Environmental Defense Fund Comments on

Ten Problem Formulations under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2018-0210 (Problem Formulations for Risk Evaluations To Be Conducted Under Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Thursday, August 16, 2018

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the problem formulations for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

EDF is first providing comments addressing all of the problem formulations for the first 10 chemicals. While our comments are broadly applicable to all of the problem formulation documents, we include examples from specific documents to illustrate flaws and limitations. Later in these comments, we provide more detailed comments on each chemical-specific problem formulations. It should be noted that many of the issues identified in these chemical-specific comments are also applicable to other problem formulations. EDF requests that EPA consider all of these comments as they apply to each problem formulation.

EDF previously provided comments on the scopes for these ten chemicals. In those comments, EDF identified a variety of legal violations and other problems with EPA's approach to these risk evaluations. Unfortunately, those same violations and problems appear in the problem formulations, along with new ones. EDF incorporates and reiterates those points here as well.[1] Similarly, EDF has, as part of a broader coalition, filed a Brief explaining why the Risk Evaluation Rule is illegal and arbitrary and capricious. For these same reasons, it is illegal and arbitrary and capricious for EPA to follow the Rule in developing

[1] EDF Comments on Ten Scopes under the Toxic Substances Control Act, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

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these risk evaluations. EDF incorporates and reiterates those points here as well. We attach that Brief as Appendix A. EPA should fix all of these problems in its draft risk evaluations.

The following short citations will be used throughout EDF's comment to refer to each of the ten problem formulations:

- U.S. EPA, Problem Formulation of the Risk Evaluation for Asbestos (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0131 (hereinafter "Problem Formulation for Asbestos").
- U.S. EPA, Problem Formulation of the Risk Evaluation for 1-Bromopropane (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0741-0067 (hereinafter "Problem Formulation for 1-BP").
- U.S. EPA, Problem Formulation of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-) CASRN: 56-23-5 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0733-0068 (hereinafter "Problem Formulation for Carbon Tetrachloride").
- U.S. EPA, Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0071 (hereinafter "Problem Formulation for HBCD").
- U.S. EPA, Problem Formulation of the Risk Evaluation for 1,4-Dioxane (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064 (hereinafter "Problem Formulation for 1,4-Dioxane").
- U.S. EPA, Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0742-0083 (hereinafter "Problem Formulation for DCM").
- U.S. EPA, Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0076 (hereinafter "Problem Formulation for NMP").
- U.S. EPA, Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0080 (hereinafter "Problem Formulation for Perchloroethylene").
- U.S. EPA, Problem Formulation of the Risk Evaluation for Trichloroethylene (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0737-0083 (hereinafter "Problem Formulation for TCE").
- U.S. EPA, Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0048 (hereinafter "Problem Formulation for PV 29").

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COMMENTS APPLICABLE TO ALL TEN PROBLEM FORMULATIONS

1. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use, exposures, or hazards.

In its prior scoping documents, EPA stated that it had authority to exclude conditions of use. In our comments on those documents, EDF explained that this approach is foreclosed under the statute, and EDF incorporates those arguments here.[2] Similarly, EDF incorporates the arguments presented in our Brief attached as Appendix A at 21-40.

In the problem formulations, EPA states that it will also exclude hazards and exposures under the condition of use as well. TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain exposure pathways and hazards is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the problem formulations themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of the conditions of use, exposures, and hazards related to a chemical substance. EPA should evaluate all of the evidence of conditions of use, exposure, and hazard; not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, considering all of its hazards, exposures, and conditions of use.

i) The plain text requires EPA to consider all hazards, exposures, and conditions of use.

Statutory interpretation should begin, as always, with the language of the statute. The plain language of the risk evaluation provision supports the interpretation that EPA must consider all hazards, exposures, and conditions of use as necessary "to determine whether a *chemical substance* presents an unreasonable risk." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). This directive expresses Congress's clear intent that EPA evaluate the risks posed by "a chemical substance" as a whole. Congress consistently used the phrase "a chemical substance" to describe the object of priority designations and risk evaluations. 15 U.S.C. § 2605(b)(1)-(4), (i) (using the phrase 14 times). This language requires EPA to consider all hazards and exposures that contribute to the total risk presented by the chemical substance as a whole.

This whole-substance focus begins during prioritization. The definitions of high- and low-priority substances make clear that it is the "substance" that receives the designation, not selected conditions of

[2] EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp. 4-11, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

use, exposures, or hazards. *See id.* § 2605(b)(1)(B). The provision requiring EPA to select the first ten chemicals also directed that the risk evaluations be "conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan," making the object of these risk evaluations the chemical substances as a whole. *Id.* § 2605(b)(2)(A). As EPA reasoned in the Prioritization Rule, "[t]he statute is clear that EPA is to designate the priority of the 'chemical substance'—not a condition of use for a chemical substance." 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) (citing 15 U.S.C. § 2605(b)(1)(A)). Similarly, EPA must prioritize the whole chemical, and EPA is not directed to prioritize only certain hazards or exposures. Indeed, the prioritization process expressly "shall include a consideration of the hazard and exposure potential of a chemical substance," without any basis for EPA to limit that consideration to only certain hazards or exposures. 15 U.S.C. § 2605(b)(1)(A).

EPA must also conduct risk evaluations on "a chemical substance" as a whole. For example, TSCA provides that "[u]pon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the *substance*." 15 U.S.C. § 2605(b)(3)(A) (emphasis added). Similarly, the statute directs EPA to determine either that "a *chemical substance* presents" or "does not present an unreasonable risk." *Id.* § 2605(i)(1)-(2) (emphasis added). Congress also uses the phrase "a chemical substance" or "chemical substances" in many other places in TSCA's risk evaluation provisions. *See, e.g., id.* § 2605(b)(4)(G) (setting deadlines for completing evaluation for "a chemical substance"), (b)(2)(A), (b)(2)(B), (b)(3)(A), (c)(1).

The plain language of the risk evaluation provisions requires EPA to consider all available information about hazards, exposures, and conditions of use, without limitation. TSCA § 6(b)(4)(F)(i) expressly requires that EPA "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(i). Thus, if there is "available information on hazards and exposures," then EPA must integrate and assess that information as part of the risk evaluation. Similarly, TSCA § 6(b)(4)(F)(iv) requires that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." *Id.* § 2605(b)(4)(F)(iv). This provision requires EPA to take into account exposures unless EPA can establish that they are irrelevant. Finally, TSCA § 6(b)(4)(F)(v) requires that EPA "describe the weight of the scientific evidence for the identified hazard and exposure." *Id.* § 2605(b)(4)(F)(v).

All of these provisions direct EPA to consider a chemical's hazards, exposures, and conditions of use, and none of them include any language providing EPA with any discretion to ignore any hazards, exposures, or conditions of use. While EPA previously articulated a legal theory (albeit flawed) for ignoring certain conditions of use, EPA has not pointed to any legal basis for ignoring hazards or exposures under the conditions of use being analyzed in a risk evaluation. EPA has pointed to no textual basis for these exclusions.

Moreover, when EPA promulgates risk-management regulations under TSCA § 6(a):

> [EPA] shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

15 U.S.C. § 2605(c)(2)(A). In order to accurately draft this statement, EPA will have to have considered all of the hazards posed by a chemical (i.e., its effects on human health and the environment) as well as all exposures. EPA cannot accurately describe "the magnitude of the exposure of human beings to the chemical substance," if EPA has ignored numerous exposures. 15 U.S.C. § 2605(c)(2)(A)(i). Similarly, EPA cannot accurately describe "the magnitude of the exposure of the environment" for chemicals, *id.* § 2605(c)(2)(A)(ii), if EPA has ignored the vast majority of environmental exposures, as EPA proposes to do. Congress specifically intended for EPA to "satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself." 114 Cong. Rec. S3517 (daily ed. June 7, 2016). Thus, EPA must evaluate all hazards and exposures in its risk evaluations.

Moreover, TSCA requires that EPA evaluate a chemical's risk "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2605(b)(4)(A). By excluding certain hazards, exposures, and conditions of use for reasons that bear no relationship to risk, EPA is considering nonrisk factors. For example, by excluding exposures because they could be regulated under another statute, EPA is considering a nonrisk factor.

Textually, EPA's approach also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. Congress also specified that EPA must consider the reasonably available "hazard and exposure information." It would undermine this directive if EPA chooses to ignore certain hazards or exposures.

ii) TSCA's overall structure requires EPA to consider all hazards, exposures, and conditions of use.

Moreover, EPA's pick-and-choose approach cannot be squared with the overall structure of TSCA.

As EPA reasoned in its proposed Risk Evaluation Rule, when discussing conditions of use, that TSCA "provides no criteria for EPA to apply" for selecting hazards, exposures, and conditions of use for analysis shows that the Agency does not have "license to choose" among those hazards, exposures, and conditions of use for analysis. 82 Fed. Reg. 7562, 7566 (Jan. 19, 2017). The precision with which Congress prescribed EPA's implementation of section 6 supports this reading. Section 6 lays out detailed directions for EPA. *See* 15 U.S.C. § 2605(b)(1)(A) (mandating considerations for priority designations), (b)(4)(D) (identifying risk factors to include in a risk evaluation's scope), (b)(4)(F)(i)-(v)

(detailing requirements for conducting risk evaluations); *see also id.* § 2605(a) (specifying possible risk management measures). These provisions indicate that Congress did not mean to allow EPA to exclude hazards, exposures, or conditions of use from risk evaluation without any criteria or instruction. *Cf. NRDC, Inc. v. EPA*, 863 F.2d 1420, 1432 (9th Cir. 1988) (invalidating regulatory procedure that "is wholly silent as to what factors the agency is to consider in granting exceptions" and provides "no discernible standard [for] limit[ing] th[at] discretion").

Indeed, when Congress intended EPA to exercise discretion under TSCA, it said so explicitly. *See, e.g.*, 15 U.S.C. §§ 2613(f) (granting EPA "[d]iscretion" in handling claims to protect confidential information), 2608(a) (instructing EPA, if it "determines, in the Administrator's discretion," that an unreasonable risk may be prevented under a federal law administered by another agency, to notify the agency), 2608(b), 2605(b)(4)(E)(iv)(II). That Congress purposefully included the language of discretion "in one section of the statute but omit[ted] it in another section of the same Act" shows that Congress did not intend EPA to use discretion to pick and choose which hazards, exposures, and conditions of use to consider in prioritization and risk evaluation. *Hernandez v. Ashcroft*, 345 F.3d 824, 834 (9th Cir. 2003) (quoting *Andreiu v. Ashcroft*, 253 F.3d 477, 480 (9th Cir. 2001) (en banc)).

Implicitly recognizing that Congress did not grant EPA boundless discretion to exclude exposures, EPA suggests that it will "focus its analytical efforts on exposures that are likely to present the greatest concern." *See, e.g.*, Problem Formulation for Perchloroethylene at 15. But no language in TSCA limits EPA to this "greatest concern" or "greatest potential for risk" focus. Nor does EPA point to any statutory terms that even arguably supply such a limitation.

TSCA's provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," as a whole, not for specific or limited hazards, exposures, or conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined sources of exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if exposures resulting from "any combination" of conditions of use present an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of the exposures resulting from these activities to assess whether *any combination* presents such a risk.

iii) TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all hazards, exposures, and conditions of use to assess a chemical substance as a whole.

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures and hazards at the outset undermines that purpose. And science and logic do not support EPA's exclusions. As explained below in Sections 1.C and

5, EPA's exclusions of certain exposures result in incoherent problem formulations where EPA acknowledges ample evidence of exposure, for example, in the monitoring data, but then refuses to look at those very exposures in its final analysis. Willfully ignoring these exposures at the outset is contrary to the purpose of TSCA's risk evaluations, as well as the law's requirement that EPA rely on the best available science. EPA is imposing blinders on its analysis by asserting authority to refuse to look at certain exposures, including known exposures, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious.

iv) The legislative history requires EPA to integrate a chemical's exposure and hazard information and nothing suggests that EPA can ignore existing exposures and hazards.

Numerous statements in the legislative history reveal that Congress intended for EPA to assess "risk" based on "the integration of hazard and exposure information about a chemical." S. Rep. No. 114-67 at 17 (June 18, 2015); 161 Cong. Rec. H4551 at H4556 (daily ed. June 23, 2015) ("The risk evaluation itself only asks does the chemical present an unreasonable risk of injury to health or the environment. That is a science question based on a combination of hazard and actual exposure."). Senator Vitter described an accurate assessment of risk as turning on integrating exposure and hazard information. *See* 162 Cong. Rec. S3511 at S3519 (daily ed. June 7, 2016) ("Exposure *potential*, when integrated with the hazard *potential* of a chemical, determines a chemical's potential for risk.") (emphases added). Congress intended for EPA to integrate all available information about exposure and hazard when assessing risk, as reflected in this history and the text of TSCA.

No statement in the legislative history suggests that EPA may ignore exposures or hazards when assessing the risk presented by a chemical substance. In its Risk Evaluation Rule, EPA relied on a floor statement from a single Senator to justify its interpretation that it had discretion to choose the conditions of use for analysis. 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). As EDF has previously explained,[3] the legislative history as a whole does not justify EPA's approach to conditions of use, but here EPA has even less basis for its approach; EPA has not pointed to any statement in the legislative history supporting its approach of ignoring certain exposures or hazards.

B. EPA's own risk evaluation rule requires that EPA consider all relevant hazards and all exposures under the conditions of use within the risk evaluation.

EDF disagrees with EPA's final Risk Evaluation Rule for numerous reasons, as discussed in our prior comments and in litigation challenging that rule. EDF reiterates and incorporates those points here. *See* Appendix A. Nonetheless, even EPA's final Risk Evaluation Rule requires EPA to consider all relevant hazards and exposures under the conditions of use within the risk evaluation. The Rule specifically requires that: "Relevant *potential* human and environmental hazards will be evaluated." 40 C.F.R. § 702.41(d)(3) (emphasis). Thus, EPA must consider any relevant "potential" hazards when preparing a risk evaluation. *See also* 40 C.F.R. § 702.41(d)(2) ("The hazard assessment process will identify the types

[3] EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp.7-8, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

of hazards to health or the environment posed by the chemical substance under the condition(s) of use within the scope of the risk evaluation."). The Rule also requires that: "[e]xposure information related to potential human health or ecological hazards of the chemical substance will be reviewed in a manner consistent with the description of best available science and weight of scientific evidence." 40 C.F.R. § 702.41(e)(3). When preparing the risk characterization, EPA shall "[t]ake into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the condition(s) of use of the chemical substance." 40 C.F.R. § 702.43(a)(4). Thus, EPA must consider all hazards and all exposures under the conditions of use. None of these duties are qualified or provide an authority for EPA to exclude hazards or exposures from analysis.

Other provisions of the rule confirm this reading. EPA requires manufacturer requests for risk evaluations to "include or reference *all* available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request." 40 C.F.R. § 702.37(b)(4) (emphasis added). Thus, manufacturers must submit all available information on hazard and exposure under the identified conditions of use because EPA must consider all hazards and exposures when preparing risk evaluations.

In the preamble to the rule, EPA commits to considering all hazards and exposures under the conditions of use:

> The Administrator will consider relevant factors including, but not limited to: The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use.

82 Fed. Reg. at 33,735. EPA thus committed to considering the "effects of the chemical substance on health and human exposure to such substance under the conditions of use." *Id.* These commitments are not qualified or accompanied by any assertion of discretion to ignore effects or exposure information under the conditions of use. EPA cannot fulfill this duty without considering all the hazards and sources of human exposure under the conditions of use.

Similarly, in the preamble, EPA states that "[u]sing reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use." 82 Fed. Reg. at 33,742. EPA cannot prepare an accurate quantitative estimate for exposure if EPA has excluded exposure pathways. "For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, [and] implications at the species, population, and community level." 82 Fed. Reg. at 33,743. EPA cannot accurately discuss the magnitude of the effects on the environment or the spatial and temporal patterns of those effects if EPA ignores the vast majority of the environmental exposures, as EPA proposes to do.

Moreover, in the preamble to the rule, while EPA went to great lengths to describe its alleged discretion to pick-and-choose conditions of use, EPA never stated that it had discretion to exclude hazards or exposures related to conditions of use within the risk evaluation. EPA's failure to assert any discretion

to exclude exposures and hazards reflects that EPA, in fact, lacks any such discretion. Similarly, in the preamble to the risk evaluation rule, EPA asserted that it had authority to ignore conditions of use under other agencies' jurisdiction. 82 Fed. Reg. at 33,729 (July 20, 2017). This is incorrect, but EPA never asserted that it had authority to ignore exposures under EPA's jurisdiction. Once again, EPA's silence on this issue in its rule highlights that EPA could not justify such discretion. In sum, EPA's arguments for excluding certain conditions of use cannot simply be extended mindlessly to exclude consideration of exposures and hazards. *See United States Sugar Corp. v. EPA*, 830 F.3d 579, 650 (D.C. Cir. 2016) (agency may not assume a rationale for one exemption identically applies elsewhere).

C. The problem formulations are incoherent and arbitrary and capricious because of EPA's approach to hazard, exposure, and conditions of use.

EPA's illegal approach to exposures leads it to put "blinders" on regarding risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." State Farm, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, hazards, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (i), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain exposures inconsistently throughout the documents.

For example, as detailed more below, early in the problem formulations, EPA describes information revealing that these chemicals are released or disposed of through numerous environmental media and that exposures occur through numerous media. But EPA then systematically excludes many of these pathways of exposure from its future risk evaluation. Thus, EPA (correctly) describes the factual reality that exposures to humans and the environment occur through these environmental pathways. But EPA then imposes blinders on its analysis by excluding these pathways from further consideration. This is the definition of arbitrary and capricious conduct.

EPA's draft risk evaluations should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section 8 below), and that information should inform EPA's evaluation of the risks of the chemicals. If there is a real-world or reasonably foreseen exposure or hazard, then EPA should not ignore it.

2. EPA should not refuse to further analyze exposure pathways on a cursory basis, and in any event, EPA still needs to consider those exposures when evaluating the combined exposures.

Throughout the problem formulations, EPA illegally decides not to analyze certain exposures further—effectively excluding certain exposure pathways—based on, at best, cursory, unpersuasive, and unsupported analyses (often contradicting other statements in the record). With these rushes to judgment, EPA all but concludes no unreasonable risk from certain exposures based on little analysis

and with no indication that it intends to revisit those exposures or risks in combination with those it does intend to analyze further.

As just one example, EPA plans to ignore the oral pathway of exposure to perchloroethylene for consumers based on an unsupported assertion that such exposure will be limited due to absorption and volatilization, *despite* the same problem formulation acknowledging that infants and children may well experience oral exposure through mouthing. *See* Problem Formulation for Perchloroethylene at pp. 57, 46. More examples of this problematic approach appear in the chemical-specific comments below.

When EPA declines to analyze a pathway further, EPA must have developed and applied a sound, rational basis for assessing the exposure level, supported by scientific evidence. In addition, EPA cannot then effectively ignore the exposure. Rather, EPA still must consider how the exposure may combine with other sources of exposure, so EPA must actually assess the level of exposure from the pathway individually and then consider how it combines with other sources of exposure.

3. EPA must analyze background exposures in all of the problem formulations.

In some but not all problem formulations, EPA indicates it will take into account background levels of exposure in various media. For example, in the HBCD problem formulation, EPA states:

> For HBCD, EPA plans to analyze background levels for indoor dust, indoor air, ambient air, surface water, sediment, soil, dietary food sources, aquatic biota, and terrestrial biota. EPA has not yet determined the background levels in these media or how they may be used in the risk evaluation.

Problem Formulation for HBCD at pp. 56-57. For HBCD, EPA similarly repeats its intention to look at background levels in its Exposure Conceptual Model. *Id.* at 99-105.

EPA needs to include consideration of such exposures in all of its problem formulations for the reasons articulated in Section 1. It is the total level of exposure to a chemical that determines risk, and this includes exposures that EPA is legally required to evaluate in its risk evaluations arising from conditions of use of a chemical, and exposures that, as EPA notes in the HBCD problem formulation, "are not generally attributable to any one use or source." *Id.* at 62.

However, EPA's consideration of background levels can in no way justify EPA's decisions to exclude various conditions of use and exposure pathways, which need to be included in the problem formulations and directly evaluated.

4. **EPA should analyze past conditions of use because they are reasonably foreseen, while also developing significant new use rules for those conditions of use.**

   A. **Past conditions of use are known to have occurred in the past and are certainly reasonably foreseen conditions of use, absent compelling evidence that they will not resume.**

As argued further in Section 1, EPA must consider all conditions of use when preparing a risk evaluation under TSCA § 6, including so-called legacy uses, associated disposals, and legacy disposals. EDF has previously articulated these arguments and incorporates the arguments here.[4]

In several of the problem formulations, EPA has identified past conditions of use that it indicates it will exclude from its risk evaluations. Problem Formulation for Asbestos at pp. 19-21; Problem Formulation for 1,4-Dioxane at p. 18; Problem Formulation for HBCD at pp. 20-24. Past conditions of use that are not currently ongoing are "known" to have occurred in the past, and these conditions of use are definitely "reasonably foreseen." 15 U.S.C. § 2602(4). Congress included "reasonably foreseen" circumstances within TSCA with the express goal of ensuring that EPA swept more broadly than known (or intended) uses; EPA cannot evade that duty by limiting its analysis to conditions of use with evidence of current, ongoing use—such an interpretation would effectively limit EPA's analysis to "known" uses. While there may well be circumstances in which a use that is not currently occurring could be said to be not "reasonably foreseen" at this time, the term surely cannot be read in such a way that only uses that are known to be current are "reasonably foreseen" as that would read it out of existence and collapse the inquiry to one where a use must be "known" to be considered "reasonably foreseen."

Reasonably foreseen is a term of art with a long history in the law; it is well established under the law that "[a] natural and probable consequence is a foreseeable consequence. But to be reasonably foreseeable [t]he consequence need not have been a strong probability; a possible consequence which might reasonably have been contemplated is enough." *People v. Medina*, 209 P.3d 105, 110 (Cal. 2009) (internal citations and quotation marks omitted). Numerous courts have recognized that circumstances are reasonably foreseen when similar circumstances have occurred in the past. *See, e.g.*, *McKown v. Simon Prop. Grp., Inc.*, 344 P.3d 661, 663 (Wash. 2015); *Burns v. Penn Cent. Co.*, 519 F.2d 512, 515 (2d Cir. 1975). The fact that these conditions of use occurred in the past establishes that they are reasonably foreseen.

It is hard to see how the mere cessation of use, particularly if it ceased recently, is by itself sufficient to render the use not "reasonably foreseen." The concept of "reasonably foreseen" wraps in uses that have never before existed if there is a logical rationale for thinking that such a use could occur; if a use has actually occurred, but merely halted, it is clearly not speculation that the chemical substance being evaluated could be used in that way; it is only a question of how likely it is that the chemical could be used that way again. EPA, however, does not appear to have undertaken such analyses. Rather, in some problem formulations, the Agency seems to accept at face value assertions by industry in phone calls and other communications (that do not appear to be publicly available) that uses have ended, or

[4] EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp. 4-11 (Sept. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069; *see also* Appendix A.

have ended and will not be resumed. Problem formulation for HBCD at pp. 20-24; Problem formulation for 1,4-Dioxane at p. 18. In some cases, EPA has not examined the reasons the use came to the end, while in others the reasons given are only assertions that merit closer scrutiny.

The time period in which a use is alleged to have ceased is sometimes only in the past few years, clearly within the statutory timeframe for a chemical substance to be deemed active under the Inventory Notification Rule required by § 8(b)(4)(A), where TSCA specifies a ten-year period dating from enactment back to June 22, 2006. 15 U.S.C. § 2607(b)(4)(A). While that time period is not directly applicable here, it would seem incongruous that a use that would lead to a chemical substance being deemed active, rather than inactive, could simply be disregarded without analysis when determining what circumstances of use are "reasonably foreseen."

As EPA itself acknowledged in its recently proposed significant new use rule for certain uses of asbestos, absent a regulation governing the resumption of an old condition of use, "the importing or processing of" a chemical for a past use that is no longer ongoing "may begin at any time." 83 Fed. Reg. at 26,927. Thus, the condition of use is reasonably foreseen absent a legal ban on it. Even if a chemical is no longer used for a particular condition of use, persons may resume past uses in response to economic, regulatory, or other changes. For example, in the problem formulation for 1-BP, EPA states that few dry cleaners still use 1-BP as a dry cleaning solvent, but EPA also acknowledges that it is reasonably foreseen that such use may increase in response to increasing regulation of perchloroethylene for that use. See Problem Formulation for 1-BP at p. 20. Similarly, other past conditions of use that have been phased out may resume in response to economic changes and regulatory shifts. *If* a chemical had a particular condition of use in the past, EPA should analyze that condition of use absent compelling evidence that the use will not resume in the future.

B. In the meantime, EPA should promulgate significant new use rules to govern past conditions of use as a stopgap measure.

For reasons articulated at length elsewhere in these comments (see Sections 1 and 4.A), EDF considers EPA's exclusions of past uses from its risk evaluations to be at odds with the requirements of TSCA, including because absent a regulatory ban they still constitute reasonably foreseen conditions of use of the chemicals. Such uses need to be included in the risk evaluations.

However, for uses that are no longer ongoing, EPA can and should – as a stopgap measure – promulgate significant new use rules (SNURs) requiring any company intending to commence manufacture or processing of a chemical for such a use to first notify EPA and requiring that EPA review the proposed activity to determine whether it may present an unreasonable risk.

EPA has proposed such a SNUR for uses of asbestos it has identified as no longer ongoing. 83 Fed. Reg. 26,922 (June 11, 2018). EDF provided comments on that SNUR, which we incorporate and reiterate here.[5] EDF recommends that EPA initiate the development of SNURs for uses of the other chemicals

[5] EDF Comments on Asbestos; Significant New Use Rule, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0159-1269.

addressed by the current problem formulations that are no longer ongoing, taking into account the important qualifications and recommendations included in our comments.

5. EPA cannot ignore ongoing, real-world exposures because they are occurring despite another EPA-administered statute that could potentially cover those exposures.

As established above, EPA must assess all hazards and exposures when evaluating the risk presented by a chemical substance. For this same reason, EPA must consider all real-world, intended, and reasonably foreseen exposures that occur even if they fall under the jurisdiction of other EPA-administered statutes. In all but one of the problem formulations, EPA states that "EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist." *See, e.g.*, Problem Formulation for NMP at p. 49.

Similar language appears in nine of the ten problem formulation documents. This approach is illegal and arbitrary and capricious for numerous reasons, including because TSCA requires EPA to analyze all exposures for the reasons discussed above. This approach also violates the text and structure of TSCA for additional reasons unique to this rationale for excluding exposures.

As discussed in more detail below, first and foremost this approach is factually and scientifically inaccurate. For numerous sources of exposure, EPA treats the overall exposure from a particular pathway as "zero" or non-existent despite the fact that the available evidence thoroughly establishes that exposure is occurring at levels well above zero regardless of any actions taken under the other statutes EPA invokes. Thus, in reality, human beings and the environment are experiencing levels of exposure that EPA is willfully ignoring. EPA is choosing to adopt false factual assumptions, and "[r]eliance on facts that an agency knows are false at the time it relies on them is the essence of arbitrary and capricious decisionmaking." *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017). This approach also violates the requirements to act "consistent with the best available science" and to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (k). Thus, for example, in its problem formulation for perchloroethylene, EPA states that its inclusion criteria for data sources reporting environmental fate data expressly do not include consideration of "fate endpoints, associated processes, media and exposure pathways" "to human and ecological receptors from environmental releases and waste stream [sic] associated with industrial and commercial activities," in violation of the duty to consider all reasonably available information. *See* Problem Formulation for Perchloroethylene at p. 160. The problem formulations do not establish that the regulation of these chemical substances under other statutes will eliminate exposures, and in fact, the problem formulations and publicly available evidence all establish that exposures continue to occur in the real-world despite these statutes. EPA cannot ignore those exposures.

In addition, EPA must consider the possibility that these exposures, *combined with other sources of exposure*, could present an unreasonable risk. EPA's decision to ignore exposures one-by-one rather

than look at combined exposure is inherently inaccurate and will invariably lead to an underestimation of exposure and risk.

Furthermore, EPA has not established that these environmental statutes "adequately assess and effectively manage exposures." EPA's bald assertions to the contrary do not make it so. In any event, that is not the legally correct standard under TSCA. As explained below, EPA can only rely on statutory authorities other than TSCA in compliance with TSCA § 9 (notably, the TSCA § 9 process occurs after EPA has completed a comprehensive risk evaluation finding unreasonable risk). To comply with TSCA § 9, EPA must find that those authorities eliminate the risks EPA has previously identified or reduce them to a sufficient extent under TSCA § 9(b)(1), and TSCA requires that EPA reduce risk "to the extent necessary so that [the chemical] no longer presents [an unreasonable risk of injury to health or the environment]." *See* 15 U.S.C. §§ 2608(b)(1), 2605(a). In addition, under TSCA § 9(b)(2) EPA must consider "all relevant aspects of the risk" when deciding whether to regulate under TSCA or another statute. *Id*. § 2608(b)(2). EPA has not met any of these standards in the problem formulations, and EPA's statements that the exposures are adequately assessed and effectively managed under other statutes are legally irrelevant (even if they were true).

When relying on these other statutory authorities, EPA merely provides a list of various regulatory standards and criteria that EPA indicates apply or could apply to certain sources of the chemicals. EPA provides no analysis whatsoever as to: the extent to which the standards or criteria cover the full range of exposure to the chemical through the pathway; the extent and magnitude of releases of the chemical allowed under each of the regulatory standards or criteria; or any other factors that would be necessary to analyze to determine the extent and nature of potential risk allowed under the standards. In particular, TSCA § 6(b)(4)(F)(iv) requires that, in conducting a risk evaluation, EPA evaluate "the likely duration, intensity, frequency, and number of exposures," 15 U.S.C. § 2605(b)(4)(F)(iv), including exposures resulting from those allowable emissions, discharges, or releases. EPA needs to provide this analysis, and EPA cannot simply point to regulation under another statute to bypass the analysis. EPA has also not acknowledged, let alone analyzed, the overall risks to the general population or to vulnerable subpopulations due to the combination of exposures arising from the various sources for which standards exist, not to mention in combination with additional emission sources not subject to any standard. EPA has made no attempt to reconcile any such risk with that allowed under TSCA.

EPA offers only vague claims, such as that EPA "as appropriate, has reviewed, or is in the process of reviewing remaining risks." No specifics as to the status of or timeline for such reviews have been provided, and no indication is made as to when and on what basis such reviews are deemed "appropriate." Nor have the results of any such reviews, if they have been completed, been provided, let alone analyzed in the context of TSCA's requirements.

At a minimum, EPA has completely failed to establish that these statutes reduce exposure to zero. To the contrary, it is thoroughly clear that humans and the environment continue to experience significant exposures through the excluded pathways. To prepare a scientifically accurate risk evaluation, EPA must analyze the exposures through those pathways.

A. The text and overall structure of TSCA makes it clear that EPA has to analyze exposures, even if they have been or could be assessed under another statute.

In contrast to the scoping documents, EPA now asserts that it has discretion to exclude "certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes." *See, e.g.*, Problem Formulation for Perchloroethylene at p. 15. But EPA provides no textual basis for ignoring those exposures. Instead, in a footnote, EPA cites to its discussion regarding "conditions of use," but even assuming for the sake of argument that EPA has authority to exclude conditions of use, such power does not justify excluding exposures related to conditions of use still within the scope of the risk evaluation, as EPA proposes to do. Nothing in TSCA's risk evaluation provision authorizes EPA ignoring exposures because of other statutory authorities, and as explained above, EPA has to analyze all exposures including these exposures. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, Congress expressly excluded certain chemicals or uses of chemicals regulated under other statutes when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide." *See id.* § 2602(2)(B)(ii). Thus, when Congress intended for EPA not to regulate certain exposures because they were regulated under other specific EPA-administered statutes, Congress expressly excluded those exposures. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other exposures where they fall under other federal regulatory schemes.

Second, in TSCA's risk evaluation provision, Congress specifically intended for EPA to "conduct risk evaluations *** to determine whether a chemical substance presents an unreasonable risk of injury to *** the environment," 15 U.S.C. § 2605(b)(4)(A), but EPA's approach has eliminated almost all analysis of environmental exposures. EPA has largely read the requirement to evaluate risks to the environment out of the statute, but this approach violates a fundamental tenant of statutory interpretation. A. SCALIA & B. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 174 (2012) ("If possible, every word and every provision is to be given effect *** None should needlessly be given an interpretation that causes it to duplicate another provision or to have no consequence."). Moreover, Congress enacted this requirement that EPA analyze risks to the environment against the backdrop of the existing environmental statutes; if Congress had considered them per se sufficient, Congress would not have included this mandate in TSCA. But Congress did.

Third, Congress specifically directed EPA to analyze the risks of chemicals presented "under the conditions of use," and Congress consciously decided to specify that "disposal" is a condition of use under TSCA. "Conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or *disposed of*." 15 U.S.C. § 2602(4) (emphasis added). In the problem formulations, EPA systematically excludes exposures through disposal based on a variety of theories,

and in doing so, EPA is ignoring Congress's direction that it assess risks associated with the conditions of use, including disposal. Similarly, EPA is ignoring exposures from other conditions of use, such as "manufactur[ing]," "process[ing]," and potentially distribution in commerce, by for example ignoring the emissions from the manufacturing and processing facilities. Congress expressly included all of these circumstances within the definition of "conditions of use," and EPA should not ignore the exposures resulting from them.

Fourth, TSCA § 9(b) provides that EPA "shall coordinate *actions* taken under [TSCA] with *actions* taken under other Federal laws administered in whole or in part by the Administrator." 15 U.S.C. § 2608(b) (emphases added). While EPA is supposed to coordinate the "actions" under each statute, this provision does not contemplate EPA excluding exposures from the analyses prepared under TSCA. Indeed, the remaining language of TSCA § 9(b) highlights that Congress intended for EPA to prepare risk evaluations analyzing all exposures, including those that might be addressed under another authority.

Under TSCA § 9(b)(1), EPA can only choose to rely on other authorities "[i]f [EPA] determines that a risk to health or the environment associated with a chemical substance or mixture *could be eliminated or reduced to a sufficient extent* by actions taken under the authorities contained in such other Federal laws." 15 U.S.C. § 2608(b)(1) (emphasis added). Thus, Congress provided a standard that EPA must meet before relying on other authorities: with respect to the "risk to health or the environment" presented by a chemical, the other authority must either "eliminate[]" that risk or "reduce [the risk] to a sufficient extent." *Id.* Reduction in risk must be "sufficient" as defined by TSCA, and the word "extent" cross-references the basic standard set forth in section 6(a). *See* 15 U.S.C. § 2605(a). Section 6(a) provides that if EPA determines that a substance or mixture "presents an unreasonable risk of injury to health or the environment," EPA "shall" apply requirements to the "substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk." *Id.* Thus, EPA may only rely on actions under another statute if those actions will reduce an identified risk "to the extent necessary so that [it] no longer presents [an unreasonable risk of injury to health or the environment]." EPA cannot assume that other statutes, with different standards, meet the requirements of TSCA.

