, the kit would seem new and incomplete on its own, which to me would seem within scope of CAA 202.

I also noted the Agency's NPRM text in 1037.801, "…a new motor vehicle may include previously used parts." I presume that would include previously used engine parts.

Finally, the text under EO 13045 does not seem to take into account and/or build from the HD Phase 2 RTC, Appendix A to Section 14, pp. 1960-1968.

On a separate topic, it was good to see that OAR now has a confirmed AA.

Have a good Veterans Day weekend,

-Matt

**From:** Charmley, William [mailto:charmley.william@epa.gov]
**Sent:** Thursday, November 9, 2017 4:41 PM
**To:** Matthew Spears <MSpears@emamail.org>
**Subject:** Re: EPA Notice of Proposed Rulemaking "Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits"

Matt

A few things on this topic you may find interesting:

Sierra Club v. EPA 18cv3472 NDCA

Attachments Prod 1

ED_002061_00259402-00014

**From:** Charmley, William [mailto:charmley.william@epa.gov]
**Sent:** Thursday, November 9, 2017 4:41 PM
**To:** Matthew Spears <MSpears@cmamail.org>
**Subject:** Re: EPA Notice of Proposed Rulemaking "Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits"

Matt

A few things on this topic you may find interesting:

- we have finished testing of one Glider in Ann Arbor, and have a s come on the lab right now. I think we will release a test report on both vehicles in the next week to 10 days, once we have

ED_001620_00001293

finished testing and the test report

- last week I saw a quote that the DTNA CEO has said Daimler will not to backwards, independent of the outcome of EPAs reconsideration rule

- in the last Few days, ATA has decided to oppose any change in the Glider regulations established in the Phase 2 rule. I think they may be putting out a statement on that topic

- the ASD team reached out recently to Tennessee Tech. We had a good technical discussion with them, and I think we will be able to document for the record what we have learned, which will explain why the Tennessee Tech results are so different than what we have seen. As you know, emissions testing requires deep skills and experience, and while the Tennessee Tech team is well intentioned, I believe that have a lot to learn. I guess that is good, since they are a university, and learning is part of why you go to college.

I hope all is well with you.

All my best

Bill

Sent from my iPhone

On Nov 9, 2017, at 4:07 PM, Matthew Spears <MSpears@emamail.org> wrote:

Sad.

From: Cullen, Angela [mailto:cullen.angela@epa.gov]
Sent: Thursday, November 16, 2017 11:05 AM
To: Berry Steve; Tim.Schimmel@mkdrucker.com; Privacy
Subject: RE: 2nd Glider

Tim and Steve,

We are planning to complete our testing of the second glider today. Therefore, the vehicle would be available for pickup tomorrow or any day after that. We do not have staff on-site during the weekend or on Thursday, Nov. 23, but any other day would work. Please let me know what works best for you. I will be out of the office tomorrow, so please feel free to use Connie Hart as a contact. She can be reached at 734-214-4340 or hart.connie@epa.gov.

Again, thank you very much for all of the work that you put into this project so that we could test these two gliders.

ED_001620_00001941

Angela

To: Cullen, Angela[cullen.angela@epa.gov]; Charmley, William[charmley.william@epa.gov]
From: Berry Steve
Sent: Thur 11/16/2017 4:16:19 PM
Subject: Glider Testing

Hello Angela and Bill

That's good news, Angela. Thank you.

Does EPA have an interest to test Glider 3, probably a reman engine rather than Fitzgerald Special?

Also, are you planning to make the data available? When ?

Finally, have you gotten a copy of the TN Tech report? Does EPA intend to request it?

Steve

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Sent from my iPhone

# TEXAS DEPARTMENT OF AGRICULTURE
## COMMISSIONER SID MILLER

August 8, 2018

Anne Idsal
Administrator, U.S. Environmental Protection Agency
Region 6
Dallas, TX

Dear Ms. Idsal,

I am again reaching out to you to present alternative solutions to the current treatment of Fever Ticks in Texas. It was unfortunate that you decided not to attend the meeting scheduled yesterday at the Texas Department of Agriculture to discuss options to the matter at hand.

However, I have met with the industry and discussed the different options available. One is short-term and the others are long-term. I would also look forward to any other suggestions you might have.

The short-term solution would be to continue to allow the use of the spray box for the next 45 days, and propose an acceptable permanent solution during the 45 days. This would include giving the producer the option to not have young calves, older, or convalescent cattle sprayed in the spray box. The owner would need to supply the labor to separate the cattle not going through the spray box.

A short-term and long-term solution is to allow the cattle to run through the spray box, but catch the animal's head outside the spray box prior to treatment, and manually spray the head. This treatment would be in accordance with the product label.

Another option is to develop a new spray box that meets the ventilation requirements under the pesticide label.

All solutions require that USDA-APHIS provide that the Memorandum of Understanding between them and the Texas Animal Health Commission (TAHC) permit TAHC personnel to be supervised as pesticide applicators under the USDA-APHIS applicator license.

I would like to implement these changes immediately upon your agreement.

If you have any questions do not hesitate to contact me.

Sincerely,

Sid Miller
Commissioner

P.O. Box 12847
Austin, Texas 78711

TexasAgriculture.gov

(512) 463-7476
Fax: (888) 223-8861

USDA

United States Department of Agriculture

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Washington, DC
20250

August 7, 2018

The Honorable Sid Miller
Commissioner
Texas Department of Agriculture
Post Office Box 12847
Austin, Texas 78711

Dear Commissioner Miller:

As you are aware, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) established a Permanent Quarantine Zone (PQZ) under the Cattle Fever Tick Eradication Program (CFTEP) to prevent the spread and re-establishment of the Cattle Fever Tick (CFT) in the United States. USDA and the Texas Animal Health Commission (TAHC) have cooperatively administered the CFTEP since it was created in 1906. The PQZ is approximately a 500-mile buffer zone between Mexico and the rest of the U.S. to protect the entire U.S. cattle industry from the re-establishment of the CFT. USDA values the long-standing cooperation with TAHC, the Texas Department of Agriculture (TDA), and producers to mitigate the devastating impact the CFT has on livestock and stream of commerce.

The CFT poses severe health risks to cattle and carries microscopic parasites that attack and destroy red blood cells causing acute anemia, high fever, and enlargement of the spleen and liver resulting in mortality of up to 70-90% in infected cattle. In addition to the devastating health impacts on cattle and various wildlife, the CFT also creates significant economic burdens to U.S. cattle producers operating within or around the PQZ. This economic impact, coupled with the treatments required to eradicate the CFT once established, are expensive and burdensome on the cattle industry. We estimate that if the CFT were to re-establish its historical range in the United States, the U.S. cattle industry could face losses of approximately $1.5 billion annually.

As part of our multi-faceted strategy to mitigate the health and economic impacts, as well as the potential spread of CFT, USDA-APHIS and TAHC deploy a suite of treatment options available to producers seeking to transport their livestock out of the PQZ in order to participate in commerce. One of those critical options, which is intended to mitigate the stress on animals and the economic burden on producers, includes the use of spray boxes. USDA has treated cattle in spray boxes with various pesticides since the 1970s to assist in the eradication of the CFT.

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Producers retain the option to truck their cattle to dipping stations staged throughout the PQZ; however, many producers prefer treating their cattle in spray boxes to mitigate costs and reduce the stress on their animals, especially during the hot summer months. The portable spray boxes allow producers within the PQZ, who may choose not to transport their cattle or may not have readily available access to dipping vats, an alternative method of treatment to facilitate their ability to move their cattle out of the PQZ and participate in commerce.

We learned through social media postings that TDA has issued a "Stop Use" order on or about July 31, 2018, preventing the continued operation of USDA-APHIS and TAHC spray boxes. The Department wishes to express significant concern if TDA's action prohibits or limits the use of this valuable, safe, and effective tool in the cattle fever tick program.

Several cattle producer groups, livestock organizations, and other impacted stakeholder sent the enclosed letter to USDA and the Texas Congressional delegation on August 4, 2018, stating their strong concern over TDA's recent actions and enumerating their support for the continued use and deployment of spray boxes as a critical tool under the CFTEP.

USDA is committed to working collaboratively with TDA, TAHC, and the impacted producers to ensure the availability of as many tools and treatment options as practicable to assist in the continued efforts to eradicate the CFT and reduce the regulatory burdens on producers seeking to participate in commerce outside of the PQZ.

USDA stands ready to assist TAHC, TDA, and our stakeholders in this process.

Sincerely,

Michael Watson
Associate Administrator
Animal and Plant Health Inspection Service

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
REGION 6
1445 ROSS AVENUE, SUITE 1200
DALLAS, TEXAS 75202 – 2733

Office of the Regional Administrator

August 10, 2018

Commissioner Sid Miller
Texas Department of Agriculture
P.O. Box 12847
Austin, TX 78711

Dear Commissioner Miller:

Thank you for your letter regarding the use of spray boxes and your desire to find short and long-term solutions to Texas' ongoing fever tick eradication efforts.

I look forward to engaging in discussions with Texas Department of Agriculture (TDA), United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Texas Animal Health Commission (TAHC), and the cattle industry in the days to come.

In the meantime, please do not hesitate to contact me at 214-665-2100 or your staff may Randall Rush, Region 6 Agriculture Policy Advisor, at 214-665-7107 or rush.randall@epa.gov if we can provide any information or help with discussion logistics.

Sincerely,

Anne L. Idsal
Regional Administrator

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United States Department of Agriculture

July 23, 2018

Richard Keigwin, Director
Office of Pesticide Programs (7501P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Keigwin,

USDA appreciates the opportunity to comment on the "National Marine Fisheries Service Biological Opinion Issued under Endangered Species Act: Chlorpyrifos, Diazinon, and Malathion" (EPA-HQ-OPP-2018-0141), announced by the Environmental Protection Agency (EPA) on March 23, 2018. Chlorpyrifos, diazinon, and malathion are crucial insecticides for protecting agricultural crops and animals, are critical to USDA plant protection programs mandated by Congress and carried out by the Agricultural Plant Health and Inspection Service (APHIS), and are key in the combat to protect public health from disease vectors including mosquitoes and other insects.

USDA has grave concerns about this biological opinion (BiOp) and strongly urges EPA to repudiate its findings and reinitiate consultation with the National Marine Fisheries Service (NMFS). This BiOp does not accurately assess the risk to endangered species, if any, posed by pesticides, because NMFS fails to establish that the data, assumptions, and analytical methods used, as well as the conclusions reached, are supported by facts and rational reasoning. USDA is concerned that the BiOp likely arrives at erroneous or unsupported jeopardy determinations and fails to address the shortcomings identified by the Fourth Circuit Court of Appeals in *Dow AgroSciences v. National Marine Fisheries Service*. This 2013 opinion found the previous version of the BiOp (for these same three chemicals) to be arbitrary and capricious and remanded it to NMFS for correction.

Further, it is critical to dispel any suggestion that inaccuracies or overestimates underlying the jeopardy determinations can be overlooked in favor of implementing the reasonable and prudent alternative (RPA) associated with this BiOp. Some may try to argue that the RPA offers a viable path forward by eliminating even a hypothetical possibility of jeopardy. This is manifestly not the case, as the RPA in this BiOp is ill-conceived, unsupported by facts, and could never be implemented. NMFS has failed to assess economic feasibility of the RPA in accordance with the Fourth Circuit opinion and at the same time has not even established that the proposed RPA

Office of Pest Management Policy
1400 Independence Avenue SW
Washington, D.C. 20250-0314
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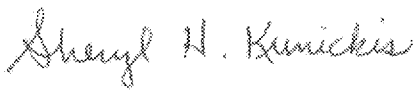
would successfully mitigate the supposed jeopardy determinations. The inability or unwillingness of NMFS to develop a truly *reasonable* and *prudent* RPA highlights the importance of developing accurate and reliable jeopardy determinations first.

USDA has attached comments outlining the Department's concerns. Section 1 is an executive summary, Section 2 provides brief responses to the questions posed by EPA in its Federal Register announcement, and Sections 3 and 4 contain the bulk of USDA's concerns and suggestions on the BiOp's jeopardy determinations and RPA, respectively.

America's farmers, ranchers, and foresters already protect, improve, and restore natural resources, including species habitat. Taxpayers, through USDA programs, along with partners across the country, have contributed to the protections of all species, including those that are threatened and endangered, while enjoying the abundance produced by farmers, ranchers, and foresters. These conservation programs may be a wiser investment than the thousands of work-hours that produced thousands of pages of information that cannot be implemented.

Sincerely,



Sheryl H. Kunickis, Ph.D.
Director

Office of Pest Management Policy
1400 Independence Avenue SW
Washington, D.C. 20250-0314
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## SECTION 1: EXECUTIVE SUMMARY

This biological opinion (BiOp) for chlorpyrifos, diazinon, and malathion is the unfortunate, but not wholly unexpected, outcome of the gridlocked, contentious, and highly litigious process of interagency consultation for pesticide registration under Section 7 of the Endangered Species Act (ESA). One major factor contributing to these problems has been the National Marine Fisheries Service's (NMFS) steadfast refusal to conduct assessments based on reasonable assumptions, proper analytical methods, and the best available scientific and commercial data. This has occurred irrespective of the sustained objections of other agencies and over the course of several presidential administrations. This BiOp is, once again, the result of a floundering ESA consultation process for pesticide registrations that creates no positive outcomes:

- Endangered species are not protected because risk is not accurately calculated or characterized;
- Farmers may lose pest management tools not because they pose a risk, but because the federal government has repeatedly failed to meet its obligations under ESA;
- The federal government wastes significant resources on a duplicative and inefficient multi-agency assessment process for pesticide registrations.

USDA has outlined some of the major shortcomings of this BiOp in this document and strongly urges NMFS and its partner agencies to reconsider all parts of this highly problematic BiOp and of the larger pesticide consultation process.

*Issues with Jeopardy Determination*

The revised NMFS BiOp is based on findings of purported pesticide risk that are not adequately explained and appear to not be the product of reasoned decision-making.

- NMFS improperly attempts to estimate risk using the output from R-plot analyses, even though these are only valid for identifying worst-case risk pathways at a screening level.
- The standards for estimating the amount of overlap between pesticide usage areas and endangered species habitat are unsupported in the BiOp.
- NMFS skews uncertainty towards finding heightened risk by speculatively discussing "risk modifiers" such as future water temperatures and the "likely" effects of pesticide mixtures, without proper characterization of these modifiers or any consideration of other modifiers that may refine or lower the potential risk estimates.

Analyses were not based upon the best scientific data available and NMFS seemed to ignore available, reliable pesticide usage data. Instead, NMFS fell back on illogical assumptions that lead to overstated estimates of pesticide usage that bias the analysis heavily in favor of finding high risk. In one scenario, USDA found that NMFS' estimate of acres treated with malathion within a given area was a nearly 500-fold overestimate compared to actual, confirmed treated acreage (page 10, below). Rational consideration of best available pesticide usage data (even using conservative, state-level percent-crop-treated information to project county-level estimates) would greatly improve the risk estimates in this BiOp.

- NMFS' failure to utilize best available data conflicts with the National Research Council's report "Assessing Risks to Endangered and Threatened Species from Pesticides," which recommends that ESA risk assessments should avoid the use of data that are irrelevant and lacking a reasonable theoretical basis for extrapolation (p. 7). Additionally, the report recommends that "the agencies should, at a minimum, subject all information to a review based on OMB criteria of "objectivity, utility, and integrity," (p. 45), which to USDA's knowledge NMFS did not pursue for this BiOp.
- NMFS also seemed to ignore the directions of the Fourth Circuit Court of Appeals, which in its 2013 ruling remanded a previous version of this BiOp for containing many of the same infirmities USDA has identified in the current version. This BiOp continues to rely "on a selection of data, tests, and standards that [do] not always appear to be logical, obvious or even rational." See *Dow AgroSciences v. National Marine Fisheries Service*, 707 F.3d 462 (4th Cir. 2013).

On the whole, NMFS's methodology, decisions, and analytical opaqueness combine to make the BiOp's risk conclusions appear far more problematic than they actually are, resulting in a biased, arbitrary, and pre-judged assessment outcome for chlorpyrifos, diazinon, and malathion.

*Issues with the RPA*

NMFS does not provide (1) an explanation or justification for the proposed RPA and how it might prevent jeopardy of listed species, or (2) an economic and technological feasibility analysis for this RPA. Therefore, the "RPA" in this BiOp does not meet the requirements for an RPA set by 50 CFR 402.02, and USDA is concerned that its inclusion without a proper basis renders the BiOp arbitrary and capricious under the Administrative Procedure Act.

In addition to its legal shortcomings, the "RPA" is impractical and impossible to implement for American agriculture, because all RPA options are extremely burdensome and likely not economically feasible:

- Some growers could face major yield losses if certain pesticide uses are removed from the label (i.e. banned).
- Construction of wide, 300-meter (approximately 1,000-foot) buffers could cost growers between $2,000 and $22,000 per 1,000 feet of field perimeter, not including the cost of foregone income for in-field buffers or the cost of ongoing maintenance.
- The RPA incorporates a point system through which, in theory, growers could earn points for certain mitigation actions. Earning a certain number of points would allow them to continue using the three pesticides subject to this BiOp. However, this point system was adopted wholesale from one designed for agriculture in the European Union. Encouraging the use of a mitigation system designed for a wholly different continent and regulatory system is highly questionable, particularly without in-depth review or study. Ultimately this point system could force growers to adopt conservation practices costing thousands of dollars per acre that are not compatible with U.S. or regional agricultural practices.

## SECTION 2: RESPONSES TO QUESTIONS EPA POSED IN THE FEDERAL REGISTER NOTICE ANNOUNCING THE BIOLOGICAL OPINION

1. *Comments on the scientific approaches and data sources used to support the BiOp and reach determinations for the listed species and critical habitat.*

In Section 3 of this document, USDA provides a detailed description of the shortcomings of the scientific approaches and data sources NMFS used to support the BiOp and, in particular, the jeopardy determinations for listed species and adverse modification determinations for designated critical habitat.

2. *Comments on the RPAs and RPMs. Can they be reasonably implemented? If not, describe why not. Are there different measures that may provide equivalent protection to the ones in the BiOp but result in less impact to pesticide users?*

The proposed RPAs and RPMs lack a firm grounding in facts and cannot be reasonably implemented. NMFS has failed to satisfy its obligation to ensure economic and technological feasibility of the RPA; it has not established that the proposed RPA would even prevent jeopardy; nor has it provided any defensible, quantitative connection between the proposed mitigations and risk reduction. Moreover, USDA strongly reiterates that no mitigation should be considered until reasonable, accurate, and reliable jeopardy determinations are made, which this BiOp has failed to do. Because the jeopardy determination methodology and conclusions are so flawed, USDA does not propose alternative RPAs or RPMs at this time. For a full discussion of the weaknesses of NMFS' proposed RPA, see Section 4 of this document.

3. *Comments on national- and state-level use and usage data and information. In particular, EPA is seeking usage data and information for non-agricultural use sites (e.g., nurseries, managed forests, pasture, rights-of-way, golf courses, and wide-area mosquito control). If possible, provide sources of data and information that should be considered.*

NMFS has repeatedly failed to address easily available and reliable pesticide usage data in favor of claiming that it must analyze *purely hypothetical and unrealistic* pesticide use scenarios extrapolated from maximum use authorizations and geographic use ranges derived from pesticide labels. To USDA's knowledge, NMFS has not provided a coherent justification for why such an approach (often referred to as "the label is the law") is necessary, advisable, or even allowable under ESA when reliable data describing how pesticides are *actually* used are readily available. Throughout this document, USDA provides numerous examples of how such data could be used to refine NMFS' risk and exposure estimates for jeopardy determinations.

Many reliable data sources that are in use by other agencies for non-agricultural use sites are available, including usage information collected by the California Department of Agriculture and industry-specific reports produced by the industry consulting group Kline and Company. Efforts are also currently underway by the Fish and Wildlife Service and other federal agencies to document the availability of pesticide usage data within the United States.

## SECTION 3: RISK ASSESSMENTS AND JEOPARDY DETERMINATIONS

*Introduction*

The revised National Marine Fisheries Service (NMFS) Biological Opinion (BiOp) is based on conclusions about pesticide exposure that are not adequately explained or supported and are not the product of reasoned decision-making. The BiOp is not based on the best commercial and scientific data available, because it continues to ignore available pesticide usage data in favor of assuming that pesticides are used *everywhere* and *all the time* up to the theoretical maximum authorized by the pesticide label. NMFS makes these critical assumptions without adequate explanation or support. The BiOp uses highly conservative, screening-level, model-derived exposure estimates as proxies for "likely" exposure pathways when even a quick review of real-world pesticide usage practices and available data reveals that such exposure scenarios are not at all realistic. The connection between risk estimates and jeopardy determinations is not transparent, and the analysis is systemically biased towards inevitable mitigation of these unrealistic jeopardy determinations. No reasonable characterization of risk is provided and no satisfactory explanation was given for why such risk estimates would warrant mitigation, given the low likelihood of occurrence. As a result, the BiOp relies on a biased and arbitrary selection of data, assumptions, and risk standards that do not appear to be logical, obvious, or rational.

USDA is particularly concerned that this BiOp ignores guidelines provided by the Fourth Circuit Court of Appeals in its 2013 ruling that remanded a previous version of this BiOp back to NMFS.[1] Specifically, the Fourth Circuit concluded "that the BiOp was not the product of reasoned decision-making in that [NMFS] failed to explain or support several assumptions critical to its opinion." The court further criticized NMFS for relying "on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational" and for not explaining the choices made in the BiOp "with sufficient clarity to enable [the court] to review their reasonableness." USDA finds that the current, December 2017, BiOp suffers from significant infirmities that are very similar to those the Fourth Circuit cited as grounds for remanding the November 2008 BiOp back to NMFS.

For this and future BiOps, USDA strongly urges NMFS to clarify and adhere to an appropriate standard when determining which effects of the registration of these pesticides are too remote to consider. The Endangered Species Act (ESA) regulations in 50 CFR 402.02 identify indirect effects of an action as those that occur later in time, but are still reasonably certain to occur. Here, use of pesticides by growers and other private parties will occur after the action (registration review of the pesticide) has concluded and is properly classified as an indirect effect. Therefore, USDA calls on NMFS to explicitly limit its consideration of pesticide use to those types, locations, rates, and frequencies of use that are *reasonably certain to occur* based on the *best available data* that NMFS is required to use under the ESA. The remainder of our comments will demonstrate that NMFS has fallen short of this standard (or any other applicable

[1] *Dow AgroSciences v. National Marine Fisheries Service*, 707 F.3d 462 (4th Cir. 2013).



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 1 ED_002061E_00000914-00006

standard under the ESA or the Administrative Procedure Act) by basing its jeopardy determinations on a wide range of unrealistic and unjustified assumptions.

While NMFS repeatedly fails to integrate the best available state (and, in the case of California, even local-level) pesticide usage data, it presents as "likely" a number of risk outcomes that are derived from usage and application assumptions that pose issues. Despite making token changes from the EPA Biological Evaluations (BEs) and its own prior published BiOp, which had been remanded by the Fourth Circuit, the ultimate risk and likelihood determinations for endangered and threatened species and designated critical habitat are still opaque subjective determinations rather than transparent and quantitatively defensible risk-based conclusions. NMFS' analysis fails to take into account existing mitigation and commonly adopted usage practices, which have driven overall usage of organophosphate insecticides down over the past 20 years. Despite this readily available information, NMFS implicitly assumes usage of organophosphate pesticides would or could increase sharply in the future and points to this hypothetical potential for increased usage over the next 15 years as a reason to characterize even its highly conservative analysis as potentially not conservative enough. The BiOp assumes that usage of some organophosphate chemicals occurs on crops where they are not even registered and combines crops into groups in a way that projects usage on areas (and at times of the year) where usage is not plausible under current label limitations. It further assumes that pesticides are applied on an area-wide basis across crop groups (essentially simultaneously) at rates that are economically and biologically untenable, simply because such use is theoretically possible under labeled use directions. In doing so, NMFS fails to make use of the best available data and refuses to utilize more refined and more appropriate probabilistic methods and characterization tools that could assess jeopardy likelihood under far more realistic conditions.

In addition to unrealistic usage projections, the BiOp retains an unsupported assumption that species are exposed to toxic levels of pesticides for a four-day period for population modeling (despite available data on likely ecological fate and degradation) and fails to explain why this assumption was retained. It may give rise to an erroneous impression that probabilistic considerations were taken into account, when in reality, upper-bound usage and exposure assumptions (combined with conservative hazard endpoints) continue to fundamentally underpin all risk findings. The BiOp includes ill-supported and arbitrarily low standards for linking the amount of hypothetical overlap between habitat and cropland to a particular risk finding—essentially projecting "high" risk likelihood for any area that has 5% overlap with a crop where pesticide use is registered. The analysis further assumes, without scientific support, that tank mixtures of organophosphate pesticides with other active ingredients and increasing aquatic temperatures are both likely to occur and likely to widely increase risks. These were the only two "environmental baseline" parameters considered in the analysis, and both were projected to increase risks without any consideration of potential modifiers that could decrease risks.

On the whole, the BiOp systematically highlights potential variability that makes risk estimates worse, while simultaneously being dismissive of variability or available data that would potentially reduce risk estimates or better characterize the likelihood of risk. The ultimate jeopardy determinations are thus justified by opaque allusions to "professional judgement,"

which is in fact biased towards overstating actual risk. This approach results in an arbitrary, capricious, and pre-judged assessment outcome for chlorpyrifos, diazinon, and malathion.

*R-plot Analysis: NMFS Inappropriately Uses This Screening-Level Tool in its Jeopardy Determinations*

The R-plot tool presented by NMFS in Chapter 3 of the BiOp was used to summarize available toxicity and modeled exposure information by use site. USDA agrees that this graphical presentation could be useful to identify theoretically plausible routes of potential exposure. However, it is not a valid tool for evaluating the "effect of exposure" to groups of individuals and designated critical habitat in the absence of appropriate characterization. This analytical framework is heavily weighted toward finding high risk to the species and should merely be considered a *screening* tool. The resulting effects estimate is based upon distributions of the most sensitive endpoints identified, by taxa and effect measure. The linkage between the estimated environmental exposure concentration (EEC) shown in the R-plot graph and EEC data provided in the EPA BEs is unclear. Ideally the reader should be able to determine the simulation scenario and assumptions used by EPA to generate the EEC data depicted in R-plot, but it is not possible to ascertain any characteristics of the EEC other than the averaging period.

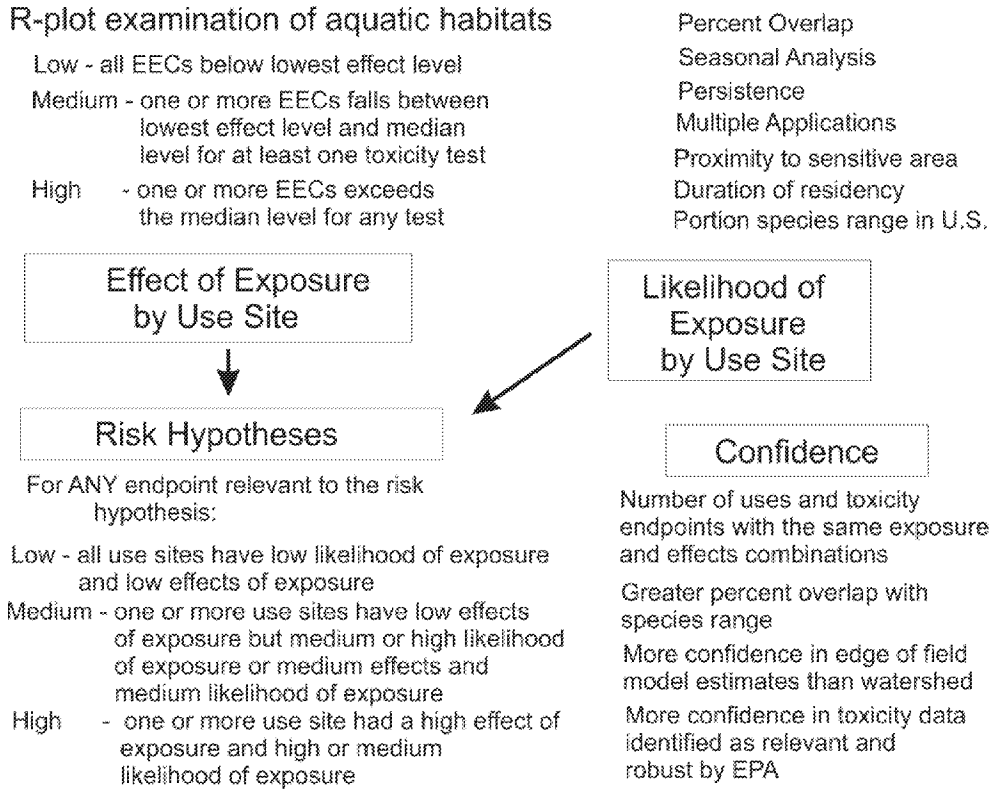
NMFS improperly uses this screening-level output, without real-world context, to rank the effects of the pesticides on species as "low," "medium," or "high." If any single EEC exceeds the median response endpoint of 50% for any toxicity test, the effects are ranked as "high" (see Fig. 1). This assumes all of the toxicity endpoints are equally important for species survival and viability and that all aquatic habitats are also equally important to the species. This analytical framework does not require estimation of actual environmental concentrations.

The likelihood-of-exposure assessment is based on a formulaic analysis of seven factors (see Fig. 1). Categorization is based on a series of yes/no questions as well as a crude estimate for species overlap with pesticide use sites or the duration of occupancy by the species in the habitat (see Fig. 1). High likelihood of exposure usually results when 5% or more of a species' range overlaps with a use site, making overlap an especially influential category (discussed later). There is also a yes/no designation for persistence, with any chemical that is expected to be detected in water for 100 days listed as "yes" even though it is not clear what constitutes a significant presence. Finally, there is a yes/no designation for multiple applications, but this is based solely on label directions and not on the actual likelihood of multiple applications for any given use, which should have been derived from available usage data.

By basing its analytical framework on these simplistic factors and by not explaining its underlying reasoning or consulting available usage data, NMFS fails to establish a rational connection between real-world environmental conditions and pesticide use on the one hand, and the results of the assessments contained in the BiOp on the other. The information used to assess confidence in the conclusions was not real-world data, instead it reflected the same worst-case scenarios that inform the framework. Moreover, the assumption used in the fish population modeling that species are exposed to the EECs for a continuous 96 hours was rejected by the Fourth Circuit in 2013, mostly because NMFS failed to explain how this assumption was

"appropriately reflective of conditions in the real-world environment," and was found to render the previous BiOp arbitrary and capricious. USDA points out that the current BiOp is not an improvement over the previous one in that respect, and that no valid explanation is given for the 96-hour exposure assumption.

**Figure 1.**




*NMFS Used Highly Conservative Outputs from the EPA BEs without Further Refinement or Proper Characterization, Resulting in Misleading and Unrealistic Conclusions*

While USDA's objections to the conclusions of the NMFS BiOp are multi-faceted, one primary source of conservatism used from the outset of the analysis are the modeled EECs from the EPA BEs. These EECs are derived from intentionally conservative assumptions and model inputs, which were developed for use by EPA for the purposes of screening-level analyses. EPA's pesticide water calculator (PWC) estimates pesticide concentrations in surface water by modeling movement of pesticide residues from treated fields (or drift from a pesticide application) into a non-flowing farm pond. For some habitat bins, EPA also adds modifiers to provide somewhat refined estimates for flowing water and marine habitats. But for all cases, runoff is modeled based upon historical weather data, with EECs derived from relatively rare (1-in-10-year or 1-in-30-year) precipitation events modeled to occur after pesticide applications at the highest possible label rates (i.e., these are worst-case, screening-level EECs). The PWC also looks at the drift component of off-field movement, which happens at the time of application,

utilizing the AgDrift model. AgDrift models movement of pesticide residue off-field for aerial and ground applications, accounting for various droplet sizes and wind speeds, among other factors (EPA, undated).

While these approaches are, again, quite valid for producing screening-level risk assessments in a pesticide regulatory context, their utility is limited for assessing likely risk outcomes in the natural environment (e.g., effects that must be reasonably certain to occur to be properly considered). The model inputs underpinning the PWC have room for refinement, but typically worst-case inputs are used for the percentage of area being treated within the model farm-pond watershed, worst-case soil parameters are used for runoff, and a 1-in-10-year precipitation event coinciding with label maximum levels of usage is the default setting. The BiOp fails to provide any useful characterization of the relative likelihood of these conservative inputs for eventual R-plot evaluation. Instead, it treats the outputs as estimates for what would actually be expected to happen in treated areas. There is no characterization of how rare such EEC occurrence is expected to be, when typical application dates, typical agronomic practices, commonly adopted runoff mitigations, likelihood of rainfall events, and actual proximity to water bodies are considered. The "percentiles" of EECs used in R-plots are not a distribution of actual likelihood of occurrence under typical usage conditions, but rather represent a distribution of highly conservative estimates derived from screening-level methodology. NMFS then uses these values with misplaced confidence that they represent the range of likely EECs that would be expected to occur, and without characterizing what the estimates truly represent. NMFS stretches the interpretation of the model output even further when it represents the risk for an entire cropping area within a given ESU without regard to its actual proximity to water bodies, except for a loose description of "confidence" (where NMFS states it has higher confidence in risk findings for near shore habitats and lower confidence for large bodies or marine habitats).

USDA notes that the drift component (AgDrift) of EEC calculation is also quite conservative. This is well illustrated by a recently published study that compared model outputs from a screening-level assessment with iterative outputs that accounted for various input refinements. Both were compared with results from a controlled field study (during a dry season, so that observed EECs could be attributed to drift, without a runoff component) to demonstrate the large difference in results from conservative screening-level assumptions. The authors found that screening-level assumptions resulted in 45-fold higher estimated concentrations compared to those associated with the field study and its accompanying model refinement. (Winchell et al, 2018). USDA again acknowledges that a conservative approach to drift modeling is appropriate for use in screening-level assessments, as long as scenarios that "fail" the screening-level assessment are refined and further investigated before final risk conclusions are drawn. Not only does NMFS fail to move beyond a screening-level assessment, it does not acknowledge the significant conservatism of this approach and fails to characterize the variability around these estimates that would be expected under real usage conditions. Even if refined models were not used to produce EECs (which USDA acknowledges could be difficult and onerous when assessing exposure for numerous ESUs), such characterization information would *greatly* inform the questions of exposure likelihood (or confidence) used in making jeopardy determinations, which is discussed further below.

*NMFS Failed to Consider Available and Reliable Pesticide Usage Data, Leading to an Overestimate of Pesticide Use*

Exposure estimates (which directly determine the likelihood of an adverse effect occurring) in this BiOp are derived from imprecise evaluation criteria. Use areas are based on a five-year crop data layer file, which assumes that any crop with a registered use for a pesticide is being treated to the fullest extent authorized by the pesticide label (i.e., maximum application rate, maximum number of applications, with annual treatment at this level). While a minimum, median, and maximum are reported for the percent overlap of each crop group (a marginal improvement over what was provided in the EPA BEs), the assumption that all cropped areas are "treated areas" skews the analysis toward a high-exposure conclusion. Most of the use groups that have more than 5% of an overlap with an ESU are categorized as "high" likelihood, and this designation is not adequately explained or justified, outside of the implicit assumption that all of that overlap area *must* be treated if it *could potentially* be treated. There are instances in which 5% or more overlap does NOT result in "high" likelihood of exposure. In Table 3 on page 34 of the BiOp, a high percent overlap in combination with a medium portion of the species range within the United States results in medium likelihood of exposure, whereas high percent overlap in combination with low persistence and category 2 of species duration of use (explained on p. 32) results in medium likelihood of exposure. Curiously, the first line and the 10th line of Table 3 are identical except one is labeled high likelihood of exposure while the other is labeled medium. From a practical standpoint, a likelihood call of either "medium" or "high" can still result in a positive jeopardy call regardless, and the reasons underlying this call are not clearly explained.

In any case, such broadly conservative estimates for use site overlap with ESU and critical habitat do not account for the low likelihood of usage at maximum label rates on a site-by-site basis. Nor does it account for the generally low likelihood of repeated applications, nor for label-limited timing on many uses that are inappropriately lumped together and are further unlikely to occur simultaneously. All of this information is readily available for probabilistic consideration using commercially and publicly available pesticide usage data, even at the state level. Instead, the BiOp assumes that 100% of each crop group area is treated at the maximum label rate and multiple times (in accordance only with label restrictions). Usage to this extent is unrealistic from both an economic and a pest-management standpoint. A projection based on this assumption would indicate application of one or more orders of magnitude more pesticide material (chlorpyrifos, diazinon, and malathion) in ESU areas alone than is currently produced and applied in the entirety of the United States.

The following two examples demonstrate the degree to which NMFS overestimated treated acreage in the BiOp when compared to reliable pesticide usage data from EPA- and USDA-recognized best available data sources (EPA and USDA use these data routinely for regulatory work on pesticides, including in human health and ecological risk assessments). Both agencies have made determinations of their quality as the best available data that are in compliance with the criteria set forth in the Data Quality Act. For the active ingredient malathion, USDA did a cross walk comparison of the ESU acres on the West Coast associated with use sites that were deemed to be high-risk uses by individual ESU (BiOp Chapter 26.2) with best-available use data

(MRD, 2013-2017). NMFS' estimated percent of high-risk use-site acreage associated with each of these ESUs was back-calculated from ESU acreage reports in Chapter 17 of the BiOp. USDA then compared NMFS' estimate of high-risk use-site acreage for a given ESU to the total reported number of treated acres *within the entire state(s)* in which that ESU was located. As an example, if NMFS identified the orchards and vineyards crop group as high risk in an ESU that straddles the California-Oregon border, USDA would compare the orchard/vineyard use-site acreage that NMFS claims exists within this ESU to the total malathion-treated orchard/vineyard acreage *in all of California and Oregon* (as derived from best-available pesticide usage data). USDA found that NMFS' estimate of how many acres were treated within a given ESU typically exceeded what the best-available data indicate should be the total number of treated acres for the *entire state (or states)* that contains the ESU. In fact, NMFS' estimate of ESU treated acres exceeded USDA's estimate of total state treated acres by more than *20-fold* (MRD, 2013-2017). Under no circumstances should an estimate that varies so widely from best-available data be used in a BiOp which is subject to the best-available data requirements of ESA and the prohibition on arbitrary and capricious decision-making codified in the Administrative Procedure Act.

USDA notes that the magnitude of the overestimate in the example above is probably even greater. While state-level data are the most reliable and best available data for most states, California presents a situation where more localized data are available. As an example, USDA analyzed these more granular reporting data produced by the California Department of Agriculture from the California Pesticide Usage Reporting Program (PUR). Since pesticide usage reporting is mandatory in California, the information collected is *census-like data*, as they represent a measure of actual usage across the entire sum of actual treated acres, as compared to *sample data*, which allow a projection based on a survey of a subset of treated acres. USDA analyzed PUR-reported malathion usage in the counties containing the Central Coast California Steelhead ESU.[2] NMFS identified orchards and vineyards (approximately 94,520 acres, or 3.21% overlap with the 824,556-acre ESU) and pasture (approximately 426,120 acres, or 14.47% overlap) to be the two agricultural use sites posing high risk to this ESU (Section 17.20, p. 2910).[3] Actual California usage data from PUR indicate that annual average total acres treated from 2013-2017 (which includes multiple treatments to a single acre of land in a given year) in all the counties touched by this ESU was 160 acres for pasture and 930 acres for orchard and vineyard crops. Assuming there is no overlap in acreage between these two use-site groupings, NMFS' estimate of 520,640 acres of high-risk orchard/vineyard and pasture use is an almost 500-fold overestimate in comparison to the 1,090 acres that were actually treated with malathion annually in these counties. NMFS declined to use California PUR census data—a gold-standard data source for pesticide usage—which appears to be in conflict with the requirement of the ESA that best available data be used.

[2] The Central California Steelhead ESU falls within the California counties of Alameda, Contra Costa, Marin, Mendocino, Napa, San Francisco, San Mateo, Santa Clara, Santa Cruz, Solano, and Sonoma.
[3] Wheat, other grains, and other crops appear to be erroneously included as high risk use sites in Table 7, 26.2.3.

NMFS' rejection of these data leads NMFS to assume that all use-site areas that could theoretically be treated actually are treated, which is presented as a default assumption in determining exposure likelihood. USDA reiterates that NMFS failed to provide any meaningful criteria or justification for their 3 levels of overlap (>=5%, 1-5%, and <1%) that correspond to high, medium, and low likelihood calls for exposure. But even if pesticide usage data were not used to refine such estimates quantitatively, available usage data could still help refine NMFS' categorization of low, medium, and high likelihood, given the drastic differences in observed real-world usage versus assuming that all acres that can be treated will be treated. Further, it would inform the confidence behind risk estimates. It poses an issue to conclude a high likelihood of exposure for a pesticide that is estimated quantitatively and conservatively to be used on a tiny proportion of a given use site's acreage.

NMFS insists that the lack of highly localized usage data prevents it from concluding low likelihood of exposure at any one site, since maximum label-rate usage is allowed by label directions. But in reality, the totality of NMFS' exposure estimates already presents a far more untenable and systemic overestimation of exposure by treating every acre of cropland where use is registered as a worst-case scenario. This is in spite of decades of historical data that indicate usage has never come remotely close to reaching such a high level, and that overall usage of organophosphate insecticides is actually trending downward over time.

The actual proximity of cropland to water bodies within a given ESU is not considered at all. It is simply assumed that usage will result in runoff to water bodies (i.e., habitat within the ESU), yielding EECs in line with those modeled by the EPA farm-pond scenario (and some bins further modified to account for flowing water). In reality, these runoff estimates would only be germane for the small fraction of cropland or use sites that are adjacent to actual aquatic habitat. NMFS does address water proximity nominally in terms of relative proximity to water for qualitative confidence (i.e., higher confidence in edge of field effects vs. watershed-wide, see Fig. 1).

NMFS' crop group "lumping" approach assumes that usage happens anywhere and everywhere where registered use sites exist, even if usage cannot actually occur on all the crops within each respective group. Worse, it also assumes that peak concentrations, driven by simultaneous application, would happen on all of the crops in a given use group on the same day, even though it is known that application dates would vary widely between crops, or even potentially between target pests within the same crop. Readily available pesticide usage data could have been used to show a proportional breakdown of pesticide application timing by use site, and would have illustrated how assuming simultaneous applications significantly overestimates usage.

Even without taking usage data into account, there are already a number of existing label mitigations and typical usage practices that are widely known for a number of uses. For example, for chlorpyrifos usage in tree fruits, most applications (except on sour cherries) are labeled only for pre-bloom or trunk-only spray use, the latter of which would have a much lower typical application rate per acre, and essentially zero potential for drift to surface water. For malathion, almonds are lumped into the "orchard and vineyard" crop group, based upon the approach proposed in the EPA BE, and almonds account for a high proportion of acreage in a number of

ESUs. However, malathion is not labeled for use on almonds (EPA, 2009), so counting this area in the crop grouping bin will lead to overstated usage assumptions.

The assumptions of 100% overlap between ESU and use site for mosquito control, wide-area, and forestry applications (used only for small spot treatments and APHIS-approved programs that already underwent ESA consultations to preclude impacts) lack a rational connection to facts. Even a cursory investigation of application practices would have practically eliminated these use sites from consideration as major sources of exposure, given the impracticability, cost, and likely poor efficacy of treating such wide areas. But because NMFS' assessment is based solely on existing label instructions, as opposed to common knowledge and best-available data on how pesticides are actually used, NMFS assumed that chemicals such as chlorpyrifos and malathion are widely and indiscriminately applied over massive geographic scales (including entire ESUs) at levels, and with resulting application costs, that do not align with reality.

While USDA understands and acknowledges that no single data source would be sufficient to fully document usage parameters for every square meter of critical habitat that overlaps with cropping area, state level usage data provide a very useful tool for risk characterization and provide evidence of the relatively low likelihood of the R-plot outputs for many cropping scenarios. State-level pesticide usage data are reliable for understanding the relative infrequency of application at the label maximum limitations and should have been used to develop more accurate characterization of exposure likelihood by use site and ESU. This is particularly true given the long period of time that these insecticides have been used (i.e., there are significant historical data to document overall usage trends) and the availability of monitoring data showing that current usage patterns are not likely to adversely affect a number of the taxa of concern (discussed more later).

Further, probabilistic approaches are available to conduct more refined assessments at watershed scales that take into account pesticide degradation (rather than assuming peak concentrations persist for 96 hours), varied land management practices, usage, etc. One example of this approach is Whitfield Aslund et al. (2017), which determined a de minimis risk to three salmon ESUs in California for the related organophosphate insecticide dimethoate.

*Confidence Determinations Based on Mag-Tool and Salmon Population Models Are Circular, Self-Reinforcing and Thus Inherently Flawed*

The BiOp uses additional simulations to determine the level of confidence in the results of the qualitative R-plots risk conclusions. This analysis expresses a higher degree of confidence in the risk determinations when the results of these simulations are in agreement with the qualitative assessments. At least one of these simulation tools (MagTool) is in a draft form and has not been peer reviewed or used for regulatory purposes by EPA. The salmon population model (only applicable for three taxa discussed in the BiOp) produces community- to population-level effects estimates, but little background or validation information on the model was provided.

While the outputs of these tools are compared to R-plots to provide "weight of evidence," in reality they still utilize the same EECs that are derived from upper-bound screening-level methodology. So in this way, the comparative value is circular. And from a practical standpoint,

the output does little to affect jeopardy determinations for most taxa (i.e., non-salmonids), since the magnitude of any given "high" risk outcome from an R-plot could be downgraded only to "medium" if the output of the tools disagreed. In most cases, "medium" and "high" designations for risk ultimately lead to the same jeopardy findings, so long as the exposure likelihood is classified as "high," meaning overlap with use-site locations exceeds the arbitrary 5% threshold.

Ultimately, NMFS' extrapolation of effects from individuals up to population levels is not transparent and does not address the realism of the various criteria underpinning a determination on the likelihood of risk and exposure. While the methodological approach is couched as "weight of evidence," the reality is that each of these tools rely upon the same flawed conservative inputs and thus add little to the analysis. Any "validation" these tools purportedly provide appears to be circular and self-reinforcing. For example, while watershed-level analyses are deemed "probabilistic" because they dispense with an assumption that all use groups would be treated on the same day, the ultimate analysis still relies on a reiteration of numerous upper-bound inputs and worst-case exposure scenarios, which combine to provide an outcome that is only useful for screening-level assessment purposes, not real-world jeopardy determinations.

*Risk Modifiers: Risk Estimates Are Only Modified in One Direction*

Information from the status of the species, environmental baseline, and cumulative effects are treated as risk modifiers for the effects and likelihood risk determination. These risk modifiers are evaluated qualitatively. Two of the modifiers – environmental baseline and cumulative effects – are evaluated based on defining only two characteristics. If one or both of these characteristics is negative, then the modifier is assigned a large negative effect. Taking the environmental baseline as an example, there is no further refinement to ascertain the actual exposure levels or effects due to the pattern of exposure to either elevated temperatures or pesticide mixtures.

The evaluation of pesticide mixtures assumes that mixtures will result in synergistic effects, even though the science of estimating impacts of mixtures is not a settled area. The BiOp cites a journal article finding increased inhibition of acetylcholinesterase and liver carboxylesterase activity in mixtures of the organophosphates ethoprop and malathion. However, the BiOp does not attempt to evaluate the types of mixtures expected in the environment and their spatial extent or temporal duration. There is no consensus on the application of mixtures tools employed by NMFS. The conclusion drawn in the BiOp is that the likelihood of mixtures occurring increases as a greater number of unique pesticides is used in a watershed, and that these mixtures will increase some deleterious effect to a significant level for the population. A quantitative treatment is not presented. The BiOp reduces the question of the effect of mixtures on a particular species to a finding of low or high risk of jeopardy from the environmental baseline based on whether and to what extent these mixtures are expected in the species' habitat. The use of this analysis in the overall jeopardy determination lacks sufficient detail to understand differences in risk determinations between species that individually have findings of exposure to pesticide mixtures and high temperatures.

The overall risk to the species is defined by the formulaic assignment of a risk category based on the three levels of likelihood of exposure and three levels of effects. The confidence associated with these risk categories is based on other simulations providing similar results. There is no independent review of these simulation models. The criteria for high confidence in the results of the qualitative assessments rely on circular reasoning. For example, the BiOp states that the greater the percentage of site overlap, the higher the confidence in a rank of high risk for a particular risk hypothesis. This assumes that usage results in exposure and that exposure results in risk. Further, since usage is assumed for all use sites without consideration of available data, then what really is being projected is that the existence of use sites results in risk. Site overlap is a component in the exposure assessment which is a component in the ranking of the risk hypothesis. This should express confidence that the series of qualitative assessments is functioning as expected rather than actual confidence in the result.

There is no analysis presented to address the impact of error associated with incorrect categorization in the effects, exposure, or overall qualitative assessments. The propagation of error in one of the foundational assessments—effects or exposure—is carried through to the finding of overall risk and jeopardy.

*The Jeopardy Determinations Fail to Assess Likely, Real-World Risks and Should Be Disregarded*

Because of these approaches discussed above, and the lack of defensible explanation for many of the skewed methodological choices, this BiOp mischaracterizes what "high" likelihood of pesticide exposure means within any real-world context. Screening-level assumptions and estimates are used from the outset of the analysis, based on the methodology of the EPA BEs, and the further additions of iterative upper-bound assumptions compound the likelihood overestimate throughout the course of the analysis. The BiOp's conclusions are particularly questionable given that the three pesticides assessed have been used for decades without any evidence of problematic environmental exposure on the order of what is being presented as "likely" by this BiOp. When actual monitoring data have been evaluated (including monitoring that was done prior to significant organophosphate mitigation in the mid-to-late 2000s), most concentrations fall well below those EECs used to support NMFS risk and jeopardy conclusions. For example, a multi-year surface-water monitoring analysis conducted by the Washington State Departments of Ecology and Agriculture concluded that "Pesticide concentrations found likely do not directly affect salmonids," though effects to salmon prey were discussed as plausible (Sargeant et al., 2013).

The NMFS analytical framework does not require estimation of actual environmental concentrations. The starting point for the risk analysis is not based on actual spatial and temporal concentrations in the environment but on assumptions of upper-bound exposure levels (and the risks associated with them), with a formulaic analysis of the factors contributing to likelihood of exposure used in the BiOp. The separate qualitative assessments are treated as independently reinforcing one another, but are actually correlated with one another. For example, species overlap in the exposure assessment should be associated with the effect of exposure aquatic habitat bin.

This approach delivers a set of risk estimates that are plainly unrealistic compared to likely organophosphate exposure outcomes in the real world, and NMFS leaves this level of conservatism unmodified (and ultimately unaddressed) in the BiOp. Generally, when high risk is indicated by a screening-level risk assessment, a more highly refined or probabilistic risk assessment must be conducted to provide a robust picture of risk and allow the decision maker to make management decisions based on actual risk rather than potential risk. NMFS has not shown any inclination toward conducting such a probabilistic analysis, despite the availability of examples of such analyses in the published literature. Instead, the NMFS BiOp provides no refinement or useful risk characterization, and simply carries forward the input of worst-plausible numbers into a risk analysis framework that is further inclined toward overestimating risk and risk likelihood. It intentionally carries this systematic error forward to culminate in jeopardy determinations that have almost no utility for managing ecological risks. This makes the approach ill-suited for the intended purpose of a BiOp, which is to assess likely, real-world risks to threatened and endangered species.

## SECTION 4: REASONABLE AND PRUDENT ALTERNATIVE

*Introduction*

NMFS attempts to include a reasonable and prudent alternative (RPA) in this BiOp. As envisioned by ESA section 7 and the ESA regulations, issuing an RPA gives NMFS the opportunity to suggest to EPA an alternative course of action (in this case, additional conditions to be placed on the continued registration of the pesticide) that would avoid jeopardy. USDA's primary concern is that this BiOp does not accurately assess the risk to endangered species, if any, posed by pesticides, because NMFS fails to establish that the data, assumptions, and analytical methods used, as well as the conclusions reached, are supported by facts and rational reasoning. As discussed in the previous section, USDA is concerned that the BiOp likely arrives at erroneous or unsupported jeopardy determinations and fails to address the shortcomings identified by the Fourth Circuit in *Dow AgroSciences v. National Marine Fisheries Service*.[3] This 2013 opinion found the previous version of the BiOp (for these same three chemicals) to be arbitrary and capricious and remanded it to NMFS for correction.

Even though this BiOp's jeopardy determinations, without which no RPA would be necessary, are highly questionable, it is important to discuss why the RPA itself is also flawed and impractical. This is critical to dispelling any suggestion that inaccuracies or overestimates underlying the jeopardy determinations can be overlooked, because implementing the associated RPA would provide an easy "out" by eliminating even a hypothetical possibility of jeopardy. The RPA in this BiOp is ill-conceived, unsupported by facts, not feasible, and could never be implemented, highlighting the crucial need to develop reasonable, accurate, and reliable jeopardy determinations first.

Under the ESA regulations, RPAs are defined as "alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat."[4] In *Dow Agrosciences*, the Fourth Circuit chastised NMFS for failing to evaluate the economic impact of requiring uniform buffers as part of an RPA. Even though the court strongly implied that the regulations require RPAs to be economically feasible not just for the federal government, but for regulated industry as well, NMFS' response in the current BiOp argues that an RPA must only be feasible for the government (i.e., the action agency) to implement. NMFS bases its position on a couple of lower court and state court decisions, without addressing the far more recent 2013 Fourth Circuit opinion that *directed* NMFS to evaluate economic feasibility and strongly implied that economic feasibility under the regulations is broader than just the feasibility for the federal government.

USDA's position is that an RPA must be feasible not only for the action agency, but also for the regulated industry, including pesticide registrants and growers. To read 50 CFR 401.02 as requiring an RPA to be feasible only for the action agency would render the feasibility requirement entirely meaningless for every ESA consultation on a federal permitting action, because approving, disapproving, or modifying a permit will almost always be "economically

[3] 707 F.3d 462 (4th Cir. 2013).
[4] 50 CFR 401.02.

feasible" for the government. Moreover, an RPA that is not economically feasible for regulated industry or the applicant would also fail the parallel requirement that an RPA must be implementable in a manner consistent with the intended purpose of the action. For these reasons, interpreting the feasibility requirement as NMFS does makes little sense, a view which was echoed by the Fourth Circuit in *Dow Agrosciences*.

In addition to NMFS' failure to respond appropriately to *Dow Agrosciences*, USDA would like to emphasize the following three points of concerns with the RPA:

*1. This BiOp fails to evaluate or explain whether the RPA is economically feasible for the government, the applicant, or growers.*

NMFS made no attempt to analyze the economic and technological feasibility of the RPA. In *Greenpeace v. NMFS*, a decision which NMFS quotes in the BiOp (26-2, p.3456), the court concludes that "[i]t remains an open question whether this requirement [that an RPA be "economically and technologically feasible"] should be interpreted as referring only to whether the RPA is feasible for the agency, or whether it relates to the effects on third parties."[5] The 2013 opinion of the Fourth Circuit in *Dow Agrosciences* suggested that NMFS is responsible for analyzing both the impacts on the agency and the effects on industry. While bringing its jeopardy determinations into compliance with the legal requirements of ESA and the Administrative Procedure Act should be NMFS' highest priority (see Section 3 of these comments), it should then also perform an appropriate analysis of the economic and technological feasibility of any future RPA.

*2. The RPA is so burdensome that it is likely not economically feasible.*

*Burden on Growers*

RPA Element 1 (26-4, p. 3469) suggests three alternative methods to reduce pesticide loading for use sites deemed high risk. These alternatives, along with USDA's justifications for why they are not economically feasible, include:

- <u>RPA Element 1(a)</u>: Remove label authorization for all high risk uses.

  Growers are rational individuals making business decisions, and ultimately will not employ pest management techniques unless they are necessary. With that said, it is impossible to not expect an impact on growers when the use of a pesticide that a grower is currently utilizing is eliminated. These impacts can be in the form of reduced yields or higher incidence of pest injury from the adoption of less efficacious alternatives, which can result in loss of market access. Additionally, growers may be impacted by limitations from label restrictions on alternative pesticides, increased costs for applications, or the need for specialized application equipment which a farm may not have at its disposal. For example, EPA (2015) found that in the absence of chlorpyrifos for use at planting, growers of brassica crops such as broccoli, cabbage, and cauliflower could face yield losses of nearly 50%. Furthermore, growers who have options to substitute other active

[5] 55 F. Supp. 2d 1248, 1267 (W.D. Wash. 1999)

ingredients may face issues with international trade in cases where Maximum Residue Levels (MRLs) are not established in other countries for these alternative compounds.

- RPA Element 1(b): Modify labels to include standard buffers and vegetative filter strips: 300 meter no-spray buffer for all aerial applications; 150 meter buffer for all ground applications; 6 meter vegetative filter strip for all applications.

  Buffers and filter strips are difficult for any farmer to implement and maintain, and successful implementation is affected by a variety of factors, including field size, soil type, geographic region, crop grown, and local climate. Feasibility can be further impacted by conflicting regulations or market-imposed requirements, such as food safety specifications that require areas of bare soil around fields without vegetation, as one example. A one-size-fits-all approach ignores the field-level practicalities of successful implementation that takes each of these variables into consideration. The ability of growers to avoid foregone income from in-field installations is another important consideration to account for when gauging the burden associated with this RPA.

  As discussed in Table 1 below, the estimated installation cost of buffers in California ranges from $90/acre to $1,000/acre. Thus, for fields receiving ground applications, a 150-meter (500-foot) buffer could cost about $1,000-$11,000 per 1,000 feet of field perimeter that is affected. Using the same assumptions, a 300-meter (approximately 1,000-foot) buffer for aerial applications could easily cost a grower $2,000-$22,000 per 1,000 feet of field perimeter. On top of this cost, vegetative filter strips have associated costs of around $55-$309/acre. This does not include the cost of on-going maintenance. Further, off-field buffers can be a potential source of infection and infestation and could allow for the recolonization of weeds, insects, and disease-causing pathogens. Depending on pest species and biology, there are instances where buffers have been documented to increase pest pressure and ultimately might be incompatible with certain agricultural operations and endangered species conservation efforts. For example, Ratnadass et al. (2012) shows that pressures from pests with a broad host range, high dispersal ability, and long overwintering mechanisms can make buffers infeasible for growers. While there are instances where buffers may be feasible, there is no simple one-size-fits-all solution for all growers of all crops. Again, it is critical that NMFS conduct a robust analysis of the economic feasibility to better understand the repercussions from this RPA.

- RPA Element 1(c) Point System: Implement a combination of risk reduction measures to reduce pesticide drift, runoff, and drainage.

  NMFS relied on a point system developed for the European Union called "Mitigating the Risks of Plant Protection Products in the Environment" (MAgPIE) that is pertinent to farming systems across Europe and the regulatory framework of those European countries. The average U.S. farm is ten times larger than the average European farm (Eurostat, 2016; USDA, 2018) and operates under laws and regulations of the United States, not European laws and regulations. Assumptions that what may work in Europe will work in the United States are without basis, as these mitigation measures have not been vetted for U.S. production systems. NMFS failed to explain both its reliance on

MAgPIE and why it chose to not rely on the USDA for information regarding agricultural conservation practices in the United States. NMFS states: "These RPAs were drafted using the best available information on current agricultural practices and pesticide reduction strategies . . . ." However, there is no indication in the BiOp that USDA or any agricultural conservation experts operating in the United States were ever contacted to provide feedback on what constituted best available information for U.S. cropping systems. The outreach of one federal agency to other expert agencies within the U.S. government on agricultural conservation is an obvious first step to pursue prior to proposing agricultural conservation practices that are required to use "best available data."

Not only is the European MAgPIE point system incompatible with U.S. agricultural practices, it is likely impossible for a grower to achieve the required 80-point score without incurring significant economic burden. Consider the following scenario: A grower applying malathion is subject to these risk reduction measures. The grower's reliance on malathion to manage specific pest pressures and avoid the development of resistance prohibits his or her ability to rely on a different active ingredient. Walking through the activities in Chapter 26-8 (p. 3473) that merit points under MAgPIE:

- Spray Drift Reduction Technology (DRT) (20-75 points): While growers could earn points for using DRT, the EPA DRT Program currently does not have any approved DRT products (EPA, 2018a). USDA questions how this RPA can be "technologically feasible" when growers have no EPA DRT-approved products available to them at this time.

- Spot Applications and/or Granular Treatments (80 points): The practicality of using spot applications or granular treatments is completely dependent on the active ingredient and the pest being targeted. For example, over the past five years (MRD, 2012-2017), malathion was never once reported as being used as a granular treatment across 60 surveyed crops. This is likely due to such products not even being registered for such use sites, which may indicate that such formulations or application methods are not technically or economically feasible. Further, if NMFS had used available data or done any basic research on typical usage practices in its jeopardy determination, it would have discovered that many of the use sites characterized as "high risk" are in fact only localized spot treatments to begin with. For example, the "wide-area" and "forestry" uses of chlorpyrifos are only applied as localized spot treatments and thus should never have been characterized as a high-risk scenario in the first place.

- Participation in Stewardship Programs (80 points): NMFS proposed that a grower can participate in NMFS' recognized Pesticide Stewardship Plans as a way to acquire points under MAgPIE. In the BiOp, NMFS provides an example of a certification program, Salmon-Safe, which can satisfy this requirement. However, Salmon-Safe (2018) has a list of banned chemicals that cannot be applied by farms seeking certification, which includes malathion, chlorpyrifos, and diazinon. This list is based

solely on hazard (i.e., acute aquatic LC50/EC50, without an exposure component, and thus is not based on the risk to salmonids). As NMFS quotes in the BiOp (p. 519), "Salmon-Safe has produced a list of 'high hazard' pesticides which, if used, would prevent a site from becoming certified. If a grower wants an exception, they must provide written documentation that demonstrates a clear need for use of the pesticide, that no safer alternatives exist, and that the method of application (such as timing, location, and amount used) represents a negligible risk to water quality and fish habitat." USDA questions what standards these independent certification entities would use in making a determination of "clear need," as it appears to be a subjective determination. Based on NMFS' example of an approved certifier, it is plausible that obtaining this certification requires a de facto ban on the use of these pesticides, which would lead to no grower ever viewing this as an option for accruing points under the point system. USDA is very concerned that a federal entity such as NMFS would outsource the awarding of points, which is essentially a decision as to whether a grower will remain in compliance with the BiOp, to a private, non-governmental organization that is not transparent regarding the criteria for their risk determinations or subject to any oversight or control by any branch of the federal government.

- Vegetative filter strips, "bunds" (a European term for edge-of-field embankments), vegetated ditches, riparian plantings, retention ponds, and functional riparian systems alongside waterways (varying points): All of these options cost a significant amount of money. Example estimates of these costs are provided in Table 1, per estimates for the state of California from USDA NRCS (2018a). Vegetated ditch costs reflect estimates from New England states, noting that this method of conservation is not even recorded as an implemented practice in many of the states under NMFS jurisdiction. For all these practices, significant technical limitations to their applicability exist, such as required topography, soil texture, field slope, and compatibility with particular cropping systems. For guidance on such limitations, refer to the NRCS Conservation Practice Standards (2018b).

Table 1. Examples of Costs for RPA MAgPIE Point System Agricultural Conservation Practices in California

| BiOp Practice | Closest Matching Equivalent NRCS Practice | NRCS Practice Cost | Unit |
|---|---|---|---|
| No Spray Buffer[1] | Field Border | $90-$1,005 | Per acre |
| Vegetative filter strips | Filter Strip | $165-$927 | Per acre |
| Bunds (i.e., a European term for edge-of-field embankments)[2] | (1) Terrace | $3,500-$9,800 | Per typical 2,500 foot terrace |
| | (2) Water Sediment Control Basin | $3,750-$3,960 | Per typical 700 $yd^3$ of excavated earth |

| | | | |
|---|---|---|---|
| Vegetated Ditches[3] | Hillside Ditch with Vegetation (costs are additive) | $2.95-$3.13 | Per cubic yard (channel equipment) |
| | | $1.52-$1.88 | Per foot (hand labor) |
| Retention Ponds[4] | Constructed Wetland | $1,420-$11,385 | Small (0.1 acre) to Large (>0.5 acre) |
| Functional Riparian Systems Along Waterways | (1) Riparian Herbaceous Cover | $1,300-$13,500 | Per acre |
| | (2) Riparian Forest Buffer | $211-$6,285 | Per acre |
| No-Till or Reduced Tillage | (1) No-Till/Strip-Till | $20 | Per acre |
| | (2) Residue and Tillage Management, Reduce Till | $21 | Per acre |
| | (3) No-Till Adaptive Management | $245 | Per acre |
| | (4) No-Till/Strip-Till with Herbicide and No Cover Crop | $45 | Per acre |

Source: USDA NRCS California Payment Schedule (USDA NRCS, 2018a). Cost estimates for different NRCS agricultural conservation practices are constructed from a variety of reliable sources, including feedback from local experts. Estimates differ across states and regions. The costs supplied in this table reflect installation costs; however, the ongoing cost of maintenance must also be considered, as well as the value of foregone income from installations that must be made in-field, with the cost of such installations greatly varying due to factors such as crop, region, and the shape and size of the field.

[1] The point system requires between a 10 to 300 meter (i.e., ~30 to 1,000 foot) buffer, depending on the intended mitigation.

[2] Depending on how bunds are defined, their NRCS equivalent term could either be considered terraces or water sediment control basins. Example costs for both terraces and water sediment control basins are provided.

[3] Hillside ditches are only implemented in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Costs reflect 2017 non-vegetated hillside ditch costs; vegetated hillside ditch costs are not a recognized NRCS practice and thus cost estimates provided here should be considered an underestimate due to the additional costs of installing and maintaining vegetation.

[4] Although it is unclear in the BiOp, it appears that MAgPIE intends for retention pond requirements to be a function of the contributing area to runoff. Thus a range of potential costs from NRCS scenarios are provided.

Given the issues with stewardship programs, DRT, and the use of granular formulations and spot treatment applications, the only option for a grower to earn a sufficient number of points to satisfy this system is to undertake one or more of the incredibly burdensome practices outlined in Table 1, which further demonstrates the need for NMFS to design RPAs that are economically feasible *for regulated industry*. NMFS should also provide concrete evidence that this is the case in their economic feasibility study, and discuss how the BiOp is consistent with *Dow Agrosciences.* Additionally, NMFS has established no quantitatively defensible, causal connection between the proposed mitigations and reduced pesticide exposure to endangered species. Without establishing causality between mitigating measures and exposure or harm averted, requiring the measures in this RPA is arbitrary and capricious and could force growers out of business, especially given the current agricultural financial climate.

*Burden on Registrants:*

In addition to the burden on growers, all three elements of the proposed RPA would result in economic hardship for registrants. Not only could the transition of growers to alternative pesticides or to lower volumes of the products they are currently using impact registrants' market shares temporarily, in many cases they could completely lose their customers as they may not have patent rights, labeled products, or access to alternative technical grade active ingredients that would allow them to quickly regain lost market share. The process of getting pesticides registered and on the market is no simple task, with the average cost for a new registration at over $600,000, new uses for an existing registered pesticide at nearly $200,000, and fees set to rise again in the near future. Furthermore it takes months if not years for these registrations to be approved (EPA, 2018b). Additionally, companies must be able to pay off the typical $250-$300 million and 11 years of research and development that goes into new products, which takes years of sales to recoup. Disrupting this recovery of investments is a disincentive for companies to pursue finding new chemistries and can stagnate technological advancements. Ultimately, this can lead to delayed registrations which can manifest a myriad of unintended consequences, such as the expedited development of pest resistance as growers may have a scarcer number of active ingredients representing fewer modes of action with which to rotate their application. This effect is also (ironically) counter-productive to the very ecological protection goals espoused by NMFS, because it delays the availability of newer and safer materials that would displace older chemistries over time.

*3. The mitigations suggested by the RPA are unsupported by facts and reasoning, making it unclear whether this RPA, if it was even possible to implement, would actually avoid jeopardy.*

In order to qualify as an RPA, a set of mitigating measures must be successful in preventing jeopardy. NMFS does not explain how this RPA would prevent jeopardy, and a review of the RPA's provisions provides little indication that it would do so.

- Major inconsistencies between chapters outlining use sites of concern versus those that are listed as necessitating RPAs exist. As stated on page 3470, "the point system is only required for high risk uses. High risk uses are those which received a high rating for effect of exposure and a high or medium rating for likelihood of exposure as presented in the Effects of the Proposed Action." However, in dozens of cases there are use sites where RPAs are suggested despite this standard not being met. In all cases, additional use sites were listed as requiring RPAs beyond those indicated in previous chapters. Errors such as this only further support the need for NMFS to carefully outline and fully disclose all assumptions and methods used in jeopardy and adverse modification determinations (see earlier comments for examples).

- As stated in the BiOp, Section 26.5 b: "Prohibit application of pesticide products when soil moisture is at field capacity, or when a storm event likely to produce runoff from the treated area is forecasted (by NOAA/National Weather Service, or other similar forecasting service) to occur within 48 hours following application." Since 2011, USDA has repeatedly attempted, unsuccessfully, to inform NMFS that this RPM (which has appeared in previous BiOps) is technically inaccurate and uses incorrect verbiage. The best timing for pesticide applications is when soil is at field capacity. It would appear that

NMFS is confusing field capacity with soil saturation. "Field capacity (Cc) corresponds to the superior limit of available water and represents the moisture of the soil after drainage of the water contained in the macropores by gravity action. This moisture condition favors higher absorption of water and nutrients by the plants" (Alves de Oliveira, 2015). Soil saturation is a condition in which all pore spaces between soil particles are temporarily or permanently filled with water, a condition at which pesticide product application is at high risk of runoff (FAO, 1985).

- Other Best Management Practice (BMP) efforts already in place have not been accounted for in determining the need for an RPA, nor does the BiOp make any clear link of causation between the measures and the impacts on endangered species. USDA is always available to assist NMFS in better understanding what practices are in place, especially those supported by NRCS.

Overall, NMFS fails to satisfy its legal obligations in promulgating the RPAs in this BiOp, because it does not provide (1) any explanation or justification for the proposed RPA and how it might prevent jeopardy, and (2) any economic and technological feasibility analysis for this RPA. USDA is very concerned that the "RPA" in this BiOp does not meet the requirements for an RPA set by 50 CFR 402.02, that its inclusion without a proper basis renders the BiOp arbitrary and capricious, and that, in addition to its legal shortcomings, this "RPA" is impractical and could not be implemented by American agriculture.

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# Update on ESA Pesticide Consultations

June 19, 2017

# Background: Endangered Species Act (ESA) Obligations for Pesticide Decisions

- Why are pesticide decisions impacted by the ESA?
  - Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the "actions" they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (jointly the Services)
  - For EPA's Office of Pesticide Programs (OPP), the actions we authorize are the sale, distribution, and use of pesticides according to the product labeling
- Conventional pesticide decisions impacted by ESA:
  - Registration review actions (~50-60/yr)
  - New chemical registrations (~10-12/yr)
  - New use registrations (~50-60/yr)
  - Section 18 Emergency Exemptions (~100/yr)
  - Section 24(c) Special Local Need (SLN) registrations (~200/yr)

# Background

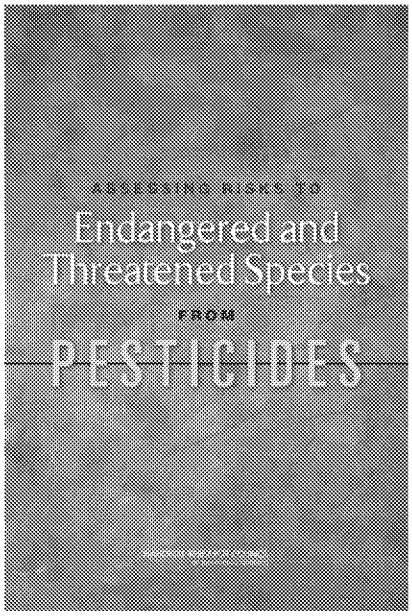
- ESA Authority
  - Section 7(a)(2) of ESA: EPA makes "effects determination" for individual listed species in a biological evaluation (BE):
    - No effect (NE) – no consultation required
      - Overview Document-compliant method (2004): Risk Quotient (RQ) < listed species Level of Concern (LOC)
      - NAS-recommended method (2013): No geospatial co-occurrence of pesticide use footprint with listed species range
    - Not likely to adversely affect (NLAA) – informal consultation; concurrence from Services
    - Likely to adversely affect (LAA) – formal consultation including Biological Opinion (BiOp) from Services (jeopardy/no jeopardy determination)

- Nationwide consultations must consider direct/indirect effects to 1850 listed species and 600+ designated critical habitats

# Background - OPP History with the Services

- Disagreement on:
  - Scientific methods to assess the risk of pesticides to listed species
  - Specific actions needed to protect listed species
- EPA has completed over 200 chemical-specific BEs as the result of court-imposed ESA obligations. The Services have issued 9 BiOps based on court-mandated schedules. None of these BEs or BiOps were nationwide evaluations.
  - Time required to complete BiOp is lengthy (typically 2-3 yrs)
  - EPA has often been unable to follow the science logic behind the BiOps
- Of 7 BiOps for listed Pacific Northwest salmon species submitted by NMFS (covering 32 chemicals), EPA has implemented only one (thiobencarb); NMFS 1st BiOp was overturned.
  - Reasonable and Prudent Alternatives (RPAs)/Reasonable and Prudent Measures (RPMs) not feasible/practical to implement:
    - Arbitrary spray drift buffers
    - Lack of a target concentration where effects to listed salmon do not cause jeopardy
- EPA has implemented 2 BiOps submitted by FWS for Rozol and Kaput rodenticides
  - Geographically-specific Bulletins which restrict product use or timing of application

# NAS Report Implementation

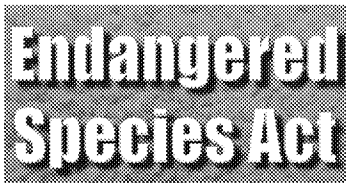



- Released on April 30, 2013
- Developed in response to a joint request by EPA, NMFS, FWS, and USDA in 2011 to address scientific areas of disagreement
- Recommended 3-step process that integrates ecological risk assessment methods with ESA Section 7 consultations
- Goal: unified interagency approach with agreement on process across all steps
- Multiple interagency workshops where interim methods for EPA's BEs (Steps 1 and 2) have been developed
- Several stakeholder meetings held to engage public on potential refinements
- Interim methods need streamlining to meet available resources
- Final BEs for chlorpyrifos, diazinon, and malathion released in January 2017

# NAS Report Implementation

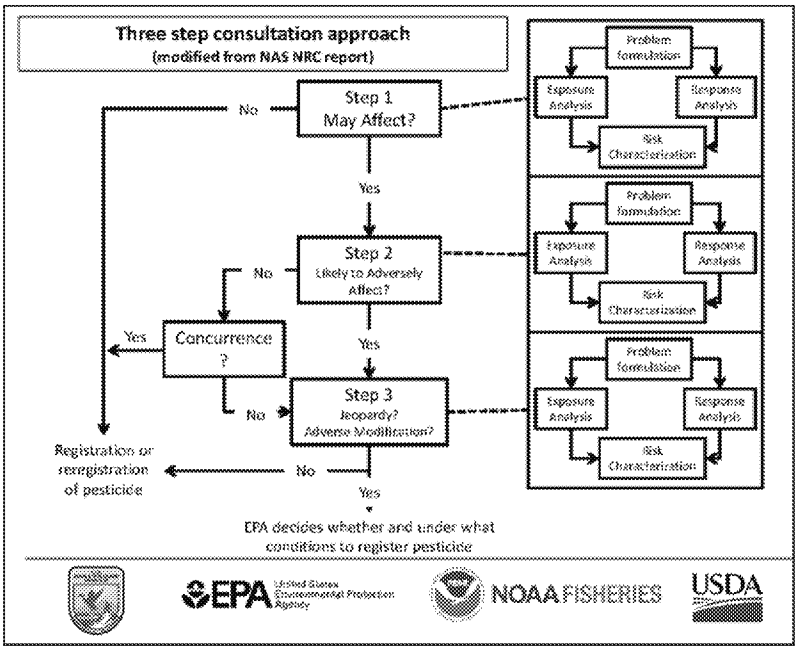
- The **Biological Evaluation** (BE) determines whether registered pesticides adversely affect one or more individuals of a listed species and/or their designated critical habitats
  - Step 1 ["No Effect/May Affect" Determination]
  - Step 2 ["Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA) Determination]

- The **Biological Opinion** (BiOp) determines whether the registration of a pesticide is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its designated critical habitat
  - Step 3 ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]



# Methodology for Pesticide Consultations

The draft process follows the 2013 NAS recommendations for a 3-step approach:

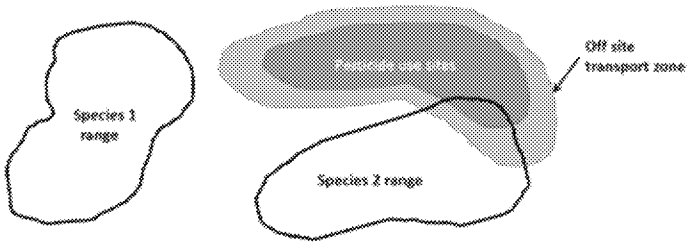



The draft BE process was developed in close coordination with the Services – EPA has worked very hard to provide information in Steps 1 and 2 that the Services said they would need to conduct Step 3.

7

# Overview of the BE Method – Step 1

- Two sets of spatial data are compared
  - Pesticide exposure area
    - Based on national-level GIS data to identify potential use sites
    - Buffered to account for transport to levels that potentially represent effects (based on most sensitive toxicity data)
  - Species range – provided by Services
- No Effect /May Affect determination
  - Based on whether or not there is overlap of the potential exposure area and the species range
    - No Effect (*i.e.*, no overlap) – no need to seek consultation with Services
    - May Affect (*i.e.*, overlap) – move to step 2



# Overview of the BE Method –Step 2

- Step 2
  - Weight-of-Evidence Approach
    - Risk and confidence evaluated for multiple lines of evidence (mortality, growth, reproduction and other sublethal effects) based on estimated exposure and effects thresholds
    - Incident data
    - Qualitative discussion of mixtures and abiotic influence (e.g., temperature, pH) on toxicity
- Intended to answer the questions:
  - Is there a potential for an individual's fitness to be reduced?
  - Is there a potential for important physical and biological features of a species habitat to be adversely affected?
- Describes the process for making Likely to Adversely Affect(LAA)/Not Likely to Adversely Affect (NLAA) Determinations
  - LAA – species/critical habitat moves to Step 3 (jeopardy/adverse modification determination)
  - NLAA – concurrence from the Services

Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

From Anita

Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

# Stakeholder Concerns

- April 13, 2017 letter from registrants of 3 pilot OPs to political leadership of EPA and the Services requesting:
  - EPA to withdraw the BEs
  - Services to stop work on the BiOps
  - Services to modify settlement agreements to allow more time to complete consultation
- Registrants/Growers:
  - Too large and complex; inadequate comment period
  - Current methods are not sustainable
  - Do not account for taxon-specific toxicity data early enough in the process
  - Overly conservative
  - GIS layers used are too broad (for use site and species range layers)
  - Use of invalid and un-reviewed studies
  - Need to consider public health, usage data and benefits
- NGOs
  - Too large and complex
  - Generally agreed with the overall process

Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

# United States Department of the Interior

FISH AND WILDLIFE SERVICE

NOV 14 2017

Marietta Echeverria
Director, Environmental Fate and Effects Division
Office of Pesticide Programs
Division Mail Code 7507P
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Dear Ms. Echeverria,

On January 18, 2017, the U.S. Fish and Wildlife Service (Service) received the Environmental Protection Agency's (EPA) draft Biological Evaluations (BEs) on the effects of reregistering chlorpyrifos, malathion, and diazinon under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and request to initiate formal consultation under section 7 of the Endangered Species Act of 1973, as amended (ESA). As you are aware, this effort was one of the most complex section 7 consultations ever attempted. While we appreciate the collaboration with the Service and others that informed the development of these BEs, after further review and lessons learned in consideration of the BEs the Service is requesting additional information necessary to complete formal consultation. (See interagency consultation regulations at 50 CFR §402.14). Specifically, we request:

- A revised effects analysis for each chemical that reflects the best scientific and commercial data that is currently available or which can be obtained during the consultation – the standard for information required under 50 CFR §402.14(d) for an action agency when seeking formal consultation – regarding actual use, including extrapolation to areas where actual use data does not exist or cannot be obtained. The revised effect analyses should also seek to predict effects from future usage that is reasonably certain to occur during the time period of the label authorization but is not reflected in current actual use data.

- A revised effects analysis for each chemical that eliminates from analysis geographic areas identified by EPA where these pesticides are not used and where such use is not likely during the time period of the label authorization, or where listed species or designated critical habitats would not otherwise be exposed to use of the pesticide (e.g., certain states, high elevation areas, uninhabited islands).

In addition, the Service also suggests that the EPA monitor available use and usage information to determine if the manner of actual use remains consistent with assumptions of use and usage considered in the consultation process.

Under the regulations, indirect effects are "those that are caused by the proposed action and are later in time, but are reasonably certain to occur." 50 C.F.R. 402.02. The effects analysis determines the action area, which is "all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action." 50 C.F.R. 402.02. We must keep in mind the ESA regulations when considering the action description and effects analysis.

In the course of developing the draft and final biological opinions and associated incidental take statements, the Service requests that EPA facilitate coordination with the registrants and user groups to develop, if necessary, any reasonable and prudent alternatives to avoid violation of section 7(a)(2) of the Act and any reasonable and prudent measures necessary or appropriate to minimize the impact of your action on listed species.

This letter also serves as a request to extend the consultation, in accordance with 50 C.F.R. 402.14(e). Upon receipt of the above requested information, the Service will work with EPA to establish a schedule to complete consultation on the proposed actions.

If you have any questions or concerns about this request or the consultation process in general, please feel free to call me at 202-208-4646 or Deputy Assistant Director Gina Shultz at 703-358-1985.

Sincerely,

Gary Frazer
Assistant Director - Ecological Services

**FOR PUBLICATION**

# UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

| | |
|---|---|
| IN RE PESTICIDE ACTION NETWORK NORTH AMERICA; NATURAL RESOURCES DEFENSE COUNCIL, INC., | No. 14-72794 |
| PESTICIDE ACTION NETWORK NORTH AMERICA; NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, *Respondent*. | ORDER |

Filed July 18, 2017

Before: Diarmuid F. O'Scannlain, A. Wallace Tashima, and M. Margaret McKeown, Circuit Judges.

## SUMMARY*

### Mandamus

The panel denied the motion for further mandamus relief filed by Pesticide Action Network North America and Natural Resources Defense Council, which alleged that the United States Environmental Protection Agency ("EPA")'s denial of the Council's administrative petition, seeking to revoke all food tolerances and cancel all registration of a pesticide called chlorpyifos, was inadequate.

In a published order on August 10, 2015, the panel ordered EPA to respond to the Council's administrative petition. In a subsequent published order, the panel directed EPA to take "final action" by March 31, 2017. The EPA denied the Council's petition on March 29, 2017.

The Council filed the present mandamus motion asserting that EPA's denial was inadequate because it contained no new safety findings, and made no final determination as to whether chlorpyifos food tolerances must be revoked.

The panel held that EPA had complied with the panel's previous orders by issuing a "final response to the petition." The panel further held that the Council's mandamus motion was premature, and its substantive objections to the EPA's denial must first be made through the administrative process mandated by statute.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

## COUNSEL

Patti A. Goldman and Kristen Boyles, Earthjustice, Seattle, Washington, for Petitioners.

Erica M. Zilioli, Environmental Defense Section; Jeffrey H. Wood, Acting Assistant Attorney General, Environment & Natural Resources Division; United States Department of Justice, Washington, D.C.; Mark Dyner, Office of General Counsel; United States Environmental Protection Agency, Washington, D.C.; for Respondents.

Stanley H. Abramson, Donald C. McLean, Kathleen R. Heilman, and Sylvia G. Costelloe, Arent Fox LLP, Washington, D.C., for Amici Curiae Dow Agrosciences LLC.

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## ORDER

In 2007, Pesticide Action Network North America and Natural Resources Defense Council (collectively, "PANNA") filed an administrative petition with the United States Environmental Protection Agency ("EPA"). The petition sought to revoke all food tolerances and cancel all registration of a pesticide called chlorpyifos. In 2014, having grown frustrated with EPA's inertia, PANNA petitioned this court for a writ of mandamus to force the agency to issue a response, which PANNA acknowledged could include "a final denial order . . . if that is how EPA decides to resolve [it]."

On August 10, 2015, we ordered EPA to "issue *either* a proposed or final revocation rule *or* a full and final response" to PANNA's administrative petition. *In re Pesticide Action*

*Network N. Am.*, 798 F.3d 809, 814 (9th Cir. 2015) (emphasis added). We later directed EPA to "take final action" on the petition by March 31, 2017. *In re Pesticide Action Network N. Am.*, 840 F.3d 1014, 1015 (9th Cir. 2016).

EPA denied the petition on March 29, 2017. *See* 82 Fed. Reg. 16,581 (Apr. 5, 2017). PANNA promptly filed a motion for "further mandamus relief," asserting that EPA's denial was inadequate because it contained "no new safety findings" and no "final determination as to whether chlorpyifos food tolerances must be revoked." In short—and in its own words—PANNA's motion faulted EPA for "fail[ing] to act *on the substance* of the petition."

PANNA's complaints arrive at our doorstep too soon. Although we previously condemned EPA's "egregious" delay in responding to PANNA's petition, the agency has now complied with our orders by issuing a "final response to the petition." *See In re Pesticide Action Network N. Am.*, 798 F.3d at 811; *see also* 21 U.S.C. § 346a(d)(4)(A)(iii) (providing that one valid agency response to a petition challenging a pesticide's tolerances is to "issue an order denying the petition").

These mandamus proceedings have addressed the *timing*, not the *substance*, of EPA's response. *See In re Pesticide Action Network N. Am.*, 798 F.3d at 813 ("The only question before us is whether EPA's delay in responding to the administrative petition warrants the extraordinary remedy of mandamus."). Now that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute. *See* 21 U.S.C. §§ 346a(g)(2), (h)(1); 40 C.F.R. §§ 178.65, 180.30(b). PANNA implicitly recognizes as much by acknowledging

that "[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining judicial review" of EPA's final response to the petition. Only at that point may we consider the merits of EPA's "final agency action." *See* 5 U.S.C. § 704. Although EPA dragged its heels for nearly a decade, it has now done what we ordered it to do.

PANNA's motion for further mandamus relief is **DENIED**.

**ANNOUNCEMENT ON JUNE 18**

## Accomplishment

On June 18, 2018, EPA is scheduled to approve Oklahoma's first-in-the-nation application to operate a state permit program regulating the disposal of coal combustion residuals (CCR or coal ash) from electric utilities. This will mark the **first time** EPA has approved a state permit program for CCR using the new authority that Congress provided EPA in 2016. **First in the nation.**

## CCR Background at EPA

In April 2015, EPA published a final rule under the Resource Conservation and Recovery Act (RCRA) that designated CCR as nonhazardous waste and established national requirements governing the disposal of CCR in landfills and surface impoundments. Unlike the Clean Air Act and the Clean Water Act, which are generally implemented by states through permit programs that are approved by EPA, RCRA originally did not authorize EPA to regulate CCR as nonhazardous waste through state permit programs. Instead, utilities were responsible for directly implementing the requirements of EPA's 2015 CCR rule, which were enforceable only through citizen suits.

## JMI's Work in Congress

*(Below is entire legislative history, dates, hearings, and votes)*

As chairman of the Senate Environment and Public Works Committee, Senator Inhofe led **two hearings** examining the challenges of the 2015 CCR rule and the need for legislation to allow Oklahoma and other states to regulate CCR through EPA-approved state permit programs rather than through the self-implementing requirements of the CCR rule. Representatives of electric utilities and states testified in favor of amending RCRA to allow state permit programs because they would be able to tailor the requirements for disposing of CCR to address the specific risks and concerns posed by an individual utility, rather than through the one-size-fits-all national standards in the 2015 CCR rule.

Chairman Inhofe worked on a bipartisan basis with then-ranking member Barbara Boxer, other members of the Senate, and colleagues in the House of Representatives, along with states, the utility sector, and environmental groups, to craft compromise legislation giving states authority to regulate CCR through permit programs. This legislation was included as part of the Water Infrastructure Improvements for the Nation Act, which passed the Senate by a vote of 78 to 21 and was enacted into law in December 2016.

Under the WIIN Act authority, EPA is required to approve within 180 days of receipt a state's application to operate a permit program in lieu of the 2015 CCR rule if the Administrator determines the state's program will require electric utilities to comply with the requirements of the 2015 CCR rule or successor regulations. However, an approved state program may allow individual permits to include technical requirements that vary from the requirements of the 2015 CCR rule or successor regulations so long those site-specific requirements are at least as protective of the federal requirements.

**EPA's Work Implementing the New Law**

On April 28, 2017, EPA Administrator Scott Pruitt wrote to the nation's governors informing them about the WIIN Act and encouraging them to submit applications to operate state permit programs. EPA issued interim final guidance on August 10, 2017 to assist states in developing their program applications and providing a framework for how EPA would process the applications.

Oklahoma initially submitted its draft application on July 31, 2017. On December 21, 2017, EPA informed Oklahoma that its application was complete, triggering the 180-day review deadline. EPA hosted a public hearing in Oklahoma City on February 13, 2018, about Oklahoma's application. Separately, EPA is considering changes to the 2015 CCR rule to facilitate the transition to permit programs and to allow use of alternative-risk based standards. EPA published a proposed rule on March 15, 2018, containing more than a dozen potential changes. EPA plans to propose additional changes later this year.

**Legislative History in 114th Congress**

**June 17, 2015 -- Chairman Inhofe led an oversight hearing of the Environment and Public Works Committee examining EPA's 2015 final rule to regulate the disposal of coal combustion residuals from electric utilities. Chairman Inhofe made the following statement at the hearing:**

"This is an important issue that cuts across the Committee's areas of jurisdiction—from the regulation of waste, to the impact of EPA's other rules on electric utilities, and to the importance of coal ash to highways and infrastructure projects. EPA has extensively studied the safety of coal ash. For decades, coal ash has been regulated as nonhazardous waste by states. It is also worth noting that coal ash is an important ingredient in concrete and helps extend the lifespan of and control costs for the concrete used in roads and bridges. In fact, many State Departments of Transportation require the use of coal ash in their road projects."

**March 2, 2016 -- Chairman Inhofe led a hearing of the Environment and Public Works Committee to consider the bipartisan Improving Coal Combustion Residuals Regulation Act (S. 2446), focusing on how to development state permit programs to regulate CCR. Chairman Inhofe made the following statement at the hearing:**

"I agree with the EPA's decision that coal ash is a non-hazardous waste, and I can assure you, in case you are wondering, that there are not 60 votes in the United States Senate that would change that ruling, so Congress should amend RCRA to authorize the State permitting programs for coal ash. The President supports it.

"As Ranking Member Boxer noted at last year's hearing on EPA's coal ash regulation, authorizing State permitting programs 'is really not that different from so many other laws. If you want to talk about permitting, I would be happy to work with you to make that fix, if necessary.' Now, I agree. I see no reason why coal ash should not be regulated through the EPA's approved State permitting programs, just like air, water, and hazardous waste.

"I have served in different capacities ... . I have served as mayor of a major city; I have served in the State legislature; I have served in Congress; and I have served in the Senate. It has been my experience

that the closer you get to the people, the more local, the more responsible the decisions are, because they can find you. You can hide up here; you can't hide when you're in a city council. So I reject the idea that you can't count on ... States to protect us. I don't agree with that at all."

**After the legislative hearing, Chairman Inhofe pursued new compromise legislation, referred to as the Coal Combustion Residuals Regulatory Improvement Act, with ranking member Boxer and the original sponsors of S. 2446. This compromise legislation was included as part of S. 2848, the Water Resources Development Act of 2016, which was passed by a vote of 95 to 3 in the Senate on September 15, 2016. Chairman Inhofe applauded the inclusion of the bipartisan Coal Combustion Residuals Regulatory Improvement Act in WRDA 2016. Chairman Inhofe issued the following statement:**

"This bipartisan legislation that is in WRDA 2016 gives states the needed flexibility and authority to regulate coal ash to best support their state economies while also protecting the health of families and communities," Inhofe said. "This provision provides utilities the regulatory certainty they have been seeking and corrects the implementation problems with EPA's recent coal ash rule. I thank Sens. Hoeven and Manchin for keeping this issue alive in recent years and Ranking Member Boxer, Sen. Capito and the other EPW Committee members for coming together to craft this compromise language. I look forward to working with my colleagues in the House of Representatives to getting this compromise coal ash legislation enacted into law."

**The Environmental Council of the States issued a statement supporting the Senate's passage of the CCR legislation as part of the Water Resources Development Act:**

"The Environmental Council of the States commends the Senate on its passage yesterday of the Coal Combustion Regulatory Improvement Act (Act), authorizing states to develop and carry out programs to control coal combustion residual (CCR) units. Included as Section 8001 in S. 2848 of the Water Resources Development Act (WRDA) 2016, the Act amends the Resource Recovery and Conservation Act to allow states to directly oversee and enforce CCR unit compliance, in a manner consistent with the U.S. Environmental Protection Agency's April 2015 final CCR rule (80 Fed. Reg. 21,302). ECOS long has supported states having such authority, and ECOS representatives have testified in both the Senate and House several times over the years on the importance of legislative action on the CCR issue. ECOS extends its deep appreciation to the Senators who led the effort to advance the Act. ECOS also thanks the state experts who offered their expertise and experience with CCR facilities to inform the process, and in particular our colleagues at the Association of State and Territorial Solid Waste Management Officials who were steadfastly dedicated to the issue."

**December 5, 2017 – Senator Inhofe worked on a bipartisan basis with colleagues in the Senate and House to ensure the final deal on the Water Infrastructure Improvements for the Nation Act (WIIN Act) included compromise legislation negotiated by Senator Inhofe to authorize state permit programs for regulating coal combustion residuals from electric utilities. Senator Inhofe released the following statement:**

"We're pleased that the final WIIN package builds off the Senate passed provision and provides the authority that states have been seeking to regulate coal ash through authorized state permit programs," the senators said. "This new permitting authority fixes the main problems with the recent coal ash regulation issued by the Environmental Protection Agency, by removing citizen suits as the sole means of enforcement and allowing states to tailor permit requirements on a case-by-case basis. We're happy

that we were able to work with our colleagues in the House and Senate on a bipartisan basis to get this important legislation across the finish line."

**December 9, 2016 – By a vote of 78 to 21, the Senate passed the Water Infrastructure Improvements for the Nation Act (WIIN Act), which included compromise legislation negotiated by Senator Inhofe to authorize state permit programs to regulate coal combustion residuals. Senator Inhofe released the following statement:**

"I am pleased that the WIIN Act has crossed the finish line with strong, bipartisan support," Inhofe said. "This bill – soon to be law – fulfills many important Oklahoma priorities. It helps Oklahoma rural electric cooperatives and the families they serve by returning the regulation of coal combustion residuals to states."

The inclusion of the coal ash legislation in the WIIN Act garnered broad support from the utility sector:

"Public Service Company of Oklahoma and American Electric Power strongly support the water resources bill, and appreciate Senator Inhofe's strong leadership in its passage. In particular, we applaud the Senator's efforts on a provision in the WIIN bill that solves the major shortcomings of current federal regulation of coal combustion residuals (CCRs), by giving states the primary authority over CCRs through state permit programs," said Stuart Solomon, president and COO of the Public Service Company of Oklahoma.

"EEI thanks Senator Inhofe for his leadership in completing the water resources bill, which contains critically important provisions for the safe management of coal ash. As the EPA's coal ash regulation goes into effect and our industry begins to close coal ash basins, these legislative provisions will enable states to be more involved in the permitting process for the closure of basins. Permanently closing basins in a manner that puts safety first, protects the environment, and minimizes impacts to communities and customers is vitally important to our industry," said Tom Kuhn, president of the Edison Electric Institute.

"America's electric co-ops are extremely grateful to Chairman Inhofe for championing the WIIN Act, which will bolster co-ops' efforts to provide affordable and reliable electricity to rural America. Because of his hard work, this bill promotes critical infrastructure projects pertaining to hydropower, flood control, water supply and emergency management. This bill is a win for America's rural electric consumers, and we appreciate the chairman's unwavering support for provisions that inject greatly needed certainty into the regulation of coal ash by giving states clear permitting authority and reducing litigation," said Jim Matheson, CEO of NRECA.

"OG&E greatly appreciates Senator Inhofe's leadership in including his coal ash provision in the 'Water Infrastructure Improvements for the Nation Act' conference report. His provision resolves a legislative stalemate to the satisfaction of both the electric industry and environmentalist community. The Inhofe provision brings legal certainty and predictability to the generation of electricity that will benefit Oklahoma electric customers, beneficial users of coal ash and the environment," said Paul Renfrow, vice president of public affairs for OG&E Energy Corp.

**December 16, 2016 -- The WIIN Act was signed into law (PL-114-322). Senator Inhofe's Coal Ash provision is Section 2301.**

**Department of Energy**
Washington, DC 20585

APR 27 2018

Mr. Andrew Wheeler
Deputy Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code 1101A
Washington, DC 20460

Dear Deputy Administrator Wheeler:

The Mercury Export Ban Act (MEBA) [P.L. 110-414] assigns responsibility for long-term management and storage of elemental mercury to the Department of Energy (DOE). The MEBA, as amended, requires the DOE to begin operating an elemental mercury management and storage facility by January 1, 2019, for elemental mercury generated within the United States. However, the current regulatory framework does not address disposal of elemental mercury.

We are working to hold a workshop May 9-10, 2018, in Washington, D.C., to discuss environmentally sound treatment and disposal options. We expect the workshop will be attended by elemental mercury generators, treatment and storage companies, and impacted state and Federal regulatory agencies. No commitments or obligations are expected from any company or organization.

We believe that the value of the workshop would be significantly improved by Environmental Protection Agency (EPA) Headquarters and Regional Office participation (e.g., Office of Land and Emergency Management, Regions 6, 9, and 10). However, we understand through discussions with your staff, that although EPA is interested in making progress on elemental mercury treatment and disposal, there may not be any EPA representation at the workshop. While I understand that EPA has many priorities and resource challenges, I extend my personal request that appropriate Headquarters and regional staff attend the workshop to hear issues and discuss potential solutions associated with this important national environmental issue.

Thank you in advance for considering EPA participation. If you have any questions, please feel free to contact me or Mr. Mark Senderling, Deputy Assistant Secretary for Waste and Materials Management, at (202) 586-0785.

Sincerely,

Anne Marie White
Assistant Secretary
for Environmental Management

cc: Barry Breen, EPA/OLEM
Barnes Johnson, EPA/OLEM/ORCR
Betsy Devlin, EPA/OLEM/ ORCR/MRWMD
Kim M. Kirkland, EPA/OLEM/ORCR/MEWMD/WCB
Veronica Darwin, EPA/OLEM
Mark Gilbertson, EM-4
Mark Senderling, EM-4.2

Message

**From**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]
**Sent**: 10/19/2017 2:56:50 PM
**To**: Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; 'Underwood, Patricia M CIV (US)' [patricia.m.underwood.civ@mail.mil]; Michael_Hickey@[redacted]; James_A._Laity@[redacted] Michael_C_Jensen@[redacted] Sullivan, Maureen SES OSD OUSD ATL (US [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US [jim.rudroff@navy.mil]; Grafton, Gail M. (MSFC-AS10)[CH2M Hill] [gail.m.grafton@nasa.gov]; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US [karen.e.colmie.civ@mail.mil]; Mcneill, Mike A (HQ-LD020) [mike.a.mcneill@nasa.gov]; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [redacted]]; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Paul_A_Winters@[redacted] Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Tomiak, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d67fe354a4d06be80afa6eb65e614-Tomiak, Rob]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Hayes, Thomas M. (HQ-MB000) [thomas.m.hayes@nasa.gov]
**CC**: Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; David Rostker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd257b595]; [redacted]h; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]
**Subject**: RE: TSCA Interagency Meeting - follow-up

Ryan
Please include NASA OGC lead Thomas (Tom) Hayes) as he and I will represent NASA. I have taken the liberty of including Tom in the email invite list. His email is:
Thoomas.m.hayes@nasa.gov.

Thanks.

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
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linda.s.wennerberg@nasa.gov

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**From:** Schmit, Ryan [mailto:schmit.ryan@epa.gov]
**Sent:** Tuesday, October 17, 2017 2:23 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Mottley, Tanya <Mottley.Tanya@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Cherepy, Andrea <Cherepy.Andrea@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; 'Underwood, Patricia M CIV (US)' <patricia.m.underwood.civ@mail.mil>; Michael_Hickey@Ex. 6 Personal Privacy (PP) James_A._Laity@Ex. 6 Personal Privacy (PP) Michael_C_Jensen@Ex. 6 Personal Privacy (PP) Sullivan, Maureen SES OSD OUSD ATL (US <maureen.sullivan18.civ@mail.mil>; Rudroff, James G CIV USN (US <jim.rudroff@navy.mil>; Grafton, Gail M. (MSFC-AS10)[CH2M Hill] <gail.m.grafton@nasa.gov>; Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US <karen.e.colmie.civ@mail.mil>; Mcneill, Mike A (HQ-LD020) <mike.a.mcneill@nasa.gov>; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick <Suzanne.Fitzpatrick@fda.hhs.gov>; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD <fjh1@cdc.gov>; Jones, Danielle Y. EOP/OMB <Danielle_Y_Jones@Ex. 6 Personal Privacy (PP)>; James_H_Kim@Ex. 6 Personal Privacy (PP); Waqar, Tayyaba <tayyaba.waqar@sba.gov>; Paul_A_Winters@Ex. 6 Personal Privacy (PP); Wise, Louise <Wise.Louise@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Corrales, Mark <Corrales.Mark@epa.gov>; Tomiak, Robert <tomiak.robert@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
**Cc:** Hartman, Mark <Hartman.Mark@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Blunck, Christopher <Blunck.Chris@epa.gov>; David Rostker <David.Rostker@sba.gov>; david.rostker.sba@Ex. 6 Personal Privacy (PP); Knight, Kelly <knight.kelly@epa.gov>
**Subject:** RE: TSCA Interagency Meeting - follow-up

Hi folks,
Thanks for the great meeting today. As discussed, EPA will be setting up a separate meeting of general counsel folks to further discuss the legal issue of "TSCA applicability to other federal agencies." If your organization is interested in participating, please send me a preferred point-of-contact at your earliest convenience.
Thanks in advance,
Ryan
(202)564-0610

Message

**From**: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]

**Sent**: 11/17/2017 1:54:16 PM

**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; patricia.m.underwood.civ@mail.mil; Michael_Hickey[Ex. 6 Personal Privacy (PP)]; James_A._Laity@[Ex. 6 Personal Privacy (PP)]; Michael_C_Jensen[Ex. 6 Personal Privacy (PP)]; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; mike.a.mcneill@nasa.gov; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Danielle_Y_Jones@[Ex. 6 Personal Privacy (PP)]; James_H_Kim@[Ex. 6 Personal Privacy (PP)]; [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; tayyaba.waqar@sba.gov; Paul_A_Winters@[Ex. 6 Personal Privacy (PP)]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Peffers, Mel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b6116fbb41448b38b3caefc882165fe-Peffers, Melissa]; Tomiak, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d67fe354a4d06be80afa6eb65e614-Tomiak, Rob]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; maureen.sullivan18.civ@mail.mil; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; David Rostker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd257b595]; david.rostker.sba@gmail.com; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]

**Subject**: TSCA Interagency Policy Group: Discussion Document Input

TSCA Interagency Policy Group Colleagues,

I want to extend my thanks and appreciation to those who spent time reviewing and providing thoughtful comments last week on our discussion document, particularly within such a short time frame. We have incorporated your feedback to the extent possible and relevant to the purpose of the discussion document, and have now released it and other meeting materials to the public at the following site: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/possible-approaches-identifying-potential-candidates.

We received comments indicating that some were looking for a draft framework document, with an articulated path to a final agency action/document/procedure. How we move down such a path is a discussion we will take up with the Policy Group early next year. However, the intent of the current discussion document and the December public meeting is to get public input on approaches for identifying potential candidates for prioritization, and to initiate a dialogue on a path forward that will allow EPA to fulfill its responsibilities for chemical prioritization, evaluation, and management under TSCA. There also were a number of commenters who noted the lack of procedural elements, such as a specific process for interagency review. We agree that interagency review is important, and remain committed to engaging and collaborating with partner federal agencies as we move through this process.

There also were comments around the implementation of the draft approaches presented in the discussion document. These included how EPA would identify chemical information gaps, conduct a testing or information-collection program, or communicate to the public the results of any early efforts. While we did not address these questions in the discussion document, they will be valuable, together with public comments, in moving from this dialogue stage of the process to developing an approach or set of approaches to identify candidates for chemical prioritization under TSCA.

Thank you once again. Your comments helped tremendously to improve the overall quality and clarity of the document, and will inform our implementation efforts moving forward.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Schmit, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7077ECBAC4914A00AD465398F92BBE78-SCHMIT, RYAN]
**Sent**: 10/16/2017 4:11:49 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; 'Underwood, Patricia M CIV (US)' [patricia.m.underwood.civ@mail.mil]; Michael_Hickey@[redacted]; James_A._Laity@[redacted] Michael_C_Jensen@[redacted]; Sullivan, Maureen SES OSD OUSD ATL (US [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US [jim.rudroff@navy.mil]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US [karen.e.colmie.civ@mail.mil]; mike.a.mcneill@nasa.gov; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [redacted]; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Paul_A_Winters@[redacted]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Tomiak, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d67fe354a4d06be80afa6eb65e614-Tomiak, Rob]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]
**CC**: OP ADP Calendar [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af50820711fc45cea9973d8219ea9d58-OP ADP Cale]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; David Rostker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd257b595]; david.rostker.sba@gmail.com; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]
**Subject**: RE: TSCA Interagency Meeting - Agenda
**Attachments**: Agenda for TSCA Interagency Policy 10.17.17, v3.docx

Folks, please see attached agenda for tomorrow's meeting. A call-in # will be added to the calendar invite shortly.
Thanks,
Ryan

(202)564-0610

-----Original Appointment-----
**From:** Marshall, Venus **On Behalf Of** Beck, Nancy
**Sent:** Friday, September 29, 2017 7:38 AM
**To:** Beck, Nancy; Morris, Jeff; Mottley, Tanya; Pierce, Alison; Cherepy, Andrea; Henry, Tala; Doa, Maria; 'Underwood, Patricia M CIV (US)'; Michael_Hickey@[redacted]v; James_A._Laity@[redacted]Michael_C_Jensen@[redacted] Sullivan, Maureen SES OSD OUSD ATL (US; Rudroff, James G CIV USN (US; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US; mike.a.mcneill@nasa.gov; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD; Jones, Danielle Y. EOP/OMB; James_H_Kim@[redacted]; Waqar, Tayyaba; Paul_A_Winters@[redacted]; Wise, Louise; Rodan, Bruce; Corrales, Mark; Schmit, Ryan; Tomiak, Robert; Hanley, Mary; Bertrand, Charlotte
**Cc:** OP ADP Calendar; Hartman, Mark; Scheifele, Hans (Scheifele.Hans@epa.gov); Blunck, Christopher; Rostker, David J.; david.rostker.sba@gmail.com; Knight, Kelly
**Subject:** TSCA Interagency Meeting
**When:** Tuesday, October 17, 2017 9:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** DCRoomEast3156/DC-EPA-EAST-OCSPP

**I hope you will be able to join us for our rescheduled meeting on October 17th. We will be sending an agenda soon. In the meantime, I wanted you to have advance notice of the new meeting time.**

**Nancy**

Message

**From**: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
**Sent**: 10/31/2017 4:40:33 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; patricia.m.underwood.civ@mail.mil; Michael_Hickey@[redacted]; James_A._Laity@[redacted] Michael_C_Jensen@[redacted]; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; mike.a.mcneill@nasa.gov; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Danielle_Y_Jones@[redacted]; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; tayyaba.waqar@sba.gov; Paul_A_Winters@[redacted]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Peffers, Mel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b6116fbb41448b38b3caefc882165fe-Peffers, Melissa]; Tomiak, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e43d67fe354a4d06be80afa6eb65e614-Tomiak, Rob]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; maureen.sullivan18.civ@mail.mil; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; David Rostker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd257b595]; [redacted]m; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
**Subject**: TSCA Interagency Policy Group - Follow-Up Items
**Attachments**: Identifying Prioritization Candidates Discussion Document draft 10.31.17.docx

**Flag**: Flag for follow up

TSCA Interagency Policy Group,

As indicated at our last meeting, EPA's Office of Pollution Prevention and Toxics (OPPT) is continuing to prepare for a public meeting on December 11 regarding approaches and tools for identifying potential candidates for the TSCA existing chemical prioritization process. To further that dialogue, we've developed a draft discussion document that is attached to this email. This is a draft document, so please do not distribute it. If there are any major comments on the document, we would appreciate having your feedback by no later than close of business on November 6. Any comments can be provided to Ryan Schmit of my staff (schmit.ryan@epa.gov). EPA plans to release the discussion document to the public, along with additional meeting materials, by November 10. We will do our best to incorporate input from this group prior to public release. However, this will not be the only opportunity to engage on this subject. EPA expects the dialogue with all of you and our interested stakeholders to continue for approximately 6 months.

Additionally, as a reminder, EPA and DOD will be coordinating a side legal discussion regarding the applicability of TSCA to other federal agencies. If you haven't already done so and your organization is interested in participating, please send an appropriate point-of-contact to, again, Ryan Schmit of my staff (schmit.ryan@epa.gov).

Thanks,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Blair, Susanna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6C869B985F3D43DB982C18AAABD826BD-BLAIR, SUSA]
**Sent**: 8/7/2018 12:42:12 PM
**To**: Smith, Peterj [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=688ee4f05da54e91bc5420aa19e30f1b-PSmith03]
**CC**: Tyree, JamesN [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Tyree, JamesN]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]; Alison Pierce
Ex. 6
**Subject**: Re: Pre-Prioritization: Draft Letters to our Internal Agency and Federal Partners

Hi Peter and James,
There are two products here- the white paper and a letter requesting priority chemicals from Agencies. This discussion is on the letter.
Historically Jeff or myself would something like these to our partners and for this one I imagine it would be Jeff. I can send our list of inter and intra agency people as soon as I get in.

Sent from my iPhone

On Aug 7, 2018, at 8:38 AM, Smith, Peterj <Smith.Peterj@epa.gov> wrote:

Hi James,

**Deliberative Process / Ex. 5**

Please let me know if/how I can help!

Best,
Peter

Sent from my iPhone

On Aug 7, 2018, at 7:59 AM, Tyree, JamesN <tyree.jamesn@epa.gov> wrote:

+ Peter Smith

I recall OMB being interested in facilitating the letter transmission across the federal govt. Peter, is that correct?

**James Tyree, P.E.**
Office of Chemical Safety and Pollution Prevention
U.S. EPA
202-564-2658

---

**From:** Bertrand, Charlotte
**Sent:** Monday, August 06, 2018 4:45 PM
**To:** Tyree, JamesN <tyree.jamesn@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Morris, Jeff <Morris.Jeff@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Keller, Kaitlin <keller.kaitlin@epa.gov>; Alison Pierce
Ex. 6
**Subject:** RE: Pre-Prioritization: Draft Letters to our Internal Agency and Federal Partners

Thanks, I am ok with the letters, however, can I get a sense of who will send out the EPA memo and who at EPA it is going? Also, at what level do we want to see a response? Should it come from OD, DAA, AA?

---

**From:** Tyree, JamesN
**Sent:** Monday, August 06, 2018 3:06 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Morris, Jeff <Morris.Jeff@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Keller, Kaitlin <keller.kaitlin@epa.gov>; Alison Pierce
Ex. 6
**Subject:** RE: Pre-Prioritization: Draft Letters to our Internal Agency and Federal Partners

Hi,
Bringing this back up to the top of your emails since we were busy talking white paper today.

**James Tyree, P.E.**
Office of Chemical Safety and Pollution Prevention
U.S. EPA
202-564-2658

**From:** Alison Pierce Ex. 6
**Sent:** Thursday, August 02, 2018 8:46 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>

**Cc:** Morris, Jeff <Morris.Jeff@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Keller, Kaitlin <keller.kaitlin@epa.gov>; Tyree, JamesN <tyree.jamesn@epa.gov>
**Subject:** Pre-Prioritization: Draft Letters to our Internal Agency and Federal Partners

Nancy -

Per your request, attached for your review are:

1) a revised version of the note we'd like to send to the TSCA Interagency group (in red-line so you can see your edits reflected);
2) a similar note that we'd send to other program offices (in red-line so that you can see where this deviates from the TSCA Interagency note); and
3) the spreadsheet we'd use to collect that information.

Best,
Alison

Message

**From**: Camacho, Iris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5598D2CC8E3C4302AFF255A840A991DC-CAMACHO, IRIS]
**Sent**: 3/26/2018 5:13:52 PM
**To**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; patricia.m.underwood.civ@mail.mil; Michael_Hickey@omb.eop.gov; James_A._Laity@omb.eop.gov; Michael_C_Jensen@ceq.eop.gov; maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; david.rostker.sba@gmail.com; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]; Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]
**CC**: Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; Hearl, Frank J. (CDC/NIOSH/OD) [fjh1@cdc.gov]; Schaeffer, Val - OSHA [Schaeffer.Val@dol.gov]
**Subject**: Call will be rescheduled-----RE: Draft EPA Systematic Review Document

This call will be rescheduled for tomorrow.

**********
Iris A. Camacho, Ph.D.
Branch Chief, Assessment Branch 1
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
William Jefferson Clinton Building East, 6308-A
Washington, DC 20460
Phone: 202-564-1229
Work hours: 8:00 am – 4:30 pm
Work cell phone: Ex. 6
Telework phone:
Email: camacho.iris@epa.gov

-----Original Appointment-----
**From:** Morris, Jeff
**Sent:** Monday, March 26, 2018 9:47 AM
**To:** Morris, Jeff; Beck, Nancy; Mottley, Tanya; Pierce, Alison; Henry, Tala; Doa, Maria; patricia.m.underwood.civ@mail.mil; Michael_Hickey@omb.eop.gov; James_A._Laity@omb.eop.gov; Michael_C_Jensen@ceq.eop.gov; maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; Suzanne_Fitzpatrick; zkz1@cdc.gov; fhearl@cdc.gov; david.rostker.sba@gmail.com; Knight, Kelly; Widawsky, David; Camacho, Iris; Blair, Susanna
**Cc:** Scheifele, Hans; Hartman, Mark; Blunck, Christopher; Hearl, Frank J. (CDC/NIOSH/OD); Schaeffer, Val - OSHA
**Subject:** Draft EPA Systematic Review Document
**When:** Monday, March 26, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Call in

Two documents attached.

Call in numbe **Ex. 6**

Adobe Connect: http://epawebconferencing.acms.com/tscasr/

Message

**From**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]
**Sent**: 3/23/2018 6:50:25 PM
**To**: Camacho, Iris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5598d2cc8e3c4302aff255a840a991dc-Camacho, Iris]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; 'Underwood, Patricia M CIV (US)' [patricia.m.underwood.civ@mail.mil]; Michael_Hickey Deliberative Process / Ex. 5 James_A._Laity Deliberative Process / Ex. 5 Michael_C_Jensen Deliberative Process / Ex. 5 Sullivan, Maureen SES OSD OUSD ATL (US [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US [jim.rudroff@navy.mil]; Grafton, Gail M. (MSFC-AS10)[CH2M Hill] [gail.m.grafton@nasa.gov]; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US [karen.e.colmie.civ@mail.mil]; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD [fjh1@cdc.gov]
**CC**: Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; David Rostker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd257b595]; david.rostker.sba@gmail.com; Knight, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47fc4b0c90f94826a1d9a48381f4009f-Knight, Kel]; Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]
**Subject**: RE: Draft EPA Systematic Review Document

Iris
I have tested the link and entered using my name as a guest. However, there is no presentation to review. Please share the presentation with us all to foster better preparation for the Monday meeting.

Many thanks.

Linda

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
MS-2T89
300 E Street SW
Washington, DC 20546-0001

Tel: 202/358-4558

Ex. 6
Fax: 202/358-3948
linda.s.wennerberg@nasa.gov

**From:** Camacho, Iris [mailto:Camacho.Iris@epa.gov]
**Sent:** Friday, March 23, 2018 2:44 PM
**To:** Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Mottley, Tanya <Mottley.Tanya@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; 'Underwood, Patricia M CIV (US)' <patricia.m.underwood.civ@mail.mil>; Michael_Hickey Deliberative Process / Ex. 5 James_A._Laity Deliberative Process / Ex. 5 Michael_C_Jensen Deliberative Process / Ex. 5 Sullivan, Maureen SES OSD OUSD ATL (US <maureen.sullivan18.civ@mail.mil>; Rudroff, James G CIV USN (US <jim.rudroff@navy.mil>; Grafton, Gail M. (MSFC-AS10)[CH2M Hill] <gail.m.grafton@nasa.gov>; Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US <karen.e.colmie.civ@mail.mil>; Suzanne_Fitzpatrick <Suzanne.Fitzpatrick@fda.hhs.gov>; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD <fjh1@cdc.gov>
**Cc:** Hartman, Mark <Hartman.Mark@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Blunck, Christopher <Blunck.Chris@epa.gov>; David Rostker <David.Rostker@sba.gov>; david.rostker.sba@gmail.com; Knight, Kelly <knight.kelly@epa.gov>; Widawsky, David <Widawsky.David@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>
**Subject:** RE: Draft EPA Systematic Review Document

HI,
Below is the Adobe connect link for the presentation on Monday afternoon.
http://epawebconferencing.acms.com/tscasr/

**********
Iris A. Camacho, Ph.D.
Branch Chief, Assessment Branch 1
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
William Jefferson Clinton Building East, 6308-A
Washington, DC 20460
Phone: 202-564-1229
Work hours: 8:00 am – 4:30 pm
Work cell phone Ex. 6
Telework phone
Email: camacho.iris@epa.gov

**From:** Morris, Jeff
**Sent:** Tuesday, March 20, 2018 4:55 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Mottley, Tanya <Mottley.Tanya@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; 'Underwood, Patricia M CIV (US)' <patricia.m.underwood.civ@mail.mil>; Michael_Hickey Deliberative Process / Ex. 5 James_A._Laity Deliberative Process / Ex. 5 Michael_C_Jensen Deliberative Process / Ex. 5 Sullivan, Maureen SES OSD OUSD ATL (US <maureen.sullivan18.civ@mail.mil>; Rudroff, James G CIV USN (US <jim.rudroff@navy.mil>; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US <karen.e.colmie.civ@mail.mil>; Suzanne_Fitzpatrick <Suzanne.Fitzpatrick@fda.hhs.gov>; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD <fjh1@cdc.gov>
**Cc:** Hartman, Mark <Hartman.Mark@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Blunck, Christopher <Blunck.Chris@epa.gov>; David Rostker <David.Rostker@sba.gov>; david.rostker.sba@gmail.com; Knight, Kelly <knight.kelly@epa.gov>; Widawsky, David <Widawsky.David@epa.gov>; Camacho, Iris <Camacho.Iris@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>
**Subject:** Draft EPA Systematic Review Document

Dear Colleagues,

As you are likely aware, EPA's Office of Chemical Safety and Pollution Prevention (OPPT) is working diligently to meet its statutory requirements under TSCA. We are currently finalizing the TSCA Problem Formulation documents for the first 10 chemical risk evaluations. These documents will refine the TSCA Scope documents that were published last year and constitute an additional interim step prior to the publication of the draft risk evaluations. We anticipate sending these documents for your review in the coming weeks.

In addition, our office has been implementing the principles of systematic review in the risk evaluation process. This entails using a structured process for identifying, evaluating and integrating evidence for both the hazard and exposure assessments. This will ensure that assessments rely on the best available science and the weight of the scientific evidence, which are the science standards required by TSCA. We have prepared the attached draft document entitled, "*Application of Systematic Review in TSCA Risk Evaluations*", that describes the systematic review process that EPA/OPPT will use for chemical risk evaluations. The document also describes the data quality evaluation criteria that EPA will use to critically appraise the various data streams supporting the risk evaluations.

**Ex. 6**

If you have any comments on the document, please submit them by Wednesday, March 28, to Iris Camacho (Camacho.Iris@epa.gov).

All the best,

Jeff Morris

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 1/11/2018 9:38:41 PM
**To**: Ex. 6
**Subject**: FW: still at OMB?

---

**From:** Beck, Nancy
**Sent:** Thursday, January 11, 2018 4:37 PM
**To:** 'Levenbach, Stuart . EOP/OMB' Ex. 6
**Subject:** RE: still at OMB?

Are you there yet? Need serious NMFS help.

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

---

**From:** Levenbach, Stuart . EOP/OMB Ex. 6
**Sent:** Thursday, November 30, 2017 9:10 AM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>
**Subject:** RE: still at OMB?

Hi, Nancy.

I am at OMB. No start date yet at NOAA. Expect it to be later in December or early January.

Hear you are doing great things at EPA. Keep up the good work.

Stu

---

Stuart Levenbach, PhD
Senior Policy Analyst, Natural Resources and Environment Branch
OMB | Office of Information and Regulatory Affairs
Ex. 6

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Wednesday, November 29, 2017 7:37 PM
**To:** Levenbach, Stuart . EOP/OMB <Stuart_Levenbach Ex. 6
**Subject:** still at OMB?

Stuart,
Been hearing rumors and wondering where you are?
I hope all is well.
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 5/11/2018 10:21:32 PM
**To**: Mancini, Dominic J. EOP/OMB [redacted] Ex. 6
**CC**: john.kraemer@[redacted] Ex. 6 Personal Privacy (PP)
**Subject**: RE: Quick Question

Dom,
Yes—JK and I have the list! Happy hour is indeed much needed and it would be great to see you! JK used to work with Ross to set it up—but I guess we need to move Ross to the Alumni list.
I'm not sure I have the time to organize, but I would love to attend and can get the list to the right organizer. Let me know what you think is best.

Yes James is doing his next detail with us starting Monday—we have lots of rules he can dig into for us before we send them your way!

Nancy

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 2[redacted] Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

---

**From:** Mancini, Dominic J. EOP/OMB [[redacted] Ex. 6 Personal Privacy (PP)
**Sent:** Friday, May 11, 2018 2:49 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>
**Subject:** Quick Question

Hey I heard you are the keeper of the OIRA Alum list? We haven't had a happy hour in a bit and seems like a good idea. Let me know if you want to organize or don't have enough time, thanks. I also hear James is going to work with you soon: congrats!

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 7/31/2018 8:55:50 PM
**To**: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC**: James Kim [JKim@CleaningInstitute.org]
**Subject**: Re: Brian

Ex. 6

Yes, please sign the card for me and I can also contribute to food gift.
Thanks.

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

On Jul 31, 2018, at 4:52 PM, Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)> wrote:

Ex. 6

Message

**From**: Schmit, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7077ECBAC4914A00AD465398F92BBE78-SCHMIT, RYAN]

**Sent**: 6/12/2017 8:32:39 PM

**To**: Michael_Hickey@[redacted]; James_A._Laity@[redacted]; Brenda_Mallory@[redacted]; Marna_A_McDermott@[redacted]; Michael_C_Jensen@[redacted]; maureen.sullivan18.civ@mail.mil; patricia.m.underwood.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; :mike.a.mcneill@nasa.gov: [mike.a.mcneill@nasa.gov:]; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD) [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [redacted]; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]

**CC**: Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Symmes, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9339d98405486fb7109fe4ab65b7be-Symmes, Brian]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]; Hofmann, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44408bf728cd4eb5b81d295816b0c8f1-AHofmann]

**Subject**: FYI: Scopes for Risk Evaluation of First 10 Chemicals under TSCA

**Attachments**: TCE_TSCA Scope_OMB Version_06-09-17.docx; PigmentViolet29_TSCA Scope_OMB Version_06-09-17.docx; PERC_TSCA Scope_OMB Version_06-09-17.docx; NMP_TSCA Scope_OMB Version_06-09-17.docx; Methylene Chloride_TSCA Scope_OMB Version_06-09-17.docx; HBCD_TSCA Scope_OMB Version_06-09-17.docx; Dioxane_TSCA Scope_OMB Version_06-09-17.docx; CCl4_TSCA Scope_OMB Version_06-09-17.docx; Bromopropane_TSCA Scope_OMB Version_06-09-17.docx; Asbestos_TSCA Scope_OMB Version_06-09-17.docx

TSCA Interagency Policy Group,
FYI, OCSPP is pleased to provide the latest working drafts of the risk evaluation scope documents for the first 10 chemicals under TSCA. OMB will also be sharing these documents with the staff Interagency reviewers who have been engaged on the TSCA Framework rules. Any comments can be directed to Angela Hofmann (hofmann.angela@epa.gov no later than COB this Wednesday (6/14)
Thanks,
Ryan

Ryan N. Schmit
Special Assistant
Office of Chemical Safety and Pollution Prevention (OCSPP)

Phone: 202-564-0610
Email: schmit.ryan@epa.gov

Message (Encrypted)

**From**: Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]
**Sent**: 4/19/2018 10:44:48 AM
**To**: Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Sullivan, Maureen SES OSD OUSD ATL (US) [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US) [jim.rudroff@navy.mil]; Colmie, Karen E CIV OSD OGC (US) [karen.e.colmie.civ@mail.mil]; Anita.K.Meyer@usace.army.mil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebb41195f2324548959139e28c25b8a6-Anita.K.Meyer@usace.army.mil]; Putzrath, Resha M CIV USN NAVMCPUBHLTHCEN PORS (US) [resha.m.putzrath.civ@mail.mil]; Michael_Hickey@[Ex. 6 Personal Privacy (PP)]; James_A._Laity@[Ex. 6 Personal Privacy (PP)]; James_H_Kim@[Ex. 6 Personal Privacy (PP)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Paul_A_Winters@[Ex. 6 Personal Privacy (PP)]; Danielle_Y_Jones@[Ex. 6 Personal Privacy (PP)]; Margo_Schwab@[Ex. 6 Personal Privacy (PP)]; Szabo, Aaron L. EOP/CEQ [Ex. 6] gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; schaeffer.val@dol.gov; Charles.Maresca@sba.gov; birnbaumls@niehs.nih.gov; brian.berridge@nih.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Middendorf, Paul (CDC/NIOSH/OD [pkm2@cdc.gov]; Strickland, Maria (CDC/NIOSH/OD [kvl9@cdc.gov]; Piacentino, John D. (CDC/NIOSH/OD [gjt4@cdc.gov]; Keenan, Amanda K. (CDC/NIOSH/EID [yls5@cdc.gov]; Schulte, Paul A. (CDC/NIOSH/EID [pas4@cdc.gov]
**CC**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]
**Subject**: RE: [Non-DoD Source] EPA/OPPT Briefing on six draft Problem Formulations (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

CLASSIFICATION: UNCLASSIFIED

Susanna,
Thank you for the opportunity to submit questions. We have had a chance to formulate one (but I am sure will have many more once we have time to digest the documents further).

It is as follows:

**Deliberative Process / Ex. 5**

Thank you,
Tricia

-----Original Message-----
From: Blair, Susanna [mailto:Blair.Susanna@epa.gov]
Sent: Wednesday, April 18, 2018 12:45 PM
To: Underwood, Patricia M CIV (US) <patricia.m.underwood.civ@mail.mil>; Sullivan, Maureen SES OSD OUSD ATL (US) <maureen.sullivan18.civ@mail.mil>; Rudroff, James G CIV USN (US) <jim.rudroff@navy.mil>; Colmie, Karen E CIV OSD OGC (US) <karen.e.colmie.civ@mail.mil>; Anita.K.Meyer@usace.army.mil; Putzrath, Resha M CIV USN NAVMCPUBHLTHCEN PORS (US) <resha.m.putzrath.civ@mail.mil>; Michael_Hickey@[Ex. 6 Personal Privacy (PP)] James_A._Laity@[Ex. 6 Personal Privacy (PP)]; James_H_Kim@[Ex. 6] Paul_A_Winters@[Ex. 6 Personal Privacy (PP)]; Danielle_Y_Jones@[Ex. 6 Personal Privacy (PP)]; Margo_Schwab@[Ex. 6]; Szabo, Aaron L. EOP/CEQ

<Aaron.L.Szabo@[redacted]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; schaeffer.val@dol.gov; Charles.Maresca@sba.gov; birnbaumls@niehs.nih.gov; brian.berridge@nih.gov; Suzanne_Fitzpatrick <Suzanne.Fitzpatrick@fda.hhs.gov>; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Middendorf, Paul (CDC/NIOSH/OD <pkm2@cdc.gov>; Strickland, Maria (CDC/NIOSH/OD <kvl9@cdc.gov>; Piacentino, John D. (CDC/NIOSH/OD <gjt4@cdc.gov>; Keenan, Amanda K. (CDC/NIOSH/EID <yls5@cdc.gov>; Schulte, Paul A. (CDC/NIOSH/EID <pas4@cdc.gov>
Cc: Morris, Jeff <Morris.Jeff@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>
Subject: [Non-DoD Source] EPA/OPPT Briefing on six draft Problem Formulations

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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Hello everyone,

This is a reminder that the briefing on the 6 draft problem formulations is tomorrow at noon.

As we prepare for this meeting, it would be helpful to hear if there are any topics that you want to be sure we discuss tomorrow. We would like to be able to tee these up for the topic leads. If you could send any topics/questions/comments by COB today, that would be extremely helpful. We recognize the short notice, and thank you again for your feedback on these documents.

Best,
Susanna

---

Susanna W. Blair, PhD

Special Assistant

Office of Pollution Prevention and Toxics

William Jefferson Clinton Building - East, MC7401M

Washington DC 20460

202.564.4371 (office) | [redacted] (cell) | Blair.susanna@epa.gov < Caution-mailto:Blair.susanna@epa.gov >

CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED

Message

**From**: Bromberg, Kevin L. [kevin.bromberg@sba.gov]
**Sent**: 6/15/2018 1:30:17 PM
**To**: Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Underwood, Patricia M CIV (US [patricia.m.underwood.civ@mail.mil]; Wennerberg, Linda S. (HQ-LD020 [linda.s.wennerberg@nasa.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Winters, Paul A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Fine, Leah R. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC**: Eisenreich, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f06330ff6bd84fccb272c208db491240-Eisenreich, Karen]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]
**Subject**: RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Before the documents are made public – with the opportunity for the peer reviewers to modify or ask questions about the peer review questions at their scheduled meeting in late June.

---

**From:** Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Sent:** Thursday, June 14, 2018 5:49 PM
**To:** Bromberg, Kevin L.; Morris, Jeff; Waqar, Tayyaba; Underwood, Patricia M CIV (US; Wennerberg, Linda S. (HQ-LD020; Moore, Beth; Brenner, Sara A. EOP/OSTP; Jones, Danielle Y. EOP/OMB; Schwab, Margo EOP/OMB; Szabo, Aaron L. EOP/CEQ; Barringer, Jody M. EOP/OMB; Falk Curtin, Edna T. EOP/OMB; Winters, Paul A. EOP/OMB; Fine, Leah R. EOP/OMB
**Cc:** Eisenreich, Karen; Fehrenbacher, Cathy; Henry, Tala; Beck, Nancy; Bertrand, Charlotte; Baptist, Erik; Blair, Susanna
**Subject:** RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Kevin, **Deliberative Process / Ex. 5**
**Deliberative Process / Ex. 5**

---

**From:** Bromberg, Kevin L. <kevin.bromberg@sba.gov>
**Sent:** Thursday, June 14, 2018 5:41 PM
**To:** Morris, Jeff <Morris.Jeff@epa.gov>; Waqar, Tayyaba <tayyaba.waqar@sba.gov>; Underwood, Patricia M CIV (US <patricia.m.underwood.civ@mail.mil>; Wennerberg, Linda S. (HQ-LD020 <linda.s.wennerberg@nasa.gov>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP <Ex. 6 Personal Privacy (PP)>; Jones, Danielle Y. EOP/OMB Ex. 6 Personal Privacy (PP)>; Schwab, Margo EOP/OMB Ex. 6 Personal Privacy (PP)>; Laity, Jim A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Szabo, Aaron L. EOP/CEQ Ex. 6 Personal Privacy (PP)>; Barringer, Jody M. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Falk Curtin, Edna T. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Winters, Paul A. EOP/OMB <P Ex. 6 Personal Privacy (PP)>; Fine, Leah R. EOP/OMB <Ex. 6 Personal Privacy (PP)
**Cc:** Eisenreich, Karen <Eisenreich.Karen@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>;

Baptist, Erik <Baptist.Erik@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>
**Subject:** RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Given the short amount of time for review, here are some preliminary potentially helpful suggestions:

1.
2. **Deliberative Process / Ex. 5**
3.

---

**From:** Morris, Jeff [mailto:Morris.Jeff@epa.gov]
**Sent:** Wednesday, June 13, 2018 1:03 PM
**To:** Waqar, Tayyaba; Bromberg, Kevin L.; Underwood, Patricia M CIV (US; Wennerberg, Linda S. (HQ-LD020; Moore, Beth; Brenner, Sara A. EOP/OSTP; Jones, Danielle Y. EOP/OMB; Schwab, Margo EOP/OMB; Laity, Jim A. EOP/OMB; Szabo, Aaron L. EOP/CEQ; Barringer, Jody M. EOP/OMB; Falk Curtin, Edna T. EOP/OMB; Paul Winters; Fine, Leah R. EOP/OMB
**Cc:** Eisenreich, Karen; Fehrenbacher, Cathy; Henry, Tala; Beck, Nancy; Bertrand, Charlotte; Baptist, Erik; Blair, Susanna
**Subject:** Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

TWG Colleagues,

Attached are the draft exposure and use assessment (with supplemental document), draft hazard information summaries, and the draft peer review charge questions, for the five PBT chemicals subject to EPA review under TSCA. We have a hard deadline to put the documents out for public comment on Monday, June 18. Therefore, we ask that you limit any comments this week to the charge questions. We would need any comments on the charge questions by COB this Thursday in order to incorporate them into the documents for Monday's release.

However, we don't formally initiate the peer review until June 29. Therefore, if the TWG needs more time to review and comment on the charge, and/or would like to provide comments on the other documents before the peer review starts, please send any comments to Susanna Blair, at blair.susanna@epa.gov, by COB Monday, June 25. Of course we will consider comments after that date, but likely will not be able to get them to the peer reviewers before their review starts.

Thank you for engaging with us on this effort.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From:** Linda LawhornBrown - NOAA Federal [linda.lawhornbrown@noaa.gov]
**Sent:** 6/7/2018 5:49:01 PM
**To:** Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**CC:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bernhardt, David Ex. 6 Personal Privacy (PP) todd_willens@ios.doi.gov; EComstock@doc.gov; Uthmeier, James (Federal) [James.Uthmeier@doc.gov]; stuart.levenbach@noaa.gov; Stephen.Vaden@ogc.usda.gov; raymond.starling@osec.usda.gov; Herz, James P. EOP/OMB Ex. 6 Personal Privacy (PP); Emma_K_Roach@o Ex. 6 Personal Privacy (PP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=459adeb9f2894e7784b9b3407687c21c-Emma_K_Roach@ Ex. 6 Personal Privacy (PP) Moran, John S. EOP/WHO Ex. 6 Personal Privacy (PP); Brooke, Francis J. EOP/WHO [Francis.J.Brooke@ Ex. 6 Personal Privacy (PP); Prandoni, Christopher D. EOP/CEQ [Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; gareth_rees@ios.doi.gov; Teague, Anne (Federal) [ATeague@doc.gov]; Dankert, Charles M. EOP/OMB [Charles.M.Dankert Ex. 6 Personal Privacy (PP)
**Subject:** Re: Next ESA WG call

# Hi Alexander, Stuart Levenbach is available June 20 at 3pm for this call. Thank you.

On Thu, Jun 7, 2018 at 1:43 PM, Domesle, Alexander R. EOP/CEQ <Alexander.R.Domesle@ Ex. 6 Personal Privacy (PP)> wrote:

Dear ESA Pesticide Working Group members,

As discussed at our last meeting on May 18, CEQ is convening regular (roughly monthly) calls to monitor progress on the ESA/pesticides initiative. We propose scheduling a 30-minute call on **Wednesday, June 20, at 3:00pm**. If you have an irresolvable conflict, please provide some other times when you are available on Wednesday, June 20, and Friday, June 22.

We encourage the signatory agencies – EPA, DOI, DOC – and USDA to obtain a progress update from their staffs in advance of this meeting. This will allow us to compare notes and identify any challenges that might be addressed by the Working Group. A draft agenda is included below and the timeline developed by technical working group on pesticide usage data is attached. If you have any additional agenda items you would like to include, please provide these to me no later than Monday, June 18.

Thank you!

**DRAFT AGENDA**

Deliberative Process / Ex. 5

**Alexander Domesle**

Senior Advisor for Natural Resources

Council on Environmental Quality

Executive Office of the President

Ex. 6 Personal Privacy (PP)

www.whitehouse.gov/ceq

--
**Linda Lawhorn-Brown**
**Office of the Under Secretary, NOAA/U.S. Department of Commerce**
**14th & Constitution Ave, NW, Suite 51030**
**Washington, D.C. 20230**
**(202) 482-3436**

Message

**From**: Domesle, Alexander R. EOP/CEQ [/ Ex. 6 Personal Privacy (PP)
**Sent**: 6/7/2018 5:43:28 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bernhardt, David Ex. 6 todd_willens@ios.doi.gov; EComstock@doc.gov; Uthmeier, James (Federal) [James.Uthmeier@doc.gov]; stuart.levenbach@noaa.gov; Stephen.Vaden@ogc.usda.gov; raymond.starling@osec.usda.gov; Herz, James P. EOP/OMB [ Ex. 6 Personal Privacy (PP) Emma_K_Roach@ Ex. 6 Personal Privacy (PP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=459adeb9f2894e7784b9b3407687c21c- Ex. 6 Personal Privacy (PP) ]; Moran, John S. EOP/WHO [ Ex. 6 Personal Privacy (PP) ]; Brooke, Francis J. EOP/WHO [ Ex. 6 Personal Privacy (PP) ]
**CC**: Prandoni, Christopher D. EOP/CEQ [ Ex. 6 Personal Privacy (PP) ]; Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; gareth_rees@ios.doi.gov; Teague, Anne (Federal) [ATeague@doc.gov]; linda.lawhornbrown@noaa.gov; Dankert, Charles M. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]
**Subject**: Next ESA WG call
**Attachments**: milestones_timeline_interagency_usage_ 5-30-18_final.docx

Dear ESA Pesticide Working Group members,

As discussed at our last meeting on May 18, CEQ is convening regular (roughly monthly) calls to monitor progress on the ESA/pesticides initiative. We propose scheduling a 30-minute call on **Wednesday, June 20, at 3:00pm**. If you have an irresolvable conflict, please provide some other times when you are available on Wednesday, June 20, and Friday, June 22.

We encourage the signatory agencies – EPA, DOI, DOC – and USDA to obtain a progress update from their staffs in advance of this meeting. This will allow us to compare notes and identify any challenges that might be addressed by the Working Group. A draft agenda is included below and the timeline developed by technical working group on pesticide usage data is attached. If you have any additional agenda items you would like to include, please provide these to me no later than Monday, June 18.

Thank you!

**DRAFT AGENDA**

**Deliberative Process / Ex. 5**

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality

Executive Office of the President
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

Message

**From:** Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)
**Sent:** 6/4/2018 7:33:02 PM
**To:** Brooke, Francis J. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Neumayr, Mary B. EOP/CEQ Ex. 6 Personal Privacy (PP)]; Herz, James P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Blair, Robert B. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; 'maureen.sullivan18.civ@mail.mil' [maureen.sullivan18.civ@mail.mil]; Kratsios, Michael J. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; 'Jonathan.Brightbill@usdoj.gov' [Jonathan.Brightbill@usdoj.gov]; Maresca, Charles A. [Charles.Maresca@sba.gov]
**CC:** Brenner, Sara A. EOP/OSTP [Ex. 6 Personal Privacy (PP) ov]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Palmieri, Rosario A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Subject:** Policy Coordination Committee - Chemicals
**Attachments:** TWG draft agenda 6-7-18.docx; Principles 6-7-18.docx

Dear Colleagues,

Thank you for your agreement to be part of the Chemical Exposure and Risk Assessment and Management (CERAM) Policy Coordination Council (PCC). Attached please find the proposed principles for the PCC. This PCC provides an interagency forum for discussing upcoming or proposed chemical exposure and risk assessment and management actions, and will be supported by the TWG which will discuss upcoming actions, review draft assessments, and inform the PCC on important issues. Through this PCC, Federal agencies that are planning such actions will alert the Executive Office of the President (EOP) and sister Federal agencies who will be impacted by those actions and provide an opportunity to identify differences in scientific perspectives and the implications of those differences on Federal equities, as well as to provide input into the peer review process before public commitments are made.

As indicated when we last spoke, **we are also forming a Technical Working Group (TWG).** The purpose of the TWG is to share information about upcoming and ongoing chemical exposure and risk assessment and management actions, and ensure that Federal agencies who are directly impacted by those actions, particularly from a budgetary or policy perspective, collaborate on those activities as early in the process as possible and speak with one voice across the Federal government. That is, the TWG's purpose is to implement the first two of the attached principles (early collaboration; TWG to facilitate discussions) and to facilitate implementation of the last principle (consistent public communication). The TWG will inform and support eventual decisions by agency leadership. To encourage free and frank sharing of ideas and opinions, all TWG discussions (whether in person, on the phone, or through email) are deliberative until or unless a decision is made to make agency comments or interim drafts part of the public record. Assessments addressed by the TWG are by definition, preliminary, and any materials circulated are presumed deliberative absent a contrary determination by the circulating agency.

In identifying your agency's participant(s) in the TWG, we'd like you to nominate one or more representatives with sufficient knowledge of the chemical exposure and risk assessment processes to identify both science and science-policy questions, and with close ties to the agency's toxicologists, epidemiologists, and other health science specialists as well as the arm of the agency that would implement any risk management or regulatory actions that might result from the planned chemical exposure and risk assessment or management actions. Individuals on the group must have access to their policy official and demonstrated experience working in a collaborative interagency environment. Below we list individuals that we have worked with in the past from your agency on interagency reviews related to chemical exposure and risk assessments. Feel free to supplement and/or substitute with your preferred representative(s).

EPA: Jeff Morris
DOD: Tricia Underwood
NASA: Linda Wennerberg
DOE: Beth Moore
SBA: Kevin Bromberg, Tabby Waqar
OSTP: Sara Brenner

**Deliberative Process / Ex. 5**

**We are scheduling this meeting for Thursday, June 7 at 4PM in the New Executive Office Building, Room 10258. As such please get back to me by COB Tuesday with the contact information of your agency's representative to the TWG.** A draft agenda for the June 7 meeting is attached.

Please don't hesitate to contact me with questions or concerns.

Best regards,
Jim

---

**James Kim, Ph.D., DABT**
Office of Information and Regulatory Affairs
Office of Management and Budget

**Ex. 6**

Message

**From:** Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Sent:** 6/14/2018 2:18:10 AM
**To:** 'Underwood, Patricia M CIV (US)' [patricia.m.underwood.civ@mail.mil]
**CC:** Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Winters, Paul A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Fine, Leah R. EOP/OMB [Ex. 6 Personal Privacy (PP)] Eisenreich, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f06330ff6bd84fccb272c208db491240-Eisenreich, Karen]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Sullivan, Maureen SES OSD OUSD ATL (US) [maureen.sullivan18.civ@mail.mil]
**Subject:** RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

All, lets discuss this at our MeCL meeting tomorrow. jim

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**From:** Underwood, Patricia M CIV (US) <patricia.m.underwood.civ@mail.mil>
**Sent:** Wednesday, June 13, 2018 4:29 PM
**To:** Laity, Jim A. EOP/OMB <Ex. 6 Personal Privacy (PP)>
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**Subject:** Re: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

All,
I had the impression Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 How do we resolve this?

Best regards,

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Washington, DC 20460

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**To**: Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]; Laity, Jim A. EOP/OMB Ex. 6 Personal Privacy (PP)
**CC**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP Ex. 6 Personal Privacy (PP); Schwab, Margo EOP/OMB Ex. 6 Personal Privacy (PP); Szabo, Aaron L. EOP/CEQ Ex. 6 Personal Privacy (PP); Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP); Winters, Paul A. EOP/OMB Ex. 6 Personal Privacy (PP) Fine, Leah R. EOP/OMB Ex. 6 Personal Privacy (PP); Eisenreich, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f06330ff6bd84fccb272c208db491240-Eisenreich, Karen]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Sullivan, Maureen SES OSD OUSD ATL (US) [maureen.sullivan18.civ@mail.mil]; James_H_Kim Ex. 6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]
**Subject**: RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Adding Jim Kim to the chain.

Thanks,
Danielle Y. Jones
Ex. 6 Personal Privacy (PP)

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**Sent:** Wednesday, June 13, 2018 4:29 PM
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Message

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Jim,

# Deliberative Process / Ex. 5

Jeff

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**Sent:** Wednesday, June 13, 2018 1:03 PM
**To:** Waqar, Tayyaba <tayyaba.waqar@sba.gov>; kevin.bromberg@sba.gov; Underwood, Patricia M CIV (US <patricia.m.underwood.civ@mail.mil>; Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP < Ex. 6 Personal Privacy (PP) >; Jones, Danielle Y. EOP/OMB Ex. 6 Personal Privacy (PP) Schwab, Margo EOP/OMB Ex. 6 Personal Privacy (PP) ; Laity, Jim A. EOP/OMB Ex. 6 Personal Privacy (PP) Szabo, Aaron L. EOP/CEQ < Ex. 6 Personal Privacy (PP) >; Barringer, Jody M. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Falk Curtin, Edna T. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Paul Winters Ex. 6 Personal Privacy (PP) >; Fine, Leah R. EOP/OMB < Ex. 6 Personal Privacy (PP)
**Cc:** Eisenreich, Karen <Eisenreich.Karen@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>;

Baptist, Erik <Baptist.Erik@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>
**Subject:** Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

TWG Colleagues,

Attached are the draft exposure and use assessment (with supplemental document), draft hazard information summaries, and the draft peer review charge questions, for the five PBT chemicals subject to EPA review under TSCA. We have a hard deadline to put the documents out for public comment on Monday, June 18. Therefore, we ask that you limit any comments this week to the charge questions. We would need any comments on the charge questions by COB this Thursday in order to incorporate them into the documents for Monday's release.

However, we don't formally initiate the peer review until June 29. Therefore, if the TWG needs more time to review and comment on the charge, and/or would like to provide comments on the other documents before the peer review starts, please send any comments to Susanna Blair, at blair.susanna@epa.gov, by COB Monday, June 25. Of course we will consider comments after that date, but likely will not be able to get them to the peer reviewers before their review starts.

Thank you for engaging with us on this effort.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]
**Sent**: 6/13/2018 8:10:39 PM
**To**: Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Underwood, Patricia M CIV (US [patricia.m.underwood.civ@mail.mil]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)] Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Winters, Paul A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Fine, Leah R. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC**: Eisenreich, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f06330ff6bd84fccb272c208db491240-Eisenreich, Karen]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]
**Subject**: RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Jim
Thanks for the clarification. However, the extremely truncated review times undercuts meaningful interagency review and the ability EPA to incorporate technical input to strengthen the Chemical Risk Assessment process.

Respectfully
Linda

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
MS-2T89
300 E Street SW
Washington, DC 20546-0001

Tel: 202/358-4558
Cell: Ex. 6 Personal Privacy (PP)
Fax: 202/358-3948
linda.s.wennerberg@nasa.gov

---

**From:** Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Sent:** Wednesday, June 13, 2018 4:04 PM
**To:** Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Waqar, Tayyaba <tayyaba.waqar@sba.gov>; kevin.bromberg@sba.gov; Underwood, Patricia M CIV (US <patricia.m.underwood.civ@mail.mil>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP

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**Subject:** RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Linda, My understanding is that the Thursday deadline is only for comments that you want to be incorporated before the documents go out for public comment. EPA will be accepting comments after that time to inform the version that goes to peer review (on both the charge and the documents). Jeff, please confirm that this is correct. jim

---

**From:** Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>
**Sent:** Wednesday, June 13, 2018 3:22 PM
**To:** Morris, Jeff <Morris.Jeff@epa.gov>; Waqar, Tayyaba <tayyaba.waqar@sba.gov>; kevin.bromberg@sba.gov; Underwood, Patricia M CIV (US <patricia.m.underwood.civ@mail.mil>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP < Ex. 6 Personal Privacy (PP) >; Jones, Danielle Y. EOP/OMB < Ex. 6 Personal Privacy (PP) />; Schwab, Margo EOP/OMB < Ex. 6 Personal Privacy (PP) />; Laity, Jim A. EOP/OMB < Ex. 6 Personal Privacy (PP) Szabo, Aaron L. EOP/CEQ < Ex. 6 Personal Privacy (PP) Barringer, Jody M. EOP/OMB <J Ex. 6 Personal Privacy (PP) >; Falk Curtin, Edna T. EOP/OMB < Ex. 6 Personal Privacy (PP) Winters, Paul A. EOP/OMB <F Ex. 6 Personal Privacy (PP) >; Fine, Leah R. EOP/OMB < Ex. 6 Personal Privacy (PP)
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**Subject:** RE: Interagency Technical Working Group (TWG) on Chemicals -- Draft EPA PBT documents

Jeff
Please clarify when these comments are due? My read is that they are due tomorrow (Thursday) COB?

As for the direction to only comment on the charge questions, I am questioning how one can provide meaningful input on charge questions without the time to review the draft document under peer review. Am I to assume that this constitutes interagency review?

Respectfully,

Linda

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
MS-2T89
300 E Street SW
Washington, DC 20546-0001

Tel: 202/358-4558
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Fax: 202/358-3948
linda.s.wennerberg@nasa.gov

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<patricia.m.underwood.civ@mail.mil>; Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP < Ex. 6 Personal Privacy (PP) >; Jones, Danielle Y. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Schwab, Margo EOP/OMB < Ex. 6 Personal Privacy (PP) >; Laity, Jim A. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Szabo, Aaron L. EOP/CEQ < Ex. 6 >; Barringer, Jody M. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Falk Curtin, Edna T. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Paul Winters < Ex. 6 Personal Privacy (PP) >; Fine, Leah R. EOP/OMB < Ex. 6 Personal Privacy (PP)
**Cc:** Eisenreich, Karen <Eisenreich.Karen@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>
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Thank you for engaging with us on this effort.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From:** Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
**Sent:** 4/23/2018 9:45:20 PM
**To:** James_H_Kim@[redacted]/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Palmieri, Rosario A. EOP/OMB [[redacted] Laity, Jim A. EOP/OMB [James_A._Laity@[redacted] Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Szabo, Aaron L. EOP/CEQ [[redacted]; Moran, John S. EOP/WHO [[redacted]]; Bremberg, Andrew P. EOP/WHO [[redacted]]; Herz, James P. EOP/OMB [[redacted] Brooke, Francis J. EOP/OVP [[redacted] jonathan.brightbill@usdoj.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Margo EOP/OMB [[redacted]]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aefcd454ba3e46cabf84a79129583e64-eric.t.gormsen@usdoj.gov]; Neumayr, Mary B. EOP/CEQ [[redacted]]; Hickey, Mike J. EOP/OMB [Ex. 6] Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject:** RE: EPA NPRM Call Regulatory Science
**Attachments:** EPA Response to OIRA- Data Access Draft 4-23-18 .docx

All,

Thanks again for your time and attention on this matter. Attached are responses to OIRA's suggested revisions. Other than a few minor additions and edits, we are comfortable with the revisions including the updated language for § 124.219.

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

---

**From:** Kim, Jim H. EOP/OMB [[redacted]
**Sent:** Monday, April 23, 2018 2:16 PM
**To:** Palmieri, Rosario A. EOP/OMB <[redacted]>; Laity, Jim A. EOP/OMB <[redacted]>; Bolen, Brittany <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ <[redacted]>; Moran, John S. EOP/WHO <[redacted]>; Bremberg, Andrew P. EOP/WHO <[redacted]>; Herz, James P. EOP/OMB <[redacted]> Brooke, Francis J. EOP/OVP <[redacted]>; jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB <[redacted]>; Schwab, Justin <Schwab.Justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Woods, Clint <woods.clint@epa.gov>; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ <[redacted]>; Hickey, Mike J. EOP/OMB [redacted]
**Subject:** RE: EPA NPRM Call Regulatory Science

Dear Interagency Reviewers:

Here are OIRA's suggested r Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Jim

---

**From:** Kim, Jim H. EOP/OMB
**Sent:** Monday, April 23, 2018 10:59 AM
**To:** Palmieri, Rosario A. EOP/OMB < Ex. 6 Personal Privacy (PP) ; Laity, Jim A. EOP/OMB < Ex. 6 Personal Privacy (PP) ; 'Bolen, Brittany' <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ < Ex. 6 Personal Privacy (PP) >; Moran, John S. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Bremberg, Andrew P. EOP/WHO < Ex. 6 Personal Privacy (PP) Herz, James P. EOP/OMB < Ex. 6 Personal Privacy (PP) ; Brooke, Francis J. EOP/OVP < Ex. 6 Personal Privacy (PP) ; jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB Ex. 6 Personal Privacy (PP) ; 'schwab.justin@epa.gov' <schwab.justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; woods.clint@epa.gov; David.Gualtieri@usdoj.gov; Eric.T.Gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ < Ex. 6 Personal Privacy (PP) >
**Subject:** RE: EPA NPRM Call Regulatory Science

Hi all,

Please find attached some additional edits for discussion at 11AM.

Thanks,
Jim

-----Original Appointment-----
**From:** Palmieri, Rosario A. EOP/OMB
**Sent:** Monday, April 23, 2018 8:58 AM
**To:** Palmieri, Rosario A. EOP/OMB; Laity, Jim A. EOP/OMB; 'Bolen, Brittany'; Szabo, Aaron L. EOP/CEQ; Moran, John S. EOP/WHO; Bremberg, Andrew P. EOP/WHO; Herz, James P. EOP/OMB; Brooke, Francis J. EOP/OVP; jonathan.brightbill@usdoj.gov; Beck, Nancy; Schwab, Margo EOP/OMB; 'schwab.justin@epa.gov'; Kim, Jim H. EOP/OMB; Yamada, Richard (Yujiro); woods.clint@epa.gov; David.Gualtieri@usdoj.gov; Eric.T.Gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ
**Subject:** EPA NPRM Call Regulatory Science
**When:** Monday, April 23, 2018 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial-In: ( Ex. 6 Personal Privacy (PP)

Message

**From:** Kim, Jim H. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Sent:** 4/23/2018 6:16:18 PM
**To:** Palmieri, Rosario A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Bremberg, Andrew P. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Herz, James P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Brooke, Francis J. EOP/OVP [Ex. 6 Personal Privacy (PP)]; jonathan.brightbill@usdoj.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aefcd454ba3e46cabf84a79129583e64-eric.t.gormsen@usdoj.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Hickey, Mike J. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Subject:** RE: EPA NPRM Call Regulatory Science
**Attachments:** data Access Draft -OIRA Response to EPA - 4-23-18 oira4.DOCX

Dear Interagency Reviewers:

Here are OIRA's suggested [Deliberative Process / Ex. 5]

**Deliberative Process / Ex. 5**

Jim

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**Sent**: 4/23/2018 2:58:33 PM
**To**: Palmieri, Rosario A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Bremberg, Andrew P. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Herz, James P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Brooke, Francis J. EOP/OVP [Ex. 6 Personal Privacy (PP)]; jonathan.brightbill@usdoj.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aefcd454ba3e46cabf84a79129583e64-eric.t.gormsen@usdoj.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
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**To:** Palmieri, Rosario A. EOP/OMB; Laity, Jim A. EOP/OMB; 'Bolen, Brittany'; Szabo, Aaron L. EOP/CEQ; Moran, John S. EOP/WHO; Bremberg, Andrew P. EOP/WHO; Herz, James P. EOP/OMB; Brooke, Francis J. EOP/OVP; jonathan.brightbill@usdoj.gov; Beck, Nancy; Schwab, Margo EOP/OMB; 'schwab.justin@epa.gov'; Kim, Jim H. EOP/OMB; Yamada, Richard (Yujiro); woods.clint@epa.gov; David.Gualtieri@usdoj.gov; Eric.T.Gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ
**Subject:** EPA NPRM Call Regulatory Science
**When:** Monday, April 23, 2018 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** Dial-In: [Ex. 6 Personal Privacy (PP)]

Message

**From**: Gross, Mackenzie A. EOP/WHO [Ex. 6 Personal Privacy (PP)]
**Sent**: 5/22/2018 10:01:11 PM
**To**: Starling, Ray A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Klippenstein, Brian - OSEC, Washington, DC [Brian.Klippenstein@osec.usda.gov]; Bonvillian, Marcus D. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Epstein, Gerald L. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Santerre, Charlie R. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Klein, Ethan A. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Cunliffe, Laura M. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Talento, Kathryn F. EOP/WHO [Ex. 6 Personal Privacy (PP)] Callahan, Julie E. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Bomer Lauritsen, Sharon E. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Doherty, Julia M. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Doty, George E. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Willems, Clete R. EOP/NSC [Ex. 6 Personal Privacy (PP)]; Lorenz, Andrew R. EOP/NSC [Ex. 6 Personal Privacy (PP)] Mamacos, Peter D. EOP/NSC [Ex. 6 Personal Privacy (PP)] Borio, Luciana L. EOP/NSC [Ex. 6 Personal Privacy (PP)]; Hoskins, Dudley - OSEC, Washington, DC [Dudley.Hoskins@osec.usda.gov]; Adcock, Rebeckah - OSEC, Washington, DC [Rebeckah.Adcock@osec.usda.gov]; Klippenstein, Brian - OSEC, Washington, DC [Brian.Klippenstein@osec.usda.gov]; Chou, Fan-Li - ARS [Fan-Li.Chou@ARS.USDA.GOV]; Adjemian, Michael K. EOP/CEA [Ex. 6 Personal Privacy (PP)]; Davis, May M. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Policy Coordinator Ex. 6 Personal Privacy (PP) Pinkos, Stephen M. EOP/OVP [Ex. 6 Personal Privacy (PP)]; Abram, Anna [Anna.Abram@fda.hhs.gov]; ritu.nalubola@fda.hhs.gov; stephen.ostroff@fda.hhs.gov; Butterfield, Nicholas W. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Keller, Catherine B. EOP/WHO [Ex. 6 Personal Privacy (PP)] Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Campau, Anthony P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Palmieri, Rosario A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Aguilar, Brenda L. EOP/OMB [Ex. 6 Personal Privacy (PP)] Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Dunn, Patrick M [DunnPM@state.gov]; Peter Haas - U.S. Department of State (HaasPD@state.gov) [HaasPD@state.gov]; SinghM9@state.gov; crowells@state.gov
**Subject**: Agricultural Biotechnology PCC
**Attachments**: Biotechnology Executive Action Proposal.docx; 5-18-18 biotech SOC v2.DOCX

All,

Thank you all for your participation in last Friday's Agricultural Biotech PCC. It was a great discussion and we look forward to many more. Please find the Summary of Conclusions from the Agricultural Biotech PCC from last Friday.

As a reminder, please remember Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks and have a great evening!

Mackenzie

Message

**From**: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
**Sent**: 5/9/2018 8:30:02 PM
**To**: patricia.m.underwood.civ@mail.mil; maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; karen.e.colmie.civ@mail.mil; Anita.K.Meyer@usace.army.mil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebb41195f2324548959139e28c25b8a6-Anita.K.Meyer@usace.army.mil]; resha.m.putzrath.civ@mail.mil; Michael_Hickey@[redacted]; James_A._Laity@[redacted] James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Paul_A_Winters@[redacted]; Danielle_Y_Jones@[redacted]v; Margo_Schwab@[redacted] Aaron.L.Szabo@[redacted]v; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; schaeffer.val@dol.gov; Charles.Maresca@sba.gov; tayyaba.waqar@sba.gov; birnbaumls@niehs.nih.gov; masten@niehs.nih.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce58615a43ec4347b15792aa8e15f549-masten@niehs.nih.gov]; Lowit, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d3428a2c0b84d5099124a0460babd53-Anna B. Lowit]; Reaves, Elissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=031646294ce14535ae428ab2f8d388c4-Reaves, Elissa]; Lavoie, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ac7844f12646c095e4e9093a941623-Lavoie, Emma]; Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Hoff, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7869a2d513614599a4b29144c3442d24-Hoff, Dale]; Murphy, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cee611862fe44c8aa27d42d5f50c991-DMURPHY]; Ohanian, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f119491e2ba8476381a39c57a456ac55-EOhanian]; Foos, Brenda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18b24f2f79414190852a748bf650d2b9-Bperkovi]; Cooperstein, Sharon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8f9aa31d9a74db0a06f94ee51274d51-Cooperstein, Sharon]; Johnson, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf046c29b1604a0e9f712b671c4f3ce5-Johnson, Ann]; Wills, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca379f4ec8204787ad79dcfda6071c12-JWILLS]; Frithsen, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3743bd6f3c345baaae407c1d6f78e92-FRITHSEN, JEFF]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Euling, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb0873315ed244fa852df546e1191e4c-Euling, Susan]; Congleton, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Congleton, Johanna]; Axelrad, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6a51eaa06cef403abd7d28275fd278b4-DAxelrad]; Dzubow, Rebecca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=403ca1721f3d43d38de9189a93a95b76-Dzubow, Rebecca]; Wray, Austin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c272e58301e46acae6a3582eefd4b8a-Wray, Austi]; Pope-Varsalona, Hannah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dab948af94374835ba29cf6674f0eb04-Pope-Varsal]; Lowit, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1aeb8079b3324e22bf4467598df6c522-Lowit, Michael]; Odenkirchen, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e6bf402eed49ca8172e0849067d334-Edward W Odenkirchen]; Aldridge, Ashlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c33eb73ed46a481cb0e741b6bb706233-Aldridge, Ashlee]; Niman, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8893877540d416d880562dd19ab78a4-Niman, Aaro]; Miller, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa0582f5ba6540c687844f9289a4f74f-David J. Miller]; Barone, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4f8618acbba418da24c110f3123a2af-Barone, Stan]; Burden, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aca392a7aea849bfbce1fdbc1a1ed88e-Burden, Susan]; Raffaele, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc48281bbab34bf5bf3ab1a63780d5ca-Kathleen Raffaele]; Foster, Stiven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d242767f304355ad415ec856988213-sfoste02]; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; brian.berridge@nih.gov; MBabich@cpsc.gov; KHatlelid@cpsc.gov; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Middendorf, Paul (CDC/NIOSH/OD [pkm2@cdc.gov]; Strickland, Maria (CDC/NIOSH/OD [kvl9@cdc.gov]; Piacentino, John D. (CDC/NIOSH/OD [gjt4@cdc.gov]; Keenan, Amanda K. (CDC/NIOSH/EID [yls5@cdc.gov]; Schulte, Paul A. (CDC/NIOSH/EID [pas4@cdc.gov]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]

**Subject**: EPA TSCA Problem Formulations: Remaining 4 Draft Documents

**Attachments**: 1-BP Problem Formulation Document_MASTER COPY_Draft_May_08_2018B.PDF; NMP DRAFT PF_(5-8-18).pdf; HBCD Problem Formulation DRAFT 050818 CLEAN for reviewB.PDF; PV29 Final Draft Problem Formulation_5-8-18_inter-intra.pdf

**Importance**: High

Dear Colleagues,

First, I want to thank you again for your review of the previous six draft problem formulation documents. Please find attached the remaining four problem formulations for review. They are:

1-Bromopropane
N-methylpyrrolidone (NMP)
Pigment violet 29
Cyclic Aliphatic Bromide Cluster (HBCD)

Unlike the first six chemicals you reviewed, these four are not hazardous air pollutants and therefore a main difference between these and the previous six are in the treatment of air pathways (see conceptual models and accompanying text).

The structure of these documents should be familiar, so we are not planning to schedule a phone discussion of them. However, if there are red-flags or show-stoppers, we are happy to set something up, either with you individually or with the entire review group.

We have found your comments on the first six documents to be extremely thoughtful and ultimately very useful to us. However, because of time constraints we have not yet incorporated changes based on your previous comments into the four problem formulations we are sending today. So if you do not see an edit you requested, that does not mean it has not been made. But please feel free to add it again if you wish. However, do not feel you need to, as we are working through all of those changes while you are reviewing these documents.

We ask that you send any comments/edits by COB May 16 to Susanna Blair (blair.susanna@epa.gov) and Cathy Fehrenbacher (Fehrenbacher.cathy@epa.gov).

Thank you so much for helping us develop these documents.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Kevin Wheeler - NOAA Federal [Kevin.Wheeler@noaa.gov]
**Sent**: 3/8/2018 10:01:40 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject**: RE: Here are the NOAA GC/OPR comments on the EPA docket announvement
**Attachments**: EPA Biop Combined Comments from GC, NMFS and Unsec.docx

**Flag**: Flag for follow up

Here you go...

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Thursday, March 8, 2018 3:06 PM
**To:** Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>; Stuart Levenbach <stu.levenbach@noaa.gov>
**Cc:** Christopher D. EOP/CEQ Prandoni <Ex. 6 Personal Privacy (PP)>; Baptist, Erik <Baptist.Erik@epa.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>
**Subject:** RE: Here are the NOAA GC/OPR comments on the EPA docket announvement

Ok.- we have 2 separate sets of comments so it's a bit confusing which you want.
Is there one version which incorporates the other or are they really 2 separate sets of comments?

Thanks,
Nancy

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

---

**From:** Stuart Levenbach - NOAA Federal [mailto:stuart.levenbach@noaa.gov]
**Sent:** Thursday, March 8, 2018 2:54 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Stuart Levenbach <stu.levenbach@noaa.gov>
**Cc:** Christopher D. EOP/CEQ Prandoni <Ex. 6 Personal Privacy (PP)>; Baptist, Erik <Baptist.Erik@epa.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>
**Subject:** RE: Here are the NOAA GC/OPR comments on the EPA docket announvement

Yes, and several of the comments are mine. I thought they were all for style and clarity, but let me know if there is something problematic in there.

Direct Ex. 6

Stu

---

Stuart Levenbach, PhD
Chief of Staff
National Oceanic and Atmospheric Administration
Main: Ex. 6 Personal Privacy (PP)

Stuart.levenbach@noaa.gov

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Thursday, March 08, 2018 2:40 PM
**To:** Stuart Levenbach
**Cc:** Christopher D. EOP/CEQ Prandoni; Baptist, Erik
**Subject:** Fwd: Here are the NOAA GC/OPR comments on the EPA docket announvement

Stu,
Has NMFS/NOAA leadership signed off on these?
Thanks,
Nancy


Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov


Begin forwarded message:

> **From:** "Keigwin, Richard" <Keigwin.Richard@epa.gov>
> **Date:** March 8, 2018 at 2:34:39 PM EST
> **To:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Cc:** "Bertrand, Charlotte" <Bertrand.Charlotte@epa.gov>, "Keller, Kaitlin" <keller.kaitlin@epa.gov>, "Echeverria, Marietta" <Echeverria.Marietta@epa.gov>, "Guilaran, Yu-Ting" <Guilaran.Yu-Ting@epa.gov>
> **Subject: FW: Here are the NOAA GC/OPR comments on the EPA docket announvement**
>
> We just received these comments from NOAA/NMFS. Please advise regarding how you would like us to proceed.
>
> **From:** Cathy Tortorici - NOAA Federal [mailto:cathy.tortorici@noaa.gov]
> **Sent:** Thursday, March 08, 2018 2:33 PM
> **To:** Keigwin, Richard <Keigwin.Richard@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
> **Subject:** Here are the NOAA GC/OPR comments on the EPA docket announvement
>
> Dear all -
>
> Our people at NOAA did not realize that they were supposed to send these to you. So my front office asked me to send these comments to you all. These are comments from my Office of Protected Resources and NOAA General Counsel. as well as comments coming from NOAA.
>
> If you can please forward these comments to Nancy Beck I would appreciate it since you said she was leading this document review process.
>
> I would be happy to talk to whomever you want at EPA about these comments.
>
> Thanks so much -
>
> Cathy T.

--

Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
Ex. 6
cathy.tortorici@noaa.gov

Message

**From**: Kevin Wheeler - NOAA Federal [Kevin.Wheeler@noaa.gov]
**Sent**: 3/8/2018 9:04:13 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**CC**: Stuart Levenbach - NOAA Federal [Stuart.Levenbach@noaa.gov]
**Subject**: RE: Here are the NOAA GC/OPR comments on the EPA docket announvement

Nancy,

I will consolidate the comments and get you a final document today.

Kevin

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Thursday, March 8, 2018 3:06 PM
**To:** Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>; Stuart Levenbach <stu.levenbach@noaa.gov>
**Cc:** Christopher D. EOP/CEQ Prandoni <Ex. 6 Personal Privacy (PP)>; Baptist, Erik <Baptist.Erik@epa.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>
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Is there one version which incorporates the other or are they really 2 separate sets of comments?

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Nancy

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Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

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**Sent:** Thursday, March 8, 2018 2:54 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Stuart Levenbach <stu.levenbach@noaa.gov>
**Cc:** Christopher D. EOP/CEQ Prandoni <Ex. 6 Personal Privacy (PP)>; Baptist, Erik <Baptist.Erik@epa.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>
**Subject:** RE: Here are the NOAA GC/OPR comments on the EPA docket announvement

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Direct: Ex. 6 Personal Privacy (PP)

Stu

---

Stuart Levenbach, PhD

Chief of Staff
National Oceanic and Atmospheric Administration
Main: (Ex. 6 Personal Privacy (PP))
Stuart.levenbach@noaa.gov

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Thursday, March 08, 2018 2:40 PM
**To:** Stuart Levenbach
**Cc:** Christopher D. EOP/CEQ Prandoni; Baptist, Erik
**Subject:** Fwd: Here are the NOAA GC/OPR comments on the EPA docket announvement

Stu,
Has NMFS/NOAA leadership signed off on these?
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Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: (Ex. 6 Personal Privacy (PP))
Beck.Nancy@epa.gov

Begin forwarded message:

> **From:** "Keigwin, Richard" <Keigwin.Richard@epa.gov>
> **Date:** March 8, 2018 at 2:34:39 PM EST
> **To:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Cc:** "Bertrand, Charlotte" <Bertrand.Charlotte@epa.gov>, "Keller, Kaitlin" <keller.kaitlin@epa.gov>, "Echeverria, Marietta" <Echeverria.Marietta@epa.gov>, "Guilaran, Yu-Ting" <Guilaran.Yu-Ting@epa.gov>
> **Subject: FW: Here are the NOAA GC/OPR comments on the EPA docket announvement**
>
> We just received these comments from NOAA/NMFS. Please advise regarding how you would like us to proceed.
>
> **From:** Cathy Tortorici - NOAA Federal [mailto:cathy.tortorici@noaa.gov]
> **Sent:** Thursday, March 08, 2018 2:33 PM
> **To:** Keigwin, Richard <Keigwin.Richard@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
> **Subject:** Here are the NOAA GC/OPR comments on the EPA docket announvement
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> Our people at NOAA did not realize that they were supposed to send these to you. So my front office asked me to send these comments to you all. These are comments from my Office of Protected Resources and NOAA General Counsel. as well as comments coming from NOAA.
>
> If you can please forward these comments to Nancy Beck I would appreciate it since you said she was leading this document review process.
>
> I would be happy to talk to whomever you want at EPA about these comments.

Thanks so much -

Cathy T.

--

Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
Ex. 6
cathy.tortorici@noaa.gov

Message

**From:** Todd Willens [todd_willens@ios.doi.gov]
**Sent:** 3/8/2018 4:54:44 PM
**To:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**CC:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Subject:** Re: Notice of public comment for NMFS BiOps

**Flag:** Flag for follow up

10-4

Todd Willens
Assistant Deputy Secretary
U.S. Department of the Interior
1849 C Street, NW - MIB Room 6116
Washington, DC 20240

On Mar 8, 2018, at 11:16 AM, Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)> wrote:

**Deliberative Process / Ex. 5**

Chris

**From:** Todd Willens [mailto:todd_willens@ios.doi.gov]
**Sent:** Tuesday, March 6, 2018 6:40 PM
**To:** beck.nancy@epa.gov
**Cc:** Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)
**Subject:** Fwd: Notice of public comment for NMFS BiOps

Nancy, please see suggested edits attached.

Todd Willens
Assistant Deputy Secretary
U.S. Department of the Interior

1849 C Street, NW - MIB Room 6116
Washington, DC 20240

---------- Forwarded message ----------
From: **Prandoni, Christopher D. EOP/CEQ**
<Ex. 6 Personal Privacy (PP)>
Date: Fri, Mar 2, 2018 at 5:20 PM
Subject: Notice of public comment for NMFS BiOps
To: "EComstock@doc.gov" <EComstock@doc.gov>, "stu.levenbach@noaa.gov" <stu.levenbach@noaa.gov>, "Moran, John S. EOP/WHO" <Ex. 6 Personal Privacy (PP)>, "Stephen.Vaden@ogc.usda.gov" <Stephen.Vaden@ogc.usda.gov>, "todd_willens@ios.doi.gov" <todd_willens@ios.doi.gov>, "Ex. 6 Personal Privacy (PP)" Ex. 6 Personal Privacy (PP), "Domesle, Alexander R. EOP/CEQ" Ex. 6 Personal Privacy (PP)
Cc: "Beck.Nancy@epa.gov" <Beck.Nancy@epa.gov>, "baptist.erik@epa.gov" <baptist.erik@epa.gov>

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

> **From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Date:** March 2, 2018 at 4:57:45 PM EST
> **To:** "Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP)" Ex. 6 Personal Privacy (PP)
> **Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
> **Subject: Notice of public comment period**
>
> Chris,
>
> Attached is the language for our draft FR notice asking for public comments on the BiOps.
>
> Can you please share with the working group—I don't seem to have a good email list of everyone.
>
> Its fine if you want to have them send any comments/suggestions directly to me.
>
> Of course a quick turnaround is appreciated.

Many thanks,
Nancy

**********
********

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

<Note to Reader for NMFS 2017 BiOp.2.28.18 FWS comments_AD comments_CP_AD....docx>

Message

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Sent:** 3/8/2018 4:16:22 PM
**To:** Todd Willens [todd_willens@ios.doi.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**CC:** Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Subject:** RE: Notice of public comment for NMFS BiOps
**Attachments:** Note to Reader for NMFS 2017 BiOp.2.28.18 FWS comments_AD comments_CP_AD....docx

# Deliberative Process / Ex. 5

Chris

**From:** Todd Willens [mailto:todd_willens@ios.doi.gov]
**Sent:** Tuesday, March 6, 2018 6:40 PM
**To:** beck.nancy@epa.gov
**Cc:** Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)
**Subject:** Fwd: Notice of public comment for NMFS BiOps

Nancy, please see suggested edits attached.

Todd Willens
Assistant Deputy Secretary
U.S. Department of the Interior
1849 C Street, NW - MIB Room 6116
Washington, DC 20240

---------- Forwarded message ----------
From: **Prandoni, Christopher D. EOP/CEQ** Ex. 6 Personal Privacy (PP)
Date: Fri, Mar 2, 2018 at 5:20 PM
Subject: Notice of public comment for NMFS BiOps
To: "EComstock@doc.gov" <EComstock@doc.gov>, "stu.levenbach@noaa.gov" <stu.levenbach@noaa.gov>, "Moran, John S. EOP/WHO" Ex. 6 Personal Privacy (PP) y>, "Stephen.Vaden@ogc.usda.gov" <Stephen.Vaden@ogc.usda.gov>, "todd_willens@ios.doi.gov" <todd_willens@ios.doi.gov>, Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP), "Domesle, Alexander R. EOP/CEQ"

Ex. 6 Personal Privacy (PP)
Cc: "Beck.Nancy@epa.gov" <Beck.Nancy@epa.gov>, "baptist.erik@epa.gov" <baptist.erik@epa.gov>

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

> **From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Date:** March 2, 2018 at 4:57:45 PM EST
> **To:** "Prandoni, Christopher D. EOP/CEQ
> Ex. 6 Personal Privacy (PP)"
> Ex. 6 Personal Privacy (PP)>
> **Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
> **Subject: Notice of public comment period**
>
> Chris,
>
> Attached is the language for our draft FR notice asking for public comments on the BiOps.
>
> Can you please share with the working group—I don't seem to have a good email list of everyone.
>
> Its fine if you want to have them send any comments/suggestions directly to me.
>
> Of course a quick turnaround is appreciated.
>
> Many thanks,
> Nancy
>
> **********
>
> Nancy B. Beck, Ph.D., DABT
>
> Deputy Assistant Administrator
>
> Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: 2 Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

Message

**From:** Holman, Amy E [HolmanAE@state.gov]
**Sent:** 5/16/2018 9:07:14 PM
**To:** Brady, Lillie J. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Dunn, Patrick M [DunnPM@state.gov]; Starling, Ray A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Blase, Brian C. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Epstein, Gerald L. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Santerre, Charlie R. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Cunliffe, Laura M. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Callahan, Julie E. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Bomer Lauritsen, Sharon E. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Dougherty, Emily I. EOP/USTR [Ex. 6 Personal Privacy (PP)]; Doty, George E. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Willems, Clete R. EOP/NSC [Ex. 6 Personal Privacy (PP)] Lorenz, Andrew R. EOP/NSC [Ex. 6 Personal Privacy (PP)] Mamacos, Peter D. EOP/NSC [Ex. 6 Personal Privacy (PP)] Borio, Luciana L. EOP/NSC [Ex. 6 Personal Privacy (PP)]; Adjemian, Michael K. EOP/CEA [Ex. 6 Personal Privacy (PP)] Davis, May M. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Pinkos, Stephen M. EOP/OVP [Ex. 6 Personal Privacy (PP)]; Butterfield, Nicholas W. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Keller, Catherine B. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Oister, William III CIV USSS [William.Oister@usss.dhs.gov]; Kratsios, Michael J. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Ritu.Nalubola@fda.hhs.gov; Stephen.Ostroff@fda.hhs.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; dudley.hoskins@osec.usda.gov; rebeckah.adcock@osec.usda.gov; brian.klippenstein@osec.usda.gov; Policy Coordinator [Ex. 6 Personal Privacy (PP)]; Singh, Manisha [SinghM9@state.gov]; Haas, Peter D [HaasPD@state.gov]; Campau, Anthony P. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Talento, Kathryn F. EOP/WHO [Ex. 6] Ziemer, Robert T. EOP/NSC [Ex. 6 Personal Privacy (PP)]; Aguilar, Brenda L. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC:** Mendelsohn, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=720b16e1b31742738a728d8d2814beef-Mendelsohn, Mike]; Gross, Mackenzie A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Klein, Ethan A. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Sutton, Abe J. EOP/WHO [Ex. 6 Personal Privacy (PP)] Bonvillian, Marcus D. EOP/WHO [Ex. 6] Doherty, Julia M. EOP/USTR [Ex. 6 Personal Privacy (PP)]
**Subject:** RE: Biotechnology PCC

Thanks, Brian. [Deliberative Process / Ex. 5] Amy

-----Original Appointment-----
**From:** McFeeters, Brian D **On Behalf Of** Brady, Lillie J. EOP/WHO
**Sent:** Wednesday, May 16, 2018 5:04 PM
**To:** Dunn, Patrick M; Holman, Amy E
**Subject:** FW: Biotechnology PCC
**When:** Friday, May 18, 2018 11:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** EEOB 210/212

[Deliberative Process / Ex. 5]?