TSCA requires that EPA eliminate the "unreasonable risk," *id.* and that unreasonable risk of injury to health or the environment must be identified under TSCA § 6(b)(4)(A) "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator." 15 U.S.C. § 2605(b)(4)(A). Thus, TSCA's standard requires EPA to resolve risks identified without consideration of costs or other nonrisk factors, and EPA must specifically consider risks to vulnerable subpopulations. Generally speaking, the other EPA-administered statutes do not have this same standard. Some of these statutes allow consideration of nonrisk factors and do not explicitly require consideration of vulnerable subpopulations. EPA cannot simply assume that regulatory efforts that meet the requirements of those statutes will also meet TSCA's requirement that EPA eliminate unreasonable risks. And Congress's decision to enact the TSCA standard reflects that Congress wanted EPA, when implementing TSCA, to meet that standard; EPA cannot rely on its fulfillment of a different standard under a different statute to evade that duty.

Under TSCA § 9(b)(2) Congress directed EPA to consider certain factors to resolve overlaps in EPA's statutory jurisdictions after completing the risk evaluation. Specifically, in determining whether to address a risk under TSCA or another statutory authority administered by EPA, EPA "shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk," among other things. *Id.* § 2608(b)(2). Thus, EPA has to analyze "all relevant aspects of the risk" in its risk evaluations, *before* deciding whether to address particular risks through TSCA or another statutory authority. Congress would not have included this requirement if Congress had meant for EPA to simply defer to current regulatory approaches to those chemicals at the outset before conducting a risk evaluation.

Among other concerns, if EPA just ignores risks arising from exposures that fall within other statutes' jurisdiction, then EPA will lack the information necessary to prepare the necessary analyses under TSCA § 9(b)(2). TSCA § 9(b) clearly contemplates that EPA will analyze all these exposures in risk evaluations and then meet its duties under TSCA § 9(b) based, in part, on the analyses prepared in the risk evaluations. As reflected in TSCA § 6, Congress expressly chose to separate risk evaluation and risk management into different procedural steps (with risk evaluation preceding risk management), to ensure that EPA provided a robust risk evaluation uncolored by nonrisk factors or other risk management concerns.

Notably, in its problem formulations, EPA makes no showing that its actions under other statutes reduce the risk "to the extent necessary so that [it] no longer presents [an unreasonable risk of injury to health or the environment]," and EPA does not present any actual analysis of "all relevant aspects of the risk" arising from the ignored exposures. So EPA has undisputedly failed to comply with TSCA § 9(b). Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring exposures that fall within another statute's jurisdiction.

Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes some exposures at the outset that may be able to be addressed under another authority, particularly when any risk management under the other authority would not reduce exposure to zero.

B. EPA's approach to the general population and subpopulations highlights that its decision to exclude exposures under other EPA-administered statutes is illegal and arbitrary and capricious.

i) EPA must analyze whether 1,4-dioxane, carbon tetrachloride, methylene chloride, N-methylpyrrolidone, perchloroethylene, and trichloroethylene present a risk to the general population because the record establishes that the general population is exposed to these chemicals.

EPA states that it will not analyze general population exposures for 1,4-dioxane, carbon tetrachloride, methylene chloride, N-methylpyrrolidone (NMP), perchloroethylene, and trichloroethylene (TCE) because EPA considers its existing regulatory programs sufficient. Problem Formulation for 1,4-Dioxane

at p. 49; Problem Formulation for Carbon Tetrachloride at p. 56; Problem Formulation for DCM at p. 65; Problem Formulation for NMP at p. 59; Problem Formulation for Perchloroethylene at p. 73; Problem Formulation for TCE at p. 62.

EPA's approach is illegal for the reasons given above. In addition, the reasonably available information establishes that the general population experiences significant exposures to these chemicals, and it is irrational to ignore those exposures in light of this evidence. For example:

For 1,4-dioxane: EPA acknowledges that the general population may be exposed from inhalation of ambient air, through drinking water, and exposure during washing and bathing. Problem Formulation for 1,4-Dioxane at p. 31.

For carbon tetrachloride: EPA's first-tier analysis suggests that 6% of reported facility discharge levels result in drinking water estimates above EPA's minimum contaminant level. *See* Problem Formulation for Carbon Tetrachloride at p. 38.

For NMP: "Oral exposure to NMP is expected to be a relevant route of exposure for the general population. Individuals may be exposed to NMP levels that occur in drinking water and/or well water." Problem Formulation for NMP at p. 36.

For methylene chloride: "Due to its variety of uses and subsequent release to the environment, methylene chloride is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water, including sources used for drinking water supplies, sediment, soil and food products." Problem Formulation for DCM at p. 35. "[L]evels of methylene chloride in the ambient air are widespread and shown to be increasing." *Id.* at 39.

For perchloroethylene: "A subset of National Health and Nutrition Examination Survey (NHANES) data (1999-2000) reported in Lin et al. (2008) show the presence of perchloroethylene in 77% of human blood samples from non-smoking U.S. adults." Problem Formulation for Perchloroethylene at p. 42. Perchloroethylene also is a common contaminant in air, soil, surface water, and drinking water, and EPA cannot ignore those exposures which are occurring under its existing regulatory regimes.

For trichloroethylene: "TCE is one of the most frequently detected organic solvents in U.S. ground water. The U.S. Geological Survey (USGS) conducted a national assessment of VOCs in ground water, including TCE. Between 1985 and 2001, the detection frequency of TCE was 2.6%, with a median concentration of 0.15 µg/m3 (U.S. EPA, 2011c; Zogorski et al., 2006)." Problem Formulation for TCE at p. 34. "TCE has been detected in drinking water systems through national and state-wide monitoring efforts." *Id.* at 34. "The Third National Health and Nutrition Examination Survey (NHANES III) analyzed blood concentrations of TCE in non-occupationally exposed individuals in the United States and found that 10% of those sampled had TCE levels in whole blood at or above the detection limit of 0.01 ppb (U.S. EPA, 2011c)." *Id.* "The general population may ingest TCE via contaminated drinking water and other ingested media. It is anticipated that ingestion of drinking water containing TCE, for on-going TSCA uses, represents the primary route of oral exposure for this chemical." *Id.* at 38.

Given ample evidence that the general population in fact experiences exposures to these chemicals under EPA's current regulatory regimes, it is arbitrary and capricious for EPA to adopt an approach to risk evaluation that disregards the risks presented to the general population.

ii) EPA cannot accurately evaluate potentially exposed or susceptible subpopulations such as fenceline communities if EPA excludes the vast majority of exposure pathways leading to their greater exposure.

In numerous problem formulations, EPA correctly recognizes that a potentially exposed or susceptible subpopulation includes those "groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution or use sites)." *See, e.g.*, Problem for Perchloroethylene at p. 47. But EPA then plans to ignore the vast majority of pathways that cause these groups to face greater exposures—such as through releases to air, water, and land. EPA provides no rational explanation for how it will accurately and effectively evaluate the actual risk faced by these subpopulations while ignoring these exposures. Moreover, EPA's (correct) recognition that these groups face greater exposure highlights that it is irrational for EPA to ignore the pathways leading to these exposures.

In addition, as EPA correctly recognizes, TSCA specifically requires that EPA protect these subpopulations because they face greater exposure. And, EPA's existing regulations under other statutes, which may not have been developed with a focus on these particular subpopulations, may not always be "sufficient" under the TSCA standard.

C. The listing of asbestos, 1-4 dioxane, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene as hazardous air pollutants does not result in zero exposures to them through the air pathway; EPA should analyze the real-world exposures.

EPA excluded exposures to asbestos, 1-4 dioxane, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene through the air pathway because they are listed as hazardous air pollutants (HAP) under the Clean Air Act (CAA). Problem Formulation for Asbestos at p. 42; Problem Formulation for 1,4-Dioxane at pp. 42-43; Problem Formulation for Carbon Tetrachloride at p. 48; Problem Formulation for DCM at p. 54; Problem Formulation for Perchloroethylene at pp. 59-60; Problem Formulation for TCE at p. 54.

This approach is unreasonable for the reasons given above, but in addition, EPA has not made the necessary showing that the established HAPs eliminate any unreasonable risk and EPA has not assessed all relevant aspects of the risk. As EPA acknowledges in each of these problem formulations, the listing as a HAP leads to a technology-based standard for certain stationary sources. *See, e.g.*, Problem Formulation for Asbestos at p. 42. Such regulations do not necessarily eliminate exposures. Moreover, EPA is relying on "technology-based" standards, but under TSCA § 9, EPA can only rely on another statutory authority if it reduces exposures "to a sufficient extent" under TSCA, 15 U.S.C. § 2608(b)(1), and TSCA specifically requires that EPA eliminate the unreasonable risk, see 15 U.S.C. § 2605(a), without

reference to technology. EPA cannot assume that other statutes, with different standards, meet the requirements of TSCA.

i) EPA's Clean Air Act authority is not a comprehensive substitute for TSCA.

EPA's mandate to control toxic air pollutants under the Clean Air Act (CAA) differs from TSCA's provisions applicable to the same substances and thus does not presumptively address the same scope of risks. EPA points to CAA Sections 111 and 112, 42 U.S.C. §§ 7411-12, as an adequate proxy for TSCA regulations that would address the "ambient air pathway" of exposure to toxic air pollutants covered under both statutes, yet the statutory structures that empower EPA to control these pollutants through CAA regulation are different from EPA's authority to regulate or even prohibit the production or use of these substances under TSCA.

CAA Sections 111 and 112 differ in scope and approach as compared to TSCA. EPA points to CAA Section 112 which requires EPA to promulgate regulations applicable to sources of listed hazardous air pollutants including: 1,4-dioxane, carbon tetrachloride, methylene chloride, trichloroethylene, and perchloroethylene. Section 112 instructs EPA to list and regulate substances for which "emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects." 42 U.S.C. § 7412(b)(2). As EPA acknowledges, under the CAA "For stationary source categories emitting [Hazardous Air Pollutants] HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment." Problem Formulation for Perchloroethylene at p. 59. Under section 112(d)(1), EPA sets source-specific "standards for each category or subcategory of major sources and area sources of hazardous air pollutants listed." 42 U.S.C. § 7412(d)(1). This source-specific regulatory scheme requires EPA to:

> require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources in the category or subcategory to which such emission standard applies.

Id. § 7412(d)(2). This approach reflected in section 112 is distinct from TSCA which empowers EPA look at the risk posed by the chemical broadly without necessarily focusing on source-specific technology, costs of regulation, or what standards are "achievable" for each source category. Indeed, as explained previously, TSCA requires that EPA evaluate a chemical's risk "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2605(b)(4)(A). In addition, TSCA requires EPA to consider the "conditions of use" of a chemical, with no distinction drawn between stationary sources and other sources. As a result, EPA cannot presumptively assume that section 112 regulation would necessarily address all the risks that TSCA requires the agency to identify and ameliorate.

Similarly, EPA points to CAA Section 111, 42 U.S.C. § 7411, as a basis for declining to evaluate risks associated with the ambient air pathway under TSCA. But, like section 112, section 111 differs in material respects from the approach embodied in TSCA. Section 111 requires EPA to set and periodically update standards of performance for categories of new stationary sources and existing stationary sources of pollution that cause or contribute "significantly, to air pollution which may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7411(b). In setting "standard[s] of performance" for each source category or even sub-category of sources, EPA must select a standard that "reflects the degree of emission limitation achievable through the application of the best system of emission reduction which (taking into account the cost of achieving such reduction and any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated." 42 U.S.C. § 7411(a)(1). TSCA's regime likewise diverges from this approach in its focus on the risks posed by chemical substances and EPA actions that can ameliorate those risks.

In addition to these substantive differences, existing standards under sections 111 and 112 are subject to different procedural requirements. For example, the CAA's source-specific standards under Section 111 are structured around a series of 8-year intervals for review and Section 112's list of substances is reviewed every 5 years, along with other periodic reviews called for under Section 112. EPA is also subject to a series of consent decrees for required reviews under Section 112(f)(2) and Section 112(d)(6), often setting longer timelines for new rulemaking. As a result, many of the category specific regulations under these provisions are in various stages of being updated. Accordingly, even if there were some substantive alignment between TSCA and the CAA provisions EPA cites—which is not the case, as we describe above—it would be manifestly arbitrary and capricious for the Agency to determine that CAA standards that have not been updated for many years, or even decades, presumptively discharge EPA's present-day responsibility to assess the risks these chemicals pose under TSCA.

ii) The problem formulations contain information establishing that there is exposure through ambient air.

Indeed, the problem formulations themselves establish that exposures through air persist for these chemicals despite any regulation under the CAA, and it is arbitrary and capricious for EPA to ignore those exposures. For EPA to treat these exposure levels as "zero" when they are known not to be does not comport with the best available science. For example:

<u>For asbestos</u>: EPA acknowledges that asbestos fibers occur in the air, with a 10-fold higher concentration of asbestos in cities (0.0001 fibers/ml) than in rural areas (0.00001 fibers/ml). Problem Formulation for Asbestos at p. 29.

<u>For 1,4-dioxane</u>: EPA states that a total of 62,596 lbs of the chemical were released to the air in 2015 according to the EPA Toxics Release Inventory (TRI). Problem Formulation for 1,4-Dioxane at p. 26. Both indoor and outdoor monitoring detected 1,4-dioxane. *Id.* at 28. "Of a total of 1397 collected samples, there were 948 non-detects (68%) and 449 detections (32%), which ranged from 0.005 to 0.96 ppb." Id.

For carbon tetrachloride: EPA states that a total of 104,838 lbs of the chemical were released to the air in 2015 according to TRI. Problem Formulation for Carbon Tetrachloride at p. 33. "According to the 2015 National Air Toxics Inventory, ambient air monitoring trends from 2003 to 2013 have shown that *** carbon tetrachloride average concentrations have slightly increased in the atmosphere over the 10-year period." *Id.* at 34.

For methylene chloride: EPA states that a total of 2,542,146 lbs of the chemical were released to the air in 2015 according to TRI. Problem Formulation for DCM at p. 34. "Ambient air samples worldwide have shown measured levels of methylene chloride." *Id.* at 35. EPA reports "monthly mean concentrations ranging from approximately 30-80 parts per trillion" in the mid-latitude northern hemisphere, with concentrations remaining the same or increasing with time. *Id.*

For perchloroethylene: EPA states that a total of 714,631 lbs of the chemical were released to the air in 2015 according to TRI. Problem Formulation for Perchloroethylene at p. 38. "EPA air monitoring data from 2013 reported detection of perchloroethylene in 77% of ambient air samples, with 58% of detects above the method detection limit. Indoor air concentrations of perchloroethylene tend to be greater than concentrations in outdoor air." *Id.* at 40. "[P]erchloroethylene was measured in 44.3% of 555 homes in three US cities. In this study, the median concentration was 0.56 µg/m3 and the 99th percentile was 20.9 µg/m3." *Id.* at 41.

For trichloroethylene: EPA states that a total of 1,880,569 lbs of the chemical were released to the air in 2015 according to TRI. Problem Formulation for TCE at p. 32. "TCE has been detected in ambient air across the United States, though ambient levels vary by location and proximity to industrial activities. *** A summary of the ambient air monitoring data for TCE (i.e., measured data) in the United States from 1999 to 2006 suggests that TCE levels in ambient air have remained fairly constant in ambient air for the United States since 1999, with an approximate mean value of 0.23 µg/m3." *Id.* at 33. EPA also mentions a number of studies reporting indoor air levels of TCE in residences, schools, and stores. *Id.* at 34.

iii) Additional information sources reveal that exposures through ambient air are occurring, and these additional information sources indicate that EPA's current analyses underestimate the exposure level through this pathway.

Moreover, EPA should not limit its analysis of air emissions to TRI data. EPA should also consider the data available from the National Emissions Inventory (NEI), which tend to reveal significantly greater levels of air emissions of, and thus air pathway exposures to, these chemicals. EPA cannot reasonably ignore this available information about air emissions and resulting exposures of these chemicals. As revealed in the below chart, despite the Clean Air Act protections, there are significant annual emissions and thus exposures through the air pathway for these chemicals.

	TRI 2016			NEI 2014
Chemical	**Fugitive Air Emissions (lbs)**	**Point Source Air Emissions (lbs)**	**TOTAL**	**(lbs)**
1,4-Dioxane	10,522	45,210	55,732	134,484
Asbestos (Friable)	106	178	284	1,561
Carbon tetrachloride	38,719	332,945	371,664	203,889
Dichloromethane (DCM)	1,272,089	1,335,196	2,607,285	14,271,645
Tetrachloroethylene (Perc)	313,197	354,705	667,902	7,941,891
Trichloroethylene (TCE)	1,442,918	687,349	2,130,267	12,191,695

EPA should analyze these exposures and the risks they present to both human health and the environment, including terrestrial species. With more than 14 million lbs of methylene chloride and more than 12 million lbs of trichloroethylene emitted to the air in 2014, it is absurd to treat the overall exposure through this pathway as if it were "zero."

Moreover, EPA should be collecting and analyzing information about exposure levels through the ambient air pathway, particularly near sites where people may experience greater exposure due to their proximity to conditions of use or contamination sites. As just one example, recently, a professional environmental engineering company measured exposures to perchloroethylene and trichloroethylene in Franklin, Indiana, in the ambient air, finding perchloroethylene at 171.73 µg/m3 and trichloroethylene at 52.61 µg/m3.[6] The firm also measured these chemicals in 14 different residences, finding additional indoor air exposures. By excluding pathways such as the ambient air pathway, EPA will seriously underestimate the levels of exposure.

In addition, this particular example highlights that EPA cannot adequately assess the risks faced by subpopulations consisting of people experiencing greater exposure due to their proximity to conditions of use without assessing pathways such as the ambient air pathway. If EPA ignores the ambient air pathway, EPA will completely ignore these exposure levels in Franklin, Indiana, and potentially similar exposure levels at locations across the country. EPA should use its information authorities to obtain

[6] *See* Edison Wetland Association, 2018 Residential Vapor Sampling "Mundell" Report p.9, https://www.edisonwetlands.org/johnson-county-in.

additional information about exposure levels experienced by the subpopulations living near conditions of use.

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Given evidence of real-world exposure through the air pathway, EPA must evaluate those exposures in its risk evaluations. In particular, EPA needs to consider whether these exposures combine with other sources of exposure in a manner that leads to an unreasonable risk, including to certain subpopulations. EPA cannot rationally exclude these exposures from its analysis.

D. Real-world exposures still occur through drinking water, and EPA cannot ignore those real-world exposures when assessing the risk presented by a chemical substance.

Based on various rationales, EPA decided to effectively ignore all exposures through drinking water for all ten chemicals. The systematic decision to ignore all exposures through this pathway is arbitrary and capricious because the available evidence reveals that exposures do occur through this pathway. Analyzing exposure through drinking water is also particularly important for EPA to obtain an accurate estimate of the exposure of infants and children, often a potentially exposed or susceptible subpopulation. *See, e.g.*, Problem Formulation for Perchloroethylene at p. 48 ("Drinking water could be a significant source of perchloroethylene ingestion exposure for children, who drink roughly four times as much water as adults.").

i) The existence of a Maximum Contaminant Level does not result in zero exposures to asbestos, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene through drinking water; EPA should analyze the real-world exposures.

EPA will exclude exposures to asbestos, carbon tetrachloride, methylene chloride, perchloroethylene, trichloroethylene through drinking water because EPA has set an enforceable Maximum Contaminant Level (MCL) under the Safe Drinking Water Act (SDWA). Problem Formulation for Asbestos at pp. 42-43; Problem Formulation for Carbon Tetrachloride at pp. 48-49; Problem Formulation for DCM at p. 54; Problem Formulation for Perchloroethylene at p. 60; Problem Formulation for TCE at p. 54.

This approach is unreasonable for the reasons given above, but in addition, EPA has not made the necessary showing that the established MCLs eliminate any unreasonable risk and EPA has not assessed all relevant aspects of the risk. As EPA itself acknowledges in each of these problem formulations, the MCLs are only set at the level "feasible" which "refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL." *See, e.g.*, Problem Formulation for Asbestos at p. 43. Thus, MCLs are based on non-risk factors and do not necessarily eliminate exposures.

Specifically, the contaminant level set under the SDWA considers "non-risk" factors, and the MCL is not sufficient to eliminate risks. While EPA must set a maximum contaminant level goal (MCLG) that is fully protective of health for drinking water contaminants, 42 U.S.C. § 300g-1(b)(1)(E); *see also* 42 U.S.C. § 300g-1(b)(4)(A), the MCLG is not the national drinking water standard. Rather, the agency must establish a maximum contaminant level (MCL) that is as close to the MCLG "as is feasible," considering

technological limitations and costs, and promulgate a national primary drinking water regulation (NPDWR) for the contaminant based on the MCL. 42 U.S.C. § 300g-1(b)(4)(B). In other words, the contaminant level EPA actually sets for safe drinking water is less protective than the MCLG because it accounts for feasibility and costs, which are non-risk factors that EPA may not consider during the risk evaluation process.

Chemical	**MCLG (mg/L)**	**MCL (mg/L)**
Asbestos	7 million fibers per liter (MFL)	7 MFL
Carbon tetrachloride	0	.005
Methylene Chloride	0	.005
Perchloroethylene	0	.005
Trichloroethylene	0	.005

Notably, the MCLG for four of these chemicals is zero, indicating that in order to avoid adverse effects on human health from drinking water EPA believes that these contaminants should not be in drinking water at any level. Because the MCL for these chemicals is higher, EPA must, among other things, address in the draft risk evaluation the risks posed by ongoing exposure to the chemicals at levels in drinking water below the MCL.

EPA has also failed to amend the MCLs for two of these chemicals, even though EPA has identified them as appropriate for revision. EPA is required to review and revise the drinking water standards every six years, as appropriate. 42 U.S.C. § 300g-1(b)(9). EPA's second six-year review of the NPDWRs concluded that the NPDWRs for trichloroethylene and perchloroethylene are candidates for regulatory revision.[7] More specifically, for both chemicals EPA stated that based on occurrence/exposure data and their cancer classifications "a revision to the MCL may provide a meaningful opportunity to reduce public health risks."[8] EPA also indicated that "analytical feasibility could be as much as 10 times lower (~ 0.0005 mg/L)" for both chemicals.[9] At this level, occurrence of both chemicals is "relatively widespread."[10]

However, it does not appear that EPA has done anything to act on this decision. Rather, EPA's website indicates that "a health assessment is in process [and] new analytical feasibility and treatment

[7] 75 Fed. Reg. 15,500 (Mar. 29, 2010), https://www.federalregister.gov/documents/2010/03/29/2010-6624/national-primary-drinking-water-regulations-announcement-of-the-results-of-epas-review-of-existing.
[8] *Id.* at 15,565 (TCE), 15,558 (perchloroethylene).
[9] *Id.* at 15,565 (TCE), 15,558 (perchloroethylene).
[10] *Id.* at 15,565 (TCE), 15,558 (perchloroethylene).

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technology information may justify a revision."[11] It has now been eight years since EPA first identified these chemicals for revision, and nothing has been done. Since that time, EPA has conducted its third six-year review of the NPDWRS and specifically excluded TCE and perchloroethylene from that review because they were subject to "recently completed, ongoing or pending regulatory actions."[12] 82 Fed. Reg. 3518, 3520 (Jan. 11, 2017). Yet there is no indication that EPA is taking any action on these two chemicals.

In addition, the SDWA does not regulate all sources of drinking water. It is estimated that more than 13 million households rely on private wells for drinking water in the United States.[13,14] The national drinking water standards established under the SDWA do not apply to private wells. *See* 42 U.S.C. § 300f(1) (a "primary drinking water regulation" only applies to "public water systems"); 42 U.S.C. § 300f(4)(A) (a "public water system" is a system that "has at least fifteen service connections or regularly serves at least twenty-five individuals"). Therefore, exposures to these chemicals in drinking water from private wells is not addressed by the SDWA and need to be evaluated in the draft risk evaluation.

Moreover, the problem formulations themselves establish that exposures through drinking water persist for these chemicals despite any regulations under the SDWA, and it is arbitrary and capricious for EPA to ignore those exposures. For EPA to treat these exposure levels as "zero" when they are known not to be does not comport with the best available science. In particular, the problem formulations acknowledge that both perchloroethylene and trichloroethylene are common contaminants of ground water, surface water, and drinking water. It is particularly arbitrary and capricious to ignore exposures that are known to be common and potentially a significant source of risk.

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[11] Six-Year Review 2 of Drinking Water Standards, https://www.epa.gov/dwsixyearreview/six-year-review-2-drinking-water-standards#summary-table (last visited Jul. 31, 2018).

[12] Elsewhere, EPA indicates that carbon tetrachloride, methylene chloride, perchloroethylene, trichloroethylene (plus four more chemicals), were not included in the third six-year review because "these chemicals are being evaluated as part of the Group Regulation of Carcinogenic Volatile Organic Compound." U.S. EPA, *The Analysis of Regulated Contaminant Occurrence Data from Public Water Systems in Support of the Third Six-Year Review of National Primary Drinking Water Regulations: Chemical Phase Rules and Radionuclides Rules* at 1-1 (Dec. 2016), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0627-0147. However, the development of a group NPDWR for Carcinogenic Volatile Organic Compounds (VOCs) is in long-term action under EPA's Spring 2018 Regulatory Agenda. https://resources.regulations.gov/public/custom/jsp/navigation/main.jsp (last visited Jul. 30, 2018) (select "Environmental Protection Agency" and search for "volatile organic compound").

[13] PRIVATE DRINKING WATER WELLS, https://www.epa.gov/privatewells (last visited Jul. 31, 2018) (citing the US Census American Housing Survey 2015).

[14] An estimated 44.5 million people in the United States, or 14 percent of the population, provided their own water for domestic use in 2010. U.S. Geological Survey, *Estimated Use of Water in the United States in 2010* (2014), https://pubs.usgs.gov/circ/1405/pdf/circ1405.pdf.

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For asbestos: Some U.S. drinking water supplies may contain 10-300 million asbestos fibers per liter. Problem Formulation for Asbestos at p. 29.

For carbon tetrachloride: 118 water systems reported mean concentrations of carbon tetrachloride greater than the Minimum Reporting Level (MRL) of 0.5 µg/L, which EPA's Office of Water has determined is the level showing a meaningful opportunity to improve public health. Problem Formulation for Carbon Tetrachloride at p. 35. The U.S. Geological Survey has also detected carbon tetrachloride in community water systems. *Id.*

For methylene chloride: EPA reported that methylene chloride has been detected in ground water and surface water, "including finished drinking water, through varied national monitoring efforts and water quality databases." Problem Formulation for DCM at p. 36. "Data compiled between 1992 and 2001 from NAWQA showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water." *Id.*

For perchloroethylene: EPA acknowledged that "Perchloroethylene is a common contaminant in municipal drinking water supplies and ground water." Problem Formulation for Perchloroethylene at p. 41. "The general population may ingest perchloroethylene via contaminated drinking water, ground water and/or surface water." *Id.* at 46. Perchloroethylene contamination in U.S. surface water and ground water has been reported in 19.6% of samples and at 13.2% of sites, with detection in surface water occurring more frequently than in ground water. *Id.* at 41. Indeed, thirty-six states reported drinking water systems with at least one detection above the MCL. *Id.* Thus, even if the MCL were sufficient, it is not being met for perchloroethylene.

For trichloroethylene: EPA acknowledged that it is "one of the most frequently detected organic solvents in U.S. ground water." Problem Formulation for TCE at p. 34. "TCE has been detected in drinking water systems through national and state-wide monitoring efforts." *Id.* EPA acknowledged that it had ample evidence of TCE in drinking water monitoring data, and EPA cannot rationally treat TCE exposure through drinking water as "zero" when EPA knows these exposures continue to occur.

Given evidence of real-world exposure, EPA must assess those exposures in its risk evaluations. EPA cannot rationally exclude them from analysis.

ii) EPA's failure to regulate 1,4-dioxane and N-methylpyrrolidone (NMP) in drinking water does not justify EPA's decision to ignore exposures through drinking water; EPA should analyze the real-world exposures.

EPA is excluding exposures to 1,4-dioxane and N-methylpyrrolidone (NMP) through drinking water on an even more irrational and illegal basis. Specifically, EPA has not yet established any regulatory standard for these two chemicals under the Safe Drinking Water Act. Instead, they are on the Contaminant Candidate List, which EPA acknowledges "is a list of *unregulated* contaminants that are known or anticipated to occur in public water systems and that may require regulation." Problem Formulation for 1,4-Dioxane at p. 43 (emphasis added); Problem Formulation for NMP at p. 49. By EPA's own

acknowledgement, there are likely exposures to these chemicals through drinking water systems and they remain unregulated.

This approach is unreasonable for the reasons given above, but in addition, EPA does not even have the fig-leaf that these chemicals are regulated under other statutes. Numerous additional steps would need to be taken to actually regulate these chemicals under SDWA, which have not been taken. The vague statement that the chemical is "currently being evaluated"—with no specification of what outcomes may result or any timeline for further action toward regulation—provides no basis for EPA's assertion that its risks are being "adequately assess[ed] and effectively manage[d]." Problem Formulation for 1,4-Dioxane at pp. 42-43. An agency cannot ignore ongoing, current exposures on the theory that the agency might regulate that exposure at some uncertain point in the future. If a regulation is not legally in-place and in-force, EPA cannot rationally give it any weight. Among other things, it would be arbitrary and capricious to consider speculative future regulations that have not been promulgated through rulemaking and do not yet have legal effect.

EPA also cannot reasonably assume that it will know whether a final regulation will be finalized or, if so, the final regulation's conditions, until it has entered into and completed the notice-and-comment process for the regulation. *See Nat'l Rest. Ass'n v. Solis*, 870 F. Supp. 2d 42, 50 (D.D.C. 2012) ("[C]omments received by the agency are expected to shape the outcome of a final rule."). "The whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different and improved from the rules originally proposed by the agency." *Trans-Pac. Freight Conf. of Japan/Korea v. Fed. Mar. Comm'n*, 650 F.2d 1235, 1249 (D.C. Cir. 1980). Thus, EPA cannot assume that any (entirely speculative) future MCL would provide adequate protection.

Moreover, the data in the problem formulations establishes that exposures through drinking water to 1,4-dioxane are likely and a cause for concern. As a factual matter, these exposures are occurring and EPA must consider them. With respect to NMP, it appears that EPA needs to perform further analysis regarding whether exposures are factually likely through drinking water.

<u>For 1,4-dioxane</u>: Of the 4,915 water systems monitored, 1,077 systems had detections of 1,4-dioxane in at least one sample. Problem Formulation for 1,4-Dioxane at p. 43. "341 systems (6.9%) had results at or above 0.35 µg/L (which corresponds to a 1 in a million-lifetime cancer risk)." *Id.* "Reported levels of 1,4-dioxane in groundwater range from 3 to 31,000 µg/L (ATSDR, 2012; USGS, 2002)." *Id.* at 28. EPA also acknowledged that some studies report 1,4-dioxane in surface water, though data are more limited and further study of surface water levels seems appropriate. *Id.* To ignore drinking water exposure when 1,4-dioxane has often been reported at hazardous levels is fundamentally arbitrary and capricious and a threat to public health.

iii) EPA needs to obtain actual data on potential exposure to HBCD, Pigment Violet 29, and 1-BP through drinking water exposures.

For the remaining three chemicals, EPA has included the drinking water pathway within the risk evaluation but has also insisted that it will perform no further analysis. See Problem Formulation for HBCD at pp. 51-52; Problem Formulation for PV 29 at p. 32; Problem Formulation for 1-BP at p. 53.

Instead, EPA provided at most a page's worth of analysis of this entire pathway for each chemical, and the resulting analysis largely fails to establish that EPA has sound reasons for failing to analyze this exposure pathway further.

First, EPA acknowledges that it has almost no data to justify these aspects of its analysis. See Problem Formulation for HBCD at pp. 51-52 ("Drinking water monitoring data is generally unavailable."); Problem Formulation for PV 29 at pp. 23, 32; Problem Formulation for 1-BP at p. 53 ("[T]here is no data of 1-BP found in US drinking water."). While EPA relies on the physical-chemical properties of these chemicals to estimate that concentrations of these chemicals in water are low, EPA has not established that these concentrations and exposures will not be significant, particularly in conjunction with other exposure pathways. EPA should use its available information authorities to fill these information gaps rather than assume "zero" exposure, particularly since EPA's analyses at best establish that the exposure levels may be low, not nonexistent.

Second, with respect to HBCD, EPA's analysis seems inconsistent with its earlier discussion of HBCD in the environment. "HBCD has been detected in a wide variety of environmental media." Problem Formulation for HBCD at p. 35. "HBCD is *** expected to be present in ambient air, indoor air and surface water." *Id*. EPA also acknowledges that "[t]he general population including populations living near industrial and commercial facilities processing, using or disposing of HBCD may be exposed by incidental ingestion of surface water and suspended particulates and by ingestion of HBCD from uptake (via direct or indirect deposition into water bodies or soil) from the environment into food sources." *Id*. at 50. Given widespread detections of HBCD in the environment, including surface water, it is arbitrary and capricious for EPA to assume low exposures through drinking water based on a lack of drinking water monitoring data. EPA also argues that it can ignore these exposures because the contribution of exposure is "expected to be low compared to other exposures," *id*. at 52, but without more analysis, EPA cannot conclude that those lower exposures are not significant, particularly when analyzed in combination with other exposures to HBCD. Even assuming EPA has established that other exposures are likely to be more significant, EPA has not established that EPA does not need to analyze how drinking water exposure may add to the overall risk.

E. Real-world exposures still occur through ambient water, and EPA cannot ignore those real-world exposures when assessing the risk to human health presented by a chemical substance.

Based on numerous rationales, EPA decided to effectively ignore all risks to human health arising from exposures through ambient water for nine of the ten chemicals.[15] The systematic decision to ignore the vast majority of exposures through this pathway is arbitrary and capricious because the available evidence reveals that exposures do occur through this pathway.

[15] EPA has correctly recognized that it must still analyze human exposures through ambient water from HBCD. *See* Problem Formulation for HBCD at p. 51.

i) The existence of a recommended water quality criterion for human health does not result in zero exposures to asbestos, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene through ambient water; EPA should analyze the real-world exposures.

In discussing its approach to assessing risk to human health, EPA states it will exclude exposures to asbestos, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene through ambient water because, under the Clean Water Act (CWA), EPA has recommended water quality criteria for protection of human health which are available for adoption into state water quality standards and to permitting authorities. See Problem Formulation for Asbestos at p.43; Problem Formulation for Carbon Tetrachloride at p. 49; Problem Formulation for DCM at p. 55; Problem Formulation for Perchloroethylene at pp. 60-61; Problem Formulation for TCE at pp. 54-55.

This approach is unreasonable for the reasons give above, but in addition, EPA has not made the necessary showing that the recommended water quality criteria it has set eliminate any unreasonable risk and EPA has not assessed all relevant aspects of the risk. Indeed, EPA has not even established or shown that these recommended water quality criteria meet EPA's illegal standard that these criteria "adequately assess and effectively manage exposures."

1) EPA has not addressed several reasons that its Clean Water Act authority is not a comprehensive substitute for action under TSCA.

Under the Clean Water Act (CWA), EPA establishes recommended water quality criteria, but not all states have updated their criteria to reflect the current CWA criteria. *See* 80 Fed. Reg. 36,986 (June 29, 2015). There is often significant variation between EPA's recommended criteria (shown in the table below) and the criteria adopted by the states.