Brian

-----Original Appointment-----
**From:** Brady, Lillie J. EOP/WHO <[Ex. 6]>
**Sent:** Wednesday, May 16, 2018 4:24 PM
**To:** Brady, Lillie J. EOP/WHO; Starling, Ray A. EOP/WHO; Blase, Brian C. EOP/WHO; Epstein, Gerald L. EOP/OSTP; Santerre, Charlie R. EOP/OSTP; Cunliffe, Laura M. EOP/WHO; Callahan, Julie E. EOP/USTR; Bomer Lauritsen, Sharon E. EOP/USTR; Dougherty, Emily I. EOP/USTR; Doty, George E. EOP/WHO; Willems, Clete R. EOP/NSC; Lorenz, Andrew R. EOP/NSC; Mamacos, Peter D. EOP/NSC; Borio, Luciana L. EOP/NSC; Adjemian, Michael K. EOP/CEA; Davis, May M. EOP/WHO; Pinkos, Stephen M. EOP/OVP; Butterfield, Nicholas W. EOP/WHO; Keller, Catherine B. EOP/WHO; Oister,

William III CIV USSS; Kratsios, Michael J. EOP/OSTP; Ritu.Nalubola@fda.hhs.gov; Stephen.Ostroff@fda.hhs.gov; Beck.Nancy@epa.gov; dudley.hoskins@osec.usda.gov; rebeckah.adcock@osec.usda.gov; brian.klippenstein@osec.usda.gov; Policy Coordinator; Singh, Manisha; Haas, Peter D; Dunn, Patrick M; Campau, Anthony P. EOP/OMB; Talento, Kathryn F. EOP/WHO; Ziemer, Robert T. EOP/NSC; Aguilar, Brenda L. EOP/OMB; Laity, Jim A. EOP/OMB
**Cc:** Mendelsohn, Mike; Gross, Mackenzie A. EOP/WHO; Abram, Anna; Klein, Ethan A. EOP/OSTP; Sutton, Abe J. EOP/WHO; Bonvillian, Marcus D. EOP/WHO; Doherty, Julia M. EOP/USTR
**Subject:** Biotechnology PCC
**When:** Friday, May 18, 2018 11:30 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** EEOB 210/212

All,

This will be the first meeting of the Biotechnology PCC following the release of the Interagency Task Force on Agriculture and Rural Prosperity's report to the President. This PCC will discuss a set of interagency actions to improve the navigability of the biotechnology regulatory system by small and mid-sized innovators and to expedite the commercialization of biotechnology products.

The read-ahead is attached.

ROOM ASSISGNMENT: EEOB 210/212

SECURITY LINK **Ex. 6**

**Invitees:**

NEC (Ray Starling; Brian Blase)
OSTP (Jerry Epstein; Charlie Santerre)
DPC (Laura Cunliffe; Katy Telento)
USTR ( Julie Callahan; Sharon Bomer; Julie Daugherty)
WHCO (Jed Doty)
INTECON (Clete Willems; Andrew Lorenz)
NSC (Peter Mamacos; Tim Ziemer; Luciana Borio)
USDA (Dudley Hoskins; Rebekah Adcock; Brian Klippenstein)
CEA (Mike Adjemian)
DCOS (May Davis)
OVP (Stephen Pinkos)
FDA (Anna Abram; Ritu Nalubola; Stephen Ostroff)
Staff Sec (Nick Butterfield; Catherine Keller)
EPA (Nancy Beck)
OIRA (Anthony Campau)
State (Peter Haas; Patrick Dunn; Manisha Singh)

**Official**
UNCLASSIFIED

Message

**From:** Todd Willens [todd_willens@ios.doi.gov]
**Sent:** 3/6/2018 11:39:44 PM
**To:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**CC:** Christopher Prandoni Ex. 6 Personal Privacy (PP)
**Subject:** Fwd: Notice of public comment for NMFS BiOps
**Attachments:** ATT00001.htm; Note to Reader for NMFS 2017 BiOp.2.28.18 FWS comments.docx

Nancy, please see suggested edits attached.

Todd Willens
Assistant Deputy Secretary
U.S. Department of the Interior
1849 C Street, NW - MIB Room 6116
Washington, DC 20240

---------- Forwarded message ----------
From: **Prandoni, Christopher D. EOP/CEQ** < Ex. 6 Personal Privacy (PP) >
Date: Fri, Mar 2, 2018 at 5:20 PM
Subject: Notice of public comment for NMFS BiOps
To: "EComstock@doc.gov" <EComstock@doc.gov>, "stu.levenbach@noaa.gov" <stu.levenbach@noaa.gov>, "Moran, John S. EOP/WHO" < Ex. 6 Personal Privacy (PP) >, "Stephen.Vaden@ogc.usda.gov" <Stephen.Vaden@ogc.usda.gov>, "todd_willens@ios.doi.gov" <todd_willens@ios.doi.gov>, " Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP) >, "Domesle, Alexander R. EOP/CEQ" < Ex. 6 Personal Privacy (PP) >
Cc: "Beck.Nancy@epa.gov" <Beck.Nancy@epa.gov>, "baptist.erik@epa.gov" <baptist.erik@epa.gov>

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** March 2, 2018 at 4:57:45 PM EST
**To:** "Prandoni, Christopher D. EOP/CEQ
( Ex. 6 Personal Privacy (PP)
Ex. 6 Personal Privacy (PP)
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
**Subject: Notice of public comment period**

Chris,

Attached is the language for our draft FR notice asking for public comments on the BiOps.

Can you please share with the working group—I don't seem to have a good email list of everyone.

Its fine if you want to have them send any comments/suggestions directly to me.

Of course a quick turnaround is appreciated.

Many thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

Message

**From**: Prandoni, Christopher D. EOP/CEQ [C Ex. 6 Personal Privacy (PP)
**Sent**: 2/20/2018 5:02:53 PM
**To**: Moran, John S. EOP/WHO [ Ex. 6 Personal Privacy (PP) ]; Daniel Jorjani [daniel.jorjani@sol.doi.gov]
**CC**: Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; richard.goeken@sol.doi.gov; PDavidson@doc.gov; kristen.l.gustafson@noaa.gov; Corinne.Snow@usdoj.gov; Jean.Williams@usdoj.gov; Stephen.Vaden@ogc.usda.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]; todd_willens@ios.doi.gov; EComstock@doc.gov; Peg Romanik [peg.romanik@sol.doi.gov]
**Subject**: RE: ESA-FIFRA MOA Action Plan

New proposed time: **Thursday 2/22 at 11am.**

If this time does not work, please send me windows when you are available Thursday.

Chris

---

**From:** Moran, John S. EOP/WHO
**Sent:** Tuesday, February 20, 2018 11:51 AM
**To:** Daniel Jorjani <daniel.jorjani@sol.doi.gov>; Prandoni, Christopher D. EOP/CEQ
<Ex. 6 Personal Privacy (PP)
**Cc:** Leopold.Matt@epa.gov; baptist.erik@epa.gov; richard.goeken@sol.doi.gov; PDavidson@doc.gov; kristen.l.gustafson@noaa.gov; Corinne.Snow@usdoj.gov; Jean.Williams@usdoj.gov; Stephen.Vaden@ogc.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>; todd_willens@ios.doi.gov; EComstock@doc.gov; Peg Romanik <peg.romanik@sol.doi.gov>
**Subject:** RE: ESA-FIFRA MOA Action Plan

# Deliberative Process / Ex. 5

Regards,

John S. Moran
Associate Counsel to the President
Ex. 6 Personal Privacy (PP) (w)
Ex. 6 Personal Privacy (PP) (c)

---

**From:** Daniel Jorjani [mailto:daniel.jorjani@sol.doi.gov]
**Sent:** Tuesday, February 20, 2018 11:42 AM
**To:** Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)>
**Cc:** Leopold.Matt@epa.gov; baptist.erik@epa.gov; richard.goeken@sol.doi.gov; PDavidson@doc.gov; kristen.l.gustafson@noaa.gov; Corinne.Snow@usdoj.gov; Jean.Williams@usdoj.gov; Stephen.Vaden@ogc.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>; todd_willens@ios.doi.gov; EComstock@doc.gov; Moran, John S. EOP/WHO Ex. 6 Peg

Romanik <peg.romanik@sol.doi.gov>
**Subject:** Re: ESA-FIFRA MOA Action Plan

Adding Peg Romanik

Sent from my iPhone

On Feb 20, 2018, at 11:39 AM, Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP) wrote:

Colleagues,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5. I propose we meet this **Thursday (2/22) at 3:00. CEQ is happy to host in 730 Jackson Place.**

Please let me know if that time does not work for you or if you think someone else from your agency should also attend.

Thank you very much and hopefully we can make this work.
Chris

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

Message

**From**: Schwab, Margo EOP/OMB Ex. 6
**Sent**: 4/24/2018 2:09:13 AM
**To**: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]
**CC**: James_H_Kim@ Ex. 6 Personal Privacy (PP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Palmieri, Rosario A. EOP/OMB Ex. 6 Personal Privacy (PP); Laity, Jim A. EOP/OMB Ex. 6 Personal Privacy (PP); Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Szabo, Aaron L. EOP/CEQ Ex. 6 Personal Privacy (PP); Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Bremberg, Andrew P. EOP/WHO Ex. 6 Personal Privacy (PP) Herz, James P. EOP/OMB Ex. 6 Personal Privacy (PP) Brooke, Francis J. EOP/OVP [Ex. 6 Personal Privacy (PP)]; jonathan.brightbill@usdoj.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aefcd454ba3e46cabf84a79129583e64-eric.t.gormsen@usdoj.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Hickey, Mike J. EOP/OMB [Ex. 6 Personal Privacy (PP)] Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject**: RE: EPA NPRM Call Regulatory Science

You can make that change in email address when you submit the final version to ROCIS in the morning.

---

**From:** Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
**Sent:** Monday, April 23, 2018 10:06 PM
**To:** Woods, Clint <woods.clint@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>
**Cc:** Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)>; Kim, Jim H. EOP/OMB Ex. 6 Personal Privacy (PP); Palmieri, Rosario A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Laity, Jim A. EOP/OMB Ex. 6
Bolen, Brittany <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Bremberg, Andrew P. EOP/WHO <Ex. 6 Personal Privacy (PP)
Herz, James P. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)>; jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ Ex. 6 Personal Privacy (PP)
Hickey, Mike J. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Leopold, Matt <Leopold.Matt@epa.gov>
**Subject:** Re: EPA NPRM Call Regulatory Science

I believe Tom Sinks email should be:

staff_osa@epa.gov

Could someone make that quick change? Thanks much

Sent from my iPhone

On Apr 23, 2018, at 9:58 PM, Woods, Clint <woods.clint@epa.gov> wrote:

Should be attached - Thanks!

<EPA Response to OIRA- Data Access Draft 4-23-18_ OMB response final 9.45.docx>

On Apr 23, 2018, at 9:06 PM, Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)> wrote:

Will you be able to send a final version tonight?

Sent from my iPhone

On Apr 23, 2018, at 9:00 PM, Woods, Clint <woods.clint@epa.gov> wrote:

Deliberative Process / Ex. 5

On Apr 23, 2018, at 8:28 PM, Schwab, Margo EOP/OMB
Ex. 6 Personal Privacy (PP)> wrote:

Deliberative Process / Ex. 5

**From:** Woods, Clint <woods.clint@epa.gov>
**Sent:** Monday, April 23, 2018 5:45 PM
**To:** Kim, Jim H. EOP/OMB
Ex. 6 Personal Privacy (PP); Palmieri, Rosario A. EOP/OMB Ex. 6 Personal Privacy (PP); Laity, Jim A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Bolen, Brittany <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)> Bremberg, Andrew P. EOP/WHO
Ex. 6 Personal Privacy (PP); Herz, James P. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)>; jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)>; Schwab, Justin <Schwab.Justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Hickey, Mike J. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Leopold, Matt <Leopold.Matt@epa.gov>
**Subject:** RE: EPA NPRM Call Regulatory Science

All,

Thanks again for your time and attention on this matter. Attached are responses to OIRA's suggested revisions. Other than a few minor additions and edits, we are comfortable with the revisions including the updated language for § 124.219.

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

**From:** Kim, Jim H. EOP/OMB
Ex. 6 Personal Privacy (PP)
**Sent:** Monday, April 23, 2018 2:16 PM
**To:** Palmieri, Rosario A. EOP/OMB
Ex. 6 Personal Privacy (PP); Laity, Jim A. EOP/OMB
Ex. 6 Personal Privacy (PP); Bolen, Brittany <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Bremberg, Andrew P. EOP/WHO

Ex. 6 Personal Privacy (PP)>; Herz, James P. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)> jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)>; Schwab, Justin <Schwab.Justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Woods, Clint <woods.clint@epa.gov>; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Hickey, Mike J. EOP/OMB <Ex. 6 Personal Privacy (PP)>
**Subject:** RE: EPA NPRM Call Regulatory Science

Dear Interagency Reviewers:

Here are OIRA's suggested revisions consistent with the discussion on this morning's call. Deliberative Process / Ex. 5

**Deliberative Process / Ex. 5**

Jim

---

**From:** Kim, Jim H. EOP/OMB
**Sent:** Monday, April 23, 2018 10:59 AM
**To:** Palmieri, Rosario A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Laity, Jim A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; 'Bolen, Brittany' <bolen.brittany@epa.gov>; Szabo, Aaron L. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Bremberg, Andrew P. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Herz, James P. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)>; jonathan.brightbill@usdoj.gov; Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB <Ex. 6 Personal Privacy (PP)>; 'schwab.justin@epa.gov' <schwab.justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; woods.clint@epa.gov; David.Gualtieri@usdoj.gov; Eric.T.Gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)>
**Subject:** RE: EPA NPRM Call Regulatory Science

Hi all,

Please find attached some additional edits for discussion at 11AM.

Thanks,
Jim

-----Original Appointment-----
**From:** Palmieri, Rosario A. EOP/OMB
**Sent:** Monday, April 23, 2018 8:58 AM
**To:** Palmieri, Rosario A. EOP/OMB; Laity, Jim A. EOP/OMB; 'Bolen, Brittany'; Szabo, Aaron L. EOP/CEQ; Moran, John S. EOP/WHO; Bremberg, Andrew P. EOP/WHO; Herz, James P. EOP/OMB; Brooke, Francis J. EOP/OVP; jonathan.brightbill@usdoj.gov; Beck, Nancy; Schwab, Margo EOP/OMB; 'schwab.justin@epa.gov'; Kim, Jim H. EOP/OMB; Yamada, Richard (Yujiro); woods.clint@epa.gov; David.Gualtieri@usdoj.gov; Eric.T.Gormsen@usdoj.gov; Neumayr, Mary B. EOP/CEQ
**Subject:** EPA NPRM Call Regulatory Science
**When:** Monday, April 23, 2018 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where** Ex. 6

<EPA Response to OIRA- Data Access Draft 4-23-18_ OMB response.docx>

Message

**From**: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
**Sent**: 4/24/2018 1:58:10 AM
**To**: Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC**: James_H_Kim [Ex. 6 Personal Privacy (PP)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Palmieri, Rosario A. EOP/OMB [Ex. 6 Personal Privacy (PP)] Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Bremberg, Andrew P. EOP/WHO [Andrew.P.Bremberg@[Ex. 6 Personal Privacy (PP)]; Herz, James P. EOP/OMB [James.P.Herz@[Ex. 6 Personal Privacy (PP)]; Brooke, Francis J. EOP/OVP [Ex. 6 Personal Privacy (PP)]; jonathan.brightbill@usdoj.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; David.Gualtieri@usdoj.gov; eric.t.gormsen@usdoj.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aefcd454ba3e46cabf84a79129583e64-eric.t.gormsen@usdoj.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Hickey, Mike J. EOP/OMB [Ex. 6 Personal Privacy (PP)] Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject**: Re: EPA NPRM Call Regulatory Science
**Attachments**: EPA Response to OIRA- Data Access Draft 4-23-18_ OMB response final 9.45.docx; ATT00001.htm

**Flag**: Flag for follow up

Should be attached - Thanks!

Message

**From**: Domesle, Alexander R. EOP/CEQ [Ex. 6]
**Sent**: 8/6/2018 9:15:38 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bernhardt, David [dwbernhardt@ios.doi.gov]; todd_willens@ios.doi.gov; EComstock@doc.gov; Uthmeier, James (Federal) [James.Uthmeier@doc.gov]; stuart.levenbach@noaa.gov; Stephen.Vaden@ogc.usda.gov; Herz, James P. EOP/OMB [Ex. 6]; Emma_K_Roach@[Ex. 6][/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=459adeb9f2894e7784b9b3407687c21c-Emma_K_Roach[Ex. 6]]; Moran, John S. EOP/WHO [Ex. 6]; Brooke, Francis J. EOP/WHO [Ex. 6]
**CC**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; gareth_rees@ios.doi.gov; Teague, Anne (Federal) [ATeague@doc.gov]; linda.lawhornbrown@noaa.gov; Dankert, Charles M. EOP/OMB [Ex. 6]
**Subject**: Next ESA WG call

Dear ESA Pesticide Working Group members,

CEQ is looking to schedule the next meeting of the ESA Pesticide WG for next week. The proposed format is a 30-minute teleconference, similar to the call in late June. **Please share your availability for Wednesday, August 15, and Thursday, August 16 with me.** We will try to accommodate everyone, but at a minimum we will ensure high-level representation from each of the agencies.

Once again, **we encourage the signatory agencies – EPA, DOI, DOC – and USDA to obtain a progress update from their staffs in advance of this meeting.** This will allow us to compare notes and identify any challenges that might be addressed by the Working Group. If you have any additional agenda items you would like to add to the draft agenda below, please provide these to me by early next week.

Thank you!

DRAFT AGENDA

**Deliberative Process / Ex. 5**

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
**Ex. 6**
www.whitehouse.gov/ceq

Message

**From**: Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]
**Sent**: 3/19/2018 10:42:15 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject**: RE: as discussed

I have forwarded and requested an internal meeting. Will keep you updated but feel free to check back towards the end of next week.

Stu

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Monday, March 19, 2018 5:59 PM
**To:** Stuart Levenbach - NOAA Federal
**Subject:** FW: as discussed

2nd time a charm!

---

**From:** Beck, Nancy
**Sent:** Monday, March 19, 2018 5:58 PM
**To:** 'Levenbach, Stuart . EOP/OMB' < Ex. 6 Personal Privacy (PP)
**Subject:** as discussed

Stu,
See attached. Happy to discuss.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

Message

**From**: Vaden, Stephen - OGC [Stephen.Vaden@ogc.usda.gov]
**Sent**: 3/5/2018 8:25:34 PM
**To**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**Subject**: RE: Notice of public comment for NMFS BiOps
**Attachments**: Federal Register Notice ESA BiOps with OGC and OPMP edits.docx

All,

USDA's comments are attached.

Stephen

---

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Sent:** Friday, March 02, 2018 5:21 PM
**To:** EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Vaden, Stephen - OGC <Stephen.Vaden@ogc.usda.gov>; todd_willens@ios.doi.gov; [Ex. 6 Personal Privacy (PP)] Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Cc:** Beck.Nancy@epa.gov; baptist.erik@epa.gov
**Subject:** Notice of public comment for NMFS BiOps

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

> **From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Date:** March 2, 2018 at 4:57:45 PM EST
> **To:** "Prandoni, Christopher D. EOP/CEQ ([Ex. 6 Personal Privacy (PP)]" [Ex. 6 Personal Privacy (PP)]
> **Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
> **Subject: Notice of public comment period**
>
> Chris,
> Attached is the language for our draft FR notice asking for public comments on the BiOps.
> Can you please share with the working group—I don't seem to have a good email list of everyone.
> Its fine if you want to have them send any comments/suggestions directly to me.
> Of course a quick turnaround is appreciated.

Many thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

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Message

**From**: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]
**Sent**: 3/5/2018 7:50:55 PM
**To**: EComstock@doc.gov
**CC**: Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Subject**: ESA; Examples of NMFS Recognizing Implementation Timelines for RPMs

Earl,

It was nice to meet you a few weeks ago [Deliberative Process / Ex. 5]

Deliberative Process / Ex. 5

Please let me know if you have any questions or need additional information on EPA's past ESA consultations with NMFS.

Best,

**Erik Baptist**
Senior Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsyvlania Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

Message

**From**: Blair, Susanna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6C869B985F3D43DB982C18AAABD826BD-BLAIR, SUSA]
**Sent**: 4/18/2018 4:45:06 PM
**To**: patricia.m.underwood.civ@mail.mil; maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; karen.e.colmie.civ@mail.mil; Anita.K.Meyer@usace.army.mil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebb41195f2324548959139e28c25b8a6-Anita.K.Meyer@usace.army.mil]; resha.m.putzrath.civ@mail.mil; Michael_Hickey@[redacted]; James_A._Laity@[redacted]v; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Paul_A_Winters@[redacted] Danielle_Y_Jones@[redacted] Margo_Schwab@[redacted] Szabo, Aaron L. EOP/CEQ [redacted]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; schaeffer.val@dol.gov; Charles.Maresca@sba.gov; birnbaumls@niehs.nih.gov; brian.berridge@nih.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Middendorf, Paul (CDC/NIOSH/OD [pkm2@cdc.gov]; Strickland, Maria (CDC/NIOSH/OD [kvl9@cdc.gov]; Piacentino, John D. (CDC/NIOSH/OD [gjt4@cdc.gov]; Keenan, Amanda K. (CDC/NIOSH/EID [yls5@cdc.gov]; Schulte, Paul A. (CDC/NIOSH/EID [pas4@cdc.gov]
**CC**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]
**Subject**: EPA/OPPT Briefing on six draft Problem Formulations

Hello everyone,

This is a reminder that the briefing on the 6 draft problem formulations is tomorrow at noon.

As we prepare for this meeting, it would be helpful to hear if there are any topics that you want to be sure we discuss tomorrow. We would like to be able to tee these up for the topic leads. If you could send any topics/questions/comments by **COB today**, that would be extremely helpful. We recognize the short notice, and thank you again for your feedback on these documents.

Best,
Susanna

**Susanna W. Blair, PhD**
Special Assistant
Office of Pollution Prevention and Toxics
William Jefferson Clinton Building - East, MC7401M
Washington DC 20460
202.564.4371 (office) | [redacted] (cell) | Blair.susanna@epa.gov

Message

**From**: Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]
**Sent**: 1/30/2018 11:06:08 PM
**To**: Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]
**CC**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]
**Subject**: Re: Call-in Number

We had a call with just the lawyers, which just ended. James Uthmeier and Kirstin Gustafson were on. We think we have a good path forward here. I think James will follow up with you guys so that you can either give EPA a green-light or propose any tweaks you think are needed.

John

John S. Moran
Associate Counsel to the President
[Ex. 6 Personal Privacy (PP)] (w)
(c)

On Jan 30, 2018, at 5:31 PM, Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov> wrote:

> Is there a call on the language in the re-initiation letter? I have not seen the call-in information.

Message

**From**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]
**Sent**: 2/2/2018 4:10:05 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
**Subject**: Re: draft letter

I can do 2 to 2:30. Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Friday, February 2, 2018 at 10:58 AM
**To:** "Prandoni, Christopher D. EOP/CEQ" <Ex. 6 Personal Privacy (PP)>, "Comstock, Earl (Federal)" Ex. 6 @doc.gov>, "Moran, John S. EOP/WHO" <Ex. 6 Personal Privacy (PP)>, "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

2-2:30 or after 4:30 are the best windows for me.
Thanks,
Nancy

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

---

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Sent:** Friday, February 2, 2018 10:50 AM
**To:** Comstock, Earl (Federal) <Ex. 6 @doc.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Moran, John S. EOP/WHO Ex. 6 Personal Privacy (PP); Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

Hey gang,

**Deliberative Process / Ex. 5**

Chris

---

**From:** Comstock, Earl (Federal) [mailto:Ex. 6 @doc.gov]
**Sent:** Thursday, February 1, 2018 6:14 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)

Moran, John S. EOP/WHO [redacted] Ex. 6 Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Thanks Nancy. [redacted] Deliberative Process / Ex. 5

[redacted] Deliberative Process / Ex. 5

Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ ([redacted] Ex. 6 Personal Privacy (PP) )" [redacted] Ex. 6 Personal Privacy (PP) >, "Moran, John S. EOP/WHO" <[redacted] Ex. 6 Personal Privacy (PP) >, "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>, "Comstock, Earl (Federal)" [redacted] Ex. 6 @doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: [redacted] Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

Message

**From**: Madans, Jennifer H. (CDC/OPHSS/NCHS) [jhm4@cdc.gov]
**Sent**: 7/20/2018 8:15:00 PM
**To**: Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Schwab, Margo EOP/OMB [Ex. 6]; Queen, Susan G. (CDC/OPHSS/NCHS) [sgq1@cdc.gov]
**Subject**: RE: Disclosure Review

Thanks Kaitlin, I will be around those days and have set aside the time. 11:30 on the 9th would be better but I can do 11. I am out of the office next week but this gives extra time to touch base before the call.

---

**From:** Keller, Kaitlin <keller.kaitlin@epa.gov>
**Sent:** Friday, July 20, 2018 3:44 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Madans, Jennifer H. (CDC/OPHSS/NCHS) <jhm4@cdc.gov>; Schwab, Margo EOP/OMB [Ex. 6]; Queen, Susan G. (CDC/OPHSS/NCHS) <sgq1@cdc.gov>
**Subject:** RE: Disclosure Review

Hi Jennifer,

I'd be happy to help facilitate intros and/or a pre-brief for you with the team. Unfortunately I learned today that Columbia had a conflict with the 7/30 date so the call is now tentatively scheduled for either 8/7 at 2pm or 8/9 at 11am, but it will be confirmed early next week. Just wanted to first flag that in case the new date/time doesn't work for you.

I'll email you separately with a couple of the team POCs so you can reach out to them directly to coordinate and follow-up as needed.

Thank you,
Kaitlin

Kaitlin Keller, Special Assistant
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
(202) 564-7098

---

**From:** Beck, Nancy
**Sent:** Thursday, July 19, 2018 6:36 PM
**To:** Madans, Jennifer H. (CDC/OPHSS/NCHS) <jhm4@cdc.gov>; Schwab, Margo EOP/OMB [Ex. 6]; Queen, Susan G. (CDC/OPHSS/NCHS) <sgq1@cdc.gov>
**Cc:** Keller, Kaitlin <keller.kaitlin@epa.gov>
**Subject:** RE: Disclosure Review

Jennifer,
Many many thanks. I believe the call with Columbia University is on the 30th at 1pm.
I'm looping in Kaitlin Keller our special assistant for pesticides. She can facilitate introductions with our team and perhaps a pre-call with our science leads if that would be helpful to you.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

**From:** Madans, Jennifer H. (CDC/OPHSS/NCHS) [mailto:jhm4@cdc.gov]
**Sent:** Thursday, July 19, 2018 6:33 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB < Ex. 6 >; Queen, Susan G. (CDC/OPHSS/NCHS) <sgq1@cdc.gov>
**Subject:** RE: Disclosure Review

Hi Nancy, I've spoken to Susan and given our schedules it would be easier for me to be on the call. If an additional call is needed we might involve other staff. Let me know the particulars about the call. I will be out of the office next week but back on the 30th.//Jennifer

**From:** Madans, Jennifer H. (CDC/OPHSS/NCHS)
**Sent:** Wednesday, July 18, 2018 12:26 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Schwab, Margo EOP/OMB < Ex. 6 >; Queen, Susan G. (CDC/OPHSS/NCHS) <sgq1@cdc.gov>
**Subject:** RE: Disclosure Review

Hi Nancy,
Nice to hear from you.
I've been out of the office for two weeks on leave. I'll be in tomorrow and will talk to Susan about this.
We will be back to you as soon as we can.
Jennifer

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Sent:** Tuesday, July 17, 2018 6:13 PM
**To:** "Schwab, Margo EOP/OMB" Ex. 6 "Madans, Jennifer H. (CDC/OPHSS/NCHS)" <jhm4@cdc.gov>,"Queen, Susan G. (CDC/OPHSS/NCHS)" <sgq1@cdc.gov>
**Subject:** RE: Disclosure Review

Thanks for the intro (re-intro) Margo!
Jennifer and Susan-- we are looking for someone that can help us with a call we have on July 30th. We have a paper from a University and we would like to encourage release of the raw data but the University is worried about release. We'd like someone to join the call that can provide them with some suggestions regarding how this can be done. Its an epidemiology paper looking at pesticide exposures and health effects.

Many thanks!
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

-----Original Message-----
From: Schwab, Margo EOP/OMB Ex. 6

Sent: Tuesday, July 17, 2018 5:26 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; jhm4@cdc.gov; sgq1@cdc.gov
Subject: Disclosure Review

Jennifer and Susan- Would NCHS be able to provide EPA with technical assistance in working with a university to deidentify their data or provide a mechanism for access (eg FSRDC). Jennifer, I am pretty sure that you met Nancy when she worked at OMB. I know that NCHS already provided an overview of principles and practices to EPA's office of research and development, but this is a much more focused request. Thanks in advance.

Sent from my iPhone

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent**: 1/30/2018 9:14:36 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**CC**: Comstock, Earl (Federal) [Ex. 6]@doc.gov]; Uthmeier, James (Federal) [JUthmeier@doc.gov]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]; Moran, John S. EOP/WHO [Ex. 6]; Starling, Ray A. EOP/WHO [Ex. 6]; Bernhardt, David [dwbernhardt@ios.doi.gov]
**Subject**: RE: FW: Final MOA
**Attachments**: EPA MOA 01-30-2018 Redline_DOC.DOCX

Attached is a document with Commerce's final edits [Deliberative Process / Ex. 5]
[Deliberative Process / Ex. 5]

DOI and EPA – can you let me know if the attached version allows you to recommend that the Administrator or Secretary sign the attached MOA.

Thank you all!

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Tuesday, January 30, 2018 11:48 AM
**To:** Prandoni, Christopher D. EOP/CEQ <[Ex. 6]; Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Comstock, Earl (Federal) [Ex. 6]@doc.gov>; Uthmeier, James (Federal) <JUthmeier@doc.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>; Moran, John S. EOP/WHO [Ex. 6]>; Starling, Ray A. EOP/WHO [Ex. 6]>; Bernhardt, David <dwbernhardt@ios.doi.gov>
**Subject:** RE: FW: Final MOA

Chris,
EPA supports your responses.

Many thanks,
Nancy

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
[Ex. 6]
beck.nancy@epa.gov

---

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent:** Tuesday, January 30, 2018 11:22 AM
**To:** Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Comstock, Earl (Federal) [Ex. 6]@doc.gov>; Uthmeier, James (Federal) <JUthmeier@doc.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>; Moran, John S. EOP/WHO [Ex. 6]>; Starling, Ray A. EOP/WHO [Ex. 6]; Bernhardt,

David <dwbernhardt@ios.doi.gov>
**Subject:** RE: FW: Final MOA

Thank you, Stu.

All – see my response to DOC's proposed changes. Let me know if you accept them and whether Secretary Ross would be willing to sign today or tomorrow am. Administrator Pruitt is speaking tomorrow at 3pm and we want to get this out the door.

Thank you everyone for trying to get this done.

Chris

**From:** Stuart Levenbach - NOAA Federal [mailto:stuart.levenbach@noaa.gov]
**Sent:** Tuesday, January 30, 2018 6:55 AM
**To:** Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Comstock, Earl (Federal) <[Ex. 6]@doc.gov>; Uthmeier, James (Federal) <JUthmeier@doc.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>; Bernhardt, David <dwbernhardt@ios.doi.gov>
**Subject:** Fwd: FW: Final MOA

All-

NMFS added a comment to the version with comments from NOAA GC. Attached is the consolidated document and DOC/NOAA has no further comments on the MOA.

Stu

Message

**From**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]
**Sent**: 2/1/2018 11:13:34 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ ([Ex. 6] [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6] Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
**Subject**: Re: draft letter
**Attachments**: NMFS_reinitiation_letter2.1.18DRAFT+NOAAGCedits[1].docx

**Flag**: Follow up

Thanks Nancy. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ ([Ex. 6]' [Ex. 6]>, "Moran, John S. EOP/WHO" <[Ex. 6], "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>, "Comstock, Earl (Federal)" <[Ex. 6]@doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent**: 1/30/2018 4:21:54 PM
**To**: Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**CC**: Comstock, Earl (Federal) [Ex. 6]@doc.gov]; Uthmeier, James (Federal) [JUthmeier@doc.gov]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]; Moran, John S. EOP/WHO [Ex. 6]]; Starling, Ray A. EOP/WHO [Ex. 6] Bernhardt, David [dwbernhardt@ios.doi.gov]
**Subject**: RE: FW: Final MOA
**Attachments**: ESA MOA Draft 2018-01-29+NOAA GC edits_NMFS_CEQ.DOCX

Thank you, Stu.

All – see my response to DOC's proposed changes. Let me know if you accept them and whether Secretary Ross would be willing to sign today or tomorrow am. Administrator Pruitt is speaking tomorrow at 3pm and we want to get this out the door.

Thank you everyone for trying to get this done.

Chris

**From:** Stuart Levenbach - NOAA Federal [mailto:stuart.levenbach@noaa.gov]
**Sent:** Tuesday, January 30, 2018 6:55 AM
**To:** Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Comstock, Earl (Federal) [Ex. 6]@doc.gov>; Uthmeier, James (Federal) <JUthmeier@doc.gov>; Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>; Bernhardt, David <dwbernhardt@ios.doi.gov>
**Subject:** Fwd: FW: Final MOA

All-

NMFS added a comment to the version with comments from NOAA GC. Attached is the consolidated document and DOC/NOAA has no further comments on the MOA.

Stu

Message

**From**: Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]
**Sent**: 1/30/2018 11:54:55 AM
**To**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**CC**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]; Uthmeier, James (Federal) [JUthmeier@doc.gov]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]; Bernhardt, David [Ex. 6 Personal Privacy (PP)]
**Subject**: Fwd: FW: Final MOA
**Attachments**: ESA MOA Draft 2018-01-29+NOAA GC edits_NMFS.docx

All-

NMFS added a comment to the version with comments from NOAA GC. Attached is the consolidated document and DOC/NOAA has no further comments on the MOA.

Stu

Message

**From:** Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]
**Sent:** 1/30/2018 1:31:04 AM
**To:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Christopher D. EOP/CEQ Prandoni [{ Ex. 6 Personal Privacy (PP) }; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**CC:** Earl Comstock (Federal)[ Ex. 6 @doc.gov]; James Uthmeier (Federal) [JUthmeier@doc.gov]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]
**Subject:** Fwd: Final MOA
**Attachments:** ATT00001.htm; ESA MOA Draft 2018-01-29+NOAA GC edits.docx

Comments attached from NOAA GC. Possible we get another set from NMFS but COB has passed and sending these in the interest of time.

NOAA and DOC policy has reviewed and had no concerns.

Stu

Sent from my iPhone

Begin forwarded message:

> **From:** Kristen Gustafson - NOAA Federal <kristen.l.gustafson@noaa.gov>
> **Date:** January 29, 2018 at 5:00:41 PM EST
> **To:** Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>
> **Cc:** Chris Oliver - NOAA Federal <chris.w.oliver@noaa.gov>, Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>, Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>, Samuel Rauch - NOAA Federal <samuel.rauch@noaa.gov>, Emma Htun <emma.htun@noaa.gov>
> **Subject: Re: FW: Final MOA**
>
> Hi Stu,
> Attached are NOAA GC's comments on the current draft MOA. If you download the document, you can see comment bubbles explaining why we have flagged these particular areas of concern. The final edit has no corresponding comment bubble, but is intended to make clear that any stakeholder engagement would need to be consistent with the requirements of FACA which, depending on the circumstances, could place certain limitations or conditions.
> Thanks,
> Kristen

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Sent**: 1/29/2018 2:55:01 PM
**To**: Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]; Comstock, Earl (Federal [Ex. 6 @doc.gov]; todd_willens@ios.doi.gov; Bernhardt, David [Ex. 6 Personal Privacy (PP)] Stephen.Vaden@ogc.usda.gov
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Subject**: RE: Draft EPA reinitiation letter

EPA will plan on sending a similar version of this letter today. Contact Nancy or Erik if you would like to see final text. Thank you.

---

**From:** Prandoni, Christopher D. EOP/CEQ
**Sent:** Friday, January 26, 2018 10:37 AM
**To:** Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>; 'Comstock, Earl (Federal' <Ex. 6 @doc.gov>; todd_willens@ios.doi.gov; Bernhardt, David <Ex. 6 Personal Privacy (PP)> Stephen.Vaden@ogc.usda.gov
**Cc:** 'Beck, Nancy' <Beck.Nancy@epa.gov>; 'Baptist, Erik' <Baptist.Erik@epa.gov>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Domesle, Alexander R. EOP/CEQ <Ex. 6 Personal Privacy (PP)>
**Subject:** Draft EPA reinitiation letter

All –

Attached is EPA's letter to reinitiate informal consultation with NMFS on the registration of chlorpyrifos, diazinon and malathion. EPA would like to send this to NMFS today so please let Nancy know, and copy me on the email, if you have any concerns with the proposed letter. I made a few suggestions that are tracked in the document.

Thank you,
Chris

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

Message

**From**: Henry, Tala [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8BFC0A617A4A43BAA8856541C70622BE-THENRY02]
**Sent**: 8/9/2018 8:57:22 PM
**To**: patricia.m.underwood.civ@mail.mil; maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; karen.e.colmie.civ@mail.mil; Anita.K.Meyer@usace.army.mil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebb41195f2324548959139e28c25b8a6-Anita.K.Meyer@usace.army.mil]; resha.m.putzrath.civ@mail.mil; Michael_Hickey[Ex. 6]James_A._Laity@[Ex. 6] Paul_A_Winters[Ex. 6]; Danielle_Y_Jones[Ex. 6] Margo_Schwab[Ex. 6]Szabo, Aaron L. EOP/CEQ [Aaron.L.Szabo@[Ex. 6]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; schaeffer.val@dol.gov; Charles.Maresca@sba.gov; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; birnbaumls@niehs.nih.gov; masten@niehs.nih.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce58615a43ec4347b15792aa8e15f549-masten@niehs.nih.gov]; brian.berridge@nih.gov; MBabich@cpsc.gov; KHatlelid@cpsc.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; Middendorf, Paul (CDC/NIOSH/OD [pkm2@cdc.gov]; Strickland, Maria (CDC/NIOSH/OD [kvl9@cdc.gov]; Piacentino, John D. (CDC/NIOSH/OD [gjt4@cdc.gov]; Keenan, Amanda K. (CDC/NIOSH/EID [yls5@cdc.gov]; Schulte, Paul A. (CDC/NIOSH/EID [pas4@cdc.gov]; KMacMahon@cdc.gov; CWhittaker@cdc.gov
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Hartman, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7eeb1ab7c7a74b40bf9bfded67e7fafd-Mark A Hartman]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]
**Subject**: Request for Priorities for TSCA Risk Evaluations
**Attachments**: prioritization fed partners_8918.pdf; Interagency TSCA 6b1 chemical nomination template.xlsx; tsca_work_plan_chemicals_2014_update-final.pdf

**Flag**: Flag for follow up

Dear Colleagues,
Please find attached, a request for your input on behalf of Jeff Morris, Director of the Office of Pollution Prevention and Toxics.

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent**: 3/2/2018 10:20:36 PM
**To**: EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO [Ex. 6]; Stephen.Vaden@ogc.usda.gov; todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Domesle, Alexander R. EOP/CEQ [Ex. 6]
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**Subject**: Notice of public comment for NMFS BiOps
**Attachments**: Note to Reader for NMFS 2017 BiOp.2.28.18.docx; ATT00001.htm

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

> **From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
> **Date:** March 2, 2018 at 4:57:45 PM EST
> **To:** "Prandoni, Christopher D. EOP/CEQ [Ex. 6]" [Ex. 6]>
> **Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
> **Subject: Notice of public comment period**
>
> Chris,
> Attached is the language for our draft FR notice asking for public comments on the BiOps.
> Can you please share with the working group—I don't seem to have a good email list of everyone.
> Its fine if you want to have them send any comments/suggestions directly to me.
> Of course a quick turnaround is appreciated.
>
> Many thanks,
> Nancy
>
> **********
> Nancy B. Beck, Ph.D., DABT
> Deputy Assistant Administrator
> Office of Chemical Safety and Pollution Prevention
> P: 202-564-1273
> [Ex. 6]
> beck.nancy@epa.gov

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent**: 1/31/2018 9:19:56 PM
**To**: Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Comstock, Earl (Federal) [Ex. 6]@doc.gov]; Todd Willens [todd_willens@ios.doi.gov]; Downey Magallanes [downey_magallanes@ios.doi.gov]; Bernhardt, David [dwbernhardt@ios.doi.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Starling, Ray A. EOP/WHO [Ex. 6]; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6] Domesle, Alexander R. EOP/CEQ [Ex. 6]; Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6]]; Stephen.Vaden@ogc.usda.gov; Herz, James P. EOP/OMB [Ex. 6]
**Subject**: Executed MOA
**Attachments**: Executed ESA-FIFRA MOA 1.31.18.pdf

**Flag**: Flag for follow up

Feel free to distribute. Great work and thank you.

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
[Ex. 6]
www.whitehouse.gov/ceq

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6
**Sent**: 1/26/2018 3:37:12 PM
**To**: Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]; Comstock, Earl (Federal [EComstock@doc.gov]; todd_willens@ios.doi.gov; Bernhardt, David [dwbernhardt@ios.doi.gov]; Stephen.Vaden@ogc.usda.gov
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Moran, John S. EOP/WHO [Ex. 6]; Domesle, Alexander R. EOP/CEQ [Ex. 6]
**Subject**: Draft EPA reinitiation letter
**Attachments**: NMFS_reinitiation_letter1.25.18DRAFT-CP.DOCX

**Flag**: Flag for follow up

All –

Attached is EPA's letter to reinitiate informal consultation with NMFS on the registration of chlorpyrifos, diazinon and malathion. EPA would like to send this to NMFS today so please let Nancy know, and copy me on the email, if you have any concerns with the proposed letter. I made a few suggestions that are tracked in the document.

Thank you,
Chris

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
[Ex. 6]
www.whitehouse.gov/ceq

Message

**From**: Burke, Marcella [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5066626EC70846439B8D3F6C35D92BE8-BURKE, MARC]
**Sent**: 12/7/2017 12:38:17 AM
**To**: David Bernhardt [dwbernhardt@ios.doi.gov]; Willens, Todd [todd_willens@ios.doi.gov]
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Christopher.D.Prandoni Ex. 6
**Subject**: Draft DOI Letter to EPA - "Applicant" Language
**Attachments**: EPA-HQ-OPP-2012-0442-0038.pdf

Attorney Client / Ex. 5

Please let me know if you have any questions or comments.

**Marcella Burke**
Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsyvlania Ave. NW
Washington, DC 20460
(202) 564-1609
burke.marcella@epa.gov

**From:** Willens, Todd [mailto:todd_willens@ios.doi.gov]
**Sent:** Wednesday, December 6, 2017 5:47 PM
**To:** Burke, Marcella <burke.marcella@epa.gov>
**Cc:** David Bernhardt <dwbernhardt@ios.doi.gov>; Baptist, Erik <baptist.erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Christopher.D.Prandoni Ex. 6
**Subject:** Re: Draft DOI Letter to EPA

we are planning on being on.

**Todd Willens**
**Assistant Deputy Secretary**
**U.S. Department of the Interior**
**1849 C Street, NW -- MIB Room 6116**
**Washington, DC 20240**
**office: 202-208-6291**

NOTE: *Every email I send or receive is subject to release under the Freedom of Information Act.*

On Wed, Dec 6, 2017 at 4:55 PM, Burke, Marcella <burke.marcella@epa.gov> wrote:

David and Todd – as a quick follow up, would you like to plan on a call at 6:15? If so, we have set up a tentative line. Please advise, thanks.


**Marcella Burke**

Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsyvlania Ave. NW

Washington, DC 20460

(202) 564-1609

burke.marcella@epa.gov


---

**From:** Burke, Marcella
**Sent:** Wednesday, December 6, 2017 2:52 PM
**To:** 'David Bernhardt' <dwbernhardt@ios.doi.gov>
**Cc:** todd_willens@ios.doi.gov; Baptist, Erik <baptist.erik@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>; 'Christopher.D.Prandoni@ Ex. 6
**Subject:** RE: Draft DOI Letter to EPA

David –

**Deliberative Process / Ex. 5**

# Attorney Client / Ex. 5

Thanks,

Marcella

**Marcella Burke**

Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsyvlania Ave. NW

Washington, DC 20460

(202) 564-1609

burke.marcella@epa.gov

**Marcella Burke**

Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsyvlania Ave. NW

Washington, DC 20460

(202) 564-1609

burke.marcella@epa.gov

**From:** David Bernhardt [mailto:dwbernhardt@ios.doi.gov]
**Sent:** Wednesday, December 6, 2017 11:56 AM
**To:** Burke, Marcella <burke.marcella@epa.gov>
**Cc:** todd_willens@ios.doi.gov; Baptist, Erik <baptist.erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
**Subject:** Re: Draft DOI Letter to EPA

I can participate on a call after 6:15.

Sent from my iPhone

On Dec 6, 2017, at 11:32 AM, Burke, Marcella <burke.marcella@epa.gov> wrote:

David –

**Attorney Client / Ex. 5**

Thanks,

Marcella

**Marcella Burke**

Deputy General Counsel

Office of General Counsel

U.S. Environmental Protection Agency

1200 Pennsyvlania Ave. NW

Washington, DC 20460

(202) 564-1609

burke.marcella@epa.gov

Message

**From**: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]
**Sent**: 12/15/2017 10:04:15 PM
**To**: Michael.J.Catanzaro[Ex. 6]Raymond.A.Starling[Ex. 6]; Bonfitto, Jordan P. EOP/WHO [Ex. 6]; Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; todd_willens@ios.doi.gov; Bernhardt, David [dwbernhardt@ios.doi.gov]; JUthmeier[Ex. 6] Mary.B.Neumayr[Ex. 6] Francis.J.Brooke[Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Domesle, Alexander R. EOP/CEQ[Ex. 6]
**Subject**: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement
**Attachments**: ESA MOA draft 2017-12-15.docx

All,

Attached for your review and consideration, please find a revised draft Memorandum of Agreement. I will defer to CEQ on process from here.

Best,

**Erik Baptist**
Senior Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsyvlania Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

Message

**From**: Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]
**Sent**: 1/12/2018 9:57:53 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]; Christopher.D.Prandoni Ex. 6
**CC**: Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]
**Subject**: RE: NMFS letter to EPA

Nancy,

Appreciate the clarification. We are working on this and Brandon will reply to the group.

Stu

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Friday, January 12, 2018 4:17 PM
**To:** Brandon Elsner - NOAA Federal <brandon.elsner@noaa.gov>; Christopher.D.Prandoni Ex. 6
**Cc:** Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>
**Subject:** RE: NMFS letter to EPA

Yes. It addresses timelines for RPAs but not the RPMs (which are more critical).

Thanks.
Nancy

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

**From:** Brandon Elsner - NOAA Federal [mailto:brandon.elsner@noaa.gov]
**Sent:** Friday, January 12, 2018 2:32 PM
**To:** Christopher.D.Prandoni Ex. 6 Beck, Nancy <Beck.Nancy@epa.gov>
**Cc:** Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>
**Subject:** NMFS letter to EPA

Chris and Nancy,

We wanted to make sure you were aware of this letter from NOAA's NMFS to EPA dated January 10,2018. If you have any questions my number is Ex. 6

Thanks,

Brandon

Message

**From**: Clark, Sharon [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6821D9DDE270456CAA67A7114E49F707-CLARK, SHARON]
on behalf of Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
**Sent**: 3/27/2018 7:53:52 PM
**To**: patricia.m.underwood.civ@mail.mil; Michael_Hickey@Ex. 6 James_A._Laity Ex. 6 Michael_C_Jensen@Ex. 6 maureen.sullivan18.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Charles.Maresca@sba.gov; Karen E CIV OSD OGC (US [karen.e.colmie.civ@mail.mil]; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; fjh1@cdc.gov; schaeffer.val@dol.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Camacho, Iris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5598d2cc8e3c4302aff255a840a991dc-Camacho, Iris]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]
**Subject**: OPPT's Systematic Review Guidance Follow-up

Good afternoon,

Thank you all for attending Iris's briefing on our Systematic Review Guidance. She passed on that there is frustration with timing, and the request to extend the deadline for comments. We very much appreciate your involvement and feedback, so if needed please take until COB Monday April 2nd to provide written feedback to Iris.

Additionally, Iris passed on that it would useful to have a discussion on this document. I will send an invitation for this on Wednesday April 4th at noon. We understand this is a large amount of material, and agree that a dialogue would be very useful. Iris with review the written feedback prior to this meeting and have any subject matter experts available to field questions. Additionally, myself and Nancy Beck plan to attend.

I don't believe I have everyone that attended the briefing on this email list, so please pass it on to your colleagues.

Best,

Jeff

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent**: 1/12/2018 8:22:06 PM
**To**: Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**CC**: Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]
**Subject**: RE: NMFS letter to EPA

Yup. Thanks, Brandon.

Chris

**From:** Brandon Elsner - NOAA Federal [mailto:brandon.elsner@noaa.gov]
**Sent:** Friday, January 12, 2018 2:32 PM
**To:** Prandoni, Christopher D. EOP/CEQ <[Ex. 6]; Beck.Nancy@epa.gov
**Cc:** Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>
**Subject:** NMFS letter to EPA

Chris and Nancy,

We wanted to make sure you were aware of this letter from NOAA's NMFS to EPA dated January 10,2018. If you have any questions my number is [Ex. 6]

Thanks,

Brandon

Message

**From**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]
**Sent**: 2/6/2018 1:15:33 AM
**To**: Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ [Ex. 6 ]Moran, John S. EOP/WHO [Ex. 6 ]Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject**: Re: draft letter

**Deliberative Process / Ex. 5**

Earl

Sent from my iPhone

On Feb 2, 2018, at 6:24 PM, Schwab, Justin <Schwab.Justin@epa.gov> wrote:

Dear All,

**Deliberative Process / Ex. 5**

Best,

Justin

---

**From:** Comstock, Earl (Federal) [mailto:[Ex. 6 ]@doc.gov]
**Sent:** Thursday, February 1, 2018 6:14 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Prandoni, Christopher D. EOP/CEQ ([Ex. 6 ]Moran, John S. EOP/WHO [Ex. 6 ]Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Thanks Nancy. **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Earl

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ [redacted] Ex. 6
<[redacted] Ex. 6 "Moran, John S. EOP/WHO"
[redacted] Ex. 6 "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>,
"Comstock, Earl (Federal)" <[redacted] Ex. 6 @doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
[redacted] Ex. 6
beck.nancy@epa.gov

<EDIT NMFS_reinitiation_letter2.1.18DRAFT+NOAAGCedits1 (002).docx>

Message

**From**: Delahoyde, Magdelana A. EOP/WHO [Ex. 6]
**Sent**: 11/29/2017 8:47:36 PM
**To**: Starling, Ray A. EOP/WHO [Ex. 6]; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Bonfitto, Jordan P. EOP/WHO [Ex. 6] Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Uthmeier, James (Federal) [JUthmeier@doc.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Domesle, Alexander R. EOP/CEQ [Ex. 6]; Dourson, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb29bf491d9a4c3ab569022bcd205a0a-Dourson, Mi]; Smith, Katherine R. EOP/CEQ [Ex. 6]; Rees, Gareth [gareth_rees@ios.doi.gov]
**Subject**: NEC PCC: Follow up on ESA Section 7

Hello,

We have multiple conflicts for this meeting next week and need to reschedule.

Please let me know if you have an **unresolvable conflict** on Tuesday, Dec. 5th at 5:00pm. If needed, a conference call line can also be set up.

Thank you!
Maggie

Message

**From:** Rees, Gareth [gareth_rees@ios.doi.gov]
**Sent:** 11/28/2017 4:56:50 PM
**To:** Delahoyde, Magdelana A. EOP/WHO [Ex. 6]
**CC:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Subject:** Re: Dates for ESA Section 7 Meeting

I've got a large outside group coming in at 2 but will see if I can push them back to 2:30 so we could do 1pm.

On Tue, Nov 28, 2017 at 11:47 AM, Delahoyde, Magdelana A. EOP/WHO [Ex. 6] wrote:

Hi Rees,

Noon is tough. Can he do anything between 1-3pm?

**From:** Rees, Gareth [mailto:gareth_rees@ios.doi.gov]
**Sent:** Tuesday, November 28, 2017 10:58 AM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>
**Cc:** Delahoyde, Magdelana A. EOP/WHO <[Ex. 6]>; Prandoni, Christopher D. EOP/CEQ <[Ex. 6]>

**Subject:** Re: Dates for ESA Section 7 Meeting

I could make a noon meeting work for David.

Thanks

On Tue, Nov 28, 2017 at 10:49 AM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Noon to 3pm could work for me on the 5th.

Thanks Maggie!

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
[Ex. 6]
Beck.Nancy@epa.gov

On Nov 28, 2017, at 10:45 AM, Delahoyde, Magdelana A. EOP/WHO
<Ex. 6> wrote:

Any day next week works for me! So should we shoot for Dec. 5?

**From:** Rees, Gareth [mailto:gareth_rees@ios.doi.gov]
**Sent:** Tuesday, November 28, 2017 10:29 AM
**To:** Delahoyde, Magdelana A. EOP/WHO [Ex. 6]
**Cc:** beck.nancy@epa.gov; Prandoni, Christopher D. EOP/CEQ <Ex. 6>
**Subject:** Re: Dates for ESA Section 7 Meeting

Hi Maggie

Is there a particular day you are looking at? I do know that our senior staff have an off-site leadership thing on the 7th-8th which is going to make things a little more complicated.

Thanks

On Tue, Nov 28, 2017 at 9:45 AM, Delahoyde, Magdelana A. EOP/WHO
<Ex. 6> wrote:

Hi Nancy and Rees,

I'm trying to reschedule the Dec. 6th meeting next week and need to hopefully get windows from both of you that work for your schedules. Can you let me know some windows to work with?

Thanks!
Maggie

--

Gareth C. Rees

Office to the Deputy Secretary

U.S. Department of the Interior

Tel: 202-208-6291

Fax: 202-208-1873

Cell: Ex. 6

--

Gareth C. Rees

Office to the Deputy Secretary

U.S. Department of the Interior

Tel: 202-208-6291

Fax: 202-208-1873

Ex. 6

--

Gareth C. Rees

Office to the Deputy Secretary

U.S. Department of the Interior

Tel: 202-208-6291

Fax: 202-208-1873

Ex. 6

Message

**From:** Prandoni, Christopher D. EOP/CEQ [( Ex. 6 Personal Privacy (PP)
**Sent:** 1/12/2018 4:15:52 PM
**To:** stu.levenbach@noaa.gov
**CC:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject:** FW: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement
**Attachments:** ESA MOA Draft 2018-01-10.docx

For our conversation later today.

**From:** Domesle, Alexander R. EOP/CEQ
**Sent:** Wednesday, January 10, 2018 1:51 PM
**To:** Baptist, Erik <Baptist.Erik@epa.gov>; Catanzaro, Michael J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Starling, Ray A. EOP/WHO <Ex. 6 Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; todd_willens@ios.doi.gov; Bernhardt, David Ex. 6 Personal Privacy (PP)>; JUthmeier@doc.gov; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO Ex. 6 Personal Privacy (PP)>; Herz, James P. EOP/OMB <Ex. 6 Personal Privacy (PP)>
**Cc:** Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP)
**Subject:** RE: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement

Dear colleagues,

Attached is the revised draft of the MOA between EPA, DOI, and DOC on establishing a working group on the ESA pesticide consultation process. Since the previous draft was circulated by Erik on December 15, we received very helpful feedback from EPA, DOI, DOC, and USDA, in addition to reviewing it internally here at CEQ. All resulting changes to the document have been captured in tracked changes. A few of the edits submitted we think could be further improved; in these cases we proposed alternative language in a comment in the margin.

Please review this document, including our proposed language in the margins. We intend for this to be the final review, so please identify any outstanding objections or concerns. **We would very much appreciate receiving any final comments by COB Tuesday, January 16.**

Please don't hesitate to reach out if you have any questions.
Thank you,

Alex

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
Ex. 6 Personal Privacy (PP)
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

**From:** Domesle, Alexander R. EOP/CEQ
**Sent:** Monday, December 18, 2017 10:13 AM

**To:** Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Starling, Ray A. EOP/WHO Ex. 6 Personal Privacy (PP); Bonfitto, Jordan P. EOP/WHO <J Ex. 6 Personal Privacy (PP) Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; todd_willens@ios.doi.gov; Bernhardt, David <Ex. 6 Personal Privacy (PP)>; JUthmeier@doc.gov; Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; Brooke, Francis J. EOP/OVP <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)
**Subject:** Re: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement

Thanks, Erik. If possible, please send any final feedback by the end of this week. CEQ is happy to collect the comments and identify any areas of disagreement that may need to be resolved. After that, the signatory agencies can discuss how and when to get this signed.

Thank you,
Alex

Alexander Domesle
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
Ex. 6 Personal Privacy (PP)

On Dec 15, 2017, at 17:04, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

> All,
>
> Attached for your review and consideration, please find a revised draft Memorandum of Agreement. I will defer to CEQ on process from here.
>
> Best,
>
> **Erik Baptist**
> Senior Deputy General Counsel
> Office of General Counsel
> U.S. Environmental Protection Agency
> 1200 Pennsyvlania Ave., NW
> Washington, DC 20460
> (202) 564-1689
> baptist.erik@epa.gov
>
> <ESA MOA draft 2017-12-15.docx>

Message

**From**: Lyons, Troy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=15E4881C95044AB49C6C35A0F5EEF67E-LYONS, TROY]
**Sent**: 10/26/2017 6:51:16 PM
**To**: Brown, Byron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9242d85c7df343d287659f840d730e65-Brown, Byro]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Forsgren, Lee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a055d7329d5b470fbaa9920ce1b68a7d-Forsgren, D]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Greenwalt, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c13775b8f424e90802669b87b135024-Greenwalt,]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bodine, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2cc6086fcc44c3be6b5d32b262d983-Bodine, Sus]
**CC**: Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Darwin, Henry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ae8e9d24eeb4132b25982e358efbd9d-Darwin, Hen]; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]; Shimmin, Kaitlyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=becb3f33f9a14acd8112d898cc7853c6-Shimmin, Ka]; Frye, Tony (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58c08abdfc1b4129a10456b78e6fc2e1-Frye, Rober]; Cory, Preston [preston.cory@mail.house.gov]
**Subject**: Participation Request: Wheeler Murder Board

**Importance**: High

Colleagues—

This is a good problem to have, but we are organizing another murder board to support the nomination of Andrew Wheeler. To assist your colleagues at CEQ, the murder board will be for Andrew and Kathleen Hartnett-White, the nominee to head the CEQ. We plan to facilitate this mock hearing for the two of them next Friday.

Our last murder board was a great success due in large part to your participation, and I would like to recreate the that dynamic as much as possible. Please let me know if you are would like to play the role of a Senator for Andrew and Kathleen's murder board.

Tony, Christian Rodrick and Kaitlyn have done a fantastic job compiling opposition research and questions. Our goal is to provide these materials to participants by Monday

**Friday, November 3**

| | |
|---|---|
| **Murder Board** | **10:00—12:30** |
| **Hearing Review/Debrief** | **12:30—1:30** |

**Troy M. Lyons**
Associate Administrator
Office of Congressional & Intergovernmental Relations
U.S. Environmental Protection Agency
Ex. 6

Message

**From**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]
**Sent**: 2/2/2018 11:35:36 PM
**To**: Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject**: Re: draft letter

**Deliberative Process / Ex. 5**

---

**From:** "Schwab, Justin" <Schwab.Justin@epa.gov>
**Date:** Friday, February 2, 2018 at 6:24 PM
**To:** "Comstock, Earl (Federal)" <Ex. 6 @doc.gov>, "Beck, Nancy" <Beck.Nancy@epa.gov>, "Prandoni, Christopher D. EOP/CEQ (Ex. 6)" <Ex. 6>, "Moran, John S. EOP/WHO" [Ex. 6] "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Leopold, Matt" <Leopold.Matt@epa.gov>
**Subject:** RE: draft letter

Dear All,

**Deliberative Process / Ex. 5**

Best,

Justin

---

**From:** Comstock, Earl (Federal) [mailto Ex. 6 @doc.gov]
**Sent:** Thursday, February 1, 2018 6:14 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; P Ex. 6 Ex. 6 Moran, John S. EOP/WHO Ex. 6 >; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Thanks Nancy, Deliberative Process / Ex. 5

**Deliberative Process / Ex. 5**

Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ" Ex. 6 Ex. 6, "Moran, John S. EOP/WHO" Ex. 6 "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>, "Comstock, Earl (Federal)" < Ex. 6 @doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

Message

**From**: Schwab, Justin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EED0F609C0944CC2BBDB05DF3A10AADB-SCHWAB, JUS]
**Sent**: 2/2/2018 11:24:09 PM
**To**: Comstock, Earl (Federal) [EComstock@doc.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Prandoni, Christopher D. EOP/CEQ (Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) [Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) ; Moran, John S. EOP/WHO [John.S.Moran@ Ex. 6 Personal Privacy (PP) ]; Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
**Subject**: RE: draft letter
**Attachments**: EDIT NMFS_reinitiation_letter2.1.18DRAFT+NOAAGCedits1 (002).docx

Dear All,

As discussed just now, here is a targeted edit to address the issue that occupied most of the discussion Deliberative Process / Ex. 5

**Deliberative Process / Ex. 5**

Please let us know if this sufficiently addresses *this* particular issue.

Best,

Justin

---

**From:** Comstock, Earl (Federal) [mailto:EComstock@doc.gov]
**Sent:** Thursday, February 1, 2018 6:14 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Prandoni, Christopher D. EOP/CEQ (Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) v) <Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) >; Moran, John S. EOP/WHO <John.S.Moran@ Ex. 6 Personal Privacy (PP) >; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Thanks Nancy. **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ (Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) )" <Christopher.D.Prandoni@ Ex. 6 Personal Privacy (PP) >, "Moran, John S. EOP/WHO" <John.S.Moran@ Ex. 6 Personal Privacy (PP) >, "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>, "Comstock, Earl (Federal)" <EComstock@doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

Message

**From**: Comstock, Earl (Federal) [Ex. 6 @doc.gov]
**Sent**: 2/2/2018 4:46:57 PM
**To**: Prandoni, Christopher D. EOP/CEQ [Ex. 6]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Levenbach, Stuart (Federal) [Stuart.Levenbach@noaa.gov]
**CC**: Moran, John S. EOP/WHO [Ex. 6]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
**Subject**: Re: draft letter

Thanks Chris. Talk to everyone at 5:30 pm. Earl

---

**From:** "Prandoni, Christopher D. EOP/CEQ" [Ex. 6]>
**Date:** Friday, February 2, 2018 at 11:28 AM
**To:** "Beck, Nancy" <Beck.Nancy@epa.gov>, "Comstock, Earl (Federal)" <[Ex. 6]@doc.gov>, "Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>
**Cc:** "Moran, John S. EOP/WHO" [Ex. 6], "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

Great. Let's use this line:

Participant Dial-[Ex. 6]
Participant Code

Thank you everyone.

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Friday, February 2, 2018 11:16 AM
**To:** Prandoni, Christopher D. EOP/CEQ <[Ex. 6]; Comstock, Earl (Federal) [Ex. 6]@doc.gov>; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Moran, John S. EOP/WHO [Ex. 6]>; Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

5:30 is good for me.

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
[Ex. 6]
beck.nancy@epa.gov

---

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Sent:** Friday, February 2, 2018 11:14 AM
**To:** Comstock, Earl (Federal) <[Ex. 6]@doc.gov>; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>

**Cc:** Moran, John S. EOP/WHO [Ex. 6]; Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

5:30 works for me.

---

**From:** Comstock, Earl (Federal) [mailto:[Ex. 6]@doc.gov]
**Sent:** Friday, February 2, 2018 11:13 AM
**To:** Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>
**Cc:** Prandoni, Christopher D. EOP/CEQ [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Could we do 5:30 pm today? I have conflicts from 2:30 to 5:30 today Earl

---

**From:** Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov>
**Date:** Friday, February 2, 2018 at 11:10 AM
**To:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Cc:** "Prandoni, Christopher D. EOP/CEQ" [Ex. 6] "Comstock, Earl (Federal)" <[Ex. 6]@doc.gov>, "Moran, John S. EOP/WHO" [Ex. 6] "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

I can do 2:30-3 and after 4.

On Fri, Feb 2, 2018 at 10:58 AM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

> 2-2:30 or after 4:30 are the best windows for me.
>
> Thanks,
>
> Nancy
>
> ---
>
> Nancy B. Beck, Ph.D., DABT
>
> Deputy Assistant Administrator, OCSPP
>
> P: 202-564-1273
>
> [Ex. 6]
>
> beck.nancy@epa.gov
>
> ---
>
> **From:** Prandoni, Christopher D. EOP/CEQ [[Ex. 6]
> **Sent:** Friday, February 2, 2018 10:50 AM

**To:** Comstock, Earl (Federal) <EComstock@doc.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Moran, John S. EOP/WHO [Ex. 6]; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** RE: draft letter

Hey gang,

**Deliberative Process / Ex. 5**

Chris

---

**From:** Comstock, Earl (Federal) [mailto:EComstock@doc.gov]
**Sent:** Thursday, February 1, 2018 6:14 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Prandoni, Christopher D. EOP/CEQ <[Ex. 6]
Moran, John S. EOP/WHO [Ex. 6]>; Levenbach, Stuart (Federal) <Stuart.Levenbach@noaa.gov>
**Cc:** Baptist, Erik <Baptist.Erik@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
**Subject:** Re: draft letter

Thanks Nancy [Deliberative Process / Ex. 5]

**Deliberative Process / Ex. 5**

Earl

---

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** Thursday, February 1, 2018 at 10:42 AM
**To:** "Prandoni, Christopher D. EOP/CEQ [Ex. 6]"
[Ex. 6], "Moran, John S. EOP/WHO" [Ex. 6]
"Levenbach, Stuart (Federal)" <Stuart.Levenbach@noaa.gov>, "Comstock, Earl (Federal)"
<[Ex. 6]@doc.gov>
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
**Subject:** draft letter

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

Ex. 6

beck.nancy@epa.gov

Message

**From**: Domesle, Alexander R. EOP/CEQ [Ex. 6]
**Sent**: 1/23/2018 7:26:56 PM
**To**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Catanzaro, Michael J. EOP/WHO [Ex. 6] Starling, Ray A. EOP/WHO [Ex. 6] Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; todd_willens@ios.doi.gov; Bernhardt, David [dwbernhardt@ios.doi.gov]; JUthmeier@doc.gov; Brooke, Francis J. EOP/OVP [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6] Herz, James P. EOP/OMB [Ex. 6] Winters, Paul A. EOP/OMB [Ex. 6]; stuart.levenbach@noaa.gov
**CC**: Neumayr, Mary B. EOP/CEQ [Ex. 6] Prandoni, Christopher D. EOP/CEQ [Ex. 6]
**Subject**: Working Group on ESA Section 7 Consultations for Pesticides; Memorandum of Agreement
**Attachments**: ESA MOA Draft 2018-01-18.docx

Dear colleagues,

The attached document is a revised draft of the MOA to create a WG on the pesticide consultation process. All new edits (since the last revised draft was sent out on January 10) have been marked with tracked changes. Edits from the earlier round of comments that were accepted by the group have been integrated and are no longer marked. **Please let us know by COB Friday (January 26) if you have any final concerns.**

Thank you,
Alex

---

**From:** Domesle, Alexander R. EOP/CEQ
**Sent:** Wednesday, January 10, 2018 1:51 PM
**To:** Baptist, Erik <Baptist.Erik@epa.gov>; Catanzaro, Michael J. EOP/WHO <[Ex. 6]; Starling, Ray A. EOP/WHO [Ex. 6] Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; todd_willens@ios.doi.gov; Bernhardt, David <dwbernhardt@ios.doi.gov>; JUthmeier@doc.gov; Brooke, Francis J. EOP/OVP [Ex. 6]; Moran, John S. EOP/WHO <[Ex. 6]>; Herz, James P. EOP/OMB <J[Ex. 6]
**Cc:** Neumayr, Mary B. EOP/CEQ <[Ex. 6]>; Prandoni, Christopher D. EOP/CEQ <[Ex. 6]
**Subject:** RE: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement

Dear colleagues,

Attached is the revised draft of the MOA between EPA, DOI, and DOC on establishing a working group on the ESA pesticide consultation process. Since the previous draft was circulated by Erik on December 15, we received very helpful feedback from EPA, DOI, DOC, and USDA, in addition to reviewing it internally here at CEQ. All resulting changes to the document have been captured in tracked changes. A few of the edits submitted we think could be further improved; in these cases we proposed alternative language in a comment in the margin.

Please review this document, including our proposed language in the margins. We intend for this to be the final review, so please identify any outstanding objections or concerns. **We would very much appreciate receiving any final comments by COB Tuesday, January 16.**

Please don't hesitate to reach out if you have any questions.
Thank you,

Alex

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
Ex. 6
www.whitehouse.gov/ceq

---

**From:** Domesle, Alexander R. EOP/CEQ
**Sent:** Monday, December 18, 2017 10:13 AM
**To:** Baptist, Erik <Baptist.Erik@epa.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO Ex. 6; Starling, Ray A. EOP/WHO <Ex. 6>; Bonfitto, Jordan P. EOP/WHO <Ex. 6> Stephen.Vaden@ogc.usda.gov; Rebeckah.Adcock@osec.usda.gov; Beck, Nancy <Beck.Nancy@epa.gov>; todd_willens@ios.doi.gov; Bernhardt, David <dwbernhardt@ios.doi.gov>; JUthmeier@doc.gov; Neumayr, Mary B. EOP/CEQ <Ex. 6>; Brooke, Francis J. EOP/OVP Ex. 6>; Moran, John S. EOP/WHO Ex. 6; Prandoni, Christopher D. EOP/CEQ
Ex. 6
**Subject:** Re: Working Group on ESA Section 7 Consultations; Draft Memorandum of Agreement

Thanks, Erik. If possible, please send any final feedback by the end of this week. CEQ is happy to collect the comments and identify any areas of disagreement that may need to be resolved. After that, the signatory agencies can discuss how and when to get this signed.

Thank you,
Alex

Alexander Domesle
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
Ex. 6

On Dec 15, 2017, at 17:04, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

> All,
>
> Attached for your review and consideration, please find a revised draft Memorandum of Agreement. I will defer to CEQ on process from here.
>
> Best,
>
> **Erik Baptist**
> Senior Deputy General Counsel
> Office of General Counsel
> U.S. Environmental Protection Agency

1200 Pennsyvlania Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

<ESA MOA draft 2017-12-15.docx>

Message

**From:** Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**Sent:** 7/1/2018 4:58:59 PM
**To:** Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Wennerberg, Linda S. (HQ-LD020 [linda.s.wennerberg@nasa.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Sara.A.Brenner2@[Ex. 6 Personal Privacy (PP)]]; Jones, Danielle Y. EOP/OMB [Danielle_Y_Jones@[Ex. 6 Personal Privacy (PP)]]; Schwab, Margo EOP/OMB [Margo_Schwab@[Ex. 6 Personal Privacy (PP)]]; Szabo, Aaron L. EOP/CEQ [Aaron.L.Szabo@[Ex. 6 Personal Privacy (PP)]]; Barringer, Jody M. EOP/OMB [Jody_M._Barringer@[Ex. 6 Personal Privacy (PP)]]; Falk Curtin, Edna T. EOP/OMB [Edna_F._Curtin@[Ex. 6 Personal Privacy (PP)]; Paul Winters Paul_A_Winters@[Ex. 6 Personal Privacy (PP)]) ["Paul WintersPaul_A_Winters"@[Ex. 6 Personal Privacy (PP)]]); Fine, Leah R. EOP/OMB [Ex. 6 Personal Privacy (PP)]
**CC:** Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Nickerson, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=148f2c1c05b54f358e29c59b841664aa-Wnicker]
**Subject:** RE: [Non-DoD Source] Methylene Chloride: Information on Sub-lethal effects (UNCLASSIFIED)
**Attachments:** OMB Comments - methylene chloride 6-27-18.docx

Jeff: Attached are OIRA comments on both the 2014 risk assessment and the supplemental materials you sent to the TWG on June 22. [Deliberative Process / Ex. 5]

[Deliberative Process / Ex. 5]

[Deliberative Process / Ex. 5]?

[Deliberative Process / Ex. 5]

>
> Please feel free to call if you would like to discuss further.
>
> Jim
>

-----Original Message-----
From: Morris, Jeff <Morris.Jeff@epa.gov>
Sent: Tuesday, June 26, 2018 2:38 PM
To: Underwood, Patricia M CIV (US) <patricia.m.underwood.civ@mail.mil>; Waqar, Tayyaba <tayyaba.waqar@sba.gov>; kevin.bromberg@sba.gov; Wennerberg, Linda S. (HQ-LD020 <linda.s.wennerberg@nasa.gov>; Moore, Beth <Beth.Moore@em.doe.gov>; Brenner, Sara A. EOP/OSTP <Sara.A.Brenner2@[Ex. 6 Personal Privacy (PP)]; Jones, Danielle Y. EOP/OMB <Danielle_Y_Jones@[Ex. 6 Personal Privacy (PP)]>; Schwab, Margo EOP/OMB <Margo_Schwab@[Ex. 6 Personal Privacy (PP)]>; Laity, Jim A. EOP/OMB <James_A._Laity@[Ex. 6 Personal Privacy (PP)]>; Szabo, Aaron L. EOP/CEQ <Aaron.L.Szabo@[Ex. 6 Personal Privacy (PP)]>; Barringer, Jody M. EOP/OMB <Jody_M._Barringer@[Ex. 6 Personal Privacy (PP)]>; Falk Curtin, Edna T. EOP/OMB <Edna_F._Curtin@[Ex. 6 Personal Privacy (PP)]>; Paul Winters Paul_A_Winters@[Ex. 6 Personal Privacy (PP)]) <"Paul WintersPaul_A_Winters"@[Ex. 6 Personal Privacy (PP)]>; Fine, Leah R. EOP/OMB <Leah.R.Fine@[Ex. 6 Personal Privacy (PP)]>
Cc: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>
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All the best,

Jeff

Jeffery T. Morris, PhD
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US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

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Thanks,
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As information prior to interagency review of EPA's final rule on methylene chloride, the attached document provides:

* Deliberative Process / Ex. 5
Deliberative Process / Ex. 5
*
* Deliberative Process / Ex. 5

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Jeff

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Message

**From**: Bromberg, Kevin L. [kevin.bromberg@sba.gov]
**Sent**: 6/29/2018 9:15:48 PM
**To**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Wennerberg, Linda S. (HQ-LD020 [linda.s.wennerberg@nasa.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Sara.A.Brenner2@ Ex. 6 Personal Privacy (PP) ]; Jones, Danielle Y. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Schwab, Margo EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Laity, Jim A. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Szabo, Aaron L. EOP/CEQ [ Ex. 6 ] Barringer, Jody M. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Falk Curtin, Edna T. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Paul Winters [ Ex. 6 Personal Privacy (PP) ] [ Ex. 6 Personal Privacy (PP) ] Fine, Leah R. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]
**CC**: Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Nickerson, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=148f2c1c05b54f358e29c59b841664aa-Wnicker]
**Subject**: RE: [Non-DoD Source] Methylene Chloride: Information on Sub-lethal effects (UNCLASSIFIED)

We generally endorse many of the technical and policy comments made by DOD and NASA. By filing this comment, we are not agreeing that interagency review on this rulemaking should start on July 2.

As some of you know, SBA Advocacy has already filed public comments recommending that EPA withdraw the proposed rule. EPA did not establish that there are unreasonable risks from use of this product that cannot be accommodated by risk management requirements or other means, in lieu of a ban of unknown scope now being considered by the agency. The SBREFA report contains much useful discussion about the lack of safe alternatives that are equally effective, among other important issues.

With regard to the sub-lethality acute endpoints, the excerpted document does not establish that (1) there is a significant number of sub-lethal acute effects experienced by consumers and workers or (2) that the sub-lethal effects are sufficiently adverse and involve more than temporary adverse effects to support a regulatory determination. We do not recall whether the sub-lethal effects were considered as part of the 2014 risk assessment peer review. Further, the 2014 risk assessment was properly criticized for unrealistic exposure scenarios, which would further compromise any examination of sub-lethal effects.

EPA also promised to peer review the July 2016 ''Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal'' before promulgation of the final rule, probably recognizing that the 2014 analysis would not be sufficient alone to justify a final rule. This peer review has not occurred.

We look forward to a robust technical and policy level discussion on these issues.

Kevin Bromberg

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From: Morris, Jeff [mailto:Morris.Jeff@epa.gov]
Sent: Tuesday, June 26, 2018 2:38 PM
To: Underwood, Patricia M CIV (US); Waqar, Tayyaba; Bromberg, Kevin L.; Wennerberg, Linda S. (HQ-LD020; Moore, Beth; Brenner, Sara A. EOP/OSTP; Jones, Danielle Y. EOP/OMB; Schwab, Margo EOP/OMB; Laity, Jim A. EOP/OMB; Szabo, Aaron L. EOP/CEQ; Barringer, Jody M. EOP/OMB; Falk Curtin, Edna T. EOP/OMB; Paul Winters [ Ex. 6 ]; Fine, Leah R. EOP/OMB
Cc: Bertrand, Charlotte; Baptist, Erik; Beck, Nancy; Blair, Susanna; Nickerson, William
Subject: RE: [Non-DoD Source] Methylene Chloride: Information on Sub-lethal effects (UNCLASSIFIED)

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Message (Digitally Signed)

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**Sent**: 6/29/2018 8:09:13 PM
**To**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Wennerberg, Linda S. (HQ-LD020 [linda.s.wennerberg@nasa.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Brenner, Sara A. EOP/OSTP [Ex. 6 Personal Privacy (PP)] Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Schwab, Margo EOP/OMB [Ex. 6 Personal Privacy (PP)]; Laity, Jim A. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Szabo, Aaron L. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Barringer, Jody M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; Falk Curtin, Edna T. EOP/OMB [Ex. 6 Personal Privacy (PP)] Paul Winters [Ex. 6 Personal Privacy (PP)] [Ex. 6 Personal Privacy (PP)]; Fine, Leah R. EOP/OMB [Ex. 6 Personal Privacy (PP)]
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**Subject**: RE: [Non-DoD Source] Methylene Chloride: Information on Sub-lethal effects (UNCLASSIFIED)
**Attachments**: DoD_Comment_MeCl Rule_Description of Acute Sub-lethal Effects (21 Jun 2018).pdf; smime.p7s

CLASSIFICATION: UNCLASSIFIED

Jeff,
Thank you for providing the extension for comment. We greatly appreciate the opportunity to provide input on the document prepared by EPA that provides additional insights on the sub lethal effects considered in the risk evaluation of methylene chloride and the economic analysis. You indicated that you are proposing to enter the final rule into interagency review on Monday, July 2nd. However, DoD concerns remain unaddressed. Please consider the following points:

**Deliberative Process / Ex. 5**

Thank you for considering our comments and look forward to further discussion about an approach that can address small shop worker risks while maintaining sophisticated industrial applications.

Best regards,
Tricia

Patricia Underwood, PhD, DABT, MBA
Deputy for Chemical and Material Risk Management

Office of the Deputy Assistant Secretary of Defense (Energy, Installations & Environment)
ESOH Directorate
4800 Mark Center Drive
Box#56, Suite 17D08
Alexandria, VA 22350

Ph:703-901-8747

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**From**: Gross, Mackenzie A. EOP/WHO [Ex. 6 Personal Privacy (PP)]
**Sent**: 6/29/2018 8:41:03 PM
**To**: Santerre, Charlie R. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Kratsios, Michael J. EOP/OSTP [Ex. 6 Personal Privacy (PP)]; Cunliffe, Laura M. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Talento, Kathryn F. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Slater, Abigail A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; 'Abram, Anna' [Anna.Abram@fda.hhs.gov]; Ostroff, Stephen [Stephen.Ostroff@fda.hhs.gov]; 'Nalubola, Ritu' [Ritu.Nalubola@fda.hhs.gov]; Klippenstein, Brian - OSEC, Washington, DC [Brian.Klippenstein@osec.usda.gov]; 'Adcock, Rebeckah - OSEC, Washington, DC' [Rebeckah.Adcock@osec.usda.gov]; 'Chou, Fan-Li - ARS' [Fan-Li.Chou@ARS.USDA.GOV]; 'Hoskins, Dudley - OSEC, Washington, DC' [Dudley.Hoskins@osec.usda.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Mendelsohn, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=720b16e1b31742738a728d8d2814beef-Mendelsohn, Mike]
**Subject**: Ag Biotech follow-up

Hi team, thanks for another great biotech discussion today!

For next steps, we're asking that each Agency lay out what steps they can take to facilitate the review of any priority products. There were a lot of ideas that sounded like they fit the bill mentioned in today's meeting (such as using the IR-4 program or enhancing customer service as developers put their data packages togetehr) and I think it would be helpful to flesh out those ideas somewhat.

Please get me an outline for what you think your Agency can do in this space by **COB Monday, July 9**. We'll then have a follow up meeting to discuss further.

Thanks and I hope everyone has a great weekend!

Mackenzie

Message

**From**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]
**Sent**: 6/29/2018 8:20:49 PM
**To**: Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Laity, James A. Ex. 6 Personal Privacy (PP)
**CC**: denise.r.thaller@nasa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f74bb85e1d480ab8f99417660740fc-denise.r.th]; Mcneill, Mike A (HQ-LD020) [mike.a.mcneill@nasa.gov]; Underwood, Patricia M CIV (US) (patricia.m.underwood.civ@mail.mil) (patricia.m.underwood.civ@mail.mil) [patricia.m.underwood.civ@mail.mil]; Ex. 6 Personal Privacy (PP) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Jones, Danielle Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP) v]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject**: NASA comments on the proposed Methylene Chloride Ban
**Attachments**: Methylene chloride ban documentation review NASA 06-29-18.docx

All;
Attached are the NASA comments, as per EPA and OMB's request. Please let me know if you have any questions or need clarification.

NASA appreciates the option to comment and the extension to support our review.

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
MS-2T89
300 E Street SW
Washington, DC 20546-0001

Tel: 202/358-4558
Ex. 6
Fax: 202/358-3948
linda.s.wennerberg@nasa.gov

Message

**From**: Jones, Lisa M. EOP/OMB [ Ex. 6 Personal Privacy (PP)
**Sent**: 11/3/2017 3:17:11 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject**: RE: Kim Johnson

Ex. 6 Personal Privacy (PP)

**From:** King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
**Sent:** Friday, November 3, 2017 11:07 AM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Jones, Lisa M. EOP/OMB < Ex. 6 Personal Privacy (PP)
**Subject:** RE: Kim Johnson

Ex. 6 Personal Privacy (PP)

Y

**From:** Beck, Nancy <Beck.Nancy@epa.gov>
**Sent:** Friday, November 3, 2017 11:00:18 AM
**To:** Jones, Lisa M. EOP/OMB
**Cc:** King, Heidi (NHTSA)
**Subject:** Re: Kim Johnson

Ex. 6 Personal Privacy (PP)

Miss you still!
Nancy.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Nov 3, 2017, at 10:56 AM, Jones, Lisa M. EOP/OMB < Ex. 6 Personal Privacy (PP) wrote:

Hi Nancy and Heidi,

Ex. 6 Personal Privacy (PP)

<image001.png>

Message

**From**: Delahoyde, Magdelana A. EOP/WHO [Ex. 6 Personal Privacy (PP)]
**Sent**: 11/28/2017 2:45:54 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Rees, Gareth [gareth_rees@ios.doi.gov]
**CC**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Subject**: Dates for ESA Section 7 Meeting

Hi Nancy and Rees,

I'm trying to reschedule the Dec. 6th meeting next week and need to hopefully get windows from both of you that work for your schedules. Can you let me know some windows to work with?

Thanks!
Maggie

Message

**From**: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
**Sent**: 7/2/2018 10:11:09 PM
**To**: Wennerberg, Linda S. (HQ-LD020) [linda.s.wennerberg@nasa.gov]
**CC**: Laity, James A. [Ex. 6 Personal Privacy (PP)]; denise.r.thaller@nasa.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f74bb85e1d480ab8f99417660740fc-denise.r.th]; Mcneill, Mike A (HQ-LD020) [mike.a.mcneill@nasa.gov]; Underwood, Patricia M CIV (US) (patricia.m.underwood.civ@mail.mil) (patricia.m.underwood.civ@mail.mil) [patricia.m.underwood.civ@mail.mil]; James_H_Kim@[Ex. 6 Personal Privacy (PP)]v [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Jones, Danielle [Ex. 6 Personal Privacy (PP)]; kevin.bromberg@sba.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a79a0f905cda421984b3523ea0beaf85-kevin.bromberg@sba.gov]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Moore, Beth [Beth.Moore@em.doe.gov]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
**Subject**: Re: NASA comments on the proposed Methylene Chloride Ban

TWG colleagues,

I wish to thank DOD, NASA, OMB, and SBA for the thoughtful comments. EPA is reviewing them this week. We will get back with you as soon as possible with next steps.

All the best,

Jeff

Sent from my iPhone

On Jun 29, 2018, at 4:20 PM, Wennerberg, Linda S. (HQ-LD020) <linda.s.wennerberg@nasa.gov> wrote:

All;
Attached are the NASA comments, as per EPA and OMB's request. Please let me know if you have any questions or need clarification.

NASA appreciates the option to comment and the extension to support our review.

Linda S. Wennerberg, Ph.D.
Environmental Management Division
NASA Headquarters
MS-2T89
300 E Street SW
Washington, DC 20546-0001

Tel: 202/358-4558
Cell: [Ex. 6 Personal Privacy (PP)]
Fax: 202/358-3948
linda.s.wennerberg@nasa.gov

<Methylene chloride ban documentation review NASA 06-29-18.docx>

Message

**From**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Sent**: 7/27/2017 3:43:57 PM
**To**: Roslyn_Sellars@FWS.gov [Roslyn_Sellars@fws.gov]; Milhouse, Gloria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a424462e03c4a82ba83121d59d8b34d-Gmilhous]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Keigwin, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=151baabb6a2246a3a312f12a706c0a05-Richard P Keigwin Jr]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Perlis, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b74bb55bb480452d99e3e4fd07c06889-RPERLIS]; Echeverria, Marietta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36c56b7169144626bd6aadea25992d4e-Marietta Echeverria]; Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Greenwalt, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c13775b8f424e90802669b87b135024-Greenwalt,]; Marshall, Venus [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbd81a18f6ad447f90b8abbcb90fe9db-Venus Ashton]; Dyner, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd0cdc2070545e5852c81739f765bc5-MDYNER]; Bolen.Birttany@epa.gov; greg_j_sheehan@fws.gov; Chris Oliver - NOAA Federal [chris.w.oliver@noaa.gov]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Pease, Anita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbbef4b4951144499885d4cdf88d46d0-Anita Pease]; Jakob, Avivah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca1aecd941984ff2939fe77425b0e2f3-Jakob, Avivah]; Erik Noble - NOAA Federal [erik.noble@noaa.gov]; Uthmeier, James (Federal) [JUthmeier@doc.gov]; Vaden, Stephen - OGC [Stephen.Vaden@ogc.usda.gov]
**CC**: Catanzaro, Michael J. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Neumayr, Mary B. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Shultz, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userd6a2f351]; gary_frazer@fws.gov; Knorr, Michele [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e2165e5c2224bac8d33c2f857c33886-MKnorr]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Starling, Ray A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Kunickis, Sheryl - OSEC [Sheryl.Kunickis@osec.usda.gov]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Seale, Viktoria Z. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**Subject**: RE: Biological opinion update

Due to the expected turnout, we will be moving the meeting to the Lincoln Room at the White House Conference Center. The White House Conference Center is located at 726 Jackson Place, right next to CEQ, and does not require any preclearance. You will need to bring your ID. We will have a staffer bouncing between the Lincoln Room and the entrance to the White House Conference Center to try to make sure everyone gets in without incident.
For those of you who cannot attend the meeting in person, below are all the conference line details:
Participant Dial-In: ( Ex. 6 Personal Privacy (PP)
Participant Code: Ex. 6 Personal Privacy (PP)

Thank you for working with us and I look forward to seeing everyone tomorrow. My direct line is Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP) - please don't hesitate to call.

Chris

-----Original Appointment-----
From: Prandoni, Christopher D. EOP/CEQ
Sent: Thursday, July 20, 2017 5:30 PM
To: Prandoni, Christopher D. EOP/CEQ; Roslyn_Sellars@FWS.gov; Milhouse, Gloria; Schwab.Justin@epa.gov; Keigwin.Richard@epa.gov; Baptist.Erik@epa.gov; Dravis.Samantha@epa.gov; Perlis.Robert@epa.gov; Echeverria.Marietta@epa.gov; Bennett, Tate; Greenwalt.Sarah@epa.gov; Marshall, Venus; dyner.mark@epa.gov; Bolen.Birttany@epa.gov; greg_j_sheehan@fws.gov; Chris Oliver - NOAA Federal; Wise.Louise@epa.gov; pease.anita@epa.gov; Jakob, Avivah; Erik Noble - NOAA Federal; Uthmeier, James (Federal); Vaden, Stephen - OGC
Cc: Catanzaro, Michael J. EOP/WHO; Neumayr, Mary B. EOP/CEQ; Gina_Shultz@fws.gov; gary_frazer@fws.gov; Knorr, Michele; Beck, Nancy; Starling, Ray A. EOP/WHO; Kunickis, Sheryl - OSEC; Bolen, Brittany; Viktoria Z. EOP/CEQ Seale Ex. 6 Personal Privacy (PP)
Subject: Biological opinion update
When: Friday, July 28, 2017 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 726 Jackson Place, the White House Conference Center

Due to the expected turnout, we will be moving the meeting to the Lincoln Room at the White House Conference Center. The White House Conference Center is located at 726 Jackson Place, right next to CEQ, and does not require any preclearance. You will need to bring your ID. We will have a staffer bouncing between the Lincoln Room and the entrance to the White House Conference Center to try to make sure everyone gets in without incident.
For those of you who cannot attend the meeting in person, below are all the conference line details:
Participant Dial-In: Ex. 6 Personal Privacy (PP)
Participant Code: Ex. 6 Personal Privacy (PP)

Thank you for working with us and I look forward to seeing everyone tomorrow. My direct line is Ex. 6 Ex. 6 - please don't hesitate to call.
Chris

Feel free to forward to others in your offices.

I will update the invite with call-in information sometime next week. In the meantime, feel free to call me at Ex. 6 Personal Privacy (PP) if anything comes up.

Below is my original invite:

Hey everyone,

If I don't already know you, my name is Chris Prandoni and I am the Associate Director for Natural Resources over here at CEQ. Included on this email are EPA, FWS, Commerce, and USDA representatives. Since there are a lot of new faces in town, myself included, I have spoken to either you or someone else at your agency about the desire for the Services to update the rest of the federal family on the biological opinions for chlorpyrifos, malathion, and diazinon.

The idea would be for FWS and NMFS to take about 20 minutes each to explain the status of their opinions and then open it up for questions. I know this is a quick turnaround, but ideally we could all get together at CEQ's office in Jackson Place 730 next Tuesday (7/25) or Wednesday (7/26). If you are unsure about whom within your agency to invite to this meeting, there should be someone from your agency copied on this email who can help you identify the correct people to coordinate with.

Since there are a lot of moving parts, whenever an agency identifies a window that works for their team, feel free to propose that time or window to the group. Of course feel free to call me with any questions you may have. My direct is Ex. 6 Personal Privacy (PP)

Thank you very much; look forward to working with all of you.

Chris

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
Executive Office of the President
www.whitehouse.gov/ceq

Message

**From**: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
**Sent**: 6/22/2018 4:11:44 PM
**To**: Tayyaba tayyaba.waqar@sba.gov; Kevin L.kevin.bromberg@sba.gov; US [Patricia M CIV patricia.m.underwood.civ@mail.mil]; HQ-LD020 [Linda S.linda.s.wennerberg@nasa.gov]; Beth Beth.Moore@em.doe.gov; Sara A.EOP/OSTP S[redacted] Danielle Y.EOP/OMB [redacted] Margo EOP/OMB [redacted] Jim A.EOP/OMB [redacted] Aaron L.EOP/CEQ [redacted] Jody M.EOP/OMB [redacted] Edna T.EOP/[redacted] Paul Winters [redacted] Leah R.EOP/OMB [redacted]
**CC**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]
**Subject**: Methylene Chloride: Information on Sub-lethal effects
**Attachments**: Methylene Chloride Sub-Lethal Effects 21 June 2018.docx

TWG Colleagues,

As information prior to interagency review of EPA's final rule on methylene chloride, the attached document provides:

- [redacted]

[redacted]

- [redacted]
- [redacted]

This is a very short, simple document, so we would appreciate any comments by noon Tuesday, June 26. Please send any comments to Susanna Blair at Blair.susanna@epa.gov. If a short call is needed Monday afternoon or Tuesday morning to clarify anything in the document, please let Susanna know and we will set it up. Thanks very much for working with us on this.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

Message

**From**: Cleland-Hamnett, Wendy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B84439FCDF02426ABD539D8BB6C9EF6F-CLELAND-HAMNETT, WENDY]
**Sent**: 8/1/2017 6:33:17 PM
**To**: 'Underwood, Patricia M CIV (US)' [patricia.m.underwood.civ@mail.mil]; Michael_Hickey@[redacted] James_A._Laity@[redacted] Michael_C_Jensen@[redacted]; Sullivan, Maureen SES OSD OUSD ATL (US [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US [jim.rudroff@navy.mil]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US [karen.e.colmie.civ@mail.mil]; mike.a.mcneill@nasa.gov; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [redacted] James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]; Paul_A_Winters@[redacted]
**CC**: Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
**Subject**: TSCA Implementation Senior Policy Group

**Flag**: Flag for follow up

Dear Colleagues,

As you are likely aware, the last few months have been an extraordinarily busy time for TSCA implementation in the EPA's Office of Chemical Safety and Pollution Prevention. Since our last meeting in May, and with incredible support and assistance from you and your staffs, EPA successfully met a number of milestones as required under the law. June 22, 2017 marked not only the one-year anniversary of the TSCA amendments, but the finalization of three TSCA "Framework" rules (Prioritization, Risk Evaluation, and Active/Inactive Inventory), publication of guidance for persons interested in submitting draft risk evaluations to the EPA, and publication of the scope of risk evaluations for the first 10 chemicals. This could not have been achieved without your help, and, on behalf of the Agency, I'd like to extend my sincerest gratitude.

However, much work on TSCA implementation remains to be done. We plan to schedule another meeting of our Senior Policy Group for September to give a more in-depth update on the next phase(s) of TSCA implementation - including preparations for stakeholder discussions on Pre-Prioritization, New Chemicals, and the Strategic Plan for Non-Animal Testing, ongoing risk evaluation and risk management activities, and more - and to hear from you on best practices moving forward. Stay tuned for a scheduling invite.

In the interim, OCSPP is continuing to move forward on the development of Problem Formulation documents for the first 10 chemical risk evaluations. The Problem Formulation documents will refine the Scope documents, as an

additional interim step, prior to publication of draft risk evaluations. EPA expects to publish these ten Problem Formulation documents in December 2017. We continue to welcome relevant hazard and exposure information on these chemicals from our interagency partners. If your organization has such information to share, we'd encourage you to do so as soon as possible by reaching out to the staff point of contact for the particular chemical listed on our website, here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten. These staff points of contact can also help answer additional questions you may have regarding the Scope documents, or next steps in the process.

Finally, if you have not already heard, I want to let you know that I have decided to retire from federal service at the end of August. I have enjoyed my 38 years at EPA immensely, and particularly the opportunity to work with smart, dedicated collegial people across the federal government, such as yourselves. Jeff Morris, who is the Director of the Office of Pollution Prevention and Toxics, will be taking over the helm of our Senior Policy Group. Jeff can be reached at 202-564-3810. Louise Wise and Nancy Beck, both Deputy Assistant Administrators in OCSPP, also will be happy to take your calls. They can be reached on 202-564-2910.

Again, I thank you for your continued support of EPA and OCSPP during these critical early times of TSCA implementation. My very best wishes to all of you in the future.

Wendy

Wendy Cleland-Hamnett
Acting Assistant Administrator
Principal Deputy Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
202-564-2910
cleland-hamnett.wendy@epa.gov

Message

**From:** Hickey, Mike J. EOP/OMB [Ex. 6 Personal Privacy (PP)
**Sent:** 5/3/2017 9:53:25 PM
**To:** Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Laity, Jim A. EOP/OMB Ex. 6 Personal Privacy (PP); Mallory, Brenda EOP/CEQ [Ex. 6 Personal Privacy (PP); McDermott, Marna A. EOP/CEQ Ex. 6 Personal Privacy (PP); Jensen, Michael C. EOP/CEQ Ex. 6 Personal Privacy (PP) maureen.sullivan18.civ@mail.mil; patricia.m.underwood.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; :mike.a.mcneill@nasa.gov: ["⬜error⬜5.1.2⬜ 553 source routing not allowed."@domain.invalid]; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Williamson, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b1209cc553b4cbe9a59f3e47dc0a312-TrWillia]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Vendinello, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3951cb8019444df48b4d969cdf56f188-Lvendi02]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
**CC:** Hearl, Frank J. (CDC/NIOSH/OD) [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [Ex. 6 Personal Privacy (PP) James_H_Kim@Ex. 6 Personal Privacy (PP)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Winters, Paul A. EOP/OMB [Ex. 6 Personal Privacy (PP)
**Subject:** RE: TSCA Interagency Policy Group (Call in number Ex. 6 Personal Privacy (PP), access code Ex. 6 Personal Privacy (PP))

-----Original Appointment-----
**From:** Milhouse.Gloria@epa.gov [mailto:Milhouse.Gloria@epa.gov] **On Behalf Of** Cleland-Hamnett, Wendy
**Sent:** Wednesday, May 3, 2017 1:14 PM
**To:** Wise, Louise; Morris, Jeff; Blair, Susanna; Rodan, Bruce; Corrales, Mark; Beck, Nancy; Hickey, Mike J. EOP/OMB; Laity, Jim A. EOP/OMB; Mallory, Brenda EOP/CEQ; McDermott, Marna A. EOP/CEQ; Jensen, Michael C. EOP/CEQ; maureen.sullivan18.civ@mail.mil; patricia.m.underwood.civ@mail.mil; jim.rudroff@navy.mil; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; karen.e.colmie.civ@mail.mil; :mike.a.mcneill@nasa.gov:; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick; zkz1@cdc.gov; fhearl@cdc.gov; Cherepy, Andrea; Williamson, Tracy; Henry, Tala; Vendinello, Lynn; Schmit, Ryan
**Cc:** Hearl, Frank J. (CDC/NIOSH/OD); Jones, Danielle Y. EOP/OMB; Kim, Jim H. EOP/OMB; Doa, Maria
**Subject:** TSCA Interagency Policy Group (Call in number Ex. 6 Personal Privacy (PP), access code Ex. 6 Personal Privacy (PP))

**When:** Thursday, May 4, 2017 1:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** DCRoomEast3371C/DC-EPA-EAST-OCSPP-IO-OPMO

Agenda:

**Deliberative Process / Ex. 5**

Message

**From:** Todd Willens [todd_willens@ios.doi.gov]
**Sent:** 6/18/2018 9:50:23 PM
**To:** Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)]
**CC:** Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bernhardt, David Ex. 6 Personal Privacy (PP); Brooke, Francis J. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Dankert, Charles M. EOP/OMB [Ex. 6 Personal Privacy (PP)]; EComstock@doc.gov; Herz, James P. EOP/OMB Ex. 6 Personal Privacy (PP); Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Emma_K_Roach@Ex. 6 Personal Privacy (PP) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=459adeb9f2894e7784b9b3407687c21c-Emma_K_Roach@Ex. 6 Personal Privacy (PP)]; Stephen.Vaden@ogc.usda.gov; Teague, Anne (Federal) [ATeague@doc.gov]; Uthmeier, James (Federal) [James.Uthmeier@doc.gov]; Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; gareth_rees@ios.doi.gov; linda.lawhornbrown@noaa.gov; raymond.starling@osec.usda.gov; stuart.levenbach@noaa.gov
**Subject:** Re: [EXTERNAL] Next ESA WG call

Looks good, thanks!

On Mon, Jun 18, 2018 at 3:52 PM Domesle, Alexander R. EOP/CEQ <Ex. 6 Personal Privacy (PP)> wrote:

**DRAFT AGENDA**

**Deliberative Process / Ex. 5**

For questions or scheduling issues, contact:

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

--
Todd Willens
Assistant Deputy Secretary
U.S. Department of the Interior
1849 C Street, N.W.
Washington, DC 20240
202-208-6291

Message

**From**: Domesle, Alexander R. EOP/CEQ [ Ex. 6 Personal Privacy (PP)
**Sent**: 6/18/2018 8:28:27 PM
**To**: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bernhardt, David [ Ex. 6 Personal Privacy (PP) ]; todd_willens@ios.doi.gov; EComstock@doc.gov; Uthmeier, James (Federal) [James.Uthmeier@doc.gov]; stuart.levenbach@noaa.gov; Stephen.Vaden@ogc.usda.gov; raymond.starling@osec.usda.gov
**CC**: Prandoni, Christopher D. EOP/CEQ [ Ex. 6 Personal Privacy (PP) ]; Herz, James P. EOP/OMB [ Ex. 6 Personal Privacy (PP) ]; Brooke, Francis J. EOP/WHO [ Ex. 6 Personal Privacy (PP) ]; Emma_K_Roach@ [ Ex. 6 Personal Privacy (PP) ] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=459adeb9f2894e7784b9b3407687c21c-Emma_K_Roach@ [ Ex. 6 Personal Privacy (PP) ]; Moran, John S. EOP/WHO [ Ex. 6 Personal Privacy (PP) ]
**Subject**: ESA WG reminder/rescheduling

Dear ESA Pesticide Working Group members,

You should have received a notification that the next ESA Working Group call has been moved to this Friday at 2:30pm due to some scheduling conflicts. It appears that this time works for at least one individual from each agency, but we hope as many of you as possible will join.

I also wanted to briefly remind you of the agenda, which is pasted below. If you have not already done so, we encourage you to get an update from your career/technical staff before Friday on how current efforts are going, specific roadblocks in their way, and any suggestions for how this Working Group might be able to help. We hope to have a productive conversation on Friday.

Thank you and please let me know if you have any questions.
Alex

AGENDA

**Deliberative Process / Ex. 5**

Alexander Domesle
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
[ Ex. 6 Personal Privacy (PP) ]

On Jun 7, 2018, at 13:43, Domesle, Alexander R. EOP/CEQ < Ex. 6 Personal Privacy (PP) > wrote:

Dear ESA Pesticide Working Group members,

As discussed at our last meeting on May 18, CEQ is convening regular (roughly monthly) calls to monitor progress on the ESA/pesticides initiative. We propose scheduling a 30-minute call on **Wednesday, June 20, at 3:00pm**. If you have an irresolvable conflict, please provide some other times when you are available on Wednesday, June 20, and Friday, June 22.

We encourage the signatory agencies – EPA, DOI, DOC – and USDA to obtain a progress update from their staffs in advance of this meeting. This will allow us to compare notes and identify any challenges that might be addressed by the Working Group. A draft agenda is included below and the timeline developed by technical working group on pesticide usage data is attached. If you have any additional agenda items you would like to include, please provide these to me no later than Monday, June 18.

Thank you!

**DRAFT AGENDA**

**Deliberative Process / Ex. 5**

**Alexander Domesle**
Senior Advisor for Natural Resources
Council on Environmental Quality
Executive Office of the President
**Ex. 6 Personal Privacy (PP)**
www.whitehouse.gov/ceq

<milestones_timeline_interagency_usage_ 5-30-18_final.docx>

Message

**From**: Schmit, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7077ECBAC4914A00AD465398F92BBE78-SCHMIT, RYAN]

**Sent**: 6/14/2017 12:47:27 PM

**To**: Underwood, Patricia M CIV (US) [patricia.m.underwood.civ@mail.mil]; Michael_Hickey@[redacted]; James_A._Laity@[redacted] Brenda_Mallory@[redacted] Marna_A_McDermott@[redacted]; Michael_C_Jensen@[redacted] Sullivan, Maureen SES OSD OUSD ATL (US) [maureen.sullivan18.civ@mail.mil]; Rudroff, James G CIV USN (US) [jim.rudroff@navy.mil]; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US) [karen.e.colmie.civ@mail.mil]; :mike.a.mcneill@nasa.gov: [mike.a.mcneill@nasa.gov:]; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ea0cbe73e0543fa9f5e71188cb177c7-Suzanne_Fit]; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD) [fjh1@cdc.gov]; Jones, Danielle Y. EOP/OMB [[redacted]; James_H_Kim@[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec269b1b62f14ed187c0115b1eb24e3f-James_H_Kim]; Waqar, Tayyaba [tayyaba.waqar@sba.gov]

**CC**: Widawsky, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6ecd0fcbebb4a59a34d9d1ee85cc7a5-Widawsky, David]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Symmes, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9339d98405486fb7109fe4ab65b7be-Symmes, Brian]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Corrales, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ea2aab1b6ef46d1938a9d447fb2fdb6-Corrales, Mark]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]; Hofmann, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44408bf728cd4eb5b81d295816b0c8f1-AHofmann]; Jones, Danielle Y. EOP/OMB [Danielle_Y_Jones@omb.eop.gov]

**Subject**: RE: [Non-DoD Source] FYI: Scopes for Risk Evaluation of First 10 Chemicals under TSCA

TSCA Interagency Policy Group,

To follow up on my previous message, we recognize that this is a very short timeline and appreciate input you're able to provide given the statutory deadlines for publication. Based on feedback from a number of folks, OCSPP has now decided to accept comments until Thursday COB (6/15), and would just ask those agencies intending to submit comments to be available for discussion on or before Friday 6/16 if needed. Again, comments should be directed to Angela Hofmann, director of OCSPP's Regulatory Coordination Staff.

The scope documents for the first 10 chemicals are not as refined or specific as EPA intends future ones to be. Additionally, there was not sufficient time to take public comment on draft documents. For these reasons, EPA will publish and take public comment on a Problem Formulation document which will refine the current scopes, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. The Problem

Formulation documents are expected to be released within approximately 6 months of publication of the scope, and will offer an additional opportunity for this Policy group to engage with OCSPP.

In terms of immediate next steps, OCSPP will work swiftly to incorporate edits and/or resolve issues identified by this group. OCSPP expects to publish the first 10 scope documents and a Federal Register Notice next week. OCSPP will also re-open the existing dockets for the first 10 chemicals to allow for the submission of additional data or information that could be useful to the Agency in conducting problem formulation, the next step in the process of conducting the risk evaluations for these chemicals.

Thanks in advance,
Ryan
(202)564-0610

---

**From:** Underwood, Patricia M CIV (US) [mailto:patricia.m.underwood.civ@mail.mil]
**Sent:** Tuesday, June 13, 2017 3:53 PM
**To:** Schmit, Ryan <schmit.ryan@epa.gov>; Michael_Hickey@[redacted]; James_A._Laity@[redacted] Brenda_Mallory@[redacted] Marna_A_McDermott@[redacted]; Michael_C_Jensen@[redacted]; Sullivan, Maureen SES OSD OUSD ATL (US) <maureen.sullivan18.civ@mail.mil>; Rudroff, James G CIV USN (US) <jim.rudroff@navy.mil>; gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US) <karen.e.colmie.civ@mail.mil>; :mike.a.mcneill@nasa.gov: <mike.a.mcneill@nasa.gov:>; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick <Suzanne.Fitzpatrick@fda.hhs.gov>; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD) <fjh1@cdc.gov>; Jones, Danielle Y. EOP/OMB <[redacted] James_H_Kim@[redacted]; Waqar, Tayyaba <tayyaba.waqar@sba.gov>
**Cc:** Widawsky, David <Widawsky.David@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Symmes, Brian <Symmes.Brian@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Corrales, Mark <Corrales.Mark@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Jones, Danielle Y. EOP/OMB [redacted]
**Subject:** RE: [Non-DoD Source] FYI: Scopes for Risk Evaluation of First 10 Chemicals under TSCA

Ryan,
Thank you for your message. Unfortunately the proposed timeline will not afford DoD with enough time to provide a meaningful review. We are refraining from commenting and will seek to engage at a later date to provide feedback on the scoping for each of the 10 chemicals.

Please provide us with additional information regarding the review process that EPA plans to follow. For example, will these documents be published in the federal register?

Thank you,
Tricia
Patricia Underwood, PhD, DABT, MBA
Deputy for Chemical and Material Risk Management
Office of the Deputy Assistant Secretary of Defense (Energy, Installations & Environment)
ESOH Directorate
4800 Mark Center Drive
Box#56, Suite 17D08
Alexandria, VA 22350
Ph: 703-901-8747
Patricia.m.underwood.civ@mail.mil

---

**From:** Schmit, Ryan [schmit.ryan@epa.gov]
**Sent:** Monday, June 12, 2017 4:32 PM
**To:** Michael_Hickey@[redacted] James_A._Laity@[redacted] Brenda_Mallory@[redacted] Marna_A_McDermott@[redacted]; Michael_C_Jensen@[redacted] Sullivan, Maureen SES OSD OUSD ATL (US); Underwood, Patricia M CIV (US); Rudroff, James G CIV USN (US); gail.m.grafton@nasa.gov; linda.s.wennerberg@nasa.gov; Perry.Bill@dol.gov; Swirsky.Stephanie@dol.gov; Charles.Maresca@sba.gov; Colmie, Karen E CIV OSD OGC (US); :mike.a.mcneill@nasa.gov:; Luciana.borio@fda.hhs.gov; Suzanne_Fitzpatrick; zkz1@cdc.gov; fhearl@cdc.gov; Hearl, Frank J. (CDC/NIOSH/OD); Jones, Danielle Y. EOP/OMB; James_H_Kim@[redacted]; Waqar, Tayyaba
**Cc:** Widawsky, David; Henry, Tala; Symmes, Brian; Beck, Nancy; Morris, Jeff; Blair, Susanna; Wise, Louise; Rodan, Bruce; Corrales, Mark; Doa, Maria; Cleland-Hamnett, Wendy; Hofmann, Angela
**Subject:** [Non-DoD Source] FYI: Scopes for Risk Evaluation of First 10 Chemicals under TSCA

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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TSCA Interagency Policy Group,
FYI, OCSPP is pleased to provide the latest working drafts of the risk evaluation scope documents for the first 10 chemicals under TSCA. OMB will also be sharing these documents with the staff Interagency reviewers who have been engaged on the TSCA Framework rules. Any comments can be directed to Angela Hofmann (hofmann.angela@epa.gov < Caution-mailto:hofmann.angela@epa.gov > no later than COB this Wednesday (6/14)
Thanks,
Ryan

Ryan N. Schmit
Special Assistant
Office of Chemical Safety and Pollution Prevention (OCSPP)
Phone: 202-564-0610
Email: schmit.ryan@epa.gov

Message

**From:** Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent:** 3/8/2018 7:39:42 PM
**To:** Stuart Levenbach [stu.levenbach@noaa.gov]
**CC:** Christopher D. EOP/CEQ Prandoni [ Ex. 6 ] Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**Subject:** Fwd: Here are the NOAA GC/OPR comments on the EPA docket announvement
**Attachments:** Note to Reader for NMFS 2017 BiOp.2.28.18 OPR.docx; ATT00001.htm; Note to Reader for NMFS 2017 BiOp.2.28.18_NOAA GC.docx; ATT00002.htm

Stu,
Has NMFS/NOAA leadership signed off on these?
Thanks,
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
Ex. 6
Beck.Nancy@epa.gov

Begin forwarded message:

**From:** "Keigwin, Richard" <Keigwin.Richard@epa.gov>
**Date:** March 8, 2018 at 2:34:39 PM EST
**To:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Cc:** "Bertrand, Charlotte" <Bertrand.Charlotte@epa.gov>, "Keller, Kaitlin" <keller.kaitlin@epa.gov>, "Echeverria, Marietta" <Echeverria.Marietta@epa.gov>, "Guilaran, Yu-Ting" <Guilaran.Yu-Ting@epa.gov>
**Subject: FW: Here are the NOAA GC/OPR comments on the EPA docket announvement**

We just received these comments from NOAA/NMFS. Please advise regarding how you would like us to proceed.

**From:** Cathy Tortorici - NOAA Federal [mailto:cathy.tortorici@noaa.gov]
**Sent:** Thursday, March 08, 2018 2:33 PM
**To:** Keigwin, Richard <Keigwin.Richard@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>
**Subject:** Here are the NOAA GC/OPR comments on the EPA docket announvement

Dear all -

Our people at NOAA did not realize that they were supposed to send these to you. So my front office asked me to send these comments to you all. These are comments from my Office of Protected Resources and NOAA General Counsel. as well as comments coming from NOAA.

If you can please forward these comments to Nancy Beck I would appreciate it since you said she was leading this document review process.

I would be happy to talk to whomever you want at EPA about these comments.

Thanks so much -

Cathy T.

--

Cathy Tortorici
Chief, ESA Interagency Cooperation Division
Office of Protected Resources
NOAA's National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910
(w) 301.427.8495
Ex. 6
cathy.tortorici@noaa.gov

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 3/5/2018 9:29:32 PM
**To**: Vaden, Stephen - OGC [Stephen.Vaden@ogc.usda.gov]; Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP) EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO Ex. 6 Personal Privacy (PP) todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Domesle, Alexander R. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**CC**: Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]
**Subject**: RE: Notice of public comment for NMFS BiOps

Thank you Stephen!

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

**From:** Vaden, Stephen - OGC [mailto:Stephen.Vaden@ogc.usda.gov]
**Sent:** Monday, March 5, 2018 3:26 PM
**To:** Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP) v>; EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Domesle, Alexander R. EOP/CEQ Ex. 6 Personal Privacy (PP)>
**Cc:** Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>
**Subject:** RE: Notice of public comment for NMFS BiOps

All,

USDA's comments are attached.

Stephen

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Sent:** Friday, March 02, 2018 5:21 PM
**To:** EComstock@doc.gov; stu.levenbach@noaa.gov; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP) Vaden, Stephen - OGC <Stephen.Vaden@ogc.usda.gov>; todd_willens@ios.doi.gov; dwbernhardt@ios.doi.gov; Domesle, Alexander R. EOP/CEQ <Ex. 6 Personal Privacy (PP)
**Cc:** Beck.Nancy@epa.gov; baptist.erik@epa.gov
**Subject:** Notice of public comment for NMFS BiOps

Colleagues - please see Nancy's request below and the attached draft notice of public comment for NMFS's chlorpyrifos, diazinon, and malathion biop. Since this is a short document, let's all get her comments by cob Monday.

Thank you for the quick turnaround.

Chris

Sent from my iPhone

Begin forwarded message:

**From:** "Beck, Nancy" <Beck.Nancy@epa.gov>
**Date:** March 2, 2018 at 4:57:45 PM EST
**To:** "Prandoni, Christopher D. EOP/CEQ ( Ex. 6 Personal Privacy (PP)
Ex. 6 Personal Privacy (PP)
**Cc:** "Baptist, Erik" <Baptist.Erik@epa.gov>
**Subject: Notice of public comment period**

Chris,
Attached is the language for our draft FR notice asking for public comments on the BiOps.
Can you please share with the working group—I don't seem to have a good email list of everyone.
Its fine if you want to have them send any comments/suggestions directly to me.
Of course a quick turnaround is appreciated.

Many thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

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Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 1/29/2018 10:09:00 PM
**To**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**CC**: Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Kevin Wheeler - NOAA Federal [kevin.wheeler@noaa.gov]; Brandon Elsner - NOAA Federal [brandon.elsner@noaa.gov]
**Subject**: Re: Call today or tomorrow am?

What time will this call be? 7:30?
And I presume no more than 15 min?
Thanks.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Jan 29, 2018, at 5:06 PM, Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP) > wrote:

Fine with me. Let's use this info:

Participant Dial-In: Ex. 6 Personal Privacy (PP)

Participant Code: Ex. 6 Personal Privacy (PP)

Sent from my iPhone

On Jan 29, 2018, at 4:53 PM, Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov> wrote:

Can we do an evening call? I'm booked through 7:30 PM.

---

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Sent:** Monday, January 29, 2018 4:34 PM
**To:** Beck, Nancy
**Cc:** Stu Levenbach - NOAA Federal; Moran, John S. EOP/WHO; Baptist, Erik
**Subject:** Re: Call today or tomorrow am?

I can be available whenever.

Sent from my iPhone

On Jan 29, 2018, at 4:24 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

My preference is for today so we can move this.
Thanks.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

**From:** Prandoni, Christopher D. EOP/CEQ Ex. 6 Personal Privacy (PP)
**Sent:** Monday, January 29, 2018 4:08 PM
**To:** Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)
**Subject:** Call today or tomorrow am?

Hey Nancy,

Are you available to chat with Stu, John, and me today or tomorrow about the draft letter?

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
Ex. 6
www.whitehouse.gov/ceq

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 1/29/2018 9:11:05 PM
**To**: Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)]; Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]; Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)
**Subject**: RE: Call today or tomorrow am?

Yes. I'm in an all day meeting til 7 but can step out. Just let me know what time works. Perhaps 5:15, but I can be flexible.

---

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

**From:** Prandoni, Christopher D. EOP/CEQ [Ex. 6 Personal Privacy (PP)
**Sent:** Monday, January 29, 2018 4:08 PM
**To:** Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>
**Subject:** Call today or tomorrow am?

Hey Nancy,

Are you available to chat with Stu, John, and me today or tomorrow about the draft letter?

Chris Prandoni
Associate Director for Natural Resources
Council on Environmental Quality
Ex. 6 Personal Privacy (PP)
www.whitehouse.gov/ceq

Message

**From**: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent**: 2/1/2018 3:42:05 PM
**To**: Prandoni, Christopher D. EOP/CEQ (Ex. 6 [(Ex. 6 Moran, John S. EOP/WHO Ex. 6 Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]; Comstock, Earl (Federal) [ecomstock@doc.gov]
**CC**: Erik Baptist (baptist.erik@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Justin Schwab (schwab.justin@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]
**Subject**: draft letter
**Attachments**: NMFS_reinitiation_letter2.1.18DRAFT.docx

Based on the discussions, attached is a revised draft letter. Please send us any comments or suggestions by 6pm today or reach out to me if you have questions.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
Ex. 6
beck.nancy@epa.gov

Message

**From:** Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent:** 3/28/2018 3:08:41 PM
**To:** Stuart Levenbach - NOAA Federal [stuart.levenbach@noaa.gov]
**Subject:** Re: as discussed

Sounds good. thanks Stu and enjoy vacation!

---

Nancy B. Beck, Ph.D. DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Mar 28, 2018, at 11:03 AM, Stuart Levenbach - NOAA Federal <stuart.levenbach@noaa.gov> wrote:

I have an internal meeting scheduled 4/4 with staff to discuss. Several people on leave (including me) this week so we couldn't land it earlier.

Nancy, I will give you a call after the meeting.

On Wed, Mar 28, 2018 at 10:12 AM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:
On Monday he was still coordinating with staff. I'm looping him in here in case there is an update.

---

Nancy B. Beck, Ph.D. DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Mar 28, 2018, at 10:09 AM, Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)> wrote:

How did this conversation go?

---

**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]
**Sent:** Thursday, March 22, 2018 12:22 PM
**To:** Baptist, Erik <Baptist.Erik@epa.gov>; Prandoni, Christopher D. EOP/CEQ <Ex. 6 Personal Privacy (PP)
**Subject:** RE: as discussed

I was planning to check in with Stuart tomorrow. He did acknowledge receipt and that he was sharing internally..

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
beck.nancy@epa.gov

**From:** Baptist, Erik
**Sent:** Thursday, March 22, 2018 12:19 PM
**To:** Beck, Nancy <Beck.Nancy@epa.gov>; Prandoni, Christopher D. EOP/CEQ
Ex. 6 Personal Privacy (PP)
**Subject:** RE: as discussed

Seeing that it was sent March 19, perhaps we should convene a call/meeting next week to see what more NOAA needs and/or determine what their timing is?

**Erik Baptist**
Senior Deputy General Counsel
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

**From:** Beck, Nancy
**Sent:** Thursday, March 22, 2018 12:16 PM
**To:** Baptist, Erik <Baptist.Erik@epa.gov>; Prandoni, Christopher D. EOP/CEQ
Ex. 6 Personal Privacy (PP)
**Subject:** FW: as discussed

FYI—our proposed timeline has been shared with NOAA.

**From:** Beck, Nancy
**Sent:** Monday, March 19, 2018 5:59 PM
**To:** 'Stuart Levenbach - NOAA Federal' <stuart.levenbach@noaa.gov>
**Subject:** FW: as discussed

2nd time a charm!

**From:** Beck, Nancy
**Sent:** Monday, March 19, 2018 5:58 PM
**To:** 'Levenbach, Stuart . EOP/OMB' < Ex. 6 Personal Privacy (PP)
**Subject:** as discussed

Stu,

See attached. Happy to discuss.

Thanks,
Nancy

**********

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

Message

**From:** Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
**Sent:** 1/13/2018 5:33:38 PM
**To:** Stu Levenbach - NOAA Federal [stu.levenbach@noaa.gov]
**Subject:** Re: NMFS letter to EPA

Ok. Just call my cell Ex. 6 Personal Privacy (PP) I'm around.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Jan 13, 2018, at 12:22 PM, Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov> wrote:

Have to run an errand in 30 minutes. That's a good time for me to call. Thanks

On Sat, Jan 13, 2018 at 10:26 AM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

I'm around all weekend. Let me know a good time to chat.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: Ex. 6 Personal Privacy (PP)
Beck.Nancy@epa.gov

On Jan 13, 2018, at 9:41 AM, Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov> wrote:

Nancy-

We are preparing the memo for Secretary Ross. Would like it to be constructive a conversation as possible. Could you share with us any specific topics / requests?

As an aside, my after-hours personal cell is Ex. 6 Personal Privacy (PP)

Stu

On Fri, Jan 12, 2018 at 4:17 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Yes. It addresses timelines for RPAs but not the RPMs (which are more critical).

Thanks.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

**From:** Brandon Elsner - NOAA Federal [mailto:brandon.elsner@noaa.gov]
**Sent:** Friday, January 12, 2018 2:32 PM
**To:** Ex. 6 Personal Privacy (PP) Beck, Nancy <Beck.Nancy@epa.gov>
**Cc:** Kevin Wheeler - NOAA Federal <kevin.wheeler@noaa.gov>; Stu Levenbach - NOAA Federal <stu.levenbach@noaa.gov>
**Subject:** NMFS letter to EPA

Chris and Nancy,

We wanted to make sure you were aware of this letter from NOAA's NMFS to EPA dated January 10,2018. If you have any questions my number is Ex. 6 Personal Privacy (PP)

Thanks,

Brandon

Message

**From**: Oberg, Elizabeth A. EOP/WHO Ex. 6
**Sent**: 11/21/2017 2:22:19 PM
**To**: Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Jack Oberg Ex. 6
**Subject**: RE: RSVP for the Holiday Open House

Wanted to make sure you all filled this out ☺

This is just a friendly reminder.

---

**From:** Oberg, Elizabeth A. EOP/WHO
**Sent:** Thursday, November 16, 2017 9:33 AM
**To:** 'Abboud, Michael' <abboud.michael@epa.gov>; Jack Oberg < Ex. 6
'r Ex. 6
**Subject:** FW: RSVP for the Holiday Open House

Yo! Use the GUEST RSVP (highlighted in YELLOW) link to fill out just your information AS IT APPEARS ON YOUR LICENSE.

Don't mess this up haha its gonna be a nightmare to have the social office fix anything because they are SO swamped during the holidays.

Liz

---

**From:** The White House [mailto:noreply@whitehouse.gov]
**Sent:** Thursday, November 16, 2017 9:22 AM
**To:** Oberg, Elizabeth A. EOP/WHO Ex. 6
**Subject:** RSVP for the Holiday Open House

Dear Elizabeth Oberg,

We are delighted you will be joining us for the Holiday Open House on December 4 2017 - 7:30 PM! Please use the two links below to RSVP.

Ex. 6

If you have any additional questions please reach out to Ex. 6

Ex. 6

Thank you,

The White House Visitors Office

Message

**From**: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60D0C681A16441A0B4FA16AA2DD4B9C5-BLOCK, MOLL]
**Sent**: 8/2/2018 3:47:00 PM
**To**: Whieldon, Esther [Esther.Whieldon@spglobal.com]; Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b293283291dc44e0b5d1c36be9281d8a-Press]; NHTSAmedia@dot.gov
**Subject**: RE: EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

Esther –

The call was this morning at 9:00 AM. I'm sorry you never received the call in info. I will send you a recording of the pen and pad when we receive it.

---

**From:** Whieldon, Esther [mailto:Esther.Whieldon@spglobal.com]
**Sent:** Thursday, August 2, 2018 8:54 AM
**To:** Press <Press@epa.gov>; NHTSAmedia@dot.gov
**Subject:** Re: EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

I have yet to receive the call-in information. Kindly send it asap. Thanks, Esther

---

**From:** Whieldon, Esther
**Sent:** Thursday, August 2, 2018 8:29:55 AM
**To:** press@epa.gov; NHTSAmedia@dot.gov
**Subject:** Re: EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

Please send me the dial in information. Thanks, Esther

Esther Whieldon
Senior reporter on climate, energy and ESG
T: 571-814-2085
Ex. 6
S&P Global Market Intelligence
1700 North Moore Street, Suite 1110
Arlington, VA 22209
Esther.Whieldon@spglobal.com

We're News, not Ratings:

https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/index

From: EPA Press Office
Sent: Thursday, August 2, 7:36 AM
Subject: EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles
To: Whieldon, Esther

EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

WASHINGTON

(August 2, 2018) — Today, August 2, at 9:00 A.M. ET, officials from the Environmental Protection Agency and U.S. Department of Transportation will host a pen and pad conference call to discuss proposed national fuel economy standards for MY 2021-2026 vehicles.

WHAT:

Pen and pad press conference call to discuss proposed national fuel economy standards for MY 2021-2026 vehicles.

WHO:

Bill Wehrum, EPA Assistant Administrator

WHO:

Heidi King, NHTSA Deputy Administrator

DATE:

Thursday, August 2, 2018

TIME:

9:00-9:30 A.M. ET

To participate, please RSVP to

NHTSAmedia@dot.gov

. You will be provided the dial-in number at that time.

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Washington, D.C. 20004

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Message

**From:** jc.rodriguez@law360.com [jc.rodriguez@law360.com]
**Sent:** 8/2/2018 12:07:46 PM
**To:** NHTSAmedia@dot.gov; Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b293283291dc44e0b5d1c36be9281d8a-Press]
**Subject:** Re: EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

Hello, my name is Juan Carlos Rodriguez and I'm a reporter at Law360. I am RSVPing for the conference call, can you please send me the details? Thank you.

On Thu, Aug 2, 2018 at 7:36 AM, EPA Press Office <press@epa.gov> wrote:

## EPA and U.S. DOT NHTSA Officials Host Pen and Pad Conference Call on New Fuel Economy Standards for MY 2021-2026 Vehicles

**WASHINGTON** (August 2, 2018) — Today, August 2, at 9:00 A.M. ET, officials from the Environmental Protection Agency and U.S. Department of Transportation will host a pen and pad conference call to discuss proposed national fuel economy standards for MY 2021-2026 vehicles.

**WHAT**: Pen and pad press conference call to discuss proposed national fuel economy standards for MY 2021-2026 vehicles.

**WHO**: Bill Wehrum, EPA Assistant Administrator
Heidi King, NHTSA Deputy Administrator

**DATE**: Thursday, August 2, 2018

**TIME**: 9:00-9:30 A.M. ET

To participate, please RSVP to NHTSAmedia@dot.gov. You will be provided the dial-in number at that time.

**Visit The EPA's Newsroom**

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

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--
Juan Carlos Rodriguez
Senior Environment Reporter

Legal News & Data
111 West 19th Street
5th Floor
New York, NY 10011
Office: 646-783-7197

Ex. 6

Follow me on Twitter

Follow Law360 on Twitter

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 12/4/2017 8:40:27 PM
**To**: Ex. 6
**Subject**: FW: Holiday Open House Boarding Pass

---

**From:** Oberg, Elizabeth A. EOP/WHO Ex. 6
**Sent:** Monday, December 4, 2017 3:37 PM
**To:** Abboud, Michael <abboud.michael@epa.gov>
**Subject:** Fwd: Holiday Open House Boarding Pass

Send this to Megh. Just hit my inbox

They said to share this w my guests!

Sent from my iPhone

Begin forwarded message:

> **From:** "The White House" <no-reply@whitehouse.gov>
> **Date:** December 4, 2017 at 3:35:45 PM EST
> **To:** < Ex. 6
> **Subject: Holiday Open House Boarding Pass**
> **Reply-To:** "White House - Executive Office of the President" < Ex. 6
> Ex. 6

We are delighted you will be joining us for the Holiday Open House on 12/4/2017 7:30:00 PM! Please click here for your boarding pass. Please share your boarding pass with your guests.

Groups should enter the White House complex at the corner of **15th Street and Alexander Hamilton Place.** Volunteers are posted to direct groups as they arrive. Groups should arrive **15 minutes before their scheduled tour time**. Late arrivals may not be accommodated.

Groups who arrive for a tour should **not** bring:

- Video cameras, including any action camcorders, cameras with detachable lenses, tablets, tripods, monopods, and camera sticks.
- Handbags, book bags, backpacks or purses
- Food or beverages, tobacco products, personal grooming items (i.e. makeup, lotion, etc.)
- Strollers
- Any pointed objects
- Aerosol containers
- Guns, ammunition, fireworks, electric stun guns, mace, martial arts weapons/devices, or knives of any size

There are no storage facilities available at the White House to check a bag or a prohibited item. If it is raining, umbrellas are permitted. Cameras, cell phones, and cell phones with cameras are allowed, however there is no talking or texting on your phone inside the White House.

All guests 18 years of age or older will need to present **a valid, government-issued photo I.D.** with information matching the name previously submitted for clearance. Individuals without acceptable identification or whose identification does not exactly match the name or data cleared for entry may be denied entry. All guests under age 18 must be accompanied by an adult.

Acceptable forms of ID include:

- Valid Government-issued United States drivers license
- Valid Government-issued United States identification card
- Valid United States or other official government-issued passports
- Valid United States State Department ID
- For foreign nationals, only VALID passports are accepted
- All foreign nationals must present ID, regardless of age. No foreign-issued state IDs, foreign-issued driver's licenses, expired passports, or other forms of identification will be accepted.

Holiday Open Houses are self-guided, however United States Secret Service officers are posted in every room to provide historical information about the room and the White House. Please feel free to ask them questions.

White House tours are subject to last minute cancellation. Please call

Ex. 6

On behalf of President and Mrs. Trump, we hope that your group enjoys their visit to the White House.

Thank you,

White House Visitors Office

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 11/24/2017 8:55:23 PM
**To**: Ex. 6
**Subject**: Fwd: DUE TODAY

Sent from my iPhone

Begin forwarded message:

**From:** "Oberg, Elizabeth A. EOP/WHO" Ex. 6
**Date:** November 24, 2017 at 9:56:05 AM EST
**To:** "Abboud, Michael" <abboud.michael@epa.gov>
**Subject: DUE TODAY**

11/28/2017 1:00 PM

Ex. 6

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 11/24/2017 5:22:14 PM
**To**: Ex. 6
**Subject**: Fwd: DUE TODAY

Fill out the link below. It's due today. It's just information as it appears on your drivers license. Text me if you have any questions. I would have Neal fill it out to just in case he can come.

Sent from my iPhone

Begin forwarded message:

**From:** "Oberg, Elizabeth A. EOP/WHC Ex. 6
**Date:** November 24, 2017 at 8:56:05 AM CST
**To:** "Abboud, Michael" <abboud.michael@epa.gov>
**Subject: DUE TODAY**

11/28/2017 1:00 PM

Ex. 6

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 7/11/2018 2:58:08 PM
**To**: Ex. 6
**Subject**: FW: Great meeting you

---

**From:** Plans, Barry (OST) [mailto:barry.plans@dot.gov]
**Sent:** Monday, January 29, 2018 11:39 AM
**To:** Abboud, Michael <abboud.michael@epa.gov>
**Subject:** RE: Great meeting you

Yes Michael, Ex. 6 Let's stay in touch. Barry

**Barry Plans**
**Senior Advisor**
**Office Of The Secretary**
**W81-308**
**U.S. Department of Transportation**
**1200 New Jersey Ave. SE**
**Washington, DC 20590**
Barry.Plans@dot.gov
Ex. 6

---

**From:** Abboud, Michael [mailto:abboud.michael@epa.gov]
**Sent:** Monday, January 29, 2018 11:00 AM
**To:** Plans, Barry (OST) <barry.plans@dot.gov>
**Subject:** Great meeting you

Barry great to meet you Saturday, always a blast when Healy's involved! Wanted to drop you a note with my contact info and stay in touch.

Michael Abboud
U.S. Environmental Protection Agency
Press Secretary
Ex. 6

Message

**From:** Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent:** 7/11/2018 2:53:49 PM
**To:** Ex. 6 Personal Privacy (PP)
**Subject:** FW: Farewell Friends

---

**From:** Ross, Tyler E. EOP/WHO [Ex. 6]
**Sent:** Wednesday, March 14, 2018 4:03 PM
**To:** Ross, Tyler E. EOP/WHO <Ex. 6 Personal Privacy (PP)>
**Cc:** Anderson, Alexander J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Gunn, Ashley L. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Giuliani, Andrew H. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Munisteri, Stephen P. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Chalkey, Richard J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Clifton, Patrick A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Georges, Liza B. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Curry, Cat E. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Morgen, Hunter M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Walsh, Brian K. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Sewell, Jack B. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Jack, Brian T. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Henson, Clayton T. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Leighton, Rosalyn A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; O'Connell, James M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Trainer, Nick A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Smith, Ja'Ron K. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Zadrozny, John A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Salvi, Mary E. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Zager, Samantha L. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Wilkins, Catherine E. EOP/WHO <Ex. 6 Personal Privacy (PP)> Goad, Robert T. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Doocey, Sean E. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Campau, Alexandra P. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Lyons, Derek S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Clift, McKenzie C. EOP/OVP <Ex. 6 Personal Privacy (PP)>; Potter, Caroline J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Pritchard, Bethany L. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Hudson, Bethany B. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Paranzino, Anthony M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; 'abboud.michael@epa.gov'; 'jason.chung@treasury.gov'; 'Roma.Daravi@sba.gov'; 'alex_hinson@ios.doi.gov'; Baitel, Rachael EOP/WHO <Ex. 6 Personal Privacy (PP)>; Gabriel, Robert EOP/WHO <Ex. 6 Personal Privacy (PP)>; Smith, Steven M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Riggs, Charlotte R. EOP/WHO <Ex. 6 Personal Privacy (PP)>; McCann, Meghan B. EOP/WHO <Ex. 6 Personal Privacy (PP)> Koenig, Andrew D. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Goyer, Jim L. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Dearborn, Rick A. EOP/OVP <Ex. 6 Personal Privacy (PP)>; Freeland, Jeff K. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Grove, Sara E. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Mahfouz, Michael D. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Galkowski, James J. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Fields, Tyler T. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Bucci, Kristine A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Braid, Duncan M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Callaghan, Christine B. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Veletsis, Alexandra E. EOP/WHO <Ex. 6 Personal Privacy (PP)>; MacDonnell, Patrick P. EOP/WHO <Ex. 6 Personal Privacy (PP)>; El-Fakir, Alexander T. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Sant, Richard B. EOP/OVP <Ex. 6 Personal Privacy (PP)>; Parker, Nathaniel A. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Brian.Morgenstern@treasury.gov; Garcia, Chris (Federal <CGarcia@mbda.gov>; Cytryn, Jen B. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Wall, Kathryn E. EOP/OVP <Ex. 6 Personal Privacy (PP)> Roscoe, John M. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Gray, Christopher S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Hoelscher, Douglas L. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Kirkland, William H. EOP/WHO <Ex. 6 Personal Privacy (PP)> Castillo, Hannah J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Swift, Heather <heather_swift@ios.doi.gov>; Laura Rigas <laura_rigas@ios.doi.gov>;

Flynn, Matthew J. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Doyle, Emma K. EOP/OMB < Ex. 6 Personal Privacy (PP) >; Hanlon, Daniel EOP/OMB < Ex. 6 Personal Privacy (PP) >; Westerhout, Madeleine E. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Jarmula, Ryan L. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Joannou, Tom W. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Cabaniss, Anna Katherine K. EOP/WHO Ex. 6 Personal Privacy (PP) ; Cole, Catherine A. EOP/WHO < Ex. 6 Personal Privacy (PP) >; Sant, Richard B. EOP/OVP Ex. 6 Personal Privacy (PP) ; Ferrer Piran Basualdo, Austin G. EOP/WHO < Ex. 6 Personal Privacy (PP) >; alex_hinson@ios.doi.gov; Spencer, Noelle N. EOP/OVP Ex. 6 Personal Privacy (PP) ; Cabaniss, Anna Katherine K. EOP/WHO Ex. 6 Personal Privacy (PP) Purucker, Katherine M. EOP/OVP < Ex. 6 Personal Privacy (PP) >; Peede, Bobby L. EOP/WHO Ex. 6 Personal Privacy (PP)
**Subject:** Farewell Friends

To my friends and colleagues,

Today will be my last day with the White House team. This has been the greatest honor of my life and working with you all has made the experience all the more extraordinary.

I am grateful for the relationships I have built with many of you. I hope to stay in touch in the future, and I look forward to contributing to the President's agenda from the outside and as we approach 2020.

My personal contact info is below:
Ex. 6 Personal Privacy (PP)

Ex. 6

Best wishes to everyone and I look forward to seeing you around this great city of ours!

Best,

Tyler Ross

***I know I have inadvertently left some off this email. Please feel free to forward my information to them.

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 7/11/2018 2:51:08 PM
**To**: Ex. 6 Personal Privacy (PP)
**Subject**: FW: Great meeting you

---

**From:** Ehrsam, Lauren E. EOP/NSC [mailto Ex. 6 Personal Privacy (PP)
**Sent:** Tuesday, July 10, 2018 3:20 PM
**To:** Abboud, Michael <abboud.michael@epa.gov>
**Subject:** RE: Great meeting you

It was great to meet you, too! Def let me know when you're coming by.

---

**From:** Abboud, Michael <abboud.michael@epa.gov>
**Sent:** Tuesday, July 10, 2018 10:09 AM
**To:** Ehrsam, Lauren E. EOP/NSC < Ex. 6 Personal Privacy (PP)
**Subject:** Great meeting you

Lauren-

Great meeting you last night! Wanted to drop you a line to stay in touch. Hopefully I'll see you around the EEOB soon!

**Michael Abboud**
U.S. Environmental Protection Agency
Office of Public Affairs
M: Ex. 6 Personal Privacy (PP)

Message

**From**: Carol Lee Rawn [rawn@ceres.org]
**Sent**: 3/15/2018 4:05:08 PM
**To**: Pruitt, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=757bedfd70ca4219b6d8046f5ce5681e-Pruitt, Sco]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
**CC**: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; heidi.king@dot.gov; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Michael.J.Catanzaro@[redacted] Ex. 6
**Subject**: Company letter re. National Program and s. 177 states
**Attachments**: March 15 S177 Letter .pdf

Dear Administrator Pruitt,

Attached please find a letter from a network of 47 major employers across the country expressing support for the current National Program due to its significant economic and environmental benefits, and opposition to any efforts to undermine states' rights to realize those benefits. Thank you for your consideration.

Sincerely,
Carol Lee Rawn

Carol Lee Rawn
Director, Transportation Program
Ceres
99 Chauncy Street
Boston, MA 02111-1703
(W) 617-247-0700, 104 (please note that my extension has changed)
(M) [redacted] Ex. 6
rawn@ceres.org
www.ceres.org

Message

**From**: Clarke, Jeff [jclarke@ngvamerica.org]
**Sent**: 5/30/2018 6:52:55 PM
**To**: elaine.l.chao@dot.gov; Pruitt, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=757bedfd70ca4219b6d8046f5ce5681e-Pruitt, Sco]
**CC**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Loren.Smith@dot.gov
**Subject**: Mid-term Evaluation Determination
**Attachments**: NGVA MTE Letter 5 30 2018 Final.pdf

Please accept the attached comments in regards to the Mid-Term Evaluation and any future proposed regulations.

If there are any questions about this communication please contact me.

Sincerely,

Jeff Clarke
General Counsel & Director, Regulatory Affairs
NGVAmerica
400 N. Capitol St. NW, Washington, D.C. 20001
202.824.7364 [o] | Ex. 6 [m]
ngvamerica.org; ngv.com

**********

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Message

**From:** Brooke, Francis J. EOP/WHO Ex. 6
**Sent:** 8/2/2018 7:15:43 PM
**To:** David Schwietert [DSchwietert@autoalliance.org]; Jeffrey A. Rosen (Jeff.rosen@dot.gov) [Jeff.rosen@dot.gov]; heidi.king@dot.gov; Geoff.burr@dot.gov; Wheeler, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17a1669ef5b54fba8cb457845308787e-Wheeler, An]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
**CC:** Mitch Bainwol [MBainwol@autoalliance.org]; John Bozzella [jbozzella@globalautomakers.org]
**Subject:** RE: Joint letter to President Trump on from Auto Alliance and Global Automakers

Great, thanks Dave.

Best,

Francis

---

**From:** David Schwietert <DSchwietert@autoalliance.org>
**Sent:** Thursday, August 2, 2018 2:17 PM
**To:** Brooke, Francis J. EOP/WHO < Ex. 6 ; Jeffrey A. Rosen (Jeff.rosen@dot.gov) <Jeff.rosen@dot.gov>; heidi.king@dot.gov; Geoff.burr@dot.gov; Andrew Wheeler (wheeler.andrew@epa.gov) <wheeler.andrew@epa.gov>; 'wehrum.william@epa.gov' <wehrum.william@epa.gov>; 'Jackson, Ryan' <jackson.ryan@epa.gov>
**Cc:** Mitch Bainwol <MBainwol@autoalliance.org>; John Bozzella <jbozzella@globalautomakers.org>
**Subject:** [EXTERNAL] Joint letter to President Trump on from Auto Alliance and Global Automakers
**Importance:** High

Francis,

Following the joint NPRM that was released earlier today by DOT and EPA, I wanted to transmit the joint auto association letter that I mentioned we would be sending to the President, as well as a related letter to Governor Brown in California.

As I noted after yesterday's trade roundtable discussion, these letters are intended to reiterate the importance of maintaining One National Program via a negotiated agreement between the federal government and California. We know the true work now begins following the release of the NPRM and various proposals for public comment.

I have also included senior DOT and EPA officials and staff on this email, similar to my outreach yesterday concerning our statement regarding the NPRM announcement.

Please let us know if you have any questions.

Dave

**Joint Auto Alliance and Global Automakers Statement regarding the Joint NPRM:**

*Today DOT and EPA jointly released their proposed rule for future vehicle efficiency standards to seek consideration of and comments on a range of scenarios. This is the process included as part of the 2012 joint rulemaking between the federal government and California to ensure fuel economy standards are based on the best available data and reflect marketplace realities, and we will be offering feedback during the comment period.*

***Today, the Auto Alliance and Global Automakers release this statement:***

**"We applaud the President and the Administration for releasing this much anticipated proposal that includes a variety of standards for public consideration. Automakers support continued improvements in fuel economy and flexibilities that incentivize advanced technologies while balancing priorities like affordability, safety, jobs, and the environment. With today's release of the Administration's proposals, it's time for substantive negotiations to begin. We urge California and the federal government to find a common sense solution that sets continued increases in vehicle efficiency standards while also meeting the needs of America's drivers."**

David Schwietert
Executive Vice President, Federal Government Relations & Public Policy
P: 202-326-5521 | dschwietert@autoalliance.org

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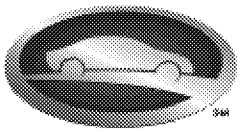

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803 7th Street, NW
Suite 300
Washington, DC 20001
Main Phone: 202-326-5500
Main Fax: 202-326-5567

>https://autoalliance.org/<

*Curious to know how the Auto sector impacts your state or district -- Click here. To get a better understanding of how America's automobile industry is one of the most powerful engines driving the U.S. economy, click here.*

Message

**From:** Alice Henderson [ahenderson@edf.org]
**Sent:** 3/25/2018 4:48:09 AM
**To:** Mabel_E._Echols [Ex. 6]
**CC:** Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; heidi.king@dot.gov; Lieske, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c836c7dea7054dd8807120a1d401cac8-Lieske, Christopher]; Ann Mesnikoff [AMesnikoff@elpc.org]; mpage@citizen.org
**Subject:** Request for Meeting on EPA Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards (RIN: 2060-AT77)

March 24, 2018

Neomi Rao
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue NW
Washington, D.C. 20503

Dear Administrator Rao:

The Environmental Defense Fund (EDF), the Environmental Law & Policy Center, and Public Citizen respectfully request a meeting with you or the appropriate OIRA personnel pursuant to Executive Order 12,866, regarding the Environmental Protection Agency's Notice, *Reconsideration of Final Determination: Mid Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light Duty Vehicles* (RIN: 2060-AT77).

The OIRA website indicates EPA's Notice was received on March 23rd. Because of the potential for EPA to issue the Notice within the next week or soon thereafter, we respectfully request an immediate meeting at the earliest possible time. We are available to meet as soon as Monday, March 26th – or any day during the week of March 26th through March 30th. This is a matter of vital importance to public health and the environment, and it is essential that we have an opportunity to meet with OIRA.

I can be reached at ahenderson@edf.org or (303) 447-7205 to schedule a meeting.

Thank you for your attention to this important issue.

Best regards,
Alice Henderson

**Alice Henderson**
Attorney, U.S. Clean Air

**Environmental Defense Fund**
2060 Broadway, Suite 300
Boulder, CO 80302
T 303 447 7205
C [Ex. 6]
**ahenderson@edf.org**
**edf.org**

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Appointment

**From**: Delahoyde, Magdelana A. EOP/WHO [Ex. 6]
**Sent**: 11/30/2017 2:27:34 PM
**To**: Owens, James (OST) [James.Owens@dot.gov]; Harris, Jeffrey M. EOP/OMB [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Szabo, Aaron L. EOP/CEQ [Ex. 6]; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; mharrington@NADA.org; dgreenhaus@nada.org [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5db3b616db3405bbc0bcaf0d8053dea-dgreenhaus@nada.org]; akoblenz@nada.org

**Subject**: Canceled: Meeting to discuss [Deliberative Process / Ex. 5]
**Location**: Cordell Hull, EEOB 208 (WAVES link in calendar notes)

**Start**: 11/30/2017 4:00:00 PM
**End**: 11/30/2017 5:00:00 PM
**Show Time As**: Free

**Importance**: High

**Recurrence**: (none)

This meeting is being rescheduled for next week. Sorry for confusion!

Maggie

Message

**From**: Catanzaro, Michael J. EOP/WHO Ex. 6
**Sent**: 1/22/2018 2:22:33 PM
**To**: Stem, Anthony W. EOP/WHO (Intern) Ex. 6; heidi.king@dot.gov; jimmi.nassar@dot.gov; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]; shannon.stewart@arb.ca.gov; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**CC**: Eisner-Poor, Kaitlyn E. EOP/WHO Ex. 6
**Subject**: RE: CAFE Meeting with California ARB (WAVES Link and Phone Info in Calendar Notes)

All, please fill out this WAVES form to get into the EEOB.

Ex. 7(C)

-----Original Appointment-----
**From:** Stem, Anthony W. EOP/WHO (Intern)
**Sent:** Thursday, January 18, 2018 4:52 PM
**To:** Stem, Anthony W. EOP/WHO (Intern); Catanzaro, Michael J. EOP/WHO; heidi.king@dot.gov; jimmi.nassar@dot.gov; Wehrum.bill@epa.gov; Lewis.Josh@epa.gov; dominguez.alexander@epa.gov; shannon.stewart@arb.ca.gov; Gunasekara.Mandy@epa.gov
**Subject:** CAFE Meeting with California ARB (WAVES Link and Phone Info in Calendar Notes)
**When:** Monday, January 22, 2018 9:15 AM-10:15 AM (UTC-05:00) Eastern Time (US & Canada).
**Where:** EEOB 230A

Ex. 7(C)

Host Dial-In: Ex. 6
Leader Code: Ex. 6
Participant Dial-In: Ex. 6
Participant Code: Ex. 6

Message

**From**: Delahoyde, Magdelana A. EOP/WHO Ex. 6
**Sent**: 11/29/2017 8:36:08 PM
**To**: Moran, John S. EOP/WHO Ex. 6
**CC**: Owens, James (OST) [James.Owens@dot.gov]; Harris, Jeffrey M. EOP/OMB Ex. 6 Palmieri, Rosario A. EOP/OMB Ex. 6 Neumayr, Mary B. EOP/CEQ Ex. 6; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Szabo, Aaron L. EOP/CEQ Ex. 6; Catanzaro, Michael J. EOP/WHO Ex. 6; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; mharrington@NADA.org; dgreenhaus@nada.org [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5db3b616db3405bbc0bcaf0d8053dea-dgreenhaus@nada.org]; akoblenz@nada.org
**Subject**: RE: Meeting to discuss Deliberative Process / Ex. 5

We're actually going to reschedule this for next week. I'm hoping for 4:00pm on Thursday, December 7th.

If anyone has an unresolvable **conflict**, please let me know ASAP!

Sorry for all the emails, and thank you!!
Maggie

---

**From:** Moran, John S. EOP/WHO
**Sent:** Wednesday, November 29, 2017 3:25 PM
**To:** Delahoyde, Magdelana A. EOP/WHO <Ex. 6>
**Cc:** Owens, James (OST) <James.Owens@dot.gov>; Harris, Jeffrey M. EOP/OMB <Ex. 6>; Palmieri, Rosario A. EOP/OMB <Ex. 6>; Neumayr, Mary B. EOP/CEQ <Ex. 6>; dravis.samantha@epa.gov; bolen.brittany@epa.gov; Gunasekara.mandy@epa.gov; baptist.erik@epa.gov; Szabo, Aaron L. EOP/CEQ <Ex. 6>; Catanzaro, Michael J. EOP/WHO <Ex. 6>; wehrum.william@epa.gov; mharrington@NADA.org; Greenhaus, Doug <DGREENHAUS@NADA.org>; akoblenz@nada.org
**Subject:** Re: Meeting to discuss Deliberative Process / Ex. 5

I have a conflict at 10:30 that may affect others as well.

John S. Moran
Associate Counsel to the President
Ex. 6 (w)
(c)

On Nov 29, 2017, at 2:26 PM, Delahoyde, Magdelana A. EOP/WHO <Ex. 6> wrote:

Hi All,

We've had a scheduling conflict come up for the Deliberative Process / Ex. 5 meeting at 11am tomorrow morning.

The new time will be 10:30am on Friday morning, but wanted to double check that works for everyone before I sent the update. A conference call line can be set up as well.

Does 10:30am work on Friday morning? Please let me know!

Maggie

Message

**From**: Toni Vigil [tvigil@westgov.org]
on behalf of James Ogsbury [jogsbury@westgov.org]
**Sent**: 11/28/2017 6:53:30 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Bowles, Jack [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78e63acc248f41328768db82d95464c3-JBOWLES]; Hoelscher, Douglas L. EOP/WHO [redacted] Ex. 6
**Subject**: Congratulations from WGA
**Attachments**: EPA Wehrum Congratulations FINAL.pdf

Dear Assistant Administrator Wehrum:

Attached please find a letter, on behalf of Western Governors, to congratulate you on your position with the Administration. WGA is deeply interested in, and has adopted policies regarding, activities within the jurisdiction of your agency. We look forward to introducing you to those policies and working together to achieve their realization.

If you have any questions or require further information, please do not hesitate to contact me. In the meantime, with warm regards and best wishes, I am

Respectfully,

James D. Ogsbury
Executive Director
Ph: 303-623-9378

Message

**From:** Achanta, Chandana L. EOP/OMB Ex. 6
**Sent:** 4/6/2018 8:43:18 PM
**To:** Jeffrey.Wood@usdoj.gov; Jonathan.Brightbill@usdoj.gov; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
**CC:** Theroux, Rich P. EOP/OMB Ex. 6 Laity, Jim A. EOP/OMB Ex. 6 ; Palmieri, Rosario A. EOP/OMB Ex. 6 Whiteman, Chad S. EOP/OMB Ex. 6
**Subject:** for your review: Initial Drafts of CAFE NPRM and RIA
**Attachments:**

Deliberative Process / Ex. 5

Hello All

Deliberative Process / Ex. 5

Thanks!

Chandana

**Ex. 6**

Appointment

**From**: kara.fischer@dot.gov [kara.fischer@dot.gov]
**Sent**: 12/21/2017 7:41:11 PM
**To**: Wood, Steve (NHTSA) [Steve.Wood@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Barnard, Brian (NHTSA) [brian.barnard@dot.gov]; Fischer, Kara (NHTSA) [kara.fischer@dot.gov]; Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Gregory Powell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userca60cd5e]; Ryan Hagen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81a84ec4]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Owens, James (OST) [James.Owens@dot.gov]; Catanzaro, Michael J. EOP/WHO Ex. 6
**CC**: Ryan Keefe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user40c95f6a]; Brianna Jean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraa78e4cb]; Blincoe, Larry (NHTSA) [Larry.Blincoe@dot.gov]; Pickrell, Don H (Volpe) [Don.Pickrell@dot.gov]; Posten, Ryan (NHTSA) [ryan.posten@dot.gov]

**Subject**: Canceled: NHTSA/EPA Modeling working session
**Location**: ConfRm-HQ-W40-302 (NHTSA)

**Start**: 12/21/2017 8:00:00 PM
**End**: 12/21/2017 10:00:00 PM
**Show Time As**: Free

**Importance**: High

**Recurrence**: (none)

Appointment

**From**: Dana.Douglas@dot.gov [Dana.Douglas@dot.gov]
**Sent**: 12/19/2017 4:11:17 PM
**To**: Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Owens, James (OST) [James.Owens@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Gregory Powell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userca60cd5e]; Ryan Hagen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81a84ec4]; Wood, Steve (NHTSA) [Steve.Wood@dot.gov]; Fischer, Kara (NHTSA) [kara.fischer@dot.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Woods, Clinton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]

**Subject**: Canceled: Continued modeling discussion
**Location**: ConfRm-HQ-W42-302

**Start**: 12/19/2017 8:30:00 PM
**End**: 12/19/2017 10:30:00 PM
**Show Time As**: Free

**Importance**: High

**Recurrence**: (none)

This meeting occurrence scheduled for today is cancelled. Follow up to occur on this Thursday's scheduled meeting.

Call-in: Ex. 6 passcode: Ex. 6

Message

**From**: Konkus, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=555471B2BAA6419E8E141696F4577062-KONKUS, JOH]
**Sent**: 8/1/2018 4:02:16 PM
**To**: Henning, Alexa A. EOP/WHO [Ex. 6; Deere, Judd P. EOP/WHO Ex. 6
**CC**: Ditto, Jessica E. EOP/WHO [Ex. 6 marianne.mcinerney@dot.gov; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Magyarits, Caroline S. EOP/WHO Ex. 6 Hurley, Carolina L. EOP/WHO Ex. 6
**Subject**: RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

Thank you. We will begin booking these now.

---

**From:** Henning, Alexa A. EOP/WHO [mailto Ex. 6
**Sent:** Wednesday, August 1, 2018 11:26 AM
**To:** Deere, Judd P. EOP/WHO < Ex. 6 >; Konkus, John <konkus.john@epa.gov>
**Cc:** Ditto, Jessica E. EOP/WHO < Ex. 6 >; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>; Magyarits, Caroline S. EOP/WHO < Ex. 6 Hurley, Carolina L. EOP/WHO < Ex. 6 >
**Subject:** RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

Thanks for sending, John. I know the Acting Administrator is testifying today so let us know the status about the radio bookings if they're locked in, adding any additional, etc. let us know how we can assist.

---

**From:** Deere, Judd P. EOP/WHO
**Sent:** Tuesday, July 31, 2018 4:15 PM
**To:** Konkus, John <konkus.john@epa.gov>; Henning, Alexa A. EOP/WHO < Ex. 6
**Cc:** Ditto, Jessica E. EOP/WHO < Ex. 6 >; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>
**Subject:** RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

**Deliberative Process / Ex. 5**

---

**From:** Konkus, John <konkus.john@epa.gov>
**Sent:** Tuesday, July 31, 2018 3:34 PM
**To:** Henning, Alexa A. EOP/WHO < Ex. 6
**Cc:** Ditto, Jessica E. EOP/WHO < Ex. 6 ; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>; Deere, Judd P. EOP/WHO < Ex. 6
**Subject:** CAFE Press Calls for Admin Wheeler / Draft / Deliberative

Alexa: Per the meeting earlier today, this is what we'd like to do with Acting Administrator Wheeler on the regional side for Thursday's announcement:

**Thursday: 11:00am – 12:00pm**
Print: Jessica Wehrman, Columbus Dispatch
Print: Todd Spangler, Detroit Free Press
Radio: WJR, Detroit

**Friday: 9:30am – 10am**
Print: Mark Pace, Chattanooga Times Free Press
Radio: KMBZ, Kansas City, MO

Thank you!

John Konkus
Environmental Protection Agency
Deputy Associate Administrator for Public Affairs
Mobile: Ex. 6

Message

**From**: Deere, Judd P. EOP/WHO [redacted]
**Sent**: 7/31/2018 9:54:09 PM
**To**: Henning, Alexa A. EOP/WHO [redacted]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]
**CC**: Ditto, Jessica E. EOP/WHO [redacted] marianne.mcinerney@dot.gov; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Post, Andy (OST) [Andy.Post@dot.gov]
**Subject**: RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

+Andy from DOT as well.

DOT team, if you could send us where you want DOT folks for local TV coverage we can start working on that. I think I have your list for local print but feel free to include.

---

**From:** Henning, Alexa A. EOP/WHO
**Sent:** Tuesday, July 31, 2018 4:22 PM
**To:** Deere, Judd P. EOP/WHO <[redacted]; Konkus, John <konkus.john@epa.gov>
**Cc:** Ditto, Jessica E. EOP/WHO <[redacted]>; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>
**Subject:** RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

[redacted]?

---

**From:** Deere, Judd P. EOP/WHO
**Sent:** Tuesday, July 31, 2018 4:15 PM
**To:** Konkus, John <konkus.john@epa.gov>; Henning, Alexa A. EOP/WHO <[redacted]
**Cc:** Ditto, Jessica E. EOP/WHO <[redacted]; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>
**Subject:** RE: CAFE Press Calls for Admin Wheeler / Draft / Deliberative

[redacted]

---

**From:** Konkus, John <konkus.john@epa.gov>
**Sent:** Tuesday, July 31, 2018 3:34 PM
**To:** Henning, Alexa A. EOP/WHO <[redacted]
**Cc:** Ditto, Jessica E. EOP/WHO [redacted]; marianne.mcinerney@dot.gov; Abboud, Michael <abboud.michael@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Block, Molly <block.molly@epa.gov>; Deere, Judd P. EOP/WHO <[redacted]
**Subject:** CAFE Press Calls for Admin Wheeler / Draft / Deliberative

Alexa: Per the meeting earlier today, this is what we'd like to do with Acting Administrator Wheeler on the regional side for Thursday's announcement:

**Thursday: 11:00am – 12:00pm**
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Print: Todd Spangler, Detroit Free Press
Radio: WJR, Detroit

**Friday: 9:30am – 10am**
Print: Mark Pace, Chattanooga Times Free Press
Radio: KMBZ, Kansas City, MO

Thank you!

John Konkus
Environmental Protection Agency
Deputy Associate Administrator for Public Affairs
Mobile: Ex. 6

Message

**From:** Rateike, Bradley A. EOP/WHO Ex. 6
**Sent:** 3/29/2018 3:40:22 PM
**To:** marianne.mcinerney@dot.gov; andy.post@dot.gov; jrockas@doc.gov; Czwartacki, John S. EOP/OMB Ex. 6; Wood, Jacob A. EOP/OMB Ex. 6; Burris, Meghan K. EOP/OMB Ex. 6; Baker, Coalter Ex. 6; Swift, Heather [heather_swift@ios.doi.gov]; laura_rigas@ios.doi.gov; russell_newell@ios.doi.gov; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; tim.murtaugh@oc.usda.gov; meghan.rodgers@oc.usda.gov; michawn.rich@oc.usda.gov; Jake.Wilkins@osec.usda.gov; nathan.bailey@ed.gov; Hill, Elizabeth [Elizabeth.Hill@ed.gov]; bob.haus@hq.doe.gov; Turenne, William [William.Turenne@hq.doe.gov]; Hynes, Shaylyn [Shaylyn.Hynes@hq.doe.gov]; grappone.jeffrey.y@dol.gov; holland.Eric.W@dol.gov; ryan.a.fisher12.civ@mail.mil; Sayegh, Tony E. EOP/WHO Ex. 6; Brian.Morgenstern@treasury.gov; Barry, Ashleigh (OAWP [Ashleigh.Barry@va.gov]; Casin.Spero@va.gov
**Subject:** Infrastructure messaging content in advance of POTUS speech
**Attachments:** Infrastructure - Ohio Speech Factsheet.pdf

Infrastructure Cabinet Communicators,

**Deliberative Process / Ex. 5**

Thank you!

Brad

Brad Rateike
Director of Cabinet Communications
White House Office of Communications
Ex. 6
Desk: Ex. 6
Mobile Ex. 6

**President Trump's Remarks in Richfield, OH**

**Excerpts as Prepared for Delivery**

# Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

**CEA Report: The Economic Benefits and Impacts of Expanded Infrastructure Investment**

Today, the Council of Economic Advisers (CEA) released a report detailing the potential economic benefits from a comprehensive public infrastructure program. Please see below for the executive summary and read the full report here.

In this paper, CEA investigates the likely impacts from a comprehensive public infrastructure program. The program includes a 10-year, $1.5 trillion program of infrastructure investment as well as new administrative and regulatory policies intended to increase efficiency and speed delivery of infrastructure projects. CEA assesses the likely impacts of the program across three key domains: GDP growth, time needed for project completion, and labor market opportunities for infrastructure workers.

- CEA estimates that a 10-year, $1.5 trillion program of infrastructure investment could add between 0.1 and 0.2 percentage point to average annual real growth in gross domestic product (GDP). We further argue that getting the greatest possible impact from the program will require using our existing assets more efficiently, for example by using congestion pricing to allocate scarce capacity to its best uses.
- CEA notes that the average time needed to complete final Environmental Impact Statements (EIS) reached 5.1 years for EIS completed in 2016, up from 4.7 years from two years earlier. CEA also finds that the average time needed to approve pipeline permit applications submitted to the Federal Energy Regulatory Commission (FERC) has risen over time and estimates that the median days needed for approval of pipeline project applications submitted in 2015 was 472 days. Speeding up the time needed to complete infrastructure projects is valuable because it accelerates the receipt of project benefits. CEA notes that the full Federal environmental and permitting process includes many components, of which compliance with the National Environmental Policy Act (NEPA) is only one element. Contingent on the projected impacts of a project, both the lead Federal agency and other agencies may have to issue permits to satisfy Federal laws, and each of those determinations would also be subject to a NEPA determination by that agency. Overall, the entire process can include many studies and procedures that occur prior to the initiation of one agency's NEPA process and continue after that agency's NEPA process has concluded.
- Expanded infrastructure investment would also have direct implications for American workers. The President's plan would likely result in the employment of 290,000 to 414,000 additional infrastructure workers, on average, over a 10-year window, although these employment gains may be offset by losses elsewhere in the economy. Infrastructure jobs are particularly lucrative for, and disproportionately employ, workers with a high school degree or less. Infrastructure workers with a high school degree or less earn 14 percent more in median hourly wages than non-infrastructure occupations, while a subset of these workers, in skilled trades, obtain an even higher median hourly earnings premium of 32 percent.

**PRESIDENT DONALD J. TRUMP'S PLAN TO EXPAND INFRASTRUCTURE INVESTMENT WILL BUILD A STRONGER AMERICAN ECONOMY**

*"I am asking both parties to come together to give us safe, fast, reliable, and modern infrastructure that our economy needs and our people deserve." – President Donald J. Trump*

**GROWING THE AMERICAN ECONOMY: Expanding infrastructure investment would increase American economic growth and prosperity.**

- President Donald J. Trump's proposal for rebuilding infrastructure in America uses $200 billion in Federal funds to spur at least $1.5 trillion in infrastructure investments.
- According to an analysis by the Council of Economic Advisers (CEA), a 10-year $1.5 trillion infrastructure investment program could add between 0.1 and 0.2 percentage points to annual average gross domestic product (GDP) growth.
- Stronger GDP growth from increased infrastructure investment would help boost the American economy, raise wages for American workers, and improve the standard of living in American communities.

**GENERATING ECONOMIC OPPORTUNITY FOR AMERICAN WORKERS: New investments in infrastructure would provide American workers with well-paying job opportunities.**

- A major infrastructure investment program would provide employment opportunities for Americans who did not attend college.
- CEA estimates that a $1.5 trillion infrastructure investment would result in the employment of 290,000 to 414,000 additional infrastructure workers, on average, over a ten-year window.
    - There are an estimated 350,000 infrastructure workers currently unemployed and available to fill positions.
    - The positive effect on employment could be even greater if States loosen licensing requirements that prevent workers from working across State lines.
- Increasing infrastructure employment would especially benefit workers with fewer years of education.
    - In 2016, 62 percent of infrastructure workers had a high school degree or less.
    - Infrastructure jobs pay workers without any college education median hourly wages that are 14 percent higher than other occupations.
    - Skilled trade jobs often involved in infrastructure work provide a wage premium of 32 percent.
- President Trump's plan includes reforms to improve access to education and workforce-development programs, including expanding Pell Grant eligibility to high-quality, short-term programs and reauthorizing the Carl D. Perkins Career and Technical Education Act.
    - These reforms would help prepare American workers to fill infrastructure jobs as well as jobs in other sectors of the economy.

**DELIVERING PROJECTS TO AMERICAN COMMUNITIES SOONER: Inefficient Federal permitting and review processes are slowing down infrastructure projects, delaying community access to needed improvements.**

- The time it takes for infrastructure projects to navigate Federal environmental reviews is increasing, creating further delays for much-needed infrastructure projects.
    - The final Environmental Impact Statements issued in 2016 took an average of 5.1 years to complete, up more than 8 percent from 2014.
    - Average Federal permit approval times have also increased in some sectors.
- Reforming Federal regulations and permitting processes to speed up project completion times would give communities faster access to rebuilt and modernized infrastructure.

- Reducing project completion times would give communities quicker access to the time savings, health and safety benefits, and increased business activity that come along with infrastructure investments.
- The President's plan for rebuilding infrastructure in America shortens the environmental review process to two years and establishes a "one agency, one decision" structure.

Message

**From**: Rateike, Bradley A. EOP/WHO [redacted]
**Sent**: 2/6/2018 7:15:34 PM
**To**: Czwartacki, John S. EOP/OMB [redacted] Sarah.Isgur.Flores@usdoj.gov; charmaine.yoest@hhs.gov; nathan.bailey@ed.gov; dana.w.white6.civ@mail.mil; John.Ullyot@va.gov; Patricia.Gibson@sba.gov; jonathan.hoffman@hq.dhs.gov; bob.haus@hq.doe.gov; Emerson, Jeffrey W. EOP/USTR [redacted] Amy.C.Thompson@hud.gov; grappone.jeffrey.y@dol.gov; Tony.Sayegh@treasury.gov; laura_rigas@ios.doi.gov; adams.chaney@fan.gov; tim.murtaugh@oc.usda.gov; GoldsteinIS@state.gov; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; jrockas@doc.gov; marianne.mcinerney@dot.gov; ronalddb@ucia.gov; brian.hale@dni.gov; Farah, Alyssa A. EOP/OVP [redacted] Burris, Meghan K. EOP/OMB [redacted] Baker, Coalter [redacted] Wood, Jacob A. EOP/OMB [redacted]; Lloyd, Matt (OS/ASPA) [Matt.Lloyd@hhs.gov]; Murphy, Ryan (OS/ASPA) [Ryan.Murphy1@hhs.gov]; Daravi, Roma S. [Roma.Daravi@sba.gov]; Williams, Raffi [Raphael.L.Williams@hud.gov]; Summers, Charles E II SES OSD PA (US) [charles.e.summers4.civ@mail.mil]; Brian.Morgenstern@treasury.gov; Shah, Raj S. EOP/WHO [Raj.S.Shah@who.eop.gov]; Strom, Natalie M. EOP/WHO [Natalie.M.Strom@who.eop.gov]; Kennedy, Adam R. EOP/WHO [redacted]; Sadler, Kelly J. EOP/WHO [redacted] Dorr, Kaelan K. EOP/WHO [redacted] Schlapp, Mercedes V. EOP/WHO [redacted] Nasim, Laura F. EOP/WHO [redacted]; Ferre, Helen A. EOP/WHO [redacted]; Ditto, Jessica E. EOP/WHO [redacted]; Gidley, Hogan H. EOP/WHO [redacted]; Boza-Holman, Sofia M. EOP/OVP [redacted] Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Giuda, Michelle [GiudaM@state.gov]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Hill, Elizabeth [Elizabeth.Hill@ed.gov]; Breinig, Amelia J. EOP/USTR [redacted]; Claffey, Lauren [lauren.claffey@hq.dhs.gov]; Davis, Emily K. EOP/USTR [redacted]
**Subject**: FW: FY 19 Budget Topline Messaging
**Attachments**: Draft top line talking points 180206.pdf

Attached are talking points for the FY 19 budget. Please be sure one person per agency is available to join us on the 2:30 p.m. call.

Thank you!

Brad

Brad Rateike
Director of Cabinet Communications
White House Office of Communications
[redacted]
Desk: [redacted]
Mobile: [redacted]

Message

**From**: Bowman, Liz [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3D4D94D3E4B4B1F80904056703EBC80-BOWMAN, ELI]
**Sent**: 8/10/2017 5:37:26 PM
**To**: Marianna McInerney (marianne.mcinerney@dot.gov) [marianne.mcinerney@dot.gov]; Moore, Allison (OST) [A.Moore@dot.gov]
**CC**: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]
**Subject**: RE: EPA/DOT Press Release on MTE/CAFE - Quote?

Sorry, adding more of our comms folks here to assist b/c I am about to head into a meeting and we want to make sure this gets out as soon as it's ready. Thanks again – Liz

---

**From:** Bowman, Liz
**Sent:** Thursday, August 10, 2017 1:36 PM
**To:** Marianna McInerney (marianne.mcinerney@dot.gov) <marianne.mcinerney@dot.gov>; Moore, Allison (OST) <A.Moore@dot.gov>
**Cc:** Bolen, Brittany (bolen.brittany@epa.gov) <bolen.brittany@epa.gov>; Samantha Dravis (dravis.samantha@epa.gov) <dravis.samantha@epa.gov>
**Subject:** EPA/DOT Press Release on MTE/CAFE - Quote?

Hi Marianna – I have updated the press release with edits from our OGC and policy team. Since this is a joint announcement and FR notice, do you all want to Deliberative Process / Ex. 5 If so, please send it over to me when you get a chance. Thank you – Liz, Ex. 6

Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Liz Bowman
U.S. Environmental Protection Agency (EPA)
Office: 202-564-3293

Message

**From**: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
**Sent**: 7/26/2018 10:57:21 PM
**To**: Andy.Post@DOT.gov
**Subject**: just left you a message

Andy-

Just talked with Judd over at the White House, Deliberative Process / Ex. 5
Call back when you can.

**Michael Abboud**
U.S. Environmental Protection Agency
Office of Public Affairs
M: Ex. 6

Message

**From**: McInerney, Marianne (OST) [marianne.mcinerney@dot.gov]
**Sent**: 8/10/2017 11:16:23 AM
**To**: Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]
**CC**: Owens, James (OST) [James.Owens@dot.gov]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Graham, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26722dfde5b34925b0ad9a8dd4aff308-Graham, Amy]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Brown, Byron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9242d85c7df343d287659f840d730e65-Brown, Byro]; Moore, Allison (OST) [A.Moore@dot.gov]
**Subject**: RE: Final FR Notice on MTE

Liz:

Would it be possible to understand what time this release will be distributed and to receive a copy of the final Register notice?
Related, is there outreach to stakeholders or the Hill on this notice?

Appreciate working with you on this.
Thank you
Marianne

Marianne McInerney
Office of the Secretary
U.S. Department of Transportation
Mobile: Ex. 6

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**From:** Bowman, Liz [mailto:Bowman.Liz@epa.gov]
**Sent:** Wednesday, August 09, 2017 9:08 PM
**To:** McInerney, Marianne (OST)
**Cc:** Owens, James (OST); Bolen, Brittany; Dravis, Samantha; Graham, Amy; Wilcox, Jahan; Hewitt, James; Abboud, Michael; Konkus, John; Brown, Byron
**Subject:** Re: Final FR Notice on MTE

We don't really do tick-tocks or prep additional talkers since this isn't a new issue for the administrator. Unfortunately, this already got leaked, so press already know. But, happy to participate in anything you all want us to.

Sent from my iPhone

On Aug 9, 2017, at 7:36 PM, McInerney, Marianne (OST) <marianne.mcinerney@dot.gov> wrote:

Liz

Thank you for sending this file. We will review and come back to you with our collective comments. May I ask if you have a Tick Tock, talkers and if you will be briefing any media in advance or after release.

Thank you
Marianne

Marianne McInerney
Office of the Secretary
U.S. Department of Transportation
Mobile: Ex. 6

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**From:** Bowman, Liz [mailto:Bowman.Liz@epa.gov]
**Sent:** Wednesday, August 09, 2017 7:30 PM
**To:** Owens, James (OST); McInerney, Marianne (OST)
**Cc:** Bolen, Brittany; Dravis, Samantha; Graham, Amy; Wilcox, Jahan; Hewitt, James; Abboud, Michael; Konkus, John; Brown, Byron
**Subject:** RE: Final FR Notice on MTE

Hi Marianne and James – Attached, and below, please find our draft press statement for tomorrow. Please send us relevant edits to incorporate/include DOT/NHTSA. Once we incorporate edits (and a quote if you want to include it), we will finalize and plan to send this out tomorrow morning. If you have any questions, I can be reached at 202-309-3416. Thank you – Liz

EPA OPENS COMMENT PERIOD FOR MID-TERM EVALUATION
OF GHG STANDARDS FOR CARS AND LIGHT TRUCKS

**Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

For more information, please visit: https://www.epa.gov/regulations-emissions-vehicles-and-engines/midterm-evaluation-light-duty-vehicle-ghg-emissions.

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**From:** Bolen, Brittany
**Sent:** Wednesday, August 9, 2017 7:11 PM
**To:** Bowman, Liz <Bowman.Liz@epa.gov>
**Cc:** marianne.mcinerney@dot.gov
**Subject:** Fwd: Final FR Notice on MTE

Liz, just confirming you're in touch with Marianne at DOT (CC'd) on this release for tomorrow.

Thanks,
Brittany

Sent from my iPhone

Begin forwarded message:

**From:** "Owens, James (OST)" <James.Owens@dot.gov>
**Date:** August 9, 2017 at 6:53:55 PM EDT
**To:** "Bolen, Brittany" <bolen.brittany@epa.gov>
**Cc:** "Smith, Loren (OST)" <Loren.Smith@dot.gov>, "Baptist, Erik" <baptist.erik@epa.gov>, "Dravis, Samantha" <dravis.samantha@epa.gov>, "Gunasekara, Mandy" <Gunasekara.Mandy@epa.gov>, "Catanzaro, Michael J. EOP/WHO" <Ex. 6>, "Campau, Anthony P. EOP/OMB" <Ex. 6>, "McInerney, Marianne (OST)" <marianne.mcinerney@dot.gov>
**Subject: RE: Final FR Notice on MTE**

Hi Brittany.

I'm glad that all is well!