EPA's National Recommended Water Quality Criteria for Four of the First Ten Chemicals:[16]

Chemical Name	**Human Health Criteria for w+o (µg/L)**	**Human Health Criteria for o (µg/L)**
TCE	0.6	7
Carbon tetrachloride	0.4	5
Perchloroethylene	10	29
Methylene chloride	20	1,000

[16] There are two sets of human health criteria: (1) exposure through organisms only (o), and (2) exposure to water and organisms (w+o). NATIONAL RECOMMENDED WATER QUALITY CRITERIA - HUMAN HEALTH CRITERIA TABLE, https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table.

For example, Illinois has set its human health criteria for TCE at 25 µg/L and has no human health criteria for perchloroethylene.[17] Maryland has set its human health criteria for TCE, carbon tetrachloride, and methylene chloride at higher levels than the current EPA recommended water quality criteria.[18] Other examples of states adopting less stringent standards are available. Given that some states have water quality criteria that are significantly less protective than EPA's recommendations, EPA cannot rely on its recommendations to assume that the risks are adequately managed, much less that they result in zero exposure.

EPA has also not assessed whether the established criteria, which EPA set and were adopted to varying extents by states in the past, reflect the current best available science regarding the risk presented by these chemicals. For example, EPA acknowledges that EPA may need to update its water quality criteria for some of these chemicals (though, inexplicably, not for others). *See, e.g.*, Problem Formulation for Carbon Tetrachloride at p. 49 ("EPA may update its CWA section 304(a) water quality criteria for carbon tetrachloride in the future under the CWA."); Problem Formulation for DCM at p. 55.

Moreover, while EPA relies on the CWA to dismiss the entire ambient water pathway, EPA never acknowledges the ongoing uncertainty surrounding the definition of "waters of the United States"[19] regulated under the CWA. EPA itself has stated that since the Supreme Court's decision in *Rapanos v. United States*, 547 U.S. 715 (2006), there has been uncertainty regarding the regulatory reach of the CWA. The EPA Office of Inspector General has stated that "*Rapanos* has created a lot of uncertainty with regards to EPA's compliance and enforcement activities. Processing enforcement cases where there is a jurisdictional issue has become very difficult."[20] EPA cannot assume that all ambient water is adequately managed under the CWA when EPA itself expresses ongoing uncertainty over the jurisdictional reach of the CWA.

Indeed, EPA has asserted that *Solid Waste Agency of Northern Cook County v. Army Corps of Engineers*, 531 U.S. 159 (2001), "squarely eliminate[d] CWA jurisdiction over isolated waters that are intrastate and non-navigable, where the sole basis for asserting CWA jurisdiction is the actual or potential use of the waters as habitat for migratory birds that cross state lines in their migrations." Advance Notice of Proposed Rulemaking on the Clean Water Act Regulatory Definition of "Waters of the United States," 68

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[17] DERIVED WATER QUALITY CRITERIA, http://www.epa.illinois.gov/topics/water-quality/standards/derived-criteria/index (last visited Aug. 16, 2016).
[18] NUMERICAL CRITERIA FOR TOXIC SUBSTANCES IN SURFACE WATERS, http://www.dsd.state.md.us/comar/comarhtml/26/26.08.02.03-2.htm (last visited Aug. 16, 2018).
[19] EPA's main webpage summarizes the ongoing litigation regarding the 2015 regulation that finalized a definition of "waters of the United States." *See* ABOUT WATERS OF THE UNITED STATES, https://www.epa.gov/wotus-rule/about-waters-united-states (last visited Aug. 11, 2018).
[20] U.S. EPA, Office of Inspector General, *Congressionally Requested Report on Comments Related to Effects of Jurisdictional Uncertainty on Clean water Act Implementation* (Apr. 2009), https://www.epa.gov/sites/production/files/2015-11/documents/20090430-09-n-0149.pdf.

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Fed. Reg. 1991, 1996 (Jan. 15, 2003). Therefore, it makes even less sense that EPA would assume that the CWA will ensure that all ambient waters are adequately managed.

Furthermore, EPA cannot assume that the CWA has adequately managed the discharge of all these chemicals because there are recognized lapses in the regulatory process. EPA's Office of Inspector General has reported that:

> Management controls put in place by the EPA to regulate and control hazardous chemical discharges from sewage treatment plants to water resources have limited effectiveness. The EPA regulates hazardous chemical discharges to and from sewage treatment plants, but these regulations are not effective in controlling the discharge of hundreds of hazardous chemicals to surface waters such as lakes and streams. Sewage treatment plant staff do not monitor for hazardous chemicals discharged by industrial users.[21]

At the time of the report by the Inspector General, there was no database of the information submitted by dischargers, nor was a compilation of the information available to officials in the regions or states that were interviewed.

Considering the documented lack of awareness regarding chemical discharges into and out of wastewater treatment plants, and EPA's own acknowledged failure to regulate discharges through this pathway, EPA should commit to analyzing any exposures through this pathway in its risk evaluations.

In sum, EPA has failed to analyze numerous aspects of its exercise of its CWA authority that amply demonstrate that EPA cannot dismiss the entire ambient water pathway simply because EPA has established water quality criteria. EPA must analyze the ambient water pathway in the risk evaluations.

2) *The problem formulations contain information establishing that there is exposure through ambient water.*

In any event, the recommended water quality criteria clearly do not eliminate exposures. As EPA itself acknowledges in the problem formulations, discharges are still permissible for these chemicals. *See, e.g.*, Problem Formulation for Perchloroethylene at p. 121 ("Perchloroethylene may also be discharged to waterways if proper permits are held."). A number of the problem formulations cite evidence of the presence of the chemicals in ambient water as well as drinking water:

For asbestos: EPA has evidence of asbestos in drinking water supplies, as described above, and EPA also has evidence that "asbestos has been detected in many different freshwater fishes and mussels from bodies of water contaminated with asbestos." Problem Formulation for Asbestos at p. 29.

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[21] U.S. EPA, Office of Inspector General, *More Action is Needed to Protect Water Resources from Unmonitored Hazardous Chemicals* at 3 (Sept. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/20140929-14-p-0363.pdf.

For carbon tetrachloride: EPA has evidence of carbon tetrachloride bring widespread in the environment and in drinking water supplies. See Problem Formulation for Carbon Tetrachloride at p. 35. EPA should assess whether the data reveal carbon tetrachloride being widespread in ambient water as well.

For methylene chloride: EPA acknowledges that methylene chloride is detected in surface water. Problem Formulation for DCM at p. 36. EPA cannot assume that methylene chloride has nonexistent exposure through ambient water when the data show it is present.

For perchloroethylene: "Perchloroethylene has been found in air, soil, surface water, salt water, drinking water, aquatic organisms and terrestrial organisms." Problem Formulation for Perchloroethylene at p. 40. EPA reports that perchloroethylene contamination of drinking water and ground water is common. Perchloroethylene was detected in surface water and ground water in 19.6% of samples, with surface water contamination being more common than ground water exposure. *Id.* at 41. With evidence of widespread water contamination, EPA cannot rationally ignore exposures to perchloroethylene through ambient water.

For trichloroethylene: EPA reported detections in surface water at a maximum of 50 ppb and average of 4.5 ppb. Problem Formulation for TCE at p. 34. An average of 4.5 ppb is not zero, and EPA should consider how this exposure may combine with exposures from other pathways to assess the overall risk from TCE.

EPA should look to the real-world exposures for these chemicals to assess their risk. The problem formulations provide relatively little information about the monitoring results for these chemicals in surface water. EPA should examine and summarize that exposure information when evaluating the risks presented by these chemicals; if that information is insufficient, EPA should use its authorities to require the development of additional needed information.

ii) EPA's failure to regulate 1,4-dioxane under the Clean Water Act does not justify EPA's decision to ignore exposures through ambient water; EPA should analyze the real-world exposures.

EPA is excluding exposures to 1,4-dioxane through ambient water on an even more irrational and illegal basis. *See* Problem Formulation for 1,4-Dioxane at pp. 43-44. EPA discusses the issue of a water quality criterion for 1,4-dioxane, but EPA never acknowledges that it has not yet set a human health criterion for 1,4-dioxane.[22] As EPA itself later admits in the problem formulation, only a single state has developed a water quality standard for human health for 1,4-dioxane. *See, e.g.*, Problem Formulation for 1,4-Dioxane at pp. 44 ("Currently, only one state (Colorado) includes human health criteria for 1,4-

[22] *See* NATIONAL RECOMMENDED WATER QUALITY CRITERIA - HUMAN HEALTH CRITERIA TABLE, https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria-table (last visited Aug. 16, 2018).

dioxane in their water quality standards."). EPA's failure to regulate 1,4-dioxane under the CWA cannot justify EPA's decision to exclude this pathway, for reasons previously articulated in Section 5.D.ii.

Moreover, the factual record establishes that 1,4-dioxane is present in water sources, and EPA should use its information authorities to obtain needed additional information about its presence in ambient water. EPA has evidence of 1,4-dioxane in drinking water supplies, as described above, and evidence of 1,4-dioxane in groundwater. Problem Formulation for 1,4-Dioxane at p. 28. EPA has acknowledged that it has "relatively fewer data available on 1,4-dioxane in surface water," so EPA should use its information authorities to obtain more data. *Id.*

iii) EPA needs to obtain actual data on potential exposure to NMP, Pigment Violet 29, and 1-BP through ambient water exposures.

For the remaining three chemicals, EPA included the ambient water pathway within the risk evaluation but also insisted that it would perform no further analysis. *See* Problem Formulation for NMP at p. 47; Problem Formulation for PV 29 at p. 32; Problem Formulation for 1-BP at p. 53. Instead, once again, EPA provided at most a page's worth of analysis of this pathway for each chemical, and the resulting analysis largely fails to establish that EPA has sound reasons for failing to analyze this exposure pathway further.

As with drinking water, EPA acknowledges that it has almost no data to justify this aspect of its analysis. *See* Problem Formulation for NMP at p. 47 ("Environmental monitoring data were not identified for NMP."); Problem Formulation for PV 29 at p. 23 ("EPA did not find environmental monitoring data (e.g., presence in air, soil, sediment, surface water, or biota)"); *see also* Problem Formulation for 1-BP at p. 34. While EPA invokes the physical-chemical properties of these chemicals to declare that concentrations of these chemicals in water are low, EPA has not established that these concentrations and exposures will not be significant, particularly in conjunction with other exposure pathways. EPA should use its available information authorities to fill these information gaps rather than assume low exposure.

For example, in the absence of any actual monitoring data for NMP, EPA conducted a questionable "first-tier exposure analysis." Problem Formulation for NMP at p. 47. *See* Section 47.A.ii for detail on concerns about this first-tier analysis. While EPA suggests that these predicted exposures, standing alone, would not likely present a risk, EPA should consider whether these exposures could present a risk when combined with exposures through other sources, such as air and other exposures EPA intends to exclude, as well as the exposures that EPA is analyzing through the risk evaluations.

F. Real-world exposures still occur through disposal pathways, and EPA cannot ignore those real-world exposures when assessing the risk presented by a chemical substance.

For every chemical substance except Pigment Violet 29,[23] EPA contends that due to regulation of disposal under the Resource Conservation and Recovery Act (RCRA), the Clean Air Act (CAA), the Safe

[23] While EPA retains the disposal pathway for Pigment Violet 29, EPA gives it an incredibly cursory analysis and intends not to analyze it further, relying on the "design standards for Subtitle-D lined landfills" and expectations about its tendency to leach. *See* Problem Formulation for PV 29 at p. 33. EPA

Drinking Water Act (SDWA), and various state programs, EPA can ignore all exposures from all disposal-related pathways and associated activities (e.g., collection, processing, storage and transport). Problem Formulation for Asbestos at pp. 43-44; Problem Formulation for 1-BP at pp. 54-55; Problem Formulation for 1,4-Dioxane at pp. 44-45; Problem Formulation for Carbon Tetrachloride at pp. 50-51; Problem Formulation for HBCD at pp. 52-53; Problem Formulation for DCM at pp. 55-57; Problem Formulation for NMP at pp. 50-51; Problem Formulation for Perchloroethylene at pp. 61-63; Problem Formulation for TCE at pp. 55-56.

This approach is unreasonable for the reasons given above. EPA has not made the necessary showing that these regulations eliminate any unreasonable risk and EPA has not assessed all relevant aspects of the risk. Indeed, EPA has not even established or shown that these disposal regulations meet EPA's illegal standard that these regulations "adequately assess and effectively manage exposures." For example, EPA has not shown or established that disposal in a RCRA Subtitle C hazardous waste landfill or a RCRA Subtitle D non-hazardous waste landfill would actually reduce unreasonable risk to a sufficient extent. EPA's approach is also arbitrary and capricious for a variety of reasons.

With respect to asbestos, 1-BP, HBCD, and methylene chloride, the problem formulations indicate that the chemical is not listed as a hazardous waste under RCRA. Problem Formulation for Asbestos at p. 43 ("Asbestos is not regulated as a RCRA hazardous waste under RCRA Subtitle C."); Problem Formulation for 1-BP at p. 92 ("Currently, 1-BP is not regulated under federal regulations as a hazardous waste."); Problem Formulation for HBCD at pp. 52-53 ("HBCD is not classified as a RCRA hazardous waste."); Problem Formulation for NMP at pp. 50-51 (not referring to any listing). EPA cannot rely on the RCRA regulatory regime as a basis for ignoring exposures under TSCA when EPA has not even issued a regulatory decision under RCRA for these chemicals.

Moreover, while EPA invokes the standards for RCRA Subtitle C landfills as providing sufficient protection, not all disposal occurs in such landfills. For example, EPA acknowledges that the majority of asbestos land disposal does not occur in RCRA Subtitle C landfills. Problem Formulation for Asbestos at pp. 43-44. Similarly, for NMP, the vast majority of off-site releases to land (~2.7 million pounds in 2016) went to landfills other than RCRA Subtitle C landfills. Problem Formulation for NMP at pp. 50-51. Even chemicals allegedly managed under RCRA can be or are disposed of in non-hazardous waste landfills. For example, EPA's TRI reporting on 1-BP showed that most of the releases to the land were to "other off-site landfills," not RCRA Subtitle C landfills. Problem Formulation for 1-BP at p. 34. EPA cannot rely on regulations that do not apply to protect against risks.

Even for those chemicals regulated under RCRA, EPA acknowledges that disposal also occurs in Subtitle D municipal solid waste (MSW) landfills and industrial-non-hazardous and construction/demolition waste landfills (which are primarily regulated under state regulatory programs). These disposal approaches do not need to meet the requirements of Subtitle C landfills, thus EPA's invocation of the Subtitle C standards does not justify ignoring exposures from these disposals. While the purpose of

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should obtain some actual monitoring and testing information to assess whether its conclusion is accurate.

RCRA subtitle C is at least to "protect human health and the environment," *see, e.g.*, 42 U.S.C. §§ 6922(a), 6924(a), subtitle D is intended "to assist in developing and encouraging methods for the disposal of solid waste which are environmentally sound and which maximize the utilization of valuable resources including energy and materials *** and to encourage resource conservation." 42 U.S.C. § 6941. Therefore, EPA's exclusions based on the regulations under subtitle D potentially raise even greater, unaddressed, public health concerns than EPA's exclusions under subtitle C.

In addition, states impose varying requirements on such landfills under their delegated RCRA Subtitle D authorities. For example, EPA indicates that some state programs may not include requirements for liners to limit release of landfill leachate.

EPA itself has acknowledged that enforcement and regulation under RCRA is inconsistent, so EPA cannot simply assume that RCRA implementation provides a basis for ignoring exposures under TSCA. As the Office of Inspector General explained the challenges of the RCRA system:

> The Hazardous and Solid Waste Amendments of 1984 (HSWA) amended RCRA and added provisions including land disposal restrictions, RCRA corrective action for solid waste management units and regulation of small-quantity generators. When the EPA creates new hazardous waste rules, it does so under the authority of either or both of these laws. Rules promulgated under HSWA authority are immediately effective in all states and are administered by the EPA until states become authorized for those rules. In contrast, *rules promulgated under RCRA authority (non-HSWA rules) cannot be enforced by the EPA in states with an authorized base program and do not go into effect until these states become authorized for the rules.*[24]

According to the OIG, the fact that a number of rules are not yet adopted by the states and cannot be enforced by EPA "creates a regulatory gap and risk to human health and the environment, and an inconsistent regulatory landscape across the states."[25] OIG's report states that "there are almost 1,300 instances of required rules for which various state hazardous waste programs have not been authorized. Of the rules for which states have not received authorization, there are about 500 each of HSWA and non-HSWA rules, and about 300 rules that have components of both."[26]

When states do not keep their hazardous waste programs up to date, it means citizens in different states are unevenly protected from hazardous waste-related risks. This is critical because "60,000 RCRA facilities exist in the United States, generating and managing 30 to 40 million tons of hazardous waste

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[24] U.S. EPA, Office of Inspector General, *Incomplete Oversight of State Hazardous Waste Rule Authorization Creates Regulatory Gaps and Human Health and Environmental Risks* at 2 (Jul. 2018), https://www.epa.gov/sites/production/files/2018-07/documents/_epaoig_20180731-18-p-0227.pdf (emphasis added).
[25] *Id.* at 11.
[26] *Id.* at 12; *see also* AUTHORIZATION STATUS BY RULE, https://www.epa.gov/sites/production/files/2018-06/documents/authorization_status_by_rule.pdf (last visited Aug. 10, 2018) (documenting for each state whether they have adopted the RCRA regulations).

annually. Eighty percent of all U.S. citizens live within a 3-mile radius of a RCRA-regulated hazardous waste generator or treatment storage and disposal facility, and 50 percent of citizens live within a 1-mile radius."[27] Therefore, EPA cannot rely on any assumption of consistent implementation and enforcement of RCRA to ensure that all exposures have been adequately managed.

Indeed, many of the problem formulations themselves establish that exposures from disposal persist for these chemicals despite RCRA regulations, and it is arbitrary and capricious for EPA to ignore those exposures. For EPA to treat these exposure levels as "zero" when they are known to exist does not comport with the best available science.

To be sure, EPA often appears to have less monitoring information that speaks to whether a particular exposure arises from disposal or some other source, and EPA also appears to have less monitoring information about these chemicals' presence in soil, sediment, and leachate, than it does for their presence in water or air. *See, e.g.*, Problem Formulation for TCE at p. 34 ("Compared with other environmental media, there is a relative lack of nationally representative monitoring data on levels of TCE in ambient soil."). As EDF has previously explained, EPA must consider "reasonably available" information, and thus EPA must both consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information. EDF incorporates and reiterates those points here as well.[28] EPA should use those authorities to obtain additional information about the exposures arising from disposal for these chemicals.

EPA cannot assume that exposure from disposal is zero just because it could be regulated under other authorities. For example, the problem formulations contain information suggesting that exposures may arise from disposal. In particular, as detailed below, asbestos appears in sewage sludge, and EPA has data showing that 1,4-dioxane, HBCD, methylene chloride, NMP, and trichloroethylene are present in landfill leachate, despite the various regulations that allegedly render these exposures insignificant.

For asbestos: EPA acknowledged that "[a]sbestos fibers can be found in soils, sediments, lofted in air and windblown dust, surface water, ground water and biota." Problem Formulation for Asbestos at p. 26. "Asbestos fibers have been measured in U.S. municipal sewage sludges, with asbestos fiber content up to 10% of ashed sludge by volume." *Id*. at 29.

For 1,4-dioxane: EPA acknowledges that "1,4-Dioxane has also been detected in landfill leachate." Problem Formulation for 1,4-Dioxane at p. 28.

For HBCD: "There may be releases of HBCD from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill." Problem Formulation for HBCD at p. 34. "Disposal of EPS and XPS foam may result in releases to the environment as a result of demolition of buildings or material

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[27] U.S. EPA, Office of Inspector General, *EPA Has Not Met Statutory Requirements for Hazardous Waste Treatment, Storage and Disposal Facility Inspections, but Inspection Rates Are High* at 1 (March 2016), https://www.epa.gov/sites/production/files/2016-03/documents/20160311-16-p-0104.pdf.
[28] EDF Comments on Ten Scopes under the Toxic Substances Control Act pp.11-15, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

that is left on or in the soil." *Id.* "Articles that contain HBCD may release HBCD to the environment during use or through recycling and disposal." *Id.* at 35. "HBCD has been widely detected in both the environment and biota." *Id.* at 35. "HBCD is expected to be present at relatively higher levels in sediment, soil and indoor dust." *Id.* "HBCD has been detected in leachate and HBCD containing materials are sent to landfill as part of disposal." *Id.* at 103.

For methylene chloride: EPA acknowledges that various studies and databases provide hundreds of measurements of methylene chloride in soil and sediment. Problem Formulation for DCM at p. 36. "In a literature review of various VOC concentrations found in landfill leachates, Klett et al. (2005) found methylene chloride ranged in concentration from 1.0 – 58,200 µg/L. Staples et al. (1985) reported that methylene chloride was found in 20% of sediment samples in the STORET database." *Id.* at 36-7.

For NMP: "NMP has been detected in industrial landfill leachate." Problem Formulation for NMP at p. 33. "NMP has been detected in wastewater." *Id.*

For perchloroethylene: "Perchloroethylene has been found in air, soil, surface water, salt water, drinking water, aquatic organisms and terrestrial organisms. Historic industrial, commercial and military use of perchloroethylene, including unregulated or improper disposal of perchloroethylene wastes, has resulted in location-specific soil and ground water contamination." Problem Formulation for Perchloroethylene at p. 40.

For trichloroethylene: "TCE is widely detected in a number of environmental media. *** TCE is frequently found at Superfund sites as a contaminant in soil and ground water." Problem Formulation for TCE at p. 33.

G. Real-world exposures still occur through biosolids pathways, and EPA cannot ignore those real-world exposures when assessing the risk presented by a chemical substance.

Based on numerous rationales, EPA decided to effectively ignore all risks arising from exposures through biosolids for at least seven of the ten chemicals (EPA's problem formulations are unclear about how it will consider biosolids for two of them).[29] The systematic decision to ignore the vast majority of exposures through this pathway is arbitrary and capricious because the available evidence reveals that exposures do occur through this pathway for at least three of these chemicals.

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[29] EPA has correctly recognized that it must still analyze exposures through biosolids for HBCD. *See* Problem Formulation for HBCD at p.51. EPA is unclear in its discussion of biosolids and 1,4-dioxane. *Compare* Problem Formulation for 1,4-Dioxane at p. 9 ("EPA plans to include surface water exposure to aquatic vertebrates, invertebrates and aquatic plants, exposure to sediment organisms and exposure to 1,4- dioxane in land-applied biosolids in the risk evaluation."), *with id.* at 42 ("EPA does not plan to further analyze other releases to land during risk evaluation, including biosolids application to soil."). EPA provides a cursory analysis of biosolids for Pigment Violent 29 but then states that "land application of biosolids *** is outside of scope of this assessment." Problem Formulation for PV 29 at p. 33.

i) EPA cannot ignore known exposures from biosolids for carbon tetrachloride and perchloroethylene on the theory that EPA may someday regulate them under CWA Section 405(d).

In the problem formulations, EPA acknowledges that its sewage surveys and biennial reviews for biosolids have identified carbon tetrachloride and perchloroethylene as toxic chemicals occurring in biosolids. Problem Formulation for Carbon Tetrachloride at p. 49; Problem Formulation for Perchloroethylene at p. 61. Given the known presence of these chemicals in biosolids and the potential for exposure, EPA must analyze these exposures when assessing whether these chemicals present an unreasonable risk.

EPA states that it will disregard these exposures because "EPA can potentially regulate those pollutants under CWA 405(d), based on a subsequent assessment of risk. EPA's Office of Water is currently developing modeling tools in order to conduct risk assessments for chemicals in biosolids. Because the biosolids pathway for [these chemicals are] currently being addressed in the CWA regulatory analytical process, this pathway will not be further analyzed in the risk evaluation." *See, e.g.*, Problem Formulation for Perchloroethylene at p.61. On its face, these statements are contradictory and irrational. EPA admits that the pathways are not yet being addressed, and the relevant office has not even developed models to address these pathways. EPA cannot rationally exclude a known pathway of exposure under TSCA because EPA "can potentially" regulate that pathway through a different mechanism at some unknown date in the future.

As explained above in Section 5.D.ii, if a regulation is not legally in-place and in-force, EPA cannot rationally give it any weight. Among other things, it would be arbitrary and capricious to consider speculative future regulations that have not been promulgated through rulemaking and do not yet have legal effect.

ii) EPA knows of evidence that asbestos is present in biosolids, so EPA must analyze this pathway of exposure.

The problem formulation for asbestos acknowledges that asbestos has been detected in biosolids in the United States. *See* Problem Formulation for Asbestos at p. 29. "EPA has identified literature which indicates that asbestos has been detected in biosolids from municipal wastewater treatment." *Id.* at 42. EPA asserts, without explanation, that it is expected that concentrations of asbestos in biosolids will be low. *Id.* But EPA provides no evidence supporting the conclusion that the concentrations will be low. In addition, asbestos is a particularly hazardous substance, so even low concentrations of asbestos may present an unreasonable risk. Without further analysis and evidence, EPA cannot simple assume that asbestos' presence in biosolids will not present an unreasonable risk.

iii) EPA should obtain some actual monitoring data to confirm its biosolids predictions for 1-BP, 1,4-dioxane, methylene chloride, NMP, and TCE, and to the extent EPA excludes biosolids on the theory that the chemical will instead enter other pathways, EPA must consider those exposure pathways.

For 1-BP, 1,4-dioxane, methylene chloride, NMP, and TCE, EPA states that these chemicals are expected to either enter the aqueous component and/or volatilize to air, and thus asserts EPA can ignore the biosolids exposure pathway. *See, e.g.*, Problem Formulation for 1-BP at pp. 53-54; Problem Formulation for 1,4-Dioxane at p. 42; Problem Formulation for DCM at p. 53; Problem Formulation for NMP at p. 48; Problem Formulation for TCE at pp. 53.

EPA should obtain some monitoring data to confirm these analyses, but in any event, EPA cannot rationalize ignoring exposures from biosolids on the basis that these chemicals will enter the water and air and then also choose to ignore the exposure pathways through water and air. EPA's justification for ignoring the biosolids pathways for these chemicals highlights that EPA's decision to ignore other pathways is particularly arbitrary and capricious.

iv) EPA needs to better explain its approach to Pigment Violet 29 and biosolids, and EPA should assess this exposure pathway more robustly than it has.

In contrast to the chemicals discussed above, EPA draws the opposite conclusion for Pigment Violet 29, emphasizing that because sorption to biosolids is expected to be strong, it can assume low levels of leaching (allowing EPA to rationalize its disregarding the drinking water and ambient water pathways), but then stating that "land application of biosolids is not expected to be a release pathway for the manufacturer, so this pathway is outside of scope of this assessment." Problem Formulation for PV 29 at p. 33. EPA's explanation in this cursory analysis is difficult to follow: EPA notes that the manufacturer of Pigment Violet 29 sends its sludge to a RCRA Subtitle D landfill, *id.*, but it is not clear why that would mean EPA can therefore disregard exposures from biosolids. Given Pigment Violet 29's expected presence in biosolids, EPA should analyze this pathway unless EPA has empirical evidence showing that it will not lead to exposures.

H. EPA must analyze all the environmental risks presented by asbestos, HBCD, methylene chloride, perchloroethylene, and trichloroethylene through ambient water.

EPA recognizes that it must evaluate the risks to aquatic species arising from exposures through water for asbestos, HBCD, methylene chloride, perchloroethylene, and trichloroethylene. Problem Formulation for Asbestos at p. 41; Problem Formulation for HBCD at pp. 50-51; Problem Formulation for DCM at p. 53; Problem Formulation for Perchloroethylene at p. 59; Problem Formulation for TCE at p. 53.

But EPA has not committed to analyzing the risks to terrestrial species from exposure through ambient water for any of these chemicals except HBCD, despite the fact that terrestrial species also can experience exposures through surface water. *But see* Problem Formulation for HBCD at p. 50 ("Aquatic and terrestrial ecological receptors may also be directly exposed due to proximity to surface water and sediment."). When EPA evaluates the risks presented by exposure through ambient water, EPA must consider the risks presented to terrestrial ecological receptors as well as aquatic species.

EPA provides no convincing explanation for excluding exposures to terrestrial or sediment-dwelling organisms for asbestos, methylene chloride, perchloroethylene, and trichloroethylene. For asbestos,

EPA acknowledges that once in water, asbestos will eventually settle into sediments, and that EPA is still reviewing the literature regarding the risk; EPA should not complete its evaluation of this risk until it has completed the literature review and can accurately establish that exposure levels through these media present no unreasonable risk. Problem Formulation for Asbestos at p. 42. For methylene chloride, EPA states it will not further analyze exposure to terrestrial organisms through water, sediment, or migration from biosolids via soil deposition, based on the argument that "[t]errestrial species exposures to MC in water are orders of magnitude below hazardous concentrations." (Appendix E, pp. 139-140) Yet it is far from clear how EPA arrived at this conclusion. *See* Section 43.A for further discussion. For perchloroethylene, EPA simply does not address terrestrial organisms' exposure to surface water (though EPA acknowledges it must analyze exposure to sediment-dwelling organisms). Problem Formulation for Perchloroethylene at p. 12. For trichloroethylene, EPA simply asserts that "physical chemical properties do not support an exposure pathway through water and soil pathways" to terrestrial organisms, but EPA provides no analysis of why this is so.

I. EPA cannot rely on its actions under other authorities when there are numerous problems with compliance, implementation, and enforcement under those authorities.

EPA cannot ignore exposure through these pathways for the reasons given above, but in addition, it is arbitrary and capricious for EPA to assume zero exposure through other pathways based on EPA-administered statutes when EPA has documented extensive problems with compliance, implementation, and enforcement of these statutes.

i) EPA's own analyses establish that State enforcement of these environmental statutes is inconsistent and often deficient.

There are multiple EPA reports documenting enforcement problems with EPA's environmental statutes.[30] Specifically, these reports have noted that "data quality, identification of violations, issuing enforcement penalties and other enforcement actions in a timely and appropriate manner, and general oversight issues" are all key issues impacting the enforcement of these statutes.[31]

Generally, EPA's regional offices provide oversight to ensure that the state enforcement programs are following EPA's guidance, policies, and regulations.[32] Despite EPA oversight, which is a separate concern, state enforcement of these statutes has been found deficient in a number of cases. For instance:

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[30] U.S. EPA, Office of Inspector General, *EPA Must Improve Oversight of State Enforcement* at App. B, p. 32-34 (Dec. 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20111209-12-p-0113.pdf (identifying a long list of GAO and OIG reports documenting deficiencies in enforcement of environmental statutes).
[31] *Id.* at 32.
[32] U.S. Government Accountability Office, *EPA-State Enforcement Partnership Has Improved, but EPA's Oversight Needs Further Enhancement* at 1 (Jul. 2007), https://www.gao.gov/products/GAO-07-883.

- According to a 2011 OIG report, **North Dakota** appears "philosophically opposed to taking enforcement action."[33] For instance, during the entire period of the report (FYs 2003-2009), the state assessed no penalties against known CWA violators.[34]
- In **Louisiana** multiple petitions have been filed by citizens to remove the state's delegated authorities under the CWA, CAA, and RCRA.[35] The poor performance under these statues was attributed to "a lack of resources, natural disasters, and a culture in which the state agency is *expected to protect industry*."[36]
- The **U.S Virgin Islands** "has not met program requirements for numerous activities related to implementing the Clean Air Act, Clean Water Act, Safe Drinking Water Act, and Underground Storage Tank/Leaking Underground Storage Tank programs. These activities included monitoring environmental conditions, conducting compliance inspections and enforcing program requirements."[37]

Notably, even where enforcement of these statutes has been consistently deficient, EPA has generally not de-authorized states. According to the 2011 OIG report, "the threat of EPA revoking a state's authorization [is] moot because there is a general understanding that no EPA region has the resources to operate a state program. This reality undercuts EPA's strongest tool for ensuring that authorized states adequately enforce environmental laws: de-authorization."[38] Although EPA has taken steps in a number of cases to improve state programs, ultimately implementation and enforcement of these statutes remains deficient in a number of states, resulting in continued excessive exposure to these chemicals through air, water, and land. These exposures EPA must be assessed under TSCA.

Below are a few more specific examples, among many, of deficiencies under each of the statutes.

Safe Drinking Water Act: As explained above, EPA has excluded exposures to drinking water for several of the chemicals based on the assumed effectiveness of state implementation and enforcement of the SDWA. A 2011 GAO report states that EPA often receives unreliable data from the states.[39] EPA relies

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[33] U.S. EPA, Office of Inspector General, *EPA Must Improve Oversight of State Enforcement* at 17 (Dec. 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20111209-12-p-0113.pdf.
[34] *Id.* at 15.
[35] *Id.* at 16.
[36] *Id.* (emphasis added).
[37] U.S. EPA, Office of Inspector General, *Conditions in the U.S. Virgin Islands Warrant EPA Withdrawing Approval and Taking Over Management of Some Environmental Programs and Improving Oversight of Others* (April 2015), https://www.epa.gov/sites/production/files/2015-09/documents/20150417-15-p-0137.pdf; U.S. EPA Region 2, *National Strategy Oversight Plan* at 3 (Mar. 2016), https://www.documentcloud.org/documents/2992740-Region-2-State-Oversight-Plan-March-2016-v2.html.
[38] U.S. EPA, Office of Inspector General, *EPA Must Improve Oversight of State Enforcement* at 17 (Dec. 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20111209-12-p-0113.pdf.
[39] U.S. Government Accountability Office, *Unreliable State Data Limit EPA's Ability to Target Enforcement Priorities and Communicate Water Systems' Performance* (June 2011), https://www.gao.gov/products/GAO-11-381.

on state data to determine whether there is compliance with the SDWA. Without reliable data EPA has no way to verify that the requirements of the SDWA are being met by the states.

Here is one example of deficient state enforcement of the SDWA:

- **Pennsylvania**: EPA sent a letter in December 2016 to the Pennsylvania Department of Environmental Protection, stating that the department lacks the necessary staff to enforce safe drinking water standards and that the lack of staff has caused the number of unaddressed Safe Drinking Water Act violations to nearly double in the past five years, from 4,298 to 7,922.[40]

Clean Water Act: EPA has also excluded exposures to ambient water for numerous chemicals based on the assumed "effectiveness" of the CWA's National Pollution Discharge Elimination System (NPDES) program and the water quality criteria process.

But over half of assessed U.S. river and stream miles violate state water quality standards.[41] EPA's own analysis, provided below, indicates that waters remained impaired throughout the United States, despite the CWA standards.

Assessed Water of the United States[42]

	Size of Water							
	Rivers and Streams (Miles)	Lakes, Reservoirs, and Ponds (Acres)	Bays and Estuaries (Square Miles)	Coastal Shoreline (Miles)	Ocean and Near Coastal (Square Miles)	Wetlands (Acres)	Great Lakes Shoreline (Miles)	Great Lakes Open Water (Square Miles)
Good Waters	516,800	5,392,817	11,516	1,285	617	569,328	106	1
Threatened Waters	4,495	30,309						
Impaired Waters	586,910	13,158,111	44,619	3,330	6,218	665,979	4,354	39,230
Total Assessed Waters	1,108,205	18,581,237	56,135	4,615	6,836	1,235,307	4,460	39,231
Total Waters	3,533,205	41,666,049	87,791	58,618	54,120	107,700,000	5,202	196,343
Percent of Waters Assessed	31.4	44.6	63.9	7.9	12.6	1.1	85.7	20.0

EPA also publishes the Annual Noncompliance Report, which summarizes enforcement data for facilities with individual NPDES permits but that are not major dischargers.[43] According to the 2015 report, the percentage of facilities with formal enforcement actions compared to facilities with violations was merely 8.9% in 2015.[44] Below are a few examples of enforcement deficiencies:

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[40] Letter from Jon M. Capacasa, Director, EPA Region III Water Protection Division, to Lisa D. Daniels Director, Pa. Dep't of Envtl. Prot. Bureau of Safe Drinking Water (Dec. 30, 2016), https://drive.google.com/file/d/0B4Y3VQLxjkxObjZ0ZXlSVDZvRWc/view.