Deliberative Process / Ex. 5 - DOT

Deliberative Process / Ex. 5 I've reached out to our experts to quickly review the draft you forwarded (thank you for doing that!) and we'll let you know tomorrow morning if we have any further comments. Once our agencies are all set on text, we'll make arrangements for signatures tomorrow.

I'm copying our Public Affairs chief, Marianne McInerney, for coordination on rollout. Would you put your press affairs official in touch with her? There's bound to be a ton of attention paid to this notice.

Thanks!
-James

***
James C. Owens
U.S. Department of Transportation
Office: Ex. 6
Email: j.owens@dot.gov
Cell:
Office: Ex. 6

---

**From:** Bolen, Brittany [mailto:bolen.brittany@epa.gov]
**Sent:** Wednesday, August 09, 2017 6:06 PM
**To:** Owens, James (OST)
**Cc:** Smith, Loren (OST); Baptist, Erik; Dravis, Samantha; Gunasekara, Mandy; Catanzaro, Michael J. EOP/WHO; Campau, Anthony P. EOP/OMB
**Subject:** Re: Final FR Notice on MTE

Sure.

Sent from my iPhone

On Aug 9, 2017, at 6:03 PM, Owens, James (OST) <James.Owens@dot.gov> wrote:

Hi - I'm in a meeting right now - are you available for a quick call at or after 645 this evening?

Sent from my iPhone

On Aug 9, 2017, at 5:13 PM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:

Hi James and Loren –
Any update on whether DOT can join the FR notice? We've worked hard the last two days to incorporate NHTSA and OIRA's edits into the notice (attached), and are ready for signature **tomorrow morning**.
Please let me know if you have any questions, my work cell is Ex. 6
Thanks,
Brittany

---

**From:** Owens, James (OST) [mailto:James.Owens@dot.gov]
**Sent:** Thursday, August 3, 2017 5:41 PM
**To:** Bolen, Brittany <bolen.brittany@epa.gov>; Catanzaro, Michael J. EOP/WHO <Ex. 6>; Campau, Anthony P. EOP/OMB <Ex. 6>
**Cc:** Baptist, Erik <baptist.erik@epa.gov>; Dravis, Samantha <dravis.samantha@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Subject:** RE: Draft MTE Notice

Thanks. We'll review and get back to you as soon as we can.

***
James C. Owens
U.S. Department of Transportation
Office Ex. 6
Email: j.owens@dot.gov
Cell:
Office Ex. 6

---

**From:** Bolen, Brittany [mailto:bolen.brittany@epa.gov]
**Sent:** Thursday, August 03, 2017 2:32 PM
**To:** Owens, James (OST); Catanzaro, Michael J. EOP/WHO; Campau, Anthony P. EOP/OMB
**Cc:** Baptist, Erik; Dravis, Samantha; Gunasekara, Mandy
**Subject:** RE: Draft MTE Notice

James, Mike, and Anthony—
We had a few more edits this morning. See attached.
Thanks,
Brittany

---

**From:** Owens, James (OST) [mailto:j.owens@dot.gov]
**Sent:** Wednesday, August 2, 2017 8:42 PM
**To:** Bolen, Brittany <bolen.brittany@epa.gov>; Catanzaro, Michael J. EOP/WHO <Ex. 6
**Cc:** Baptist, Erik <baptist.erik@epa.gov>; Dravis, Samantha <dravis.samantha@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Subject:** RE: Draft MTE Notice

Thanks Brittany. We'll review and will try to get back to you if we have any major concerns tomorrow. Deliberative Process / Ex. 5 - DOT

Deliberative Process / Ex. 5 - DOT

***
James C. Owens
U.S. Department of Transportation
Office: Ex. 6
Email: j.owens@dot.gov
Cell:
Office: Ex. 6

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**From:** Bolen, Brittany [mailto:bolen.brittany@epa.gov]
**Sent:** Wednesday, August 02, 2017 8:27 PM
**To:** Owens, James (OST); Catanzaro, Michael J. EOP/WHO
**Cc:** Baptist, Erik; Dravis, Samantha; Gunasekara, Mandy
**Subject:** Draft MTE Notice

James and Mike – as discussed, attached is the latest draft of the notice. Can you please let us know by tomorrow whether you have any major concerns?
Thanks,
Brittany

**Brittany Bolen**
Deputy Associate Administrator, Office of Policy
U.S. Environmental Protection Agency
(202) 564-3291
Bolen.Brittany@epa.gov

<FRN Request for Comment on MTE Reconsideration_8.9.2017.docx>

Message

**From**: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53D1A3CAA8BB4EBAB8A2D28CA59B6F45-GUNASEKARA,]
**Sent**: 2/25/2018 11:28:45 PM
**To**: Starling, Ray A. EOP/WHO [Ex. 6]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]; Meyer, Seth - OCE [SMeyer@oce.usda.gov]
**CC**: Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Subject**: RE: Recap - CONFIDENTIAL AND PRE-DECISIONAL
**Attachments**: Deliberative Process / Ex. 5

Hi All:
Attached is Deliberative Process / Ex. 5 Please let Bill or I know if you have any questions.
Best,
Mandy

---

**From:** Starling, Ray A. EOP/WHO [mailto: Ex. 6
**Sent:** Friday, February 23, 2018 1:32 PM
**To:** Dravis, Samantha <dravis.samantha@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Meyer, Seth - OCE <SMeyer@oce.usda.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO < Ex. 6
**Subject:** Recap - CONFIDENTIAL AND PRE-DECISIONAL

Colleagues,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

My recommendation would be Deliberative Process / Ex. 5

Thanks,
-Ray

**Ray A. Starling**
*Special Assistant to the President*
National Economic Council

Deliberative Process / Ex. 5

Message

**From**: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53D1A3CAA8BB4EBAB8A2D28CA59B6F45-GUNASEKARA,]
**Sent**: 2/23/2018 6:59:19 PM
**To**: Starling, Ray A. EOP/WHO [Ex. 6]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]; Meyer, Seth - OCE [SMeyer@oce.usda.gov]
**CC**: Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Subject**: RE: Recap - CONFIDENTIAL AND PRE-DECISIONAL
**Attachments**: Deliberative Process / Ex. 5

Thank you, Ray. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

---

**From:** Starling, Ray A. EOP/WHO [mailto [Ex. 6]
**Sent:** Friday, February 23, 2018 1:32 PM
**To:** Dravis, Samantha <dravis.samantha@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Meyer, Seth - OCE <SMeyer@oce.usda.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO <[Ex. 6]
**Subject:** Recap - CONFIDENTIAL AND PRE-DECISIONAL

Colleagues,

Deliberative Process / Ex. 5

My recommendation would be Deliberative Process / Ex. 5

Thanks,
-Ray

**Ray A. Starling**
*Special Assistant to the President*
National Economic Council

Deliberative Process / Ex. 5

Message

**From**: Dravis, Samantha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ECE53F0610054E669D9DFFE0B3A842DF-DRAVIS, SAM]
**Sent**: 2/23/2018 6:34:38 PM
**To**: Starling, Ray A. EOP/WHO Ex. 6
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]; Meyer, Seth - OCE [SMeyer@oce.usda.gov]; Catanzaro, Michael J. EOP/WHO Ex. 6
**Subject**: Re: Recap - CONFIDENTIAL AND PRE-DECISIONAL

**Deliberative Process / Ex. 5**

Sent from my iPad

On Feb 23, 2018, at 1:32 PM, Starling, Ray A. EOP/WHO <Raymond.A.Starling@who.eop.gov> wrote:

Colleagues,

**Deliberative Process / Ex. 5**

My recommendation would be **Deliberative Process / Ex. 5**
**Deliberative Process / Ex. 5**

Thanks,
-Ray

**Ray A. Starling**
*Special Assistant to the President*
National Economic Council

**Deliberative Process / Ex. 5**

Message

**From**: Young, Joby - OSEC, Washington, DC [Joby.Young@osec.usda.gov]
**Sent**: 12/15/2017 8:37:24 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]
**Subject**: RE: follow up

That works. I will send you all a calendar invitation. Thank you.

Joby Young

Chief of Staff – Office of Congressional Relations

United States Department of Agriculture
Mobile: Ex. 6

---

**From:** Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
**Sent:** Friday, December 15, 2017 3:25 PM
**To:** Young, Joby - OSEC, Washington, DC <Joby.Young@osec.usda.gov>
**Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>
**Subject:** Re: follow up

Does 5:00 Monday work?

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 15, 2017, at 12:14 PM, Young, Joby - OSEC, Washington, DC <Joby.Young@osec.usda.gov> wrote:

> Hi guys,
>
> What is a good time to connect via conference call on Monday?

Joby Young

Chief of Staff – Office of Congressional Relations

<image002.jpg> United States Department of Agriculture
Mobile: Ex. 6

**From:** Young, Joby - OSEC, Washington, DC
**Sent:** Thursday, December 14, 2017 12:40 PM
**To:** Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>
**Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Baptist, Erik <baptist.erik@epa.gov>; Catanzaro, Michael J. EOP/WHO <Ex. 6>; Starling, Ray A. EOP/WHO <Ex. 6>; LINDEN, RALPH - OGC <RALPH.LINDEN@OGC.USDA.GOV>
**Subject:** Re: follow up

Hi Ryan,

Happy to coordinate. I will try you at the number below.

Joby Young
Chief of Staff
Office of Congressional Relations
United States Department of Agriculture
Mobile: Ex. 6

Please excuse brevity and typos
Sent from my iPhone

On Dec 14, 2017, at 12:14 PM, Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov> wrote:

> Ralph Linden copied here will also participate and Joby can help coordinate.
>
> Sent from my iPhone
>
> On Dec 13, 2017, at 7:03 PM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:
>
> Heidi, Deliberative Process / Ex. 5
>
> Deliberative Process / Ex. 5

Ryan Jackson
Chief of Staff
U.S. Environmental Protection Agency
Ex. 6

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Message

**From**: Starling, Ray A. EOP/WHO [Ex. 6]
**Sent**: 2/26/2018 3:38:56 PM
**To**: Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Meyer, Seth - OCE [SMeyer@oce.usda.gov]
**CC**: Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Subject**: RE: Recap - CONFIDENTIAL AND PRE-DECISIONAL

**Importance**: High

Mandy and team EPA,

**Deliberative Process / Ex. 5**

Thanks,
-Ray

---

**From:** Green, Heidi - OSEC, Washington, DC [mailto:Heidi.Green@osec.usda.gov]
**Sent:** Sunday, February 25, 2018 9:54 PM
**To:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Starling, Ray A. EOP/WHO [Ex. 6]; Dravis, Samantha <dravis.samantha@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Meyer, Seth - OCE <SMeyer@oce.usda.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Subject:** RE: Recap - CONFIDENTIAL AND PRE-DECISIONAL

Mandy, thank you for your work on this idea. Attached are USDA edits, we tracked changes. We believe it is critical that

**Deliberative Process / Ex. 5**

Thank you,
Heidi

**From:** Gunasekara, Mandy [mailto:Gunasekara.Mandy@epa.gov]
**Sent:** Sunday, February 25, 2018 6:29 PM
**To:** Starling, Ray A. EOP/WHO <Ex. 6>; Dravis, Samantha <dravis.samantha@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Meyer, Seth - OCE <SMeyer@oce.usda.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO <Ex. 6
**Subject:** RE: Recap - CONFIDENTIAL AND PRE-DECISIONAL

Hi All:
Deliberative Process / Ex. 5 Please let Bill or I know if you have any questions.
Best,
Mandy

**From:** Starling, Ray A. EOP/WHO [mailto Ex. 6
**Sent:** Friday, February 23, 2018 1:32 PM
**To:** Dravis, Samantha <dravis.samantha@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Meyer, Seth - OCE <SMeyer@oce.usda.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO <Ex. 6
**Subject:** Recap - CONFIDENTIAL AND PRE-DECISIONAL

Colleagues,

Deliberative Process / Ex. 5

My recommendation Deliberative Process / Ex. 5

Thanks,
-Ray

**Ray A. Starling**
*Special Assistant to the President*
National Economic Council

# Deliberative Process / Ex. 5

Message

**From**: Bradbury, Steven (OST) [Steven.Bradbury@dot.gov]
**Sent**: 4/25/2018 3:05:15 PM
**To**: Palmieri, Rosario A. EOP/OMB [Ex. 6] Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Owens, James (OST) [James.Owens@dot.gov]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Mancini, Dominic J. EOP/OMB [Ex. 6]
**Subject**: RE: Request - 15 minute process call - late afternoon today

4:00 works for me. Thx.

Steven G. Bradbury
General Counsel
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590
steven.bradbury@dot.gov
(202) 366-4702

---

**From:** Palmieri, Rosario A. EOP/OMB [mailto [Ex. 6]
**Sent:** Wednesday, April 25, 2018 11:02 AM
**To:** Leopold.Matt@epa.gov; Wehrum, Bill <Wehrum.Bill@epa.gov>; Bradbury, Steven (OST) <Steven.Bradbury@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>; 'schwab.justin@epa.gov' <schwab.justin@epa.gov>; 'Bolen, Brittany' <bolen.brittany@epa.gov>; Mancini, Dominic J. EOP/OMB [Ex. 6]
**Subject:** Request - 15 minute process call - late afternoon today

Colleagues,

We need to have a short process-only call today. I'm going to send around an invitation for 4PM today. If I can't get critical mass, I'll try 5PM, and then solicit additional options.

I appreciate your assistance in scheduling.

Thank you,

Rosario

Message

**From**: Szabo, Aaron L. EOP/CEQ Ex. 6
**Sent**: 7/30/2018 1:06:18 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**CC**: Leopold, Matt (OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Brightbill, Jonathan (ENRD) (Jonathan.Brightbill@usdoj.gov) [Jonathan.Brightbill@usdoj.gov]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Brooke, Francis J. EOP/WHO [Ex. 6
**Subject**: RE: Meeting on Deliberative Process / Ex. 5

Based on the responses, I asked Jeremy to set up a meeting for 4:30 – 5:30. Please fill out the WAVES form when you receive it.

Thanks.

---

**From:** Wehrum, Bill <Wehrum.Bill@epa.gov>
**Sent:** Sunday, July 29, 2018 5:21 PM
**To:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Leopold, Matt (OGC) <Leopold.Matt@epa.gov>; Szabo, Aaron L. EOP/CEQ <Ex. 6>; Brightbill, Jonathan (ENRD) (Jonathan.Brightbill@usdoj.gov) <Jonathan.Brightbill@usdoj.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Brooke, Francis J. EOP/WHO <Ex. 6
**Subject:** Re: Meeting on Deliberative Process / Ex. 5

Works for me too.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Jul 29, 2018, at 5:05 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

> 4:30-530 works for me
>
> Sent from my iPhone
>
> On Jul 29, 2018, at 3:57 PM, Leopold, Matt (OGC) <Leopold.Matt@epa.gov> wrote:
>
> > I'm available from 1-2 and 4:30-5:30
> >
> > Sent from my iPhone
> >
> > On Jul 29, 2018, at 1:19 PM, Szabo, Aaron L. EOP/CEQ <Ex. 6 wrote:

Hi all,

I was wondering if we could schedule a 1hr meeting on Tuesday between 1-2pm or 3-5pm. If you can let me know what time works for you, I would greatly appreciate it. Once I receive a consensus time, I will send out a scheduler.

Thank you very much and please let me know if you have any questions.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
Ex. 6 (Desk)
(Cell)
Ex. 6

Message

**From**: Owens, James (OST) [James.Owens@dot.gov]
**Sent**: 7/17/2018 2:53:59 AM
**To**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**CC**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Aizcorbe, Christina (OST) [Christina.Aizcorbe@dot.gov]; King, Heidi (NHTSA) [heidi.king@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]
**Subject**: Re: Rulemaking Closeout Items (plus update on Monday NAS meeting)

Thanks! Go Harper!

James C. Owens
Deputy General Counsel
U.S Department of Transportation
1200 New Jersey Ave., S.E.
Washington, D.C. 20590
Ex. 6
James.Owens@dot.gov

On Jul 16, 2018, at 10:27 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

Hey James,
Following up from our earlier discussion – Deliberative Process / Ex. 5 I'll follow-up on the narrative response status early tomorrow. Bill and I will be in North Carolina, but available via phone should anything come up. Hope you enjoyed the game!
Best,
Mandy

---

**From:** Owens, James (OST) [mailto:James.Owens@dot.gov]
**Sent:** Friday, July 13, 2018 5:20 PM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>
**Cc:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Aizcorbe, Christina (OST) <Christina.Aizcorbe@dot.gov>; King, Heidi (NHTSA) <heidi.king@dot.gov>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>
**Subject:** Rulemaking Closeout Items (plus update on Monday NAS meeting)

Bill:

It looks like we have just a couple of items left to closeout from the interagency process in advance of Monday's call. Would you ask your folks to check on the status of these items? They are:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Best,
-James

***

James C. Owens
Deputy General Counsel
U.S. Department of Transportation
Ex. 6
James.owens@dot.gov

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 7/13/2018 10:26:12 PM
**To**: Owens, James (OST) [James.Owens@dot.gov]
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Aizcorbe, Christina (OST) [Christina.Aizcorbe@dot.gov]; King, Heidi (NHTSA) [heidi.king@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]
**Subject**: Re: Rulemaking Closeout Items (plus update on Monday NAS meeting)

Hi James, **Deliberative Process / Ex. 5**

Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Jul 13, 2018, at 5:20 PM, Owens, James (OST) <James.Owens@dot.gov> wrote:

Bill:

It looks like we have just a couple of items left to closeout from the interagency process in advance of Monday's call. Would you ask your folks to check on the status of these items? They are:

**Deliberative Process / Ex. 5**

Best,
-James

***
James C. Owens
Deputy General Counsel

U.S. Department of Transportation
Ex. 6
James.owens@dot.gov

Appointment

**From**: kara.fischer@dot.gov [kara.fischer@dot.gov]
**Sent**: 12/21/2017 7:41:11 PM
**To**: Wood, Steve (NHTSA) [Steve.Wood@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Barnard, Brian (NHTSA) [brian.barnard@dot.gov]; Fischer, Kara (NHTSA) [kara.fischer@dot.gov]; Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Gregory Powell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userca60cd5e]; Ryan Hagen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81a84ec4]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Owens, James (OST) [James.Owens@dot.gov]; Catanzaro, Michael J. EOP/WHO [Ex. 6]
**CC**: Ryan Keefe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user40c95f6a]; Brianna Jean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraa78e4cb]; Blincoe, Larry (NHTSA) [Larry.Blincoe@dot.gov]; Pickrell, Don H (Volpe) [Don.Pickrell@dot.gov]; Posten, Ryan (NHTSA) [ryan.posten@dot.gov]

**Subject**: Canceled: NHTSA/EPA Modeling working session
**Location**: ConfRm-HQ-W40-302 (NHTSA)

**Start**: 12/21/2017 8:00:00 PM
**End**: 12/21/2017 10:00:00 PM
**Show Time As**: Free

**Importance**: High

**Recurrence**: (none)

Appointment

**From**: Delahoyde, Magdelana A. EOP/WHO [redacted] Ex. 6
**Sent**: 11/30/2017 2:27:34 PM
**To**: Owens, James (OST) [James.Owens@dot.gov]; Harris, Jeffrey M. EOP/OMB [redacted] Ex. 6
Palmieri, Rosario A. EOP/OMB [redacted] Ex. 6; Moran, John S. EOP/WHO [redacted] Ex. 6
Neumayr, Mary B. EOP/CEQ [redacted] Ex. 6 Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Szabo, Aaron L. EOP/CEQ [redacted] Ex. 6; Catanzaro, Michael J. EOP/WHO [redacted] Ex. 6; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; mharrington@NADA.org; dgreenhaus@nada.org [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5db3b616db3405bbc0bcaf0d8053dea-dgreenhaus@nada.org]; akoblenz@nada.org

**Subject**: Canceled: Meeting to discuss [redacted] Deliberative Process / Ex. 5
**Location**: Cordell Hull, EEOB 208 (WAVES link in calendar notes)

**Start**: 11/30/2017 4:00:00 PM
**End**: 11/30/2017 5:00:00 PM
**Show Time As**: Free

**Importance**: High

**Recurrence**: (none)

Message

**From**: heidi.king@dot.gov [heidi.king@dot.gov]
**Sent**: 12/1/2017 12:56:45 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: jimmi.nassar@dot.gov
**Subject**: Bill, Heidi's mobile contact information

Bill,

My mobile and direct phone lines so you'd always be able to reach me in the coming months:

Mobile phone: Ex. 6
Desk phone: Ex. 6

Personal mobile (an option on weekends): Ex. 6

I also copy Jimmi Nassar, policy advisor to both our Exec Director and myself and generally the person who knows where to find me.

heidi

NHTSA

Heidi R. King
Deputy Administrator
U.S. Department of Transportation
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590
Office: 202-366-1836

Message

**From**: Tamm, James (NHTSA) [james.tamm@dot.gov]
**Sent**: 2/22/2018 9:07:30 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Hengst, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c414e2bf04a246bb987d88498eefff06-Hengst, Benjamin]
**Subject**: FW: Pre-Decisional Deliberative: Materials for Deliberative Process / Ex. 5
**Attachments**: Deliberative Process / Ex. 5

---

**From:** Tamm, James (NHTSA)
**Sent:** Thursday, February 22, 2018 4:00 PM
**To:** Theroux, Richard P. ( Ex. 6 Achanta, Chandana L. < Ex. 6 ; Laity, Jim Ex. 6 charmley.william@epa.gov; 'Olechiw, Michael' <olechiw.michael@epa.gov>; Bolon, Kevin <Bolon.Kevin@epa.gov>
**Subject:** Pre-Decisional Deliberative: Materials for Deliberative Process / Ex. 5

Please see the attached materials for today's meeting.

Message

**From**: Winberg, Steven [Steven.Winberg@hq.doe.gov]
**Sent**: 1/24/2018 12:20:04 PM
**To**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Harlow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a9a34e31fc4fe6b2beaddda2affa44-Harlow, Dav]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]
**CC**: Simmons, Daniel [Daniel.Simmons@ee.doe.gov]; Maddox, Mark [MRMaddox@hq.doe.gov]; Vincent, Kenneth [Kenneth.Vincent@Hq.Doe.Gov]; Fitzsimmons, Alexander [Alexander.Fitzsimmons@ee.doe.gov]
**Subject**: Meeting with DOE Fossil Energy Office
**Attachments**: Mercury MACT and data errors (002).docx

Bill
First, thank you for meeting with us on January 12. We look forward to working with you and your team on NSR reform. Please let us know what we can do to assist.

**Deliberative Process / Ex. 5 - DOE**

# Deliberative Process / Ex. 5 - DOE

Steven Winberg
Assistant Secretary
Office of Fossil Energy
Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585
202 586 6660

Message

**From**: Wiggins, Jeremy G. EOP/WHO [Ex. 6]
**Sent**: 7/31/2018 8:59:55 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; grover.burthey@dot.gov; Menezes, Mark [Mark.Menezes@hq.doe.gov]; EComstock@doc.gov; Neumayr, Mary B. EOP/CEQ [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Davis, May M. EOP/WHO [Ex. 6]]; Calabria, Mark A. EOP/OVP [Ex. 6] Policy Coordinator [Ex. 6] Pinkos, Stephen M. EOP/OVP [Ex. 6] Herz, James P. EOP/OMB [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6] FannonFR@state.gov; Brooke, Francis J. EOP/WHO [Ex. 6] Griffith, P. Wells W. EOP/NSC [Ex. 6] Szabo, Aaron L. EOP/CEQ [Ex. 6] Derentz, Landon R. EOP/NSC [Ex. 6]; loren.smith@dot.gov; Johnson, Marquita L [JohnsonML5@state.gov]
**Subject**: [Deliberative Process / Ex. 5]

Good evening,

NEC is hosting a [Deliberative Process / Ex. 5] on August 7th at 12:00pm in EEOB 208. Please RSVP your attendance. All proxies and plus ones must be approved. If you have any questions about the content of the meeting please reach out to Francis Brooke, [Ex. 6] A calendar invite will be going out momentarily.

WAVES Link: [Ex. 7(C)]

Invitees
EPA- Bill Wehrum, Mandy Gunasekara
DOT- Grover Burthey
DOE- Menezes, Dan Simmons
DOC- Earl Comstock
CEQ-Mary Neumayr
WHCO-Moran
DCOS-May
OVP – Mark Calabria, Steve Pinkos
OMB-Herz
OIRA –Rosario
DOS – Frank Fannon
Wells, Landon, Aaron

Thank you,
Jeremy

*Jeremy Wiggins*
*Executive Assistant*
*National Economic Council*

Message

**From**: Wiggins, Jeremy G. EOP/WHO Ex. 6
**Sent**: 8/8/2018 2:53:32 PM
**To**: Stuart Levenbach [stuart.Levenbach@noaa.gov]; Griffith, P. Wells W. EOP/NSC Ex. 6 Calabria, Mark A. EOP/OVP Ex. 6 Herz, James P. EOP/OMB Ex. 6 ; Neumayr, Mary B. EOP/CEQ Ex. 6 ]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Christina.Aizcorbe@dot.gov
**Subject**: Deliberative Process / Ex. 5

Good morning,

NEC is hosting a Deliberative Process / Ex. 5 for 1.5hrs on August 27th or 28th. Please provide as much availability as possible by COB August 9th.

Best,
Jeremy

Message

**From**: Pruitt, Scott [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=757BEDFD70CA4219B6D8046F5CE5681E-PRUITT, SCO]
**Sent**: 5/22/2018 3:28:57 PM
**To**: Lawrence.A.Kudlow; Ex. 6
**Subject**: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Scott

Message

**From:** Liddell, Christopher P. EOP/WHO [Ex. 6]
**Sent:** 4/8/2018 8:11:09 PM
**To:** Wilbur Ross [Ex. 6]; Lighthizer, Robert E. EOP/USTR [Ex. 6]; Knight, Shahira E. EOP/WHO [Ex. 6]; Kudlow, Larry A. EOP/WHO [Ex. 6] Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Rosen, Jeff (OST) [jeff.rosen@dot.gov]; Bremberg, Andrew P. EOP/WHO [Ex. 6]; Eissenstat, Everett H. EOP/WHO [Ex. 6]; Hook, Brian H [HookBH@state.gov]; Rao, Neomi J. EOP/OMB [Ex. 6] Lyons, Derek S. EOP/WHO [Ex. 6]; McGahn, Donald F. EOP/WHO [Ex. 6]; Vought, Russell T. EOP/OMB [Ex. 6]
**CC:** Davis, May M. EOP/WHO [Ex. 6]; Moorhead, Quellie U. EOP/WHO [Ex. 6]
**Subject:** Read out from POTUS meeting on [Deliberative Process / Ex. 5]

All,

# Deliberative Process / Ex. 5

Any questions, let me know,
Chris

---

**From:** Policy Coordinator
**Sent:** Thursday, April 5, 2018 8:22 PM
**To:** Liddell, Christopher P. EOP/WHO <[Ex. 6]>; Knight, Shahira E. EOP/WHO <[Ex. 6]>; Kudlow, Larry A. EOP/WHO <[Ex. 6]>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Rosen, Jeff (OST) <jeff.rosen@dot.gov>; Bremberg, Andrew P. EOP/WHO <[Ex. 6]>; Lighthizer, Robert E. EOP/USTR <[Ex. 6]>; Eissenstat, Everett H. EOP/WHO <[Ex. 6]>; Hook, Brian H <HookBH@state.gov>; Rao, Neomi J. EOP/OMB <[Ex. 6]>; Lyons, Derek S. EOP/WHO <[Ex. 6]>; McGahn, Donald F. EOP/WHO <[Ex. 6]>; Vought, Russell T. EOP/OMB [Ex. 6]; Wilbur Ross [Ex. 6]
**Cc:** Policy Coordinator [Ex. 6]
**Subject:** RE: Agenda and Read Ahead for Meeting on [Deliberative Process / Ex. 5]

Attached please find the summary of conclusions from today's meeting. Thank you all for your input, and we will follow up with next steps.

**From:** Policy Coordinator
**Sent:** Wednesday, April 4, 2018 8:17 PM
**To:** Liddell, Christopher P. EOP/WHO <Ex. 6>; Knight, Shahira E. EOP/WHO <Ex. 6>; Kudlow, Larry A. EOP/WHO <Ex. 6>; 'Wehrum, Bill' <Wehrum.Bill@epa.gov>; Rosen, Jeff (OST) <jeff.rosen@dot.gov>; Bremberg, Andrew P. EOP/WHO <Ex. 6>; Lighthizer, Robert E. EOP/USTR <Ex. 6>; Eissenstat, Everett H. EOP/WHO <Ex. 6>; Hook, Brian H <HookBH@state.gov>; Rao, Neomi J. EOP/OMB <Ex. 6>; Lyons, Derek S. EOP/WHO <Ex. 6>; McGahn, Donald F. EOP/WHO <Ex. 6>; Vought, Russell T. EOP/OMB <Ex. 6>; 'Wilbur Ross' Ex. 6
**Cc:** Policy Coordinator <Ex. 6>
**Subject:** Agenda and Read Ahead for Meeting on Deliberative Process / Ex. 5

Below please find tomorrow's agenda for the meeting on Deliberative Process / Ex. 5 Attached please find the compiled responses from agencies regarding EPA proposal, and summaries of alternative proposals.

We will see you at 9:00 AM in the Ex. 7(C)

# Deliberative Process / Ex. 5

Message

**From:** Ex. 6 OSEC, Washington, DC Ex. 6
**Sent:** 4/8/2018 4:53:27 PM
**To:** Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject:** Re: Deliberative Process / Ex. 5

Ok. Thanks. Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

Sent from my iPhone

On Apr 8, 2018, at 12:33 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:

> Steve - Thanks for your messages. Deliberative Process / Ex. 5
> Deliberative Process / Ex. 5
> Deliberative Process / Ex. 5 will get back to you as soon as I can.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> On Apr 8, 2018, at 12:18 PM, Ex. 6 OSEC, Washington, DC < Ex. 6 > wrote:
>
>> Bill,
>>
>> Just left you a voice mail on your home cell. Ex. 5 - Deliberative Process
>> Deliberative Process / Ex. 5
>>
>> Steve
>>
>> Stephen L. Censky
>> Deputy Secretary
>> U.S. Department of Agriculture
>> Office Ex. 6
>> Cell Ex. 6
>>
>> ---
>> **From:** Ex. 6 OSEC, Washington, DC
>> **Sent:** Saturday, April 7, 2018 10:39 AM
>> **To:** Wehrum.Bill@epa.gov
>> **Cc:** 'Gunasekara.Mandy@epa.gov' <Gunasekara.Mandy@epa.gov>; Brooke - OSEC Washington DC Appleton (Brooke.Appleton@osec.usda.gov) <Brooke.Appleton@osec.usda.gov>; Beach, Allie - OSEC, Washington, DC <Allison.Beach@osec.usda.gov>
>> **Subject:** RE: Deliberative Process / Ex. 5
>>
>> Bill,

Deliberative Process / Ex. 5

Also, please use this email address as the one you used yesterday was incorrect and Allie caught that and sent me the info.

Have a nice weekend.

Thanks and best regards,

Steve

Stephen L. Censky
Deputy Secretary
U.S. Department of Agriculture
Office Ex. 6

---

**From:** Ex. 6 OSEC, Washington, DC
**Sent:** Friday, April 6, 2018 10:19 PM
**To:** Wehrum.Bill@epa.gov
**Subject:** Deliberative Process / Ex. 5

Bill

Thanks. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks

Steve

Sent from my iPhone

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

Message

**From**: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53D1A3CAA8BB4EBAB8A2D28CA59B6F45-GUNASEKARA,]
**Sent**: 3/28/2018 11:23:43 PM
**To**: Appleton, Brooke - OSEC, Washington DC [Brooke.Appleton@osec.usda.gov]; Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]
**CC**: Meyer, Seth - OCE [SMeyer@oce.usda.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
**Subject**: RE: Deliberative Process / Ex. 5

Brooke, thank you for the quick response and edits. I sent over to the WH (Mike C.) with your additions.
Best,
Mandy

---

**From:** Appleton, Brooke - OSEC, Washington DC [mailto:Brooke.Appleton@osec.usda.gov]
**Sent:** Tuesday, March 27, 2018 7:37 PM
**To:** Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Meyer, Seth - OCE <SMeyer@oce.usda.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>
**Subject:** RE: Deliberative Process / Ex. 5

Mandy,

Thank you for compiling this and sending it over. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please let me know if you have any questions.

Thanks,

Brooke

---

**From:** Green, Heidi - OSEC, Washington, DC
**Sent:** Tuesday, March 27, 2018 7:14 PM
**To:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Meyer, Seth - OCE <SMeyer@oce.usda.gov>; Appleton, Brooke - OSEC, Washington DC <Brooke.Appleton@osec.usda.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>
**Subject:** Re: Deliberative Process / Ex. 5

Thanks Mandy. Ex. 5 - Deliberative Process

Sent from my iPhone

On Mar 27, 2018, at 5:00 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

Hi Heidi, Brooke and Seth,
I hope you are well. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Best,
Mandy

**Mandy M. Gunasekara**
Principal Deputy Assistant Administrator
Office of Air and Radiation
US Environmental Protection Agency

Deliberative Process / Ex. 5

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Message

**From**: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53D1A3CAA8BB4EBAB8A2D28CA59B6F45-GUNASEKARA,]
**Sent**: 3/27/2018 11:32:39 PM
**To**: Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]
**CC**: Meyer, Seth - OCE [SMeyer@oce.usda.gov]; Appleton, Brooke - OSEC, Washington DC [Brooke.Appleton@osec.usda.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]
**Subject**: Re: Deliberative Process / Ex. 5

Great and thank you

Sent from my iPhone

On Mar 27, 2018, at 4:14 PM, Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov> wrote:

Thanks Mandy. Deliberative Process / Ex. 5

Sent from my iPhone

On Mar 27, 2018, at 5:00 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

Hi Heidi, Brooke and Seth,
I hope you are well. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Best,
Mandy

**Mandy M. Gunasekara**
Principal Deputy Assistant Administrator
Office of Air and Radiation
US Environmental Protection Agency

Deliberative Process / Ex. 5

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

Message

**From:** Szabo, Aaron L. EOP/CEQ Ex. 6
**Sent:** 4/24/2018 2:19:18 PM
**To:** Cunningham, Sean [Sean.Cunningham@hq.doe.gov]; Neumayr, Mary B. EOP/CEQ Ex. 6 Brooke, Francis J. EOP/OVP Ex. 6 Palmieri, Rosario A. EOP/OMB Ex. 6 Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Catanzaro, Michael J. EOP/WHO Ex. 6 Moran, John S. EOP/WHO Ex. 6 Derentz, Landon R. EOP/NSC Ex. 6 Koenig, Andrew D. EOP/WHO Ex. 6 Herz, James P. EOP/OMB Ex. 6 McDonald, Christine A. EOP/OMB Ex. 6 Fibbe, George [George.Fibbe@hq.doe.gov]
**CC:** Szabo, Aaron L. EOP/CEQ Ex. 6
**Subject:**
**Attachments:** Deliberative Process / Ex. 5

All,

Please find attached for your records the Deliberative Process / Ex. 5 Thank you all for your edits and comments.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
Ex. 6 (Desk)
(Cell)
Ex. 6

Message

**From**: Catanzaro, Michael J. EOP/WHO Ex. 6
**Sent**: 3/7/2018 11:06:52 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; 'King, Heidi (NHTSA)' [heidi.king@dot.gov]
**CC**: Chalkey, Richard J. EOP/WHO Ex. 6
**Subject**: FW: Connect

Team, we're on for next Monday at 3:00 with Mary Nichols. Richard, can you get a call-in/invite and send to group (including Mary N.)? Thanks.

---

**From:** Nichols, Mary D. @ARB [mailto:mary.nichols@arb.ca.gov]
**Sent:** Wednesday, March 7, 2018 5:15 PM
**To:** Catanzaro, Michael J. EOP/WHO Ex. 6
**Subject:** RE: Connect

Hi, Mike. Yes, I can.
Looking forward to it.
Mary

---

**From:** Catanzaro, Michael J. EOP/WHO [mailto: Ex. 6
**Sent:** Wednesday, March 07, 2018 12:18 PM
**To:** Nichols, Mary D. @ARB <mary.nichols@arb.ca.gov>
**Subject:** Connect

Hi Mary, hope you are doing well. Can you do a call with Bill Wehrum, Heidi King, and me next Monday, at 3:00?

Best,
Mike

Message

**From:** Derentz, Landon R. EOP/NSC [Ex. 6]
**Sent:** 4/23/2018 8:11:11 PM
**To:** Herz, James P. EOP/OMB [Ex. 6]; Szabo, Aaron L. EOP/CEQ [Ex. 6] Cunningham, Sean [Sean.Cunningham@hq.doe.gov]; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Koenig, Andrew D. EOP/WHO [Ex. 6]; McDonald, Christine A. EOP/OMB [Ex. 6]; Fibbe, George [George.Fibbe@hq.doe.gov]
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]

[Deliberative Process / Ex. 5]

---

**From:** Herz, James P. EOP/OMB
**Sent:** Monday, April 23, 2018 3:43 PM
**To:** Szabo, Aaron L. EOP/CEQ <[Ex. 6]>; Cunningham, Sean <Sean.Cunningham@hq.doe.gov>; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP <[Ex. 6]>; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO <[Ex. 6]>; Moran, John S. EOP/WHO <[Ex. 6]>; Derentz, Landon R. EOP/NSC <[Ex. 6]>; Koenig, Andrew D. EOP/WHO <[Ex. 6]> McDonald, Christine A. EOP/OMB <[Ex. 6]>; Fibbe, George <George.Fibbe@hq.doe.gov>
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]

[Deliberative Process / Ex. 5]

---

**From:** Szabo, Aaron L. EOP/CEQ
**Sent:** Monday, April 23, 2018 3:32 PM
**To:** Cunningham, Sean <Sean.Cunningham@hq.doe.gov>; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP [Ex. 6]; Palmieri, Rosario A. EOP/OMB <[Ex. 6]>; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO <[Ex. 6]>; Moran, John S. EOP/WHO <[Ex. 6]>; Derentz, Landon R. EOP/NSC [Ex. 6]; Koenig, Andrew D. EOP/WHO [Ex. 6]; Herz, James P. EOP/OMB <[Ex. 6]>; McDonald, Christine A. EOP/OMB <[Ex. 6]>; Fibbe, George <George.Fibbe@hq.doe.gov>
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]

All,

Please see a revised version based on comments. Please provide me your final comments **by 6PM**.

---

**From:** Cunningham, Sean <Sean.Cunningham@hq.doe.gov>
**Sent:** Monday, April 23, 2018 11:56 AM
**To:** Szabo, Aaron L. EOP/CEQ <[Ex. 6]>; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP <[Ex. 6]>; Palmieri, Rosario A. EOP/OMB <[Ex. 6]>; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro,

Michael J. EOP/WHO < Ex. 6 ; Moran, John S. EOP/WHO Ex. 6
Derentz, Landon R. EOP/NSC Ex. 6 >; Koenig, Andrew D. EOP/WHO
< Ex. 6 >; Herz, James P. EOP/OMB < Ex. 6 McDonald, Christine A.
EOP/OMB < Ex. 6 ; Fibbe, George <George.Fibbe@hq.doe.gov>
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

DOE's comments on Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

---

**From:** Szabo, Aaron L. EOP/CEQ [mailto Ex. 6
**Sent:** Sunday, April 22, 2018 9:57 PM
**To:** Neumayr, Mary B. EOP/CEQ Ex. 6 ; Brooke, Francis J. EOP/OVP
Ex. 6 >; Palmieri, Rosario A. EOP/OMB < Ex. 6 >; Bill Wehrum
(Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO
< Ex. 6 >; Moran, John S. EOP/WHO < Ex. 6 >; Derentz, Landon R.
EOP/NSC < Ex. 6 >; Koenig, Andrew D. EOP/WHO < Ex. 6 >; Herz,
James P. EOP/OMB < Ex. 6 >; McDonald, Christine A. EOP/OMB
< Ex. 6 >; Cunningham, Sean <Sean.Cunningham@hq.doe.gov>; Fibbe, George
<George.Fibbe@hq.doe.gov>
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

All,

Please see an updated version based on comments provided. Please provide any comments **by noon Monday**.

---

**From:** Szabo, Aaron L. EOP/CEQ
**Sent:** Thursday, April 19, 2018 4:08 PM
**To:** Mary B. EOP/CEQ Neumayr ( Ex. 6 >; Brooke, Francis J.
EOP/OVP < Ex. 6 >; Rosario A. EOP/OMB Palmieri Ex. 6
Ex. 6 >; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J.
EOP/WHO < Ex. 6 ; John S. EOP/WHO Moran ( Ex. 6
< Ex. 6 >; Derentz, Landon R. EOP/NSC < Ex. 6 ; Koenig, Andrew D.
EOP/WHO Ex. 6 >; Herz, James P. EOP/OMB < Ex. 6 >; McDonald,
Christine A. EOP/OMB < Ex. 6 ; 'Sean.Cunningham@hq.doe.gov'
<Sean.Cunningham@hq.doe.gov>; 'George.Fibbe@hq.doe.gov' <George.Fibbe@hq.doe.gov>
**Subject:** FOR REVIEW BY NOON TOMORROW, APRIL 20: Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

All,

Please see attached a Deliberative Process / Ex. 5
Deliberative Process / Ex. 5 that was held on April 18. Due to the timing, please provide me with any comments **by tomorrow, April 20th at Noon**.

Thank you very much and please let me know if you have any questions.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
Ex. 6 (Desk)
(Cell)
Ex. 6

Message

**From:** Herz, James P. EOP/OMB [redacted]
**Sent:** 4/23/2018 3:10:26 PM
**To:** Szabo, Aaron L. EOP/CEQ [redacted]; Neumayr, Mary B. EOP/CEQ [redacted]; Brooke, Francis J. EOP/OVP [redacted]; Palmieri, Rosario A. EOP/OMB [redacted]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Catanzaro, Michael J. EOP/WHO [redacted]; Moran, John S. EOP/WHO [redacted]; Derentz, Landon R. EOP/NSC [redacted]; Koenig, Andrew D. EOP/WHO [redacted]; McDonald, Christine A. EOP/OMB [redacted]; Sean.Cunningham@hq.doe.gov; George.Fibbe@hq.doe.gov
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: [redacted] Act
**Attachments:** [redacted]

[redacted]

**From:** Szabo, Aaron L. EOP/CEQ
**Sent:** Sunday, April 22, 2018 9:57 PM
**To:** Neumayr, Mary B. EOP/CEQ <[redacted]>; Brooke, Francis J. EOP/OVP <[redacted]>; Palmieri, Rosario A. EOP/OMB <[redacted]>; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO [redacted]; Moran, John S. EOP/WHO <[redacted]>; Derentz, Landon R. EOP/NSC <[redacted]>; Koenig, Andrew D. EOP/WHO <[redacted]>; Herz, James P. EOP/OMB [redacted]>; McDonald, Christine A. EOP/OMB <[redacted]>; Sean.Cunningham@hq.doe.gov; George.Fibbe@hq.doe.gov
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: [redacted]
[redacted]

All,

Please see an updated version based on comments provided. Please provide any comments **by noon Monday**.

**From:** Szabo, Aaron L. EOP/CEQ
**Sent:** Thursday, April 19, 2018 4:08 PM
**To:** Mary B. EOP/CEQ Neumayr [redacted]>; Brooke, Francis J. EOP/OVP [redacted]; Rosario A. EOP/OMB Palmieri [redacted] Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO [redacted]>; John S. EOP/WHO Moran [redacted]>; Derentz, Landon R. EOP/NSC [redacted]; Koenig, Andrew D. EOP/WHO [redacted]>; Herz, James P. EOP/OMB [redacted]; McDonald, Christine A. EOP/OMB [redacted]; 'Sean.Cunningham@hq.doe.gov' <Sean.Cunningham@hq.doe.gov>; 'George.Fibbe@hq.doe.gov' <George.Fibbe@hq.doe.gov>
**Subject:** FOR REVIEW BY NOON TOMORROW, APRIL 20: S[redacted]
[redacted]

All,

Please see attached a Deliberative Process / Ex. 5 Deliberative Process / Ex. 5 that was held on April 18. Due to the timing, please provide me with any comments **by tomorrow, April 20th at Noon**.

Thank you very much and please let me know if you have any questions.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
Ex. 6 (Desk)
(Cell)
Ex. 6

Message

**From:** Cunningham, Sean [Sean.Cunningham@hq.doe.gov]
**Sent:** 4/20/2018 3:09:50 PM
**To:** Szabo, Aaron L. EOP/CEQ [Ex. 6] Neumayr, Mary B. EOP/CEQ [Ex. 6]; Brooke, Francis J. EOP/OVP [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6] Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Catanzaro, Michael J. EOP/WHO [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Derentz, Landon R. EOP/NSC [Ex. 6]; Koenig, Andrew D. EOP/WHO [Ex. 6]; Herz, James P. EOP/OMB [Ex. 6]; McDonald, Christine A. EOP/OMB [Ex. 6]; Fibbe, George [George.Fibbe@hq.doe.gov]
**Subject:** RE: FOR REVIEW BY NOON TOMORROW, APRIL 20: S[Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]
**Attachments:** [Deliberative Process / Ex. 5]

Please find DOE's edits and comments attached. [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]

Thanks,

Sean Cunningham

---

**From:** Szabo, Aaron L. EOP/CEQ [mailto:[Ex. 6]
**Sent:** Thursday, April 19, 2018 4:08 PM
**To:** Neumayr, Mary B. EOP/CEQ <[Ex. 6]>; Brooke, Francis J. EOP/OVP [Ex. 6] Palmieri, Rosario A. EOP/OMB <[Ex. 6]; Bill Wehrum (Wehrum.Bill@epa.gov) <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Moran, John S. EOP/WHO <[Ex. 6]>; Derentz, Landon R. EOP/NSC [Ex. 6]>; Koenig, Andrew D. EOP/WHO <[Ex. 6]>; Herz, James P. EOP/OMB <[Ex. 6]; McDonald, Christine A. EOP/OMB [Ex. 6]>; Cunningham, Sean <Sean.Cunningham@hq.doe.gov>; Fibbe, George <George.Fibbe@hq.doe.gov>
**Subject:** FOR REVIEW BY NOON TOMORROW, APRIL 20: [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5]

All,

Please see attached a [Deliberative Process / Ex. 5] [Deliberative Process / Ex. 5] that was held on April 18. Due to the timing, please provide me with any comments **by tomorrow, April 20th at Noon**.

Thank you very much and please let me know if you have any questions.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
[Ex. 6] (Desk)
(Cell)
[Ex. 6]

Message

**From**: Palmieri, Rosario A. EOP/OMB [redacted] Ex. 6
**Sent**: 3/6/2018 2:29:11 AM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Catanzaro, Michael J. EOP/WHO [redacted] Ex. 6; heidi.king@dot.gov; Owens, James (OST) [James.Owens@dot.gov]; Szabo, Aaron L. EOP/CEQ [redacted] Ex. 6 Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Harris, Jeffrey M. EOP/OMB [redacted] Ex. 6
**Subject**: Re: [redacted] Deliberative Process / Ex. 5

Call at 2pm Tuesday is on. Thursday meeting is canceled.

Thank you.

> On Mar 5, 2018, at 9:26 AM, Palmieri, Rosario A. EOP/OMB [redacted] Ex. 6 wrote:
>
> I am sending out two invitations to a call for this purpose - Tuesday at 2 and Thursday at 10:30. Whichever call has critical mass of acceptances by attendees will be kept and the other will be cancelled. Please respond by 5PM today to both invitations.
>
>
>
> -----Original Message-----
> From: Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
> Sent: Saturday, March 3, 2018 10:58 AM
> To: Palmieri, Rosario A. EOP/OMB <[redacted] Ex. 6
> Cc: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Catanzaro, Michael J. EOP/WHO <[redacted] Ex. 6; heidi.king@dot.gov
> Subject: [redacted] Deliberative Process / Ex. 5
>
> Rosario - [redacted] Deliberative Process / Ex. 5 I think [redacted] Deliberative Process / Ex. 5 Deliberative Process / Ex. 5 Can you help pull together a call or meeting early next week? Thanks.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/3/2018 10:27:14 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject**: Re: Vmail - I'm out, suggest Detroit

Great!

Sent from my iPhone

> On Jan 3, 2018, at 6:19 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>
> Great, thanks. I think Deliberative Process / Ex. 5
Deliberative Process / Ex. 5
>
> -----Original Message-----
> From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
> Sent: Wednesday, January 3, 2018 4:59 PM
> To: Wehrum, Bill <Wehrum.Bill@epa.gov>
> Subject: Re: Vmail - I'm out, suggest Detroit
>
> Understood! Deliberative Process / Ex. 5
>

Deliberative Process / Ex. 5

> Thank you, Bill!
>
> Sent from my iPad
>
>> On Jan 3, 2018, at 5:44 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>>
>> Thanks for getting back to me, Heidi. I suggest Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

>> If that makes sense to you, I'd like to see if we can have the initial meeting within the next few days. Deliberative Process / Ex. 5 - DOT
Deliberative Process / Ex. 5 - DOT
>>
>> Please let me know what you think. Thanks.
>>
>> -----Original Message-----
>> From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
>> Sent: Wednesday, January 3, 2018 3:19 PM
>> To: Wehrum, Bill <Wehrum.Bill@epa.gov>
>> Subject: Vmail - I'm out, suggest Detroit
>>
>> Bill,
>>
Ex. 6 It appears that NHTSA team started and ended the year-end break later than EPA, around. Ew Years weekend, perhaps we should have coordinated team vacations better.

Deliberative Process / Ex. 5

>> I suggest folks sit together when we are all in Detroit.
>>

>> Does that make sense?
>>
>> Thanks,
>>
>> Heidi
>>
>> Sent from my iPad

Message

**From**: Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Sent**: 1/22/2018 1:30:06 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; King, Heidi (NHTSA) [heidi.king@dot.gov]
**CC**: Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Owens, James (OST) [James.Owens@dot.gov]
**Subject**: RE: Mike and Bill, I'm unable to attend Monday CAFE meeting

Bill, we can start at 9:30. See you then.

-----Original Message-----
From: Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
Sent: Monday, January 22, 2018 7:50 AM
To: King, Heidi (NHTSA) <heidi.king@dot.gov>
Cc: Catanzaro, Michael J. EOP/WHO <[Ex. 6]>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>
Subject: Re: Mike and Bill, I'm unable to attend Monday CAFE meeting

No, they are not essential personnel. But, the Administrator announced Friday that we have funds to operate through this week. So, we are good for now.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

> On Jan 22, 2018, at 7:43 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>
> Bill, will OTAG GHG emissions staff will be exempted?
>
> -----Original Message-----
> From: Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
> Sent: Monday, January 22, 2018 5:16 AM
> To: King, Heidi (NHTSA) <heidi.king@dot.gov>
> Cc: Michael Catanzaro <[Ex. 6]>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>
> Subject: Re: Mike and Bill, I'm unable to attend Monday CAFE meeting
>
> Thanks Heidi. I still plan to attend, but will not get there until 9:30.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
>> On Jan 22, 2018, at 4:44 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>>
>> Good morning Mike and Bill,
>>
>> As you no doubt anticipated, I am unable to attend the Monday morning CAFÉ meeting but instead will attend to Department if Transportation/NHTSA matters related to the funding lapse.
>>
>> Heidi
>>
>> Sent from my iPhone

Message

**From:** Szabo, Aaron L. EOP/CEQ Ex. 6
**Sent:** 2/25/2018 9:42:06 PM
**To:** Brooke, Francis J. EOP/OVP Ex. 6 Palmieri, Rosario A. EOP/OMB Ex. 6 Harris, Jeffrey M. EOP/OMB Ex. 6 ; Catanzaro, Michael J. EOP/WHO Ex. 6 ; Neumayr, Mary B. EOP/CEQ Ex. 6 Moran, John S. EOP/WHO Ex. 6 ; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Owens, James (OST) [James.Owens@dot.gov]; Rosen, Jeff (OST) [jeff.rosen@dot.gov]; King, Heidi (NHTSA) [heidi.king@dot.gov]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Bradbury, Steven (OST) [Steven.Bradbury@dot.gov]; jonathan. morrison (jonathan.morrison@dot.gov) [jonathan.morrison@dot.gov]
**CC:** Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject:** RE: Deliberative Process / Ex. 5
**Attachments:** Agenda.docx

All,

Please find the agenda for the meeting attached:

Please let me know if you have any questions.

-----Original Appointment-----
**From:** Szabo, Aaron L. EOP/CEQ
**Sent:** Wednesday, February 21, 2018 12:52 PM
**To:** Szabo, Aaron L. EOP/CEQ; Brooke, Francis J. EOP/OVP; Rosario A. EOP/OMB Palmieri Ex. 6 Harris, Jeffrey M. EOP/OMB; Catanzaro, Michael J. EOP/WHO; Mary B. EOP/CEQ Neumayr Ex. 6 Moran, John S. EOP/WHO; Atkinson, Emily; Dominguez, Alexander; Jackson, Ryan; Gunasekara, Mandy; Owens, James (OST); Rosen, Jeff (OST); King, Heidi (NHTSA); Lewis, Josh; Bradbury, Steven (OST); jonathan. morrison (jonathan.morrison@dot.gov)
**Cc:** Wehrum, Bill
**Subject:** Deliberative Process / Ex. 5
**When:** Monday, February 26, 2018 11:00 AM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** EEOB 208

For those who need to be WAVED in Ex. 7(C)

Message

**From**: Tamm, James (NHTSA) [james.tamm@dot.gov]
**Sent**: 2/28/2018 4:18:13 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Hengst, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c414e2bf04a246bb987d88498eefff06-Hengst, Benjamin]; Charmley, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb1828fb00af42ffb68b9e0a71626d95-Charmley, William]; Olechiw, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f564b92ff96459ab606eb66e5892e2d-Olechiw, Michael]; Bolon, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7c0684aaef44174801c0406b51034d2-Bolon, Kevin]; Theroux, Richard P. Deliberative Process / Ex. 5 Laity, Jim
Deliberative Process / Ex. 5 Achanta, Chandana L.
Deliberative Process / Ex. 5 cwhiteman@ Deliberative Process / Ex. 5
**CC**: Mullins, Timothy (OST) [Timothy.Mullins@dot.gov]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Schade, Rebecca (NHTSA) [rebecca.schade@dot.gov]
**Subject**: RE: Pre-Decisional Deliberative Draft: Deliberative Process / Ex. 5
**Attachments**: OIRA Safety Modeling Update 02072018.pptx

Please see the attached handout which will be used for Deliberative Process / Ex. 5 in today's 11:30 meeting.

Based on the availability of DOT personnel we plan to cover the topics in the following order.

Deliberative Process / Ex. 5

Thanks.

Jim

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/22/2018 10:50:58 AM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Michael Catanzaro Ex. 6 Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Owens, James (OST) [James.Owens@dot.gov]
**Subject**: Re: Mike and Bill, I'm unable to attend Monday CAFE meeting

I believe Mary is here for a few days, and I am happy to meet once the business of furlough and orderly shutdown is completed.

Good luck today, all —

Heidi

Sent from my iPhone

> On Jan 22, 2018, at 5:23 AM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>
> Thanks Heidi. I still plan to attend, but will not get there until 9:30.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
>> On Jan 22, 2018, at 4:44 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>>
>> Good morning Mike and Bill,
>>
>> As you no doubt anticipated, I am unable to attend the Monday morning CAFÉ meeting but instead will attend to Department if Transportation/NHTSA matters related to the funding lapse.
>>
>> Heidi
>>
>> Sent from my iPhone

Message

**From:** Achanta, Chandana L. EOP/OMB Ex. 6
**Sent:** 4/11/2018 5:17:23 PM
**To:** Jeffrey.Wood@usdoj.gov; Jonathan.Brightbill@usdoj.gov; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
**CC:** Whiteman, Chad S. EOP/OMB Ex. 6
**Subject:** FW: for your review: Deliberative Process / Ex. 5
**Attachments:** Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please let me know if you have any questions.
Thanks
Chandana

Message

**From:** Ex. 6 OSEC, Washington, DC Ex. 6
**Sent:** 4/11/2018 2:46:58 PM
**To:** Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject:** Deliberative Process / Ex. 5

Bill,

Deliberative Process / Ex. 5

Thanks and best regards,

Steve

Stephen L. Censky
Deputy Secretary
U.S. Department of Agriculture
Office Ex. 6

**From:** Ex. 6
**Date:** April 10, 2018 at 10:55:17 AM EDT
**To:** Ex. 6 OSEC, Washington, DC" Ex. 6
**Subject: Re: Scott, I need your help.**

Sonny,

Thank you for your note. I want to be as responsive and helpful to this as I can, so in the interest of time, I've asked my team to reach out to yours and provide the information that they can. They can also be available if you'd like to speak to them directly on this.

I hope this helps.

Scott

---

**From:** Ex. 6 OSEC, Washington, DC Ex. 6
**Sent:** Tuesday, April 10, 2018 7:46 AM
**To:** Ex. 6
**Subject:** Scott, I need your help.

Scott,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks,

Sonny

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Message

**From**: Moore, Caroline E. EOP/OMB [redacted]
**Sent**: 1/19/2018 11:25:35 PM
**To**: Harris, Jeffrey M. EOP/OMB [redacted]; Catanzaro, Michael J. EOP/WHO [redacted]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; loren.smith@dot.gov; Palmieri, Rosario A. EOP/OMB [redacted]; Moran, John S. EOP/WHO [redacted]; jimmi.nassar@dot.gov; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Szabo, Aaron L. EOP/CEQ [redacted]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; heidi.king@dot.gov; Jonathan.Morrison@dot.gov; Mancini, Dominic J. EOP/OMB [redacted] Theroux, Rich P. EOP/OMB [redacted]; Laity, Jim A. EOP/OMB [redacted] james.owens@dot.gov; Neumayr, Mary B. EOP/CEQ [redacted]
**Subject**: [redacted] Meeting on Tuesday

Hi everyone,

I am emailing to provide you with additional information about the [redacted] meeting on Tuesday. It will take place from 1:00pm - 2:30pm in room 230A [Secretary of War Suite] of the Eisenhower Executive Office Building. I will send a calendar invite shortly. Below is a WAVES form that must be filled out by those who don't work in the EOP. The form should be straight forward, but please let me know if you have any issues. I am more than happy to assist.

If you have trouble entering the building or finding the room, feel free to give me a call. My direct line is [redacted]

Have a good weekend.

WAVES Form: [redacted]

Best,
Caroline

Message

**From**: Gunasekara, Mandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53D1A3CAA8BB4EBAB8A2D28CA59B6F45-GUNASEKARA,]
**Sent**: 6/1/2018 4:37:14 PM
**To**: Shuford, Campbell - OSEC, Washington, DC [Campbell.Shuford@osec.usda.gov]; Starling, Ray A. EOP/WHO Ex. 6; Brooke, Francis J. EOP/WHO Ex. 6
**CC**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Starling, Raymond - OSEC, Washington, DC [Raymond.Starling@osec.usda.gov]; Appleton, Brooke - OSEC, Washington DC [Brooke.Appleton@osec.usda.gov]; Beach, Allie - OSEC, Washington, DC [Allison.Beach@osec.usda.gov]
**Subject**: RE: Touch base
**Attachments**: Deliberative Process / Ex. 5

+Francis Brooke

Let's use our conference line:
Ex. 6
Conference ID: Ex. 6

Finally, I've attached a one-pager we developed to help guide the discussion. Look forward to connecting soon.
Best,
Mandy

---

**From:** Shuford, Campbell - OSEC, Washington, DC [mailto:Campbell.Shuford@osec.usda.gov]
**Sent:** Friday, June 1, 2018 12:32 PM
**To:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Starling, Ray A. EOP/WHO <Ex. 6
**Cc:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Starling, Raymond - OSEC, Washington, DC <Raymond.Starling@osec.usda.gov>; Appleton, Brooke - OSEC, Washington DC <Brooke.Appleton@osec.usda.gov>; Beach, Allie - OSEC, Washington, DC <Allison.Beach@osec.usda.gov>
**Subject:** RE: Touch base

Mandy,

12:45PM works well. Should we have Ray and the Deputy call you at Ex. 6

---

**From:** Gunasekara, Mandy [mailto:Gunasekara.Mandy@epa.gov]
**Sent:** Friday, June 1, 2018 12:22 PM
**To:** Starling, Ray A. EOP/WHO <Ex. 6
**Cc:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>; Starling, Raymond - OSEC, Washington, DC <Raymond.Starling@osec.usda.gov>
**Subject:** RE: Touch base

Perfect – 12:45 works for us and is preferred, but we can make 3:30 work. Please have Dep. Sec. Censky and whoever else join from your end. Thank you

---

**From:** Starling, Ray A. EOP/WHO [mailto Ex. 6
**Sent:** Friday, June 1, 2018 12:19 PM
**To:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Campbell.Shuford@osec.usda.gov; Raymond.Starling@osec.usda.gov
**Subject:** Re: Touch base

Absolutely will make time. May I ask Deputy Secretary Censky to join our call? Maybe around 12:45 or post 3:30 PM?

Looping in Campbell as she can help us all coordinate and adding my USDA email as this one will die on Monday.

Thanks,
-Ray

Ray A. Starling
Special Assistant to the President
National Economic Council

On Jun 1, 2018, at 12:11 PM, Gunasekara, Mandy <Gunasekara.Mandy@epa.gov> wrote:

> Hey Ray,
> Bill and I'd like to touch base regarding Deliberative Process / Ex. 5 Is there a time that is good today? You can reach us whenever on Ex. 6
>
> **Mandy M. Gunasekara**
> Principal Deputy Assistant Administrator
> Office of Air and Radiation
> US Environmental Protection Agency

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Message

**From:** McBride, Emily J. EOP/WHO Ex. 6
**Sent:** 3/9/2018 6:24:48 PM
**To:** Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
**CC:** Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Green, Heidi - OSEC, Washington, DC [Heidi.Green@osec.usda.gov]; Shuford, Campbell - OSEC, Washington, DC [Campbell.Shuford@osec.usda.gov]; Flynn, Matthew J. EOP/WHO Ex. 6; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]
**Subject:** DPP (5) Call This Afternoon

Thanks Emily! Just sent out a calendar invite with the dial in information, but here it is as well:

To access the conference as a participant, dial the number below and enter the Participant Code.
Participant Dial-In: Ex. 6
Participant Code: Ex. 6

To access the conference as the host, dial the number below and enter your Leader Code.
Host Dial-In: Ex. 6
Leader Code: Ex. 6

-Emily

---

**From:** Atkinson, Emily [mailto:Atkinson.Emily@epa.gov]
**Sent:** Friday, March 9, 2018 1:11 PM
**To:** McBride, Emily J. EOP/WHO Ex. 6
**Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>; Flynn, Matthew J. EOP/WHO Ex. 6; Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>; Lewis, Josh <Lewis.Josh@epa.gov>; Ford, Hayley <ford.hayley@epa.gov>
**Sul** DPP (5) Call This Afternoon

Hi Emily,

Bill Wehrum and Mandy Gunasekara could be available at 4pm today for a call on DPP (5) Just let us know what the best number is to dial into and they will be on the line.

Emily Atkinson
Management Analyst/Office Manager
Immediate Office of the Assistant Administrator
Office of Air and Radiation, USEPA

Room 5412B, 1200 Pennsylvania Avenue NW
Washington, DC 20460
Voice: 202-564-1850
Email: atkinson.emily@epa.gov

**From:** McBride, Emily J. EOP/WHO [mailto: Ex. 6
**Sent:** Friday, March 09, 2018 1:08 PM
**To:** Ford, Hayley <ford.hayley@epa.gov>
**Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>; Flynn, Matthew J. EOP/WHO < Ex. 6 ; Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Atkinson, Emily <Atkinson.Emily@epa.gov>
**Subject:** RE: DPP (5) Call This Afternoon

Thanks Hayley! I'll stand by for confirmation.

-Emily

**From:** Ford, Hayley [mailto:ford.hayley@epa.gov]
**Sent:** Friday, March 9, 2018 1:04 PM
**To:** McBride, Emily J. EOP/WHO < Ex. 6
**Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>; Flynn, Matthew J. EOP/WHO Ex. 6 Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Atkinson, Emily <Atkinson.Emily@epa.gov>
**Subject:** Re DPP (5) ll This Afternoon

Copying Bill and Mandy from the Air office on this. They can hop on a call. The DPP (5) meeting has concluded. They will be able to provide an update.

Emily Atkinson can offer if 4:00 works.

Sent from my iPhone

On Mar 9, 2018, at 1:00 PM, McBride, Emily J. EOP/WHO < Ex. 6 > wrote:

> DPP (5) his afternoon with whoever makes sense to be on the line.
>
> Are we saying no one from EPA can get on the line or that it wouldn't be useful to have the call until the meeting wraps?
>
> -Emily
>
> **From:** Jackson, Ryan [mailto:jackson.ryan@epa.gov]
> **Sent:** Friday, March 9, 2018 12:58 PM
> **To:** McBride, Emily J. EOP/WHO < Ex. 6 >; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>
> **Cc:** Ford, Hayley <ford.hayley@epa.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>
> **Subject:** RE: DPP (5) Call This Afternoon
>
> I'm unsure.

**From:** McBride, Emily J. EOP/WHO [mailto Ex. 6 v]
**Sent:** Friday, March 9, 2018 12:54 PM
**To:** Jackson, Ryan <jackson.ryan@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>
**Cc:** Ford, Hayley <ford.hayley@epa.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>
**Subject:** RE: DPP (5) Call This Afternoon

That's what Heidi said! Would 4:30 or 5:00 work instead?

-Emily

---

**From:** Jackson, Ryan [mailto:jackson.ryan@epa.gov]
**Sent:** Friday, March 9, 2018 12:53 PM
**To:** McBride, Emily J. EOP/WHO < Ex. 6 >; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>
**Cc:** Ford, Hayley <ford.hayley@epa.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>
**Subject:** RE: DPP (5) Call This Afternoon

There's a meeting still going on from this morning on DPP (5) I'm unsure about this time working today.

---

**From:** McBride, Emily J. EOP/WHO [mailto: Ex. 6
**Sent:** Friday, March 9, 2018 12:49 PM
**To:** Jackson, Ryan <jackson.ryan@epa.gov>; Green, Heidi - OSEC, Washington, DC <Heidi.Green@osec.usda.gov>
**Cc:** Ford, Hayley <ford.hayley@epa.gov>; Shuford, Campbell - OSEC, Washington, DC <Campbell.Shuford@osec.usda.gov>
**Subject:** DPP (5) Call This Afternoon

Hi Ryan and Heidi-

NEC wants to have an DPP (5) call this afternoon at 4:00. Does that work for your schedules? The call will include Michael Cantazaro, Ray Starling, Dan Greenwood, Joe Lai, and Shahira Knight.

Let me know! Thanks.

**Emily J. McBride**
Associate Director
Office of Cabinet Affairs
The White House
C: Ex. 6
D: Ex. 6

Message

**From**: Grundler, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D3BE58C2CC8545D88CF74F3896D4460F-GRUNDLER, CHRISTOPHER]
**Sent**: 1/19/2018 1:11:54 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**Subject**: Re: Deliberative Process / Ex. 5

Bill and Heidi:
Mike Olechiw or Kevin Bolon will reach out to Jim Tamm regarding file transfer

Thanks

Chrid

---
Christopher Grundler, Director
Office of Transportation and Air Quality
U.S. Environmental Protection Agency
202.564.1682 (Washington DC)
734.214.4207 (Ann Arbor MI)
Ex. 6 (mobile)
www.epa.gov/otaq

On Jan 18, 2018, at 8:02 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:

> Thanks Heidi. I'm copying Chris Grundler, who can help with logistics.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> On Jan 18, 2018, at 6:30 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>
>> Thanks Bill!
>>
>> Copying Jim Tamm who will make this happen.
>>
>> Who do we send to — who is the "catcher"?
>>
>> Does the Ann Arbor team have an FTP site they'd like us to use to transfer the files?
>>
>> Heidi
>>
>> Sent from my iPhone
>>
>> On Jan 18, 2018, at 6:26 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:

Hi Heidi. My folks would like to have the following

**Deliberative Process / Ex. 5**

Once we dig into this info, we may request additional related information. But, we will not know for sure until we dive in. Thanks.

Message

**From**: Grundler, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D3BE58C2CC8545D88CF74F3896D4460F-GRUNDLER, CHRISTOPHER]
**Sent**: 1/19/2018 1:21:08 AM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**Subject**: Re: **Deliberative Process / Ex. 5**

On it. In the past we used an FTP site. Will get Jim the info.

Thanks

Chris

---
Christopher Grundler, Director
Office of Transportation and Air Quality
U.S. Environmental Protection Agency
202.564.1682 (Washington DC)
734.214.4207 (Ann Arbor MI)
**Ex. 6** (mobile)
www.epa.gov/otaq

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> Thanks Heidi. I'm copying Chris Grundler, who can help with logistics.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> On Jan 18, 2018, at 6:30 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
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>> Thanks Bill!
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>> Copying Jim Tamm who will make this happen.
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>> Who do we send to — who is the "catcher"?
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>> Heidi
>>
>> Sent from my iPhone
>>
>> On Jan 18, 2018, at 6:26 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:

Hi Heidi. My folks would like to have the following

**Deliberative Process / Ex. 5**

Once we dig into this info, we may request additional related information. But, we will not know for sure until we dive in. Thanks.

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/18/2018 10:46:59 PM
**To**: Smith, Loren (OST) [Loren.Smith@dot.gov]; Harris, Jeffrey M. EOP/OMB Ex. 6; Palmieri, Rosario A. EOP/OMB Ex. 6; Moran, John S. EOP/WHO Ex. 6; Neumayr, Mary B. EOP/CEQ Ex. 6 Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Catanzaro, Michael J. EOP/WHO Ex. 6; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Szabo, Aaron L. EOP/CEQ Ex. 6 'wehrum.william@epa.gov'; Owens, James (OST) [James.Owens@dot.gov]
**Subject**: FW: Deliberative: Deliberative Process / Ex. 5
**Attachments**: Deliberative Process / Ex. 5

Attached: the full model output provided To Bill last year.

Please do not distribute beyond this group, and NHTSA career staff looks forward to walking through the analysis on Tuesday.

Heidi

---

**From:** Tamm, James (NHTSA)
**Sent:** Wednesday, December 20, 2017 3:21 PM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>
**Subject:** Deliberative: Deliberative Process / Ex. 5

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/18/2018 10:43:00 PM
**To**: Smith, Loren (OST) [Loren.Smith@dot.gov]; Harris, Jeffrey M. EOP/OMB [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Catanzaro, Michael J. EOP/WHO [Ex. 6]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Szabo, Aaron L. EOP/CEQ [Ex. 6]; 'wehrum.william@epa.gov'; Owens, James (OST) [James.Owens@dot.gov]
**Subject**: RESENDING: Draft Table for January 11 8:30 Meeting
**Attachments**: image003.png; ATT00001.htm; [Deliberative Process / Ex. 5] ATT00002.htm

**Deliberative Process / Ex. 5**

Heidi

---

**From:** King, Heidi (NHTSA)
**Sent:** Thursday, January 11, 2018 7:50 AM
**To:** Michael Catanzaro <[Ex. 6]>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Bill Wehrum <wehrum.bill@epa.gov>
**Subject:** Fwd: **Deliberative Process / Ex. 5**

*** Deliberative Draft  Do not forward or distribute ***

I am working from a phone in NV, could one of you please share with non-career participants on this morning's call.

Heidi

Begin forwarded message:

**From:** "Tamm, James (NHTSA)" <james.tamm@dot.gov>
**Date:** January 10, 2018 at 4:19:24 PM PST
**To:** "King, Heidi (NHTSA)" <heidi.king@dot.gov>, "Morrison, Jonathan (NHTSA)" <Jonathan.Morrison@dot.gov>
**Cc:** "Green, Kevin (Volpe)" <Kevin.Green@dot.gov>, "Keefe, Ryan (Volpe)" <Ryan.Keefe@dot.gov>
**Subject:** **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

Message

**From:** Liddell, Christopher P. EOP/WHO [Ex. 6]
**Sent:** 4/2/2018 2:39:30 PM
**To:** Liddell, Christopher P. EOP/WHO [Ex. 6]; Knight, Shahira E. EOP/WHO [Ex. 6]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; geoff.burr@dot.gov; derek.kan@dot.gov; Matthew.Whitaker@usdoj.gov; Moran, John S. EOP/WHO [Ex. 6]; Donaldson, Annie M. EOP/WHO [Ex. 6]; Scott_Hommel@ios.doi.gov; juliette_lillie@ios.doi.gov; brian.mccormack@hq.doe.gov; Wayne.Smith@hq.doe.gov; Neumayr, Mary B. EOP/CEQ [Ex. 6]; Bremberg, Andrew P. EOP/WHO [Ex. 6]; Greer, Jamieson L. EOP/USTR [Ex. 6]; Teramoto, Wendy (Federal [WTeramoto@doc.gov]; Eissenstat, Everett H. EOP/WHO [Ex. 6]; Brown, Clinton S [BrownCS@state.gov]; Frideres, Taryn F [FrideresTF@state.gov]; Hook, Brian H [HookBH@state.gov]; Donnell, Kathryn L [DonnellKL@state.gov]; Eli.Miller@treasury.gov; Lyons, Derek S. EOP/WHO [Ex. 6]; Davis, May M. EOP/WHO [Ex. 6] Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; 'Bernhardt, David' [Ex. 6] 'Simmons, Daniel' [Daniel.Simmons@ee.doe.gov]; Eshbaugh, Mark J. EOP/NSC [Ex. 6]; 'Wood, Jeffrey (ENRD)' [Jeffrey.Wood@usdoj.gov]
**CC:** Shirley.Gathers@treasury.gov; Hupp, Sydney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d50089ff1a5b4c83baa0160afe2c33cb-Hupp, Sydne]; wendy.gehring@dot.gov; Errical.Bryant@usdoj.gov; russell_roddy@ios.doi.gov; Deidre.almstead@hq.doe.gov; Salvi, Mary E. EOP/WHO [Ex. 6]; Bacak, Abigail R. EOP/USTR [Ex. 6]; Leach, Macie (Federal [SLeach@doc.gov]; Willems, Clete R. EOP/NSC [Ex. 6]; Greenwood, Daniel Q. EOP/WHO [Ex. 6]; Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Vaughn, Stephen P. EOP/USTR [Ex. 6] Cobaugh, CC M. EOP/USTR [Ex. 6]; DL NSC PaperDeputies [Ex. 6] 'Ryan.Brady@treasury.gov' [Ryan.Brady@treasury.gov]; Miller, Julie L. EOP/OMB [Ex. 6] Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]
**Subject:** RE: [Deliberative Process / Ex. 5]
**Attachments:** [Deliberative Process / Ex. 5]

**Importance:** High

# Deliberative Process / Ex. 5

Thank you in advance,
Chris

---

**From:** Moorhead, Quellie U. EOP/WHO
**Sent:** Monday, April 2, 2018 8:52 AM
**To:** Liddell, Christopher P. EOP/WHO [Ex. 6]; Knight, Shahira E. EOP/WHO [Ex. 6]; jackson.ryan@epa.gov; geoff.burr@dot.gov; derek.kan@dot.gov; Matthew.Whitaker@usdoj.gov; Moran, John S. EOP/WHO [Ex. 6]; Donaldson, Annie M. EOP/WHO [Ex. 6]; Scott_Hommel@ios.doi.gov; juliette_lillie@ios.doi.gov; brian.mccormack@hq.doe.gov; Wayne.Smith@hq.doe.gov; Neumayr, Mary B. EOP/CEQ

Ex. 6 ; Bremberg, Andrew P. EOP/WHO Ex. 6 ; Greer, Jamieson L. EOP/USTR Ex. 6 Teramoto, Wendy (Federal <WTeramoto@doc.gov>; Eissenstat, Everett H. EOP/WHO Ex. 6 ; Brown, Clinton S <BrownCS@state.gov>; Frideres, Taryn F <FrideresTF@state.gov>; Hook, Brian H <HookBH@state.gov>; Donnell, Kathryn L <DonnellKL@state.gov>; Eli.Miller@treasury.gov; Lyons, Derek S. EOP/WHO Ex. 6 ; Davis, May M. EOP/WHO Ex. 6 'Wehrum, Bill' <Wehrum.Bill@epa.gov>
**Cc:** Shirley.Gathers@treasury.gov; Hupp.sydney@epa.gov; wendy.gehring@dot.gov; Errical.Bryant@usdoj.gov; russell_roddy@ios.doi.gov; Deidre.almstead@hq.doe.gov; Salvi, Mary E. EOP/WHO Ex. 6 Bacak, Abigail R. EOP/USTR Ex. 6 Leach, Macie (Federal <SLeach@doc.gov>; Willems, Clete R. EOP/NSC Ex. 6 ; Greenwood, Daniel Q. EOP/WHO Ex. 6 'Ford, Hayley' <ford.hayley@epa.gov>
**Subject:** RE: Deliberative Process / Ex. 5
**Importance:** High

Hello All,

Reminder that we are having this prep call in 8 minutes. We look forward to you joining.

Dial in information: Ex. 6 and put in the conference id Ex. 6

Kind regards,
Quellie

---

**From:** Liddell, Christopher P. EOP/WHO
**Sent:** Sunday, April 1, 2018 6:00 PM
**To:** Liddell, Christopher P. EOP/WHO Ex. 6 ; Knight, Shahira E. EOP/WHO Ex. 6 jackson.ryan@epa.gov; geoff.burr@dot.gov; derek.kan@dot.gov; Matthew.Whitaker@usdoj.gov; Moran, John S. EOP/WHO Ex. 6 ; Donaldson, Annie M. EOP/WHO Ex. 6 Scott_Hommel@ios.doi.gov; juliette_lillie@ios.doi.gov; brian.mccormack@hq.doe.gov; Wayne.Smith@hq.doe.gov; Neumayr, Mary B. EOP/CEQ Ex. 6 ; Bremberg, Andrew P. EOP/WHO Ex. 6 ; Greer, Jamieson L. EOP/USTR Ex. 6 ; Teramoto, Wendy (Federal <WTeramoto@doc.gov>; Eissenstat, Everett H. EOP/WHO Ex. 6 ; Brown, Clinton S <BrownCS@state.gov>; Frideres, Taryn F <FrideresTF@state.gov>; Hook, Brian H <HookBH@state.gov>; Donnell, Kathryn L <DonnellKL@state.gov>; Eli.Miller@treasury.gov; Lyons, Derek S. EOP/WHO Ex. 6 ; Davis, May M. EOP/WHO Ex. 6
**Cc:** Shirley.Gathers@treasury.gov; Hupp.sydney@epa.gov; wendy.gehring@dot.gov; Errical.Bryant@usdoj.gov; russell_roddy@ios.doi.gov; Deidre.almstead@hq.doe.gov; Salvi, Mary E. EOP/WHO Ex. 6 Bacak, Abigail R. EOP/USTR Ex. 6 ; Leach, Macie (Federal <SLeach@doc.gov>; Willems, Clete R. EOP/NSC Ex. 6 ; Greenwood, Daniel Q. EOP/WHO Ex. 6 ; Moorhead, Quellie U. EOP/WHO Ex. 6
**Subject:** RE: Deliberative Process / Ex. 5
**Importance:** High

Thank you to the components who have already signed up to tomorrow's call. The call will cover next steps as we prepare for Thursday's DPP (5) t 9 AM. Please remember to RSVP to Ex. 6 ASAP and register for the call at Ex. 6 using the conference ID: Ex. 6

Regards,

Chris

**From:** Liddell, Christopher P. EOP/WHO
**Sent:** Saturday, March 31, 2018 2:47 PM
**To:** Knight, Shahira E. EOP/WHO <Ex. 6>; 'jackson.ryan@epa.gov' <jackson.ryan@epa.gov>; 'geoff.burr@dot.gov' <geoff.burr@dot.gov>; 'derek.kan@dot.gov' <derek.kan@dot.gov>; 'Matthew.Whitaker@usdoj.gov' <Matthew.Whitaker@usdoj.gov>; Moran, John S. EOP/WHO <Ex. 6>; Donaldson, Annie M. EOP/WHO <Ex. 6>; 'Scott_Hommel@ios.doi.gov' <Scott_Hommel@ios.doi.gov>; 'juliette_lillie@ios.doi.gov' <juliette_lillie@ios.doi.gov>; 'brian.mccormack@hq.doe.gov' <brian.mccormack@hq.doe.gov>; 'Wayne.Smith@hq.doe.gov' <Wayne.Smith@hq.doe.gov>; Neumayr, Mary B. EOP/CEQ <Ex. 6>; Bremberg, Andrew P. EOP/WHO <Ex. 6>; Greer, Jamieson L. EOP/USTR <Ex. 6>; 'Teramoto, Wendy (Federal' <WTeramoto@doc.gov>; Eissenstat, Everett H. EOP/WHO <Ex. 6>; 'Brown, Clinton S' <BrownCS@state.gov>; 'Frideres, Taryn F' <FrideresTF@state.gov>; 'Hook, Brian H' <HookBH@state.gov>; 'Donnell, Kathryn L' <DonnellKL@state.gov>; 'Eli.Miller@treasury.gov' <Eli.Miller@treasury.gov>; Lyons, Derek S. EOP/WHO <Ex. 6>; Davis, May M. EOP/WHO <Ex. 6>
**Cc:** 'Shirley.Gathers@treasury.gov' <Shirley.Gathers@treasury.gov>; 'Hupp.sydney@epa.gov' <Hupp.sydney@epa.gov>; 'wendy.gehring@dot.gov' <wendy.gehring@dot.gov>; 'Errical.Bryant@usdoj.gov' <Errical.Bryant@usdoj.gov>; 'russell_roddy@ios.doi.gov' <russell_roddy@ios.doi.gov>; 'Deidre.almstead@hq.doe.gov' <Deidre.almstead@hq.doe.gov>; Salvi, Mary E. EOP/WHO <Ex. 6>; Bacak, Abigail R. EOP/USTR <Ex. 6>; 'Leach, Macie (Federal' <SLeach@doc.gov>; Willems, Clete R. EOP/NSC <Ex. 6> Greenwood, Daniel Q. EOP/WHO <Ex. 6>
**Subject:** Deliberative Process / Ex. 5
**Importance:** High

Good afternoon,

# Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 3/29/2018 11:52:35 AM
**To**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**CC**: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject**: RE: Catch up?

Travel safely Mandy!

**Deliberative Process / Ex. 5**

Be safe,

heidi

---

**From:** Gunasekara, Mandy [mailto:Gunasekara.Mandy@epa.gov]
**Sent:** Wednesday, March 28, 2018 8:48 PM
**To:** King, Heidi (NHTSA) <heidi.king@dot.gov>
**Cc:** Bolen, Brittany <bolen.brittany@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>
**Subject:** Re: Catch up?

Hey Heidi,
Great to hear from you and hope all is well. I'm on a flight to Denver and Bill is in the air headed back to dc. I'll defer to him and our scheduling team as to when would be a good time to catch up.Look forward to chatting soon.
Best,
Mandy

Sent from my iPhone

On Mar 28, 2018, at 1:10 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

> Team,
>
> We haven't spoken for awhile and I'd like to make sure you are getting what you need.
>
> Free for a quick catch up call?
>
> heidi

<image001.png>

**Heidi R. King**
Deputy Administrator
**U.S. Department of Transportation**
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590

Office: 202-366-1836

Message

**From:** Thompson, John E. EOP/NSC [Ex. 6]
**Sent:** 12/22/2017 9:49:45 PM
**To:** Garber, Judith G [GarberJG@state.gov]; mitchell.silk@treasury.gov; 'Wells.Griffith@hq.doe.gov' [Wells.Griffith@hq.doe.gov]; Prescott, Jennifer Y. EOP/USTR [Ex. 6] Thompson, Carrie A. (E3/AA) [cthompson@usaid.gov]; thardy@ustda.gov; douglas_domenech@ios.doi.gov; Elizabeth.Mclanahan [elizabeth.mclanahan@noaa.gov]; Johansson, Robert - OCE [RJohansson@oce.usda.gov]; Charles.McLaughlin@opic.gov; EComstock@doc.gov; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC:** Banks, George D. EOP/WHO [Ex. 6]; Eshbaugh, Mark J. EOP/NSC [Ex. 6] Abbey, Tristan C. EOP/NSC [Ex. 6] 'Talley, Trigg' [TalleyT@state.gov]; Catanzaro, Michael J. EOP/WHO [Ex. 6] Neumayr, Mary B. EOP/CEQ [Ex. 6] Palmieri, Rosario A. EOP/OMB [Ex. 6] Radford, Julie T. EOP/WHO [Ex. 6]; Baitel, Rachael EOP/WHO [Ex. 6]; Berkowitz, Avrahm J. EOP/WHO [Ex. 6] DL NSC Legal [Ex. 6] Delahoyde, Magdelana A. EOP/WHO [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Etzkorn, Ed V. EOP/OMB [Ex. 6] Peter.Wisner@treasury.gov; Dunham, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a9444681441e4521ad92ae7d42919223-SDUNHAM]; McElnea, Bill K. EOP/USTR [Ex. 6]; Giles, Misty - OSEC, Washington, DC [Misty.Giles@osec.usda.gov]; Buffo, Laura D. EOP/USTR [Ex. 6]; McElnea, Bill K. EOP/USTR [Ex. 6] Rebecca.Lawlor@treasury.gov; Allen Eisendrath [aeisendrath@usaid.gov]; ko.barrett@noaa.gov; Brooke, Francis J. EOP/OVP [Ex. 6]; Burgess, Scott H. EOP/OMB [Ex. 6]; Moorhead, Quellie U. EOP/WHO [Ex. 6]; Kim, Jayoung EOP/NSC [Ex. 6]
**Subject:** **Deliberative Process / Ex. 5**
**Attachments:**

Colleagues,

Please find attached the [Deliberative Process / Ex. 5] on December 8. Apologies for the delay in getting it out. I look forward to working with you further in 2018. Best regards,

John E. Thompson
Director for International Environment
National Security Council
[Ex. 6]

---

**From:** Thompson, John E. EOP/NSC
**Sent:** Thursday, December 7, 2017 3:52 PM
**To:** 'Garber, Judith G' <GarberJG@state.gov>; 'mitchell.silk@treasury.gov' <mitchell.silk@treasury.gov>; 'Wells.Griffith@hq.doe.gov' <Wells.Griffith@hq.doe.gov>; Prescott, Jennifer Y. EOP/USTR [Ex. 6]; 'Thompson, Carrie A. (E3/AA)' <cthompson@usaid.gov>; 'thardy@ustda.gov' <thardy@ustda.gov>; 'douglas_domenech@ios.doi.gov' <douglas_domenech@ios.doi.gov>; 'Elizabeth.Mclanahan' <elizabeth.mclanahan@noaa.gov>; 'Johansson, Robert - OCE' <RJohansson@oce.usda.gov>; 'Charles.McLaughlin@opic.gov' <Charles.McLaughlin@opic.gov>; 'EComstock@doc.gov' <EComstock@doc.gov>; 'Wehrum.Bill@epa.gov' <Wehrum.Bill@epa.gov>
**Cc:** 'George D. EOP/WHO Banks [Ex. 6]; Eshbaugh, Mark J. EOP/NSC [Ex. 6] Abbey, Tristan C. EOP/NSC [Ex. 6]; 'Talley, Trigg' <TalleyT@state.gov>; Catanzaro, Michael J. EOP/WHO [Ex. 6] Neumayr, Mary B. EOP/CEQ [Ex. 6] Palmieri, Rosario A. EOP/OMB [Ex. 6]; Radford, Julie T.

EOP/WHO [Ex. 6]; Baitel, Rachael EOP/WHO [Ex. 6]; Berkowitz, Avrahm J. EOP/WHO [Ex. 6] DL NSC Legal [Ex. 6]; Delahoyde, Magdelana A. EOP/WHO [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Etzkorn, Ed V. EOP/OMB [Ex. 6] 'Peter.Wisner@treasury.gov' <Peter.Wisner@treasury.gov>; 'Dunham, Sarah' <Dunham.Sarah@epa.gov>; Kim, Jayoung EOP/NSC [Ex. 6]; McElnea, Bill K. EOP/USTR [Ex. 6]; 'Giles, Misty - OSEC, Washington, DC' <Misty.Giles@osec.usda.gov>; Buffo, Laura D. EOP/USTR [Ex. 6]; McElnea, Bill K. EOP/USTR [Ex. 6] Rebecca.Lawlor@treasury.gov; Allen Eisendrath <aeisendrath@usaid.gov>; 'ko.barrett@noaa.gov' <ko.barrett@noaa.gov>; Kim, Jayoung EOP/NSC [Ex. 6]
**Subject:** RE: [Deliberative Process / Ex. 5] Friday December 8 - TIME CHANGE 10:30am!

Just a reminder that the meeting is at 726 Jackson Place at the White House Conference Center (not at the EEOB) at 10:30 am tomorrow morning. You will need a picture ID to get into WHCC, but no WAVES is required. Please plan to arrive about 10 minutes early to clear security.

In addition, [DPP (5)]

[DPP (5)]

John E. Thompson
Director for International Environment
National Security Council
[Ex. 6]

---

**From:** Thompson, John E. EOP/NSC
**Sent:** Monday, December 4, 2017 3:34 PM
**To:** 'Garber, Judith G' <GarberJG@state.gov>; 'mitchell.silk@treasury.gov' <mitchell.silk@treasury.gov>; 'Wells.Griffith@hq.doe.gov' <Wells.Griffith@hq.doe.gov>; Prescott, Jennifer Y. EOP/USTR [Ex. 6]; 'Thompson, Carrie A. (E3/AA)' <cthompson@usaid.gov>; 'thardy@ustda.gov' <thardy@ustda.gov>; 'douglas_domenech@ios.doi.gov' <douglas_domenech@ios.doi.gov>; 'Elizabeth.Mclanahan' <elizabeth.mclanahan@noaa.gov>; 'Johansson, Robert - OCE' <RJohansson@oce.usda.gov>; 'Charles.McLaughlin@opic.gov' <Charles.McLaughlin@opic.gov>; 'EComstock@doc.gov' <EComstock@doc.gov>; 'Wehrum.Bill@epa.gov' <Wehrum.Bill@epa.gov>
**Cc:** 'George D. EOP/WHO Banks [Ex. 6]; Eshbaugh, Mark J. EOP/NSC [Ex. 6]; Abbey, Tristan C. EOP/NSC [Ex. 6]; 'Talley, Trigg' <TalleyT@state.gov>; Catanzaro, Michael J. EOP/WHO [Ex. 6] Neumayr, Mary B. EOP/CEQ [Ex. 6]; Palmieri, Rosario A. EOP/OMB [Ex. 6]; Radford, Julie T. EOP/WHO [Ex. 6] Baitel, Rachael EOP/WHO [Ex. 6]; Berkowitz, Avrahm J. EOP/WHO [Ex. 6] DL NSC Legal [Ex. 6] Delahoyde, Magdelana A. EOP/WHO [Ex. 6]; Moran, John S. EOP/WHO [Ex. 6]; Etzkorn, Ed V. EOP/OMB [Ex. 6]; Peter.Wisner@treasury.gov; 'Dunham, Sarah' <Dunham.Sarah@epa.gov>; Kim, Jayoung EOP/NSC [Ex. 6]; McElnea, Bill K. EOP/USTR [Ex. 6]; Giles, Misty - OSEC, Washington, DC <Misty.Giles@osec.usda.gov>
**Subject:** RE: [Deliberative Process / Ex. 5] Friday December 8 - TIME CHANGE 10:30am!

A few updates on plans for [Deliberative Process / Ex. 5]

First, due to schedule conflicts, we have to move the time to 10:30 on Friday morning. My apologies for the inconvenience.

Second, the meeting will take place in the White House Conference Center (WHCC), which is at 726 Jackson Place, half a block North of the White House. The WHCC is NOT in the EEOB, and you do NOT need to do a WAVES preclearance, however, you do need to send your name to me and Jayoung Kim (cc'd above) to get your name on the list to preclear, and bring either a government ID, passport, or driver's license to get in.

Third, the draft agenda for the meeting is below, let me know if there are other items to include. We will have to be efficient with our time to cover the range of issues. Thanks, and again, sorry to move the schedule around,
John

**Deliberative Process / Ex. 5**

-----Original Message-----
From: Thompson, John E. EOP/NSC
Sent: Thursday, November 30, 2017 7:08 PM
To: Garber, Judith G <GarberJG@state.gov>; mitchell.silk@treasury.gov; 'Wells.Griffith@hq.doe.gov' <Wells.Griffith@hq.doe.gov>; Prescott, Jennifer Y. EOP/USTR [Ex. 6]; Thompson, Carrie A. (E3/AA) <cthompson@usaid.gov>; thardy@ustda.gov; douglas_domenech@ios.doi.gov; Elizabeth.Mclanahan <elizabeth.mclanahan@noaa.gov>; Johansson, Robert - OCE <RJohansson@oce.usda.gov>; Charles.McLaughlin@opic.gov; EComstock@doc.gov; Wehrum.Bill@epa.gov
Cc: 'George D. EOP/WHO Banks [Ex. 6] Eshbaugh, Mark J. EOP/NSC [Ex. 6]; Abbey, Tristan C. EOP/NSC [Ex. 6] 'Talley, Trigg' <TalleyT@state.gov>; Catanzaro, Michael J. EOP/WHO [Ex. 6] Neumayr, Mary B. EOP/CEQ [Ex. 6] Palmieri, Rosario A. EOP/OMB [Ex. 6] Radford, Julie T. EOP/WHO [Ex. 6]; Baitel, Rachael EOP/WHO [Ex. 6]; Berkowitz, Avrahm J. EOP/WHO [Ex. 6] DL NSC Legal [Ex. 6] Delahoyde, Magdelana A. EOP/WHO [Ex. 6] Moran, John S. EOP/WHO [Ex. 6]; Etzkorn, Ed V. EOP/OMB [Ex. 6]
Subject: [Deliberative Process / Ex. 5] Save The Date - Friday December 8 @ 2pm

Colleagues,

You are invited to join Special Assistant to the President Dave Banks for [Deliberative Process / Ex. 5] December 8 from 2-3:30pm. The meeting will be held in the White House complex, further logistics details and agenda to follow shortly.

I have tried to direct this email to appropriate contacts in agencies, [DPP (5)]

**DPP (5)**

John Thompson
Director for International Environment
[Ex. 6]

Message

**From**: Tamm, James (NHTSA) [james.tamm@dot.gov]
**Sent**: 2/27/2018 5:44:24 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Hengst, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c414e2bf04a246bb987d88498eefff06-Hengst, Benjamin]; Charmley, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb1828fb00af42ffb68b9e0a71626d95-Charmley, William]; Olechiw, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f564b92ff96459ab606eb66e5892e2d-Olechiw, Michael]; Bolon, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7c0684aaef44174801c0406b51034d2-Bolon, Kevin]
**CC**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Mullins, Timothy (OST) [Timothy.Mullins@dot.gov]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Schade, Rebecca (NHTSA) [rebecca.schade@dot.gov]; Theroux, Richard P. Ex. 6 ]; Laity, Jim Ex. 6 ; Achanta, Chandana L. Ex. 6 ; cwhiteman@ Ex. 6
**Subject**: Pre-Decisional Deliberative Draft: DPP (5)
**Attachments**: DPP (5)

Please see the attached feedback for Deliberative Process / Ex. 5
Jim

Message

**From**: Delahoyde, Magdelana A. EOP/WHO [redacted]
**Sent**: 12/12/2017 2:23:48 PM
**To**: Dearborn, Rick A. EOP/WHO [redacted]; McGinley, William J. EOP/WHO [redacted] Banks, George D. EOP/WHO [redacted] Brooke, Francis J. EOP/OVP [redacted] Neumayr, Mary B. EOP/CEQ [redacted]; Szabo, Aaron L. EOP/CEQ [Aaron.L.Szabo@ceq.eop.gov]; Moran, John S. EOP/WHO [redacted]; Palmieri, Rosario A. EOP/OMB [redacted]; McCormack, Brian [Brian.Mccormack@hq.doe.gov]; Owens, James (OST [James.Owens@dot.gov]; EComstock@doc.gov; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: McCann, Meghan B. EOP/WHO [redacted]; Uli, Gabriella M. EOP/WHO [redacted]; Smith, Katherine R. EOP/CEQ [redacted] Loving, Shanita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=439ce9c2d2104080a1b5908d3402bf20-Loving, Shanita]
**Subject**: [redacted]

Hi All,

I'm trying to schedule an [redacted] I know it's a busy week with filled schedules, but I'm hoping for **11:30am-12:30pm** Wednesday morning.

If anyone has deep objections to that time, please let me know ASAP! Please provide windows that do work.

Also, if you can't make it but have someone who could on your behalf, please send along their name as well.

Stay tuned!
Maggie

Message

**From**: Sullivan, Lauren - OSEC, Washington, DC [Lauren.Sullivan@osec.usda.gov]
**Sent**: 6/12/2018 10:59:31 PM
**To**: Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]
**CC**: Johansson, Robert - OCE [RJohansson@oce.usda.gov]; Ex. 6 Starling, Raymond - OSEC, Washington, DC [Raymond.Starling@osec.usda.gov]; Appleton, Brooke - OSEC, Washington DC [Brooke.Appleton@osec.usda.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; McMurray, Forrest [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=344246fb2cb643bfab4f92fe016566e2-McMurray, F]
**Subject**: RE: Call

Great- please have Administrator Pruitt call the Secretary at Ex. 6 Thank you again.

Lauren

---

**From:** Ford, Hayley [mailto:ford.hayley@epa.gov]
**Sent:** Tuesday, June 12, 2018 6:55 PM
**To:** Sullivan, Lauren - OSEC, Washington, DC <Lauren.Sullivan@osec.usda.gov>
**Cc:** Johansson, Robert - OCE <RJohansson@oce.usda.gov>; rpalmieri@ Ex. 6 ; Starling, Raymond - OSEC, Washington, DC <Raymond.Starling@osec.usda.gov>; Appleton, Brooke - OSEC, Washington DC <Brooke.Appleton@osec.usda.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; McMurray, Forrest <mcmurray.forrest@epa.gov>
**Subject:** Re: Call

Ok yes that works. We will have him call Secretary Perdue directly at that time unless I hear otherwise.

Thanks all!

Hayley

On Jun 12, 2018, at 6:30 PM, Sullivan, Lauren - OSEC, Washington, DC <Lauren.Sullivan@osec.usda.gov> wrote:

> For tomorrow, a call between the two of them will be good and then we can revisit after they talk.
>
> Let me know if 4:45pm works on your end.
>
> Thank you!
> Lauren

---

> **From:** Ford, Hayley [mailto:ford.hayley@epa.gov]
> **Sent:** Tuesday, June 12, 2018 6:06 PM
> **To:** Sullivan, Lauren - OSEC, Washington, DC <Lauren.Sullivan@osec.usda.gov>
> **Cc:** Johansson, Robert - OCE <RJohansson@oce.usda.gov>; Ex. 6 Starling, Raymond - OSEC, Washington, DC <Raymond.Starling@osec.usda.gov>; Appleton, Brooke - OSEC, Washington DC <Brooke.Appleton@osec.usda.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Wehrum, Bill

<Wehrum.Bill@epa.gov>; McMurray, Forrest <mcmurray.forrest@epa.gov>
**Subject:** Re: Call

USDA/OMB—Does OMB need to be on or will this just be the two of them?

Hayley

On Jun 12, 2018, at 5:50 PM, Sullivan, Lauren - OSEC, Washington, DC <Lauren.Sullivan@osec.usda.gov> wrote:

> Could 4:45pm work for a call tomorrow? Please also let me know the best number to call.
>
> Sent from my iPhone
>
> On Jun 12, 2018, at 4:40 PM, Ford, Hayley <ford.hayley@epa.gov> wrote:
>
> > Hi all –
> >
> > Administrator Pruitt is traveling the rest of the week but he could take this call from the road tomorrow from 12:30-2 or 4-5PM ET. Let me know what works on your end as soon as you can.
> >
> > Thanks!
> >
> > *Hayley Ford*
> > Deputy White House Liaison and Personal Aide to the Administrator
> > Environmental Protection Agency
> > ford.hayley@epa.gov
> > Phone: 202-564-2022
> > Cell: Ex. 6
> >
> > **From:** "Johansson, Robert - OCE" <RJohansson@oce.usda.gov>
> > **Date:** June 12, 2018 at 2:02:46 PM EDT
> > **To:** Ex. 6 <Ex. 6
> > **Cc:** "Starling, Raymond - OSEC, Washington, DC" <Raymond.Starling@osec.usda.gov>, "Appleton, Brooke - OSEC, Washington DC" <Brooke.Appleton@osec.usda.gov>, "wehrum.bill@epa.gov" <wehrum.bill@epa.gov>
> > **Subject: Re: Call**
> >
> > Hi Rosario,
> >
> > We would like to set up a Principals' call with the Secretary and the Administrator.
> >
> > Scheduling will likely be difficult, but to meet the aggressive timeline I suggest we try to get this call set up as soon as possible.
> >
> > I am CC'ing Ray and Brooke from USDA and Bill from

EPA to facilitate the scheduling.

Thanks Rob

Sent from my iPhone

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Message

**From:** Szabo, Aaron L. EOP/CEQ Ex. 6
**Sent:** 2/21/2018 6:57:02 PM
**To:** Bradbury, Steven (OST) [Steven.Bradbury@dot.gov]
**CC:** Rosen, Jeff (OST) [jeff.rosen@dot.gov]; Owens, James (OST) [James.Owens@dot.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; King, Heidi (NHTSA) [heidi.king@dot.gov]; Catanzaro, Michael J. EOP/WHO Ex. 6
**Subject:** RE: Deliberative Process / Ex. 5

This will be hosted by NEC, but OIRA and other relevant EOP components are invited and there attendance is expected for the meeting. Can you provide some times on Monday that would work? Monday afternoon looks best for EOP components. We would also like to schedule the meeting for 1.5 hours to make sure that we are able to cover all of the items.

Thank you very much and please let me know if you have any additional questions.

---

**From:** Bradbury, Steven (OST) [mailto:Steven.Bradbury@dot.gov]
**Sent:** Wednesday, February 21, 2018 1:17 PM
**To:** Szabo, Aaron L. EOP/CEQ Ex. 6
**Cc:** Rosen, Jeff (OST) <jeff.rosen@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>; wehrum.william@epa.gov; jackson.ryan@epa.gov; Mandy Gunasekara (gunasekara.mandy@epa.gov) <gunasekara.mandy@epa.gov>; King, Heidi (NHTSA) <heidi.king@dot.gov>; Catanzaro, Michael J. EOP/WHO Ex. 6
**Subject:** Re: Deliberative Process / Ex. 5

Aaron: Unfortunately, I'm out of town Friday and so is Jeff Rosen. Would it be possible to schedule the meeting at a time convenient for all early next week? Also, will OIRA be attending or hosting? They have a key role in the process. Thanks! Steve

Steven G. Bradbury
General Counsel
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590
steven.bradbury@dot.gov
Ex. 6

On Feb 21, 2018, at 1:02 PM, Szabo, Aaron L. EOP/CEQ Ex. 6 wrote:

> EPA said that they are available at 3pm on Friday. DOT, can you let me know if that time works for y'all?
>
> ---
>
> **From:** Szabo, Aaron L. EOP/CEQ
> **Sent:** Wednesday, February 21, 2018 12:45 PM
> **To:** 'jeff.rosen@dat.gov' <jeff.rosen@dat.gov>; 'steven.bradbury@dot.gov' <steven.bradbury@dot.gov>; james.owens (james.owens@dot.gov) <james.owens@dot.gov>; 'wehrum.william@epa.gov' <wehrum.william@epa.gov>; 'jackson.ryan@epa.gov'

<jackson.ryan@epa.gov>; Mandy Gunasekara (gunasekara.mandy@epa.gov) <gunasekara.mandy@epa.gov>; King, Heidi (NHTSA) <heidi.king@dot.gov>
**Cc:** Catanzaro, Michael J. EOP/WHO < Ex. 6
**Subject:** Deliberative Process / Ex. 5

Hello all,

I apologize for the late notice, but NEC would like to convene a meeting preferably Friday morning to Deliberative Process / Ex. 5 Could you please let me know if you are available Friday at 10 – 11am or 11 – 12pm? If you are not available at that time, can you please let me know of some times on Monday that would work. As soon as we have a confirmed time, I will send out the scheduler with the WAVES information.

Please let me know if there is anyone that I should work with in your agency to set this up.

Thank you very much for your assistance.

**Aaron L. Szabo**
Senior Counsel
Council on Environmental Quality
Ex. 6 (Desk)
(Cell)
Ex. 6

Message

**From**: Tamm, James (NHTSA) [james.tamm@dot.gov]
**Sent**: 2/16/2018 4:31:33 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Theroux, Richard P. [Ex. 6] [Ex. 6] Laity, Jim [Ex. 6] Achanta, Chandana L. [Ex. 6]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Schade, Rebecca (NHTSA) [rebecca.schade@dot.gov]; Pickrell, Don H (Volpe) [Don.Pickrell@dot.gov]; Charmley, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb1828fb00af42ffb68b9e0a71626d95-Charmley, William]; Hengst, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c414e2bf04a246bb987d88498eefff06-Hengst, Benjamin]; Olechiw, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f564b92ff96459ab606eb66e5892e2d-Olechiw, Michael]; Bolon, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7c0684aaef44174801c0406b51034d2-Bolon, Kevin]
**Subject**: RE: NHTSA Briefing Materials
**Attachments**: Deliberative Process / Ex. 5

Additional briefing materials.

---

**From:** Tamm, James (NHTSA)
**Sent:** Friday, February 16, 2018 11:04 AM
**To:** King, Heidi (NHTSA) <heidi.king@dot.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Theroux, Richard P. [Ex. 6] <[Ex. 6]>; Laity, Jim [Ex. 6] Achanta, Chandana L. [Ex. 6] Green, Kevin (VOLPE) <Kevin.Green@dot.gov>; Schade, Rebecca (NHTSA) <rebecca.schade@dot.gov>; Pickrell, Don H (VOLPE) (Don.Pickrell@dot.gov) <Don.Pickrell@dot.gov>; charmley.william@epa.gov; Hengst, Benjamin (Hengst.Benjamin@epa.gov) <Hengst.Benjamin@epa.gov>; 'Olechiw, Michael' <olechiw.michael@epa.gov>; 'Bolon, Kevin' <Bolon.Kevin@epa.gov>
**Subject:** NHTSA Briefing Materials

Message

**From**: Delahoyde, Magdelana A. EOP/WHO Ex. 6
**Sent**: 12/11/2017 9:01:36 PM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Owens, James (OST [James.Owens@dot.gov]; King, Heidi (NHTSA) [heidi.king@dot.gov]; jonathan.morrison@dot.gov
**CC**: Nassar, Jimmi (NHTSA) [jimmi.nassar@dot.gov]; Loving, Shanita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=439ce9c2d2104080a1b5908d3402bf20-Loving, Shanita]; michelle.curry@dot.gov
**Subject**: RE: [EXTERNAL] Meeting in DC

I've heard no objections so I'm moving this to 4pm tomorrow. Thanks, Everyone!

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Monday, December 11, 2017 10:17 AM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>
Cc: 'Nassar, Jimmi (NHTSA)' <jimmi.nassar@dot.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'michelle.curry@dot.gov' <michelle.curry@dot.gov>
Subject: RE: [EXTERNAL] Meeting in DC

One more try....

Does anyone object to doing this call at 4pm tomorrow? (Tuesday, December 12)

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Monday, December 11, 2017 9:43 AM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>
Cc: 'Nassar, Jimmi (NHTSA)' <jimmi.nassar@dot.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'michelle.curry@dot.gov' <michelle.curry@dot.gov>
Subject: RE: [EXTERNAL] Meeting in DC

Hi Everyone,

Due to conflicts, we're hoping to reschedule this meeting for TUESDAY, Dec. 12th at 5:00pm. The meeting will now be a call-in, instead of a meeting.

If this poses schedule problems for you, please let me know ASAP!

Maggie

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Friday, December 8, 2017 3:24 PM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>
Cc: 'Nassar, Jimmi (NHTSA)' <jimmi.nassar@dot.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'michelle.curry@dot.gov' <michelle.curry@dot.gov>
Subject: RE: [EXTERNAL] Meeting in DC

Hi Everyone,

Mike would like to schedule a pre-meeting (Monday or Tuesday) before the California meeting next week.

Here are windows for Mike. Please let me know what works for you! Happy to set up a call as well for those who can't attend in person:

Monday: 1-2:30pm, 3-4pm, 4:30-6pm
Tuesday: 1-4pm, 4:30-6pm

Please let me know what works for you.
Maggie

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Thursday, December 7, 2017 4:50 PM

To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>
Cc: 'Nassar, Jimmi (NHTSA)' <jimmi.nassar@dot.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'michelle.curry@dot.gov' <michelle.curry@dot.gov>
Subject: RE: [EXTERNAL] Meeting in DC

Hi Everyone,

We are confirmed for the meeting in California next Friday morning, December 15th, at 9am in Los Angeles. The location is Los Angeles CleanTech Incubator (LACI) 525 S. Hewitt St, Los Angeles. (FWIW- I plan to fly Mike out Thursday evening and back on an early afternoon flight on Friday.)

Delta, Virgin, and American have good direct options from DCA into LAX.

Let me know how I can be helpful. I hope this works ok for everyone!
Maggie

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Wednesday, December 6, 2017 12:30 PM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>; Harris, Jeffrey M. EOP/OMB [redacted] Ex. 6
Cc: 'Nassar, Jimmi (NHTSA)' <jimmi.nassar@dot.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'michelle.curry@dot.gov' <michelle.curry@dot.gov>
Subject: RE: [EXTERNAL] Meeting in DC

Hi All,

We're really hoping to make this work for a meeting in Sacramento the afternoon of Thursday, Dec. 14th. If you can possibly hold calendars to fly out the morning of Thursday, Dec. 14th, meet that afternoon, and then fly back to DC the morning of Dec. 15th, that would be great. I'll send over more details when I have them! Still waiting and hoping for a few schedules to fall into place.

Thanks!
Maggie

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Tuesday, December 5, 2017 11:04 AM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>; Harris, Jeffrey M. EOP/OMB [redacted] Ex. 6
Subject: FW: [EXTERNAL] Meeting in DC

Bill, James, Heidi, Jonathan, and Jeff:

I'm helping Mike plan this meeting to California next week and I wanted to work with each of your assistants to align schedules and all logistics. My plan is to get the timing set and then find the best DC-->Sacramento flight that works for the meeting.

Let me know the best person to work with on your end!

Maggie

-----Original Message-----
From: Catanzaro, Michael J. EOP/WHO
Sent: Tuesday, December 5, 2017 9:43 AM
To: Delahoyde, Magdelana A. EOP/WHO <[redacted] Ex. 6
Subject: RE: [EXTERNAL] Meeting in DC

The purpose of the meeting is to discuss CAFE-GHG standards with California regulators. Here are the attendees:

EPA: Bill Wehrum
DOT/NHTSA: James Owens, Heidi King, Jonathan Morrison
OIRA: Jeff Harris

Can you help coordinate with these folks? Also, I'll need to get a plane ticket at some point. Can you help with that, too? Thank you!

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Monday, December 4, 2017 5:14 PM
To: Catanzaro, Michael J. EOP/WHO [redacted] Ex. 6
Subject: RE: [EXTERNAL] Meeting in DC

**Deliberative Process / Ex. 5**

-----Original Message-----
From: Catanzaro, Michael J. EOP/WHO
Sent: Monday, December 4, 2017 4:45 PM
To: 'Mary Nichols' [redacted]
Cc: Delahoyde, Magdelana A. EOP/WHO [redacted]
Subject: RE: [EXTERNAL] Meeting in DC

Mary, it's a deal! Copying Maggie on my end. Look forward to it.

Best,
Mike

-----Original Message-----
From: Mary Nichols [mailto: [redacted]
Sent: Monday, December 4, 2017 4:33 PM
To: Catanzaro, Michael J. EOP/WHO < [redacted]
Subject: Re: [EXTERNAL] Meeting in DC

Good morning from Tokyo, where I am paying a long overdue visit to Japanese OEMs. [redacted]

I would be pleased to meet with you and your colleagues the week of Dec.11 in California. If there is time in your schedule we can offer a tour of our LA vehicle testing facilities and lab. My board has its monthly public meeting on Thursday the 14th in Sacramento, with a holiday party the evening before, so Wednesday or Thursday afternoon in Sacramento is probably most convenient. Shall we put our schedulers to work on this?

Best,
Mary

Sent from my iPhone

> On Dec 5, 2017, at 1:25 AM, Catanzaro, Michael J. EOP/WHO < [redacted] > wrote:
>
> Hi Mary, hope you had a great Thanksgiving holiday with your family. And thanks for making the trek with your team to DC. We found the meeting to be very helpful. We were wondering if we could return the favor by coming to meet with you in California, about next steps, sometime the week of Dec. 11, preferably later that week. And if it has to slip to early the following week, that's fine too. Thanks for considering, and look forward to meeting soon.
>
> Best,
> Mike
>
> -----Original Message-----
> From: Mary Nichols [mailto [redacted]
> Sent: Wednesday, November 8, 2017 12:23 PM
> To: Delahoyde, Magdelana A. EOP/WHO < [redacted] >; Shannon Stewart <shannon.stewart@arb.ca.gov>
> Cc: Catanzaro, Michael J. EOP/WHO < [redacted]
> Subject: Re: [EXTERNAL] Meeting in DC
>
>
> Hi Maggie. There will be 3 of us. We will have to travel on Monday. because of flight schedules and time zone changes. We hope to fly back to CA that evening, so morning would be better but we can make 2:00 work if necessary.
> I am now adding Shannon Stewart,my scheduler, who will be handling the travel details.
> Best,
> Mary Nichols
>
> Sent from my iPhone
>
>> On Nov 7, 2017, at 2:16 PM, Delahoyde, Magdelana A. EOP/WHO < [redacted] > wrote:
>>
>> Hi Mary,
>>
>> Would 2:00pm EST work for your group on November 14th? And do you know how many will be attending? I'll follow up with clearance information!
>>
>> Maggie
>>
>> -----Original Message-----
>> From: Catanzaro, Michael J. EOP/WHO
>> Sent: Tuesday, November 7, 2017 5:03 PM
>> To: 'Mary Nichols' [redacted]
>> Cc: Delahoyde, Magdelana A. EOP/WHO [redacted]

>> Subject: RE: [EXTERNAL] Meeting in DC
>>
>> Mary, thanks for getting back. Yes, the 14th works fine. Adding Maggie to help schedule. We plan to have representatives from DOT, EPA, and OIRA. Specifically, from DOT: Heidi King, Acting Administrator, NHTSA; James Owens, Deputy General Counsel, DOT; Bill Wehrum, (assuming he's confirmed Thursday to be Assistant Administrator for Air and Radiation, EPA); and Jeff Harris, Associate Administrator, OIRA. Also, we are happy to discuss the issues you raised below. Look forward to meeting.
>>
>> Best,
>> Mike
>>
>> -----Original Message-----
>> From: Mary Nichols [mailto: Ex. 6
>> Sent: Monday, November 6, 2017 9:33 PM
>> To: Catanzaro, Michael J. EOP/WHO < Ex. 6
>> Subject: [EXTERNAL] Meeting in DC
>>
>> Dear Mike,
>> I can come to DC for a meeting on the 14th. I would bring my Chief Deputy Executive Officer Steve Cliff and our lead analyst for vehicle emissions technology policy, Mike McCarthy.
>> The rest of the week is out for us because of our monthly board meeting, but if the 14th is no good we will look farther ahead on our calendars.
>> I would like to know who from the federal family will be present and also to be clear that we want to talk about schedules for action by both NHTSA and EPA. I would also like to hear what you and your colleagues gleaned from your meetings with the OEMs so we can all be on the same page as much as possible about what kind of relief is really needed in what timeframe, as well as the potential to have a real " win" for all going forward.
>> Best,
>> Mary
>>
>> Sent from my iPhone

Message

**From:** Owens, James (OST) [James.Owens@dot.gov]
**Sent:** 12/6/2017 6:02:52 PM
**To:** King, Heidi (NHTSA) [heidi.king@dot.gov]
**CC:** Delahoyde, Magdelana A. EOP/WHO [Ex. 6; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Nassar, Jimmi (NHTSA) [jimmi.nassar@dot.gov]; Loving, Shanita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=439ce9c2d2104080a1b5908d3402bf20-Loving, Shanita]; Curry, Michelle (OST) [Michelle.Curry@dot.gov]
**Subject:** Re: [EXTERNAL] Meeting in DC

I can do Friday if Tuesday doesn't work.

James C. Owens
Deputy General Counsel
U.S Department of Transportation
1200 New Jersey Ave., S.E.
Washington, D.C. 20590
Ex. 6
James.Owens@dot.gov

On Dec 6, 2017, at 12:54 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

> I know James Owens has a conflict Friday morning so if Tuesday works, that is better. But we are all trying to make it work.
>
> ---
>
> **From:** Delahoyde, Magdelana A. EOP/WHO <Ex. 6
> **Sent:** Wednesday, December 6, 2017 12:46:27 PM
> **To:** King, Heidi (NHTSA); wehrum.bill@epa.gov; Owens, James (OST); Morrison, Jonathan (NHTSA)
> **Cc:** Nassar, Jimmi (NHTSA); Loving, Shanita; Curry, Michelle (OST)
> **Subject:** RE: [EXTERNAL] Meeting in DC
>
> No—I completely understand! Let me see if I can try for a meeting Friday morning (fly out Thursday night, meet Friday morning, return to DC Friday afternoon).
>
> Does anyone object to that outline?
>
> ---
>
> **From:** King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
> **Sent:** Wednesday, December 6, 2017 12:44 PM
> **To:** Delahoyde, Magdelana A. EOP/WHO <Ex. 6>; wehrum.bill@epa.gov; Owens, James (OST) <James.Owens@dot.gov>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Harris, Jeffrey M. EOP/OMB <Ex. 6
> **Cc:** Nassar, Jimmi (NHTSA) <jimmi.nassar@dot.gov>; Loving, Shanita <Loving.Shanita@epa.gov>; Curry, Michelle (OST) <Michelle.Curry@dot.gov>
> **Subject:** RE: [EXTERNAL] Meeting in DC
>
> Maggie, Thursday afternoon is a critical leadership meeting at NHTSA representing my only chance annually to speak with and meet the NHTSA team, most of whom have never met their new leadership (Jonathan and myself). The entire agency has held this time for months to meet

with me.

If there were a way that I could reschedule that meeting, I would. But it has taken me months to get the space and AV support for the Thursday afternoon meeting.

I do not know how to resolve the schedule conflict. But perhaps I am not needed in CA.

Should I reach out to Mike and explain?

Heidi

---

**From:** Delahoyde, Magdelana A. EOP/WHO <Ex. 6
**Sent:** Wednesday, December 6, 2017 12:30:19 PM
**To:** wehrum.bill@epa.gov; Owens, James (OST); King, Heidi (NHTSA); Morrison, Jonathan (NHTSA); Harris, Jeffrey M. EOP/OMB
**Cc:** Nassar, Jimmi (NHTSA); Loving, Shanita; Curry, Michelle (OST)
**Subject:** RE: [EXTERNAL] Meeting in DC

Hi All,

We're really hoping to make this work for a meeting in Sacramento the afternoon of Thursday, Dec. 14th. If you can possibly hold calendars to fly out the morning of Thursday, Dec. 14th, meet that afternoon, and then fly back to DC the morning of Dec. 15th, that would be great. I'll send over more details when I have them! Still waiting and hoping for a few schedules to fall into place.

Thanks!
Maggie

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Tuesday, December 5, 2017 11:04 AM
To: 'wehrum.bill@epa.gov' <wehrum.bill@epa.gov>; 'Owens, James (OST' <James.Owens@dot.gov>; 'King, Heidi (NHTSA)' <heidi.king@dot.gov>; 'jonathan.morrison@dot.gov' <jonathan.morrison@dot.gov>; Harris, Jeffrey M. EOP/OMB <Ex. 6
Subject: FW: [EXTERNAL] Meeting in DC

Bill, James, Heidi, Jonathan, and Jeff:

I'm helping Mike plan this meeting to California next week and I wanted to work with each of your assistants to align schedules and all logistics. My plan is to get the timing set and then find the best DC-->Sacramento flight that works for the meeting.

Let me know the best person to work with on your end!

Maggie

-----Original Message-----
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Sent: Tuesday, December 5, 2017 9:43 AM
To: Delahoyde, Magdelana A. EOP/WHO <Ex. 6>
Subject: RE: [EXTERNAL] Meeting in DC

The purpose of the meeting is to discuss CAFE-GHG standards with California regulators. Here are the attendees:

EPA: Bill Wehrum

DOT/NHTSA: James Owens, Heidi King, Jonathan Morrison
OIRA: Jeff Harris

Can you help coordinate with these folks? Also, I'll need to get a plane ticket at some point. Can you help with that, too? Thank you!

-----Original Message-----
From: Delahoyde, Magdelana A. EOP/WHO
Sent: Monday, December 4, 2017 5:14 PM
To: Catanzaro, Michael J. EOP/WHO <Ex. 6
Subject: RE: [EXTERNAL] Meeting in DC

**Deliberative Process / Ex. 5**

-----Original Message-----
From: Catanzaro, Michael J. EOP/WHO
Sent: Monday, December 4, 2017 4:45 PM
To: 'Mary Nichols' <Ex. 6
Cc: Delahoyde, Magdelana A. EOP/WHO <Ex. 6
Subject: RE: [EXTERNAL] Meeting in DC

Mary, it's a deal! Copying Maggie on my end. Look forward to it.

Best,
Mike

-----Original Message-----
From: Mary Nichols [mailto Ex. 6
Sent: Monday, December 4, 2017 4:33 PM
To: Catanzaro, Michael J. EOP/WHO <Ex. 6
Subject: Re: [EXTERNAL] Meeting in DC

Good morning from Tokyo, where I am paying a long overdue visit to Japanese OEMs. Ex. 6
Ex. 6

I would be pleased to meet with you and your colleagues the week of Dec.11 in California. If there is time in your schedule we can offer a tour of our LA vehicle testing facilities and lab. My board has its monthly public meeting on Thursday the 14th in Sacramento, with a holiday party the evening before, so Wednesday or Thursday afternoon in Sacramento is probably most convenient. Shall we put our schedulers to work on this?

Best,
Mary

Sent from my iPhone

> On Dec 5, 2017, at 1:25 AM, Catanzaro, Michael J. EOP/WHO <Ex. 6> wrote:
>
> Hi Mary, hope you had a great Thanksgiving holiday with your family. And thanks for making the trek with your team to DC. We found the meeting to be very helpful. We were wondering if we could return the favor by coming to meet with you in California, about next steps, sometime the week of Dec. 11, preferably later that week. And if it has to slip to early the following week, that's fine too. Thanks for considering, and look forward to meeting soon.
>
> Best,
> Mike
>
> -----Original Message-----
> From: Mary Nichols [mailto Ex. 6]
> Sent: Wednesday, November 8, 2017 12:23 PM
> To: Delahoyde, Magdelana A. EOP/WHO <Ex. 6>; Shannon Stewart <shannon.stewart@arb.ca.gov>

> Cc: Catanzaro, Michael J. EOP/WHO < Ex. 6 >
> Subject: Re: [EXTERNAL] Meeting in DC
>
>
> Hi Maggie. There will be 3 of us. We will have to travel on Monday. because of flight schedules and time zone changes. We hope to fly back to CA that evening, so morning would be better but we can make 2:00 work if necessary.
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> Mary Nichols
>
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>
>> On Nov 7, 2017, at 2:16 PM, Delahoyde, Magdelana A. EOP/WHO < Ex. 6 > wrote:
>>
>> Hi Mary,
>>
>> Would 2:00pm EST work for your group on November 14th? And do you know how many will be attending? I'll follow up with clearance information!
>>
>> Maggie
>>
>> -----Original Message-----
>> From: Catanzaro, Michael J. EOP/WHO
>> Sent: Tuesday, November 7, 2017 5:03 PM
>> To: 'Mary Nichols' < Ex. 6 >
>> Cc: Delahoyde, Magdelana A. EOP/WHO < Ex. 6 >
>> Subject: RE: [EXTERNAL] Meeting in DC
>>
>> Mary, thanks for getting back. Yes, the 14th works fine. Adding Maggie to help schedule. We plan to have representatives from DOT, EPA, and OIRA. Specifically, from DOT: Heidi King, Acting Administrator, NHTSA; James Owens, Deputy General Counsel, DOT; Bill Wehrum, (assuming he's confirmed Thursday to be Assistant Administrator for Air and Radiation, EPA); and Jeff Harris, Associate Administrator, OIRA. Also, we are happy to discuss the issues you raised below. Look forward to meeting.
>>
>> Best,
>> Mike
>>
>> -----Original Message-----
>> From: Mary Nichols [mailto: Ex. 6
>> Sent: Monday, November 6, 2017 9:33 PM
>> To: Catanzaro, Michael J. EOP/WHO < Ex. 6 >
>> Subject: [EXTERNAL] Meeting in DC
>>
>> Dear Mike,
>> I can come to DC for a meeting on the 14th. I would bring my Chief Deputy Executive Officer Steve Cliff and our lead analyst for vehicle emissions technology policy, Mike McCarthy.
>> The rest of the week is out for us because of our monthly board meeting, but if the 14th is no good we will look farther ahead on our calendars.
>> I would like to know who from the federal family will be present and also to be clear that we want to talk about schedules for action by both NHTSA and EPA. I would also like to hear what you and your colleagues gleaned from your meetings with the OEMs so we can all be on the same page as much as possible about what kind of relief is really needed in what timeframe, as well as the potential to have a real "win" for all going forward.
>> Best,
>> Mary
>>
>> Sent from my iPhone

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/25/2018 11:48:46 PM
**To**: Michael Catanzaro [Ex. 6]; Harris, Jeffrey M. EOP/OMB
[Ex. 6] Palmieri, Rosario A. EOP/OMB
[Ex. 6] Owens, James (OST) [James.Owens@dot.gov]; Wehrum, Bill
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject**: **Deliberative Process / Ex. 5**
**Attachments**:

Good evening,

Hopefully the attached schedule demonstrates the reasonableness of the April 1 joint NPRM. I look forward to discussing tomorrow.

Have a good evening,

Heidi

Message

**From**: Catanzaro, Michael J. EOP/WHO [Ex. 6]
**Sent**: 1/25/2018 7:27:10 PM
**To**: 'King, Heidi (NHTSA)' [heidi.king@dot.gov]; Palmieri, Rosario A. EOP/OMB [Ex. 6]
**CC**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Harris, Jeffrey M. EOP/OMB [Ex. 6] Owens, James (OST) [James.Owens@dot.gov]
**Subject**: RE: RE: RE: RE:

I'm scheduling a call for tomorrow to go over the schedule. Calendar invite coming soon. Also, the

**Deliberative Process / Ex. 5**

-----Original Message-----
From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
Sent: Thursday, January 25, 2018 2:19 PM
To: Palmieri, Rosario A. EOP/OMB [Ex. 6]
Cc: Wehrum, Bill <Wehrum.Bill@epa.gov>; Catanzaro, Michael J. EOP/WHO <[Ex. 6]>; Harris, Jeffrey M. EOP/OMB [Ex. 6]; Owens, James (OST) <James.Owens@dot.gov>
Subject: Re: RE: RE: RE:

**Deliberative Process / Ex. 5**

Sent from my iPhone

> On Jan 25, 2018, at 2:08 PM, Palmieri, Rosario A. EOP/OMB [Ex. 6] wrote:
>
> Mike and all,
>

**Deliberative Process / Ex. 5**

>
> Thank you,
>
> Rosario
>
> -----Original Message-----
> From: Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
> Sent: Wednesday, January 24, 2018 6:40 PM
> To: King, Heidi (NHTSA) <heidi.king@dot.gov>
> Cc: Catanzaro, Michael J. EOP/WHO <[Ex. 6]>; Harris, Jeffrey M. EOP/OMB <[Ex. 6]>; Palmieri, Rosario A. EOP/OMB <[Ex. 6]>
> Subject: RE: RE: RE:
>

**Deliberative Process / Ex. 5**

> -----Original Message-----
> From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
> Sent: Wednesday, January 24, 2018 6:32 PM
> To: Wehrum, Bill <Wehrum.Bill@epa.gov>
> Cc: Catanzaro, Michael J. EOP/WHO [Ex. 6]; Harris, Jeffrey M. EOP/OMB <[Ex. 6]>; Palmieri, Rosario A. EOP/OMB [Ex. 6]
> Subject: Re: RE: RE:
>
> :-)
>
> Thanks

**Deliberative Process / Ex. 5**

>
> Sent from my iPhone
>
>> On Jan 24, 2018, at 6:28 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>>

>> Here it is.
>>
>> -----Original Message-----
>> From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
>> Sent: Wednesday, January 24, 2018 6:25 PM
>> To: Wehrum, Bill <Wehrum.Bill@epa.gov>
>> Cc: Catanzaro, Michael J. EOP/WHO {Ex. 6}; Harris, Jeffrey M. EOP/OMB {Ex. 6}; Palmieri, Rosario A. EOP/OMB {Ex. 6}
>> Subject: Re: RE:
>>
>> Bill, thanks for the link, I'm unable to get into the One Drive system, could you send the doc as an attachment?
>>
>> Thank you! Much appreciated.
>>
>> Heidi
>>
>> Sent from my iPhone
>>
>>> On Jan 24, 2018, at 6:16 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>>>
>>> I'm sending a revised version to Heidi as we speak. We should soon be able to circulate it to the broader group.
>>>
>>> -----Original Message-----
>>> From: Catanzaro, Michael J. EOP/WHO [mailto:{Ex. 6}
>>> Sent: Wednesday, January 24, 2018 6:14 PM
>>> To: Wehrum, Bill <Wehrum.Bill@epa.gov>; heidi.king@dot.gov
>>> Cc: Harris, Jeffrey M. EOP/OMB {Ex. 6} Palmieri, Rosario A. EOP/OMB {Ex. 6}
>>> Subject:
>>>
>>> Bill, Heidi, just checking in on the ETA of your joint schedule. Thanks for your help on this.
>>>
>>> Sent from my iPhone
>> {Deliberative Process / Ex. 5}

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/25/2018 2:29:49 AM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Michael Catanzaro Ex. 6; Jeffrey Harris Ex. 6; rpalmieri@omb.eop.gov; Owens, James (OST) [James.Owens@dot.gov]; Achanta, EOP/OMB Ex. 6
**Subject**: NHTSA model and inputs should be through firewall now, let us know

Bill,

Deliberative Process / Ex. 5

Please do let us know if you hear that they were not received.

All the best,

Heidi

Sent from my iPhone

Message

**From**: Whiteman, Chad S. EOP/OMB [Ex. 6]
**Sent**: 2/12/2018 3:55:50 PM
**To**: Charmley, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb1828fb00af42ffb68b9e0a71626d95-Charmley, William]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Mullins, Timothy (OST) [Timothy.Mullins@dot.gov]; Achanta, Chandana L. EOP/OMB [Ex. 6]; Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]
**CC**: Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Hengst, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c414e2bf04a246bb987d88498eefff06-Hengst, Benjamin]
**Subject**: RE: Call today at 2 or 3 pm?

Let's use this call-in:

Dial-In: Ex. 6
Code Ex. 6

---

**From:** Charmley, William [mailto:charmley.william@epa.gov]
**Sent:** Monday, February 12, 2018 10:47 AM
**To:** Whiteman, Chad S. EOP/OMB [Ex. 6]; Wehrum, Bill <Wehrum.Bill@epa.gov>; Mullins, Timothy (OST) <Timothy.Mullins@dot.gov>; Achanta, Chandana L. EOP/OMB [Ex. 6] Jim Tamm <james.tamm@dot.gov>
**Cc:** Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Hengst, Benjamin <Hengst.Benjamin@epa.gov>
**Subject:** RE: Call today at 2 or 3 pm?

I and a few of my team from Ann Arbor are available.

**Chandana and Chad** - are you going to send around a call-in number?

Thanks
Bill

-----Original Message-----
From: Whiteman, Chad S. EOP/OMB [mailto: Ex. 6
Sent: Monday, February 12, 2018 10:21 AM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>; Mullins, Timothy (OST) <Timothy.Mullins@dot.gov>; Achanta, Chandana L. EOP/OMB [Ex. 6]; Charmley, William <charmley.william@epa.gov>; Jim Tamm <james.tamm@dot.gov>
Cc: Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Hengst, Benjamin <Hengst.Benjamin@epa.gov>
Subject: RE: Call today at 2 or 3 pm?

+ Ben H.

-----Original Message-----
From: Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
Sent: Monday, February 12, 2018 10:06 AM

To: Mullins, Timothy (OST) <Timothy.Mullins@dot.gov>; Achanta, Chandana L. EOP/OMB
Ex. 6 ; Charmley, William <charmley.william@epa.gov>; Jim Tamm
<james.tamm@dot.gov>
Cc: Whiteman, Chad S. EOP/OMB Ex. 6 >; Morrison, Jonathan (NHTSA)
<Jonathan.Morrison@dot.gov>
Subject: RE: Call today at 2 or 3 pm?

2:00 works for me.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

-----Original Message-----
From: Mullins, Timothy (OST) [mailto:Timothy.Mullins@dot.gov]
Sent: Monday, February 12, 2018 9:50 AM
To: Achanta, Chandana L. EOP/OMB Ex. 6 Charmley, William
<charmley.william@epa.gov>; Jim Tamm <james.tamm@dot.gov>
Cc: Wehrum, Bill <Wehrum.Bill@epa.gov>; Whiteman, Chad S. EOP/OMB < Ex. 6
Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>
Subject: RE: Call today at 2 or 3 pm?

DOT and NHTSA are available at 2 to 3.

Thanks,
Tim

-----Original Message-----
From: Achanta, Chandana L. EOP/OMB [mailto: Ex. 6
Sent: Monday, February 12, 2018 9:45 AM
To: charmley.william@epa.gov; Tamm, James (NHTSA) <james.tamm@dot.gov>; Mullins, Timothy (OST)
<Timothy.Mullins@dot.gov>
Cc: wehrum.bill@epa.gov; Whiteman, Chad S. EOP/OMB < Ex. 6
Subject: Call today at 2 or 3 pm?

Hi all

Hope you had a great weekend!

Are you all free at 2pm or 3 pm today to discuss Deliberative Process / Ex. 5

Thanks
Chandana

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 12/20/2017 8:40:44 PM
**To**: Owens, James (OST) [James.Owens@dot.gov]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Fischer, Kara (NHTSA) [kara.fischer@dot.gov]; Wood, Steve (NHTSA) [Steve.Wood@dot.gov]; Kolodziej, Kerry (NHTSA) [Kerry.Kolodziej@dot.gov]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Loving, Shanita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=439ce9c2d2104080a1b5908d3402bf20-Loving, Shanita]; Wood, Jeffrey (ENRD) [Jeffrey.Wood@usdoj.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; jeffrey.m.harris@ Ex. 6 jonathan.brightbill@usdoj.gov; eric.grant@usdoj.gov; John.S.Moran@ Ex. 6 Bradbury, Steven (OST) [Steven.Bradbury@dot.gov]; Harlow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a9a34e31fc4fe6b2beaddda2affa44-Harlow, Dav]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Palmieri, Rosario A. EOP/OMB Ex. 6 ; Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]; kevin.green@dot.gov [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3de0c76a]; Catanzaro, Michael J. EOP/WHO Ex. 6
**CC**: Posten, Ryan (NHTSA) [ryan.posten@dot.gov]; Gregory Powell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userca60cd5e]; Ryan Hagen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user81a84ec4]; Fish, Hannah (NHTSA) [hannah.fish@dot.gov]; Blincoe, Larry (NHTSA) [Larry.Blincoe@dot.gov]
**Subject**: RE: Deliberative Process / Ex. 5

call-in: Ex. 6
access code: Ex. 6

---

**From:** King, Heidi (NHTSA)
**Sent:** Wednesday, December 20, 2017 3:34 PM
**To:** Kopko, Matthew (OST) <matthew.kopko@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; 'Fischer, Kara (NHTSA)' <kara.fischer@dot.gov>; 'Wood, Steve (NHTSA) (Steve.Wood@dot.gov)' <Steve.Wood@dot.gov>; 'Kolodziej, Kerry (NHTSA)' <Kerry.Kolodziej@dot.gov>; 'Atkinson, Emily' <Atkinson.Emily@epa.gov>; 'Loving, Shanita' <Loving.Shanita@epa.gov>; 'Wood, Jeffrey (ENRD)' <Jeffrey.Wood@usdoj.gov>; 'gunasekara.mandy@epa.gov' <gunasekara.mandy@epa.gov>; 'Wehrum.william@epa.gov' <Wehrum.william@epa.gov>; 'jeffrey.m.harris@ Ex. 6 ; 'jonathan.brightbill@usdoj.gov' <jonathan.brightbill@usdoj.gov>; 'eric.grant@usdoj.gov' <eric.grant@usdoj.gov>; 'John.S.Moran@ Ex. 6 Bradbury, Steven (OST) <Steven.Bradbury@dot.gov>; 'harlow.david@epa.gov' <harlow.david@epa.gov>; 'Wehrum, Bill' <Wehrum.Bill@epa.gov>; 'Palmieri, Rosario A. EOP/OMB' Ex. 6 ; Tamm, James (NHTSA) <james.tamm@dot.gov>; Green, Kevin (Volpe) <Kevin.Green@dot.gov>; 'Catanzaro, Michael J. EOP/WHO' Ex. 6
**Cc:** Posten, Ryan (NHTSA) <ryan.posten@dot.gov>; Powell, Gregory (NHTSA) <gregory.powell@dot.gov>; Hagen, Ryan (NHTSA) <ryan.hagen@dot.gov>; Fish, Hannah (NHTSA) <hannah.fish@dot.gov>; 'Blincoe, Larry (NHTSA) (Larry.Blincoe@dot.gov)' <Larry.Blincoe@dot.gov>
**Subject:** RE: Deliberative Process / Ex. 5

NHTSA is having audio interruption and intends to re-open the line – thank you for standing by

**From:** King, Heidi (NHTSA)
**Sent:** Wednesday, December 20, 2017 3:10 PM
**To:** Kopko, Matthew (OST) <matthew.kopko@dot.gov>; Owens, James (OST) <James.Owens@dot.gov>; Morrison, Jonathan (NHTSA) <Jonathan.Morrison@dot.gov>; Fischer, Kara (NHTSA) <kara.fischer@dot.gov>; Wood, Steve (NHTSA) (Steve.Wood@dot.gov) <Steve.Wood@dot.gov>; Kolodziej, Kerry (NHTSA) <Kerry.Kolodziej@dot.gov>; 'Atkinson, Emily' <Atkinson.Emily@epa.gov>; Loving, Shanita <Loving.Shanita@epa.gov>; Wood, Jeffrey (ENRD) <Jeffrey.Wood@usdoj.gov>; 'gunasekara.mandy@epa.gov' <gunasekara.mandy@epa.gov>; Wehrum.william@epa.gov; 'jeffrey.m.harris@[Ex. 6]; 'jonathan.brightbill@usdoj.gov' <jonathan.brightbill@usdoj.gov>; 'eric.grant@usdoj.gov' <eric.grant@usdoj.gov>; John.S.Moran@[Ex. 6] Bradbury, Steven (OST) <Steven.Bradbury@dot.gov>; 'harlow.david@epa.gov' <harlow.david@epa.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>; 'Palmieri, Rosario A. EOP/OMB' <[Ex. 6]; Tamm, James (NHTSA) <james.tamm@dot.gov>; Green, Kevin (Volpe) <Kevin.Green@dot.gov>; Catanzaro, Michael J. EOP/WHO <[Ex. 6]
**Cc:** Posten, Ryan (NHTSA) <ryan.posten@dot.gov>; Powell, Gregory (NHTSA) <gregory.powell@dot.gov>; Hagen, Ryan (NHTSA) <ryan.hagen@dot.gov>; Fish, Hannah (NHTSA) <hannah.fish@dot.gov>; Blincoe, Larry (NHTSA) (Larry.Blincoe@dot.gov) <Larry.Blincoe@dot.gov>
**Subject:** RE: [Deliberative Process / Ex. 5]

We will start at 3:15, apologies for Audio Visual difficulties!

-----Original Appointment-----
**From:** Lee, Pei (NHTSA) **On Behalf Of** King, Heidi (NHTSA)
**Sent:** Wednesday, December 20, 2017 10:29 AM
**To:** King, Heidi (NHTSA); Kopko, Matthew (OST); Owens, James (OST); Morrison, Jonathan (NHTSA); Fischer, Kara (NHTSA); Wood, Steve (NHTSA) (Steve.Wood@dot.gov); Kolodziej, Kerry (NHTSA); Atkinson, Emily; Loving, Shanita; Wood, Jeffrey (ENRD); gunasekara.mandy@epa.gov; Wehrum.william@epa.gov; jeffrey.m.harris@[Ex. 6] jonathan.brightbill@usdoj.gov; eric.grant@usdoj.gov; John.S.Moran@who.eop.gov; Bradbury, Steven (OST); harlow.david@epa.gov; Wehrum, Bill; Palmieri, Rosario A. EOP/OMB; Tamm, James (NHTSA); Green, Kevin (Volpe); Catanzaro, Michael J. EOP/WHO
**Cc:** Posten, Ryan (NHTSA); Powell, Gregory (NHTSA); Hagen, Ryan (NHTSA); Fish, Hannah (NHTSA); Blincoe, Larry (NHTSA) (Larry.Blincoe@dot.gov)
**Subject:** [Deliberative Process / Ex. 5]
**When:** Wednesday, December 20, 2017 3:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** DOT Conference Room: W40-302 (NHTSA) or see body of email for call in information

**Audio Line – Use This Number Only:**
Call in: [Ex. 6]
Access Code: [Ex. 6]

**For Screen Sharing Only** – Do Not Use the Phone Number Listed in the GoToMeeting:
[Ex. 6]
First GoToMeeting? Let's do a quick system check: https://link.gotomeeting.com/system-check

Message

**From:** King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent:** 12/20/2017 1:05:08 PM
**To:** Moran, John S. EOP/WHO [Ex. 6]
**CC:** Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject:** Re: [Deliberative Process / Ex. 5]

Thank you John [Ex. 6]

A very happy holiday to you and yours and we will have an exciting New Year together!

Warm wishes,

Heidi

Sent from my iPhone

On Dec 20, 2017, at 7:58 AM, Moran, John S. EOP/WHO <[Ex. 6]> wrote:

> Heidi and Bill,
>
> I wanted to give you a heads up [Ex. 6] and won't be able to make our 9 am Meeting. Jeff Harris from OIRA will be there, though, and he and I can follow up later as needed. If I don't see you beforehand, I hope you both enjoy the holidays and have a Happy New Year!
>
> John S. Moran
> Associate Counsel to the President
> [Ex. 6] (w)
> (c)

Message

**From**: Starling, Raymond - OSEC, Washington, DC [Raymond.Starling@osec.usda.gov]
**Sent**: 6/12/2018 6:40:57 PM
**To**: Johansson, Robert - OCE [RJohansson@oce.usda.gov]; Ex. 6
**CC**: Appleton, Brooke - OSEC, Washington DC [Brooke.Appleton@osec.usda.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Sullivan, Lauren - OSEC, Washington, DC [Lauren.Sullivan@osec.usda.gov]
**Subject**: RE: Call

+ Lauren Sullivan (Secretary Perdue's scheduler)

-----Original Message-----
From: Johansson, Robert - OCE
Sent: Tuesday, June 12, 2018 2:03 PM
To: rpalmieri@ Ex. 6
Cc: Starling, Raymond - OSEC, Washington, DC <Raymond.Starling@osec.usda.gov>; Appleton, Brooke - OSEC, Washington DC <Brooke.Appleton@osec.usda.gov>; wehrum.bill@epa.gov
Subject: Re: Call

Hi Rosario,

We would like to set up a Principals' call with the Secretary and the Administrator.

Scheduling will likely be difficult, but to meet the aggressive timeline I suggest we try to get this call set up as soon as possible.

I am CC'ing Ray and Brooke from USDA and Bill from EPA to facilitate the scheduling.

Thanks Rob

Sent from my iPhone

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/12/2018 2:09:11 AM
**To**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**CC**: Michael Catanzaro [ Ex. 6
**Subject**: Re: Deliberative Process / Ex. 5

Thanks Bill!

My POC is Jimmi Nassar.

Sent from my iPhone

On Jan 11, 2018, at 8:53 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:

> Hi Heidi. I've asked my folks for a summary of their efforts. I will pass it along when I get it.
>
> We are ready to host you and your team in Detroit and Ann Arbor. We are looking forward to it.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> On Jan 11, 2018, at 6:14 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>
>> Gentlemen,
>
> Deliberative Process / Ex. 5
>
> Heidi

**From:** King, Heidi (NHTSA)
**Sent:** Thursday, January 11, 2018 9:22:45 AM
**To:** Michael Catanzaro; Bill Wehrum
**Subject:** Here is the entire record of EPA staff seeking meeting with NHTSA as far as we are aware, let me know what's missing

Bill,

**Deliberative Process / Ex. 5**

Grateful for your support on this complicated matter,

Heidi

Sent from my iPhone

Begin forwarded message:

> **From:** "Tamm, James (NHTSA)" <james.tamm@dot.gov>
> **Date:** January 11, 2018 at 6:15:43 AM PST
> **To:** "King, Heidi (NHTSA)" <heidi.king@dot.gov>, "Morrison, Jonathan (NHTSA)" <Jonathan.Morrison@dot.gov>
> **Subject: FW: Request for CAFE Modeling Briefing Material**
>
> This is the exchange on setting up today's meeting with EPA on modeling.
>
> ---
>
> **From:** Tamm, James (NHTSA)
> **Sent:** Thursday, January 11, 2018 8:40 AM
> **To:** 'Bolon, Kevin' <Bolon.Kevin@epa.gov>
> **Cc:** Charmley, William <charmley.william@epa.gov>; Moran, Robin <moran.robin@epa.gov>; Olechiw, Michael <olechiw.michael@epa.gov>; Keefe, Ryan (VOLPE) (Ryan.Keefe@dot.gov) <Ryan.Keefe@dot.gov>; Hagen, Ryan (NHTSA) <ryan.hagen@dot.gov>
> **Subject:** RE: **Deliberative Process / Ex. 5**
>
> Kevin,
> Thanks. Today at 2 pm will work.
> Who do you expect will attend from EPA?
> Jim
>
> ---
>
> **From:** Bolon, Kevin [mailto:Bolon.Kevin@epa.gov]
> **Sent:** Wednesday, January 10, 2018 3:34 PM
> **To:** Tamm, James (NHTSA) <james.tamm@dot.gov>

**Cc:** Charmley, William <charmley.william@epa.gov>; Moran, Robin <moran.robin@epa.gov>; Olechiw, Michael <olechiw.michael@epa.gov>
**Subject:** RE: Deliberative Process / Ex. 5

Hi Jim,

Robin is in transit back from the TRB meeting in D.C. this afternoon, so she asked me to coordinate the scheduling of a meeting.

Tomorrow (Thurs) would work best for us. Would 2pm be ok?

Thank you,
Kevin

Kevin Bolon, Ph.D.
Light Duty Center, Assessment and Standards Division
National Vehicle and Fuel Emissions Laboratory
U.S. EPA, Office of Transportation and Air Quality
734-214-4331 bolon.kevin@epa.gov

Begin forwarded message below

**From:** Tamm, James (NHTSA) [mailto:james.tamm@dot.gov]
**Sent:** Wednesday, January 10, 2018 11:01 AM
**To:** Moran, Robin <moran.robin@epa.gov>
**Cc:** Charmley, William <charmley.william@epa.gov>; Olechiw, Michael <olechiw.michael@epa.gov>; kevin.green@dot.gov; Ryan Hagen <ryan.hagen@dot.gov>
**Subject:** RE: Deliberative Process / Ex. 5

Hi Robin,
Happy new year to you, Bill and Mike. Thanks for reaching out. Sorry for delayed response. I had some time off over the holidays and am catching up.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 There is flexibility in our schedules tomorrow and Friday (except Friday 10:00 – 11:00). Would either of those days work for EPA?

I'll be joining the Tuesday NAIAS tour (with Heidi, Dan Bogard and Brian Barnard). Perhaps will see several of you there.

Thanks.

Jim

**From:** Moran, Robin [mailto:moran.robin@epa.gov]
**Sent:** Thursday, January 04, 2018 4:03 PM
**To:** Tamm, James (NHTSA) <james.tamm@dot.gov>

**Cc:** Charmley, William <charmley.william@epa.gov>; Olechiw, Michael <olechiw.michael@epa.gov>
**Subject:** Deliberative Process / Ex. 5

Dear Jim,

I hope this note finds you well, and Happy New Year! I'm writing

Deliberative Process / Ex. 5

Thanks,
Robin

Robin Moran
Senior Policy Advisor
U.S. EPA, Office of Transportation and Air Quality
2000 Traverwood Dr.
Ann Arbor, MI 48105
Ex. 6 (phone)

Message

**From**: Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]
**Sent**: 1/11/2018 6:25:20 PM
**To**: Rosen, Jeff (OST) [jeff.rosen@dot.gov]; Bradbury, Steven (OST) [Steven.Bradbury@dot.gov]
**CC**: Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; King, Heidi (NHTSA) [heidi.king@dot.gov]
**Subject**: Memo re Production Schedule Information Sharing with EPA Career Staff
**Attachments**: Memo re Information Sharing 1-11-2018.pdf; DELIBERATIVE 2018-01-11_Information_sharing_memo_EPA_attachment.pdf

Please find attached a memo concerning potential information sharing with EPA career staff relating to a proposed preamble text production schedule for the joint NHTSA/EPA Rulemaking to establish light duty vehicle fuel economy/greenhouse gas emissions requirements. Please do not hesitate to contact me if you have any questions or concerns.

NHTSA

**Jonathan Morrison**
Chief Counsel
**Department of Transportation**
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590
Office: 202-366-9511

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/11/2018 1:57:14 PM
**To**: Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Barnard, Brian (NHTSA) [brian.barnard@dot.gov]; Catanzaro, Michael J. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Delahoyde, Magdelana A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]; Nassar, Jimmi (NHTSA) [jimmi.nassar@dot.gov]; Jim Tamm [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user4df22b6d]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]
**Subject**: Folks, we must regroup on Legal

When would the team like to speak on output of lawyer's meeting and also Ex. 5 DPP?

Last week, we agreed to speak on those topics at the end of this week, I had hoped those were the subjects for discussion this morning. I regret we ran out of time but am in DC tomorrow and happy to regroup.

Heidi

All times listed are in the following time zone:(UTC+00:00) Monrovia, Reykjavik

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**From:** Delahoyde, Magdelana A. EOP/WHO
**Sent:** Thursday, January 11, 2018 12:14:03 AM
**To:** Delahoyde, Magdelana A. EOP/WHO; Catanzaro, Michael J. EOP/WHO; Barnard, Brian (NHTSA); Atkinson, Emily; Gunasekara.mandy@epa.gov; Nassar, Jimmi (NHTSA); Morrison, Jonathan (NHTSA); wehrum.bill@epa.gov; Tamm, James (NHTSA); King, Heidi (NHTSA)
**Subject:** Confirmed: Ex. 5 DPP
**When:** Thursday, January 11, 2018 1:30 PM-2:00 PM.
**Where:** Call information in calendar notes!

Host Dial-In: Ex. 6 Personal Privacy (PP)
Leader Code: Ex. 6 Personal Privacy (PP)
Participant Dial-In: (202) Ex. 6 Personal Privacy (PP)
Participant Code: Ex. 6 Personal Privacy (PP)

Message

**From**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Sent**: 1/11/2018 4:51:10 AM
**To**: Catanzaro, Michael J. EOP/WHO [Ex. 6 Personal Privacy (PP)
**CC**: Delahoyde, Magdelana A. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Nassar, Jimmi (NHTSA) [jimmi.nassar@dot.gov]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]; Morrison, Jonathan (NHTSA) [Jonathan.Morrison@dot.gov]
**Subject**: Re: HOLD: ( Ex. 5 DPP

Yes I will be on, but will invite Jim Ex. 5 DPP to speak as I am without laptop

Is that ok?

Sent from my iPhone

> On Jan 10, 2018, at 8:34 PM, Catanzaro, Michael J. EOP/WHO <Ex. 6 Personal Privacy (PP)> wrote:
>
> Heidi, are you not joining the call? We need to speak with you ASAP on Ex. 5 DPP If tomorrow morning doesn't work, please send us times during the day that do.
>
> Sent from my iPhone
>
>> On Jan 10, 2018, at 7:58 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>>
>> + Jonathan
>>
>> I add Jonathan, I recall we were going to speak on Legal
>>
>> Also — it will be 5:30am here at CES so Jim Tamm (career) can speak to Ex. 5 DPP I suggest we have that conversation prior to Legal.
>>
>> Heidi
>>
>>
>> Sent from my iPhone
>>
>>> On Jan 10, 2018, at 4:20 PM, Delahoyde, Magdelana A. EOP/WHO <Ex. 6 wrote:
>>>
>>> Host Dial-In: Ex. 6 Personal Privacy (PP)
>>> Leader Code: Ex. 6 Personal Privacy (PP)
>>> Participant Dial-In: ( Ex. 6 Personal Privacy (PP)
>>> Participant Code: Ex. 6 Personal Privacy (PP)
>>>
>>> <meeting.ics>

Message

**From**: Atkinson, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB2155ADEF6A44AEA9410741F0C01D27-ATKINSON, EMILY]
**Sent**: 11/14/2017 9:58:00 PM
**To**: Nassar, Jimmi (NHTSA) [jimmi.nassar@dot.gov]
**CC**: King, Heidi (NHTSA) [heidi.king@dot.gov]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]
**Subject**: RE: Wehrum/King mtg(s) next week

Hi Jimmi,

I apologize for the delay in getting back to you.

We are reviewing this request and will get back to you shortly with scheduling options.

Emily

Emily Atkinson
Management Analyst/Office Manager
Immediate Office of the Acting Assistant Administrator
Office of Air and Radiation, USEPA
Room 5412B, 1200 Pennsylvania Avenue NW
Washington, DC 20460
Voice: 202-564-1850
Email: atkinson.emily@epa.gov

---

**From:** Nassar, Jimmi (NHTSA) [mailto:jimmi.nassar@dot.gov]
**Sent:** Tuesday, November 14, 2017 4:55 PM
**To:** Atkinson, Emily <Atkinson.Emily@epa.gov>
**Cc:** King, Heidi (NHTSA) <heidi.king@dot.gov>; Wehrum, Bill <Wehrum.Bill@epa.gov>
**Subject:** RE: Wehrum/King mtg(s) next week

Hi Emily – just following up. Do you have some times that Bill is available to meet?

Thanks,
Jimmi

---

**From:** King, Heidi (NHTSA)
**Sent:** Tuesday, November 14, 2017 4:23 AM
**To:** Wehrum.william@epa.gov; Atkinson, Emily <Atkinson.Emily@epa.gov>
**Cc:** Nassar, Jimmi (NHTSA) <jimmi.nassar@dot.gov>
**Subject:** Wehrum/King mtg(s) next week

Emily,

Bill and I spoke of meeting early next week — we may **Deliberative Process / Ex. 5 - DOT**

Deliberative Process / Ex. 5

I copy Jimmi Nassar who can help identify a time on my calendar.

Thanks for your help,

Heidi

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 5/18/2018 10:05:36 PM
**To**: Baker, Carrie L (OST) [Carrie.L.Baker@dot.gov]
**CC**: Wiggins, Jeremy G. EOP/WHO [Ex. 6 Personal Privacy (PP)]; Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
**Subject**: Re: Full List of Attendees for next Wednesday's CAFE Standards

2:30 to 3:00 works for me.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On May 18, 2018, at 1:14 PM, Baker, Carrie L (OST) <Carrie.L.Baker@dot.gov> wrote:

Deputy Secretary Rosen can do 11:15-11:45 or 2:30-3:00

---

**From:** Wiggins, Jeremy G. EOP/WHO [Ex. 6]
**Sent:** Friday, May 18, 2018 1:05 PM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Baker, Carrie L (OST) <Carrie.L.Baker@dot.gov>
**Subject:** RE: Full List of Attendees for next Wednesday's CAFE Standards

Good afternoon,

Francis is wanting to have a conference call before Wednesday with Deputy Rosen and Bill to get on the same page for the upcoming meetings. Below is Francis's availability. Please let me know which of the times work for you and I will send out a calendar invite with a dial-in.

May 22, 9:00am – 10:00am; 10:30am – 12:00pm; 2:00pm – 3:00pm; 4:00pm – 5:00pm

Thank you,

Jeremy

---

**From:** Wiggins, Jeremy G. EOP/WHO
**Sent:** Friday, May 18, 2018 12:47 PM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Baker, Carrie L (OST) <Carrie.L.Baker@dot.gov>
**Cc:** 'King, Heidi (NHTSA)' <heidi.king@dot.gov>
**Subject:** Full List of Attendees for next Wednesday's CAFE Standards

Below is the full list of attendees that I have been told will attend Wednesday's meetings. As always please let me know if anything needs to be changed.

Auto Alliance 9:30am Meeting

Mitch Bainwol, Auto Alliance + board members TBD
Steve Bradbury, DOT
James Owens, DOT
Jonathan Morrison, DOT
Bill Wehrum, EPA
Mandy Gunaskara, EPA
Matt Leopold, EPA
Francis Brooke

Mary Nichols 11:00am Meeting
Mary Nichols, Chair of the California Air Resources Board
Richard Corey, CARB Executive Officer
Steve Cliff, Chief Deputy Executive Officer
Heidi King, DOT
Steve Bradbury, DOT
Jonathan Morrison, DOT
Bill Wehrum, EPA
Mandy Gunaskara, EPA
Matt Leopold, EPA
Francis Brooke

Thank you,
Jeremy

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 4/7/2018 2:13:42 PM
**To**: Beach, Allie - OSEC, Washington, DC [Allison.Beach@osec.usda.gov]
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**Subject**: Re: RFS Information

Thanks Allie.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Apr 6, 2018, at 9:40 PM, Beach, Allie - OSEC, Washington, DC <Allison.Beach@osec.usda.gov> wrote:

> Bill,
>
> I will forward, and his email for future is Stephen.censky@osec.usda.gov.
>
> Thanks,
> Allie
>
> On Apr 6, 2018, at 6:17 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>
>> Allie – I would appreciate it if you would forward this to Steve. I don't seem to have his correct e-mail address. Thanks.
>>
>> _____
>> Bill Wehrum
>> Assistant Administrator
>> Office of Air and Radiation
>> U.S. Environmental Protection Agency
>> (202) 564-7404
>>
>> **From:** Wehrum, Bill
>> **Sent:** Friday, April 6, 2018 6:16 PM
>> **To:** 'steve.censky@osec.usda.gov' <steve.censky@osec.usda.gov>
>> **Cc:** Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; 'Beach, Allie - OSEC, Washington, DC' <Allison.Beach@osec.usda.gov>
>> **Subject:** RFS Information
>>
>> Hi Steve. In response to your request for information about small refinery exemptions, the numbers for the 2017 compliance year are not settled because several applications are still under consideration. For the 2016 compliance year, we received 20

petitions from small refineries. We granted exemptions for 19 of those, with a total exempted volume of 790 million gallons of renewable volume obligations. We denied 1 petition. Interestingly, D6 RIN prices during calendar 2017 ranged from about $0.40 to about $1.00, which is a good bit above transactional costs (which we think is in the neighborhood of 2 or 3 cents).

_____

Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 4/6/2018 10:15:43 PM
**To**: steve.censky@osec.usda.gov
**CC**: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Beach, Allie - OSEC, Washington, DC [Allison.Beach@osec.usda.gov]
**Subject**: RFS Information

Hi Steve. In response to your request for information about small refinery exemptions, the numbers for the 2017 compliance year are not settled because several applications are still under consideration. For the 2016 compliance year, we received 20 petitions from small refineries. We granted exemptions for 19 of those, with a total exempted volume of 790 million gallons of renewable volume obligations. We denied 1 petition. Interestingly, D6 RIN prices during calendar 2017 ranged from about $0.40 to about $1.00, which is a good bit above transactional costs (which we think is in the neighborhood of 2 or 3 cents).

_____

Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 3/19/2018 4:40:15 PM
**To**: Winberg, Steven [Steven.Winberg@hq.doe.gov]
**CC**: Loman, Carol (CONTR) [CAROL.LOMAN@HQ.DOE.GOV]; Desouza, Shannon (CONTR) [Shannon.Desouza@Hq.Doe.Gov]; Vincent, Kenneth [Kenneth.Vincent@Hq.Doe.Gov]; Maddox, Mark [MRMaddox@hq.doe.gov]; Daniels, Jarad [Jarad.Daniels@hq.doe.gov]
**Subject**: RE: EPA/DOE work on NSR

Absolutely. We will get back to you soon with a few suggested dates.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

---

**From:** Winberg, Steven [mailto:Steven.Winberg@hq.doe.gov]
**Sent:** Monday, March 19, 2018 12:18 PM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>
**Cc:** Loman, Carol (CONTR) <CAROL.LOMAN@HQ.DOE.GOV>; Desouza, Shannon (CONTR) <Shannon.Desouza@Hq.Doe.Gov>; Vincent, Kenneth <Kenneth.Vincent@Hq.Doe.Gov>; Maddox, Mark <MRMaddox@hq.doe.gov>; Daniels, Jarad <Jarad.Daniels@hq.doe.gov>
**Subject:** EPA/DOE work on NSR

Bill
We would like to schedule a follow-up meeting with your NSR team to discuss specifics on where DOE can assist in this important work. If you have someone send us a few dates, we can find a date and time that works for both of us.
We are happy to come to your shop or we can host.

Thanks,
Steve Winberg
DOE ASFE

**Ex. 6**

Message

**From:** Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent:** 12/15/2017 4:26:22 PM
**To:** King, Heidi (NHTSA) [heidi.king@dot.gov]
**Subject:** Re: Meeting

Can you meet us here? We can talk for a couple minutes then walk to the meeting.

Doubletree Downtown. 120 South Los Angeles Street.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 15, 2017, at 8:24 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

> Yes I am at a Westin about 2 miles from our meeting. Should I come to you for pre-meet?
>
> ---
>
> **From:** Wehrum, Bill <Wehrum.Bill@epa.gov>
> **Sent:** Friday, December 15, 2017 11:09:59 AM
> **To:** King, Heidi (NHTSA)
> **Subject:** Meeting
>
> Heidi - Are you in LA? Mike and I are in the lobby of the Doubletree.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 12/1/2017 1:10:26 PM
**To**: heidi.king@dot.gov
**CC**: jimmi.nassar@dot.gov
**Subject**: Re: Bill, Heidi's mobile contact information

Thanks Heidi. My personal cell is Ex. 6 Personal Privacy (PP). That's the best way to reach me if you can't reach me at the office.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 1, 2017, at 7:57 AM, "heidi.king@dot.gov" <heidi.king@dot.gov> wrote:

Bill,

My mobile and direct phone lines so you'd always be able to reach me in the coming months:

Mobile phone: Ex. 6 Personal Privacy (PP)
Desk phone: Ex. 6

Personal mobile (an option on weekends): Ex. 6 Personal Privacy (PP)

I also copy Jimmi Nassar, policy advisor to both our Exec Director and myself and generally the person who knows where to find me.

heidi

<image002.png>

**Heidi R. King**
Deputy Administrator
**U.S. Department of Transportation**
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590
Office: 202-366-1836

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 7/23/2018 8:59:54 PM
**To**: Rosen, Jeff (OST) [jeff.rosen@dot.gov]
**Subject**: RE: CAFE Follow Up

Thanks Jeff. Yes, I'll give them a call.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

-----Original Message-----
From: Rosen, Jeff (OST) [mailto:jeff.rosen@dot.gov]
Sent: Monday, July 23, 2018 4:59 PM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>
Subject: Re: CAFE Follow Up

Bill, unfortunately I am very jammed up today. Any chance you might be able to discuss with Steve Bradbury or Heidi King? If I am needed today, I'll be happy to talk, but may not be able to get free until around 6:45 pm or so. Let me know. Thanks.

Jeff

Sent from my iPhone

> On Jul 23, 2018, at 3:15 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>
> Jeff - Do you have time this afternoon to discuss the CAFE proposal? The Administrator asked me to follow up with you on a couple of issues. Thanks.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 6/4/2018 5:06:48 PM
**To**: Fitzsimmons, Alexander [Alexander.Fitzsimmons@ee.doe.gov]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
**CC**: Davis, Caitlin J. (CONTR) [Caitlin.Davis@EE.DOE.Gov]
**Subject**: RE: AHRI event and ENERGY STAR

Thanks Alex. See you tomorrow.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

**From:** Fitzsimmons, Alexander [mailto:Alexander.Fitzsimmons@ee.doe.gov]
**Sent:** Monday, June 4, 2018 11:31 AM
**To:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
**Cc:** Davis, Caitlin J. (CONTR) <Caitlin.Davis@EE.DOE.Gov>
**Subject:** AHRI event and ENERGY STAR

Hi Bill,

Hope all is well. Looks like we are speaking on the same panel tomorrow, and AHRI plans to ask us about Energy Star. Obviously, as we discussed a couple of weeks ago, EPA and DOE work closely on the program and we want to see that continue. For your awareness, I've attached my discussion points and pasted my Energy Star answer below:

**Q: What's your view on recent efforts to move all or portions of the Energy Star program to the Department of Energy? And maybe we should ask Alex what his view is as well….**

A: EPA and DOE work closely on Energy Star and we appreciate that collaboration. DOE has acknowledged that there are synergies between the standard setting of the appliance and equipment standards program and setting levels for appliance models to earn the Energy Star designation. This is why DOE and EPA historically have had an interagency agreement, known as a Memorandum of Understanding, assigning roles and responsibilities under the program. DOE and EPA have the ability to revisit that agreement to determine if a different assignment of roles and responsibilities may allow the program to work better. Our staffs continue to work closely to make sure Energy Star is a successful program.

Please let me know if you have any feedback or want to discuss. Look forward to seeing you tomorrow!

Best,

Alex Fitzsimmons
Chief of Staff and Senior Advisor
Office of Energy Efficiency and Renewable Energy
U.S. Department of Energy

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 6/3/2018 12:23:44 PM
**To**: staffsecretary@ Ex. 6 Personal Privacy (PP)
**CC**: Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Julie_Miller@ Ex. 6 Personal Privacy (PP) v; Jean.Daniel@osec.usda.gov; Amanda.H.Robbins@ Ex. 6 Personal Privacy (PP)
**Subject**: Fwd: For Review: Draft Ex. 5 DPP
**Attachments**: 6.1.18-Draft Ex. 5 DPP

# Deliberative Process / Ex. 5

No other comments. Thanks.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

Begin forwarded message:

**From:** "Jackson, Ryan" <jackson.ryan@epa.gov>
**Date:** June 1, 2018 at 6:43:30 PM EDT
**To:** "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Gunasekara, Mandy" <Gunasekara.Mandy@epa.gov>
**Subject: FW: For Review: Draft** Ex. 5 DPP

---

**From:** Staff Secretary [mailto:staffsecretary@v Ex. 6 Personal Privacy (PP)
**Sent:** Friday, June 1, 2018 6:43 PM
**To:** Miller, Julie L. EOP/OMB < Ex. 6 Jackson, Ryan <jackson.ryan@epa.gov>; Jean.Daniel@osec.usda.gov; Robbins, Amanda H. EOP/OMB < Ex. 6 Personal Privacy (PP)
**Cc:** Staff Secretary < Ex. 6 Personal Privacy (PP)
**Subject:** For Review: Draft I Ex. 5 DPP

EPA, OMB, and USDA,

Please see attached for a draft decision memo and two draft press statements Ex. 5 DPP
Affirmative clearance is requested by **Sunday, June 3, at noon.**

Thank you,
Staff Secretary

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 12/4/2017 2:41:10 AM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Subject**: Re: Bill, Heidi's mobile contact information

Sounds like a good plan. Thanks Heidi.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 3, 2017, at 8:28 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

**Deliberative Process / Ex. 5 - DOT**

Does that make sense? We will adapt to your recommendation —

Heidi

---

**From:** Wehrum, Bill <Wehrum.Bill@epa.gov>
**Sent:** Sunday, December 3, 2017 4:39:24 PM
**To:** King, Heidi (NHTSA)
**Subject:** Re: Bill, Heidi's mobile contact information

Heidi - What do we plan to cover in tomorrow's meeting? Is this the time for me to include key staff?

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 1, 2017, at 8:26 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

Thanks, then we'll swing by. Looking forward to it.

---

**From:** Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
**Sent:** Friday, December 01, 2017 8:25 AM
**To:** King, Heidi (NHTSA) <heidi.king@dot.gov>
**Subject:** Re: Bill, Heidi's mobile contact information

Heidi - I had my days mixed up. I will be here in DC on Monday. I will be in Ann Arbor the following Monday. We'd be happy to have you here on Monday if that works for you.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 1, 2017, at 8:14 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

> Thanks!
>
> We will speak Monday, I think you mentioned you will be in Ann Arbor so we will call and not come to EPA.
>
> Will send a few slides on Monday.
>
> Heidi
>
> ---
>
> **From:** Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
> **Sent:** Friday, December 01, 2017 8:10 AM
> **To:** King, Heidi (NHTSA) <heidi.king@dot.gov>
> **Cc:** Nassar, Jimmi (NHTSA) <jimmi.nassar@dot.gov>
> **Subject:** Re: Bill, Heidi's mobile contact information
>
> Thanks Heidi. My personal cell is Ex. 6 Personal Privacy (PP) That's the best way to reach me if you can't reach me at the office.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> On Dec 1, 2017, at 7:57 AM, "heidi.king@dot.gov" <heidi.king@dot.gov> wrote:
>
>> Bill,
>>
>> My mobile and direct phone lines so you'd always be able to reach me in the coming months:
>>
>> Mobile phone: Ex. 6 Personal Privacy (PP)

Ex. 6

Personal mobile (a Ex. 6

Ex. 6

I also copy Jimmi Nassar, policy advisor to both our Exec Director and myself and generally the person who knows where to find me.

heidi

<image002.png>

**Heidi R. King**
Deputy Administrator
**U.S. Department of Transportation**
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590
Office: 202-366-1836

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 12/1/2017 1:25:39 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Subject**: Re: Bill, Heidi's mobile contact information

Yes, makes good sense.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 1, 2017, at 8:22 AM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:

Bill – another thing - Deliberative Process / Ex. 5 - DOT

Deliberative Process / Ex. 5 - DOT

**From:** Wehrum, Bill [mailto:Wehrum.Bill@epa.gov]
**Sent:** Friday, December 01, 2017 8:10 AM
**To:** King, Heidi (NHTSA) <heidi.king@dot.gov>
**Cc:** Nassar, Jimmi (NHTSA) <jimmi.nassar@dot.gov>
**Subject:** Re: Bill, Heidi's mobile contact information

Thanks Heidi. My personal cell is Ex. 6 That's the best way to reach me if you can't reach me at the office.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 1, 2017, at 7:57 AM, "heidi.king@dot.gov" <heidi.king@dot.gov> wrote:

Bill,

My mobile and direct phone lines so you'd always be able to reach me in the coming months:

Mobile phon
Desk phone: Ex. 6

Personal mobile (an option on weekends): Ex. 6 Personal Privacy (PP)

I also copy Jimmi Nassar, policy advisor to both our Exec Director and myself and generally the person who knows where to find me.

heidi

<image002.png>

**Heidi R. King**
Deputy Administrator
**U.S. Department of Transportation**
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE., Washington, DC 20590
Office: 202-366-1836

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 1/24/2018 11:27:49 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**CC**: Catanzaro, Michael J. EOP/WHO Ex. 6 Personal Privacy (PP) Harris, Jeffrey M. EOP/OMB Ex. 6 Personal Privacy (PP); Palmieri, Rosario A. EOP/OMB Ex. 6 Personal Privacy (PP)
**Subject**: RE: RE:
**Attachments**: Ex. 5 DPP

Here it is.

-----Original Message-----
From: King, Heidi (NHTSA) [mailto:heidi.king@dot.gov]
Sent: Wednesday, January 24, 2018 6:25 PM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>
Cc: Catanzaro, Michael J. EOP/WHO < Ex. 6 Personal Privacy (PP) ; Harris, Jeffrey M. EOP/OMB Ex. 6 Personal Privacy (PP) ; Palmieri, Rosario A. EOP/OMB Ex. 6 Personal Privacy (PP)
Subject: Re: RE:

Bill, thanks for the link, I'm unable to get into the One Drive system, could you send the doc as an attachment?

Thank you! Much appreciated.

Heidi

Sent from my iPhone

> On Jan 24, 2018, at 6:16 PM, Wehrum, Bill <Wehrum.Bill@epa.gov> wrote:
>
> I'm sending a revised version to Heidi as we speak. We should soon be able to circulate it to the broader group.
>
> -----Original Message-----
> From: Catanzaro, Michael J. EOP/WHO Ex. 6 Personal Privacy (PP)
> Sent: Wednesday, January 24, 2018 6:14 PM
> To: Wehrum, Bill <Wehrum.Bill@epa.gov>; heidi.king@dot.gov
> Cc: Harris, Jeffrey M. EOP/OMB < Ex. 6 Personal Privacy (PP) Palmieri, Rosario A. EOP/OMB Ex. 6 Personal Privacy (PP)
> Subject:
>

Ex. 5 DPP

> Sent from my iPhone

Message

**From**: Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent**: 1/23/2018 1:44:23 PM
**To**: King, Heidi (NHTSA) [heidi.king@dot.gov]
**Subject**: Re: NHTSA CAFE schedule

Hi Heidi. I plan to add to your document. The format works fine.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

> On Jan 22, 2018, at 9:06 PM, King, Heidi (NHTSA) <heidi.king@dot.gov> wrote:
>
> Hi Bill,
>

Ex. 5 DPP

>
> See you tomorrow,
>
> heidi
>
> -----Original Message-----
> From: King, Heidi (NHTSA)
> Sent: Thursday, January 18, 2018 5:32 PM
> To: Smith, Loren (OST) <Loren.Smith@dot.gov>; Harris, Jeffrey M. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Palmieri, Rosario A. EOP/OMB <Ex. 6 Personal Privacy (PP)>; Moran, John S. EOP/WHO <Ex. 6 Personal Privacy (PP)>; Neumayr, Mary B. EOP/CEQ <Ex. 6 Personal Privacy (PP)> dravis.samantha@epa.gov; bolen.brittany@epa.gov; Gunasekara.mandy@epa.gov; baptist.erik@epa.gov; Catanzaro, Michael J. EOP/WHO <Ex. 6 Personal Privacy (PP)>; wehrum.bill@epa.gov; Szabo, Aaron L. EOP/CEQ <Ex. 6 Personal Privacy (PP)>; 'wehrum.william@epa.gov'; Owens, James (OST) <James.Owens@dot.gov>
> Subject: NHTSA CAFE schedule
>
> Bill,
>
> Attached is NHTSA's schedule.
>
> Heidi
>
>
> -----Original Message-----
> From: Tamm, James (NHTSA)
> Sent: Thursday, January 18, 2018 5:27 PM
> To: King, Heidi (NHTSA) <heidi.king@dot.gov>
> Subject: Re: Pls send schedule to me for sharing
>
>
>
> -----Original Message-----
> From: King, Heidi (NHTSA)
> Sent: Thursday, January 18, 2018 5:21 PM
> To: Tamm, James (NHTSA) <james.tamm@dot.gov>
> Subject: Pls send schedule to me for sharing
>
>
>
> Sent from my iPhone
> <Potential CAFE Rulemaking Timing 171208a.docx>

Message

**From:** Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent:** 12/20/2017 1:37:15 PM
**To:** Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)]
**CC:** heidi.king@dot.gov
**Subject:** Re: [Ex. 5 DPP]

Thanks for the heads up. [Ex. 6] Happy Holidays!

Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Dec 20, 2017, at 7:59 AM, Moran, John S. EOP/WHO [Ex. 6 Personal Privacy (PP)] wrote:

> Heidi and Bill,
>
> I wanted to give you a heads up that [Ex. 6] and won't be able to make our 9 am Meeting. Jeff Harris from OIRA will be there, though, and he and I can follow up later as needed. If I don't see you beforehand, I hope you both enjoy the holidays and have a Happy New Year!
>
> John S. Moran
> Associate Counsel to the President
> [Ex. 6 Personal Privacy (PP)] (w)
> [Ex. 6 Personal Privacy (PP)] c)

Message

**From:** Wehrum, Bill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33D96AE800CF43A3911D94A7130B6C41-WEHRUM, WIL]
**Sent:** 7/23/2018 12:24:15 PM
**To:** Winberg, Steven [Steven.Winberg@hq.doe.gov]
**CC:** Maddox, Mark [MRMaddox@hq.doe.gov]; Daniels, Jarad [Jarad.Daniels@hq.doe.gov]; Kislear, Jordan [Jordan.Kislear@hq.doe.gov]; Karimjee, Anhar [Anhar.Karimjee@hq.doe.gov]; Vincent, Kenneth [Kenneth.Vincent@Hq.Doe.Gov]
**Subject:** Re: CPP

Sure. Let me know if you do not get what you need from OIRA.

_____
Bill Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
(202) 564-7404

On Jul 23, 2018, at 8:05 AM, Winberg, Steven <Steven.Winberg@hq.doe.gov> wrote:

> Always happy to help.
> Will DOE be given a chance to review the supporting documentation?