[41] NATIONAL SUMMARY OF STATE INFORMATION, https://ofmpub.epa.gov/waters10/attains_nation_cy.control (last visited Jul. 31, 2018).

[42] *Id.*

[43] U.S. EPA, Office of Enforcement and Compliance Assurance, *Annual Noncompliance Report (ANCR) Calendar Year 2015* (Aug. 2016), https://echo.epa.gov/system/files/2015_ANCR.pdf.

[44] *Id.* at 7.

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- **Tennessee**: The Tennessee Department of Environment and Conservation neglected to timely penalize permit holders despite months of noncompliance, failed to assess appropriate fines, and did not report significant discharge violations from major facilities.[45]
- **Alaska**: EPA regional directors told OIG that "when the region authorized the state to run the program, both the region and OECA officials were aware that the state lacked the capacity to be successful."[46] EPA's State Review Framework for Alaska revealed that, among other serious concerns, the state does not consistently take timely or appropriate enforcement actions, inspect permitted facilities anywhere close to state goals.[47]
- **Louisiana**: Louisiana reviewed the compliance status for less than 50% of individually-permitted non-major NPDES permittees from 2010-2015.[48]

Clean Air Act: State performance also varies widely under the CAA. In 2011, the Office of the Inspector General examined the percentage of facilities inspected, the percentage of significant noncompliance or high priority violations identified per inspection, and the percentage of final actions with penalties for fiscal years 2003-2009 and found that performance varied significantly across the country, in this case "by almost 50 percentage points."[49] Below are a few specific examples of insufficient state enforcement of the CAA:

- **Florida**: The Florida Department of Environmental Protection opened only 18 air enforcement cases in 2015, compared to a previous annual average of 93.[50] Additionally, from 2013 to 2015 the state only filed one asbestos case, compared to a past annual average of 13.[51]
- **North Carolina**: "CAA metric for assessed penalties dropped by 93% statewide from about $235.000 in FY II to just under $17,000 in FY 14. During the same period the number of facilities with informal and formal enforcement actions also dropped dramatically (52% and 79%, respectively)."[52]

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[45] U.S. EPA Region 4, *State Review Framework Tennessee* at 28-35 (Sept. 2016), http://www.documentcloud.org/documents/3173730-TN-Final-SRF-Report-9-29-16.html.
[46] U.S. EPA, Office of Inspector, *EPA Must Improve Oversight of State Enforcement* at 16 (Dec. 2011), https://www.epa.gov/office-inspector-general/report-epa-must-improve-oversight-state-enforcement.
[47] U.S. EPA Region 10, *State Review Framework Alaska* at exec. summary (Dec. 2014), https://www.epa.gov/sites/production/files/2015-01/documents/srf-rd3-rev-ak.pdf.
[48] U.S. EPA, Office of Enforcement and Compliance Assurance, *Annual Noncompliance Report (ANCR) Calendar Year 2015* at 8 (Aug. 2016), https://echo.epa.gov/system/files/2015_ANCR.pdf.
[49] U.S. EPA, Office of Inspector, *EPA Must Improve Oversight of State Enforcement* at 10 (Dec. 2011), https://www.epa.gov/office-inspector-general/report-epa-must-improve-oversight-state-enforcement.
[50] Public Employees for Environmental Responsibility, *Report on Enforcement Efforts by the Florida Department of Environmental Protection* at 23 (Aug. 2016), https://www.peer.org/assets/docs/fl/8_18_16_DEP_Report_on_2015_Enforcement.pdf.
[51] *Id.*
[52] Letter from J. Scott Gordon, Director, EPA Region IV Office of Enforcement Coordination, to Donald R. van der Vaart, Secretary, N.C. Dep't of Envtl. Quality (May 9, 2016), https://assets.documentcloud.org/documents/3114598/EPA-Region-4-Letter-to-NCDEQ.pdf.

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- **Ohio**: The Region found that a number of High Priority Violations (HPV) are being resolved by the state through a permit modification/revision. EPA believes that HPV cases should be resolved through a formal enforcement action per the HPV policy, and the state disagrees.[53]

Resource Conservation and Recovery Act: As with the other statutes upon which EPA relies to avoid analyzing exposure pathways, there are serious state enforcement problems with RCRA. For example, Mississippi has not accurately identified and documented RCRA violations.[54] Additionally, despite EPA guidance that states civil penalties should recoup at least the economic benefit the violator gained through noncompliance, the state does not routinely document or consider the economic benefit.[55]

ii) Reduced EPA enforcement provides even less assurance that exposures through the excluded pathways are being effectively managed.

Under the current Administration, enforcement of these environmental statutes has been significantly curbed. For instance, management at EPA has directed EPA investigators to seek authorization before asking companies to conduct testing or sampling under the CAA, RCRA, or the CWA.[56] The memo also states that investigators need authorization if they do not have information specific to a company that it may have violated the law, or if state authorities objected to the tests.[57]

Additionally, in its proposed 2018 budget, the current Administration sought a 31 percent reduction in funding for EPA.[58] This included a 24 percent drop in EPA's enforcement budget, supposedly to avoid "duplication of enforcement actions carried out by the States."[59] The Administration's proposed budget would also cut 45 percent of the EPA grants that states rely on to fund their own enforcement programs.[60]

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[53] U.S. EPA Region 5, *State Review Framework Ohio* at 3, 38-39 (Aug. 2013), https://www.epa.gov/sites/production/files/2014-05/documents/srf-rd2-rev-oh.pdf.
[54] U.S. EPA Region 4, *State Review of Framework Mississippi* at Executive Summary (Mar. 3, 2016), https://www.epa.gov/sites/production/files/2016-03/documents/srf-rd3-rev-ms.pdf.
[55] *Id.* at 24.
[56] Memorandum from Susan Shinkman, Director, EPA Office of Civil Enforcement, to Regional Counsel, Regional Enforcement Directors and Coordinators, and OCE Division Directors (May 31, 2017), https://www.documentcloud.org/documents/4324892-EPA-Clean-Air-Act-and-Its-Power-to-Request.html#document/p60/a392202.
[57] *Id.*
[58] Office of Mgmt. & Budget, *A New Foundation for Greatness, Budget of the U.S. Government, Fiscal Year 2018* at 42 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/budget.pdf.
[59] Office of Mgmt. & Budget, *Major Savings and Reforms, Budget of the U.S. Government, Fiscal Year 2018* at 86 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/msar.pdf.
[60] *Id.* at 84.

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EPA cannot rely on its actions under other authorities when EPA has itself taken steps to ensure that those authorities are not adequately addressing the risks presented.

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In sum, EPA must analyze all exposures to these chemicals. EPA cannot legally ignore exposures that occur under other EPA-administered statutes, and treating exposures that are known to occur in the world as nonexistent is arbitrary and capricious. EPA must assess these exposures based on their real-world existence and consider how they may combine with other sources of exposure to accurately estimate the risks presented by these chemical substances. Where EPA has inadequate information, EPA should use its information authorities to obtain more information about these exposures.

6. EPA must analyze real-world exposures and not assume perfect compliance with existing regulatory limits.

In a number of the problem formulations, EPA states that in assessing environmental releases, EPA will "consider regulatory limits that may inform estimation of environmental releases."[61] *See, e.g.*, Problem Formulation for Perchloroethylene at p. 66; Problem Formulation for DCM at p. 60. Similarly, EPA suggests that, in assessing occupational exposure, EPA may assume compliance with standards and regulations established by the Occupational Safety and Health Administration (OSHA). *See, e.g.*, Problem Formulation for DCM at p. 63 ("This or other models, including the assumption of compliance with the OSHA [Permissible Exposure Limit] for methylene chloride, may be explored where models specific to conditions of use are not found."); Problem Formulation for Perchloroethylene at p. 69. As established above in Sections 5.I and 6, in reality compliance with regulatory limits is often imperfect, and EPA cannot reasonably assume that all persons are meeting regulatory limits.

For example, the perchloroethylene problem formulation acknowledges that 36 states reported drinking water systems with detections above the regulatory limit. *See, e.g.*, Problem Formulation for Perchloroethylene at p. 41. If EPA assumed compliance with the regulatory limit, EPA would be arbitrary and capricious by relying on a known falsehood.

As another example, "[a] review of five years of state records by the Environmental Integrity Project and Environment Texas shows that the state imposed penalties on *less than 3 percent* of the illegal pollution releases (588 out of 24,839) *reported by* companies during maintenance or malfunctions from 2011 through 2016, even though the incidents released more than 500 million pounds of air pollution."[62] Thus, 500 million pounds of illegal emissions were reported in Texas for 2011 through 2016: it would be irrational to assume that these emissions did not occur. Moreover, the state of Texas did not impose

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[61] Given how many environmental releases EPA has excluded outright, it is not always clear what environmental releases EPA will be analyzing.

[62] Environmental Integrity Project, *Breakdowns in Enforcement Texas Rarely Penalizes Industry for Illegal air Pollution Released during Malfunction and Maintenance* at 1 (Jul. 2017), https://www.environmentalintegrity.org/wp-content/uploads/2017/02/Breakdowns-in-Enforcement-Report.pdf (emphases added).

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penalties for 97% of these illegal pollution releases reported by companies. Of course, not all violations are promptly or accurately reported by companies, so this number may actually overestimate the level of compliance and enforcement. With such lax enforcement, compliance levels are going to be low.

Given known limitations in enforcement and compliance, it would be arbitrary and capricious for EPA to assume perfect compliance with existing regulatory limits. Instead, EPA should rely on real-world, reasonably available information.

7. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The problem formulations generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the problem formulations currently reflect. *See, e.g.*, Problem Formulation for Perchloroethylene at p. 33.

The problem formulations give no attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment.[63] Given the known accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

8. EPA must consider "reasonably available" information, and thus EPA must use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

In our prior comments on the scope documents, EDF expanded on EPA's duties to use its authorities under TSCA §§ 4 and 8 to obtain additional information about these ten chemicals, and EDF incorporates those arguments here.[64] In response to EDF's comment, EPA acknowledged its duty to consider

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[63] *See, e.g.*, *More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey*, N.Y. TIMES (Sept. 8, 2017), https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0.

[64] EDF Comments on Ten Scopes under the Toxic Substances Control Act at pp. 11-16, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

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"reasonably available information" and EPA described its efforts to gather information up to this point.[65] While EPA details its "data gathering activities," EPA has not established that these activities will result in EPA obtaining all the reasonably available information that EPA could "generate, obtain, and synthesize" if EPA also used its authorities under TSCA §§ 4 and 8 to obtain additional information. Thus, EPA has not established that it will obtain all reasonably available information.

In particular, EDF's prior comments established that relying solely on voluntary requests for information, may result in limited, biased, inaccurate, or incomplete information on the chemicals. EDF incorporates those arguments here.[66] EPA's response to this comment was that "EPA has not indicated it would rely solely on voluntary requests for information."[67] Thus, EPA appears to recognize that voluntary requests standing alone are insufficient. Despite that acknowledgement, EPA still has not relied on its available authorities to obtain additional information. EDF urges EPA to do so.

EPA's primary response to EDF's request that EPA consider all reasonably available information appears to be that the information EPA currently has is "adequate."[68] But, as a general matter, EPA has to consider all reasonably available information; TSCA does not authorize EPA to stop its analysis on the basis that EPA believes its current information is adequate. And as explained more below, it is clear that the information is not yet adequate to meet EPA's obligations under TSCA.

A. Relying on voluntary requests for information will result in limited, biased, inaccurate, or incomplete information on the chemicals.

In all but one of the problem formulations, EPA includes this or very similar language: "*EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources*, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during the risk evaluation. EPA will continue to consider new information submitted by the public." Problem Formulation for 1-BP at p. 57 (emphasis added); *see also* Problem Formulation for Asbestos at p. 47; Problem Formulation for 1,4-Dioxane at p. 47; Problem Formulation for Carbon Tetrachloride at p. 53; Problem Formulation for HBCD at p. 56; Problem Formulation for DCM at p. 59; Problem Formulation for NMP at p. 53; Problem Formulation for Perchloroethylene at p. 65; Problem Formulation for TCE at p. 58.

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[65] EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA at pp.10-14, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051.

[66] EDF Comments on Ten Scopes under the Toxic Substances Control Act at pp. 16-20, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

[67] EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA at p.13, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051.

[68] *See id.* at pp. 13, 10-14.

With this language EPA seems to acknowledge the serious data gaps it faces; yet despite clear authority to require workplace monitoring by industry and to obtain full study reports using its existing authorities, EPA resorts merely to encouraging their submission.

Rather than relying solely on voluntary submissions—an approach that has proven insufficient in the past—EPA should use its information authorities to obtain necessary information on conditions of use, exposures, hazards, and potentially exposed or susceptible subpopulations.

There are several obvious problems and limitations with this voluntary approach which EPA has still not addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to develop or obtain and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may believe that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

EPA cannot simply assume that members of the regulated community will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

B. EPA cannot rationally rely on unvetted industry submissions, and to the extent EPA relies on voluntary submissions from industry, EPA must take numerous additional steps to increase their reliability and transparency.

In the problem formulations, EPA uncritically relies on industry submissions, and this reliance does not constitute the best available science. In the most extreme examples, EPA cites to a piece of correspondence where the actual text of the correspondence is not available, nor are the surrounding circumstances or any supporting evidence. *See, e.g.*, Problem Formulation for HBCD at p. 31. From these records, it is not possible for the public to even begin to assess the accuracy of the underlying statements or EPA's conclusions based on them.

In many problem formulations, EPA cites and uses data obtained from the European Chemicals Agency (ECHA). *See, e.g.*, Problem Formulation for 1-BP at pp. 41-42; Problem Formulation for 1,4-Dioxane at pp. 33-35; Problem Formulation for Carbon Tetrachloride at pp. 31-32, 39; Problem Formulation for HBCD at pp. 21, 36, 51; Problem Formulation for NMP at pp. 32, 39; Problem Formulation for PV 29 at pp. 7-8, 12-14, 21-22, 26-28, 31-32, 37; Problem Formulation for TCE at p. 39.

However, in most cases the data are simply those submitted by companies to ECHA in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) registration dossiers, and the data have not been independently evaluated by ECHA or other government authorities in the EU. In citing

information available through ECHA, EPA must clearly distinguish between industry data that have not been evaluated, industry data that have been evaluated by ECHA or other government authorities in the EU, and information that ECHA has itself developed or provided.

To the extent it relies on voluntary submissions from industry, EPA needs to take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their submissions is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

C. EPA must obtain and make public the full studies.

EPA needs to ensure it has obtained copies of the full studies for which it cites ECHA as the source. EPA should also request that submitters always provide copies of full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

EPA also needs to make copies of full studies on which it relies available to the public, including those to which it refers in the problem formulations as identified in the European Chemicals Agency (ECHA) Database and FDA's Food Additive Petitions. *See, e.g.*, Problem Formulation for PV 29 at p. 7. As EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries.[69] Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency, including the extent to which the requirements of section 26(h) and 26(i) are met. Even the best study summaries are incomplete descriptions that do not allow for an independent examination of study quality and conclusions reached by authors. Common examples of such conclusions include, "findings were not statistically significant," "findings are within the range of historical controls," and "effects observed were non-linear [and therefore biologically questionable or irrelevant]." Divorced from the details of the actual design and results of a study, it is impossible to evaluate the appropriateness of such conclusions. It is important that EPA obtain the full studies, both so that EPA staff have access and so that EPA can make them publicly available. EPA should make such information public and easily searchable through online portals such as the Health and Environmental Research Online (HERO) database. EDF incorporates and reiterates the numerous points made in support of public access to the full studies here. *Id*. These points also support the importance of EPA obtaining the full studies.

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[69] *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074.

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D. Both the problem formulations and these comments identify numerous information gaps that EPA needs to fill using its information authorities.

Throughout these comments, EDF points to information gaps that EPA should fill with its information authorities. For example, EPA states that the available information on perchloroethylene is "insufficient to allow for a quantitative assessment of the impact of susceptibility on risk," and EPA appears to exclude certain susceptible subpopulations from analysis on this basis. Problem Formulation for Perchloroethylene at p. 53. But the available information identifies numerous subpopulations as possibly more susceptible to adverse effects. In these circumstances, EPA should use its information authorities to obtain additional information about susceptibility so that EPA can fulfill its duty to consider unreasonable risks to potentially exposed or susceptible subpopulations. Similarly, EPA should use its information authorities to fill the other gaps identified in these comments as well.

9. EPA needs to implement the requirements of TSCA § 14 when reviewing materials for the risk evaluations.

EPA has an affirmative obligation to review at least 25% of non-chemical identity confidentiality claims under TSCA, 15 U.S.C. § 2613(g), and EPA has stated that it is implementing that obligation by "review[ing] every fourth submission received that contains non-chemical identity [confidential business information (CBI)] claims."[70] Thus, on balance, EPA should be reviewing all confidentiality claims asserted in at least approximately one-fourth of the information submissions it receives. Those claims must be substantiated at the time of submission. EPA must complete reviews of confidentiality claims within 90 days of receipt of the claims, and if EPA denies a claim, EPA must disclose the information that had been claimed confidential 30 days after notifying the claimant of the denial, absent a challenge to the denial in district court. 15 U.S.C. § 2613(g)(1)(A), (g)(2)(B).

In addition, TSCA requires disclosure of "any health and safety study which is submitted under [TSCA] with respect to *** any chemical substance or mixture *** for which notification is required under section 5." 15 U.S.C. § 2613(b)(2)(A). TSCA also requires disclosure of "any information reported to, or *otherwise obtained by*, [EPA] *from* a health and safety study which relates to [such] a chemical substance. . . ." *Id.* § 2613(b)(2)(B) (emphases added). Thus, any health and safety studies and related information on these chemicals must be disclosed. TSCA defines "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." *Id.* § 2602(8). EPA has provided further details on this expansive definition of "health and safety study," explaining that it encompasses, among other things, "[a]ny data that bear on the effects of a chemical substance on health or the environment" and "[a]ny assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance." 40 C.F.R. § 720.3(k). Thus, any

[70] EPA REVIEW AND DETERMINATION OF CBI CLAIMS UNDER TSCA, https://www.epa.gov/tsca-cbi/epa-review-and-determination-cbi-claims-under-tsca (last visited Jan. 18, 2018).

health and safety study or other information on health or environmental effects or any assessment of risk EPA prepared must be disclosed. The only exception from that disclosure requirement is for "information *** that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture." 15 U.S.C. § 2613(b)(2).

In developing these risk evaluations, a large fraction of the information EPA relies on will constitute health and safety studies. All such information not subject to the two narrow exceptions needs to be made public.

10. EPA should generally utilize its prior hazard and/or dose-response values for 1,4-dioxane, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene, and EPA must explain any decision to deviate from these values.

In the last decade, EPA's Integrated Risk Information System has developed hazard and/or dose-response values for 1,4-dioxane, carbon tetrachloride, methylene chloride, perchloroethylene, and trichloroethylene. EPA should not lightly disregard this valuable work, and EPA has shown a willingness to rely on these values in the past. For each chemical, EPA must identify and explain any decision to deviate from these values, as well as the scientific basis for such deviation.

For example, in the problem formulation for trichloroethylene, EPA states:

> TCE has an existing EPA IRIS Assessment (U.S. EPA, 2011c) and an ATSDR Toxicological Profile (ATSDR, 2014a); hence, many of the hazards of TCE have been previously compiled and systematically reviewed. Furthermore, EPA previously reviewed data/information on health effects endpoints, identified hazards and conducted dose-response analysis in the TSCA Work Plan Chemical Risk Assessment of TCE (U.S. EPA, 2014c). EPA has relied heavily on these comprehensive reviews in preparing this problem formulation. EPA expects to use these previous analyses *as a starting point for identifying key and supporting studies* to inform the human health hazard assessment, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the Application of Systematic Review in TSCA Risk Evaluations document (U.S. EPA, 2018).

Problem Formulation for TCE at p. 44 (emphasis added).

The agency indicates that "many of the hazards of TCE have been previously compiled and systematically reviewed," which was in fact done in the ATSDR profile and the IRIS toxicological review. As noted in EPA's Work Plan assessment, EPA relied heavily on the IRIS toxicological review to develop the Work Plan assessment. In describing the IRIS toxicological review, EPA stated in the Work Plan Assessment:

> The assessment uses the hazard and dose-response information published in the final toxicological review that the U.S. EPA's Integrated Risk Information System (IRIS)

published in 2011 (EPA, 2011e). The TCE IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for TCE's carcinogenic and non-carcinogenic health effects resulting from lifetime inhalation and oral exposures. In addition to relying on the latest scientific information, the TCE IRIS assessment underwent several levels of peer review including agency review, science consultation on the draft assessment with other federal agencies and the Executive Office of the President, public comment, external peer review by the EPA's Science Advisory Board (SAB) in 2002, scientific consultation by the U.S. National Academy of Sciences (NAS) in 2006, external peer review of the revised draft assessment by the EPA's Science Advisory Board (SAB) in January 2011, followed by final internal agency review and EPA-led science discussion on the final draft.[71]

Given EPA's multiple, clear statements affirming the scientific rigor of the IRIS toxicological review as well as its decision to rely upon it in its 2014 Work Plan Assessment (Congress itself has given the Work Plan significant weight under TSCA), EPA must identify and explain any decision to deviate from these reviews and clearly identify in its draft risk evaluation any modifications it proposes in hazard identification and dose-response characterization, and the scientific basis for them. Any such differences must be based on compelling scientific evidence and explicitly interrogated through the peer review process.

The excerpt from the problem formulation refers to "key," "supporting," and "relevant" studies. The meaning of these descriptors is entirely unclear. EPA must explicitly define the meaning of these terms and their implications with regard to the agency's approach to systematic review and risk evaluation.

11. EPA needs to accurately identify the relevant potentially exposed or susceptible subpopulations.

A. EPA needs to identify infants, children, pregnant women, and adults of childbearing age as potentially exposed or susceptible subpopulations as appropriate for 1-BP, carbon tetrachloride, HBCD, methylene chloride, N-methylpyrrolidone, perchloroethylene, and trichloroethylene.

TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). EPA largely failed to identify these populations in the scopes, and EPA still has failed to identify many of them in the problem formulations. While EPA has, to some extent, considered some of those at greater risk due to increased exposure in the problem formulations, the agency too often defers the process of identifying populations with greater susceptibility to the risk evaluation stage.

[71] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses* at 20-21 (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to *** greater susceptibility *** may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. § 2602(12). Where the evidence before the agency shows that a chemical presents developmental or reproductive risks, then the evidence establishes that infants, children, pregnant women, and adults of child-bearing age "may be at greater risk than the general population of adverse health effects," and EPA must identify them as potentially exposed or susceptible subpopulations.

Based on the evidence already before the agency, EPA must identify these groups as potentially exposed or susceptible subpopulations for 1-BP, carbon tetrachloride, HBCD, DCM, NMP, perchloroethylene, and trichloroethylene. Problem Formulation for 1-BP at p. 44 (describing evidence of reproductive and developmental toxicity for 1-BP); Problem Formulation for Carbon Tetrachloride at p. 74 (recognizing need to rescreen for reproductive and developmental toxicity); Problem Formulation for HBCD at p. 43 (describing evidence of reproductive and developmental hazards); Problem Formulation for NMP at pp. 40-41 (recognizing that a "continuum of biologically relevant reproductive/developmental effects have been reported following NMP exposure" and noting that EPA previously identified young children and pregnant women as potentially susceptible); Problem Formulation for Perchloroethylene at p. 52 (discussing numerous studies suggesting both reproductive and developmental toxicity); Problem Formulation for TCE at p. 45 (identifying TCE as a developmental toxicant). In addition, there are data on developmental neurotoxicity for DCM that EPA failed to mention in the problem formulation.[72]

B. EPA should identify people living near disposal sites as potentially exposed or susceptible subpopulations.

EPA should identify people living near disposal sites as potentially exposed or susceptible subpopulations. These groups include (but are not limited to) those living near so-called "legacy" disposal sites. To be clear, many disposal sites are associated with activities that reflect ongoing or prospective manufacturing, processing, distribution, or use, so EPA must analyze those disposals and disposal sites even assuming EPA were correct about its asserted authority to ignore so-called legacy uses, associated disposal, and legacy disposal. But EPA should analyze all disposal sites and populations living in proximity to them; the distinctions EPA has drawn between disposals find no basis in the statute, and as explained below, TSCA expressly requires EPA to consider disposal.

As EDF previously explained in its comments on the scopes, EPA cannot rationally exclude so-called legacy uses and associated disposals. EDF incorporates and reiterates those points here as well.[73] For the same reasons, EPA cannot rationally exclude so-called legacy disposals. Along with other

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[72] *See* U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* at 80-81 (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

[73] EDF Comments on Ten Scopes under the Toxic Substances Control Act pp.8-9, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069.

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petitioners, EDF has further developed these arguments in a Brief which is attached as Appendix A. EDF incorporates and reiterates those points here. *See* Appendix A at 40-51.

In sum, a chemical's conditions of use include "the circumstances" under which the chemical is "known, or reasonably foreseen to be manufactured, processed, distributed in commerce, *used, or disposed of*." 15 U.S.C. § 2602(4) (emphasis added). Because the definition uses a disjunctive "or" list, each lifecycle stage of a chemical, standing alone, is a condition of use, even if some of the chemical's lifecycle stages have been discontinued. *See, e.g.*, *Horne v. Flores*, 557 U.S. 433, 454 (2009). So-called legacy disposals are "circumstances" under which a chemical is "known *** to be *** disposed of." 15 U.S.C. § 2602(4). As the Senate Report accompanying an early version of the amended TSCA acknowledged, "there may be exposures of concern from substances that are not currently or no longer in commerce, and the section provides EPA authority to prioritize inactive substances that meet certain criteria." S. Rep. No. 114-67, at 11. "Disposal" of a chemical substance (including products containing that substance) is not a one-time occurrence when the substance or product is buried or placed in a landfill or other waste facility, but remains ongoing after the initial act of discard. Moreover, even in its flawed risk evaluation rule, EPA stated that "EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses." 82 Fed. Reg. at 33,730. Thus, even if EPA follows its illegal rule (which it should not—EPA should give full weight to the consideration of the exposures arising from these conditions of use), EPA should consider these exposures in assessing the combined exposure faced by subpopulations near disposal sites.

Thus, EPA must analyze the exposures arising from the activities associated with disposal of a chemical substance. EPA must also identify those who face greater exposures due to their proximity to disposal sites as a "potentially exposed or susceptible subpopulation" since they are a "group of individuals within the general population identified by the Administrator who, due to *** greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12). EPA correctly recognizes that those "who live or work near manufacturing, processing, distribution or use sites" qualify as potentially exposed or susceptible subpopulations, *see, e.g.*, Problem Formulation for Perchloroethylene at p. 47. Thus, EPA recognizes that proximity to other conditions of use lead to greater exposure, but in many of the problem formulations, *see, e.g.*, *id.*, EPA irrationally ignores the potential for greater exposure to arise from proximity to disposal activities. As a matter of law, EPA must analyze this susceptible subpopulation as well. EPA should consider those who live near disposal locations, regardless of whether that disposal is so-called "legacy disposal" or "associated disposal."

Notably, in some problem formulations, EPA correctly acknowledges that it must analyze these vulnerable subpopulations. *See, e.g.*, Problem Formulation for 1,4-Dioxane at p. 32 ("Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or *disposal sites*).") (emphasis added). EPA's correct conclusion that these subpopulations merit additional analysis for some chemicals highlights that it is irrational to exclude these subpopulations for others.

Problematically, even when EPA recognizes that it must analyze those facing greater exposure due to proximity to disposal, EPA often excludes the pathways leading to this exposure from further analysis. *E.g., compare* Problem Formulation for 1,4-Dioxane at p. 32 (recognizing subpopulation), *with id*. at 44-45 (excluding disposal pathway from analysis). As EDF previously explained, this approach is irrational and incoherent. *See* above in Section 5.B.ii. EPA should not exclude those pathways for the reasons given above, and in addition, EPA cannot rationally evaluate the greater exposure these subpopulations face without analyzing these pathways. EPA has provided no rationale explaining how it plans to accurately evaluate the risks faced by these subpopulations while ignoring these pathways of exposure.

In addition, EPA should be analyzing communities who live or work near past manufacturing, processing, distribution, or use sites, even if those activities have ceased. The statute does not allow EPA to ignore conditions of use merely because they happened in the past, and in any event, the disposal at these sites remains ongoing at this time.

C. EPA should identify people living in proximity to sources of contamination as potentially exposed or susceptible subpopulations.

Most of the problem formulations correctly identify people subject to greater exposure due to their proximity to conditions of use as a potentially exposed or susceptible subpopulation.[74] For example, the 1-BP problem formulation acknowledges the need to identify this subpopulation:

> EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their greater exposure:
>
> ***
>
> - Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

Problem Formulation for 1-BP at p. 40; Problem Formulation for Asbestos at p. 32; Problem Formulation for 1,4-Dioxane at p. 32; Problem Formulation for HBCD at p. 39; Problem Formulation for DCM at p. 40; Problem Formulation for NMP at p. 37; Problem Formulation for Perchloroethylene at p. 47; Problem Formulation for TCE at p. 38.

However, such subpopulations may extend further to those in proximity to sources of contamination not necessarily linked to or able to be attributed to a specific condition of use. For example, for many of the

[74] EPA fails to identify this subpopulation for two chemicals: carbon tetrachloride and PV 29. EPA should include these subpopulations for those two chemicals as well. The reasoning that supports identifying these subpopulations for the other chemicals similarly applies here, absent a compelling explanation for excluding these subpopulations.

problem formulation chemicals, EPA has identified soil or groundwater contamination that leads to potential elevated exposures of people nearby.

TSCA defines the term "potentially exposed or susceptible subpopulation" to include "a group of individuals within the general population identified by the Administrator who, due to *** *greater exposure*, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12) (emphasis added). Thus, a subpopulation can qualify due solely to "greater exposure" to a chemical substance; the statute includes no text qualifying "greater exposure" requiring that the exposure be linked to a particular condition of use.

Thus, EPA needs to expand its list to include:

- Other groups of individuals within the general population who may experience greater exposures due to their proximity to sources of contamination (e.g., contaminated groundwater) not necessarily linked to or able to be attributed to a specific condition of use.

D. Reasonably available information reveals numerous sites where these chemicals are known to be present and thus where the subpopulations in their proximity may be at greater risk due to greater exposure.

Reasonably available information reveals that numerous sites exist where these chemicals are known to be present, leading to greater potential exposures for the subpopulations living in proximity to these sites. We summarize some of the available information below. In addition, we attach a list of some of the known sites with these chemical substances so that EPA can analyze the subpopulations potentially suffering greater exposure from these sites. *See* Appendix B.

Chemical Substance	**Number of Final and Proposed Superfund Sites with the Chemical Substance**[75]
1,4-dioxane	37
Asbestos	51
Carbon tetrachloride	240
Methylene chloride	394
Tetrachloroethylene	394
Trichloroethylene[76]	364

[75] These data come from the National Institute of Health's (NIH) ToxMap, available at https://toxmap.nlm.nih.gov/toxmap/app/.

[76] For trichloroethylene ToxMap had an option to select both "trichloroethylene" and "TCE" as Superfund pollutants. The number included in the table comes from the search for "trichloroethylene"

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12. EPA needs to ensure that environmental justice is appropriately considered, analyzed, and addressed in the risk evaluations.

Environmental justice is "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations and policies."[77] According to EPA, providing "[f]air treatment" will ensure that "no group of people should bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental and commercial operations or policies."[78] EPA has committed to integrate environmental justice into "everything" the agency does in order to "reduce[ ] disparities in the nation's most overburdened communities."[79]

Despite this commitment, and EPA's obligations to comply with Executive Order 12898 (see below), EPA has not incorporated environmental justice considerations into the problem formulations. In addition, EPA does not appear to have undertaken any outreach oriented towards ensuring the meaningful involvement of environmental justice communities in the risk evaluation process. EPA must address environmental justice in the risk evaluations, both by incorporating an analysis into the evaluations and ensuring meaningful involvement by environmental justice communities in the development of the risk evaluations.

A. The risk evaluations are subject to Executive Order 12898.

Executive Order 12898 directed federal agencies to identify and address "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." Exec. Order No. 12898, 59 Fed. Reg. 7629 (Feb. 16, 1994). EPA must comply with this duty in the Executive Order. *See Sherley v. Sebelius*, 689 F.3d 776, 784 (D.C. Cir. 2012) ("[A]s an agency under the direction of the executive branch, it must implement the President's policy directives to the extent permitted by law."). The Executive Order applies, by its own terms, to all "programs, policies, and activities" of a federal agency, and EPA's preparation of the risk evaluations undoubtedly fall within this capacious definition, qualifying as "activities" of EPA, carried out as part of its "programs" and pursuant to its "policies." As agency actions that may affect the level of protection provided to human health or the environment, the risk evaluations under TSCA must address environmental justice communities.[80] EPA's own guidance on considering environmental justice defines

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only. The search for "TCE" results in 264 final and proposed Superfund Sites. Because some of these sites overlap, but not entirely, we kept the higher number in the table.

[77] EJ 2020 GLOSSARY, https://www.epa.gov/environmentaljustice/ej-2020-glossary.

[78] *Id.*

[79] U.S. EPA, *EJ 2020 Action Agenda* at 1 (2016), https://www.epa.gov/sites/production/files/2016-05/documents/052216_ej_2020_strategic_plan_final_0.pdf.

[80] *See* U.S. EPA, *EPA's Action Development Process Interim Guidance on Considering Environmental Justice During the Development of an Action* at 18 (Jul. 2010), https://www.epa.gov/sites/production/files/2015-03/documents/considering-ej-in-rulemaking-guide-07-2010.pdf.

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"agency action" to include risk assessments.[81] EPA has articulated no theory for why the Executive Order would not apply to the risk evaluations.

Yet EPA has failed to mention, let alone adequately address, Executive Order 12898 or "environmental justice" in the problem formulations. Failure to do so violates EPA's obligations under the Executive Order.

Notably, EPA has stated that the identification of potentially exposed or susceptible subpopulations under TSCA would "carry[ ] out the spirit" of Executive Order 12898.[82] EPA's implication that the act of merely identifying "potentially exposed or susceptible subpopulations," standing alone, is sufficient to comply with the Executive Order, is plainly incorrect. The Executive Order specifically states that EPA must consider the disparate impacts of pollution on "minority populations and low-income populations."[83] The failure to do so in the problem formulation documents, in particular by failing to consider minority, low-income, and indigenous communities when identifying potentially exposed or susceptible populations, does not "carry out the spirit," or the letter, of the Executive Order. EPA must prepare an actual environmental justice analysis to comply with the Executive Order.

B. EPA's exclusions in the problem formulations violate the Executive Order by underestimating the risks faced by environmental justice communities.

EPA's decision to exclude environmental releases covered by other statutes because those statutes "adequately address" risk fails to acknowledge that other statutes have historically failed to consider environmental justice communities in permitting and enforcement. The National Environmental Justice Advisory Council (NEJAC), a federal advisory committee to EPA, has stated that:

> Environmental protection in this country has grown by individual pieces of legislation, developed to address a particular environmental media or a pressing problem like abandoned toxic sites. Environmental law has not evolved from a master game plan or unifying vision. As a result, the statutes *have gaps in coverage* and do not assure compatible controls of environmental releases to all media from all sources.[84]

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[81] *Id.* at 1.

[82] U.S. EPA, Risk Evaluation Rule Response to Comments at 1, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0109.

[83] Exec. Order No. 12898; *see also* U.S. Office of Inspector General, *EPA Needs to Consistently Implement the Intent of the Executive Order on Environmental Justice* at 9-10 (Mar. 2004), https://www.epa.gov/sites/production/files/2015-10/documents/20040301-2004-p-00007.pdf (explaining that the intent of the Executive Order, in part, was to place EPA's focus on minority and low-income communities).

[84] National Environmental Justice Advisory Council, Cumulative Risks/Impacts Work Group, *Ensuring Risk Reduction in Communities with Multiple Stressors: Environmental Justice and cumulative Risks/Impacts* at 7 (Dec. 2004), https://www.epa.gov/sites/production/files/2015-04/documents/ensuringriskreducationnejac.pdf (emphasis added).

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Those gaps in coverage were often a result of controlling pollution solely "through technology-based regulation or an individual chemical-by-chemical approach."[85] The Lautenberg Act's unique emphasis on protecting "potentially exposed or susceptible subpopulations" recognized, in part, that the historical regulation of pollutants resulted in some subpopulations, including low-income, minority, and indigenous communities, being disproportionately impacted by chemical contamination.

In addition to the general gaps in coverage, environmental justice communities are often disproportionately exposed to sources of chemical contamination. For instance, a report by the General Accounting Office revealed that:

- three-quarters of hazardous waste landfill sites in eight southeastern states were located in communities whose residents were primarily poor and African-American or Latino, and
- race and ethnicity were the most significant factors in deciding where to place landfills, waste and environmentally hazardous facilities.[86]

EPA's exclusion from the problem formulations of exposure pathways resulting from environmental releases fails to recognize that environmental justice communities have not historically been protected by other environmental statutes and are often disproportionately exposed to chemical substances through disposal and other conditions of use. These exclusions will result in unfair treatment to environmental justice communities by ensuring that they will continue to "bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental and commercial operations or policies."[87]

Moreover, EPA's exclusions of exposure pathways linked to disposal sites and legacy use, associated disposal, and legacy disposal will specifically underestimate the exposures of environmental justice communities. In fact, NEJAC has previously informed EPA of this exact concern:

> It is particularly important to recognize historical exposures in communities and tribes suffering environmental injustice. In some cases, community members were exposed to pollutants for many years in the past from facilities that are *no longer functioning or in business*. These past exposures could act to increase the body burden of a subpopulation so that vulnerable individuals start off at a higher dose. Even if the dose-response curves among the subpopulation are the same as the general population, starting off at a higher point on this curve puts the members of the vulnerable subpopulation at greater risk for exposure to the same amount of a compound than the

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[85] *Id.* at 11.

[86] General Accounting Office, *Siting Hazardous Waste Landfills and Their Correlation with Race and Economic Status of Surrounding Communities* at 13-21 (1983), https://www.gao.gov/products/RCED-83-168.

[87] EJ 2020 GLOSSARY, https://www.epa.gov/environmentaljustice/ej-2020-glossary.

general population. This fact is highly pertinent to the historical legacy of racial and economic discrimination, and the relationship of vulnerability to health disparities.[88]

Failing to consider exposures linked to disposal, legacy uses, associated disposal, and legacy disposal systematically underestimates the background level of exposures faced by many environmental justice communities. In order to determine whether those communities will face an unreasonable risk of injury from the chemicals undergoing risk evaluation, EPA must consider exposures from disposal, legacy uses, associated disposal, and legacy disposal.

13. EPA needs to accurately evaluate real-world occupational and consumer exposures.

A. EPA needs to explain how it will incorporate consideration of engineering controls, personal protective equipment (PPE), and labeling into its analyses.

All but one of the problem formulations state that EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios." *See, e.g.*, Problem Formulation for Perchloroethylene at p. 71; Problem Formulation for DCM at p. 64; Problem Formulation for Asbestos at p. 49; Problem Formulation for 1-BP at p. 66; Problem Formulation for 1,4-Dioxane at p. 49; Problem Formulation for Carbon Tetrachloride at p. 55; Problem Formulation for HBCD at p. 63; Problem Formulation for NMP at p. 57; Problem Formulation for TCE at p. 64. But EPA has provided an inadequate explanation for how EPA will consider this information or what assumptions EPA will make when doing so.

In its response to comments on its earlier Scope Documents, EPA states that: "When appropriate, in the risk evaluation, OPPT will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical."[89] As a general rule, at a minimum, EPA should always evaluate each exposure scenario without the engineering controls and PPE unless EPA has solid evidence that the scenario without engineering controls and/or PPE never occurs in the real world. In addition, EPA needs to rely on its information authorities to obtain accurate empirical evidence about how widely these measures are used as well as how effective these measures are at reducing exposure. Absent such evidence, EPA cannot assume that they are widely used or effective.

For example, Kemira submitted a comment letter alerting EPA to certain industrial applications of NMP, and in that letter, Kemira described certain "ideal" PPE worn during the use of the chemical.[90] EPA certainly cannot assume that such use of NMP will be accompanied by "ideal" PPE without strong

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[88] National Environmental Justice Advisory Council, Cumulative Risks/Impacts Work Group, *Ensuring Risk Reduction in Communities with Multiple Stressors: Environmental Justice and cumulative Risks/Impacts* at 24 (Dec. 2004), https://www.epa.gov/sites/production/files/2015-04/documents/ensuringriskreducationnejac.pdf (emphasis added).

[89] EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA p.4, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051.

[90] *See* Comment submitted by Colleen M. Snyder, Manager, Product Stewardship and Regulatory Affairs, Kemira, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0085.

evidence that people always use the relevant PPE. Instead, EPA should prepare a risk evaluation analyzing the risks without "ideal" PPE, since non-ideal scenarios could easily occur in the real world.

B. Even where engineering controls and/or PPE are used to some extent, EPA should always evaluate exposures scenarios without engineering controls and PPE in order to assess exposures and risks to those subpopulations not subject to such controls.

Rarely if ever in the real world will an exposure scenario involve 100% use and efficiency of engineering controls and/or PPE, so EPA always will need to evaluate exposure scenarios both with and without such controls. This is because, under TSCA, EPA is required to evaluate and protect against risk to potentially exposed or susceptible subpopulations including those "who, due to *** greater exposure, may be at greater risk." 15 U.S.C. § 2602(12).

If EPA has reliable affirmative evidence as to the extent of use and efficiency of use of engineering controls and PPE for a given scenario, it may be able to estimate overall exposures arising from the scenario. However, that does not absolve the agency of an obligation to evaluate exposures and risks for the subset of people for whom those controls are not in place or do not reach 100% efficiency.

Absent such empirical evidence, EPA should assume no use of engineering controls or PPE in evaluating exposure, or at least apply reasonable worst-case assumptions as to the extent and efficiency of their use.

EPA should additionally analyze the exposure scenario with engineering controls and/or PPE, to evaluate exposures for the subset of people for whom those controls are in place. In doing so, however, EPA should evaluate exposures resulting from varying efficiencies in exposure reduction achieved by the controls. Such analyses may also be valuable at a later risk management stage.

C. EPA should never rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

EPA should not inaccurately assume that people comply with all warning labels and always use PPE. EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Procurement and reliance on such data clearly constitute best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures and doing so effectively, EPA should assume that they are or may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide such information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g.,

substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures.[91] EDF incorporates and reiterates the points made in those comments here.

14. Assessment factors do not lead to conservative calculations; in fact, assessment factors account for real-world sources of variability as well as database limitations.

In the problem formulations, EPA often states that it used a "conservative approach" and "conservative assumptions" when assessing aquatic environmental exposures. *See, e.g.*, Problem Formulation for 1,4-Dioxane at p. 29. These statements at least in part appear based on EPA's use of assessment factors (AFs) in developing the concentrations of concern (COCs). In fact, AFs account for real-world sources of variability as well as database limitations, and cannot be construed as "safety factors" that yield conservative estimates. As EPA acknowledges: "The application of AFs provides a lower bound effect level that would likely encompass more sensitive species not specifically represented by the available experimental data. AFs are also account for differences in inter- and intra-species variability, as well as laboratory-to-field variability." *Id.* at 70.

The National Academy of Sciences, in its 2009 report titled *Science and Decisions: Advancing Risk Assessment* has this to say on this subject, albeit in the context of human rather than environmental health:

> Another problem *** is that the term *uncertainty factors* is applied to the adjustments made to calculate the RfD [reference dose, derived from, e.g., a no-effect level] to address species differences, human variability, data gaps, study duration, and other issues. The term engenders misunderstanding: groups unfamiliar with the underlying logic and science of RfD derivation can take it to mean that the factors are simply added on for safety or because of a lack of knowledge or confidence in the process. That may lead some to think that the true behavior of the phenomenon being described may be best reflected in the unadjusted value and that these factors create an RfD that is highly conservative. But the factors are used to adjust for differences in individual human sensitivities, for humans' generally greater sensitivity than test animals' on a milligrams-per-kilogram basis, for the fact that chemicals typically induce harm at lower doses with longer exposures, and so on. At times, the factors have been termed *safety factors*,

[91] *See, e.g.*, EDF Comments on TSCA Review and Scoping for First 10 Chemicals under the Lautenberg Act at 6 (Mar. 15, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046; EDF Comments on Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices (Nov. 21, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052.

> which is especially problematic given that they cover variability and uncertainty and are not meant as a guarantee of safety.[92]

In evaluating risks, EPA should recognize that AFs ensure greater accuracy and do not provide a safety factor rendering the evaluation "conservative."

15. EPA's discussion of its systematic review methodology is insufficiently explained and suggests that EPA is taking an approach to the evidence that violates TSCA §§ 26(i) and 26(h).

In the problem formulations, EPA states that it will rely on data and studies that meet the "systematic review" data quality criteria.

> Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018) document. *** Hazards identified by studies *meeting data quality criteria* will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

Problem Formulation for TCE at p. 69 (emphases added); *see also* Problem Formulation for 1-BP at p. 69; Problem Formulation for 1,4-Dioxane at p. 51; Problem Formulation for Carbon Tetrachloride at p. 57; Problem Formulation for HBCD at p. 71; Problem Formulation for DCM at p. 68; Problem Formulation for NMP at p. 60; Problem Formulation for Perchloroethylene at p. 75.

EPA has not explained, either here or in its OCSPP Systematic Review document, what it means for data or studies to "meet the systematic review data quality criteria." EPA must do so.

Moreover, this language suggests EPA will apply its data quality criteria in a black-or-white manner: a study is either in or out. How is this consistent with the statute's requirement that EPA take a weight-of-evidence approach? How is it consistent with the scientific standards in TSCA section 26(h), which require EPA to consider the "extent" or "degree" to which various factors characterize information, methods, models, etc. – which does not support the black-or-white approach EPA appears to intend to apply. EDF has previously explained that TSCA §§ 26(h) and 26(i) contemplate EPA weighing various information, see Appendix A at 55-57, and EPA should implement those requirements consistent with that approach.

16. EPA's description of systematic review is scientifically flawed and needs extensive revision to align with best practices and leading systematic review approaches.

EPA's description of systematic review in the problem formulations is wholly deficient. Specifically, EPA describes systematic review as follows: "EPA/OPPT generally applies a systematic review process and workflow that includes: (1) data collection, (2) data evaluation and (3) data integration of the scientific

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[92] NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT at chp. 5, p. 132 (2009), https://www.ncbi.nlm.nih.gov/pubmed/25009905 (emphases in original).

data used in risk evaluations developed under TSCA." Problem Formulation for Asbestos at p. 13; Problem Formulation for 1-BP at p. 15; Problem Formulation for 1,4-Dioxane at p. 14; Problem Formulation for Carbon Tetrachloride at p. 15; Problem Formulation for HBCD at p. 16; Problem Formulation for DCM at p. 17; Problem Formulation for NMP at p. 14; Problem Formulation for PV 29 at p. 11; Problem Formulation for Perchloroethylene at p. 18; Problem Formulation for TCE at p. 16.

A. EPA fails to address protocol development, which is a fundamental component of systematic review.

A major deficiency in this description of EPA's systematic review approach, and in its related OCSPP Systematic Review document, is the complete absence of protocol development—a fundamental component of systematic review.

As noted in the 2014 National Academy of Sciences (NAS) report that reviewed EPA's IRIS program:

> Critical elements of conducting a systematic review include formulating the specific question that will be addressed (problem formulation) and *developing the protocol* that specifies the methods that will be used to address the question (protocol development).[93]
>
> After the systematic-review questions are specified, protocols for conducting the systematic reviews to address the questions should be developed. *A protocol makes the methods and the process of the review transparent, can provide the opportunity for peer review of the methods, and stands as a record of the review.* It also minimizes bias in evidence identification by ensuring that inclusion of studies in the review does not depend on the studies' findings. Any changes made after the protocol is in place should be transparent, and the rationale for each should be stated. EPA should include protocols for all systematic reviews conducted for a specific IRIS assessment as appendixes to the assessment.[94]

EPA's IRIS program reflects this NAS recommendation by developing problem formulation and assessment protocols for each of its assessments.[95] OCSPP needs to develop full protocols for each of its risk evaluations, and should consult with the IRIS program on how best to do so in consideration of requirements under TSCA.

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[93] Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* at p. 5 (2014), https://www.ncbi.nlm.nih.gov/books/NBK230060/ (emphasis added).
[94] *Id.* at 6 (emphases added).
[95] U.S. EPA, Office of Research & Dev., National Academy of Science Committee to Review Advances Made to the IRIS Program at slide 23 (Feb. 2018), http://nas-sites.org/dels/files/2018/01/AdIRIS-15.pdf.

B. EPA fails to describe its approach to evidence integration (weight of evidence) despite claims that it has done so in the problem formulation.

EPA has also failed to describe its approach to evidence integration at all. In multiple instances, EPA points to its OCSPP Systematic Review document as providing more information on how it plans to conduct evidence integration. For example, EPA states:

> Evaluate the weight of the evidence for consumer exposures. EPA will rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. *Refer to the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018) document for more information on the general process for data integration.*

Problem Formulation for TCE at p. 65 (emphasis added); *see also, e.g.*, Problem Formulation for Asbestos at p. 52; Problem Formulation for 1-BP at p. 59; Problem Formulation for 1,4-Dioxane at p. 49; Problem Formulation for Carbon Tetrachloride at pp. 54-57; Problem Formulation for HBCD at pp. 60, 68, 70, 71; Problem Formulation for DCM pp. 62-66; Problem Formulation for NMP at p. 60; Problem Formulation for Perchloroethylene at p. 67.

In fact, EPA has not described its approach to data (evidence) integration in any of its problem formulations, nor in its OCSPP Systematic Review document. Indeed, OCSPP has not described its approach to evidence integration anywhere. Instead, it appears that EPA intends to do so in each individual draft chemical risk evaluation and in the absence of a protocol established up front. This approach is hugely problematic, lending itself to bias and inconsistency in how EPA conducts weight of evidence across risk evaluations. EPA should describe its general approach to evidence integration in a revised systematic review methodology document and then incorporate that into specific protocols it develops for each risk evaluation (see EDF's comments on EPA's OCSPP Systematic Review document).

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More broadly, in revising its approach to conducting systematic review, we recommend that OCSPP consult with IRIS, the National Toxicology Program's Office Health Assessment and Translation, and other leading experts on the application of systematic review for chemical assessment, as discussed further in EDF's comments on EPA's OCSPP Systematic Review document.[96]

[96] EDF Comments on Application of Systematic Review in TSCA Risk Evaluations (Aug. 16, 2018), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0210.

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17. EPA's vague description of its intended approach to dose-response modeling lacks sufficient explanation and scientific justification.

In eight of the problem formulations, in describing how it expects to analyze human health hazards, EPA states:

> Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA Benchmark Dose Technical Guidance Document.

Problem Formulation for 1-BP at p. 69; Problem Formulation for 1,4-Dioxane at p. 51; Problem Formulation for Carbon Tetrachloride at p. 58; Problem Formulation for HBCD at p. 72; Problem Formulation for DCM at p. 68; Problem Formulation for NMP at p. 60; Problem Formulation for Perchloroethylene at p. 75; Problem Formulation for TCE at p. 69.

For many chemicals, the biological processes underlying observed effects are not well understood or may not be understood at all. This is the case even for pharmaceuticals available on the market today. The National Research Council wrote in its 2014 report, *Review of EPA's Integrated Risk Information System (IRIS) Process*, that "if FDA were required to organize drug safety around mechanism, it would be nearly impossible to regulate many important drugs because the mechanism is often not understood, even for drugs that have been studied extensively."[97] Indeed, an earlier 2010 Nature Medicine editorial noted:

> It is true that we use many highly prescribed drugs without a clear idea of how they work—which targets they hit, what processes they alter and which of these actions are required for therapeutic efficacy. For instance, lithium, used to treat bipolar disorder, modulates many molecular targets, but which—or how many—of these are required for its beneficial effects is uncertain.[98]

EPA should fully describe how it intends to approach dose-response modeling in the absence of sufficient knowledge underlying biological processes, as will be the case with endpoints associated with numerous chemicals EPA evaluates. For example, in the context of trichloroethylene, the mechanistic

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[97] Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* at chp. 6, p. 90 (2014), https://www.ncbi.nlm.nih.gov/books/NBK230065/.
[98] Editorial, *Mechanism Matters*, 16:4 Nature Med. 347 (Apr. 2010), https://www.nature.com/articles/nm0410-347.pdf.

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basis for the identified association with Parkinson's disease is not yet fully understood,[99] yet there is compelling scientific evidence demonstrating the association.[100]

More broadly, EPA must employ health-protective approaches to dose-response modeling, as described at length in the National Academy of Sciences (NAS) report, *Science and Decisions: Advancing Risk Assessment*.[101] Among other recommendations, the NAS argued that "***cancer and noncancer responses [to chemical exposures] be assumed to be linear as a default****."[102]

18. EPA's must consider acute exposures in evaluating developmental effects.

In all but one of the problem formulations, EPA uses this or similar language:

> When conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. *For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios*. This means that it is unlikely that every hazard identified in the scope document will be considered for every exposure scenario.

Problem Formulation for TCE at p. 39 (emphasis added); *see also* Problem Formulation for Asbestos at p. 33; Problem Formulation for 1-BP at p. 41; Problem Formulation for 1,4-Dioxane at p. 32; Problem Formulation for Carbon Tetrachloride at p. 39; Problem Formulation for HBCD at p. 40; Problem Formulation for DCM at p. 41; Problem Formulation for NMP at p. 38; Problem Formulation for Perchloroethylene at p. 48.

EPA's proposal here is deeply concerning, and suggests that the agency plans to ignore its own established guidance[103] on the evaluation of chemical hazards and risks.

We will illustrate these concerns with an example for TCE. EPA's 2011 Integrated Risk Information System (IRIS) assessment[104] correctly identified fetal cardiac malformation, a developmental toxicity effect, as the most sensitive endpoint and supported by multiple lines of evidence—epidemiological, laboratory animal, metabolism, and mechanistic studies. EPA OCSPP reaffirmed this conclusion in its

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[99] Edward A. Lock, et al., *Solvents and Parkinson disease: A systematic review of toxicological and epidemiological evidence*, 266:3 TOXICOLOGY & APPLIED PHARMACOLOGY 345 (Feb. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3621032/.

[100] U.S. EPA, Office of Research & Dev., *Toxicological Review of Trichloroethylene Appendix D* (Sept. 2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/Appendix_D_0199tr.pdf.

[101] NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT (2009), https://www.ncbi.nlm.nih.gov/books/NBK214630/.

[102] *Id.* at chp. 5, p. 180.

[103] *See* U.S. EPA, *Guidelines for Developmental Toxicity Risk Assessment* (Dec. 1991), https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.

[104] U.S. EPA, *Toxicological Review of Trichloroethylene (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS)* (Sept. 2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

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2014 TCE work plan risk assessment.[105] The TCE problem formulation introduces the possibility that EPA may exclude developmental toxicity as an acute effect—a decision that would not only be odds with EPA's past assessments, proposed regulations, and guidance but also at odds with applying a health-protective approach to chemical risk evaluation.

As described in EPA's proposed section 6 proposed TCE rules[106,107] and in the 2014 TCE risk assessment, EPA relied on developmental endpoints for assessing health risks of TCE resulting from acute exposure. This is in alignment with EPA's longstanding agency-wide guidance, Guidelines for Developmental Toxicity Risk Assessment,[108] which indicates that even a single exposure to a chemical within a critical window of development may produce adverse developmental effects. For example, EPA's proposed section 6 TCE rule, Trichloroethylene (TCE) Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), states:

> As indicated in the TCE risk assessment, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy presumes that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (Ref. 5). This is the case with cardiac malformation. EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional developmental studies of TCE metabolites (Appendix N) (Ref. 2). EPA based its acute risk assessment on the most sensitive health endpoint (i.e., fetal heart malformations) representing the most sensitive human life stage (i.e., the developing fetus) (Ref. 2).[109]

EPA needs to follow this established EPA risk assessment practice, and include developmental toxicity effects in its assessment of acute exposure from chemicals. In the case of TCE, EDF strongly recommends that the agency include fetal cardiac malformations in its assessment of acute effects in addition to its assessment of chronic effects. EPA has provided no basis for deviating from this practice in its problem formulation, and to do so would deviate from using the best available science as required under TSCA.

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[105] US EPA, Office of Chemical Safety and Pollution Prevention. "TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses." June 2014. EPA Document #740-R1-4002. Available: https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

[106] Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91595, 91599 (proposed Dec. 16, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0001.

[107] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432, 7435, 7439 (proposed Jan. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001.

[108] U.S. EPA, *Guidelines for Developmental Toxicity Risk Assessment* at 4, 45 (Dec. 1991), https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.

[109] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432, 7439 (proposed Jan. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001.

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More broadly, EPA must closely examine any effect it believes to arise only from chronic exposures to determine whether in fact this is true across the diverse human population, including where potentially exposed or susceptible subpopulations may be at increased risk for effects after shorter periods of exposure compared to the general population.

19. Where EPA adopts a tiered approach to exposure analyses, EPA must not repeat the errors from its cursory dismissals of certain exposures.

In a number of the problem formulations, EPA indicates it plans to use a tiered approach in further analyzing exposure scenarios. *See, e.g.*, Problem Formulation for 1-BP at p. 63; Problem Formulation for NMP at p. 58; Problem Formulation for Asbestos at p. 73; Problem Formulation for HBCD at p. 67. Throughout our comments, EDF has criticized aspects of EPA's exposure analyses used to decide it will not conduct further analysis and its rush to judgment that certain exposures pose no unreasonable risk. These concerns, addressed in our chemical-specific comments, include (but are not limited to):

- equating a lack of information to mean there is no or low exposure;
- questionable characterization of models or assumptions as conservative;
- assertions of low exposure based on EPA "expectations" that are insufficiently justified or documented;
- dismissal of serious data gaps with no plan to fill them and instead resorting to modeling or use of data on surrogate chemicals; and
- reliance on unverified or very limited information sources to make sweeping conclusions.

To the extent that EPA's reference to using a tiered approach to exposure analysis going forward indicates EPA plans to conduct and rely on the same types of cursory analyses, these same critiques will apply and EPA's use of such analysis to discard additional exposures scenarios will be equally arbitrary and inconsistent with TSCA's requirement that EPA use the best available science.

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COMMENTS ON SPECIFIC PROBLEM FORMULATIONS

Comments on Asbestos

EDF has raised numerous serious concerns about this problem formulation throughout these comments (search for "asbestos" to locate them). Here we provide a few additional comments specific to this problem formulation.

20. EPA has unreasonably excluded conditions of use of asbestos.

In the asbestos problem formulation, EPA states that it will exclude "legacy uses, associated disposals, and legacy disposals" from the risk evaluation. U.S. EPA, Problem Formulation of the Risk Evaluation for Asbestos at p. 8 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0131. As EDF previously explained in its comments on the scope, EPA cannot rationally exclude so-called legacy uses and associated disposals. EDF incorporates and reiterates those points here as well. EDF Comments on Ten Scopes under the Toxic Substances Control Act pp.8-9, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069. For the same reasons, EPA cannot rationally exclude so-called legacy disposals. Along with other petitioners, EDF has further developed these arguments in a Brief which is attached as Appendix A. EDF incorporates and reiterates those points here. *See* Appendix A at p. 40-51.

21. Even if EPA promulgates the asbestos SNUR it recently proposed, EPA must still analyze the conditions of use it addressed and the resulting exposures and risks in its risk evaluation of asbestos.

EPA recently proposed a Significant New Use Rule (SNUR) addressing certain conditions of use of asbestos where manufacturing and processing for those uses are no longer ongoing in the United States. 83 Fed. Reg. 26,922 (June 11, 2018). EDF filed comments on this proposal, which we incorporate and reiterate here. EDF Comments on Asbestos; Significant New Use Rule, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0159-1269. As EDF noted in those comments, EPA's promulgation of this SNUR is a needed stopgap measure.

The proposed SNUR includes factual findings that support analyzing the conditions of use identified in the proposal as part of this risk evaluation. EPA acknowledged that "non-friable asbestos-containing building materials can release fibers if disturbed during building repair or demolition." 83 Fed Reg. 26,922, 26,927 (June 11, 2018) (citing 40 C.F.R. part 61, subpart M, Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP)). Thus, EPA acknowledged that these existing conditions of use continue to result in exposures and present a significant risk to the public, so EPA should be analyzing those exposures and risks in its risk evaluation. Notably, ignoring this evidence would be irrational and arbitrary because it leads to overlooking real-world risks.

As EPA noted, absent the proposed SNUR, these conditions of use could resume "at any time, without prior notice to EPA." *Id.* However, promulgation of that SNUR would not justify EPA's decision to ignore those conditions of use in its risk evaluation of asbestos. As noted above, EDF has previously articulated that EPA must consider *all* conditions of use when preparing a risk evaluation under TSCA § 6. A SNUR does not change the statutory requirement that EPA consider *all* conditions of use in its risk evaluations, especially because a SNUR does not permanently foreclose any conditions of use. A SNUR is not a ban on a condition of use, and indeed, the TSCA § 5 process contemplates that persons can submit significant new use notices with the intent of engaging in the significant new use in the future. Thus, these significant new uses remain reasonably foreseen, and only a subsequent order or rule issued by EPA following its review of a SNUN could foreclose such a condition of use.

Moreover, the existence of the SNUR does not change the fact that these conditions of use are "known" to have occurred in the past, and these conditions of use are definitely "reasonably foreseen." 15 U.S.C. § 2602(4). Congress included "reasonably foreseen" circumstances within TSCA with the express goal of ensuring that EPA swept more broadly than known (or intended) uses; EPA cannot evade that duty by limiting its analysis to conditions of uses with evidence of current, ongoing use—such an interpretation would effectively limit EPA's analysis to "known" uses. Reasonably foreseen is a term of art with a long history in the law; it is well established under the law that "[a] natural and probable consequence is a foreseeable consequence. But to be reasonably foreseeable [t]he consequence need not have been a strong probability; a possible consequence which might reasonably have been contemplated is enough." *People v. Medina*, 209 P.3d 105, 110 (Cal. 2009) (internal citations and quotation marks omitted). Numerous courts have recognized that circumstances are reasonably foreseen when similar circumstances have occurred in the past. *See, e.g.*, *McKown v. Simon Prop. Grp., Inc.*, 344 P.3d 661, 663 (Wash. 2015); *Burns v. Penn Cent. Co.*, 519 F.2d 512, 515 (2d Cir. 1975). The fact that these conditions of use occurred in the past establishes that they are reasonably foreseen. And in the SNUR, EPA acknowledged that "the importing or processing of asbestos (including as part of an article) for the significant new uses proposed in this rule may begin at any time." 83 Fed. Reg. at 26,927.

Hence, even if EPA promulgates the asbestos SNUR it recently proposed, EPA must still analyze the conditions of use the SNUR addressed and the resulting exposures and risks in its risk evaluation of asbestos.

Comments on 1-Bromopropane

22. EPA has excluded or failed to sufficiently identify and analyze relevant conditions of use, exposure pathways, hazards, and vulnerable subpopulations for 1-Bromopropane.

A. EPA has provided insufficient justification for its exclusion of certain activities from the risk evaluation based on not being conditions of use or not being expected to occur.

EPA plans to exclude certain uses of 1-bromopropane (1-BP) from the risk evaluation by concluding the activities should not be considered conditions of use:

Agricultural non-pesticidal industrial/commercial/consumer use: EPA provides only a single statement with no relevant reference as the basis for this exclusion:

> Based on information available to EPA, EPA determined that 1-BP is not used in agricultural products (non-pesticidal), only in the processing of such products.

U.S. EPA, Problem Formulation of the Risk Evaluation for 1-Bromopropane at p. 19 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0741-0067. The only source EPA cites (in Table 2-2) is the data EPA collected in 2016 under the Chemical Data Reporting (CDR) rule. This source indicates that a company in fact reported domestic manufacture of 1-BP for "industrial processing and use" in the "Pesticide, fertilizer, and other agricultural chemical manufacturing" sector, and further reported it accounted for 25% of its total production. Several questions remain:

First, EPA provides no indication of how it determined that 1-BP is "not used in agricultural products (non-pesticidal), only in the processing of such products." As written, this stands as a mere assertion by EPA.

Second, the activity reported in the CDR is clearly a "condition of use" of 1-BP, which is reported as being manufactured for this very purpose, and EPA has no basis to exclude such a condition of use simply because it entails downstream processing of agricultural products (non-pesticidal) by others, rather than being an ingredient in such products. Processing is itself a condition of use.

Third, while the CDR data indicate the chemical is an intermediate and processed as a reactant, EPA has not provided any data demonstrating unreacted 1-BP is not present in the final product as a residual.

Fourth, even were EPA to establish that 1-BP is not present as a residual in non-pesticidal agricultural products, that is no basis for a wholesale exclusion from the risk evaluation of all of the activities associated with 1-BP in this sector, including worker exposures, environmental releases, etc.

Finally, as EPA well knows, CDR reporting is subject to numerous limitations, including volume thresholds and reporting exemptions that preclude EPA from relying solely on it to conclude manufacturing or processing for a particular use is not occurring.

EPA has provided an inadequate rationale for excluding this condition of use; EPA should analyze this condition of use in the risk evaluation.

Consumer use of adhesives (except as an adhesive accelerant for arts and crafts), engine degreasing, and brake cleaning: EPA's only rationale for these exclusions is as follows:

> A review of the use of 1-BP as a solvent in adhesives, engine degreasers, and in brake cleaners showed that these uses of 1-BP are not consumer uses, except as an adhesive accelerant in arts and crafts. In all other uses of 1-BP as an adhesive, 1-BP-containing adhesives are sold through wholesale channels for commercial and industrial uses, and usually in amounts larger than consumers could use. 1-BP has never been advertised (or used) as a consumer brake cleaner or engine degreaser. ... Also, consumers will avoid the use of 1-BP as an engine degreaser or brake cleaner because 1-BP is expensive. In general, heavy duty degreasers containing 1-BP are twice the cost of other heavy duty degreasers and five times the cost of other available consumer brake cleaners. (pp. 19-20)

EPA's problem formulation fails to provide adequate support for these exclusions.

First, no sources or supporting data are cited or provided. In the accompanying Table 2-2, the only sources EPA lists, purportedly to support these exclusions, in fact do the opposite.

- For adhesives, EPA cites two sources: First, its 2016 draft Work Plan Risk Assessment for 1-BP, which was in large part driven by concerns over just such consumer uses. Second, EPA also cites a March 2017 letter submitted to EPA by EnviroTech, which clarifies that 1-BP is used as a carrier for adhesives, but does not address the assertions about consumer use, wholesale vs. retail sales, or advertising that EPA makes.[110]

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[110] The Enviro Tech letter does state, however:

> The use of nPB [n-propyl bromide, a synonym for 1-BP] in the Adhesive sector has a *sad history of over-exposure of workers*. In June, 2007, USEPA proposed to find nPB as unacceptable for use in the Adhesive, Coatings and Inks sector. Enviro Tech, along with the vast majority of our competitors and suppliers, have publically supported this proposed SNAP rule [issued under EPA's Significant New Alternatives Policy (SNAP) program, which identifies substitutes to ozone-depleting chemicals]. Unfortunately, USEPA has seen fit, without further comment, to leave the rule as only proposed by *not issuing a final rule for ten years*. After discussing the health effects of nPB in over 35 pages of text in the rule and proposed rules published ion [*sic*] 2007, we cannot understand why the USEPA would leave a rule in limbo for ten years, despite having the support of the industry that would be regulated by that rule. USEPA immediately issuing a final rule under SNAP would address an important concern shard by the industry and USEPA as noted in its TSCA documents on nPB. (p. 3, emphases added)

This excerpt is telling in that it notes that adhesive use of 1-BP remains a major concern and has not been addressed through existing regulatory authorities.

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- For brake cleaners or engine degreasers, EPA cites only its own 2017 use document, "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1-Bromopropane," ("Use document") which prominently identifies the very uses EPA now plans to exclude.

Based on EDF's own search of the docket, we located a document posted by EPA but not cited in the problem formulation for brake cleaners or engine degreasers.[111] The document, dated February 2018, purports to support EPA's assertion that 1-BP-containing brake cleaners and engine degreasers are not used by consumers. It consists of two short paragraphs of "analysis" based on a single company's "product guide." The analysis makes numerous assumptions and leaps of logic in its effort to sweepingly conclude that consumers never purchase and use 1-BP-containing brake cleaners or engine degreasers, largely built on questionable notions of consumers' preferences and knowledge.

It is indeed worth highlighting that even EPA states: "It should be noted that some consumers may purchase and use products primarily intended for commercial use." (p. 49) Yet EPA plans to omit such uses entirely.

Second, EPA's own current problem formulation contradicts itself. On p. 10 EPA states:

> Consumers and bystanders may be exposed to 1-BP from various consumer uses such as *aerosol and spray adhesives*, aerosol spot removers and aerosol *cleaning and degreasing products*. For 1-BP, EPA considers workers, occupational non-users, consumers, bystanders, and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. (p. 10, emphases added)

Third, even if EPA has evidence these uses are not currently ongoing, on what basis can it conclude the uses are not "reasonably foreseen"? Such uses have not been banned (that could be done through a rulemaking pursuant to the current risk evaluation). Nor is there any serious structural, economic or technical rationale EPA has provided for why they could not resume. As discussed in detail earlier in the comments (see Section 4.A), EPA must assume that past uses, absent a regulatory ban, are reasonably foreseen and include them in its risk evaluations.

Interestingly, EPA itself makes an argument for the potential for a different use of 1-BP to return or increase. It does so when discussing, in this same section of the problem formulation, the use of 1-BP in dry cleaning:

> EPA currently believes that few dry cleaners use 1-BP as a dry cleaning solvent. *** However, *the use of 1-BP in the dry cleaning industry remains a reasonably foreseen condition of use.* EPA is currently evaluating tetrachloroethylene (perc) under TSCA, and

[111] *See* EPA-HQ-OPPT-2016-0741-0065.