---

> **From:** Wehrum, Bill <Wehrum.Bill@epa.gov>
> **Date:** Monday, Jul 23, 2018, 5:35 AM
> **To:** Winberg, Steven <Steven.Winberg@hq.doe.gov>
> **Cc:** Maddox, Mark <MRMaddox@hq.doe.gov>, Daniels, Jarad <Jarad.Daniels@hq.doe.gov>, Kislear, Jordan <Jordan.Kislear@hq.doe.gov>, Karimjee, Anhar <Anhar.Karimjee@hq.doe.gov>, Vincent, Kenneth <Kenneth.Vincent@Hq.Doe.Gov>
> **Subject:** Re: CPP
>
> Thanks Steve. We appreciate your help on this.
>
> _____
> Bill Wehrum
> Assistant Administrator
> Office of Air and Radiation
> U.S. Environmental Protection Agency
> (202) 564-7404
>
> > On Jul 22, 2018, at 2:46 PM, Winberg, Steven <Steven.Winberg@hq.doe.gov> wrote:
> >
> > Bill
> >
> > Our staff have reviewed the initial preamble through the Interagency review process, and I understand you should be getting comments back from us in the near future Deliberative Process / Ex. 5 - DOE

Deliberative Process / Ex. 5 - DOE

>
> I would like to reiterate my offer to review for any technical support documents that you have developed Deliberative Process / Ex. 5 - DOE

Deliberative Process / Ex. 5 - DOE In addition, if there is any help needed on characterizing individual technologies, we are happy to provide additional information.
>
> Thank you,
>
> Steven Winberg
> Assistant Secretary
> Office of Fossil Energy
> Department of Energy
> 1000 Independence Avenue, SW
> Washington, DC 20585
> Ex. 6
>

WESTERN GOVERNORS' ASSOCIATION

DENNIS DAUGAARD
GOVERNOR OF SOUTH DAKOTA
CHAIR

DAVID IGE
GOVERNOR OF HAWAII
VICE CHAIR

JAMES D. OGSBURY
EXECUTIVE DIRECTOR

June 5, 2018

The Honorable William Wehrum
Assistant Administrator
Office of Air and Radiation (6103A)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Wehrum:

Thank you for your thoughtful response to Western Governors' February 12 letter on air quality policy and the efforts of the Environmental Protection Agency (EPA) to improve the functionality of the Exceptional Events Rule. We also appreciate the extension of the comment period for EPA's proposed rule, Strengthening Transparency in Regulatory Science, 83 FR 18768 (April 30, 2018), which proposes to change how EPA uses scientific data to review air quality standards. We request that EPA consult with states on the plans referenced in your response and the ensuing administrative actions.

Consultation, as noted in Western Governors' Association (WGA) Policy Resolution 2017-01, *Building a Stronger State-Federal Relationship*, requires early, meaningful, substantive government-to-government exchange between EPA and states throughout the policy process and before finalization of federal decisions that would impact state Clean Air Act (CAA) programs. To facilitate this exchange, EPA should: provide substantive information to states on policy actions EPA is considering or proposing; request input from states on potential proposals and meaningfully respond to that input prior to a decision; provide reasonable timeframes for states to submit comments; and incorporate or thoroughly consider state input in EPA's decisions. Effective consultation with states will result in EPA policy that is more effective, cost-efficient, and durable than current agency decision-making processes.

The April 12 Presidential Memorandum on National Ambient Air Quality Standards (NAAQS) addresses many of the priorities outlined in our February 12 letter. In addition, we appreciate the direction to issue timely and concurrent regulations and guidance, which was an issue highlighted in our letter, in the May 9 EPA Administrator Memorandum on NAAQS. Western Governors urge EPA to consult with states (as described above) on the implementation of the Presidential Memorandum, as well as any additional EPA memoranda on the New Source Review program and State Implementation Plans (SIPs) before they are issued.

EPA's response noted plans to revisit the 2017 Regional Haze Rule, which will also impact the Draft Regional Haze Guidance. As noted in our letter, states are already beginning the formulation of their SIPs for the second implementation period. Western Governors request that EPA address changes to the Regional Haze Rule and Guidance in consultation with western states as soon as possible.

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Suite 1700
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EPA's response also did not reference the Residential Wood Heaters New Source Performance Standard, which Western Governors urged EPA to retain. Western Governors urge EPA to consult with western states on its review of this standard.

Please utilize western states as resources with respect to these issues and the other priorities outlined in our February 12 letter. Western Governors look forward to continuing to work with you to improve state-federal communication and the consideration of state CAA programs in EPA decision-making.

Sincerely,

Dennis Daugaard
Governor of South Dakota
Chair, WGA

David Ige
Governor of Hawai'i
Vice Chair, WGA

NCAT
NATIONAL COALITION FOR
ADVANCED TRANSPORTATION

April 9, 2018

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, D.C. 20460

The Honorable Elaine L. Chao
Secretary
U.S. Department of Transportation
1200 New Jersey Ave, S.E.
Washington, D.C. 20590

Re: EPA Mid-Term Evaluation and Upcoming Joint Rulemaking

Dear Administrator Pruitt and Secretary Chao:

As members of the ***National Coalition for Advanced Transportation (NCAT)***, we write in response to the U.S. Environmental Protection Agency's April 2, 2018 Notice regarding the Mid-Term Evaluation of its Model-Year (MY) 2022-2025 greenhouse gas emission standards for light-duty vehicles (MTE Notice) and the upcoming joint rulemaking described in the notice.

The United States is undergoing an unprecedented transformation of its economy, including the simultaneous reshaping of both the transportation and energy sectors. No country is better positioned to lead the world in creating and building the transportation system of the future. We are confident that we will succeed beyond any past measure if we do not falter in our commitment to deliver to consumers anywhere in the world the highest-performance, smartest and cleanest vehicles and, consistent with this Administration's goals, the modern infrastructure needed to support them. While the MTE Notice identifies a range of uncertainties associated with this pivotal period of technology transition, we firmly believe that weakening fuel economy or greenhouse gas standards in reaction to short-term uncertainties would be self-defeating and wholly inconsistent with our shared goals of strengthening U.S. competitiveness, growing jobs and protecting our current technological superiority.

NCAT stands ready to work with you and the Administration to find a path forward that addresses any short-term challenges while preserving, and indeed accelerating, the transportation and energy transformation that consumers eagerly seek and that will help secure America's technology leadership for decades. We ask that you engage with NCAT, its members, and other stakeholders in a robust dialogue regarding how to ensure that these standards continue to reward innovation and preserve and strengthen stable growth of advanced vehicle technologies.

NCAT is a coalition of companies that supports electric vehicle (EV) and other advanced transportation technologies and related infrastructure, including business leaders engaged in energy supply, transmission and distribution; vehicle and component design and manufacturing; and charging infrastructure production and implementation, among other activities. Our members support government initiatives, including federal and state vehicle standards, that provide regulatory, financial, infrastructure and other support for emerging EV and other clean vehicle technologies to compete in the marketplace. NCAT also recognizes the critical role that California and other states play in adopting and implementing vehicle standards that support advanced technologies. Such state leadership has historically ensured that the United States remained on the cutting edge of technology development, and we see no reason to reconsider that approach at this key juncture. If stakeholders work together, we firmly believe that state and federal interests can remain aligned to ensure ongoing regulatory certainty and stable, long-term signals to guide investment.

NCAT's members are concerned by, and strongly disagree with, many of the statements in EPA's MTE Notice regarding the availability, affordability, consumer acceptance and benefits of EV technologies. EV and related technologies and infrastructure provide major economic and energy security benefits, and U.S. leadership in this space is critical to our economic health, global competitiveness and environmental quality. As detailed in our October 5, 2017 comments to EPA on its reconsideration of the January 2017 Mid-Term Evaluation final determination, there have been substantial advances in EV technologies and corresponding decreases in costs since 2012. Sales of these vehicles are increasing significantly, demonstrating growing consumer demand. U.S. and other manufacturers are scaling up investments and rapidly expanding their EV offerings across a range of vehicle types and price points. Range, performance, options and affordability are all improving rapidly, making EVs increasingly attractive to consumers. The simultaneous rapid development of autonomous vehicle technologies and on-demand transportation, both of which work synergistically with EV technologies, signal the beginning of a major transformation in our transportation system. In recognition of these trends, governments across the world are announcing policies to transition away from conventional vehicles and towards EVs, creating a race among manufacturers to capture the expanding global market for these vehicles.

To win that race, the United States must establish and maintain leadership through robust, long-term fuel economy and greenhouse gas standards at the federal level. When the current standards were adopted in 2012, it was clear that this Mid-Term Evaluation would find us where we are now – in the early stages of a transition from predominant reliance on efficiency improvements in conventional vehicles to increasingly greater reliance on EVs. While it may be tempting to look to short-term signals, the federal greenhouse gas emissions and fuel economy programs are intended to take the longer view. When we do take that longer view, all signs clearly support our readiness to make this transition. Failure to recognize, embrace and support these trends presents serious risks that the United States will lose its role as a global leader in these technologies of the future.

NCAT respectfully requests that you work closely with our members and other stakeholders in the period leading up to issuance of a proposed rule for the MY 2022-25 standards. These issues are too important and the stakes are too high to rely exclusively on the notice-and-comment rulemaking process to reach outcomes that meet our shared objectives. A more iterative,

interactive and inclusive dialogue is needed. We stand ready to work with you and others to identify solutions that can address any near-term challenges while preserving the benefits of the current standards and strengthening long-term growth of EVs and other advanced technologies.

Thank you for your consideration.

Sincerely,

Robert A. Wyman
Devin O'Connor
**Latham & Watkins LLP**
**Counsel to NCAT**
555 11th Street, NW
Washington, DC 20004-1304

**National Coalition for Advanced Transportation** (https://www.lwncat.com)

Ampaire
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Baltimore Gas & Electric
Commonwealth Edison Company
Delmarva Power
Edison International
EVgo
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Los Angeles Department of Water & Power
Pacific Gas and Electric Company
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GOVERNOR OF SOUTH DAKOTA
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GOVERNOR OF HAWAII
VICE CHAIR

JAMES D. OGSBURY
EXECUTIVE DIRECTOR

February 12, 2018

William Wehrum
Assistant Administrator
U.S. Environmental Protection Agency
Office of Air and Radiation (6103A)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Wehrum:

Following up on your discussion with the Western Governors' Association (WGA) executive team last month, this letter provides greater detail regarding the Governors' priorities for air quality policy and regulation in the West. We thank you for your outreach and look forward to working closely with the Office of Air and Radiation (OAR) of the Environmental Protection Agency.

**Air Quality Policy and Regulation in the West**

Clean air is essential for strong communities and quality of life. In the West, high elevations, extreme variations in topography, vast landscapes, and vacillating weather patterns influence air quality. The West is also disproportionately impacted by wildfires, high wind dust events, and international transport of pollutants. Pollutant sources, methods of dispersion, and types of impacted areas in the West are very different than those in the eastern United States.

The Clean Air Act (CAA) directs states to reduce emissions from criteria pollutants that states can control – not natural or international sources. Air quality in the West has benefited from significant emissions reductions over the last 20 years, but the number and types of remaining emissions sources controllable by states are somewhat limited.

To address these uniquely western issues, we believe cooperative federalism in air quality management must be strengthened. In some cases, EPA disregards state expertise and authority over air quality. In all cases, EPA should recognize state authority under the CAA and accord states sufficient flexibility to create air quality programs tailored to individual state needs, industries, and economies. WGA Policy Resolution 2017-01, *Building a Stronger State-Federal Relationship*, has more detail on the Governors' vision for the state-federal relationship.

We are especially focused on improving communications among EPA, federal and state land managers and foresters, and state air quality agencies to address wildfire in the West. Prescribed fire is an essential active management tool to mitigate the threat of catastrophic wildfires. Obstacles to prescribed fire are putting communities and western lands at unnecessary risk. When uncontrolled wildfire does occur, EPA should provide an expedited process to reduce the bureaucratic burden of and efficiently approve exceptional events demonstrations. We ask you to consider how the Agency can promote the responsible use of prescribed fire and implement the other recommendations outlined below.

CALL (303) 629-0378
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Denver, CO 80202

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**Recommendations for Improving Air Quality Policy and Regulation in the West**

***Co-Regulation***

- Federal agencies should engage with Governors and state air quality agencies as co-regulators. For example, in the Prevention of Significant Deterioration (PSD) program, EPA should clarify responsibilities and procedures to improve coordination and consultation among state agencies, EPA, and federal land managers, as well as develop guidelines and tools for the program in consultation with states.

- State CAA programs require financial and technical support from EPA and Congress. EPA must also have the resources to perform the research necessary to develop tools, templates, and guidance for states to implement effective and efficient air programs.

- EPA should consult with states prior to any decision on a potential rule or guidance and throughout the drafting process. EPA should also provide states timely implementation guidance when new and revised regulations are published.

- States require certainty and consistency to implement their CAA programs. EPA should maintain the deadline for the New Source Performance Standard (NSPS) for wood stoves and its regulations addressing mobile sources. States are depending on these reductions to comply with their State Implementation Programs (SIPs).

- Under current rules and guidance, states must monitor National Ambient Air Quality Standards (NAAQS) throughout the 20-year maintenance period, even when there is no threat of an exceedance. States should be allowed to reduce monitoring in maintenance areas that demonstrate permanent air quality below the NAAQS, which will free resources to address pollutants that remain a concern.

***Ozone***

- Uncontrollable events and conditions such as wildfire, lightning, biogenic emissions, stratospheric ozone intrusion, and transported ozone from international and interstate sources result in elevated levels of background ozone. Western Governors have significant concerns about the lack of CAA tools available to account for ozone exceedances resulting from factors outside state control.

- The West needs additional and ongoing research on background, interstate and international ozone. This research should be transparent, comprehensive and coordinated with state air quality agencies and regional organizations. With this new information, EPA should reconsider the one percent threshold for significant contribution for interstate ozone transport obligations.

***Exceptional Events***

- Exceptional event demonstrations are resource-intensive, costly and place a significant burden on strained state resources, especially when EPA does not review these state submissions in a timely manner. EPA should streamline the process for exceptional event demonstrations,

provide additional technical tools for states, and allocate resources to review state demonstrations.

- Western Governors believe the states and EPA would benefit from the following approaches to exceptional events demonstrations: (1) aggregation of multiple factors contributing to air quality to prove a single exceptional event exceedance demonstration; (2) regional exceptional event demonstrations; and (3) reference to previously submitted and approved exceptional events demonstrations for repeated event types.

- EPA should: create an online submission system for exceptional event demonstrations; develop a database with information on air quality impacts in the West (with special emphasis on wildfires); and provide a clearinghouse with tools that states can use for exceptional events demonstrations.

***Regional Haze***

- Good visibility in the 118 western Regional Haze Program Class 1 Areas, which include many of the crown jewels of the West's national parks and wilderness areas, impacts western states' economies. It is important to address mobile and international emissions sources beyond states' control in the context of western states' regional haze planning processes.

- The profound impacts of fire and smoke on the visibility at Class I areas in the West should be recognized in the Regional Haze Guidance and Rule.

- EPA provided Draft Regional Haze Guidance for the second implementation period of the Rule in July 2016, but has not finalized this guidance. States are beginning work on their SIPs for the second implementation period. Final Regional Haze Guidance is necessary to reduce uncertainty for states as they formulate their SIPs.

- Given the importance of improved visibility in the West, EPA should provide funding and resources to states throughout the planning and implementation process.

***Wildfire and Prescribed Fire***

- More frequent and intense wildfires are steadily reducing the West's gains in air quality improvement. Smoke from wildfires can cause air quality to exceed the NAAQS for particulate matter and ozone, impacting public health, safety and transportation. Prescribed fire, which is managed according to state SIPs and smoke management programs, can reduce these impacts, but is currently underutilized.

- Western Governors support the use of prescribed fire to reduce the air quality impacts from uncharacteristic wildfire in the West. Federal and state land managers should have the ability to use prescribed fires when weather and site conditions are appropriate and air quality impacts are minimized.

- Prescribed fire practices should include smoke management planning coordinated among state land managers, state air agencies, state health departments, EPA, other federal agencies, and

federal land managers. State or regional prescribed fire councils can help facilitate this coordination.

- Western Governors call on EPA and federal land managers to improve existing tools and create additional tools for states to encourage prescribed fire. These should include an exceptional events guidance for prescribed fire, and tools to address the air quality impacts from wildfire in the West.

We ask for your leadership in implementing the above recommendations at OAR. Please contact us with any questions regarding these or any other issues. We look forward to working with you to improve air quality policy and regulation in the West.

Respectfully,

Dennis Daugaard
Governor of South Dakota
Chair, WGA

David Ige
Governor of Hawaii
Vice Chair, WGA

May 17, 2018

The Honorable Elain L. Chao
Secretary
U.S. Department of Transportation
1200 New Jersey Avenue, SE
Washington, D.C. 20590

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

The Honorable Heidi King
Deputy Administrator
National Highway Traffic Safety Administration
1200 New Jersey Avenue, SE
Washington, D.C. 20590

The Honorable William Wehrum
Assistant Administrator, Air and Radiation
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Advanced Technologies Flexibility Option for Model Year 2022-2025 GHG/CAFE Standards

Dear Secretary Chao, Administrator Pruitt, Deputy Administrator King, and Assistant Administrator Wehrum:

As trade associations representing the motor vehicle parts suppliers industry, we are writing to request that you seek comment on a policy option described in this letter in the forthcoming Notice of Proposed Rulemaking (NPRM) for the Model Year (MY) 2022-2025 light-duty vehicle greenhouse gas (GHG) and corporate average fuel economy (CAFE) standards.

This option, which might be referred to as an "Advanced Technologies Flexibility Option," would provide vehicle manufacturers with additional compliance flexibilities, while maintaining robust standards. The flexibilities should include some combination of the following elements:

1) Improving and expanding existing credit programs including $CO_2$ credits for qualifying full size light-duty pickup trucks and credits for gasoline particulate filters (GPFs) installed on any type of vehicle.
2) Extending and potentially restructuring credit multipliers for EVs, PHEVs, FCVs and CNGVs and ANGVs;
3) Improving the current off-cycle credit technology program by expanding the off-cycle credit menu and raising the credit caps on both A/C efficiency credits, and the off-cycle menu credits.
4) Revise the off-cycle technology credit process to allow suppliers to directly petition EPA for a specific technology to be eligible for a provisional off-cycle credit.

This package of reforms would provide more near-term flexibility in achieving CAFE targets and national GHG reduction goals while lowering compliance costs. Improving and expanding these credit programs would provide incentives for suppliers to continue technology investments in the U.S. and further advance and deploy innovative technologies in a cost-effective manner. These additional flexibilities will strengthen our domestic manufacturing jobs, grow the economy, encourage U.S. innovation and promote the investment necessary to support continued forward progress on emission reductions and increased fuel efficiency in the years to come.

Suppliers are the largest sector of manufacturing jobs in the U.S. directly employing over 871,000 Americans. Suppliers take on both the investments and the risks associated with the development of technologies for their vehicle manufacturer customers. Suppliers have extensive long-term investments in research and development of advanced technologies to bring emission reduction and fuel efficiency technologies to market deployment. Investments in advanced technology development resulting from the CAFE and GHG program standards set in 2012 are, in part, responsible for the nearly 20% recent increase in jobs in the motor vehicle parts manufacturing industry.

We believe this Advanced Technology Flexibility Option would provide a basis for maintaining strong national standards while addressing automakers' requests for additional compliance options in the near term. The approach would help maintain a harmonized national program including both federal and state vehicle standards. Furthermore, the approach, recognizes the critical role that California and other states continue to play in reducing vehicle emissions and protecting public health.

We urge DOT and EPA to include an Advanced Technology Flexibility Option in the NPRM now under development. Such a policy will ensure continued progress on fuel efficiency and GHG/air quality while providing vehicle manufacturers additional compliance options, and preserving the role of unified standards under One National Program with California.

Ann Wilson
Senior Vice President – Government Affairs
Motor & Equipment Manufacturers Association

Dr. Rasto Brezny
Executive Director
Manufacturers of Emission Controls Association

Chris Miller
Executive Director
Advanced Engine Systems Institute

Tim Regan
President
Emissions Control Technology Association

CC: EPA Deputy Administrator Andrew R. Wheeler
DOT Deputy Secretary Jeffrey A. Rosen
EPA OTAQ Director Christopher Grundler
NHTSA Fuel Economy Division Chief Jim Tamm

Securing America's Future Energy

April 2018

# Using Fuel Efficiency Regulations to Conserve Fuel and Save Lives by Accelerating Industry Investment in Autonomous and Connected Vehicles

The Trump administration and the state of California are currently engaged in parallel processes to determine the proper level of fuel economy and greenhouse gas emission standards for light-duty vehicles for model years 2022–2025 and beyond. While California seeks to retain existing standards to meet the state's environmental objectives,[1] the federal government recently announced that the 2022–2025 standards are "not appropriate" and is now undertaking a new rulemaking.[2] The components of a compromise have been identified, in which regulators offer automakers flexibility to meet standards in the near term in exchange for increased stringency over a longer period of time.

The National Highway Traffic Safety Administration (NHTSA) is the federal agency statutorily mandated to regulate both fuel economy and safety. Historically, there has been concern that increasing fuel economy decreases safety because smaller and lighter cars are presumed to be less safe, and this concern is reemerging in the current process to set fuel economy rules for the years 2022–2025. Fortunately, NHTSA's most recent data demonstrates that the move to a footprint-based standard in 2012 (an approach in which the stringency of the standards is based on the size of the car) substantially addressed the size vs. safety concern.[3]

More consequentially, the industry is entering a phase that—if ushered in successfully—can both increase fuel economy and enhance safety benefits in a manner through which these goals reinforce each other. The rise of autonomous vehicle technology can lead to dramatic increases in vehicle safety while simultaneously driving fuel economy improvements. While these technologies are under development and the extent of their benefits is still emerging, test results offer the promise of substantially increased efficiency and improved safety through vehicle- and system-level improvements. Yet because these technologies are so new, there is neither sufficient deployment

---

[1] Office of Governor Edmund G. Brown, Jr., "Governor Brown Issues Statement on U.S. EPA Decision to Weaken Clean Car Standards," (Apr. 2, 2018) available at www.gov.ca.gov/2018/04/02/governor-brown-issues-statement-on-u-s-epa-decision-to-weaken-clean-car-standards-2/; Letter from Governor Brown to EPA Administrator Scott Pruitt, (Mar. 15, 2017) available at https://www.gov.ca.gov/wp-content/uploads/2017/09/3.15.17_Letter_to_EPA.pdf.

[2] Environmental Protection Agency, "Mid-term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022-2025 Light-duty Vehicles," (Apr. 2, 2018) ("Mid-Term Evaluation") available at www.epa.gov/sites/production/files/2018-04/documents/mte-final-determination-notice-2018-04-02.pdf.

[3] Puckett, S.M. and Kindelberger, J.C. 2016. *Relationships Between Fatality Risk, Mass, and Footprint in Model Year 2003-2010 Passenger Cars and LTVs.* Preliminary report prepared for the National Center for Statistics and Analysis, National Highway Traffic Safety Administration, Washington, D.C. June, 2016.

nor adequate understanding of the degree to which these innovations can improve vehicle efficiency and decrease emissions. Moreover, such technologies are not easily accounted for in the current regulatory regime. SAFE estimates, based on independent fuel efficiency modeling, that an 18–25 percent system-wide fuel economy savings can be realized by using existing driver assist and connected vehicle technology, and that thousands of lives can be saved annually.

Fortunately, the off-cycle credit program within the Environmental Protection Agency's (EPA) regulations to limit greenhouse gas emissions from light-duty vehicles provides a mechanism that could be used to accelerate the real-world testing, and eventual incorporation, of these technologies into the fuel economy program—not only resolving the safety-fuel economy issue once and for all but, more importantly, saving thousands of additional lives while providing further reductions in fuel demand. As part of the current ongoing discussions between automakers and regulators, parties should agree to allow automakers to earn compliance credits (for 3–5 years) as part of a research program to deploy autonomous and connected vehicle technology, collect data about the technology's performance, and share the data with regulators so that they can together evaluate the effectiveness of this emerging technology. To the extent that the testing demonstrates improvement in efficiency, lower emissions and increased safety, regulators can use the data to support permanently accounting for such efficiencies in future compliance periods.

## Background

The Trump administration is currently revisiting fuel economy and greenhouse gas emission standards established by the Obama administration in cooperation with the state of California.[4] In 2012, EPA established emission standards for model years (MYs) 2017–2025 and NHTSA established fuel economy standards for MYs 2017–2021,[5] as its statutory authority allows for setting standards for no longer than five years at a time.[6] Working together with California's regulator, the California Air Resources Board (CARB), which has legal authority under the Clean Air Act to establish its own standards,[7] the three regulating entities developed coordinated standards that allowed for consistent automotive manufacturing standards for the entire nation.[8] Because of the five-year limitation on NHTSA's authority, the regulators committed to complete a Mid-Term Evaluation by April 2018 to determine if the EPA standards required adjustment, and lay the foundation for the extension of NHTSA standards for MYs 2022-2025.[9]

There appear to be four primary positions in the stakeholder community. CARB wants to maintain aggressive emission reduction and fuel economy targets, due to its concern about the effect of

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[4] See, Mid-Term Evaluation.

[5] Environmental Protection Agency and National Highway Traffic Safety Administration, *2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards*, 77 Fed. Reg. 62,624 (Oct. 15, 2012) (CAFE Rule).

[6] 49 U.S.C. 32902 (b)(3)(B).

[7] California has the authority to issue its own standards, following issuance of a waiver from EPA, that shall be granted unless: 1) California's determination is arbitrary and capricious, 2) California does not need such standards to meet compelling and extraordinary conditions, or 3) California standards and accompanying enforcement procedures are not consistent with CAA requirements for motor vehicles. 42 U.S.C. 7543(b).

[8] CAFE Rule at 62630.

[9] CAFE Rule at 62784.


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vehicle emissions on public health and the environment.[10] EPA has determined that the current standards are too aggressive and warrant a re-examination.[11] Most automakers, concerned about the difficulty of meeting the standards with fuel prices lower than forecast and consumer preferences different than expected, are advocating for CARB and the federal regulators to reach an agreement to maintain the national standard and avoid litigation while providing some flexibility in the near term.[12] Finally, NHTSA has indicated it remains concerned about safety, citing increasing numbers of traffic fatalities in the past several years.[13]

Despite these competing priorities, several outside groups and the industry have identified the basic structure of an agreement, with regulators offering automakers some increase in flexibility through MY 2025 in exchange for tighter standards between MYs 2026–2030, which would allow time for automakers to fully navigate the revolution—that all stakeholders agree is happening—to a system dominated by new technologies and business models, including connectivity, autonomy, ridesharing, and electrification. In particular for this Issue Brief, the current negotiation offers an opportunity to establish incentives to begin deploying and testing driver assist and connected vehicle technology, which could open the door to transformational improvements in fuel economy and emission reductions in the future while saving lives. This approach would also address NHTSA's core mandate, to improve road safety and reduce traffic injuries and deaths.[14]

## The Opportunity

Autonomous vehicles (AVs) are a breakthrough technology, and many of their components or partial autonomous functions, which are already incorporated or can be incorporated into new vehicles, offer efficiency and safety improvements on their own. The development and adoption of AV technology will represent the greatest shift in automotive technology since the Model T and has the potential to rank alongside personal computing and the internet as one of the greatest technological shifts in our society in the post-World War II era. When AVs are significantly safer than current automotive technology, they are likely to substantially reduce the number of vehicle accidents as well as the injuries and costs associated with them, potentially saving tens of thousands of lives and eliminating millions of injuries each year in the United States alone.[15] The ability for AVs to closely coordinate with other vehicles will allow vehicles to travel in closer proximity to each other, increasing road capacity and reducing travel times.[16] If fully automated, AVs can offer increased

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[10] John Lippert and Ryan Beene, "California Sets Demands for Auto-Emission Talks With Trump" Bloomberg News (Sept. 27, 2017) available at www.bloomberg.com/news/articles/2017-09-22/california-sets-demands-for-talking-emissions-targets-with-trump.

[11] See, Mid-Term Evaluation at p. 1

[12] See, e.g., Auto Alliance, "Auto Alliance Statement in Response to EPA's Announcement about the Midterm Review of the Fuel Economy/GHG Program," (Apr. 2, 2018) available at autoalliance.org/2018/04/02/auto-alliance-statement-response-epas-announcement-midterm-review-fuel-economy-ghg-program/.

[13] National Highway Traffic Safety Administration, "USDOT Releases 2016 Fatal Traffic Crash Data," (October 6, 2017) available at www.nhtsa.gov/press-releases/usdot-releases-2016-fatal-traffic-crash-data.

[14] National Highway Traffic Safety Administration, "About NHTSA," available at www.nhtsa.gov/about-nhtsa.

[15] Kalra, Nidhi, and David G. Groves. *The Enemy of Good: Estimating the Cost of Waiting for Nearly Perfect Automated Vehicles*. Rand Corporation, 2017.

[16] James Anderson et al., *Autonomous vehicle technology: A guide for policymakers*, Rand Corporation at 5 (2016).


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mobility to the disabled, seniors, and low-income populations with less access to affordable transportation, transforming their lives. Fully automated AVs can also give drivers one thing of tremendous value to most Americans—an increase in personal or productive time—as time that was once spent operating a car can be reallocated while the car drives itself.

If AVs are widely deployed in ride sharing applications, as anticipated, the effects could extend further. The dominant paradigm since the invention of the car has been private vehicle ownership, but that could shift once users find it more convenient—and cost-effective—to use ride-sharing services rather than maintaining and operating their own car. That shift could affect where people choose to live and work, and where vehicles are stored, with the need for parking substantially reduced. Likewise, paring AVs with electric vehicle (EV) technology, a deployment path that appears likely because of the engineering and cost advantages of using an electric powertrain for AVs,[17] can lead to transformative shifts in our patterns of fuel usage by reducing the amount, and changing the type, of energy that we consume—improving our energy and national security in the process. Fleet autonomous vehicle deployments are expected to leverage electric drivetrains because commercial fleet operators will prioritize the total cost of ownership, and electric vehicles offer significant fuel and maintenance cost savings. The size of the opportunity is reflected in the attention that automakers and investors are directing towards AV innovation. A recent study from The Brookings Institution identified over 160 investments valued at nearly $80 billion that have been made in AV technology between 2014 and 2017, noting that it is reasonable to assume that investment in AV technology is much higher.[18]

A major obstacle to incorporating the benefits of AVs into the standards is the lack of data that demonstrates their relevance to emissions or fuel consumption. Understanding the real-world impact of these technologies is critical to designing a regulatory approach that maximizes fuel economy and safety. Generating robust data that proves the technologies' effectiveness is the first fundamental step to incorporating these potential benefits into the regulations. SAFE believes, based on fuel efficiency modeling, that an 18–25 percent system wide fuel economy savings can be realized using current driver assist and connected vehicle technology. In addition, other research indicates that fatalities will be reduced by the thousands every year using this same technology.[19] A program that incentivizes real world testing and data sharing should be a priority for all government agencies.

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[17] Lipson, Hod, and Melba Kurman. *Driverless: intelligent cars and the road ahead*. MIT Press (2016) and Jeffery Greenblatt and Susan Shaheen, Automated Vehicles, On-Demand Mobility, and Environmental Impacts, Current Sustainable/Renewable Energy Reports (2015).

[18] Cameron F. Kerry and Jack Karsten, "Gauging investment in self-driving cars," Brookings Institution (Oct. 16, 2017) available at www.brookings.edu/research/gauging-investment-in-self-driving-cars/.

[19] National Highway Traffic Safety Administration, "*Vehicle-to-Vehicle Communications: Readiness of V2V Technology for Application*," at xvi (Aug. 2014) available at www.nhtsa.gov/press-releases/us-department-transportation-issues-advance-notice-proposed-rulemaking-begin. The report includes preliminary estimates of safety benefits that show two safety applications - Left Turn Assist (LTA) and Intersection Movement Assist (IMA) – could prevent up to 592,000 crashes and save 1,083 lives saved per year. We chose those two applications for analysis at this stage because they are good illustrations of benefits that V2V can provide above and beyond the safety benefits of vehicle-resident cameras and sensors. Of course, the number of lives potentially saved would likely increase significantly with the implementation of additional V2V and V2I safety applications that would be enabled if vehicles were equipped with DSRC capability.


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## Fuel Economy Standards and Autonomous Vehicles

AVs have the ability to offer the greatest leap in fuel economy—in the shortest period of time—since the program's inception more than 40 years ago. Some of the "building block" components of AVs, including vehicle-to-vehicle, or vehicle-to-infrastructure connectivity and advanced driver assist systems, can allow cars to operate more efficiently and safely. Since accidents are a major contributor to congestion, reducing accidents improves system throughput and efficiency.[20] These and other benefits can substantially improve vehicle fuel economy and reduce fuel consumption both in individual vehicles and the transportation system as a whole. Reflecting the potential offered by AV technology, one analysis suggests that if the most far-reaching business models and structural changes enabled by AVs are adopted by the entire fleet, road capacity can be doubled.[21]

While the savings are significant, the structural limitations of the fuel economy regime make it difficult to maximize—or even minimally incentivize—these emerging benefits.[22] The fuel efficiency framework that NHTSA developed in the 1970s does not have the flexibility to capture efficiencies resulting both directly and indirectly from vehicle automation and connectivity. For both NHTSA and EPA standards, vehicle compliance is measured by running the vehicle through a predetermined set of accelerations which aim to mimic real-world conditions. This test does not have the flexibility to account for the ability of AVs to improve fuel efficiency performance by accelerating/decelerating more smoothly than humans, avoiding congestion-causing accidents, or having the foresight to take alternative, less congested routes. Including technologies in the framework of fuel efficiency regulations has been shown to accelerate adoption;[23] conversely the continued exclusion of autonomous features from this framework could delay or even permanently limit the fuel savings benefits offered by AVs and their component technologies—as has been the case with other voluntary safety-related technologies. The Insurance Institute for Highway Safety examined the rollout of safety technology and estimates that it takes 30 years for equipment to become standard on new vehicles.[24] The report estimates that, left to the market, technologies like the ones proposed in this Issue Brief (forward collision warning, blind-spot monitoring, lane-departure warning), will only become standard on all vehicles by 2043. The proposal described here would accelerate that adoption by decades, potentially saving tens of thousands of lives and million of barrels of oil.

There is a solution which saves both lives and fuel. The EPA has the authority and flexibility to address the structural problems of the program—and has used this flexibility in the past through its

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[20] See, e.g., Anthony Downs, "Traffic: Why It's Getting Worse, What Government Can Do," Brookings (Jan. 1, 2004); David Schrank, et al. "2015 urban mobility scorecard." University of Texas, at 5 (2015); NHTSA, "The Economic and Societal Impact Of Motor Vehicle Crashes, 2010 (Revised)," at 50-112 (May 2015) available at crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812013.

[21] Dimitris Milakis, Bart van Arem & Bert van Wee. "Policy and Society Related Implications of Automated Driving: A Review of Literature and Directions for Future Research," Journal of Intelligent Transportation Systems, 21:4, 324-348, 330, 340 (2017).

[22] Mersky, Avi Chaim, and Constantine Samaras. "Fuel economy testing of autonomous vehicles." Transportation Research Part C: Emerging Technologies 65 (2016): 31-48

[23] Zoepf, Stephen, "Automotive Features: Mass Impact and Deployment Characterization," M.S. Thesis, at 23, Massachusetts Institute of Technology (2011).

[24] See, e.g., Keith Laing," Car-safety features stuck in slow lane," Detroit News (Mar. 5, 2018), available at www.detroitnews.com/story/business/autos/2018/03/05/car-safety-features-slow-coming/111097598/.


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off-cycle credit program.[25] EPA could use that same flexibility, working with NHTSA, to help incentivize the accelerated deployment of connected and autonomous technologies into the light-duty fleet, for the purposes of testing the real-world emissions and safety benefits. Automakers would share the resulting data to verify the savings captured. This effort by EPA would help NHTSA achieve its two congressionally-mandated objectives of fuel economy for national security and safety.

Utilizing the off-cycle credit program for this kind of research agenda would solve two problems: The scale of commercialization and the availability of real-world data. Vehicle connectivity technology is nascent and has yet to penetrate the fleet in meaningful numbers; inclusion in a fuel efficiency framework could accelerate adoption of advanced driver-assist systems (ADAS) and encourage optimizing such systems for efficiency.[26] There remains insufficient data to fully evaluate the effectiveness of these technologies at improving fuel efficiency and reducing vehicle emissions. In addition, such a research program could identify ways real-world data could be used to more effectively assess technologies that are already part of the off-cycle credit program.

Perhaps most importantly from a process perspective, such changes could open the pathway to an agreement on fuel economy and emissions with the state of California, maintain a program that is national in scope, and create additional certainty that the automakers seek.

## How Vehicle Automation Improves Safety

According to NHTSA's analysis, performed on a small subset of crashes, vehicle to vehicle communication (V2V) could save over 1,000 lives a year.[27] A recent BCG report concluded that ADAS could prevent 28 percent of all crashes in the United States if all cars were equipped with ADAS features *that are available today*. The technologies could prevent approximately 9,900 fatalities and save about $251 billion to society each year.[28] To put these numbers in perspective, NHTSA estimates there are roughly 38,000 traffic fatalities on US roads and highways every year. ADAS, in conjunction with adaptive headlights, would improve outcomes in nearly half of fatal crashes. By comparison, seatbelts and frontal air bags saved approximately 15,000 and 2,800 lives in 2007, the latest year studied.[29] If widely deployed, ADAS technologies would be poised to join seatbelts and air bags as high-impact safety technologies.

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[25] 40 CFR 86.1869-12.

[26] ARPA-E, "Next-Generation Energy Technologies for Connected and Automated On-Road Vehicles Program Description," (Nov. 2, 2016) available at arpa-e.energy.gov/?q=arpa-e-programs/nextcar.

[27] National Highway Traffic Safety Administration, "U.S. Department of Transportation Issues Advance Notice of Proposed Rulemaking to Begin Implementation of Vehicle-to-Vehicle Communications Technology," (Aug. 18, 2014), available at www.nhtsa.gov/press-releases/us-department-transportation-issues-advance-notice-proposed-rulemaking-begin.

[28] Boston Consulting Group Inc. and Motor & Equipment Manufacturers Association, "A Roadmap to Safer Driving through Advanced Driver Assistance Systems," at 2, 13, 14 (2015), available at www.mema.org/sites/default/files/MEMA%20BCG%20ADAS%20Report.pdf.

[29] National Highway Traffic Safety Administration, "Lives Saved Calculations for Seat Belts and Frontal Air Bags," at p. 2 (Dec. 2009) available at crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811206.


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## How Vehicle Automation Improves Efficiency

There are several different pathways for new AV technology to improve vehicle efficiency and reduce fuel consumption. Some of these effects occur at the vehicle level. Other improvements occur when new transportation-related systems are deployed. Still others are the result of wide scale deployment of full AV technology. An initial review of the literature shows the potential to improve fuel economy by up to 25 percent when technologies are optimized and aggregated.[30] While more data is needed, the potential is incredibly promising and warrants serious attention. Some of the technologies and impacts are described below.

### Vehicle-Level Impacts

A new technology has a "vehicle level" impact if it improves the fuel efficiency of the vehicle equipped with the technology. This is significant because the vehicle can operate more efficiently entirely on its own, and those efficiency gains can often be measured if a testing procedure is designed to capture them. Some examples of technologies with vehicle level benefits are:

- ***Advanced Driver Assistance System***: An Advanced Driver Assistance System describes a suite of technologies that substitute for some driving decisions—prominent examples include Automatic Emergency Braking and Lane Keeping Assist. An initial review of data collected from a fleet testing ADAS systems demonstrated more than a two percent improvement in fuel efficiency, and preliminary evidence suggests that considerably higher gains are possible.[31]
    - Researchers at Carnegie Mellon University demonstrated that Adaptive Cruise Control (ACC) can be "tuned" to leverage significant fuel savings. In the absence of a policy incentive, ACC could actually reduce energy efficiency.[32]
    - ***ARPA-E's NEXTCAR Initiative:*** ARPA-E is an agency at the Department of Energy that advances high-potential, high-impact energy technologies with the capability to radically improve U.S. economic prosperity, national security, and environmental well-being. ARPA-E's NEXTCAR Initiative is funding a series of projects to develop vehicle automation technology that use connectivity and automation to co-optimize vehicle dynamic controls and powertrain operation, reducing energy consumption of the vehicle, and—in some applications—the vehicle fleet. NEXTCAR's goal is to enable at least an additional 20 percent reduction in energy consumption of future connected and automated vehicles. NEXTCAR's modeling has validated that, under certain conditions, this approach could result in a greater than 20 percent reduction in vehicle energy consumption. The program's goal is to commercialize this energy-saving technology at a cost of under $1,000 per car and under $3,000 per heavy-duty vehicle.[33]

### System-Level Impacts

A network effect occurs when the larger the numbers of people or participants to use a service or product, the greater the value of the service or product. For instance, e-mail is a more effective

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[30] SAFE analysis and additional modeling of existing literature.

[31] Dish Network Data from Pilot Program; and SAFE interviews with industry; "Case Study: Dish saves fuel with Mobileye technology", *FleetOwner* (May 6, 2016).

[32] Mersky and Samaras (2016).

[33] Chris Atkinson, "NEXTCAR – Next Generation Energy Technologies for Connected and Automated On-Road Vehicles," Presentation to NEXTCAR Launch Event (Apr. 6, 2017) available at arpa-e.energy.gov/sites/default/files/2_ARPA-E_NEXTCAR_Kickoff.pdf.


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means of communicating when more people have e-mail because there are more people you can reach with it. There are new AV technologies that have network effects that can make the transportation system more efficient. If every car had these capabilities, vehicle efficiency should improve and the number of vehicle accidents should decline. Accident-related congestion in the United States wastes nearly one billion gallons of fuel and creates about 9.5 million tons of $CO_2$ on an annual basis.[34] ADAS and connectivity could mitigate the causes of about 85 percent of crashes, which illustrates that the system-level benefits are considerable.[35]

The wide-scale adoption of collision reduction technology and vehicle connectivity can be major sources of energy savings:

- ***Cooperative Adaptive Cruise Control (CACC):*** CACC is a type of cruise control that smooths out vehicle speed and acceleration, reducing fuel consumption. Because vehicles would be nearly-instantaneously responsive to changes in other vehicle speeds, more cars could fit on the roads without increasing road capacity or reducing vehicle speeds. Significant adoption of CACC could enable smoother traffic flow, which would improve both individual vehicle efficiency and highway capacity.[36]

- ***Collision Avoidance Technology:*** An industry regulatory filing by Mercedes-Benz USA made the following claims, based in part on research from the insurance industry.[37]
  - Using Lane Keeping Assist and Blind Spot Assist in all vehicles would reduce crashes by five percent.
  - Forward Collision Warning and Adaptive Brake Assist in all vehicles would reduce crashes by 15 percent.
  - Emergency Braking and ACC in all vehicles would reduce crashes by 18 percent.

- ***Vehicle to Vehicle and Infrastructure Communication:*** This technology shares information between vehicles in close proximity to each other. When widely deployed, it improves the effectiveness of ACC because it can monitor what is happening several cars ahead and because it can direct a vehicle on a route that reduces congestion, reduces idling and saves fuel.[38]

### Full Automation will have Far Reaching Implications

Recognizing the importance of a systemwide approach, traditional automotive companies such as Ford and GM are working to rebrand themselves as "mobility companies." Indeed, among the many aspects of our transportation system that would be affected by broad adoption of AVs are

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[34] *2015 Urban Mobility Scorecard*. Texas A&M Transportation Institute and Inrix (2015); Mercedes-Benz USA. "Request for Comment (RFC) on Reconsideration of the Final Determination of the Mid-Term Evaluation of Greenhouse Gas Emission Standards for MY 2022-2025 Light-Duty Vehicles," (2017).

[35] Frost & Sullivan, "Vehicle-to-Everything Technologies for Connected Cars" (Aug. 2017).

[36] Steven Shladover, Dongyan Su, and Xiao-Yun Lu, "Impacts of Cooperative Adaptive Cruise Control on Freeway Traffic Flow," Transportation Research Record 2324, at 63-70, (2012).

[37] Comments of Mercedes-Benz USA, LLC to Proposed Rule to Establish Light-Duty Vehicle Greenhouse Gas Emissions Standards and Corporate Average Fuel Economy Standards for Model Year 2017 and Beyond; Docket Nos. EPA-H1-OAR-2010-0799; FRL-9495-2; NHTSA-2010-0131 at A-10, A-11, (2012).

[38] Department of Transportation, "Preliminary Regulatory Impact Analysis: FMVSS No. 150 Vehicle-to-Vehicle Communication Technology for Light Vehicles," (Nov. 2016) available at www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/v2v_pria_12-12-16_clean-2.pdf.


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improvements in the efficiency of the vehicles and the choice of fuels that we use.

- ***Advanced Fuels:*** Both economics and engineering suggest that the shift to shared, autonomous vehicles will go hand-in-hand with increasing use of advanced fuels.[39] AVs have lower operational and maintenance costs, as there are fewer moving parts and maintenance requirements for an electric vehicle. Full automation is likely to render vehicle ownership a less attractive economic proposition and allow on-demand fleets to serve a large fraction of travel demand.[40] Modeling shows that economic considerations make it likely that such vehicles would use an advanced fuel source (particularly electrification). Such vehicles could decrease emissions by 90 percent relative to conventional, human-driven cars and by about 70 percent relative to hybrids.[41]

- ***Light Weight Connected Vehicles***: A recent RAND Corporation report projects that by 2050 connected, lightweight AVs could reach 300-500+ MPG for lightweight, single-occupant pod cars.[42]

- ***Autonomous Vehicle Car Sharing and Ride Sharing:*** AVs will be used in car and ride sharing services, providing vehicle access to individuals who do not own the vehicle outright (such as a time share model) or individual rides to individuals traveling together in a vehicle where they are contracting a service but have no ownership stake in the vehicle (such as Uber or Lyft).
    - Vehicle performance and acceleration may be important to vehicle owners who value the prestige or experience of owning a "muscle car,"[43] but such features are less important for on-demand vehicles because riders are largely indifferent as to whether the vehicle they are riding in—and do not own—is capable of rapid acceleration. Vehicles that are engineered for efficiency instead of performance can improve efficiency by as much as 20 percent.[44]
    - A UC Berkeley study found that households with car sharing subscriptions reduced their transportation greenhouse gas footprint by up to 18 percent.[45]

In short, connectivity and autonomous vehicle technology will have a broadly positive impact on the efficiency of the U.S. transportation system. While the downstream impacts of broad AV adoption

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[39] Gardner, Greg, "*Our Autonomous Future Will Likely Be an Electric One, Here's Why*," Detroit Free Press (Sept. 23, 2016 available at http://www.govtech.com/fs/Our-Autonomous-Future-Will-Likely-Be-an-Electric-One-Heres-Why.html.

[40] Securing America's Future Energy (SAFE), *A National Strategy for Energy Security: The Innovation Revolution*, at 88, 91 (2016).

[41] Greenblatt, J. B., & Saxena, S., "Autonomous taxis could greatly reduce greenhouse-gas emissions of US light-duty vehicles," *Nature Climate Change*, *5*(9), 860-863 (2015).

[42] James Anderson et al., *Autonomous vehicle technology: A guide for policymakers*, Rand Corporation, at 31 (Figure 2.6) (2014).

[43] Zoepf (2011).

[44] Austin Brown, Jeff Gonder, and Brittany Repac, "An Analysis of Possible Energy Impacts of Automated Vehicles", *Road Vehicle Automation* (2014).

[45] Elliot Martin and Susan Shaheen, "Impacts of car2go on Vehicle Ownership, Modal Shift, Vehicle Miles Traveled, and Greenhouse Gas Emissions: An Analysis of Five North American Cities," Innovative Mobility Research and Transportation Sustainability Research Center at UC Berkeley, Working Paper July 2016, available at innovativemobility.org/wp-content/uploads/2016/07/impactsofcar2go_FiveCities_2016.pdf.


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are not fully understood, there is considerably more certainty on the impacts of the building block technologies that compose these systems. By utilizing fuel efficiency policies to better evaluate these technologies, the U.S. can not only create more opportunities to save fuel in the short-term but, can also begin the process of modernizing energy policy for the impacts of AVs for the coming decades.

### Modeling of Fuel Economy Benefits

To examine the impact of these emerging autonomous and connected technologies, SAFE contracted Air Improvement Resource,[46] to model the potential fuel economy savings if these technologies were widely deployed in the fleet. A review of two dozen studies underpinned the analysis and identified the following set of potential savings. Most of these savings are additive and, together, identify the potential to reduce fuel consumption by 18 to 25 percent if deployed throughout the fleet. The results are summarized in the chart below.

| Strategy | Vehicle Benefit (estimated over all driving, even though main benefit may be on highways) | Additional Benefit if Majority of Vehicles are Equipped | Mechanism |
|---|---|---|---|
| Driver enabled adaptive cruise control (base) | 7%-10% (assumes enabled 100% on highways) | None | Smoother driving |
| Crash warning systems | 0% | 3% | Less total crashes and therefore less idle/year |
| V2V info sharing | +2-4% | Incl in vehicle benefit | Smoother driving Level 2 |
| V2I info sharing | +1-3% | Incl in vehicle benefit | Smoother driving Level 3 and congestion avoidance |
| AVs and CAVs (w/platooning) | + 5% | Incl in vehicle benefit | Smoother driving Level 4, congestion avoidance and platooning |

The modeling further compared what this level of savings could mean for the current fuel economy program as well as what it might mean for the longer-term targets identified as necessary to reach environmental objectives. For illustration purposes, we apply California's CO2 targets to the national fleet. The chart below shows the AV technology potential in terms of emissions reduction relative to the current standard and the longer-term goals established by California and other stakeholders for 2030 and 2050. The chart shows the current EPA 2022-2025 standards (represented by the solid black line) and their associated CO2 emissions reductions through 2050. The red line represents the lower bound estimate of 18 percent reduction while the green line represents the maximum 25 percent reduction potential. The area between the black line (current standards) and the green line

[46] Air Improvement Resource, Inc. provides engineering and consulting services in the area of mobile and stationary source emissions modeling and technology evaluation. They are experts in EPA emissions modeling.


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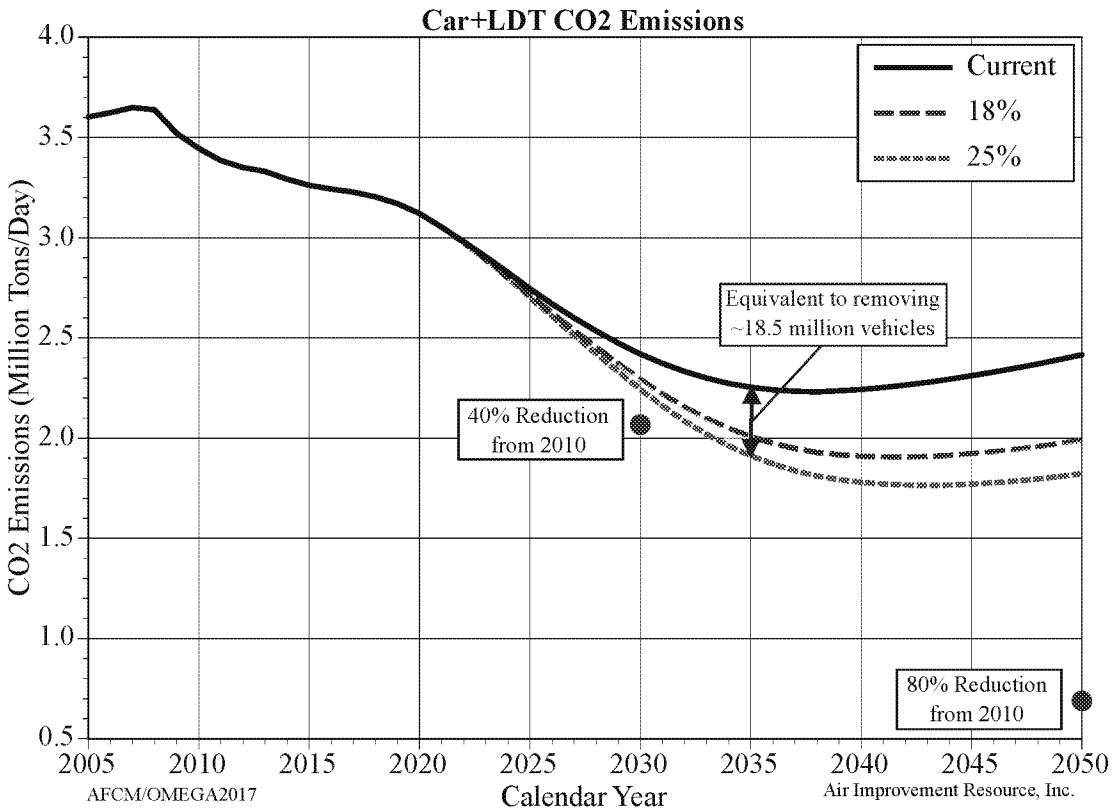
(25 percent reduction) represents the potential savings these autonomous and connected technologies could have on emissions—equaling the removal of 18.5 million vehicles from the road in 2035. The red dots represent the national equivalent of the goals set by California and other advocates as the necessary reductions in transport CO2 emissions in 2030 (40 percent reduction) and 2050 (80 percent reduction). A real-world test program that demonstrates the viability of these benefits could lead to much greater success in achieving the environmental and fuel efficiency goals for 2030 and put the transportation sector on a more promising trajectory toward the goals for 2050.




## Conclusion

To help regulators capture the benefits of this new technology, we must accelerate our understanding of its potential fuel-saving and safety benefits. To achieve this, federal regulators should partner with automakers to develop a program that deploys and collects data regarding the effectiveness of new autonomous and connected technologies to earn temporary compliance credits for the emissions and fuel economy programs. This initiative will lay the foundation for a more complete accounting of the increase in efficiency and reduction in emissions that they offer so that their benefits can be properly assessed on a permanent basis as part of these regulatory programs. Ultimately, if the technology proves effective, these technologies and business models should be incorporated into the off-cycle credit program, which is administered by EPA in consultation with NHTSA.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Autonomous and connected vehicle technology could radically improve the fuel-efficiency of the light-duty vehicle fleet, but this potential cannot be fully examined or realized under current regulatory structures. By offering automakers credit for a defined period of time for deploying AV technology and collecting data that automakers and regulators can use to assess the technology's effectiveness, regulators can remove a substantial roadblock to the development and deployment of these potentially transformative innovations. Research estimates that ADAS could prevent 28 percent of all crashes in the United States if all cars were equipped with features that are available today, preventing approximately 9,900 fatalities and saving $250 billion in societal costs every year. Furthermore, SAFE's analysis shows that 18-25 percent system-wide fuel economy saving can be realized by using existing diver assist and connected vehicle technology. By finding a way to constructively incorporate vehicle automation into the emissions and fuel economy programs, the federal government could accelerate the commercialization of life-saving and fuel-reducing technologies while simultaneously keeping the U.S. industry at the forefront of global automotive innovation.


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# MEMORANDUM

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**TO** Securing America's Future Energy

**FROM** Hogan Lovells US LLP **TELEPHONE** +1 202 637 6567

**DATE** July 15, 2018

**SUBJECT** Authority to Grant Fuel Economy Credit for Congestion Mitigation and Safety-Related Technologies Under Off-Cycle Credit Program

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Emerging technologies, such as autonomous and semi-autonomous vehicle technologies (e.g., self-driving cars), congestion avoidance technologies (e.g., GPS features), and safety and congestion mitigation technologies (e.g., technologies that help reduce collisions), hold significant promise in terms of fuel economy gains. However, these technologies have not traditionally been considered in the fuel economy calculus, which presents a significant lost opportunity to incentivize their further development and expedite their deployment. For instance, congestion avoidance and mitigation technologies can reduce time spent idling in traffic, and thus significantly increase miles per gallon.

The current Administration's reconsideration of greenhouse gas ("GHG") and corporate average fuel economy ("CAFE") standards for vehicle model years ("MYs") 2022-2025 presents an opportunity to modernize the current rules to recognize and promote the benefits of advanced technologies, including safety and congestion mitigation technologies. By crediting such technologies in fuel economy calculations, the Administration can incentivize their further development, while also providing automakers with more flexibility in achieving fuel economy standards. This memorandum discusses the authority of the National Highway Traffic Safety Administration ("NHTSA") and Environmental Protection Agency ("EPA") (collectively, "Agencies") to credit safety and congestion mitigation technologies, and identifies a regulatory pathway for ensuring these technologies are eligible for credit under the Agencies' off-cycle credit program.

## I. Executive Summary

We have been asked to evaluate whether there is a statutory bar on recognizing the fuel economy benefits of safety and congestion mitigation technologies in the CAFE program. In short, *there is no statutory prohibition on allowing congestion mitigation and safety-related technology to be credited in the CAFE and GHG programs.* However, EPA would need to take the lead on this, in consultation with NHTSA, because the technologies would be recognized as an element of the "testing and calculation procedures" for the CAFE program, the responsibility for which is vested with EPA under the statute. Moreover, the Agencies would need to make various changes to their regulations in order to remove a regulatory prohibition that exists on crediting these technologies.

## II. Background

### A. Allocation of Authority between NHTSA and EPA Under the Energy Policy and Conservation Act

The Energy Policy and Conservation Act ("EPCA"), as amended, requires NHTSA to set fuel economy standards for passenger and non-passenger vehicles, i.e. light trucks. These standards must be set at the "maximum feasible" level based on statutory factors in EPCA.[1] Importantly, however, EPCA splits responsibility for the fuel economy program between NHTSA and EPA. Although NHTSA sets the standards, "EPA establishes the procedures for testing, tests vehicles, collects and analyzes manufacturers' data, and calculates the individual and average fuel economy of each manufacturer's passenger cars and light trucks[.]"[2]

EPCA thus assigns EPA primary authority for testing and calculating the average fuel economy of vehicles so that NHTSA can determine compliance with its CAFE standards.[3] Specifically, EPCA requires that EPA "shall measure fuel economy for each model and calculate average fuel economy for a manufacturer under testing and calculation procedures prescribed by the Administrator."[4] Thus, EPA would need to take the lead in decisions that affect the way that fuel economy is measured and calculated. However, NHTSA must also be involved and must coordinate with EPA in executing this authority, as EPCA also requires that "[t]he Administrator shall report measurements and calculations under this section to the Secretary of Transportation and shall consult and coordinate with the Secretary in carrying out this section."[5]

As discussed in the next section, it is under EPA's EPCA authority under 49 U.S.C. § 32904 that the Agencies have already promulgated regulations that allow for credit to be issued for a variety of emerging technologies that increase fuel economy.[6]

### B. Background on the Off-Cycle Credit Program and Fuel Economy Improvement Values Generated Under that Program

In the 2012 Final Rule establishing MY 2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards, EPA, in coordination with NHTSA, created a program for MYs 2017-2025 to recognize air-conditioning efficiency credits and off-cycle credits.[7] Off-cycle credits provide credit for vehicle efficiency improvements that are not captured by the Federal Test Procedure and Highway Fuel Economy Test (known as the two-cycle

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[1] 49 U.S.C. § 32902(f).

[2] *See 2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards*, 77 Fed. Reg. 62,624, 62,667 (Oct. 15, 2012) ("2012 Final Rule"); 49 U.S.C. § 32904(c).

[3] 49 U.S.C. § 32904.

[4] 49 U.S.C. § 32904(c).

[5] *Id.* at § 32904(e).

[6] *See* 2012 Final Rule at 63,125 ("NHTSA expects automakers to continue increasing the use of innovative and advanced technologies . . . . additional incentive programs finalized will encourage early adoption of these innovative and advanced technologies and help to maximize both compliance flexibility and energy conservation. These incentive programs for [fuel economy] compliance are not under NHTSA's EPCA/EISA authority, but under EPA's EPCA authority . . . EPA measures and calculates a manufacturer's compliance with the [fuel economy] standards, and it will be in the calculation of fuel economy levels that the additional incentives are applied."); *see also* 2012 Final Rule at 63,131 ("All of the [fuel economy] compliance incentives discussed below are being finalized by EPA under its EPCA authority to calculate fuel economy levels for individual vehicles and for fleets."); *id.* at 62,649-50.

[7] 2012 Final Rule at 62,628, 62,649-50.

procedure).[8] In order to be eligible for credit under the off-cycle program "technologies must have a measurable, demonstrable, and verifiable real-world $CO_2$ reduction that occurs outside the conditions of the Federal Test Procedure and the Highway Fuel Economy Test."[9]

The credits obtained under the off-cycle program are referred to as "fuel consumption improvement values" for the purposes of the CAFE program.[10] The fuel consumption improvement value is equivalent to the off-cycle credits EPA issues for the purposes of the GHG program.[11] Specifically, the fuel consumption improvement value is determined "at the fleet level by converting the $CO_2$ credits determined under the EPA program (in metric tons of $CO_2$) for each fleet (car and truck) to a fleet fuel consumption improvement value. This improvement value would then be used to adjust the fleet's CAFE level upward."[12] To apply the credit, the "improvement values are subtracted from the manufacturer's two-cycle-based fleet fuel consumption value to yield a final new fleet fuel consumption value, which would be inverted to determine a final fleet fuel CAFE value."[13] Essentially, "instead of manufacturers gaining credits as done under the GHG program, a direct adjustment would be made to the manufacturer's fuel economy fleet performance value."[14] The credit is thus technically applied as a part of EPA's calculation of average fuel economy levels under its EPCA authority.[15]

To facilitate issuance of off-cycle credits, EPA, in coordination with NHTSA, created a "menu" of technologies eligible for credits with pre-defined fuel consumption improvement values.[16] For technologies that are not on the menu, the program allows manufacturers to apply for credit either (i) by demonstrating fuel economy improvements through EPA's 5-cycle test or (ii) if that will not work, through an alternative methodology developed by the manufacturer.[17] To obtain credit under the latter option, the manufacturer must submit a "detailed analytical plan" and the alternative methodology demonstration should, among other things, "use modeling, on-road testing, on-road data collection, or other approved analytical or engineering method," and "[b]e robust, verifiable, and capable of demonstrating the real-world emissions benefit with strong statistical significance[.]"[18] Where fuel consumption improvement values are sought by a manufacturer, EPA and NHTSA would consult with each other on manufacturer applications for credit under the off-cycle program.[19]

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[8] 40 C.F.R. § 86.1869-12(a) ("Manufacturers may generate credits for $CO_2$–reducing technologies where the $CO_2$ reduction benefit of the technology is not adequately captured on the Federal Test Procedure and/or the Highway Fuel Economy Test.").

[9] *Id.*

[10] 2012 Final Rule at 62,833 ("EPA, in coordination with NHTSA, is also finalizing the proposed provision allowing manufacturers to include fuel consumption reductions resulting from the use of off-cycle technologies in their CAFE compliance calculations. This provision would apply starting in MY 2017. Manufacturers may generate 'fuel consumption improvement values' essentially equivalent to EPA credits, for use in the CAFE program.").

[11] 2012 Final Rule at 62,727.

[12] *Id.* at 63,136; 62,736-37 (same); *see also* 40 C.F.R. § 600.510–12.

[13] 2012 Final Rule at 62,726.

[14] *Id.* at 63,134.

[15] *Id.* at 63,125.

[16] *Id.* at 62,832; 62,728.

[17] 40 C.F.R. § 86.1869-12(c)-(d); 2012 Final Rule at 63,134-35; *id.* at 62,839.

[18] 40 C.F.R. § 86.1869-12(d).

[19] *Id.* at § 86.1869-12(d)(3) ("With respect to fuel consumption improvement values applicable to the determination of average fuel economy under 600.510–12(c)(3) for the 2017 and later model years, EPA will consult with the U.S. Department of Transportation, National Highway Traffic Safety Administration, prior to making a decision on a manufacturer's application."); *see also* 49 U.S.C. § 32904(e) ("The Administrator shall report measurements and calculations under this section to the Secretary of Transportation and shall consult and coordinate with the Secretary in carrying out this section."); 49 C.F.R. §§ 531.6(b); 533.6; 2012 Final Rule at 63,135, 62,839-40.

Generally, the application process created by the Agencies allows manufacturers to seek credit for a wide variety of different technologies, provided that the manufacturer can demonstrate real-world fuel economy benefits. However, in the 2012 Final Rule, the Agencies carved out a blanket exception to this general rule for safety, crash avoidance, and congestion mitigation technologies based on questionable policy rationales that are by no means mandated by the statute.[20] The next sections describe the Agencies' policy decision to exclude these technologies, and the means by which the Agencies can reverse this decision to allow for these safer and more efficient technologies to be eligible for off-cycle credit.

### C. Background on Policy Decisions Prohibiting Fuel Economy Credit for Safety and Congestion Mitigation Technologies

In the 2012 Final Rule, the prior Administration's decision to disallow off-cycle credit for safety technologies was framed as a policy decision, rather than a decision based on a lack of authority. Indeed, EPCA itself does not speak to or bar consideration of crash-avoidance and other congestion mitigation technologies, or the crediting of energy efficiency improvements linked to safety features. However, in the 2012 Final Rule, the Agencies decided to categorically bar safety technologies from receiving credit under the off-cycle program.[21] Specifically, EPA's regulation at 40 C.F.R. § 86.1869–12 ("$CO_2$ credits for off-cycle $CO_2$–reducing technologies") contains a limitation that restricts the eligibility of safety technologies for off-cycle credit:

> Off-cycle credits may not be approved for crash-avoidance technologies, safety critical systems or systems affecting safety-critical functions, or technologies designed for the purpose of reducing the frequency of vehicle crashes. Off-cycle credits may not be earned for technologies installed on a motor vehicle to attain compliance with any vehicle safety standard or any regulation set forth in Title 49 of the Code of Federal Regulations.

There are two basic elements to this prohibition: (1) congestion mitigation, crash avoidance, and other technologies designed to reduce crashes are ineligible for credit; and (2) technologies that already required under federal law for safety purposes, i.e., technologies required under NHTSA Federal Motor Vehicle Safety Standards ("FMVSS"), are ineligible for credit.

With respect to congestion mitigation and crash avoidance technologies more generally, EPA identified several rationales for not allowing them to be eligible for off-cycle credit. Importantly, the "agencies agree[d] that there is a clear nexus between congestion mitigation and fuel/$CO_2$ savings for the entire on-road fleet."[22] However, they nevertheless declined to give credit due to several policy considerations.

First, the Agencies expressed uncertainty with regards to whether manufacturers would be able to quantify and verify real-world improvements in energy efficiency that resulted from the use of such technologies. The agencies reiterated that "credits should be available only for technologies providing real-world improvements, the improvements must be verifiable, and the process by which credits are granted and implemented must be transparent."[23] They concluded that these factors would not be satisfied for congestion mitigation systems and technologies that reduce the frequency

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[20] 40 C.F.R. § 86.1869-12(a).

[21] 2012 Final Rule at 62,730, 62,732-62,736, 62,836.

[22] *Id.* at 62,732.

[23] *Id.* at 62,733.

of crashes,[24] because they "indirectly" improve fuel economy of other vehicles (or the fleet as a whole) rather than the efficiency of the specific vehicle on which they are installed, and thus could be hard to verify.[25] Thus, although the Agencies expressly acknowledged the "clear nexus between congestion mitigation and fuel/$CO_2$ savings for the entire on-road fleet," they noted that "[i]t is less clear, however, whether there is a calculable relationship between congestion mitigation and fuel/$CO_2$ savings directly attributable to individual vehicles produced by a manufacturer . . . ."[26] The Agencies thus determined that in order "for a technology to be 'counted' under the credit provisions, it must make direct improvements to the performance of the specific vehicle to which it is applied."[27]

Neither of these interrelated rationales mandates the approach adopted by the Agencies in 2012 barring the use of these technologies. In terms of EPA's hesitancy to award credits for technologies that may be shown to increase fuel economy for a fleet (rather than individual vehicles), NHTSA's corporate *average* fuel economy standards are standards that apply to a manufacturer's *fleets*, rather than specific *vehicles*,[28] so this fact should not disqualify safety technology from being eligible for credit. This is especially true in light of the fact that EPA currently determines and applies the off-cycle improvement value for each manufacturer at the fleet level, not the vehicle level.[29] As described above, "all off-cycle $CO_2$ credits would be converted to a gallons-per-mile fuel consumption improvement value at a fleet level for purposes of the CAFE program."[30] Essentially, "instead of manufacturers gaining credits as done under the GHG program, a direct adjustment would be made to the manufacturer's fuel economy fleet performance value."[31] There is no reason why credit for safety technologies could not be applied on a fleet level. Also, the prohibition on eligibility for credit for safety technologies is overbroad, in that some technologies with safety benefits can spur fuel economy improvements both at the individual vehicle *and* at the fleet level.

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[24] Under this rationale, the Agencies determined not to provide "off-cycle credits for technologies and systems including, but not limited to, Electronic Stability Control, Tire Pressure Monitoring System, Forward Collision Warning, Lane Departure Warning and/ or Intervention, Collision Imminent Braking, Dynamic Brake Support, Adaptive Lighting, Blind Spot Detection, Adaptive Cruise Control, Curve Speed Warning, Fatigue Warning, systems that reduce driver distraction, and any other technologies that may reduce the likelihood of crashes." *Id.*

[25] *Id.* at 62,732-33. For instance, installing congestion mitigation safety technologies on a large number of vehicles would reduce accidents, which would reduce associated traffic, idling, and fuel waste and improve fuel economy.

[26] *Id.* at 62,732.

[27] *Id.* at 62,733.

[28] *See id.* at 62,699 ("noting that "no specific vehicle need meet its target (because standards apply to fleet average performance)").

[29] *See* 40 C.F.R. § 600.510-12(c)(1)(ii) (calculating the improvement value for off-cycle technology on a fleet basis); 2012 Final Rule at 62,839 ("The [fuel economy] improvement value for off-cycle improvements will be determined at the fleet level[.]"); *id.* at 62,738 n.312 (explaining that "EPA's calculation methodology in 40 CFR 600.510–12 does not use vehicle-specific fuel consumption adjustments to determine the CAFE increase due to the various incentives allowed under the program. Instead, EPA will convert the total $CO_2$ credits due to each incentive program from metric tons of $CO_2$ to a fleetwide CAFE improvement value"). It should be noted that EPA is subject to certain limitations on its authority to calculate a manufacturer's average fuel economy and must calculate a harmonic volume-weighted average as described in 49 U.S.C. § 32904(a)(1)(B). EPA appears to apply the fleet fuel consumption improvement value after calculating this average.

[30] 2012 Final Rule at 62,839-40.

[31] *Id.* at 63,134; *see also id.* at 62,726 ("EPA will convert the metric tons of $CO_2$ credits for air conditioning (as well as for other off-cycle technologies and for full size pick-up trucks) into *fleet-wide* fuel consumption improvement values, consistent with the way EPA would convert the improvements in $CO_2$ performance to metric tons of credits. . . . There will be separate improvement values for each type of credit, calculated separately for cars and for trucks. These improvement values are subtracted from the manufacturer's two-cycle-based *fleet* fuel consumption value to yield a final new *fleet* fuel consumption value, which would be inverted to determine a final fleet fuel CAFE value.") (emphasis added).

Granting credit for such technologies could also incentivize increased technology penetration in the fleet. Such an approach could provide a pathway to accelerate the penetration of technologies such as vehicle-to-vehicle ("V2V") communication technology in the fleet, by providing value to incent auto-manufacturers to assume the investment. By focusing only on individual vehicle improvements in isolation, and not recognizing the potential for fleet-wide gains, the Agencies may inadvertently lose the forest for the trees—especially as the automobile sector becomes a more interconnected network.

Moreover, *even if* the fuel economy gains of such technologies were difficult to quantify at the time the 2012 Final Rule was promulgated, it does not mean that they still cannot be quantified or will not be able to be quantified several years from now. The current regulations thus unnecessarily bar a whole category of potential technologies in an overbroad manner, leaving no opportunity for the Agencies to evaluate whether data may be available to justify credits in the future. Analytical capabilities and the ability to understand, monitor, and collect data regarding the efficacy of various technologies has grown exponentially since 2012. Given the pace at which technology and analytics change, a more forward-thinking approach would allow manufacturers the option to demonstrate and quantify the fuel economy benefits associated with these technologies. Thus, even if the Agencies think that quantification may currently be difficult, they should not enshrine a prohibition that may soon grow outdated in their regulations.

Indeed, the Agencies took this exact same wait-and-see approach with respect to the eligibility of other technologies in recognition of the fact that manufacturers may be able to demonstrate real-world fuel economy gains that merit credit. For instance, in the 2012 Final Rule, the Agencies also concluded that other forms of technology, such as congestion avoidance and driver-selectable technologies, could also be difficult to quantify, but did not create a similar categorical bar for these technologies.[32] Rather the Agencies left open the possibility that such technologies could be eligible for credit, and decided to review such technologies on a case-by-case basis. The Agencies should remove the categorical bar against safety and congestion mitigation technologies to allow for manufacturers the opportunity to demonstrate that credit is warranted.

The other potential rationale advanced by the Agencies for excluding safety technologies from eligibility was that NHTSA evaluates safety technologies under other regulatory programs, i.e., the New Car Assessment Program ("NCAP") and FMVSS, and these other programs provide a mechanism for evaluating, promoting, and potentially even mandating adoption of safety technologies.[33] More specifically, the Agencies explained that:

> Additional technologies may be added to the NCAP list of crash avoidance technologies when there is sufficient information and analysis to confirm their safety value. . . . Alternatively, NHTSA may conclude that such technologies are sufficiently developed, their safety benefits sufficiently clear, and relevant test procedures sufficiently defined that they should be the subject of a mandatory safety standard. NHTSA could not render a determination on such a request without thoroughly testing the technology as applied in that specific model and developing a specialized benefits analysis. The agency's higher priority would clearly have to be analyzing the

[32] In the 2012 Final Rule, EPA also emphasized that it believed that manufacturers would have a hard time demonstrating that driver-selectable and driver interactive technologies, e.g., congestion avoidance, should receive credit and would need to conduct extensive data collection. *See* 2012 Final Rule at 62,736.

[33] *Id.* at 62,733 ("[T]he agency may either promote its use through its New Car Assessment Program (NCAP) or mandate its use by issuing a Federal Motor Vehicle Safety Standard (FMVSS) requiring the technology on all or some categories of new vehicles.").

> technologies it found to offer great safety promise on a broader basis and developing standardized tests for those technologies. Therefore the agencies believe that evaluation of crash avoidance technologies is better addressed under NHTSA's vehicle safety authority than under a case-by-case off-cycle credit process.[34]

The Agencies further explained that they "believe that the advancement of crash avoidance systems specifically is best left to NHTSA's exercise of its vehicle safety authority. NHTSA looks forward to working with manufacturers and other interested parties on creating opportunities to encourage the general introduction of these technologies in the context of the NCAP program and possible safety standards."[35]

This rationale appears to be based on the notion that NHTSA should prioritize its authority under its safety mandates to encourage the adoption of advanced safety technologies. But this explanation misses the critical point that NHTSA's responsibilities under the safety program and the fuel economy program are not mutually exclusive and no-tradeoffs are required. Instead, NHTSA could leverage its expertise under these various programs so they can all reflect the multi-faceted benefits offered by congestion mitigation, crash avoidance, and other safety technologies. Indeed, NHTSA's analyses on the efficacy of various technologies under the safety program would be expected to inform the analysis of their fuel economy potential, and vice versa. Once again, the Agencies cited to no statutory bar to crediting these technologies under the fuel economy regime, and instead expressed a policy preference not to do so.

In addition to the 2012 regulatory prohibition against credit for congestion mitigation and crash avoidance technologies in general, there is also a more specific prohibition in the regulation for technologies that are already required under federal law for safety purposes, i.e., technologies that are required under NHTSA FMVSS. With respect to this narrower category of safety technologies, the Agencies explained that "EPA will not provide credits for a technology required to be used by Federal law, as EPA would consider such credits to be windfall credits (i.e. not generated as a result of the rule)."[36] This decision, once again, is a policy choice made in reference to the goals of the off-cycle credit program—to encourage adoption of fuel efficient technologies. Although not mandated by the statute, the decision to exclude the category of safety technologies that are already mandated by law, is at least consistent with the goals of the off-cycle program (although we note that the Agencies can always modify the programs goals).

However, this decision stands in stark contrast to the decision to exclude all congestion mitigation, crash avoidance, and other safety technologies, as many of these technologies are innovative and evolving and have significant potential to achieve fuel economy gains. The Agencies' decision to exclude them thus runs counter to the goals of the off-cycle program (and EPCA in general) to promote fuel efficiency and encourage the adoption of innovative fuel efficient technologies.[37] At the very least the Agencies should narrow their prohibition on eligibility only to technologies that are mandated under existing NHTSA regulations (e.g. FMVSS).

Importantly, in the explanation for the Agencies' decision to bar off-cycle credit for safety technologies, there is no reference to any statutory provision that mandates this approach, and we are not aware of any. Indeed, the entire off-cycle program was created as a function of EPA's discretion to measure and calculate average fuel economy, in coordination with NHTSA, under 49

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[34] *Id.* at 62,733.

[35] *Id.*

[36] 2012 Final Rule at 62,836.

[37] *Id.* at 62,833 (noting that the goal of the program is to "provid[e] an incentive for the development and use of additional technologies to achieve real-world reductions in $CO_2$ emissions.").

U.S.C. 32904. Thus, given that this program is a creation within EPA's discretion that is subject only to a few statutory limits (See Section III below), it is within EPA's discretion to credit safety, crash avoidance, and congestion mitigation technologies in the fuel economy calculation, provided there is a real-world fuel economy benefit to measure or calculate. EPA and NHTSA have already acknowledged that there is such a benefit.

Accordingly, the Agencies should eliminate the prohibition on applying for credit for such technologies, and NHTSA should leverage its extensive knowledge of technology safety efficacy to support such application efforts and provide guidance to assist with such efforts.

The Agencies should also go one step further and use their authority and expertise to incent and promote research on the fuel economy gains resulting from deployment of such advanced vehicle technologies. The Agencies could allow automakers to earn estimated, pre-determined credits for three to five years as part of a temporary research program through which the automakers would deploy autonomous and connected vehicle technology, collect data about the technology's performance, and share that data with the Agencies. The pre-determined credit value would be estimated based on the best available data prior to the research program. After the temporary research program is complete, data collected through the program would then be used to determine the appropriate amount of credit to award based on the effectiveness of the technology on a permanent basis. Securing America's Future Energy ("SAFE") recently determined that several of these technologies available today can obtain a fuel economy benefit of 18%-25% with most of these savings achieved system wide. However, the data SAFE used is limited due to small deployments. The research program will allow for data to be collected on a larger scale by incentivizing increased deployment. This approach will address the proverbial "chicken and egg" problem because it will incentivize a quicker deployment to achieve more real world data.

The Agencies have found it to be within their authority to incent "game-changing" technologies by providing fuel economy credit to promote their further penetration. For instance, in the 2012 Final Rule, the Agencies offered a "game-changing" technology incentive for full size pick-up trucks to promote their penetration into the fleet.[38] Similarly, the Agencies should establish a research program for the benefits obtainable from the penetration of "game-changing" autonomous vehicle and safety technologies, and make the program permanent where appropriate based on that research in order to promote their deployment.

As described in more detail below, the Agencies are permitted to change positions on this issue in a subsequent notice-and-comment rulemaking, and should do so as a part of their imminent rulemaking process.

## III. Regulatory Changes Necessary to Allow For Fuel Economy Credit for Safety and Congestion Mitigation Technologies

Because the Agencies' decision to exclude safety and congestion mitigation technologies from off-cycle eligibility was a policy decision made in a rulemaking, the Agencies are permitted to change their position through notice-and-comment rulemaking provided they acknowledge the change and provide an explanation for it as described in *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-15 (2009).

While an agency's change in position is subject to the same standard of review as other agency actions, the agency must follow certain specific requirements. Importantly, the agency *must*

[38] 2012 Final Rule at 63,131-32.

acknowledge that it is changing positions. Indeed, "the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position. An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."[39] The agency also must provide good reasons for its new policy. However, it does not need to "demonstrate to a court's satisfaction" that these reasons are better than the reasons for the old policy: "it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates."[40]

However, while an agency does not necessarily need to provide a more detailed justification for a changed policy, there are certain circumstances where it must do so, including when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account."[41] "It would be arbitrary or capricious to ignore such matters. In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy."[42]

The Agencies are free to change their position on this issue at any time, and may do so in the upcoming notice-and-comment rulemaking to reconsider the MY 2022-2025 standards as a result of EPA's Midterm Review Process.[43] Part of the rationale for reconsidering the standards is that they "present[] challenges for auto manufacturers due to feasibility and practicability, raise[] potential concerns related to automobile safety, and result[] in significant additional costs on consumers, especially low-income consumers."[44] This stated rationale for reevaluating the MY 2022-2025 standards also supports a change in the regulations regarding eligibility for off-cycle credits. The changes described below to remove the prohibition against credit for safety and congestion mitigation technologies will serve the stated reasons for the reconsidering the MY2022-2025 standards: this approach will further increase flexibility and practicability, promote safety considerations, and provide benefits for consumers. NHTSA has long considered safety concerns in setting CAFE standards,[45] and allowing safety technologies to be eligible for credit does not suffer from the same tradeoffs between safety and fuel economy that NHTSA has historically needed to balance. Here, the Agencies can achieve both objectives in tandem. To achieve these objectives, the regulations that should be changed are described below.

As noted above, the current Off-Cycle Credit Program is located at 40 C.F.R. § 86.1869–12 ("$CO_2$ credits for off-cycle $CO_2$–reducing technologies"). However, this EPA regulation contains a limitation that restricts the eligibility of safety technologies for off-cycle credit: "Off-cycle credits may not be approved for crash-avoidance technologies, safety critical systems or systems affecting

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[39] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("*Fox*").

[40] *Id.*; *see also Clean Air Council v. Pruitt*, 862 F.3d 1, at 9 (D.C. Cir. 2017) ("Although EPA had no section 307(d)(7)(B) *obligation* to reconsider the methane rule, it is free to do so as long as 'the new policy is permissible under the statute. . . , there are good reasons for it, and . . . the agency *believes* it to be better.'") (quoting *Fox*, 556 U.S. at 515).

[41] *Fox*, 556 U.S. 502 at 515.

[42] *Id.* at 15-16; *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015).

[43] *Mid-Term Evaluation of Greenhouse Gas Emissions Standards for Model Year 2022–2025 Light-Duty Vehicles; Notice; Withdrawal*, 83 Fed. Reg. 16,077, 16,078 (April 13, 2018) ("On the whole, the Administrator believes the MY 2022–2025 GHG emission standards are not appropriate and, therefore, should be revised as appropriate. EPA, in partnership with NHTSA, will further explore the appropriate degree and form of changes to the program through a notice and comment rulemaking process.").

[44] *Id.*

[45] *See* 2012 Final Rule at 62,670.

safety-critical functions, or technologies designed for the purpose of reducing the frequency of vehicle crashes. Off-cycle credits may not be earned for technologies installed on a motor vehicle to attain compliance with any vehicle safety standard or any regulation set forth in Title 49 of the Code of Federal Regulations."[46] This language would need to be deleted or amended through notice-and-comment rulemaking. EPA's regulation at 40 C.F.R. § 600.510-12(c) provides the formulas for calculating fuel improvement values and the overall average fuel economy based on the amount of off-cycle credits obtained under 40 C.F.R. § 86.1869–12. Thus, amending 40 C.F.R. § 86.1869–12 to remove the bar for safety technologies should effectively address the issue. EPA should also evaluate the requirements of the application process provided in 40 C.F.R. § 86.1869-12(e) to ensure that this process does not require information that may be inapplicable to safety technologies, and should provide additional guidance as to the types of information EPA will deem appropriate to demonstrate fuel economy reductions.[47]

In recognition of EPA's status as lead agency for fuel economy calculation purposes, NHTSA's regulations state that "[f]or model years 2017 to 2025, a manufacturer is eligible to increase the fuel economy performance of passenger cars in accordance with procedures established by EPA set forth in 40 CFR part 600, including any adjustments to fuel economy EPA allows, such as for fuel consumption improvements related to . . . off-cycle technologies."[48] The regulations further explain that "[t]he eligibility of a manufacturer to increase its fuel economy performance through use of an off-cycle technology requires an application request made to EPA in accordance with 40 CFR Part 86.1869–12 and an approval granted by EPA made in consultation with NHTSA."[49] As currently drafted, this language would not need to be changed, because it cross-references EPA's provisions. Thus, changing EPA's provisions for off-cycle credit for GHGs should also effectively change those provisions with respect to the CAFE program.

However, some of NHTSA's regulations will also need to be amended (and the cross-references may need to be updated depending on how EPA's regulations are amended). As noted above, when a manufacturer applies for credit, the Agencies' regulations require consultation between EPA and NHTSA on the applications to allow NHTSA to evaluate specific off-cycle technologies for their impact on fuel economy, and EPA's approval is "made in consultation with NHTSA."[50] In particular, the regulations require NHTSA to "consult with EPA regarding NHTSA's evaluation of the specific off-cycle technology to ensure its impact on fuel economy and the suitability of using the off-cycle technology to adjust the fuel economy performance."[51] However, the regulation also provides that "NHTSA's evaluation and review will consider:

> (1) Whether the technology has a direct impact upon improving fuel economy performance;
> (2) Whether the technology is related to crash-avoidance technologies, safety critical systems or systems affecting safety-critical functions, or technologies designed for the purpose of reducing the frequency of vehicle crashes;
> (3) Information from any assessments conducted by EPA related to the application, the technology and/or related technologies; and

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[46] 40 C.F.R. § 86.1869-12(a).

[47] As noted above, EPA is the lead agency in this process and would need to make the ultimate decision to amend its own regulations.

[48] 49 C.F.R. § 531.6(a); *see also* 49 C.F.R. § 533.6(b) (similar provision applicable to light truck fleets); *see also* 2012 Final Rule at 63,131.

[49] 49 C.F.R. § 531.6(b); *see also* 49 C.F.R. § 533.6(c) (similar provision applicable to light truck fleets).

[50] 49 C.F.R. § 531.6(b); 40 C.F.R. § 86.1869-12(d)(3); *see also* 2012 Final Rule at 62,650, 62,839-40.

[51] 49 C.F.R. § 531.6(b); *see also* 49 C.F.R. § 533.6(c) (similar provision applicable to light truck fleets).

(4) Any other relevant factors.[52]

In order to clarify that applications for off-cycle credits for safety technologies can be considered, this provision should be revised and reframed in several ways. First, the requirement that NHTSA consider "[w]hether the technology has direct impact upon improving fuel economy performance" should be revised.[53] In the 2012 Final Rule, EPA utilized the word "direct" to refer only to fuel economy improvements that occurred for the vehicle on which the technology was installed. However, as described above, EPA found that efficiency gains achieved via safety equipment were "indirect" in that they result in efficiency improvements for the fleet as a whole or other cars on the road. Although safety technologies do in fact have a significant impact on improving fuel economy, the use of the word "direct" here could create confusion given the regulatory history, and should be removed.

Second, the provision requiring that NHTSA consider "[w]hether the technology is related to crash-avoidance technologies, safety critical systems or systems affecting safety-critical functions, or technologies designed for the purpose of reducing the frequency of vehicle crashes" should be reframed and clarified. It is desirable to have NHTSA involved in evaluating the eligibility of such technologies given its expertise, However, the purpose of this provision was to require NHTSA to evaluate whether technologies implicated safety for the *purposes of excluding* them.[54] If the Agencies eliminate the prohibition on credit for these technologies, NHTSA should still be involved in evaluating them, but the provision should be clarified that the goal of such review is not too exclude them from receiving credit. The role of NHTSA in this process should also be better defined and enhanced, given its expertise in safety issues.

In addition to eliminating any regulatory provisions that hinder the eligibility of safety technologies to receive credit, the Agencies may also want to actively include language clarifying the pathway for such technologies to achieve credit and confirming that such credit is available if an adequate demonstration is made by a manufacturer. The agencies may also develop a method for quantifying the benefits of such technologies, as they have for other off-cycle technologies. New provisions for safety technologies could be inserted in 40 C.F.R. § 86.1869–12, or in a separate regulation in 40 C.F.R. Part 86, Subpart S ("General Compliance Provisions for Control of Air Pollution from New and in–Use Light–Duty Vehicles, Light–Duty Trucks, and Heavy–Duty Vehicles"). Depending on where the new provisions are inserted, changes may also need to be made to 49 C.F.R. § 531.6 and 49 C.F.R. § 533.6, which allows for off-cycle credit for the fuel economy program (for passenger vehicles and light trucks respectively) by cross-referencing EPA's off-cycle regulation at 40 C.F.R. § 86.1869–12. Any new regulation would need to also be cross-referenced here.

## IV. Legal Limitations on EPA's Authority Under EPCA Do not Bar Granting Credit for Safety and Congestion Mitigation Technologies

Section 32904(c) provides the basis for the off-cycle credit program and provides that EPA "shall measure fuel economy for each model and calculate average fuel economy for a manufacturer under testing and calculation procedures prescribed by the Administrator."[55] EPA's EPCA authority

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[52] *Id.*

[53] *Id.*

[54] 2012 Final Rule at 62,733 ("If a manufacturer has an off-cycle technology that is not included on this list and brings it to the agencies for assessment, NHTSA will determine whether it is ineligible for a credit or adjustment by reason of the agency's judgment that it is related to crash avoidance systems, is related to motor vehicle safety within the meaning of the National Traffic and Motor Vehicle Safety act, as amended, or may otherwise reduce the possibility and or frequency of vehicle crashes."); *see also id.* at 63,135.