> if EPA were to restrict the use of perc in dry cleaning, many dry cleaners might use 1-BP in their machines *absent regulatory restrictions from doing so*." (p. 20, emphases added)

This logic – that other events could later alter the extent of use of a chemical – is among the reasons why Congress required EPA to include "reasonably foreseen" conditions of use in its risk evaluations under TSCA. The same logic should have been extended to other uses EPA intends to exclude altogether.

In sum, EPA has provided inadequate and contradictory reasons for excluding the consumer uses of 1-BP as a solvent in adhesives, engine degreasers, and in brake cleaners. EPA should analyze these conditions of use in the risk evaluation.

Consumer disposal of consumer products: EPA plans not to analyze this activity based on an unsupported assumption that exposure from this activity is not expected. EPA states:

> EPA does not expect exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans. Liquid products may be recaptured in an alternate container following use (refrigerant flush or coin cleaning). (p. 39, repeated verbatim on p. 50)

EPA provides no evidence to support its expectation and anticipation. In addition, in the last sentence EPA also contradicts itself about the potential for consumer exposure; the uses it identifies as potentially involving "recapture[] in an alternative container following use" – refrigerant flush and coin cleaning – are both listed as consumer uses in Table 2-3. Consumer collection and disposal of spent 1-BP after these uses, even if done in a different container, may well lead to consumer exposures. EPA should analyze the potential exposure to consumers from disposal of consumer products.

B. Major deficiencies abound in EPA's assertion that exposures to 1-BP falling under other legal jurisdictions are adequately managed.

We have discussed earlier (see Section 5) the many legal flaws in EPA's assertion that it can ignore exposure pathways that fall under other EPA authorities and assume they "adequately assess and effectively manage" any risks. EPA's 1-bromopropane problem formulation also contains technical and scientific flaws or inaccuracies that result in EPA's failure to adequately justify on scientific grounds the sweeping exposure pathway exclusions it has proposed. To illustrate, we provide below some specific comments on examples of unsupported or insufficiently supported statements in the document.

Exclusion of landfill releases: EPA states:

> 1-BP migration to groundwater from RCRA Subtitle C landfills or RCRA Subtitle D municipal landfills regulated by the state / local jurisdictions to groundwater *will likely be mitigated* by landfill design (double liner, leachate capture for RCRA Subtitle C landfills and single liner for RCRA Subtitle D municipal landfills) and requirements to

> adsorb liquids onto solid adsorbent and containerize prior to disposal. (p. 32, emphasis added)

Reflected perhaps in the conditional language it uses ("will *likely* be mitigated"), EPA neither provides nor cites any data or analysis to support this sweeping assertion. Where authority is or can be delegated to states, as is the case with the Resource Conservation and Recovery Act (RCRA), differential state enforcement of laws and regulations can mean that the actual extent of protection from risks can vary greatly; see Section V.I. A 2011 report from EPA's Office of the Inspector General extensively documented insufficient EPA oversight of state enforcement as well as large state-to-state variations.[112]

Later in the problem formulation, EPA drops even the conditional language and asserts unequivocally as to the adequacy of existing disposal regulations – yet still fails to provide any supporting data or analysis. For example, on p. 34 EPA states without qualification: "EPA will not further analyze releases to hazardous waste landfills because these types of landfill mitigate exposure to the wastes."

Overstating of 1-BP's regulation as hazardous waste: In its zeal to rely on RCRA to exclude all disposal-related exposure pathways, EPA glosses over important distinctions in how hazardous wastes are identified under RCRA. In its general introductory discussion of applicable regulations, EPA states:

> Some industrial and commercial users use 1-BP as a general degreaser because chlorinated solvents are listed hazardous wastes under RCRA, *whereas 1-BP is not, and therefore waste containing 1-BP may not be hazardous* depending on the characteristics of the overall waste stream. (p. 20, emphasis added)

Later, however, when seeking to justify its exclusions, EPA gets rather more definitive:

> Solid wastes containing 1-BP may be regulated as a hazardous waste under the RCRA waste code D001 (ignitable liquids, 40 CFR 261.21). (p. 32)

And still later it gets even more definitive (and more inaccurate):

> 1-BP is regulated as a hazardous waste, waste code D001 (ignitable liquids, 40CFR 261.21). (p. 54)

Finally, buried in an appendix, EPA acknowledges:

> Currently, 1-BP is not regulated under federal regulations as a hazardous waste. (p. 92)

1-BP is not in fact listed as a hazardous waste under RCRA and would only be identified as one if it was disposed of in high enough concentrations to meet the characteristic of "ignitability." Yet EPA has repeatedly and inaccurately invoked disposal of 1-BP as subject to RCRA hazardous waste regulations.

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[112] U.S. EPA, Office of Inspector General, *EPA Must Improve Oversight of State Enforcement* (Dec. 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20111209-12-p-0113.pdf.

EPA should analyze the exposures resulting from disposal of 1-BP based on real scientific evidence.

Vague references to further regulation-based exclusions to come: Even where it does not intend – or at least has not yet expressed its intention – to exclude an exposure pathway or condition of use, EPA vaguely indicates it plans to further consider statutory or regulatory factors to decide whether release or exposure is unlikely or to modify exposure scenarios based on such factors. Again, no detail is provided. For example:

EPA states:

> Information from various EPA statutes (including, for example, regulatory limits, reporting thresholds, or disposal requirements) may be used to assess releases. EPA may determine that a condition of use is *unlikely to result in release* to a particular media based on existing chemical-specific regulations *even though an Emission Scenario or EPA Generic Scenario document indicates a likely release* to that same media. (p. 59, emphases added)

How EPA intends to accomplish these tasks is left a mystery. Moreover, EPA's one-directional statement that it "may determine that a condition of use is unlikely to result in release" based on existing regulations reveals its clear bias: Could not the converse – that the inadequacy of existing regulations makes it likely there will be releases – also be the case?

EPA goes on to state: "EPA will further consider the applicability of EPA regulations to 1-BP during the development of the risk evaluation." (p. 59) This statement suggests more exclusions or conclusions of no or negligible release or exposure are to come. Just what regulations EPA is referring to is far from clear however, especially since two pages later EPA notes how few there actually are for 1-BP: "1-BP is not listed on the TNSSS (Targeted National Sewage Sludge Survey), DMR (Discharge Monitoring Report), or as one of the 189 Hazardous Air Pollutants (HAPs) under Section 112(b) of the Clean Air Act. There are no specific EPA regulations regarding drinking water health advisories, ambient water quality criteria, or effluent level guidelines." (p. 61)

As discussed above in Section 6, EPA should analyze real-world exposures and not assume perfect compliance with existing regulatory limits, to the extent they do exist.

With regards to occupational exposures, EPA states:

> EPA will evaluate and consider applicable regulatory and non-regulatory exposure limits. ... OSHA has not established any occupational exposure limits for 1-BP. However, the American Conference of Governmental Industrial Hygienists (ACGIH) has adopted a recommended Threshold Limit Value (TLV) of 0.1 ppm based on a time-weighted average (TWA) over an 8-hour workday. *EPA will consider the influence of the recommended exposure limits on occupational exposures in the occupational exposure assessment*." (p. 64, emphasis added)

Here again, EPA provides no indication how it will "consider the influence of the recommended exposure limits" – which are voluntary and lack the force of law. EPA is charged with evaluating real-world exposures and should not assume compliance with voluntary exposure guidelines.

Relatedly, EPA states:

> 5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
>
> EPA will review potential data sources on engineering controls and personal protective equipment as identified in Table Apx B-6 in Appendix B and determine their applicability and incorporation into exposure scenarios during risk evaluation. (p. 66)

EPA provides no indication as to how it will "consider and incorporate" such controls or equipment into its exposure scenarios. Myriad questions arise. What assumptions will be made as to their extent of use, their efficacy, etc.? Limitations on the extent of use and the efficacy of workplace controls, especially for PPE, have been illuminated by both OSHA and EPA. EDF discusses these concerns at length in section 13 of these comments.

EPA's vague and unexplained statements about its planned analyses raise serious concerns and often lack any empirical basis. EPA must analyze occupational exposures based on the best available science, and EPA must use its information authorities to obtain reasonably available information about these exposures.

C. EPA over-relies on limited and incomplete TRI data to exclude or dismiss the significance of numerous exposure pathways.

EPA makes extensive use of the very limited 2016 data on 1-BP reported under the Toxics Release Inventory (TRI). It should be noted that 1-BP was only recently added to the TRI and 2016 was the first year it was required to be reported. That may help explain why a TRI report for 1-BP was received from only about 40% of facilities (55 of 140 facilities) expected to report the chemical, a fact EPA discusses (p. 32) but then largely ignores when citing TRI data as the basis for excluding exposure pathways or asserting low release or exposure to 1-BP. In fact, the gap between reported and actual releases may be even worse than that: EPA's summary of TRI data in Table 2-6 on page 33 of the problem formulation shows that very few facilities (often only one) reported any releases at all to various media or waste management facilities, suggesting that there may be more facilities that did not report.

EPA's decision to make sweeping exclusions of exposure pathways or assume negligible releases and exposures based on TRI data alone is troubling, given EPA's own speculation as to why such a large gap exists between the number of TRI reports it received vs. what was expected:

> The difference in estimated versus actual reporting facilities could be due to several factors such as, 1) facilities could be moving away from using 1-BP; 2) *some facilities may not yet be aware of the reporting requirements since this is the first year of*

> *reporting*; 3) *facilities could be below the threshold for reporting*. Facilities are required to report if they manufacture (including import) or process more than 25,000 pounds of 1-BP, or if they otherwise use more than 10,000 pounds of 1-BP. (pp. 32-3, emphasis added)

Beyond this paragraph, EPA never grapples with the enormous uncertainty and likely unreliability of the TRI data on which it so heavily relies, which is further explored below.

Exclusion of exposures from disposal pathways: EPA relies heavily on 2016 TRI data to justify its exclusion of disposal pathways from the 1-BP risk evaluation. For example, EPA states:

> Table 2-6 shows TRI reports approximately 58,000 pounds of disposal to *a single RCRA Subtitle C landfill*. EPA will not further analyze releases to hazardous waste landfills because these types of landfill mitigate exposure to the wastes. TRI also reports approximately 90,000 pounds of 1-BP transferred to other off-site landfills [3 in total]. Further review of TRI data indicated that all reported transfers "other off-site landfills" were to facilities permitted to manage RCRA regulated waste. (p. 34, emphasis added)

EPA has not provided to the public its "further review of TRI data." Given the inadequacy of the TRI data the agency is relying upon, it is certainly plausible that significantly more 1-BP is transferred to "other off-site landfills," which may not be subject to RCRA subtitle C requirements. As discussed above, 1-BP is not listed as a hazardous waste under RCRA.

Assumed low releases to surface water and low exposures via drinking water: EPA reports that there are no water monitoring data for 1-BP (p. 34). Despite their limitations, EPA relies nearly exclusively on TRI data to argue that it need not further analyze exposures via surface water and effectively can conclude such exposures are safe.

First, EPA appears to accept without question the reliability of TRI water release data, even though "[i]n the 2016 TRI, only 1 facility out of 55 reported releases to water." (p. 34) EPA uses the data from this one facility to conclude that this particular discharge was safe: "This facility reported 5 lbs of direct surface water discharge; assuming the release occurred over a single day, the surface water concentration in reported receiving waters is well below the COC [concentration of concern] based on EPA's preliminary calculations." (p. 34)

Then EPA uses those single-facility data to model surface water concentrations *in general*: "EPA used the reported releases from EPA's Toxics Release Inventory (TRI) to predict surface water concentrations near reported facilities for this Problem Formulation." (p. 35) EPA then definitively concludes, based on the TRI data from this one facility, that "*releases to water are very low*." (p. 35, emphasis added)

Building from there, EPA uses an analysis based on the limited TRI data, without any qualification, to assert *all drinking water* exposures are also low:

> Recent TRI reporting indicated 0 pounds released to POTWs and 5 pounds released directly to water in 2016. EPA pretreatment regulations for industrial users discharging

> wastewater to POTWs *are expected* to limit the discharge of 1-BP to POTWs and ultimately to surface water (see Section 2.3.4). Waste disposal practices and 1-BP's rapid volatilization from water *are expected* to mitigate drinking water exposure potential and there is no data of 1-BP found in US drinking water." (p. 39, emphases added)

EPA's reliance on extremely limited TRI data, coupled with unsupported "expectations" that discharges and exposures will be minimal, is capped off here with an outlandish assumption that the lack of monitoring data for 1-BP means it must not be present. Has the chemical even been looked for in drinking water? No data on that question are cited by EPA. And elsewhere EPA notes:

> Environmental monitoring data were not identified in the 2016 Draft Risk Assessment (U.S. EPA, 2016b); however, any environmental monitoring data that may result from the updated literature search will be considered. (p. 34)

EPA cannot equate a lack of evidence of 1-BP's presence in water with evidence of its absence, but that is precisely what EPA appears to be doing here.

The last step in EPA's construction of its house of cards comes on page 68:

> Environmental hazards will not be further analyzed *because exposure analysis* conducted using physical and chemical properties, fate information and *TRI environmental releases for 1-BP* show that ecological receptors are not significantly exposed to TSCA-related environmental releases of this chemical.

EPA makes a wholly exposure-based argument for its decision not to even consider the environmental hazards the chemical may present via water exposures, an approach industry interests have long advocated for, but one which fails to constitute sound science. (Later in these comments, in Section II, EDF addresses additional problems with EPA's calculations of its concentrations of concern for aquatic species.)

Rather than constructing such a tenuous line of argument to compensate for the lack of any water monitoring data for 1-BP, EPA should use its clear TSCA authority under section 4 to require the development of the data.

More broadly, EPA cannot justify its heavy reliance on TRI data without resolving the discrepancies discussed earlier that cast serious doubt on the completeness and accuracy of these data.

D. EPA has excluded without justification identified hazards of 1-BP from its quantitative risk characterization.

EPA states:

> For the 2016 Draft Risk Assessment (U.S. EPA, 2016b) on 1-BP, EPA evaluated studies for the following non-cancer hazards: acute toxicity (acute lethality at high concentrations

> only), blood toxicity, immunotoxicity, cardiovascular toxicity, liver toxicity, kidney toxicity, reproductive toxicity, developmental toxicity, and neurotoxicity. A comprehensive summary of all endpoints considered can be found in the 2016 Draft Risk Assessment. *Five health hazards were used for quantitative risk characterization* and will be evaluated using our systematic review approach. (p. 43, emphasis added)

EPA provides no explanation or justification as to why and how these five, the last five in the list of "-icities" in the above excerpt, were selected. Nor has it explained why it has excluded from the quantitative risk characterization acute toxicity (acute lethality at high concentrations only), blood toxicity, immunotoxicity, and cardiovascular toxicity that were identified in the 2016 draft risk assessment for 1-BP. It needs to do so. Absent a compelling justification supported by the best available science and reasonably available information, EPA must analyze these hazards as well when developing its quantitative risk characterization.

E. EPA has not identified all relevant potentially exposed or susceptible subpopulations.

At the end of its section on Human Health Hazards (section 2.4.2.3), EPA states:

> In developing the hazard assessment, EPA will evaluate available data *to ascertain whether* some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). (p. 45, emphasis added)

This statement stands in contrast to the analogous subsection under Human Exposure (p. 40, section 2.3.5.4), where EPA identified specific subpopulations that "EPA expects to consider in the risk evaluation due to their greater exposure." TSCA requires that EPA identify "potentially exposed or susceptible subpopulations" (TSCA section 6(b)(4)(D)), including those that "due to ... greater *susceptibility* ... may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." TSCA section 3(12).

Given the evidence of reproductive and developmental toxicity for 1-BP, it is clear that, at a minimum, adults of childbearing age, pregnant women, infants and children should be explicitly identified as such subpopulations. Other subpopulations may also warrant identification based on the available hazard data. Yet, unlike in the exposure section (p. 40), EPA has not identified *any* vulnerable populations based on greater susceptibility. This needs to be remedied.

23. EPA relies extensively on assumptions that are inconsistent or not supported with data, and on models that are not conservative, despite claims to the contrary.

<u>*Terrestrial environmental exposures*</u>: EPA states:

> *EPA does not plan to further analyze terrestrial exposures*, due to low expected toxicity (see Section 2.4.1) and low expected exposure based on the physical/chemical properties (e.g., high vapor pressure; see Section 2.1). (p. 35, emphases added)

Yet the cited section 2.4.1 provides no data that demonstrate low toxicity; rather, it cites an *absence* of toxicity data – a clear data gap EPA fails to identify or indicate whether or how it will address:

> During data screening, there were no available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is expected to be low *based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature* and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of 7.3X10-3 atm-m3/mole), high water solubility (2.4 g/L), and low log Koc (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments. (p. 41)

The physical/chemical/fate properties EPA cites may be germane to some sediment- or soil-dwelling organisms, but in no way rule out exposure of terrestrial organisms through inhalation – a pathway that EPA elsewhere acknowledges is quite relevant to the subset of terrestrial organisms otherwise known as humans. Moreover, EPA's effort to dismiss toxicity data gaps based on exposure arguments does not reflect sound science. Nor does EPA's equating a lack of on-topic hazard data with evidence of low toxicity.

EPA must use its information authorities to generate hazard data for sediment-dwelling and other terrestrial organisms.

<u>*Dermal exposures*</u>: With respect to occupational exposures, EPA states:

> [D]ermal exposure to 1-BP based on a single finite exposure event is likely negligible. *** EPA also expects the dermal absorbed fraction to be low (0.16 percent – see discussion under Dermal section of Section 2.3.5.2). However, there is potential for increased dermal penetration for uses where occluded exposure, repeated contact, or dermal immersion may occur. (pp. 36-7)

The first part of the discussion seeks to dismiss dermal exposure as insignificant based on an assumption of a single exposure event involving direct contact with skin that is also exposed to the air. But it is the second set of scenarios, which EPA treats as *exceptions*, that are far more likely to characterize occupational exposures: e.g., repeated contact, liquid or vapor trapped against skin by gloves.

In discussing consumer exposures, EPA states:

> Dermal exposure may occur via vapor/mist deposition onto skin or via direct liquid contact during use, particularly in occluded scenarios. (p. 38)

This scenario is equally or more likely to apply in occupational settings, yet is not mentioned in that section of the problem formulation (section 2.3.5.1).

Still discussing consumer exposures, EPA goes on to state:

> However, measurements of skin penetration were one to two orders or magnitude higher in occluded environments where evaporation losses were not considered (transient 10 minute exposures, or 'infinite' 3 hour exposures). Based on this information, dermal exposure in non-occluded scenarios will be a less significant route of exposure when compared to occluded scenarios, however there may be *exceptions* such as situations of transient or infinite exposures (e.g., vapor trapped against skin by gloves or continued contact with a wet rag) or where there is greater potential for dermal penetration due to longer durations of exposure. (pp. 38-9)

This extent of discussion and reference to data for occluded situations, characterized as "exceptions," are only included in the consumer section, and not provided in the occupational section on dermal exposures where they are especially likely to occur.

Later, in discussing the conceptual model for consumer activities, EPA states:

> Some products may be purchased and used as a liquid. For these uses, consumers may have dermal contact from occluded exposures such as holding a rag soaked in liquid 1-BP where limited evaporation rates and penetration may be expected to be higher in these scenarios. *EPA does not expect to further analyze dermal exposure to 1-BP vapor*, however EPA does expect to further analyze direct dermal contact with liquid 1-BP for consumers during the risk evaluation phase. (p. 49)

Yet just pages earlier (and cited just above), EPA had acknowledged the potential significance of dermal exposures to *vapor*, referring to "vapor trapped against skin by gloves or continued contact with a wet rag) or where there is greater potential for dermal penetration due to longer durations of exposure." (pp. 38-9) Why is EPA now stating it will ignore such exposures altogether?

EPA's apparent decision to exclude certain dermal exposures to 1-BP altogether, or to conclude with no further analysis that certain dermal exposures are negligible, is inconsistent with TSCA's mandate that EPA consider the combination of exposures to a chemical in assessing its risks, a requirement discussed earlier in these comments (see Section 1.A.ii). It is also not consistent with EPA's own problem formulation, where EPA states:

> Based on the physical-chemical properties and high evaporative losses compared to dermal absorption as described in Section 2.3.5.2, non-occluded dermal exposures are not expected to be the primary route of exposure for consumers, *although dermal exposures will contribute to the overall exposure*. (p. 49, emphasis added)

This logic on the need to look at all contributors to overall exposure applies to numerous pathway scenarios that EPA says it will not further analyze because inhalation is deemed the "major" exposure pathway. As discussed earlier in these comments (see Section 1.A.ii), TSCA includes nothing that allows EPA to limit itself only to assessing the "major source" of exposure to 1-BP or other chemicals. EPA must analyze dermal exposures to 1-BP, including how these exposures contribute to overall exposure.

Ingestion: EPA states:

> EPA does not plan to further analyze exposure to consumers via ingestion of 1-BP. Ingestion is not expected to be a primary route of exposure. Based on the vapor pressure, 1-BP will exist as a vapor/mist during use. (p. 38)

Yet as just noted, EPA acknowledges elsewhere that "[s]ome products may be purchased and used as a liquid." (p. 49) How can EPA wholly rule out ingestion, including by accident?

Modeling of surface water concentrations: EPA asserts that its assumption that wastewater treatment removal is 0% is conservative. However, this is not the case. EPA itself notes that "reported releases likely already account for wastewater treatment, which means any removal has already been accounted for." (p. 35) It, therefore, is a reasonable (but not necessarily conservative) assumption.

EPA also asserts that its concentrations of concern (COCs) for aquatic effects are "conservative."

Discussing its acute COC:

> The acute COC of 4,860 µg/L, derived from experimental fish endpoint, is used as a *conservative* hazard level in this problem formulation for 1-BP. (p. 42, emphasis added)

Discussing its chronic COC:

> The chronic COC of 243 µg/L, derived from experimental fish endpoint, is used as the *lower bound* hazard level in this problem formulation for 1-BP. (p. 43, emphasis added)

EPA implies that its calculations of COCs are conservative at least in part because of its use of assessments factors. The use of such factors is not conservative: They account for *real-world sources of variability as well as database limitations*, and cannot be construed as "safety factors" that yield conservative estimates.[113] As EPA states:

> The application of assessment factors is based on established EPA/OPPT methods (U.S. EPA, 2013b, 2012c) and were used in this Problem Formulation to calculate lower bound effect levels (referred to as the concentration of concern; COC) that would likely encompass more sensitive species not specifically represented by the available experimental data. Also, assessment factors are included in the COC calculation to account for differences in inter- and intra-species variability, as well as laboratory-to-field variability. (p. 42)

Notably, EPA's derivation of its chronic COC is based on no actual chronic toxicity data. EPA states:

> Since there are *no long-term chronic studies for 1-BP*, the fish 96-hr LC50 of 24.3 mg/L (the lowest acute value in the dataset) is divided by an acute-to-chronic ratio (ACR) of 10 to obtain a chronic value (ChV) for fish. (p. 43)

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[113] *See* Section 14 of these comments.

EPA should have identified this as a data gap and taken steps to address it. EPA provides no justification for its application of an "acute-to-chronic ratio" or its specific value of 10, nor does it provide even a citation to the use of such values in other contexts. Even a cursory search of the literature indicates that an ACR of at least 100 may be needed to be sufficiently protective.[114]

24. EPA's problem formulation reveals numerous data gaps, yet EPA provides no indication it intends to address any of them.

As discussed at length earlier in these comments (Section 8), EPA's assertion that it will not and need not use the enhanced authorities Congress gave it in reforming TSCA in 2016 to address information needs in conducting risk evaluations is deeply troubling. In this section we provide a list of examples of the many data gaps that plague the 1-BP risk evaluation and EPA's resort to insufficient approaches to work around the gaps without actually filling them.

1. EPA appears adamant on relying on models rather than requiring the development of information to fill gaps or resolve discrepancies and uncertainties in the available data – even where the models contribute to that uncertainty based on variable results. For example, EPA states:

> The EPI Suite™ module that predicts biodegradation rates ("BIOWIN" module) was run using default settings to estimate biodegradation rates of 1-BP under aerobic conditions. Three of the models built into the BIOWIN module (BIOWIN 2, 5 and 6) estimate that 1-BP will not rapidly biodegrade in aerobic environments, while a fourth (BIOWIN 1) estimates that 1-BP will rapidly biodegrade in aerobic environments. These results support the biodegradation data presented in the 1-BP Scope Document (EPA-HQ-OPPT-2016-0741-0049), which demonstrate a range of biodegradation rates under aerobic conditions. The model that estimates anaerobic biodegradation (BIOWIN 7) predicts that 1-BP will rapidly biodegrade under anaerobic conditions. Further, previous

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[114] *See* Martin May, et al., *Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels*, 28:1 ENVTL. SCIENCES EUROPE 16 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044967/; Jan Ahlers, et al., *Acute to chronic ratios in aquatic toxicity - Variation across trophic levels and relationship with chemical structure*, 25:11 ENVTL. TOXICOLOGY & CHEMISTRY (Dec. 2009), 10.1897/05-701R.1. ("For fish, daphnids, and algae, acute to chronic ratios (ACRs) have been determined from experimental data regarding new and existing chemicals. Only test results in accord with the European Union Technical Guidance Document (TGD) and validated by authorities were considered. Whereas the median ACRs of 10.5 (fish), 7.0 (daphnids), and 5.4 (algae) are well below the ACR safety factor of 100 as implied by the TGD, *individual ACRs vary considerably and go up to 4400. The results suggest that a safety factor of 100 is not protective for all chemicals and trophic levels.* Neither a correlation between ACR and baseline toxicity as modeled through the logarithmic octanol-water partition coefficient nor an ACR correlation across trophic levels exists. Narcosis is associated with a preference for a low ACR; nevertheless, low ACRs are frequently obtained for nonnarcotics. Analysis of chemical structures led to the derivation of structural alerts to identify compounds with a significantly increased potential for a high ACR, which may prove to be useful in setting test priorities. *At present, however, life-cycle tests are the only way to conservatively predict long-term toxicity.*") (emphases added).

assessments of 1-BP found that biodegradation occurred over a range of rates from slow to rapid [Toxicological Profile for 1-Bromopropane; (ATSDR, 2017)]. (p. 30)

2. EPA states: "*No measured bioconcentration studies for 1-BP are available*. An estimated BCF of 11 and an estimated BAF of 12 suggest that bioconcentration and bioaccumulation potential in aquatic organisms is low (BCF and BAF <1,000)." (p. 31)

Rather than require such bioconcentration studies be performed, EPA relies on models without any characterization of the resulting uncertainty associated with the conclusions it draws. Yet existing models have often been criticized as unreliable and often under-predictive of bioconcentration and bioaccumulation potential.[115]

3. EPA states: "Currently, EPA is not aware of the presence of 1-BP in recycled articles." (p. 34) This clear data gap is used by EPA to suggest that exposures from recycling activities are not of concern. In reality, it simply means the question cannot be answered without addressing the data gap.

4. EPA states: "[T]here were no available sediment, soil, nor avian toxicity studies found in the scientific literature for 1-BP. The toxicity of 1-BP is expected to be low based on the lack of on-topic environmental hazard data for 1-BP to sediment and terrestrial organisms in the published literature and the physical/chemical/fate properties (relatively high volatility (Henry's Law constant of 7.3X10-3 atm-m3/mole), high water solubility (2.4 g/L), and low log Koc (1.6) suggesting that 1-BP will only be present at low concentrations in these environmental compartments." (p. 41)

Astoundingly, EPA here relies on the lack of available data to conclude toxicity must be low.

5. EPA states: "For most high-priority chemical substances level(s) can be characterized through a combination of available monitoring data and modeling approaches." (p. 57)

EPA simply asserts this as fact, even as it seeks (as noted on this same page) more of the very same data. And for 1-BP, EPA has acknowledged there are no monitoring data available (p. 34).

6. EPA states: "Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of *default assumptions*. *** EPA will also review data sources containing estimated data and *identify data gaps*." (p. 58)

While defaults have their place, there is no excuse for EPA failing to even mention its authority to require the development and submission of the information it needs. And to date, EPA has done little to nothing to identify data gaps, and instead actively seeks to avoid doing so.

7. EPA states: "If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using EPI

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[115] *See, e.g.*, Arnot, J.A. & Frank Gobas, *A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms*, 14 ENVIRON. REV. 257-297 (2006), http://rem-main.rem.sfu.ca/papers/gobas/A%20Review%20of%20Bioconcentration%20factor%20(BCF)%20and.pdf.

Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality." (p. 60)

Again EPA skips right over any mention of mandating data development or submission.

8. EPA states: "EPA will review *reasonably available* data that may be used in developing, adapting or applying exposure models." (p. 61, emphasis added)

In its final risk evaluation rule, EPA defines "reasonably available" as information that EPA "possesses *or can reasonably generate, obtain*, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 CFR § 702.33, emphasis added. Yet, in the problem formulation, EPA makes no mention of efforts to use its authorities to generate or obtain needed information.

9. EPA states: "For some OSHA data, NAICS codes included with the data will be matched with potentially applicable conditions of use, and *data gaps will be identified where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below*." (p. 64, emphasis added)

Step 2 entails the use of data on surrogate chemicals. Step 3 entails the use of models. No step is indicated that would entail requiring submission or development of the needed data.

10. EPA states: "Review reasonably available exposure data for surrogate chemicals that have *uses and chemical and physical properties similar to 1-BP*. *** For several uses including use of adhesives, and cleaning products, EPA believes that trichloroethylene and other similar solvents may share the same or similar conditions of use and may be considered as surrogates for 1-BP." (p. 64, emphasis added)

EPA makes no mention of the need for surrogate chemicals to have similar environmental and biological fate as well as chemical and physical properties. Nor does it appear to be planning to compare the chemicals on the basis of any available toxicity information. While EDF does not oppose including surrogate data when relevant, it should not be the option of first resort and be used to excuse EPA from actively pursuing such data through its information authorities.

11. EPA states: "*If sufficient dermal toxicity studies are not identified* in the literature search to assess risks from dermal exposures, then a *route-to-route extrapolation* from the inhalation and oral toxicity studies would be needed to assess systemic risks from dermal exposures." (p. 70, emphasis added)

Again, EPA makes no mention of filling the data gap.

EPA should use its information authorities to fill the above data gaps in order to develop a risk evaluation consistent with the best available science and reasonably available information.

25. EPA's apparent effort to cast doubt on the carcinogenic potential of 1-BP is without merit.

EPA states:

> The exact mechanism/mode of action of 1-BP carcinogenesis is not clearly understood, however, *the weight-of-evidence analysis for the cancer endpoint is inconclusive* but does not rule out a probable mutagenic mode of action for 1-BP carcinogenesis. In the 2016 Draft Risk Assessment (U.S. EPA, 2016b), EPA derived an inhalation unit risk (IUR) based on lung tumors in female mice. This health hazard was used for quantitative risk characterization and will be evaluated using our systematic review approach. (p. 45, emphasis added)

EPA's assertion that "the weight-of-evidence analysis for the cancer endpoint is inconclusive" is not supported with any citations or even discussion. It is not clear whether the "inconclusive" claim is intended to apply only to mechanism/mode of action or more broadly to 1-BP's carcinogenicity. In either case, it is not consistent with the conclusions of several authoritative bodies, including EPA:

- The National Toxicology Program's (NTP) *Report on Carcinogens* concluded in 2013 that 1-BP is "reasonably anticipated to be a human carcinogen."[116]
- The Agency for Toxic Substances and Disease Registry (ATSDR) confirmed this classification in its 2017 profile:

  > The potential carcinogenicity of 1-bromopropane has been examined in bioassays in rats and mice (Morgan et al. 2011; NTP 2011). In both bioassays, animals were exposed 6 hours/day, 5 days/week for up to 105 weeks. Rats were exposed to 0, 125, 250, or 500 ppm 1-bromopropane vapors, while mice were exposed to 0, 62.5, 125, 250, or 500 ppm 1-bromopropane vapors. 1-Bromopropane was a multisite carcinogen in rats, significantly increasing the incidence of large intestine adenomas in females (500 ppm), skin keratoacanthoma in males (≥250 ppm), skin keratoacanthoma, basal cell adenoma, or squamous cell carcinoma in males (≥125 ppm), malignant mesothelioma in males (500 ppm), and pancreatic islet adenoma in males (≥125 ppm). In mice, exposure to 1-bromopropane significantly increased the incidence of combined alveolar/bronchiolar adenoma or carcinoma in females (≥62.5 ppm).[117]

- EPA's own 2016 draft risk assessment for 1-BP, based on a weight-of-evidence analysis, concluded:

  > Following EPA's Guidelines for Carcinogen Risk Assessment, *overall, the totality of the available data/information and the weight of evidence* support a

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[116] Natl'l Toxicology Program, *Report on carcinogens Monograph for 1-bromopropane* at 49 (Sept. 2013), https://ntp.niehs.nih.gov/ntp/roc/thirteenth/monographs_final/1bromopropane_508.pdf.

[117] Agency for Toxic Substances & Disease Registry, *Toxicological profile for 1-bromopropane* at pp. 77-8 (Aug. 2017), https://www.atsdr.cdc.gov/ToxProfiles/tp209.pdf.

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> justifiable basis to conclude a probable mutagenic mode of action for 1-BP carcinogenesis. 1-BP may be considered to be "*Likely to be Carcinogenic in Human* [sic]".[118]

Regarding EPA's effort in the above excerpt from the problem formulation to cast doubt on 1-BP's carcinogenic potential by stating "The exact mechanism/mode of action of 1-BP carcinogenesis is not clearly understood," EDF has addressed this tenuous argument earlier in these comments (see section 17), noting that the biological processes underlying observed effects are often not well understood but that serves as no basis to reject the actuality of the effects.

26. EPA's problem formulation contains several statements relating to confidential business information (CBI) that are or may be inconsistent with its authorities and obligations under TSCA.

1. EPA states: "Based on market information from other sources, EPA expects degreasing and spray adhesive to be the primary uses of 1-BP; however, the *exact use volumes associated with these categories are claimed CBI* in the 2016 CDR (U.S. EPA, 2016a)." (p. 27, emphasis added)

EPA's failure to conduct the timely reviews TSCA mandates of CBI claims made in submissions under the CDR – which were collected two years ago – is resulting in the public being precluded from understanding the extent of consumer uses of this chemical.

2. EPA states: The derived acute COC (4,860 ppb) and chronic COC (243 ppb) are based on environmental toxicity endpoint values (e.g., LC50) from ECHA. *Full study reports associated with these COCs were not available and will not be available in the future*." (p. 43, emphasis added)

It is not acceptable for EPA to rely only on summaries of studies without access to the full study. Nor is it appropriate for EPA to deny the public access to such studies, which clearly constitute health and safety studies under TSCA and are not eligible for CBI protection. EPA could readily require the submission of the full studies under TSCA, using its section 8 or 11(c) authority.

3. EPA states: "EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure." (p. 57)

This statement ignores the major changes made to the CBI provisions of TSCA section 14. Companies must substantiate most claims for CBI protection and EPA must review many of them within 90 days of submission of the information. Any claim that does not meet all applicable requirements cannot be protected from disclosure.

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[118] U.S. EPA, *TSCA work plan chemical risk assessment: Peer review draft 1-bromopropane: (n-Propyl bromide) Spray Adhesives, Dry Cleaning, and Degreasing Uses CASRN: 106-94-5* at 95 (2016), https://www.epa.gov/sites/production/files/2016-03/documents/1-bp_report_and_appendices_final.pdf (first emphasis added).

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Further, EPA fails to acknowledge that health and safety studies are expressly not eligible for protection as CBI under TSCA, subject only to two very narrow exceptions; see section 14(b)(2). All such information not subject to the exceptions needs to be made public.

27. Comment in response to a comment letter from Albemarle on the 1-BP problem formulation.

A comment letter was posted in the docket for this problem formulation on July 26, 2018, from Charles R. Nestrud, Attorney, Barber Law Firm on behalf of Albemarle Corporation.[119]

The comment letter makes numerous assertions that some of the information EPA provides in the problem formulation is incorrect or outdated. In doing so, the commenter repeatedly refers to information that Albemarle or others have provided to EPA, that "is now available," or that "is attached." Yet no attachments are included with the letter, and our review of the docket has not located any of the claimed information. Nor can we find them in the bibliography for the problem formulation.

The letter makes reference to multiple unpublished toxicity studies, none of which are attached to the letter or in the docket even though the letter states that "EPA has the report." The letter also refers to "six peer-reviewed manuscripts" that "have been provided to EPA." Specific citations were not provided and it does not appear that any of these manuscripts are in the docket.

EPA promptly needs to provide public access to all of the information referred to in this letter if it intends to rely on it in conducting the risk evaluation of 1-BP. Below is a list of the information referred to in the letter:

(1) ICL Big Blue MutaMouse study
(2) Enviro Tech International Big Blue MutaMouse study
(3) Albemarle's "duplicate negative" Ames test
(4) 6 peer reviewed manuscripts of entire NTP database of 2-year studies
(5) Trinity facility exposure assessment ("attached")
(6) Albemarle's usage and exposure assessment ("attached")
(7) Enviro Tech International usage and exposure scenarios

The letter also refers to additional information Albemarle intends to provide EPA "as it becomes available" or that will arise through additional work that Albemarle or Enviro Tech wishes to work with EPA to develop. EPA needs to commit to making this publicly available promptly upon its receipt or development by EPA.

[119] *See* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0010.

Comments on Carbon Tetrachloride

28. EPA has excluded or failed to sufficiently analyze numerous conditions of use and exposure pathways for carbon tetrachloride.

A. EPA's exclusion of numerous exposure pathways based on other environmental statutes fails to address the ongoing exposures posed by these pathways.

As with the problem formulations for most of the other nine chemicals, EPA has proposed to exclude a number of exposure pathways on the basis of other statutes administered by EPA. *See* U.S. EPA, Problem Formulation of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-) CASRN: 56-23-5 at pp. 48-9 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0733-0068. This approach is illegal and arbitrary and capricious for the reasons articulated above in Section 5. The evidence before the agency thoroughly establishes that exposures still occur through these pathways, and EPA should analyze these pathways to produce a risk evaluation consistent with reasonably available information and best available science.

Clean Air Act: First, EPA has stated that it does not expect to include emission pathways to air from commercial and industrial stationary sources or associated inhalation exposure of the general population or terrestrial species, because carbon tetrachloride is a hazardous air pollutant (HAP). (p. 48) EPA states that the emissions from stationary sources of carbon tetrachloride have been adequately addressed because there are technology-based standards applicable to certain releases of the chemical to ambient air, yet those regulations do not cover all releases of carbon tetrachloride to the air. For instance, the National Emissions Inventory (NEI) data from 2014 identifies 28 different sectors that released carbon tetrachloride to the air. These emission sources include, but are not limited to, chemical manufacturing, pulp and paper processing, waste disposal, oil and gas production, and fuel combustion.[120] While EPA has promulgated regulations under the Clean Air Act (CAA) for carbon tetrachloride in some chemical manufacturing areas and for plywood and composite wood products, the CAA regulations for carbon tetrachloride listed in the Appendix do not address other sources of carbon tetrachloride identified in the NEI. Additionally, for sources that are covered by the CAA regulations, the NEI indicates that those sources continue to emit carbon tetrachloride to the air (e.g., chemical manufacturing resulted in 89,839 pounds of carbon tetrachloride air emissions in 2014).

Safe Drinking Water Act: EPA will also exclude drinking water as an exposure pathway because EPA has set a Maximum Contaminant Level (MCL) "as close as feasible to a health-based" non-enforceable Maximum Contaminant Goal Level (MCLG) under the Safe Drinking Water Act. Whether a standard is "feasible" refers to the ability to monitor water quality and to treat the water, both of which are notably "nonrisk factors" that EPA is not allowed to consider in risk evaluations under TSCA. *See* 15 U.S.C. § 2605(b)(4)(A). Additionally, the MCLG is the level in drinking water at which "no known or anticipated adverse effect on the health of persons would occur." 40 C.F.R. § 141.2. If anything, this standard

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[120] *See* 2014 NATIONAL EMISSIONS INVENTORY (NEI) DATA, https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data (last visited Aug. 2, 2018) (the data for carbon tetrachloride is included in the supplement at the end of the carbon tetrachloride comment).

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(which is zero for carbon tetrachloride) is much closer to the solely risk-based standard required for risk evaluations under TSCA, yet it is not the standard by which EPA regulates drinking water.

EPA's own data indicate that this "feasibility" standard results in continuing exposures to carbon tetrachloride in drinking water. For instance, based on 2015 data cited by EPA 6% of modeled drinking water exposures were above the MCL. (p. 38) Yet in the problem formulation EPA has decided it will exclude those exposures as having been "adequately assessed" and it will assume they present zero risk. These data do not support a conclusion that carbon tetrachloride in drinking water poses no risk.

Additionally, EPA indicated that the USGS has detected carbon tetrachloride in community water systems and that the data are available through a portal. (p. 35) The problem formulation does not identify the communities, nor does it indicate whether EPA has checked the USGS database. After a rudimentary search for carbon tetrachloride in that database, EDF found that over 44,000 sites had sampling data where carbon tetrachloride was present.[121] At a minimum, EPA must address these data more comprehensively than merely stating they exist. EPA must analyze these actual exposures in its risk evaluation.

Clean Water Act: EPA also plans to exclude exposures to carbon tetrachloride through ambient water pathways. According to EPA this pathway has been addressed for human health because there is a recommended water quality criterion for carbon tetrachloride for human health under section 304(a) of the Clean Water Act (CWA). However, elsewhere in the problem formulation EPA estimate that 8% of carbon tetrachloride in wastewater remains in effluent discharged after treatment. (p. 30) EPA does not address the exposure potential of this effluent in ambient water, and instead will simply ignore such exposures.

Biosolids will also not be evaluated because EPA says its Office of Water is developing modeling tools in order to conduct risk assessments. (p. 49) While such activity is no doubt useful and may eventually lead to an actual assessment of risk and needed controls, those latter activities are speculative at this point and provide no basis for excluding such exposures from this risk evaluation. See our earlier comments in Section 5.E.

Resource Conservation and Recovery Act: In regards to disposal, EPA states it will not evaluate any pathways. Yet it has failed to provide any analysis to demonstrate the extent to which existing regulations actually eliminate associated exposures. For example, EPA states only that migration to groundwater from RCRA subtitle C landfills is "likely" to be mitigated by landfill design. (p. 33)

EPA has provided no data or analysis demonstrating that disposal of hazardous or solid wastes, even if compliant with RCRA, pose no risk to the general population, vulnerable subpopulations, terrestrial species or other receptors.

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[121] WATER QUALITY DATA, https://www.waterqualitydata.us/portal/#characteristicName=Carbon%20tetrachloride&mimeType=csv&sorted=no (last visited Jul. 18, 2018).

In sum, EPA should analyze the excluded pathways and assess the real-world exposures occurring through these pathways.

B. EPA has inappropriately excluded a number of conditions of use based on an unsubstantiated theory that exposures will be "de minimis."

EPA plans to exclude the industrial, commercial, and consumer uses of carbon tetrachloride in commercially available aerosol and non-aerosol adhesives, paints/coatings, and cleaning/degreasing solvent products because it asserts these uses will result in de minimis exposures. (pp. 20-21) This assertion bears greater scrutiny.

EPA states that domestic production and importation of carbon tetrachloride "is currently prohibited under regulations implementing the Montreal Protocol" and the Clean Air Act, but notes that this prohibition excludes carbon tetrachloride when it is transformed, destroyed, or used for "essential laboratory and analytical uses." (p. 20)

EPA also states that the Consumer Product Safety Commission (CPSC) has banned the use of carbon tetrachloride in household products since 1970, but notes there are exceptions for "unavoidable manufacturing residues *** that under reasonably foreseen conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million." (p. 20)

EPA goes on to note that the regulations implementing the Montreal Protocol and the Clean Air Act provide for "a limited number of specific manufacturing uses of carbon tetrachloride as a process agent (non-feedstock use) in which carbon tetrachloride may not be destroyed in the production process" and that "carbon tetrachloride is used in the manufacturing of other chlorinated compounds that may be subsequently added to commercially available products (i.e., solvents for cleaning/degreasing, adhesives/sealants, and paints/coatings)." (p. 20) While "EPA expects insignificant or unmeasurable concentrations of carbon tetrachloride in the manufactured chlorinated substances in the commercially available products," the only corroborating sources it provides are qualified comments, backed with no actual data, from representatives of the chemical industry asserting that the levels are low.

While the regulatory exclusions in this setting – regulation of carbon tetrachloride due to its stratospheric ozone depletion potential – may be reasonable, it is entirely unclear from the problem formulation how often the regulatory exceptions are relied on, what levels of release and exposure result, and what risks to human health or the environment these exposures pose.

In fact, releases of carbon tetrachloride to the air remain a concern to the parties to the Montreal Protocol. In 2015 (and in 2011), the parties to the Montreal Protocol released a decision requesting an investigation into the discrepancies between the levels of carbon

tetrachloride observed in the atmosphere versus reported data.[122] The decision notes with concern that

> derived emissions of carbon tetrachloride, based on its estimated lifetime and its accurately measured atmospheric abundances, have become much larger over the last decade than those from reported production and usage.[123]

The reasons given for wholly excluding these uses from EPA's risk evaluation have no basis in the law, or even in EPA's rationale for excluding uses that are "adequately addressed" by other statutes. The different purposes underlying the existing regulations in comparison to TSCA, and the fact that there are exceptions to the regulations EPA relies on to exclude these uses, indicate that any health and environmental risks resulting from still-allowed releases, including through the regulations' exceptions, may not have been addressed. EPA must include these uses in its risk evaluation and assess the risks associated with the remaining releases allowed under the regulations it cites.

Additionally, EPA's initial review of carbon tetrachloride uses identified a number of products with "commercial" uses that are available online that contained carbon tetrachloride.[124] EPA acknowledged that the sale of products containing carbon tetrachloride was foreseeable.[125] The table listed everything from carpet spot removers and adhesives, to pool paint, sealants, and drums of carbon tetrachloride available for purchase online.[126] EPA has not provided evidence refuting these uses of carbon tetrachloride,[127] and hence must address these products in the risk evaluation, since their availability online suggests there may be more than de minimis exposure to carbon tetrachloride in some consumer products.

C. EPA excludes all exposures to the general population while simultaneously stating that exposures to the general population are known or reasonably foreseeable.

EPA will exclude all exposures of carbon tetrachloride to the general population from the scope of the risk evaluation. (p. 56) This decision was made despite the fact that EPA indicates in numerous places in the problem formulation that the general population may well have exposures to carbon tetrachloride. For instance:

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[122] The Montreal Protocol on Substances that Deplete the Ozone Layer, 27th Meeting of the Parties (Nov. 2015), Decision XXVII/7: Investigation of carbon tetrachloride discrepancies, http://ozone.unep.org/node/94211.

[123] *Id.*

[124] U.S. EPA, *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Carbon Tetrachloride* at 15 (Feb. 2017), https://www.epa.gov/sites/production/files/2017-02/documents/carbon_tetrachloride.pdf.

[125] *Id.*

[126] *Id.* at 12.

[127] The Problem Formulation does include "[m]anufacturing of chlorinated compounds used in adhesives and sealants" and paints and coatings, (p. 25), but only as a commercial use.

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1. When carbon tetrachloride is released as a result of industrial or commercial uses through the air or during disposal, inhalation is a "likely exposure pathway." (p. 37)
2. People can have inhalation exposures to carbon tetrachloride vapors in the shower and while dishwashing from contaminated water. (p. 37)
3. People can have inhalation exposure from vapor intrusion into indoor environments. (p. 38)
4. People may ingest contaminated drinking water or breast milk. (p. 38)
5. People may incidentally ingest carbon tetrachloride because of presence in water used for bathing or recreation. (p. 38)

Additionally, the National Institutes of Health's Report on Carcinogens states that EPA has estimated that "8 million people living within 12.5 miles of manufacturing sites were possibly exposed to carbon tetrachloride at an average concentration of 0.5 $\mu g/m^3$ and a peak concentration of 1,580 $\mu g/m^3$."[128] Despite EPA's identification of a number of exposures to the general population that are known or certainly reasonably foreseen, EPA has simply chosen to disregard all of these exposures. EPA's assertion that other statutes adequately address these exposures (without any analysis demonstrating that this is so), while simultaneously acknowledging that those exposures continue to happen, is arbitrary and capricious. *See State Farm*, 463 U.S. at 43 (an agency decision is arbitrary and capricious when it "entirely fail[s] to consider an important aspect of the problem").

EPA must analyze these known and reasonably foreseeable exposures to the general population to produce a risk evaluation consistent with reasonably available information and best available science.

D. There are a number of major deficiencies with other exclusions EPA includes in the carbon tetrachloride problem formulation.

Beyond the categorical exclusions that EPA has specifically identified (statutory, de minimis, etc.), which are addressed above, there are a number of other exclusions that EPA has made in the problem formulation for carbon tetrachloride without sufficient explanation or justification.

EPA will not consider exposures to a known decomposition product of carbon tetrachloride, phosgene. (p. 37) Phosgene exposures will be excluded because TRI data do not show releases of carbon tetrachloride and phosgene at the same facility. While that may be the case, there is at least one facility that reported releases of carbon tetrachloride under the National Emissions Inventory (NEI) and also reported data about phosgene emissions under the NEI and phosgene manufacture under the CDR.[129]

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[128] U.S. National Toxicology Program, *Report on Carcinogens: Carbon Tetrachloride* at 2 (14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/carbontetrachloride.pdf.

[129] The 2014 NEI data states that 107 pounds of carbon tetrachloride were released from Sabic Innovative Plastics in Alabama, and that phosgene was also released from this facility. The 2016 CDR data for the same facility includes phosgene manufacture and states that "at least 100 but fewer than 500 workers" will likely be exposed to phosgene. While these data provide an incomplete picture of phosgene and carbon tetrachloride's dual presence at this facility, they indicate that EPA may have erred by relying solely on the TRI data.

EPA cannot rationally exclude this exposure by relying solely on TRI data because EPA must consider other reasonably available information. There are a number of other sources of data that are not as restrictive in scope as the TRI data, such as the NEI, that should be considered before excluding a potential exposure.[130] While EPA tries to support its exclusion by also stating that the decomposition of carbon tetrachloride is "more likely" to occur in open systems, which will allegedly not happen because EPA asserts carbon tetrachloride is only manufactured and processed in closed systems, EPA cites no sources to demonstrate that this is the case, nor does it explain how releases to the environment of carbon tetrachloride would not decompose and result in exposures to phosgene. EPA must consider carbon tetrachloride's decomposition into phosgene and any resulting exposures to phosgene.

Additionally, while not an explicitly addressed exclusion, there is no mention in the problem formulation of the potential for carbon tetrachloride to remain in the environment long after production and active use. Disregarding this is particularly problematic for carbon tetrachloride because EPA states that "[t]hough *** use has significantly decreased from a peak in the 1970's, its long half-life and previous ubiquitous use and disposal has resulted in [its] *continued presence* in various environmental media." (p. 34, emphasis added) Additionally, EPA noted that of eight HAPs monitored, "only carbon tetrachloride average concentrations have slightly increased in the atmosphere over the year period from 2003 to 2013." (p. 34) EPA does not attempt to address why there has been an increase in carbon tetrachloride concentrations in the air, nor whether or how it will address the continued presence of carbon tetrachloride in the environment.

In addition, EPA failed to acknowledge that there are Superfund sites all over the country with carbon tetrachloride contamination.[131] EPA's disregard of these sites is particularly egregious because EPA acknowledged that exposures to carbon tetrachloride persist despite its decreasing use, but then did not even attempt to offer an explanation as to why those exposures have been excluded. By remaining entirely silent on the potential exposures to carbon tetrachloride from Superfund sites, EPA's problem formulation is arbitrary and capricious. *See Ctr. for Biological Diversity v. United States BLM*, 698 F.3d 1101, 1124 (9th Cir. 2012) (concluding that it was arbitrary and capricious to entirely ignore the potential impact of groundwater withdrawals to a listed species).

E. EPA decided to "not further analyze" a number of pathways on cursory and unpersuasive grounds.

Aquatic Organisms: EPA plans to not further analyze pathways of exposure to ecological aquatic species, in part, because it asserts any carbon tetrachloride released to water will volatilize or dilute in surface water. (p. 48) EPA also states that:

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[130] *See* U.S. EPA, *Factors to Consider When Using Toxics Release Inventory Data* at 10 (2015), https://www.epa.gov/sites/production/files/2015-06/documents/factors_to_consider_6.15.15_final.pdf.

[131] Toxmap, which is provided by the National Institute of Health, indicates that there are 240 sites on the Superfund list that contain carbon tetrachloride as a pollutant. *See* https://toxmap.nlm.nih.gov/toxmap/app/; Appendix B at 7.

> EPA considered worst-case scenarios to estimate carbon tetrachloride concentrations in surface water resulting from industrial discharges. Using NPDES Discharge Monitoring Reporting data available for 2015, the largest releases of carbon tetrachloride were modeled for releases over 20 days and 250 days per year. In these *conservative* scenarios, surface water concentrations were below the acute COC [concentration of concern] for aquatic species (see Appendix E); hence there is not an acute aquatic concern. Although the chronic COC was exceeded by one facility by a factor of 3.5 (i.e., worst-case scenario) based on predicted *conservative* exposure concentrations in surface water, these carbon tetrachloride releases are not continuously released over time (i.e., chronic exposure); hence there is not a chronic aquatic concern. (p. 47, emphases added).

There are a number of concerns with EPA's assumptions here.

1. EPA says it has relied on NPDES data from 2015, and specifically included those data in its table in Appendix E. (p. 90) Yet that table does not include releases from one particular facility in 2015, a facility that released far more – 880 pounds – of carbon tetrachloride in one year than the facilities EPA included in its table, as seen below in the screenshot of EPA's ECHO database.[132] EPA does not explain why the discharges from this facility were not considered. Notably, this facility was not in violation of its NPDES permit, so there is no reason to believe it is an outlier.

Top Facility Discharges (2015)

NPDES ID	Facility Name	City, State	Report	SIC Code	HUC-12 Code	Avg Conc (mg/L)	Max Conc (mg/L)	Total Pounds (lb/yr)	Total TWPE (lb-eq/yr)	Avg Flow (MGD)
GA0003735	PINOVA, INC.	BRUNSWICK, GA		2861	030702030203	0.0474	0.5000	880	299	0.35

2. In evaluating whether there is a concern for acute exposure, EPA only considered a 20-day release scenario, not shorter (even a single-day) release scenarios. The only reason EPA provides for this decision is that it is "not a likely scenario that would be allowed under current NPDES permit requirements." (p. 90) EPA provides no support for this statement. In fact, the NPDES permits for the two highest-releasing facilities in 2015 appear to have no concentration limits on carbon tetrachloride in their NPDES permits, only monitoring requirements.[133]
3. EPA states that there is no chronic concern because carbon tetrachloride is "not "continuously released over time." It is not clear how EPA could have reached this conclusion. The facilities EPA shows as having exceeded the chronic COC by a factor of 3.5 (the first row listed in Table

[132] *See* POLLUTANT LOADING REPORT, https://echo.epa.gov/trends/loading-tool/reports/dmr-pollutant-loading?permit_id=GA0003735&year=2015 (last visited Aug. 6, 2018).
[133] *See* NPDES for Pinova, Inc. in 2015, https://echo.epa.gov/trends/loading-tool/reports/permit-limits?permit_id=GA0003735&year=2015; NPDES for Fort Bend County WCID 2 in 2015, https://echo.epa.gov/trends/loading-tool/reports/permit-limits?permit_id=TX0021458&year=2015.

App. E-1 on p. 90) are POTWs [publicly owned treatment works] that discharge 365 days per year, according to EPA's own footnote to that table.

4. EPA dismisses exceedances of its chronic COC by claiming that "surface water concentrations that slightly exceed the chronic COC are not considered statistically significant as to present a concern for aquatic organisms." (p. 90) This raises the question why EPA bothered to do the analysis in the first place, if it then not only rejects the results, but then uses a cursory analysis and hand-waving arguments as a basis for its decision to do no further analysis at all of potential risks to aquatic organisms.
5. After asserting its analysis is conservative because it relied on "worst-case scenarios," EPA then dismisses exceedances revealed by its analysis by pulling back its claimed conservative assumptions. It cannot continue to claim its analysis is conservative.
6. Even using the 20-day scenario, EPA still found that "carbon tetrachloride surface water concentrations were mostly below the COCs for aquatic species," indicating that there were still some scenarios where the COC was exceeded. (p. 90, emphasis added) Indeed, several are shown in Table Apx E-1. EPA cannot ignore those scenarios especially because it cannot rule out that the discharges may have occurred over an even shorter time period than 20 days, which would have led to more exceedances.

Thus, EPA's analysis appears to be irrational and fails to establish that carbon tetrachloride will present no risks to aquatic organisms. EPA should prepare an accurate and logical analysis of the risks to aquatic species.

Sediment and Terrestrial Organisms: Despite the lack of *any* acceptable hazard studies for either group of organisms, EPA fails to require the development of any such hazard information, and also plans to exclude (or not further analyze, it is not exactly clear which) exposures to carbon tetrachloride for sediment and terrestrial organisms because it claims exposure is "not likely" due to carbon tetrachloride's fate and transport properties. (p. 39) EPA provides no analysis to support this assertion regarding exposure, and the lack of any hazard data raises the question as to what levels of exposure would present risk.

Yet among those fate and transport properties EPA invokes is volatility. Because carbon tetrachloride volatilizes from water, terrestrial organisms may be exposed to carbon tetrachloride through inhalation. Among the chemical's other properties are "its log Koc (1.7 – 2.16) and high solubility of 793 mg/L at 25°C," which EPA uses to argue that "sorption of carbon tetrachloride to sediments and suspended solids is unlikely." (p. 47) Yet those properties also mean the chemical will more likely be present in surface waters. EPA should analyze the air and water exposures faced by terrestrial organisms given that EPA's own analysis reveals that exposure is reasonably foreseen: "Terrestrial species populations living near industrial and commercial facilities using carbon tetrachloride may be exposed via multiple routes such as *ingestion of surface waters and inhalation of outdoor air*." (pp. 35-36) (emphasis added) EPA should also use its information authorities to obtain actual hazard information.

Occupational Non-users: EPA will also not analyze nearly all exposures of occupational non-users (ONU) to carbon tetrachloride for the majority of the release exposure scenarios for the industrial/commercial

uses of carbon tetrachloride. (pp. 92-103) Specifically, EPA is excluding all but one potential dermal exposure because ONU "would not intentionally handle liquids containing carbon tetrachloride," and because only workers will be "primarily" exposed. (pp. 93-103) TSCA provides no basis for limiting EPA's risk consideration only to intentional exposures, nor to focus only on persons "primarily" exposed. Additionally, EPA has simply assumed without analysis that the potential for occupational exposures to vapors to workers and ONU "may be low" in most scenarios. (pp. 92-95) Despite these assertions, the Occupational Safety and Health Administration (OSHA) has estimated that "3.4 million workers [were] potentially [ ] exposed to carbon tetrachloride directly or *indirectly*."[134] Given this estimate, EPA must actually analyze the exposures for workers and ONU.

Also, EPA was unable "to identify occupational exposure scenarios that correspond to several conditions of use due to a lack of understanding of those conditions of use." (p. 55) Although EPA appears to be taking steps to address these gaps, EPA must clarify that the exposure scenarios that remain unclear at this stage will receive further analysis in the risk evaluation. EPA should also use its information authorities under TSCA §§ 4 and 8 to fill these information gaps.

F. EPA's basis for excluding non-occluded dermal exposures to workers lacks rationale and is inconsistent with its approach to including occluded dermal exposures.

EPA's plan to only look at occluded dermal exposures is without sufficient justification. (p. 44) Specifically, EPA states that:

> There is the potential for dermal exposures to carbon tetrachloride in *many* worker scenarios. These dermal exposures would be concurrent with inhalation exposures and the overall contribution of dermal exposure to the total exposure is expected to be small; however, there may be exceptions for occluded scenarios. *** EPA plans to further analyze dermal exposures for skin contact with liquids and vapors in occluded situations for workers.

(p. 44, emphasis added) That there is a smaller relative percentage of exposure to carbon tetrachloride from dermal versus inhalation exposure does not mean that the dermal exposure is irrelevant to evaluating carbon tetrachloride's risks in occupational settings. The contribution to overall carbon tetrachloride exposure from dermal absorption could still be significant. EPA should consider combined exposures to carbon tetrachloride via all pathways across all potential sources of exposure.

G. EPA must analyze exposures to carbon tetrachloride from organic and inorganic chemical manufacturing.

EPA has identified as a condition of use the use of carbon tetrachloride as a process agent in the manufacturing of organic and inorganic compounds. (p. 25) While EPA has not expressly indicated it will do no further analysis of this use, EPA states that carbon tetrachloride is expected to only be present

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[134] U.S. National Toxicology Program, Report on Carcinogens: Carbon Tetrachloride at 2 (14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/carbontetrachloride.pdf (emphasis added).

"as an impurity rather than serving a specific function." (p. 86) In some of the other problem formulations, *e.g.,* HBCD, EPA has excluded a condition of use if EPA decided the chemical was not intentionally present or being used to serve a specific function. This exclusion has no basis in the law, and regardless of the function, it is still a known or reasonably foreseen, even if not intended, use of the chemical. EPA must address this condition of use in the risk evaluation.

29. The carbon tetrachloride problem formulation fails to identify relevant potentially exposed or susceptible subpopulations.

EPA only identifies workers and ONU as "potentially exposed or susceptible subpopulations." (p. 38) Unlike other problem formulations for the first ten chemicals where "[o]ther groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use" are identified as "potentially exposed or susceptible subpopulations," EPA has inexplicably failed to include that category of people as potentially exposed subpopulations in this problem formulation. This omission is despite the fact that, for example, "[p]oint sources of carbon tetrachloride from industry and wind direction are responsible for localized increases in air concentration."[135]

Such subpopulations fall squarely within the statutory definition of potentially exposed and susceptible subpopulations as "a group of individuals within the general population identified by the Administrator who, due to *** greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance." 15 U.S.C. § 2602(12). EPA should expressly identify them.

EPA has also failed to identify individuals who live near sites contaminated with carbon tetrachloride (e.g., Superfund sites) as a potentially exposed or susceptible subpopulation. As stated previously, there are 240 Superfund sites where carbon tetrachloride was identified as a pollutant, and EPA must identify residents in these communities as potentially exposed or susceptible subpopulations.

Moreover, while EPA has identified certain "factors that might influence susceptibility to carbon tetrachloride" (p. 43), EPA has failed to identify specific relevant vulnerable subpopulations based on greater susceptibility.

TSCA requires that EPA identify "potentially exposed or susceptible subpopulations" (TSCA section 6(b)(4)(D)), including those that "due to *** greater *susceptibility* *** may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12).

As described in Section 11.A of these comments, evidence before the agency shows that carbon tetrachloride presents potential developmental and reproductive risks, and hence infants, children, pregnant women, and adults of child-bearing age "may be at greater risk than the general population of

[135] U.S. National Toxicology Program, Report on Carcinogens: Carbon Tetrachloride at 2 (14th ed. 2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/carbontetrachloride.pdf.

adverse health effects," and EPA must identify them as potentially exposed or susceptible subpopulations.

Carbon Tetrachloride Supplement:

2014 NEI Data for Carbon Tetrachloride	
Sector	**Emissions (LB)**
Industrial Processes - Chemical Manufacturing	89,839
Industrial Processes - Pulp & Paper	43,131
Waste Disposal	17,607
Fuel Comb - Industrial Boilers, ICEs - Biomass	12,131
Industrial Processes - Oil & Gas Production	12,050
Industrial Processes - Storage and Transfer	10,935
Industrial Processes – NEC	5,522
Fuel Comb - Electric Generation - Biomass	4,842
Fuel Comb - Industrial Boilers, ICEs - Natural Gas	3,076
Industrial Processes - Petroleum Refineries	1,169
Solvent - Industrial Surface Coating & Solvent Use	924
Fuel Comb - Electric Generation - Coal	599
Industrial Processes - Non-ferrous Metals	545
Fuel Comb - Comm/Institutional - Biomass	514
Industrial Processes - Cement Manufacturing	215
Fuel Comb - Comm/Institutional - Natural Gas	190
Industrial Processes - Ferrous Metals	130
Fuel Comb - Industrial Boilers, ICEs - Coal	103
Fuel Comb - Industrial Boilers, ICEs - Other	96

Fuel Comb - Electric Generation - Other	89
Solvent – Degreasing	54
Fuel Comb - Electric Generation - Natural Gas	42
Fuel Comb - Comm/Institutional - Other	40
Fuel Comb - Industrial Boilers, ICEs - Oil	32
Fuel Comb - Electric Generation - Oil	9
Fuel Comb - Comm/Institutional - Oil	4
Solvent - Consumer & Commercial Solvent Use	1

Comments on HBCD

30. EPA has excluded or failed to sufficiently analyze numerous conditions of use and exposure pathways for HBCD.

A. EPA has inappropriately excluded legacy uses, associated disposal, and legacy disposal of HBCD from the problem formulation.

EPA intends to exclude multiple conditions of use of HBCD based on the condition of use allegedly being "legacy." EPA should consider all of these conditions of use for reasons articulated before and incorporated by reference here. EDF Comments on Ten Scopes under the Toxic Substances Control Act, pp. 4-11 (Sept. 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069; Appendix A.

Use in High Impact Polystyrene: First, EPA has excluded the use of HBCD in High Impact Polystyrene (HIPS) as a flame retardant for electrical and electronic appliances because its use "appears to have ceased." U.S. EPA, Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) at p. 21 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0071. Notably, EPA's source for this caveated assumption is a single personal communication with one company, which EPA has not corroborated and the substance of which EPA has not made available. This is unacceptable.[136] To base a wholesale exclusion of a condition of use on such a flimsy extent of documentation that the public cannot access is simply outrageous. How is the public supposed to assess the accuracy and reliability of this comment? Moreover, that one person at one company reports that the company has ceased a particular use provides no assurance that other companies are not continuing the use. In addition, such personal communications do not reflect the best available science because EPA has failed to rely on all reasonably available information. EPA has broad authority under TSCA § 8 to require reporting industry wide under binding rules with various measures to increase reliability, and thus such broad reporting is reasonably available to EPA; EPA cannot rationally rely on unverified and potentially unrepresentative personal communications instead.

In addition to the reasons identified previously for why legacy uses must be included, *see* Section 4.A, EPA should include the use of HIPS as a condition of use because the agency has insufficient evidence that the use has stopped.

EPA states that it "believes the manufacturing, processing, or distribution in commerce for use of HBCD as a flame retardant in HIPS is not intended, known, or reasonably foreseen and is not a condition of use of HBCD." (p. 21) Even assuming EPA is correct that such use is no longer occurring and hence is not "known," that is no basis to conclude it is also not "reasonably foreseen." Congress distinguished between "known" and "reasonably foreseen" in its definition of conditions of use, and EPA cannot

[136] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation.

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equate the two. Barring a regulatory prohibition on such use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.

Following from this exclusion, EPA is also excluding the disposal of HBCD-containing HIPS and HIPS-containing electronic products as "associated disposal." (p. 21) This will result in EPA disregarding any exposures to HBCD from the management of electronic waste.[137] EPA cannot rationally ignore these ongoing exposures.

Manufacture of EPS Resin and XPS Masterbatch: EPA is excluding the manufacture of expanded polystyrene (EPS) resin and extruded polystyrene (XPS) because these uses have been phased out, allegedly, by their "major" manufacturers. (p. 21) This exclusion raises a number of concerns. First, although one comment on EPS from an industry representative is publicly available, the comment EPA cites regarding XPS is not. EPA's source for this assertion about XPS is a single personal communication with a trade association representative, which EPA has not corroborated and the substance of which EPA has not made available. This is unacceptable.[138] EPA must make this publicly available.

Second, even assuming EPA is correct that "major" manufacturers have phased out manufacture of EPS and XPS, EPA appears to have made no attempt to determine whether there are other manufacturers of EPS and XPS. EPA cannot assume that communications from representatives of the major manufacturers accurately reflects the status of *all* users of HBCD in EPS and XPS.

Lastly, even assuming that this use of HBCD has been "phased out" and that the industry has "fully transitioned" from it, that is no basis to conclude the use is also not "reasonably foreseen." Congress distinguished between "known" and "reasonably foreseen" in its definition of conditions of use, and EPA cannot equate the two. Barring a regulatory prohibition on such use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.[139]

Use in Textiles: EPA is also excluding the use of HBCD in consumer textiles, including interior fabrics in motor vehicles and children's clothing and blankets, on the basis of it being a legacy use. (p. 22) The basis for this exclusion is also a personal communication from an industry source that is not publicly

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[137] In addition to exposures from the release of HBCD from electronic waste, it appears that the disposal of HIPS (and HBCD) may occur in other ways that would likely result in exposures. *See* Using D-Limonene to Dissolve 3D Printing Support Structures (Apr. 2014), https://www.fargo3dprinting.com/using-d-limonene-dissolve-3d-printing-support-structures/ (suggesting that the product can be disposed of in the sink); *see also* HIPS Filaments, https://www.3dprima.com/filaments/hips/ (last visited Aug. 8, 2018) (noting, on a product page, that "[f]rom time to time manufacturers add flame retardants like DecaBDE or HBCD to the matrix").

[138] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation. The link in the document goes to a webpage that provides no transcript of the "personal communication."

[139] EPA cites an international ban as a reason for the phase-out of this use. (p. 21) But as EPA itself noted, (p. 31), the U.S. is not a party to the Stockholm Convention on Persistent Organic Pollutants, which banned the use, import, and export of HBCD. Moreover, under the Convention, three parties are registered to produce HBCD and six are registered to use HBCD for EPS and XPS in foam.

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available. This too is unacceptable.[140] Moreover, information EPA cites directly contradicts this rationale: Between June 2012 and March 2017, the presence of HBCD in textile products was reported by industry 44 times to Washington State. (p. 22) While EPA speculates that such items would now be caught by a SNUR it has finalized, this is not a basis for dismissing such evidence of continued use.

EPA states that "[c]urrent use in consumer textiles has not been confirmed and EPA does not believe it is known, intended, or reasonably foreseen. Therefore, use in consumer textiles is not a condition of use under which EPA will evaluate HBCD." (p. 21) As discussed above, even if this use is no longer occurring and hence is not "known," that is no basis to conclude it is also not "reasonably foreseen" that the use may begin again. The definition of conditions of use expressly distinguishes between "known" and "reasonably foreseen," therefore EPA cannot equate the two. Barring a regulatory prohibition on such use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.