[55] 49 U.S.C. § 32904(c).

under Section 32904 is broad and the agency has significant discretion, but there are several potential legal limitations on this authority. None of these limitations, however, would mandate categorically barring safety and congestion mitigation technologies or require EPA to distinguish between these technologies and other technologies currently credited under the off-cycle program.

First, any fuel economy gains achieved by emerging technologies must be quantifiable in terms of miles per gallon. EPCA defines "fuel economy" as "the average number of miles traveled by an automobile for each gallon of gasoline . . . used, as determined by the [EPA] Administrator under section 32904(c) . . . ."[56] However, there is no apparent reason why fuel economy gains from safety and congestion mitigation technologies could not be quantified in miles per gallon.

Second, EPA must use a volume-weighted average for its average fuel economy calculations. "Average fuel economy" "means average fuel economy determined under section 32904 of this title."[57] Section 32904 provides some instruction on how the Administrator must calculate average fuel economy, but also provides discretion in this regard. The major limitation is that this method of calculation is "subject to" EPA dividing "(i) the number of passenger automobiles manufactured by the manufacturer in a model year; by (ii) the sum of the fractions obtained by dividing the number of passenger automobiles of each model manufactured by the manufacturer in that model year by the fuel economy measured for that model."[58] However, the phrase "subject to" does not mean that this is the exclusive method EPA may use in the calculation, only that this method must be used at some step in the calculation. EPA has discretion to add additional elements to the overall method used. Indeed, EPA uses this method to determine fuel economy under its current regulations, but applies the off-cycle credit as an additional step in the overall procedure. As noted above, EPA determines the total off-cycle credits on a fleet-wide basis (e.g., non-passenger vehicle or light truck) in terms of megagrams of $CO_2$, and then converts this number to the fleet-wide production-weighted total value of the off-cycle technology credits for "all off-cycle technologies in the applicable fleet, expressed in gallons per mile."[59] EPA can account for off-cycle credits for safety technologies using this existing procedure.

Third, although EPCA gives EPA broad discretion to measure and calculate fuel economy, it also imposes certain limits on EPA's ability to change its testing and measurement procedures for passenger vehicles (but not light trucks).[60] Specifically, EPCA provides that the "Administrator shall measure fuel economy for each model and calculate average fuel economy for a manufacturer under testing and calculation procedures prescribed by the Administrator. However, . . . the Administrator shall use the same procedures for passenger automobiles the Administrator used for model year 1975 (weighted 55 percent urban cycle and 45 percent highway cycle), or procedures

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[56] 49 U.S.C. § 32901(a)(11); *see also* 2012 Final Rule at 63,014 ("NHTSA is required by statute to set CAFE standards in terms of miles per gallon— 'fuel economy,' as expressly defined in EPCA, means "'the average number of miles traveled by an automobile for each gallon of gasoline (or equivalent amount of other fuel) used.'").

[57] 49 U.S.C. § 32901(a)(5).

[58] *Id.* § 32904(a).

[59] *See* 40 C.F.R. § 86.1869-12(e); 40 C.F.R. §§ 600.510-12(c)(1),(c)(3)(ii); *See also* 2012 Final Rule at 62,726 ("For the CAFE program, EPA will determine fleet average fuel consumption improvement values in a manner consistent with the way fleet average $CO_2$ credits will be determined. EPA will convert the metric tons of $CO_2$ credits for air conditioning (as well as for other off-cycle technologies. . . ) into fleet-wide fuel consumption improvement values, consistent with the way EPA would convert the improvements in $CO_2$ performance to metric tons of credits. . . . There will be separate improvement values for each type of credit, calculated separately for cars and for trucks. These improvement values are subtracted from the manufacturer's two-cycle-based fleet fuel consumption value to yield a final new fleet fuel consumption value, which would be inverted to determine a final fleet fuel CAFE value.").

[60] *See* 2012 Final Rule at 62,802.

that give comparable results."[61] The legislative history of this provision explains that:

> Compliance by a manufacturer with . . . fuel economy standards is to be determined in accordance with test procedures established by the EPA Administrator by rule. Test procedures so established would be the procedures utilized by the EPA Administrator for model year 1975, or procedures which yield comparable results. The words 'or procedures which yield comparable results' are intended to *give EPA wide latitude* in modifying the 1975 test procedures to achieve procedures that are more accurate or easier to administer, so long as the modified procedure does not have the effect of substantially changing the average fuel economy standards.[62]

This provision was likely intended to ensure baseline comparability of the standards over time, while still allowing EPA "wide latitude."[63]

The language of the statute allowing for EPA to use "procedures that give comparable results" and this legislative history thus indicate that EPA has flexibility to change its measurement approach. However, EPA recognized that its pre-2012 interpretation of this provision may have limited the use of the off-cycle credit program.[64] Accordingly, in the 2012 Final Rule, EPA adopted an interpretation of the statute that the offset credit program is permissible under this provision, even though it does not have an analog in the 1975 test procedure. EPA has thus already provided a detailed analysis justifying the propriety of the off-cycle program under the terms of the statute.

Specifically, EPA explained in the 2012 Final Rule that it "considers the fuel economy results to be 'comparable results' to the 1975 procedure as there would not be a substantial impact on real world [fuel economy] stringency and benefits, given the changes in procedure are the same as provisions in EPA's companion greenhouse gas procedures and standards."[65] Thus, under the current harmonized program, EPA has concluded that it has authority to change the test procedures to credit technologies that provide real-world efficiency, even where they are not measurable under and do not have an analog in the 1975 procedure. It is unclear whether EPA would similarly conclude it could take this position under EPCA, if its GHG procedures did not also recognize those credits. EPA should thus issue parallel credits for any safety and congestion mitigation technologies under its GHG program to the extent it credits those technologies under the fuel economy program. These technologies reduce real-world emissions as well as create real-world gains in fuel economy.

In sum, the Agencies have already concluded that they have the authority to give credit for technologies under the off-cycle program as a part of the fuel economy calculation process. The

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[61] 49 U.S.C. § 32904(c).

[62] H.R. Rep. No. 94-340, at 91-92 (1975) (emphasis added); *see also* S. Rep. No. 94-516, at 157 (1975).

[63] *See id.; see also* S. Rep. No. 94-179, at 19 (1975).

[64] EPA's prior interpretations could have proven problematic for the off-cycle program. In the 2012 Final Rule, EPA considered whether changing its test procedure to allow for credit for air conditioner efficiency and off-cycle efficiency (which are not captured in the 1975 two-cycle test procedures), would "substantially change" the standards in a manner barred by this provision. EPA explained that its pre-2012 approach to analyzing this question relied on a D.C. Circuit case (which was later vacated on other grounds) interpreting this provision, and that EPA's pre-2012 approach considered whether the test procedure change (1) had a significant impact on fuel economy results, (2) reflected real world efficiency improvements, and (3) had an analog in the original 1975 test procedure such that it was substantially comparable. *See* 2012 Final Rule at 62,803. EPA noted that its procedure changes to accommodate off-cycle and air conditioning efficiencies lacked an analog in the 1975 procedure, indicating they might not be appropriate under EPA's traditional interpretation. *Id.* However, given EPA's change in interpretation in the 2012 Final Rule, EPA has already determined that this provision does not bar granting off-cycle credits.

[65] 2012 Final Rule at 62,804. EPA can change its interpretation, and it will generally receive deference provided it is not contrary to the statute or regulations.

limitations on EPA's authority under § 32904(c) thus do not stand as a prohibition to crediting other off-cycle technologies—such as safety and congestion mitigation technologies—as a part of the off-cycle program. Moreover, this provision in § 32904(c) only applies to passenger cars, and not light trucks, so EPA has even more flexibility in determining the appropriate procedures applicable to light trucks.[66]

## V. Conclusion

In sum, the Agencies have the combined authority and expertise to credit fuel economy benefits from safety, crash avoidance, and congestion mitigation technologies. Although there are some legal limitations in EPCA that the Agencies must be aware of, past agency practice in establishing the off-cycle credit program demonstrates that the Agencies have concluded that they have significant authority to recognize real-world fuel economy improvements. Accordingly, at the very least, the Agencies should eliminate the 2012 regulatory prohibition to obtaining off-cycle credits for safety-related technologies. The Agencies should also go one step further and allow automakers to earn pre-determined credits based on best available data for three to five years as part of a research program through which the automakers would deploy autonomous and connected vehicle technology, collect data about the technology's performance, and share that data with the Agencies. This additional real world data would then be used to determine the appropriate amount of credit to award based on the effectiveness of the technology on a permanent basis. Regardless of this program, the Agencies should also streamline and improve the off-cycle application process to allow manufacturers to more easily obtain credits, and NHTSA should leverage its safety expertise to provide guidance and resources to assist manufacturers in quantifying and verifying the fuel economy gains achievable through deployment of these technologies.

[66] *Id.* at 62,673 ("Under EPCA, EPA is required to use these procedures (or procedures which yield comparable results) for measuring fuel economy for cars for CAFE purposes, but not for labeling purposes. EPCA does not pose this restriction on CAFE test procedures for light trucks, but EPA does use the FTP and HFET for this purpose.").

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Securing America's Future Energy

# Memorandum

From: Securing America's Future Energy
To:
Re: Fuel Economy Off Cycle Credit Program, Flexibilities and Estimated Fuel Savings
Date: June, 2018

The following document contains a set of flexibilities and technological advances that accelerate the pace of technological innovation in the transport sector. The first section describes a set of technologies that have shown promise in simultaneously improving safety and fuel economy. Cumulatively, if widely-deployed, they could yield 18-25% fuel economy savings across the vehicle fleet. We propose a real-world test of these technologies to determine their actual safety and fuel economy benefits. The second section focuses on the advanced-fuel multiplier currently set to expire in 2021. We argue this multiplier will encourage the continued development of advanced-fuel vehicles and should be extended through 2025. The final section aggregates the savings.

**Potential Savings**

**18-25%**

System-wide fuel savings, when majority of vehicles employ technology

**9,000 lives**

annually when these technologies are deployed across a majority of the light-duty vehicle fleet.

## Section 1: Technology Innovation Accelerator

Given their early promise, we believe the technologies listed below should be encouraged as part of a mass-deployment initiative within the existing off-cycle credit program. The initiative would run for three to five years and be designed by a partnership between NHTSA, EPA and automakers. The initiative would create a mass-deployment of these technologies to provide a real-world test of their effectiveness across a broad range of technology platforms and vehicle types. In exchange for participating in the program and sharing the resulting data, the automakers would receive compliance credits for the years in which they participate in the program. If the promise of these technologies is demonstrated through the test, that information can be used to incorporate these technologies more formally into future compliance periods.

The technologies listed vary in how they will impact the total fuel consumption of the transportation system. Some improve the efficiency of the vehicle itself, while others streamline the system as a whole, and others contribute to fuel savings in both ways. As one example, accident-related congestion in the U.S. wastes almost one billion gallons of fuel every year. Adopting a suite of crash avoidance technologies known collectively as advanced driver-assistance systems (ADAS), can potentially mitigate the causes of 85 percent of crashes. These early results indicate that if these technologies were adopted on a wide scale, significant fuel efficiency benefits could be achieved. Included within this suite of technologies are features such as Lane Keeping Assist, Blind Spot Assist, Forward Collision Warning, braking technologies and Adaptive Cruise Control (ACC), which are explored in greater detail below. According to an industry claims filing by Mercedes-Benz, based in part on insurance industry research, using Lane Keeping Assist and Blind Spot Assist in all vehicles would reduce crashes by five percent; Forward Collision Warning and

Adaptive Brake Assist in all vehicles would reduce crashes by 15 percent; and using Emergency Braking and ACC in all vehicles would reduce crashes by 18 percent.[1]

However, these technologies are not currently included in vehicle fuel economy ratings because of the structural limitations of NHTSA and EPA tests. These tests run vehicles through a predetermined set of accelerations, but they lack the flexibility to account for the ability of these technologies to improve fuel economy through smoother acceleration and deceleration, avoiding congestion-causing accidents, or identifying alternative routes. Current estimates of potential fuel savings are listed below.

Such an initiative could be incorporated into two different parts of the current regulation. A detailed description is included in the appendix at the end of this memo. The changes could be made as part of the Notice of Proposed Rule Making. It is important to note that the prior administration expressly prohibited safety technologies from the off-cycle credit program. This language, a policy decision of the prior administration, would need to be amended; EPA has the authority to make such an amendment.

## ADAS: Crash Avoidance and Automatic Braking Technologies

Automatic emergency braking technologies (AEB), also known as collision avoidance systems, are designed to prevent or reduce the severity of a collision. It is also known as a pre-crash system, forward collision warning system, or collision mitigating system. In addition to saving lives and reducing property damage, these systems reduce fuel consumption by reducing accident related congestion.

**Potential Savings**

3%

System-wide fuel savings, when majority of vehicles employ technology

.42mpg

2025 combined cars and trucks mpg savings

Depending on the automaker, between 20 and 50 percent of vehicles are fitted with these technologies, which are all available today for a few hundred dollars per installation. Only 19 percent of MY2017 vehicles offered these technologies as standard features. A pilot study conducted using a single company's aftermarket warning systems in cargo vans and pickup trucks observed an 86 percent reduction in collisions and at least a two percent increase in fuel efficiency.[3]

## ADAS: Adaptive Cruise Control (ACC)

ACC allows a vehicle to slow down or speed up automatically to keep pace with the car ahead. In doing so, the need to brake or accelerate suddenly is diminished, improving fuel economy as a result. Testing has shown that ACC combined with forward collision warning technology can reduce fuel consumption by 2.8 percent on highways.[4] Additionally, because cars

**Potential Savings**

7-10%

Possible per-vehicle fuel savings, (upper bound)

1.97mpg

2025 combined cars and trucks mpg savings

[1] Comments of Mercedes-Benz USA, LLC to Proposed Rule to Establish Light-Duty Veh Standards and Corporate Average Fuel Economy Standards for Model Year 2017 and OAR-2010-0799; FRL-9495-2; NHTSA-2010-0131 at A-10, A-11, (2012).

[3] Dish Network Data from Pilot Program; and SAFE interviews with industry; "Case Study: Dish saves fuel with Mobileye technology", *FleetOwner* (May 6, 2016).

[4] U.S. DOT, "Adaptive cruise control can reduce fuel consumption by 2.8 percent on highways." (Nov. 21, 2012) https://www.itsbenefits.its.dot.gov/ITS/benecost.nsf/ID/FDC614281B2988DA85257D550068361E?OpenDocument&Query=BApp

would be nearly-instantaneously responsive to changes in other vehicles' speeds, more cars could fit on the roads without increasing road capacity or reducing vehicle speeds. Significant adoption of ACC could enable smoother traffic flow, which would also improve both individual vehicle efficiency and highway capacity.

### Additional Stop/Start Reductions

Stop/start technologies save fuel by cutting the engine when a vehicle comes to a complete stop. In congested conditions, when vehicles frequently come to a standstill, the fuel savings with this technology are cumulative. Under average driving conditions, between three and five percent of fuel can be saved. [5] However, with increased stops and traffic lights that stay red for longer periods of time, savings can rise to ten percent.[6] The technology is relatively inexpensive for automakers to install, and analysts estimate that 65 percent of vehicles will be equipped with stop/start technology in 2021.[7]

**Potential Savings**

**3-5%**

per-vehicle fuel savings, when deployed 100% on highway driving

**1.6mpg**

2025 combined cars and trucks mpg savings

### V2V, V2I Information Sharing

Vehicle-to-vehicle (V2V) and vehicle-to-infrastructure (V2I) technology shares information between vehicles and roadway infrastructure in close proximity to each other, which can augment the performance of other technologies, particularly ACC. V2X improves the effectiveness of ACC by monitoring what is happening several cars ahead, and subsequently direct a vehicle on a route that cuts congestion, reduces idling and saves fuel should an accident be identified further ahead. Furthermore, V2V has the potential to prevent 592,000 crashes and save over 1,000 lives per year.[8] Removing these crashes from U.S. roadways every year will subsequently remove the congestion experienced in the aftermath of these incidents, and forego the fuel wasted idling in traffic jams.

**Potential Savings**

**1-4%**

Possible per-vehicle fuel savings (upper bound)

**.58mpg**

2025 combined cars and light trucks mpg savings

## Section 2: Advanced-fuel Vehicle Multiplier

Advanced fuel vehicles are powered by a diverse array of fuel types, from battery-powered electric vehicles (BEVs) and plug-in hybrid electric vehicles (PHEVs) to vehicles powered by hydrogen fuel cells or natural gas. These vehicles are critical for U.S. energy security, as they provide a demand-side solution to U.S. oil dependence by opening up a wider range of fuel choices

**Potential Savings**

**1.7mpg**

2025 combined cars and light trucks mpg savings

[5] Eric Taub, "Start-Stop Technology Is Spreading (Like It or Not)" (Apr 7, 2016) New Yo
https://www.nytimes.com/2016/04/08/automobiles/wheels/start-stop-technology-is-not.html

[6] Ibid.

[7] Melissa Burden, "Stop-start systems rolling out on more cars" (Nov 3, 2016) Detroit News
https://www.detroitnews.com/story/business/autos/2016/11/03/stop-start-systems-rolling-cars/93271604/

[8] National Highway Traffic Safety Administration, "U.S. Department of Transportation Issues Advance Notice of Proposed Rulemaking to Begin Implementation of Vehicle-to-Vehicle Communications Technology," (Aug. 18, 2014)
https://www.nhtsa.gov/press-releases/us-department-transportation-issues-advance-notice-proposed-rulemaking-begin



Sierra Club v. EPA 18cv3472 NDCA Attachments Prod 2 ED_002061_00183870-00003

for consumers. This greater fuel choice is crucial for both U.S. national and economic security, as 92 percent of the U.S. transportation system currently relies on petroleum fuels—a dependence on oil that harms consumers and businesses when prices spike, and reorders U.S. foreign policy priorities. Ultimately, increasing fuel diversity and consumer choice will counter the ability of a cartel to manipulate the price of transportation fuel.

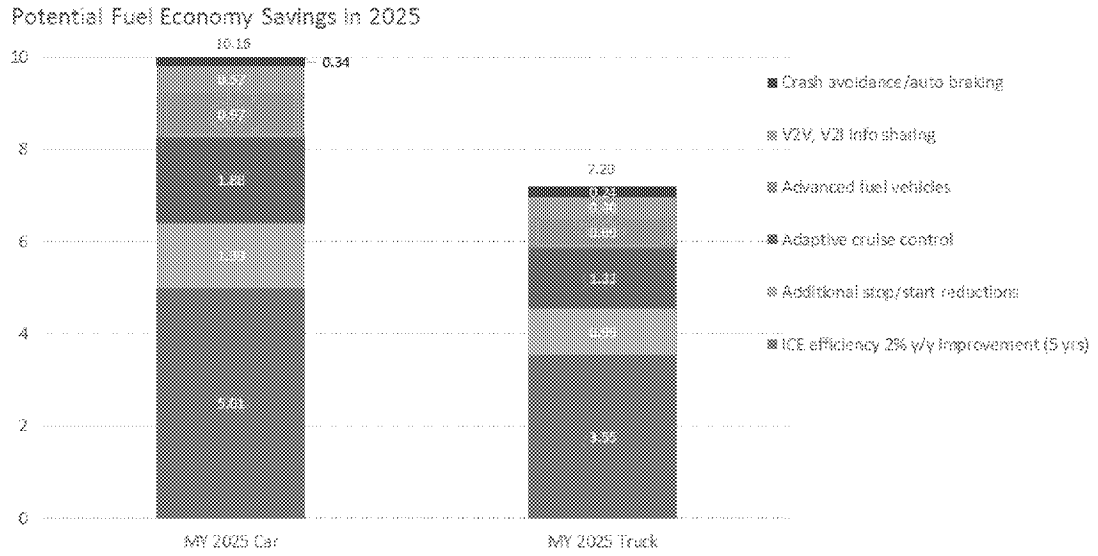
The 2x credit multiplier for automakers is currently in place until 2021. Retaining the credit beyond this date will spur further production of advanced fuel vehicles at a key moment for the technology's adoption, as production costs fall and consumer acceptance grows. Retention of the multiplier is expected to save 1.7 miles per gallon across the U.S. vehicle fleet. Even if these savings are not fully realized, greater production of advanced fuel vehicles is still an important goal because of their economic benefits: Maintaining higher levels of advanced fuel vehicle production ensures the U.S. does not cede global leadership of a rapidly growing industry to international competitors—particularly China —and electric vehicles in particular are the preferred powertrain for autonomous vehicles, which hold the potential for significant safety, mobility and energy security benefits for the U.S.

Through the regulatory review process currently underway, the EPA has the authority to eliminate the phase-out provision and extend the multiplier out to 2025. In the 2012 Final Rule the EPA formally disagreed with commenters that wanted to extend the multiplier beyond 2021. The Agency will need to explain it rationale for the change and acknowledge that it is a shift from the prior administration's policy. (See the appendix below for more details.)

## Section 3: Aggregated Benefits

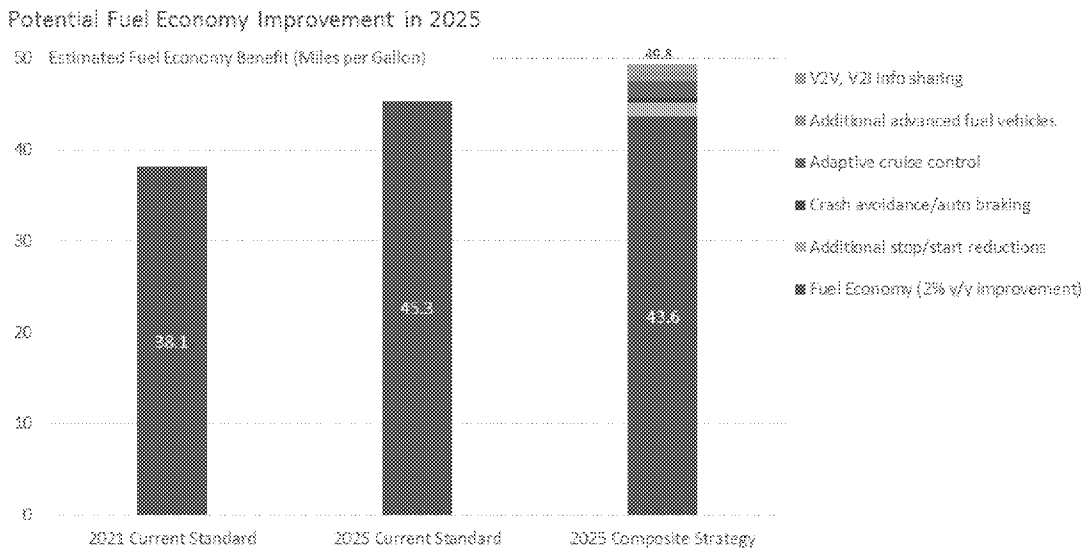
SAFE commissioned Air Improvement Resource to model the potential fuel economy savings if these technologies were widely deployed in the U.S. vehicle fleet. A review of two dozen studies underpinned the analysis, and identified the savings summarized in the table below. The majority of these savings are additive and together identify the potential to reduce fuel conusmption by 18 to 25 percent if deployed throughout the fleet.

The chart below outlines the estimated fuel economy benefits if there was widespread adoption of the technologies described above. The graph assumes an annual efficiency gain in the internal combustion engine of 2.0 percent per year between 2022 and 2025. This would lead to improvements of 5.01 miles per gallon (mpg) in cars and 36 in light trucks respectively. Additional start/stop improvements that the industry could adopt readily would add an additional 1.4 mpg for cars and 1 mpg for trucks. Adaptive cruise control, vehicle-to-vehicle (V2V) and crash avoidance has the potential account for another 2.8 mpg for cars and 2.0 mpg for trucks. Finally, further production of advanced fuel vehicles induced by the extension of the advanced fuel multiplier could contribute 1.7 mpg collectively. Altogether, this approach could provide 10.16 mpg compliance for cars and 7.2 mpg compliance for light trucks.




Source: Air Improvement Resource, Inc.

The second chart combines the benefits of cars and trucks from the previous chart in order to show the relative impact of the measures contained in our proposal. The current standard calls for an improvement in overall fleet fuel economy from 38.1 mpg in 2021 to 45.3 mpg in 2025. If such measures were fully implemented and their benefits fully realized, it would allow the standards to achieve 49.8 mpg in 2025, ten percent higher than the current 2025 obligation but with greater flexibility for industry.




Source: Air Improvement Resource, Inc.

## Appendix: Incorporation into existing regulatory structure

1. *Incorporating a pro-innovation initiative within the off-cycle credit program*

- EPA adopted the Off-Cycle Credit Program pursuant to Section 202(a) of the Clean Air Act (42 U.S.C. § 7521(a)) as it relates to greenhouse gas (GHG") emissions, and pursuant to the Energy Policy and Conservation Act ("EPCA") (specifically 49 U.S.C. § 32904) as it relates to fuel economy standards.

    - Section 202(a) of the Clean Air Act gives EPA broad authority to regulate GHGs from mobile sources, and the prior Administration concluded that it had the authority to offer credits for emission reducing technologies under the off-cycle program.

    - Section 32904 of EPCA gives EPA the authority to measure fuel economy for vehicles and calculate average fuel economy for manufacturers. Pursuant to this statutory provision, in 2012, the prior Administration concluded that it had the authority to give credit for fuel economy improving technologies under the off-cycle program as a part of the fuel economy calculation process, and offered this credit starting in FY 2017. See 2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards, 77 Fed. Reg. 62,624, 62,628, 62,649-50, 62,961, 63,125 (Oct. 15, 2012) ("2012 Final Rule").

- The current Off-Cycle Credit Program is located at 40 C.F.R. § 86.1869–12 ("CO2 credits for off-cycle CO2–reducing technologies"). A new initiative for autonomous vehicle/safety technologies could be inserted in this regulation, or in a separate regulation in 40 C.F.R. Part 86, Subpart S ("General Compliance Provisions for Control of Air Pollution from New and in–Use Light–Duty Vehicles, Light–Duty Trucks, and Heavy–Duty Vehicles"). In addition to the Off-Cycle Credit Program, EPA's regulations crediting other efficiency improvements (e.g., air conditioning efficiency) are also included in this subpart. Depending on where the new provisions are inserted, changes may also need to be made to 49 C.F.R. § 531.6, which allows for off-cycle credit for the fuel economy program by cross-referencing EPA's off-cycle regulation at 40 C.F.R. § 86.1869–12. Any new regulation would need to also be cross-referenced here.

- The current regulation contains a limitation that restricts the eligibility of safety technologies for off-cycle credit: "Off-cycle credits may not be approved for crash-avoidance technologies, safety critical systems or systems affecting safety-critical functions, or technologies designed for the purpose of reducing the frequency of vehicle crashes. Off-cycle credits may not be earned for technologies installed on a motor vehicle to attain compliance with any vehicle safety standard or any regulation set forth in Title 49 of the Code of Federal Regulations." 40 C.F.R. § 86.1869-12(a).

    - This language would need to be amended. However, the agencies are permitted to change their prior position in a notice-and-comment rulemaking (as long as they

acknowledge the change and provide an explanation for it) and can amend this regulation to allow for credit to be provided for safety-related technologies. See FCC v. Fox Television Stations, Inc., 556 U.S. 502, 514-15 (2009).

- It is important to note that the prior Administration's decision to disallow off-cycle credit for safety technologies was framed as a policy decision, rather than a decision based on a lack of statutory authority. Part of the logic for this previous limitation was that these technologies improve the fuel economy of other vehicles (or the fleet as a whole) rather than the efficiency of the specific vehicle on which they are installed. See 2012 Final Rule at 62,732-33. However, fuel economy standards apply to manufacturer fleets, rather than specific vehicles, so this should not disqualify safety technology from being eligible for credit—especially in light of the fact that EPA applies the off-cycle improvement value at the fleet level. See 2012 Final Rule at 62,839 ("The [fuel economy] improvement value for off-cycle improvements will be determined at the fleet level[.]"). Other reasons for the prior Administration's failure to recognize the benefits of safety technologies were related to its ability to quantify the benefit provided, and that it thought that such technologies were better promoted under NHTSA's safety authority. The new administration is free to revisit these policy choices. This is the purpose of the proposed "test" program as opposed to a final or permanent credit.

2. *Extending the multipliers for advanced fueled vehicles*

- Pursuant to its authority under Section 202 of the Clean Air Act, EPA adopted multipliers for advanced fuel vehicles during the FY 2017-2025 timeframe. See 2012 Final Rule at 62,812-62,816.

- EPA's regulation at 40 C.F.R. § 86.1866-12(b) provides the authority for these multipliers for the purposes of credit under EPA's GHG emissions program, and reduces credits from 2017 to 2021, when they are phased out.

  - EPA can amend this phase-out provision through notice and comment rulemaking to extend these multipliers past 2021.

  - Note, that in the 2012 Final Rule, EPA stated that "EPA disagrees with those commenters that support higher multipliers and/or multipliers of longer duration, as we believe that such incentives could lead to a significant reduction in program GHG savings, particularly if EV/PHEV/FCV sales increase significantly after MY 2021." See 2012 Final Rule at 62,813. EPA has thus previously stated that multipliers should only extend to 2021. As noted above, EPA is permitted to change its position, but it should be sure to explain its rationale and acknowledge its prior statements on the issue if it reverses it prior rulemaking.

- It is important to note that, under the prior Administration, NHTSA has interpreted its authority to offer advanced fuel incentives more narrowly and did not offer multipliers for fuel economy purposes. See 2012 Final Rule at 62,628 ("NHTSA currently interprets EPCA and EISA as precluding it from offering incentives for the alternative fuel operation of EVs, PHEVs, FCVs, and NGVs, except as specified by statute, and thus did not propose and is not including incentive multipliers comparable to the EPA incentive multipliers."); see also id. at 62,651.

    - 49 U.S.C. §§ 32904, 32905, 32906 are statutory provisions that contain specific fuel economy incentives for various kinds of alternative fuel vehicles. The prior Administration thus concluded that these provisions should govern the incentives provided to such vehicles. As NHTSA has explained: "Because 49 U.S.C. 32904(a)(2)(B) expressly requires EPA to calculate the fuel economy of electric vehicles using the Petroleum Equivalency Factor developed by DOE, which contains an incentive for electric operation already, 49 U.S.C. 32905(a) expressly requires EPA to calculate the fuel economy of FCVs using a specified incentive, and 49 U.S.C. 32905(c) expressly requires EPA to calculate the fuel economy of natural gas vehicles using a specified incentive, NHTSA believes that Congress' having provided clear incentives for these technologies in the CAFE program suggests that additional incentives beyond those would not be consistent with Congress' intent. Similarly, because the fuel economy of PHEVs' electric operation must also be calculated using DOE's PEF, the incentive for electric operation appears to already be inherent in the statutory structure." Id. at 62,651 n.87.

    - Under NHTSA's prior interpretation, a statutory amendment may be necessary to provide certain types of fuel economy incentives to alternative fuel vehicles.

NACAA
national association of clean air agencies

December 19, 2017

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Mr. William Wehrum
Assistant Administrator
EPA Office of Air and Radiation
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW
Washington, DC 20560

Dear Mr. Wehrum:

The National Association of Clean Air Agencies (NACAA) is pleased to provide the following principles and recommendations for the Environmental Protection Agency (EPA) to consider as it develops policy and regulatory initiatives intended to help improve and streamline Clean Air Act permitting.

NACAA is a national, non-partisan, non-profit association of state and local air pollution control agencies in 41 states, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the United States. The observations and recommendations conveyed in this letter are based upon that experience. The views expressed in this document do not necessarily represent the positions of every state and local air pollution control agency in the country.

NACAA's member agencies have primary responsibility for reviewing and issuing most Clean Air Act permits. We recognize the important role that permitting plays in managing our air quality and the successes that have been achieved under the Clean Air Act permitting programs. We also recognize the important role an efficient and effective permitting process plays in supporting a healthy environment and a vibrant economy. The federal New Source Review (NSR) program, as well as state and local agencies' minor source permitting programs, has spurred the development of state-of-the-art pollution control technologies and reduced air pollution from stationary sources, protecting public health while allowing our economy to grow. The federal Title V operating permits program has improved the overall quality of permits throughout the nation, thereby improving overall compliance and the practical enforceability of permit terms and conditions. Working in partnership with EPA and industry, state and local permitting authorities have achieved considerable reductions in air pollution, greatly improving the health and well-being of millions of Americans. EPA now has the opportunity to build upon the success of the permitting programs and find ways to improve the existing programs.

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NACAA has reviewed comments provided to the Department of Commerce by business and industry stakeholders in response to a Request for Information (RFI) that sought input on how federal rules and permitting requirements could be made less burdensome for domestic manufacturers. We have also reviewed EPA's *Draft FY 2018-2022 Strategic Plan*, in which the agency commits to finding ways to accelerate permitting decisions and streamlining permit processes,[1] and EPA's *Final Report on Review of Agency Actions that Potentially Burden the Safe, Efficient Development of Domestic Energy Resources Under Executive Order 13783*. Most recently, we studied the report released by the Department of Commerce that summarizes the input received from domestic manufacturers in response to the RFI, particularly the sections related to Clean Air Act permitting issues.

Clearly, air permit program streamlining will be a top priority for EPA in the coming months and years. NACAA's members, as the primary implementers of the Clean Air Act permitting programs, have extensive knowledge and experience with the permitting process and have undertaken a wide range of streamlining efforts. We therefore urge EPA to work collaboratively with state and local agencies throughout all stages of rulemaking or policy development in this area. To the extent EPA chooses to pursue reforms to the NSR program, NACAA stands ready to work with the agency to find ways to make the permitting process more streamlined and address real or perceived inefficiencies with the program.

We understand that EPA's Regulatory Reform Taskforce has been charged with preparing, by December 31, an "Action Plan" that addresses the permitting reform issues highlighted in the Commerce Department's report. As EPA works to finalize that plan, we encourage the agency to think broadly about ways in which the permitting processes can be made more efficient. In that spirit, we offer the following set of principles and recommendations on air permit streamlining.

The list below is divided into two sections. First, we present a set of "Overarching Principles." These are principles that EPA should follow in any permit streamlining initiative. Second, we offer a series of "Recommendations," including both general observations and specific ideas for EPA to consider as it develops its permit streamlining priorities.

## I. Overarching Principles

- Our purpose and responsibility as air regulators is to protect public health and the environment from the harmful effects of air pollution. Because the permitting program is one of the programs we implement to achieve this goal, any permit reform or streamlining initiative must maintain or improve upon current levels of public health and environmental protection.

- The integrity of the NSR pre-construction air permitting process is key to realizing national clean air standards in the most economical way, because the best time to control a source is at the time of its construction or major modification. It is far more cost-effective and efficient for a facility to design pollution control equipment into its operations from the inception rather than to install additional controls at a later date.

[1] NACAA submitted comments on the Draft Strategic Plan in a separate letter dated October 31, 2017. *See* http://www.4cleanair.org/sites/default/files/Documents/NACAA_Strategic_Plan_Comments_10-31-17.pdf

- The permitting process should be open, transparent and inclusive. In undertaking any policy changes aimed at improving air permitting efficiency, EPA must maintain an open, transparent process with reasonable opportunity for public participation, while being mindful of barriers to meaningful public participation in low-income and/or minority communities that may be disproportionately burdened by harmful air pollution.

## II. Recommendations

- EPA should not presume that permitting delays are always attributable to inefficient or unfairly burdensome processing by state and local permitting authorities or by the Clean Air Act permit rules themselves. In our members' experience, delays in processing air permits are often the result of applicants submitting incomplete or unapprovable applications. There are a number of actions that we believe could help improve this situation:
    - Support state efforts to improve permit application forms; develop and promote the use of checklists.
    - Create a clearinghouse for permit application forms that agencies can contribute to voluntarily and use to implement best practices.
    - Provide training for consultants and consider requiring use of a certification process for application preparers.
    - Reinvigorate and redesign the Small Business Ombudsman role to include assistance in permit application preparation for small businesses.
- State and local agencies, as well as the private sector, have an urgent need for increased training in Clean Air Act permitting. EPA should significantly increase the resources it devotes to developing, updating and providing such training. At the same time, as EPA's training functions have experienced an unfortunate decline over the past decade, regional and national-scale multi-jurisdictional organizations (including NACAA) have played an increasingly important role in developing and coordinating training opportunities for state and local air agencies. These efforts also merit increased support.
    - Update, reinvigorate and expand EPA's Air Pollution Training Institute "APTI-Learn" courses on Clean Air Act permitting.
    - Increase funding to multi-jurisdictional organizations for developing and providing training.
    - To reduce travel costs, incorporate the use of technology such as webinars and online classes, while also expanding the number of geographic locations where in-person training is offered.
- There are efficiencies to be gained through increased use of electronic permitting (or "e-permitting") at state and local agencies. Many NACAA members either have, or are actively working to implement, systems that allow air permit applications to be

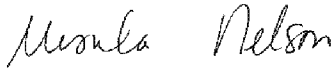
submitted, reviewed, and approved electronically. We encourage EPA to provide active support to bolster these efforts, including additional funding. EPA should work with states and localities to address implementation issues associated with the Cross Media Electronic Reporting Rule, which has presented challenges to many agencies' efforts to streamline their permitting and compliance programs.

- Many state and local agencies have achieved success in improving the efficiency of their permitting processes using techniques such as Lean, Kaizen and Six Sigma. EPA should look for ways to support these efforts.
    - Offer agencies (including EPA itself) the opportunity to map their permitting processes to provide clarity for stakeholders and help identify opportunities for streamlining and improvement.
    - Provide a toolkit for agencies to use in their efforts to evaluate creation of additional efficiencies and help introduce a uniform platform for use in such efforts.
    - Establish a "best practices" resource for state, local and federal agencies, including practices to improve communications between agencies and the regulated community such as pre-application meetings between applicants and permitting agencies.
    - Provide funding to help state and local agencies address inefficiencies in their permitting processes that are identified through use of Lean and similar techniques.
- NACAA supports the RACT/BACT/LAER Clearinghouse (RBLC) and believes it is reasonable to expect data entry by state and local agencies. That said, the RBLC is in urgent need of upgrading to a more modern, user-friendly platform. State and local agencies find the database very difficult and time-consuming to use in its present state.
- To address the declining availability of offsets for NSR permitting in some nonattainment areas (in particular, for ozone) EPA should, where state law allows, expand the geographic areas from which offsets may be secured to include areas that significantly contribute to exceedances of the pollutant in the nonattainment area (irrespective of contiguousness). EPA should also consider expanding the source categories from which offsets can be obtained, subject to the same limitation.
- EPA should focus on improving consistency across and within the EPA Regions with respect to the oversight and guidance they provide to state and local permitting programs. Regional inconsistency can lead to increased permitting times when, for example, a state agency is compelled to elevate to EPA Headquarters a question that has been addressed differently by various EPA Regions. Regional inconsistency can also result in the unequal or unfair treatment of similar sources located in different EPA Regions.

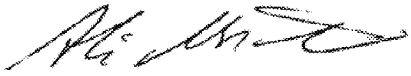
- Many state and local agencies are interested in employing approved "flexible air permitting" approaches such as Alternative Operating Scenarios and advance approvals in Title V and NSR permitting. In their experience, however, these approaches often add significant time and effort to the permitting process because of the customized nature of each flexible permit. Hence, flexible permitting can conflict with the goal of streamlining. There is also perceived variation among the EPA Regions in their level of support for flexible permitting.
    - Where flexible permitting processes are developed, there should be recognition of the time and staffing resources required to develop each flexible permit.
    - EPA should work to improve Regional consistency in this area.
    - NACAA supports EPA's plans to develop a flexible permitting website and encourages the agency to look for additional opportunities to educate state and local agencies about flexible permitting approaches that maintain or strengthen compliance and promote the development of clean technologies.

NACAA looks forward to continued engagement with EPA on air permit streamlining issues and to commenting on specific proposals. If you have any questions about the principles and recommendations outlined above, please do not hesitate to contact either of us or Karen Mongoven at NACAA (kmongoven@4cleanair.org).

Sincerely,



Ursula Nelson
(Pima County, AZ)
Co-Chair
NACAA Permitting and NSR Committee



Ali Mirzakhalili
(Delaware)
Co-Chair
NACAA Permitting and NSR Committee

# United States Senate

WASHINGTON, DC 20510

August 16, 2018

Andrew Wheeler
Acting Administrator
US Environmental Protection Agency
1200 Pennsylvania Ave NW,
Washington, DC 20004

Dear Acting Administrator Wheeler:

We write to urge your serious consideration of accommodating an important recent development potentially impacting the reliability of our nation's electric utility grid as the Agency develops much-needed revisions to the "new source" rules issued under Section 111(b) of the Clean Air Act for carbon dioxide. In particular, the existing EPA regulations limit the operation of "new" (permitted after January 8, 2014) electric generation plants to less than 40% of their annual operating capacity. However, in the case of "new" natural gas-fired "quick start" Simple Cycle Combustion Turbines (CTs) this artificial limitation, which is not required by statute, not only interferes with market economics and the economic dispatch order of generation by system operators but also creates a perverse and undesirable outcome which interferes with the ability of power pool operators to effectively and economically maintain grid reliability. This problem is especially pronounced in the face of ever changing generation mix that requires the ability to deploy immediate responses by the nation's power pools to counter increased variability.

Unlike traditional coal-fired and gas-fired electric generation units that take hours to come on line from a cold start, new "quick start" CTs can achieve full operating capacity in as little as 10 minutes. Consequently, new "quick start" CT units are uniquely valuable to the nation's power pools to address reliability challenges that are occurring with a changing generation mix in the midcontinent. These new rapid response resources are understandably important near large population centers. One new "quick start" CT facility outside of a large city in the Southwest Power Pool (SPP) has already been called on over a thousand times this year to expeditiously and economically respond to market conditions. Indeed, the current forecast by the SPP projects the need for about another 6,000 MW or more of additional "quick start" CT generation in response to added variability in the generation mix. Markets like the SPP which are seeing significant growth of variable generation have to continuously adapt their response capabilities to such growth to maintain a reliable and economic supply of electricity. Existing Section 111(b)'s artificial constraint on new generation resources such as these "quick start" CTs is deeply concerning given the evolving outlook of the SPP.

When EPA promulgated the existing 111(b) rule, the agency did not contemplate the reliability and economic value to consumers of these new "quick start" CT units despite concerns to this effect being raised in industry rulemaking comments. For "new" units that run for reliability and economic value, the limitation imposed by the existing 111(b) regulation, in combination with SPP requirements, requires the rationing of the use of the CT units in order to stay within the EPA rule's requirements and still be available to SPP to run at full daily output in the high-demand summer months. Such rationing is at odds with the evident value these "quick start" units provide to our grid's reliability. Such artificially constrained operation is contrary to market economics and potentially results in both higher cost to customers and higher emissions as units that are less efficient are necessarily called on in place of the 111(b)-restricted CT units' generation. Such artificial restriction on market operations also has the potential to restrict the flexibility generators and power pool operators need in responding to a variety of market conditions impacting reliability, including weather-related events or transmission or generation outage events on the grid. Rationing the operation of the "quick start" CT units is economically and operationally undesirable as a matter of public policy.

It would appear that any revision of the EPA 111(b) regulations should include a provision that does not counter-productively mitigate the ability of power pools to redress reliability challenges using new "quick start" CT units. We would urge you to draft a revision to the existing 111(b) rule that provides a proposal for such accommodation. In the alternative, at a minimum, we urge you to include in the proposed rulemaking a solicitation for comments from the public with regard to the advisability of such accommodation so that in any final rule EPA would have the ability to fashion a suitable provision that insures that environmental protection does not inappropriately inhibit ready implementation of new, efficient and environmentally-beneficial generation technology that can help meet the daily challenges to maintaining the reliability of our critically important electric grid.

We look forward to your reply.

Sincerely,

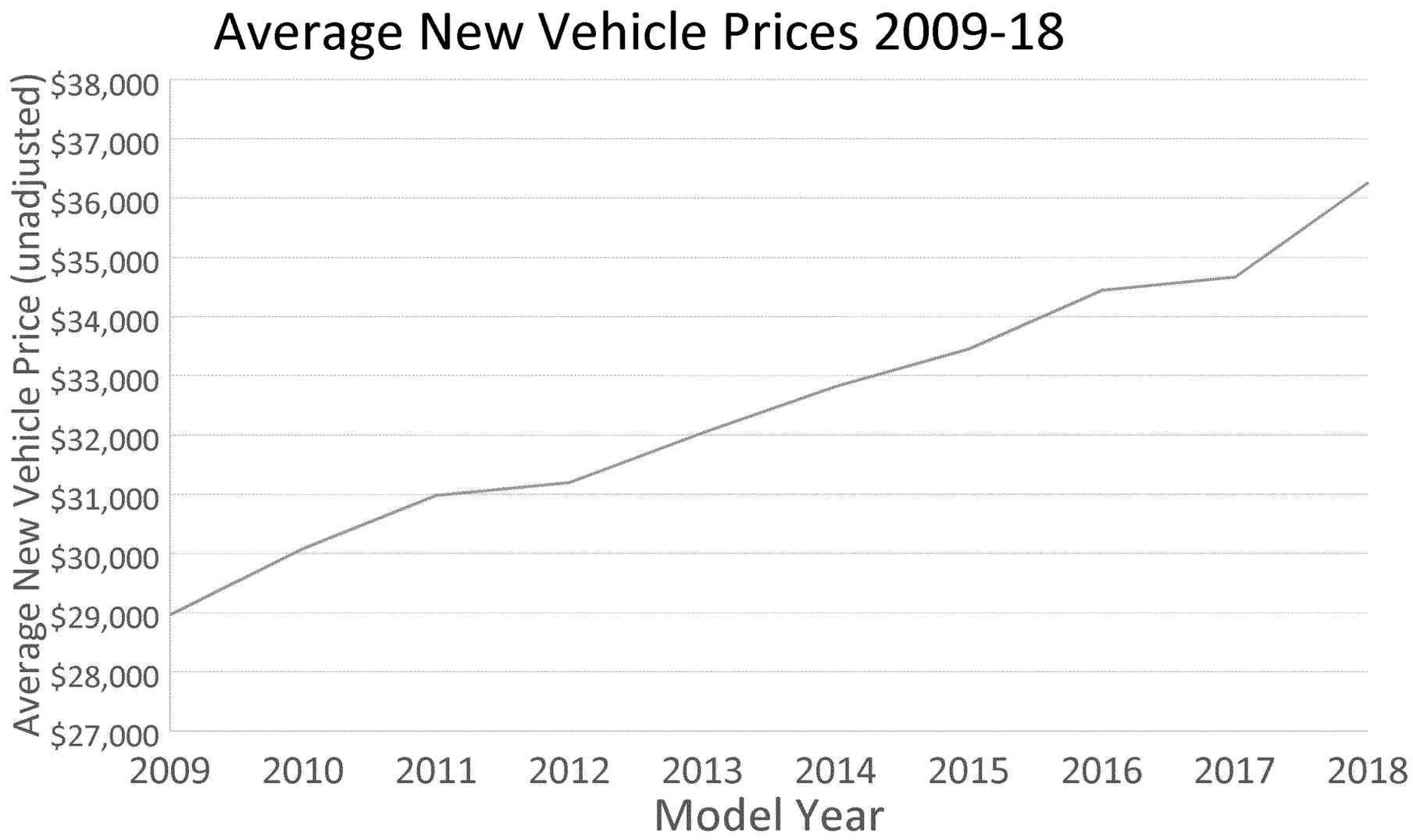
James M. Inhofe
United States Senator

James Lankford
United States Senator

# Safer, Affordable, Fuel-Efficient (SAFE) Vehicles Rule

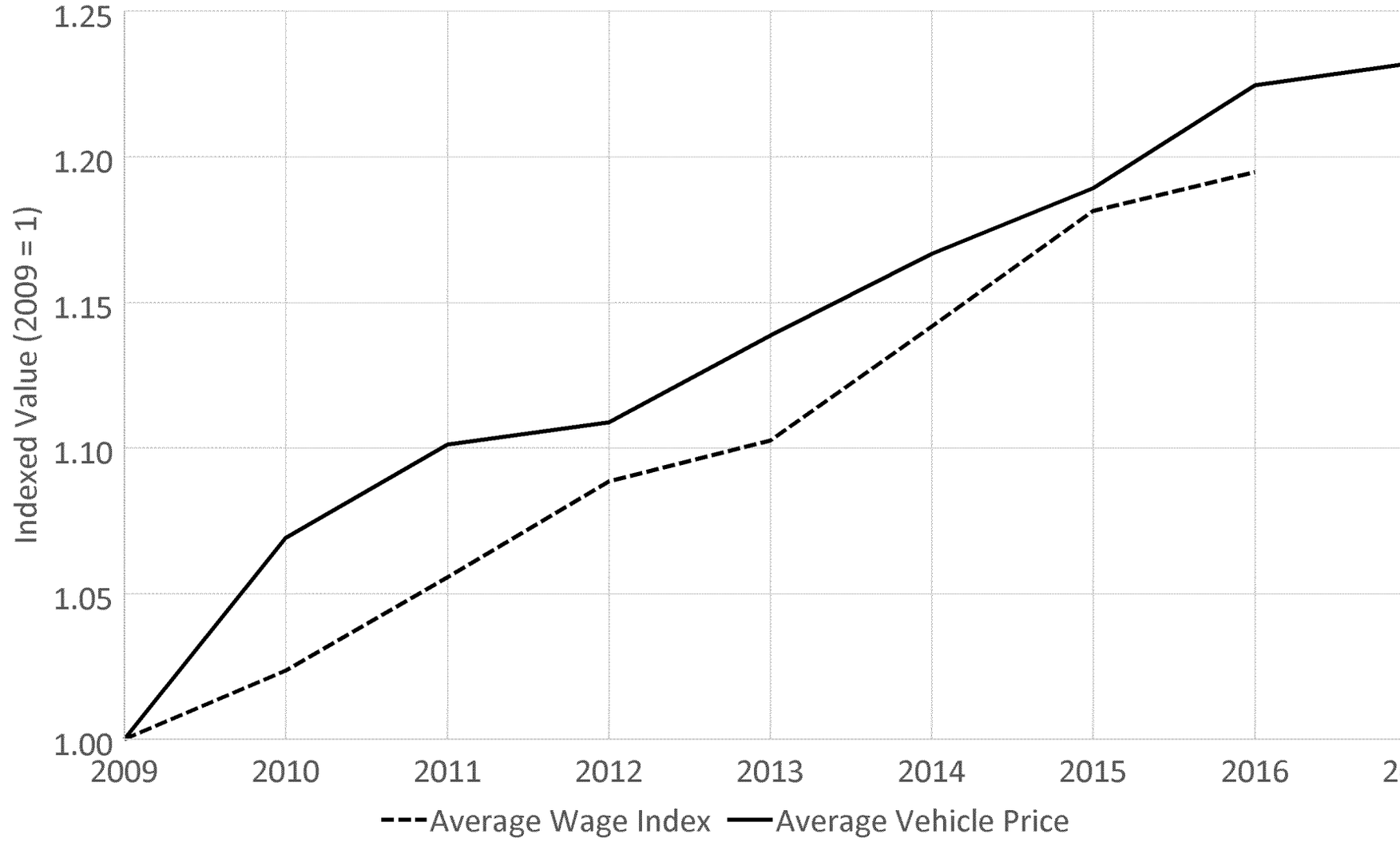
Slides

August 10, 2018

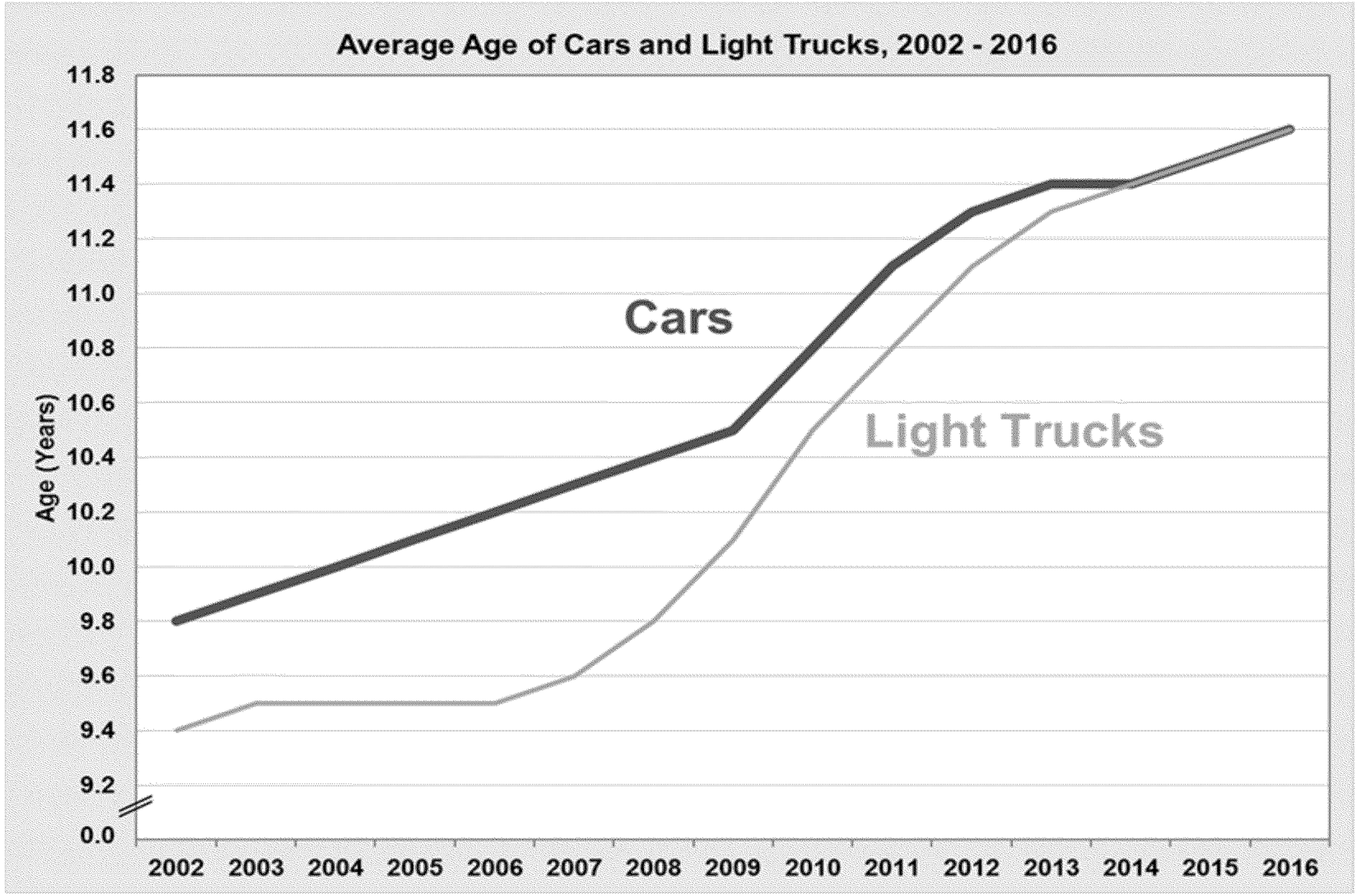



Source: NADA for model years 2009-2017, Kelly Blue Book for January 2018

# Vehicle Prices and Wages




Sources: NADA, SSA

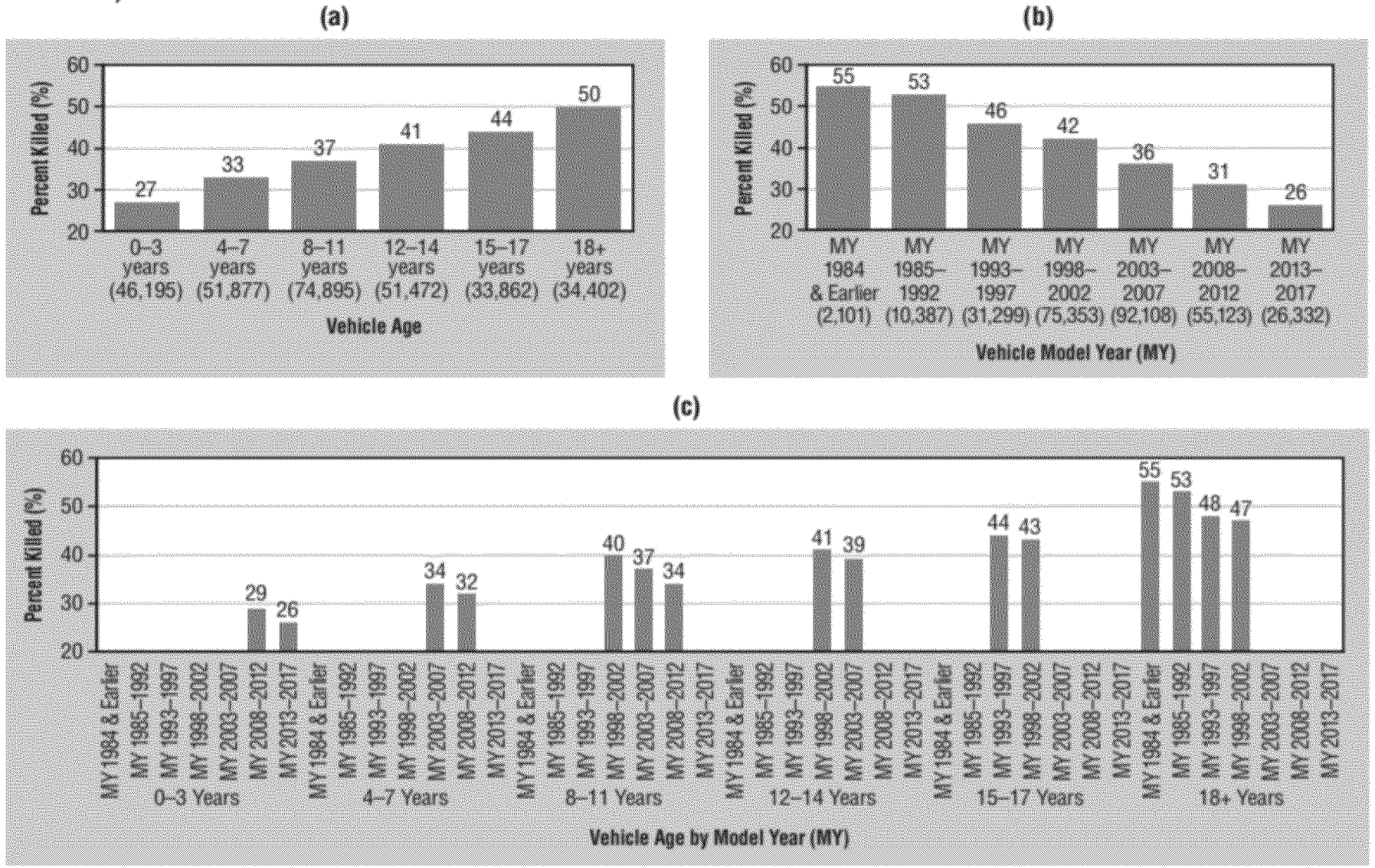



Source: Department of Energy

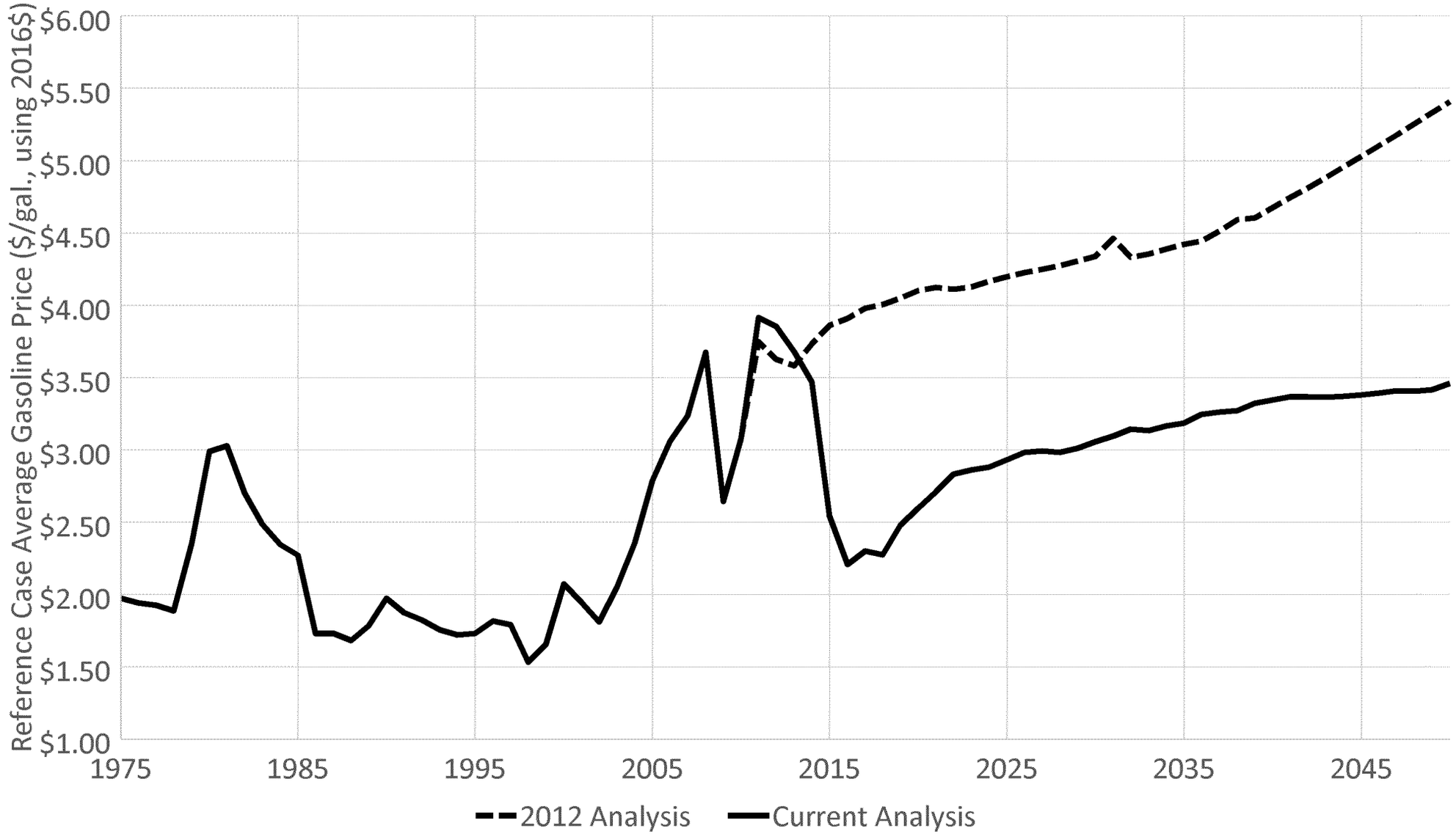
# Newer Cars are Safer Cars

Figure 1

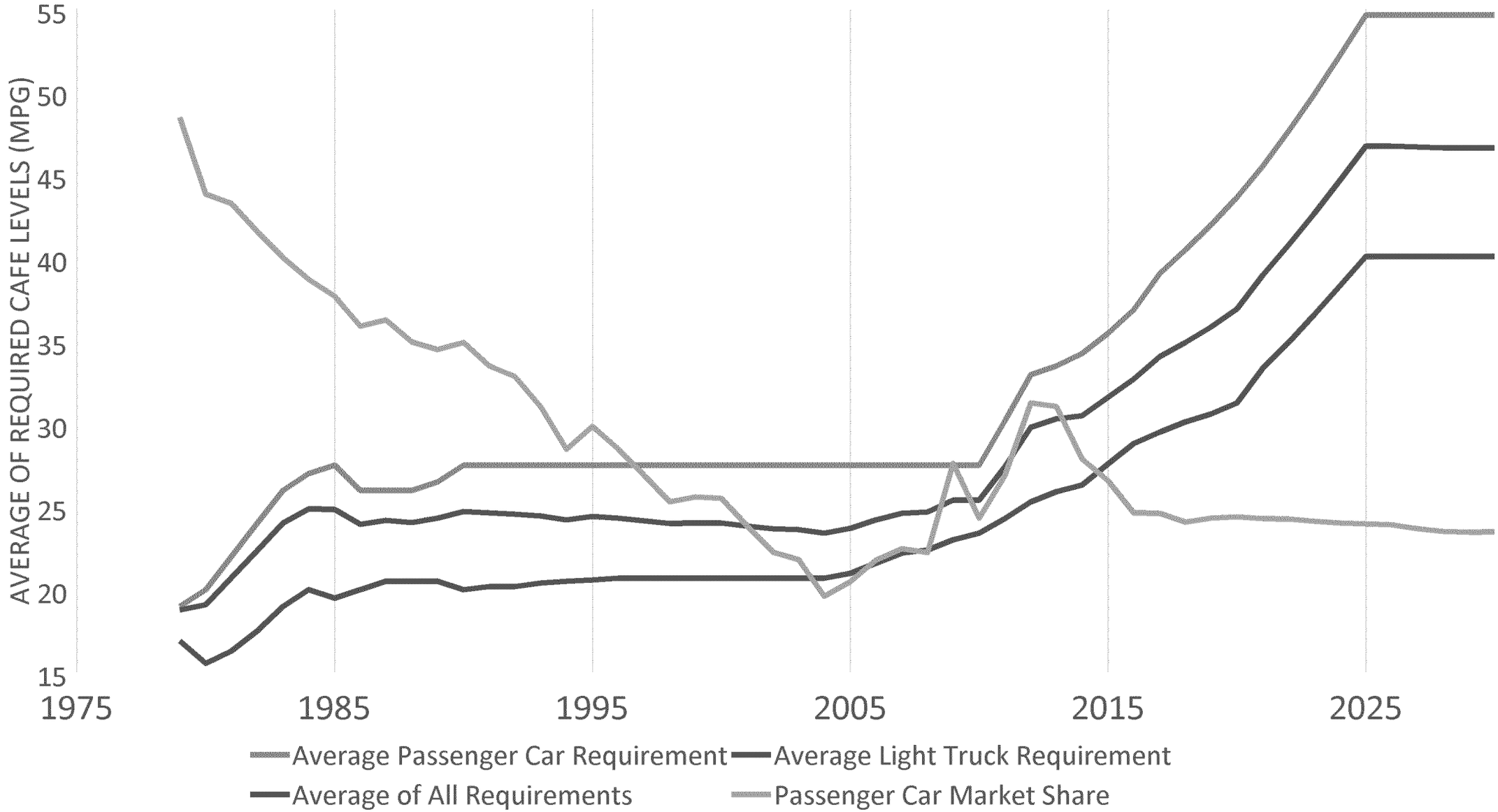
**Total Occupants (Shown in Label Text) and Percent Killed by Vehicle Age and Model Year (FARS 2012–2015 Final and 2016 ARF)**



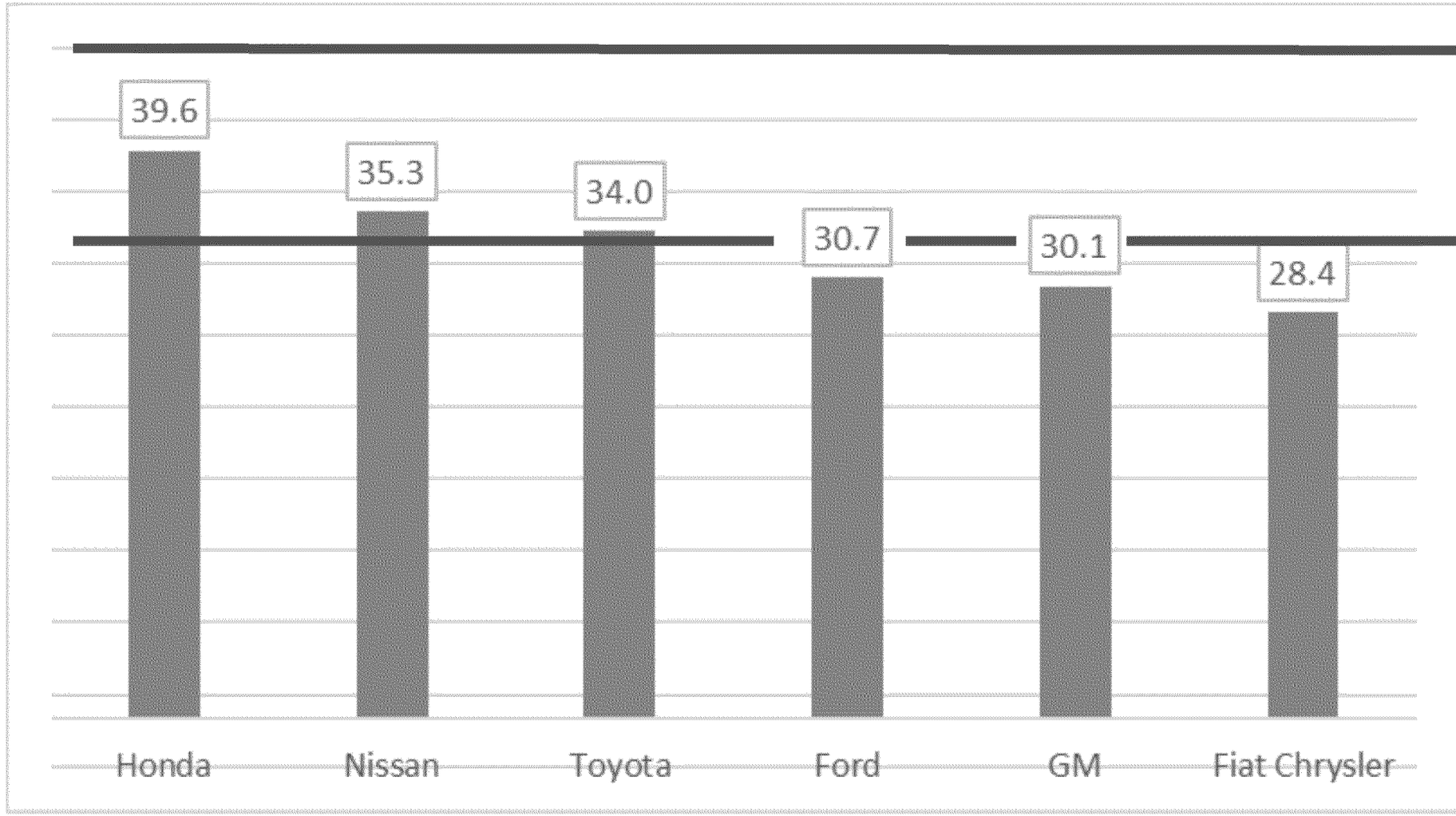
# Oil Prices (Predicted) – 2012 and current



# Existing Standards



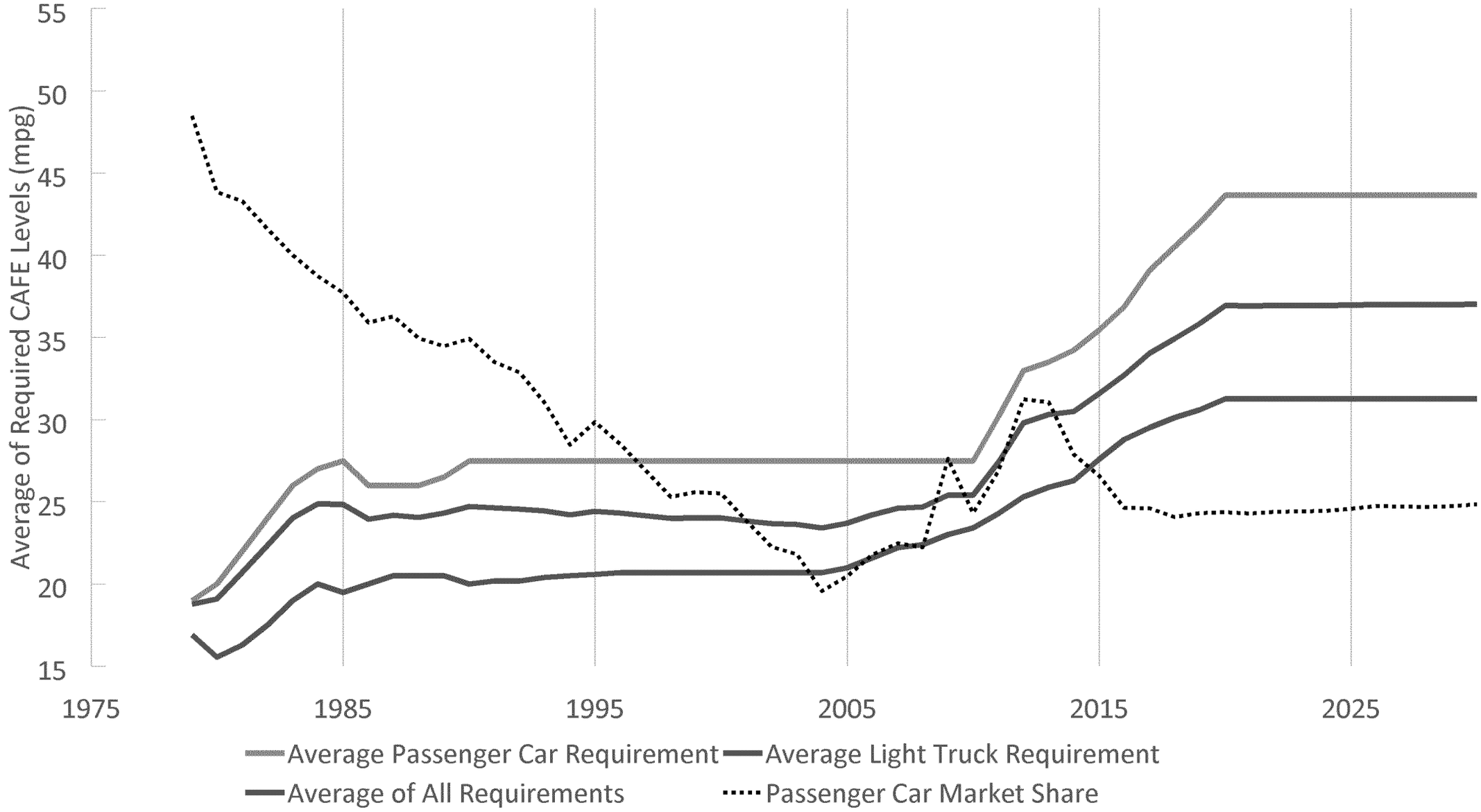
# Current Average Fuel Economy Ratings




**Existing 2025 CAFE Standard 46.7 mpg**

**2017 Average CAFE Standard 33.6 mpg**

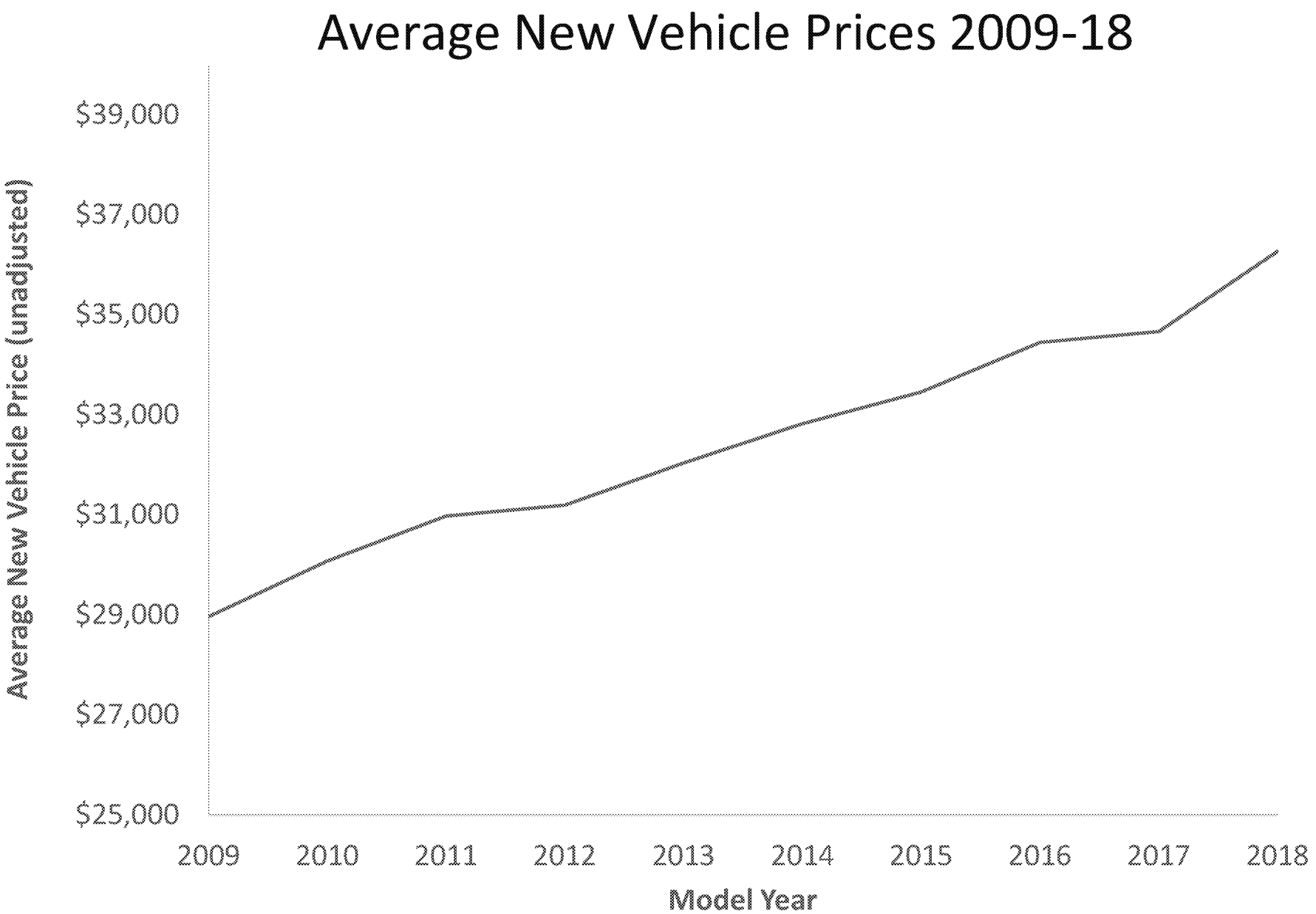
# Proposed Standards



# Estimated Costs to Consumers

| Additional Cost to Consumers | | | | |
|---|---|---|---|---|
| | Proposed Standards | | 2012 Standards | |
| | CAFE | CO2 | CAFE | CO2 |
| 2017 | 150 | 100 | 100 | 100 |
| 2018 | 350 | 200 | 350 | 350 |
| 2019 | 400 | 300 | 550 | 550 |
| 2020 | 600 | 400 | 800 | 800 |
| 2021 | 650 | 500 | 1350 | 1200 |
| 2022 | 700 | 500 | 1550 | 1400 |
| 2023 | 700 | 500 | 1750 | 1650 |
| 2024 | 700 | 500 | 1850 | 1750 |
| 2025 | 700 | 500 | 1950 | 1850 |
| 2026 | 750 | 500 | 2000 | 2100 |
| 2027 | 750 | 500 | 1950 | 2200 |
| 2028 | 700 | 500 | 1950 | 2250 |
| 2029 | 700 | 500 | 1900 | 2300 |
| 2030 | 700 | 500 | 1850 | 2250 |

Costs are on top of $1,050 - $1,100 added cost to consumers for 2012-2016 standards
(from 2010 final rule, inflated to 2016$)


Average New Vehicle Prices 2009-18
Average New Vehicle Price (unadjusted)
$39,000
$37,000
$35,000
$33,000
$31,000
$29,000
$27,000
$25,000
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
Model Year

| Year | Avg New Vehicle Selling Price | Avg Used Vehicle Selling Price | New Cars Sold Per Dealer | Current Dollars | Conversi on rate | Re-Benchmarked series NV Price | Re-Benchmarked series UV price | Chart Data | |
|---|---|---|---|---|---|---|---|---|---|
| 1950 | $2,050 | $691 | 133 | $20,151.50 | 9.83 | | | 1950 | $20,151.50 |
| 1951 | $2,230 | $804 | 110 | $20,582.90 | 9.23 | | | 1951 | $20,582.90 |
| 1952 | $2,460 | $910 | 92 | $22,263.00 | 9.05 | | | 1952 | $22,263.00 |
| 1953 | $2,540 | $816 | 137 | $22,733.00 | 8.95 | | | 1953 | $22,733.00 |
| 1954 | $2,620 | $707 | 137 | $23,632.40 | 9.02 | | | 1954 | $23,632.40 |
| 1955 | $2,830 | $700 | 175 | $25,441.70 | 8.99 | | | 1955 | $25,441.70 |
| 1956 | $2,860 | $738 | 152 | $25,139.40 | 8.79 | | | 1956 | $25,139.40 |
| 1957 | $2,810 | $801 | 153 | $23,997.40 | 8.54 | | | 1957 | $23,997.40 |
| 1958 | $2,790 | $804 | 125 | $23,324.40 | 8.36 | | | 1958 | $23,324.40 |
| 1959 | $2,840 | $843 | 169 | $23,344.80 | 8.22 | | | 1959 | $23,344.80 |
| 1960 | $2,740 | $776 | 191 | $22,221.40 | 8.11 | | | 1960 | $22,221.40 |
| 1961 | $2,760 | $779 | 174 | $22,245.60 | 8.06 | | | 1961 | $22,245.60 |
| 1962 | $2,810 | $807 | 208 | $22,339.50 | 7.95 | | | 1962 | $22,339.50 |
| 1963 | $2,860 | $821 | 225 | $22,451.00 | 7.85 | | | 1963 | $22,451.00 |
| 1964 | $2,900 | $849 | 243 | $22,533.00 | 7.77 | | | 1964 | $22,533.00 |
| 1965 | $3,030 | $938 | 282 | $23,118.90 | 7.63 | | | 1965 | $23,118.90 |
| 1966 | $3,000 | $890 | 286 | $22,050.00 | 7.35 | | | 1966 | $22,050.00 |
| 1967 | $3,200 | $1,007 | 268 | $22,944.00 | 7.17 | | | 1967 | $22,944.00 |
| 1968 | $3,240 | $1,079 | 309 | $22,194.00 | 6.85 | | | 1968 | $22,194.00 |
| 1969 | $3,400 | $1,190 | 311 | $22,032.00 | 6.48 | | | 1969 | $22,032.00 |
| 1970 | $3,430 | $1,256 | 323 | $21,060.20 | 6.14 | | | 1970 | $21,060.20 |
| 1971 | $3,730 | $1,361 | 397 | $22,044.30 | 5.91 | | | 1971 | $22,044.30 |
| 1972 | $3,690 | $1,487 | 438 | $21,069.90 | 5.71 | | | 1972 | $21,069.90 |
| 1973 | $3,930 | $1,724 | 471 | $20,829.00 | 5.3 | | | 1973 | $20,829.00 |
| 1974 | $4,390 | | 373 | $20,764.70 | 4.73 | | | 1974 | $20,764.70 |
| 1975 | $4,750 | | 367 | $20,900.00 | 4.4 | | | 1975 | $20,900.00 |
| 1976 | $5,470 | | 444 | $22,809.90 | 4.17 | | | 1976 | $22,809.90 |
| 1977 | $6,120 | | 498 | $23,990.40 | 3.92 | | | 1977 | $23,990.40 |
| 1978 | $6,470 | $3,290 | 521 | $23,292.00 | 3.6 | | | 1978 | $23,292.00 |
| 1979 | $6,950 | $3,600 | 488 | $22,309.50 | 3.21 | | | 1979 | $22,309.50 |
| 1980 | $7,530 | $3,800 | 404 | $21,460.50 | 2.85 | | | 1980 | $21,460.50 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1981 | $8,850 | $4,330 | 395 | $22,921.50 | 2.59 | | | 1981 | $22,921.50 |
| 1982 | $9,910 | $4,830 | 399 | $24,378.60 | 2.46 | | | 1982 | $24,378.60 |
| 1983 | $10,725 | $5,250 | 477 | $25,632.75 | 2.39 | | | 1983 | $25,632.75 |
| 1984 | $11,100 | $5,690 | 574 | $25,530.00 | 2.3 | | | 1984 | $25,530.00 |
| 1985 | $11,925 | $5,810 | 624 | $26,473.50 | 2.22 | | | 1985 | $26,473.50 |
| 1986 | $12,950 | $5,980 | 641 | $28,360.50 | 2.19 | | | 1986 | $28,360.50 |
| 1987 | $13,450 | $6,490 | 594 | $28,245.00 | 2.1 | | | 1987 | $28,245.00 |
| 1988 | $14,100 | $7,130 | 617 | $28,341.00 | 2.01 | | | 1988 | $28,341.00 |
| 1989 | $15,400 | $7,430 | 584 | $29,568.00 | 1.92 | | | 1989 | $29,568.00 |
| 1990 | $15,900 | $7,540 | 567 | $28,779.00 | 1.81 | | | 1990 | $28,779.00 |
| 1991 | $16,050 | $7,860 | 517 | $28,248.00 | 1.76 | | | 1991 | $28,248.00 |
| 1992 | $17,100 | $8,310 | 555 | $29,070.00 | 1.7 | | | 1992 | $29,070.00 |
| 1993 | $18,200 | $9,130 | 608 | $30,212.00 | 1.66 | | | 1993 | $30,212.00 |
| 1994 | $19,200 | $10,140 | 661 | $31,104.00 | 1.62 | | | 1994 | $31,104.00 |
| 1995 | $20,450 | $11,050 | 648 | $32,106.50 | 1.57 | | | 1995 | $32,106.50 |
| 1996 | $21,900 | $11,850 | 664 | $33,507.00 | 1.53 | | | 1996 | $33,507.00 |
| 1997 | $22,650 | $12,100 | 668 | $33,975.00 | 1.5 | | | 1997 | $33,975.00 |
| 1998 | $23,600 | $12,500 | 694 | $34,692.00 | 1.47 | | | 1998 | $34,692.00 |
| 1999 | $24,450 | $13,200 | 759 | $35,208.00 | 1.44 | | | 1999 | $35,208.00 |
| 2000 | $24,900 | $13,600 | 783 | $34,611.00 | 1.39 | | | 2000 | $34,611.00 |
| 2001 | $25,800 | $13,900 | 785 | $35,088.00 | 1.36 | | | 2001 | $35,088.00 |
| 2002 | $26,150 | $13,850 | 774 | $34,779.50 | 1.33 | | | 2002 | $34,779.50 |
| 2003 | $27,550 | $13,500 | 831 | $36,090.50 | 1.31 | | | 2003 | $36,090.50 |
| 2004 | $28,050 | $14,250 | 843 | $35,623.51 | 1.27 | | | 2004 | $35,623.51 |
| 2005 | $28,400 | $14,925 | 852 | $34,364.00 | 1.21 | | | 2005 | $34,364.00 |
| 2006 | $28,450 | $15,518 | 840 | $34,140.00 | 1.2 | | | 2006 | $34,140.00 |
| 2007 | $28,800 | $15,715 | 837 | $33,408.00 | 1.16 | | | 2007 | $33,408.00 |
| 2008 | $28,350 | $15,200 | 713 | $31,752.00 | 1.12 | | | 2008 | $31,752.00 |
| 2009 | $28,966 | $14,980 | 615 | $32,441.92 | 1.12 | $28,133 | $15,210 | 2009 | $32,441.92 |
| 2010 | $30,982 | $16,474 | 714 | $34,390.02 | 1.11 | $30,079 | $16,554 | 2010 | $34,390.02 |
| 2011 | $30,659 | $17,267 | 793 | $32,805.13 | 1.07 | $30,982 | $17,311 | 2011 | $32,805.13 |
| 2012 | $30,910 | $17,547 | 896 | $32,455.50 | 1.05 | $31,194 | $17,556 | 2012 | $32,455.50 |
| 2013 | $31,762 | $18,111 | 960 | $33,032.04 | 1.04 | $32,035 | $18,081 | 2013 | $33,032.04 |
| 2014 | $32,618 | $18,846 | 1003 | $33,270.15 | 1.02 | $32,824 | $18,839 | 2014 | $33,270.15 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2015 | $33,419 | $19,397 | 1050 | $34,087.85 | 1.02 | $33,456 | $19,400 | 2015 | $34,087.85 |
| 2016 | | | | | | | | 2016 | |
| 2017 | | | | | | | | 2017 | |
| | | | | | | | | | |
| 2016 | 34,221 | | | | | $34,449 | $19,886 | 2016 | $34,449.31 |
| 2017 | $34,335 | | | | | | | 2017 | |

In 2016, we re-benchmarked our data series. For the average transaction price data, the only changes were in the weighting. We w

| | |
|---|---|
| 2009 | $28,966 |
| 2010 | $30,079 |
| 2011 | $30,982 |
| 2012 | $31,194 |
| 2013 | $32,035 |
| 2014 | $32,824 |
| 2015 | $33,456 |
| 2016 | $34,449 |
| 2017 | $34,670 |
| 2018 | $36,270 |

eight the data by the annual number of dealerships and sales for each brand. We do not believe that this has a substantial effect on the historical series.