In a further effort to avoid including these uses, EPA "concluded" that these products did not contain "intentionally-added" HBCD. (p. 22) However, EPA chose not to explain to the public just how it reached this conclusion. It needs to do so.

Even so, while EPA asserted in the final Risk Evaluation rule that it may ignore impurities that are "unintentionally" present in another chemical substance, nowhere does EPA explain in the rule, or in this problem formulation, that it has discretion to exclude a use because it is not "intentionally added" to consumer products. 82 Fed. Reg. 33726, 33729-30 (Jul. 20, 2017). Even assuming EPA's assertion about such products is true, that is no basis to conclude it is not "known" or "reasonably foreseen." Congress specified that conditions of use extended beyond "intentioned" circumstances to include "known" and "reasonably foreseen" circumstances, and EPA has no basis for concluding that the use of HBCD in a product is not known or reasonably foreseen merely because it is not "intentionally added."

EPA also excludes commercial textiles because the use is not "ongoing." (p. 22) The basis for this assertion is several personal communications that EPA has not corroborated, one from a source identified only by partial name (Friddle, J.) without any affiliation. None of these personal communications is publicly available. As noted before, this is unacceptable,[141] and it provides no basis for the public to assess the accuracy or reliability of these communications.

EPA notes that, as of quite recently, HBCD has been used in textiles in the military, institutional and aviation applications, and hospitals and prisons. EPA states that:

> Current use in commercial textiles could not been [sic] confirmed, but EPA concludes that based on the information above, HBCD use in these textiles is not intended, known,

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[140] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation.

[141] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation.

> or reasonably foreseen. Therefore, use in commercial textiles is not a condition of use under which EPA will evaluate HBCD. (p. 22)

Even assuming EPA is correct that such use is no longer occurring and hence is not "known," that is no basis to have concluded it is also not "reasonably foreseen." Congress distinguished between "known" and "reasonably foreseen" in its definition of conditions of use, and EPA cannot equate the two. Barring a regulatory prohibition on such use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.

This exclusion is also concerning because of the potential for exposures associated with the *disposal* of these products. EPA does not even acknowledge that the disposal of commercial textiles will occur. While EPA may argue that the disposal of commercial textiles falls under its legacy-related category of "associated disposal," as described earlier in these comments (Section 4.A), EPA has no basis in the law for excluding such conditions of use. Both the use and disposal of HBCD-containing commercial textiles should be included in the risk evaluation.

Use in Adhesives: EPA has excluded use of HBCD in adhesives because, in January 2018, EPA had a personal communication with one company that manufactured an adhesive with HBCD, which apparently told EPA that, despite the use of the chemical being publicly noted on a 2017 MSDS,[142] "the company *will no longer* use HBCD in their product line." (p. 22, emphasis added) This personal communication from the industry source, which EPA has not corroborated, is not publicly available. As noted before, this is unacceptable.[143] According to EPA, the company "does not have a current supply of HBCD" and "will no longer use HBCD." (p. 22) No timeline was indicated, however, as to when the company will cease selling such products. Considering how recent this communication is, and that it involves only one company, EPA cannot on this basis determine that all such use of the chemical has or soon will cease.

EPA states: "EPA could find no evidence of ongoing manufacture, processing or distribution of adhesives using HBCD. Therefore, adhesives are not included as a condition of use for which EPA will evaluate HBCD." (pp. 22-3) Even assuming EPA is correct that such use is no longer occurring and hence is not "known," that is no basis to concluded it is also not "reasonably foreseen." Congress distinguished between "known" and "reasonably foreseen" in its definition of conditions of use, and EPA cannot equate the two. Barring a regulatory prohibition on such use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.

Use in Automotive Sector: EPA has excluded use of HBCD in the manufacture of new automobiles from the risk evaluation, based on EPA's view that the use is not ongoing. Only its use in replacement parts is to be included.

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[142] For reasons that are not clear, the link EPA provides to this MSDS does not link to the MSDS. And the link from the EPA HERO database does not link to the MSDS either.

[143] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation.

EPA bases this exclusion largely on three comments received from industry associations (p. 23) that are inconsistent and conflicting and that EPA then misinterprets. The first two commenters assert that HBCD is not used in the "manufacture of new vehicles" or "during the manufacturing process of any automotive components." These assertions are explicitly or implicitly limited to the members of those industry associations, however. The third commenter, the Alliance of Automotive Manufacturers, indicates that "this chemical is not used *during the auto manufacturing process*."[144] But the commenter goes on to state:

> However, the chemical may still be *used by some automakers* as a flame retardant in coatings of *certain components* (e.g., dashboards and headliners) and in solder paste in interior components (e.g., circuits). This chemical may also be present in adhesives and foams. (p. 23, emphases added)

This third comment, which contradicts the others, does not limit HBCD's scope to replacement parts at all, and should clearly be read as applying to *components* used in new automobiles, though not to use in *the auto manufacturing process* itself. Thus, the evidence before the agency indicates that HBCD may still be used in components of new automobiles.

Later in the document, EPA states:

> Major automobile manufacturers have phased out use of HBCD in U.S. production but continue to use it in a *few replacement parts*, according to information provided to EPA by the Alliance of Automotive Manufacturers since publication of the HBCD Scope Document. Manufacturers identified three replacement parts containing HBCD, these are absorbers (front roof rail energy) and two types of insulator panels (Alliance of Automobile Manufacturers, 2018). (p. 27, emphasis added)

The reference provided by EPA, (Alliance of Automobile Manufacturers, 2018), is yet another personal communication that EPA has not corroborated and that is not publicly available. Again, this is unacceptable.[145] The source is the same as the third commenter noted above, however, and EPA's summation of the personal communication is at odds with the earlier comment by the commenter, which is publicly available. There is no way for the public to ascertain whether the apparent contradiction is due to an inaccuracy in EPA's summary or a change in the industry association's assertion.

In any case, given this conflicting information and lack of public access to information on which EPA is relying, EPA cannot support its contention, more sweeping than its cited sources support, that "use of HBCD in the manufacture of new automobiles is not occurring (U.S. EPA, 2017c, 2012d, 2006b).

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[144] This comment's reference to use "during the auto manufacturing process" is decidedly narrower than the scope of EPA's conclusion drawn from it that applies to use "in the manufacture of new automobiles."

[145] This personal communication is not in the docket, nor is it listed in the bibliography for this problem formulation.

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Therefore, the use of HBCD in manufacture of new automobiles is not intended, known, or reasonably foreseen and therefore is not a condition of use under which EPA will evaluate HBCD." (p. 23)

Furthermore, as stated above, even assuming EPA is correct that such use is no longer occurring that is no basis to concluded it is also not "reasonably foreseen." Without a ban on this use, EPA has no basis for concluding the use is not reasonably foreseen and hence cannot exclude it from the risk evaluation.

Disposal: Although not directly addressed by EPA in the problem formulation, EPA entirely fails to mention, and hence presumably intends to exclude, so-called "legacy disposal" of HBCD-containing materials. This exclusion is especially concerning because, as EPA notes, HBCD is persistent and bioaccumulative. (p. 51) According to the problem formulation, "HBCD has been detected in a wide variety of environmental media[,] *** [and] [h]as been detected in remote areas from long range transport." (p. 35) Although EPA states that it will consider emissions to air, releases to surface waters and sediment, and application to soil of biosolids from wastewater treatment, including from disposal of HBCD or HBCD-containing materials from ongoing uses (p. 50), it is entirely unclear how EPA intends to distinguish between releases and exposures from past so-called "legacy disposals," ongoing so-called "associated disposals" of HBCD from discontinued uses, and ongoing disposal of HBCD from ongoing uses, when the chemical is so prevalent in all environmental media.[146] As EPA stated "[t]here have been changes to use patterns of HBCD over the last few years," making this analysis even more challenging. (p. 62) This issue highlights the arbitrariness and lack of scientific basis for EPA's artificial distinctions between these categories of disposal. EPA must not underestimate exposure to HBCD based on arbitrary distinctions between the sources of the contamination.

Domestic Manufacturing: Additionally, while EPA does not deem domestic manufacturing of HBCD to be a legacy condition of use, EPA has excluded it because EPA asserts the activity has recently ceased. (p. 20) EPA states in the problem formulation that it reached out to two U.S. manufacturers who indicated that they had completely replaced HBCD in their product lines and that use of stockpiles and exportation was completed in 2017. EPA received communications from the two companies that indicated they "d[id] not intend" to manufacture, import, or export HBCD in the future. (p. 20) These four personal communications linked to in the problem formulation, which EPA has not corroborated, are not publicly available. Once again, this is unacceptable.[147]

These communications, even if accurate, do not demonstrate that all domestic manufacture of HBCD has permanently ceased. While the two companies EPA communicated with were the only companies that reported domestic manufacture under the 2016 CDR, four other companies reported import of

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[146] Elsewhere, in the context of occupational exposures, EPA itself raises the need to apportion exposures to different sources: "[i]n an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA will consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix C." (p. 66)

[147] These personal communications are not in the docket, nor are they listed in the bibliography for this problem formulation.

HBCD, according to EPA's Use and Market Profile for Hexabromocyclododecane,[148] and some of these companies have domestic chemical production facilities. CDR reporting is subject to various reporting thresholds and exemptions, which means these or additional companies may domestically produce HBCD but did not report under the CDR because they fell below the volume thresholds or qualified for an exemption. Indeed, Table A-1 of EPA's Use and Market Profile for Hexabromocyclododecane lists three U.S. companies as domestic producers of HBCD that are not among the six companies that reported under the CDR. EPA appears to have had no communications with these companies, and apparently no basis for concluding that they have ceased domestic production.

As EPA stated in the problem formulation, the U.S. is not a party to the Stockholm Convention on Persistent Organic Pollutants, which banned the use, import, and export of HBCD. (p. 31) Under the Convention, three parties are registered to produce HBCD and six are registered to use HBCD for EPS and XPS in foam. (p. 31) While it is certainly progress that some U.S. manufacturers appear to have voluntarily chosen to discontinue manufacture, import, and export of HBCD, absent a regulatory ban in the U.S., there is not any assurance that such activities will not resume. Hence there is no basis to conclude the condition of use is not "reasonably foreseen." Congress distinguished between "known" and "reasonably foreseen" in its definition of conditions of use, and EPA cannot equate the two. Hence EPA cannot exclude it from the risk evaluation.

Need for a Significant New Use Rule: Because EPA has chosen to exclude all of these conditions of use for HBCD, EPA should at least promulgate a Significant New Use Rule (SNUR) as it has proposed to do for certain legacy uses of asbestos. *See* 83 Fed. Reg. 26922 (June 11, 2018), https://www.federalregister.gov/documents/2018/06/11/2018-12513/asbestos-significant-new-use-rule. Notably, for at least one of these uses, there is already a SNUR: EPA finalized a SNUR in 2015 for HBCD in consumer textiles. (p. 21) Especially where EPA has indicated that some of these uses have either yet to end or ended as recently as January 2018, at a minimum, EPA must put a SNUR in place promptly after their cessation, to ensure these uses do not begin again in the future without at least prior notification to EPA.

B. EPA's bases for excluding other conditions of use are unlawful.

Recycling of HIPS: While EPA is excluding the use of HIPS in electronic products because EPA deems it a so-called legacy use, it appears that EPA is excluding the recycling of HIPS-containing electronic products on a different basis. (p. 21) Despite recognizing that electronic products can be recycled and that HIPS-containing materials constitute more than half of the plastic materials recovered from household electronics, EPA is excluding this use because "no information was identified that confirms use of HBCD in recycled HIPS for the *purposes of flame retardancy*." (p. 21) EPA has never articulated an exclusion of conditions of use on the basis that the function served by an ongoing use is different than the function associated with a use that EPA now considers "legacy."[149] First, whether a chemical present in a

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[148] *See* Use and Market Profile for Hexabromocyclododecane (HBCD) at 7 (June 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0049.

[149] Moreover, EPA states that "[n]o information was identified that further described the processes used in recovering the plastics from electronics and how those plastics are reprocessed into other

material is serving a particular function or not has no bearing on its exposure potential, and thus EPA should be analyzing HBCD in these recycled products to obtain a scientifically accurate assessment of exposure. Second, EPA must address the risks of a chemical under its conditions of use, defined under TSCA § 3(4) to extend to known or reasonably foreseen, as well as intended, circumstances. Thus, EPA cannot exclude exposures that are known or reasonably foreseen even if they are not intended. EPA must gather the necessary information on these uses, and address any exposures from these ongoing uses.

Recycling of EPS/XPS: Additionally, despite the fact that "the primary on-going consumer use of HBCD is within EPS and XPS insulation" *and* that EPA plans to analyze certain conditions of use associated with the recycling of articles containing HBCD back into EPS and XPS insulation, EPA will only do so when the HBCD in those articles imparts intended flame retardancy to the final product. (p. 37) This exclusion has no basis in the law, or in EPA's regulations. EPA must assess HBCD in all recycled products.

Other uses: EPA also decided that a number of uses are not conditions of use, specifically, "coatings, solder, children's products including toys and car seats; furniture (such as bean bags chairs)." (p. 24) In regards to the children's products, EPA has evidence that HBCD is present in some children's products. (pp. 23-24) It appears that because the Washington state legislature determined that HBCD was not added to the products for purposes of flame retardancy, (p. 24), EPA does not consider its presence in children's products to be a "condition of use." This "reasoning" entirely fails to consider that HBCD *is present in children's products* and is therefore a known condition of use.

Also, for certain additional uses that were identified, EPA states it is "uncertain whether similar U.S. products contain HBCD. In some of the articles, HBCD is present but may not have been intentionally used." (p. 26 fn.e) But Congress directed EPA to assess chemical risks associated with reasonably foreseen and known, as well as intended, circumstances under which a chemical substance may be manufactured, processed, distributed in commerce, used, or disposed of. 15 U.S.C. § 2602(4). Evidence of HBCD's presence in products in the U.S. means that it is known or reasonably foreseen that consumers in the U.S. may use such products or otherwise be exposed to HBCD present in the products; therefore, such uses are conditions of use of HBCD. It is not clear from EPA's citation what these uses are; however, an article from 2014 indicates that there may be additional products where HBCD is present that EPA has not addressed in the problem formulation.[150]

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products." (p. 89). In light of this data gap, how can EPA reliably conclude what the purpose is of the recycled products?

[150] Manviri Rani, et al., *Hexabromocyclododecane in polystyrene based consumer products: An evidence of unregulated use*, 110 Chemosphere at 111-19 (Sept. 2014), https://www.sciencedirect.com/science/article/pii/S0045653514002252 (identifying marine buoys and food containers, among other items, has having concentrations of HBCD). This document is mentioned in EPA's bibliography on HBCD, so it is unclear why EPA would not have addressed these potential uses.

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C. EPA must further analyze drinking water as a potential exposure pathway to HBCD.

EPA stated that there is potential for oral exposure to HBCD by "ingestion of dust and soil; *drinking water* and breast milk; and edible aquatic and terrestrial biota (e.g., from fishing, hunting, gathering and farming)." (p. 38, emphasis added) However, EPA states it does not expect to further analyze exposures from drinking water sources. (pp. 38, 51) This pathway is excluded despite the fact that "drinking water monitoring data is generally unavailable." (p. 38) EPA even acknowledges that "exposures from drinking water containing HBCD are possible," but nevertheless excludes these exposures because they "are likely to be relatively lower than other oral exposure pathways." (p. 51) But TSCA includes nothing that allows EPA to limit itself only to assessing the "relatively larger" sources of exposure to HBCD or other chemicals. Ultimately, EPA relies solely on the physical-chemical and fate properties of HBCD to predict that the concentrations of HBCD in drinking water will be low. But EPA has not established that these concentrations and exposures will not be significant, particularly in conjunction with other exposure pathways. EPA should obtain additional information on this exposure pathway and analyze this pathway.

D. EPA should not exclude disposal of HBCD on the basis of other statutory authorities.

EPA will explicitly exclude all disposal pathways except disposal of construction and demolition wastes to RCRA subtitle D municipal solid waste landfills. (p. 52) EPA has failed to provide any analysis to demonstrate the extent to which existing regulations actually eliminate associated exposures. As discussed earlier in these comments at length, such statute-based exclusions have no basis in the law and are scientifically unsound (see Section 5.F).

E. EPA has improperly decided to do no further analysis on a number of human exposure pathways to HBCD.

Occupational Exposures: EPA states it generally plans to consider exposures to workers and occupational non-users (ONU). However, in the case of automobile replacement parts, EPA plans to do no further analysis on dermal and inhalation exposures to workers because "emissions of HBCD from automobile replacement parts are not expected to be significant and the EPS or XPS that comprises these replacement parts is expected to be covered with other material thereby limiting emissions." (p. 97) These statements raise numerous concerns. EPA indicated this decision by listing it in a table without any additional explanation or citation to support its "expectations." As a result, it is entirely unclear what EPA considers to be an "insignificant" level of emissions from HBCD and how it made that determination. Presumably workers are involved in applying any covering present in such parts in the first place and hence may have been exposed prior to its application. Considering that EPA is generally analyzing inhalation for all other exposure scenarios, this cursory explanation to do no further analysis of this exposure to workers is arbitrary and lacks justification.

EPA will also fail to analyze nearly all ONU *dermal* exposures to HBCD for the majority of the release exposure scenarios for the industrial/commercial uses of HBCD. Specifically, EPA is doing no further analysis on all but one potential dermal exposure because "[d]ermal exposure is expected to be primarily to workers directly involved in working with the chemical." (pp. 95-98) TSCA provides no basis

for limiting EPA's risk consideration only to direct exposures, nor to focus only on persons "primarily" exposed to the chemical.

EPA also expects to do no further analysis on worker exposure to HBCD during the distribution of bulk materials or formulated products through any exposure pathway or route, or to any subpopulation. (p. 97) EPA provided no explanation other than to assert that exposure would only occur "in the event the packaged raw material or formulated products are damaged, resulting in the potential release of HBCD." (p. 97) EPA provided no citation for this assumption, or more generally to support its conclusion that no exposure will occur during the distribution of HBCD.

Consumer Exposures: In regards to consumer exposures, EPA states it plans to look at most exposure pathways for the conditions of use it is not excluding from the risk evaluation. Notably, EPA acknowledges that consumer articles containing HBCD have long service lives and that the chemical is present during the entire useful life of the article. (p. 37) This means that the potential for consumer exposure to HBCD in electronic products and children's products, uses that EPA has chosen to ignore as "legacy," will also continue to persist. EPA will also conduct no further analysis on consumer exposure (including to children) to building and construction materials that contain HBCD, specifically insulation in residential buildings. (p. 99) This exclusion is on the basis of EPA's assertion that consumers (including children) are not likely to be in direct contact with insulation; however, EPA has not provided evidence demonstrating that children are unlikely to come into contact with insulation and, for example, place it in their mouths and hence that this activity is not reasonably foreseen. For example, children living in substandard housing where insulation may be exposed may well be exposed in this very manner.

General Population Exposures: Unlike in many of the other problem formulations, EPA states it will generally look at exposures to the general population for HBCD. (p. 38) However, EPA will only do so for exposures it has not excluded. As mentioned earlier, because EPA's information indicates that many of the uses of HBCD have only recently ceased, it is unclear how EPA will decide whether an exposure to the general population is from what it considers a "condition of use" or from a legacy use.

F. EPA's stated commitment to addressing background levels does not remedy EPA's multiple exclusions.

EPA states that:

> For HBCD, EPA plans to analyze background levels for indoor dust, indoor air, ambient air, surface water, sediment, soil, dietary food sources, aquatic biota, and terrestrial biota. EPA has not yet determined the background levels in these media or how they *may* be used in the risk evaluation. (pp. 56-57, emphasis added)

EPA similarly repeats its intention to look at background levels in its Exposure Conceptual Model (pp. 99-105). In the case of HBCD, which EPA has stated is ubiquitous in the environment, EPA *must commit* to considering background levels in the risk evaluation in order to account for exposures not able to be linked to a specific condition of use of HBCD.

However, the consideration of background levels does not provide a justification for EPA's exclusions, including its exclusions of so-called legacy uses or other past uses, from the scope of this risk evaluation. For the reasons already discussed in these comments (see Section 4.A), EPA needs to include those uses and associated exposures and directly evaluate them in its risk evaluation.

31. EPA has failed to address how it plans to fill the numerous information gaps identified in the HBCD problem formulation.

In the HBCD problem formulation two categories of information gaps can be identified. The first category includes instances where there is little to no data at all available to EPA.

For example, EPA admits that "little is known" about the recycling of foam products containing HBCD. (p. 28) EPA's scant knowledge about the recycling of foam products is problematic because EPA states elsewhere in the problem formulation that the use of HBCD in foam "accounted for 95% of all HBCD applications in the past decade," (p. 27), and that "most insulation containing HBCD is still in place." (p. 28) Despite this potentially large source of exposure, EPA offered no plan to develop additional information. EPA must identify steps it will take to address this information gap.

EPA also admitted that there is "limited information available" regarding the mild irritation and sensitizing potential of HBCD. (p. 43) Even though EPA recognized the uncertainty related to this hazard, EPA did not indicate (as it did in other instances) that this hazard would be subject to further evaluation. EPA must commit to further developing and analyzing information about these potential hazards.

EPA also stated that it would "try to obtain" additional information about how HBCD is used in automobile replacement parts. (p. 27) As this use is one of the few that EPA has not yet excluded, and one that companies have acknowledged is an ongoing use, EPA must lay out a clear plan for acquiring additional information about it. Stating that it will merely "try" to collect additional information is not sufficient.

EPA also stated that where information was not available, rather than require the development or submission of the information, it would rely on models. In particular, EPA stated that:

> If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality. (p. 60)

EPA's reliance on models as a first resort raises concerns over the resulting uncertainty associated with the conclusions it draws. It also flies in the face of the enhanced information authorities EPA was provided under the reforms made to TSCA in 2016 and raises the question once again as to why EPA refuses to use these authorities even in the face of significant information gaps.

Additionally, "EPA was not able to identify release scenarios corresponding to several conditions of use (e.g. recycling, construction and demolition) of products containing HBCD." (pp. 59, 63) This

information gap is concerning because, after EPA's numerous exclusions of conditions of use, these three conditions of use make up a significant part of the remaining scope (only eight conditions of use were identified as included in the problem formulation, p. 29). That "EPA *may* conduct industry outreach efforts, or perform supplemental, targeted literature searches to better understand the process steps involved" (p. 59, emphasis added) is not a sufficient means to address this critical data gap, nor is EPA's vague and caveated reference to outreach efforts entirely convincing. EPA must firmly commit to filling this information gap.

A second category of information gaps involves areas of uncertainty in hazard data. EPA has frequently indicated that certain effects are unknown, inconsistent, or variable. For instance:

1. "For female reproductive effects, there is some rodent evidence that HBCD may alter fertility and pregnancy outcomes as well as reduce the number of mature and developing follicles in the ovary; however, effects on reproductive organ weight are *inconsistent*." (p. 43, emphases added)
2. "There is *mixed* epidemiological data on developmental toxicity of HBCD, while animal toxicity studies suggest that early life exposure to HBCD at high doses can affect various developmental outcomes, including reduced offspring viability, decrements in pup weight and alterations in eye opening." (p. 43, emphasis added)
3. "Overall, immunological effects from HBCD exposure are *variable* and *inconsistent* across studies for endpoints such as immune organ weights, hematology or histopathology (U.S. EPA, 2014d), and its relevance to the risk evaluation will require further evaluation." (p. 43, emphases added)
4. "Although the current data does not appear to provide sufficient evidence that HBCD is carcinogenic, EPA will further evaluate genotoxicity and other cancer hazards in the risk evaluation as part of a systematic review." (p. 43)
5. "Data sources associated with indoor exposure pathways have not been comprehensively evaluated, quantitative comparisons across pathways or in relation to toxicity thresholds are not yet available." (p. 65)
6. "EPA has grouped the scenarios into 8 representative release/exposure scenarios of which 7 will be further analyzed. EPA was *not able to identify* occupational scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition)." (p. 64, emphasis added) Notably, these uses include a considerable portion of the remaining conditions of use that impact workers.

It does not appear that EPA has developed any concrete plan to address these data gaps. EPA must develop and carry out a plan for filling these gaps.

In some cases, EPA specifically indicated that it may choose not to take any steps to address a data gap. For instance, "depending on available information," EPA may analyze exposure to occupational non-users (persons who do not directly handle the chemical but perform work in an area near where the chemical is present)." (p. 36) EPA also states that:

> If sufficient toxicity studies *are not identified* in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. (p. 73, emphasis added)

EPA was given broad authority under TSCA to obtain information, *see* 15 U.S.C. §§ 2603, 2607; therefore, if EPA is lacking needed information, it must use its authorities to obtain that information, rather than avoid evaluating potential exposures, especially when the information gap involves exposures to a potentially exposed or susceptible subpopulation.

32. EPA's problem formulation contains several statements relating to confidential business information (CBI) that are or may be inconsistent with its authorities and obligations under TSCA.

The life cycle diagram for HBCD has not been fully disclosed to the public because the specific production volumes provided in the 2016 CDR were "claimed as confidential business information." (p. 30) It has been two years since EPA collected that information, and almost two years since EPA announced that HBCD would be one of the first ten chemicals reviewed under section 6, yet EPA has apparently not reviewed those CBI claims or prioritized its review of HBCD claims despite the ongoing risk evaluation. EPA's failure to conduct the timely reviews TSCA mandates of CBI claims made in submissions under the CDR is resulting in the public being precluded from understanding the conditions of use of this chemical. This information is critical to understanding the impacts of EPA's exclusions and hence such claims should immediately be reviewed (and the determinations made public).

It is also curious that the 2015 production volume remains confidential even though EPA is excluding a host of uses that were ongoing at that time (e.g., use in EPS resin and use in HIPs). (p. 30) If those companies have communicated to EPA that manufacture for some of those uses from 2015 are no longer ongoing, (p. 21), why are their site-specific volumes still confidential and the national production volume still withheld, since it allegedly no longer reflects the "ongoing" production of HBCD in the United States? EPA must ensure that these claims meet the applicable CBI requirements under TSCA.

EPA also states that EPA "may consider any relevant CBI information in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure." (p. 56) This statement ignores the major changes made to the CBI provisions of TSCA section 14. Companies must substantiate most claims for CBI protection and EPA must review many of them within 90 days of submission of the information. Any claim that does not meet all applicable requirements cannot be protected from disclosure.

33. The review of HBCD under TSCA should utilize all of the materials developed by the IRIS program before the assessment was transferred to the TSCA program.

In early 2018, it appears that EPA's Office of Research and Development (ORD) stopped its assessment of HBCD. In email correspondence between ORD and the Office of Chemical Safety and Pollution

Prevention (OCSPP),[151] ORD indicated that it had developed a number of materials in the latter half of 2017 that were not yet incorporated into the Toxicological Review. These include:

- Data extraction of animal toxicology studies into HAWC and QC;
- Study evaluation of both epidemiology and animal toxicology studies in HAWC;
- Data visualization in HAWC (including development of an exposure-response array visualization option for the HAWC software, which was used to develop new HBCD arrays);
- Literature screening of new studies and discussions of how to incorporate them into the draft;
- Development of an IRIS assessment protocol and review by agency partners;
- Preliminary development of evidence profile tables that reflect evidence integration for each hazard;
- Discussions of within- and across-stream evidence integration as well as hazard conclusions using the structured framework in the IRIS Handbook; and
- A revised structure for the Toxicological Review, primarily reflecting changes in presentation of the methods and results of the systematic review.

ORD also indicated that an RfD had been derived, and that the systematic review documents were also available.

Because, according to the email, none of these items were provided to OCSPP in early 2018, EPA should ensure that these materials have been obtained and incorporated by OCSPP into its risk evaluation for HBCD. Notably, the problem formulation only states that EPA has looked at the Preliminary Materials for the IRIS Toxicological Review of HBCD from 2014, (pp. 42, 70), which appears to be distinct from the materials ORD referenced in its letter. Moreover, since additional emails between ORD and OCSPP suggest that the frameworks and systematic reviews for HBCD differed between the two offices, it is especially critical that OCSPP look closely at the materials already derived by ORD.[152] EPA should then explain any deviations from the ORD materials.

34. EPA must look at exposures and hazards to all aquatic organisms, including marine mammals.

EPA states that it will analyze hazards of HBCD to "aquatic organisms including fish, aquatic invertebrates, aquatic plants, and sediment invertebrates" but does not mention aquatic organisms that are not fish, such as marine mammals. (p. 42) Although this list is more comprehensive than in other problem formulations (e.g., TCE), the failure to include marine mammals is a significant oversight in regards to HBCD. Numerous studies in EPA's search results for HBCD indicate that HBCD has been

[151] Available through FOIA at https://www.foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2018-004651&type=request (the documents are currently not available through the updated FOIA, but the commenter has a copy if requested).
[152] Available through FOIA at https://www.foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2018-004651&type=request (the documents are currently not available through the updated FOIA, but the commenter has a copy if requested).

found in increasing levels in marine mammals.[153] EPA must comprehensively consider all relevant aquatic organisms in its assessment of exposures to HBCD via contaminated surface water.

Moreover, unlike other problem formulations where EPA has calculated a concentration of concern in surface water, (e.g., see the problem formulation for 1-bromopropane, pp. 42-43), EPA has not done so for HBCD. Instead EPA stated that:

> The aquatic environmental hazard studies *may* be used to derive acute and chronic concentrations of concern (COC) for mortality, behavioral, developmental and reproductive or other endpoints determined to be detrimental to environmental populations. Depending on the robustness of the evaluated data for a particular organism (*e.g.* aquatic invertebrates), environmental hazard values (e.g. ECx/LCx/NOEC/LOEC, etc.) *may* be derived and used to further understand the hazard characteristics of HBCD to aquatic species. (p. 69, emphases added)

EPA must commit to collecting the information necessary to derive these values; stating that they may not do so depending on the "robustness" of the data is not a valid reason.

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[153] *See, e.g.*, Hoguet, J., et al., *Spatial and temporal trends of persistent organic pollutants and mercury in beluga whales (Delphinapterus leucas) from Alaska*, SCI. OF THE TOTAL ENV'T 449: 285-294 (2013), http://dx.doi.org/10.1016/j.scitotenv.2013.01.072; Montie, EW, et al., *Brominated flame retardants and organochlorine contaminants in winter flounder, harp and hooded seals, and North Atlantic right whales from the Northwest Atlantic Ocean*, MAR. POLLUT. BULL. 60: 1160-1169 (2009), http://dx.doi.org/10.1016/j.marpolbul.2010.04.002; Lam, JC, et al., *Temporal trends of hexabromocyclododecanes (HBCDs) and polybrominated diphenyl ethers (PBDEs) and detection of two novel flame retardants in marine mammals from Hong Kong, South China*, ENVTL. SCI. TECHNOL. 43: 6944-6949 (2009), http://dx.doi.org/10.1021/es901408t.

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Comments on 1,4-Dioxane

35. EPA has excluded or failed to sufficiently analyze numerous conditions of use and exposure pathways for 1,4-dioxane.

A. EPA has inappropriately excluded all consumer uses and all contamination of industrial, commercial and consumer products.

EPA asserts that it "did not find evidence of any current consumer uses for 1,4-dioxane and is excluding consumer uses from the scope of the risk evaluation" and that "contamination of industrial, commercial and consumer products are *not intended conditions of use* for 1,4-dioxane and will not be evaluated." U.S. EPA, Problem Formulation of the Risk Evaluation for 1,4-Dioxane at p. 18 (emphasis added) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064. For support, EPA cites its earlier scope document. *See* 1,4-Dioxane, Scope, Docket ID: EPA-HQ-OPPT-2016-0723.

In our comments on the scope document, EDF already commented at length on the illegality of these exclusions; those comments are incorporated here by reference. EDF Comments on Ten Scopes under the Toxic Substances Control Act, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069. In brief, EPA's position that it can ignore known and foreseeable conditions of use of a chemical violates the text of the law. "Conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances such as 1,4-dioxane that are present in products as impurities or byproducts because they are not "intended" essentially reads the other two scenarios out of the statute. This exclusion will result in a deficient and erroneous evaluation and determination of the chemical's risks.

EPA's scope document identified numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. And in EPA's 2015 Problem Formulation and Initial Assessment for 1,4-dioxane, EPA stated:

> EPA/OPPT concludes that exposure to consumers can result from the use of soaps and detergents and other products that contain 1,4-dioxane as a contaminant. Adult women who use multiple cosmetics and cleaning products are likely the most exposed population as determined in the Canada assessment.[154]

[154] *See* U.S. EPA, *TSCA Work Plan Chemical Problem Formulation and Initial Assessment, 1,4-Dioxane, CASRN: 123-91-1* at 28 (Apr. 2015), https://www.epa.gov/sites/production/files/2017-06/documents/14_dioxane_problem_formulation_and_intial_assessment.pdf.

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Bizarrely, EPA nonetheless concludes in its problem formulation that it "did not find evidence of any current consumer uses for 1,4-dioxane." (p. 18)[155] As discussed in detail in our earlier comments, these products are known and reasonably foreseen conditions of use leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA must analyze these conditions of use in the risk evaluation.

B. Major deficiencies abound in EPA's assertion that exposures to 1,4-dioxane falling under other legal jurisdictions are adequately managed.

We have discussed earlier (see Section 5) the many legal flaws in EPA's assertion that it can ignore exposure pathways that fall under other EPA authorities and assume they "adequately assess and effectively manage" any risks. EPA's 1,4-dioxane problem formulation also contains many technical and scientific flaws or inaccuracies. To illustrate, we provide below some specific comments on unsupported or insufficiently supported statements in the document, as examples of EPA's failure to adequately justify on scientific grounds the sweeping exposure pathway exclusions it has proposed.

Air emissions: In seeking to justify its exclusion of exposures from air emission pathways, EPA states:

> 1,4-Dioxane is a HAP. EPA has issued a number of technology-based standards for source categories that emit 1,4-dioxane to ambient air and, *as appropriate*, has reviewed, *or is in the process of reviewing remaining risks*. Because stationary source releases of 1,4-dioxane to ambient air are adequately assessed and any risks effectively managed when under the jurisdiction of the CAA, EPA does not plan to evaluate emission pathways to ambient air from commercial and industrial stationary sources or associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation. (p. 43, emphases added)

In the Appendix, EPA merely provides a list of technology-based standards for certain source categories. EPA provides no analysis whatsoever as to: the extent to which the standards cover the full range of stationary sources of this chemical; the extent and magnitude of releases of the chemical allowed under each of the standards; the duration, intensity, frequency, and number of exposures resulting from those allowable emissions (as required under TSCA section 6(b)(4)(F)(iv)); or any other factors that would be necessary to analyze and determine the extent and nature of potential risk allowed under the standards. EPA has not acknowledged, let alone analyzed, the overall risks to the general population or to vulnerable subpopulations due to the combination of exposures arising from the various sources for

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[155] Equally bizarrely, EPA states: "The 1,4-dioxane life cycle diagram (Figure 2-1) indicates that no uses of 1,4-dioxane were identified in consumer products. *EPA did not receive data, information or comments that informed a change was necessary to the scope*." (p. 41, emphasis added) This statement is, of course, demonstrably false. EPA's own scope document identifies numerous uses of 1,4-dioxane in consumer products, as did EDF's and, no doubt, many others' comments.

which standards exist, not to mention additional emission sources not subject to any standard. EPA has made no attempt to reconcile any such risk with that allowed under TSCA.

In the absence of such analyses, there is no basis whatsoever for EPA to assert that air releases of this chemical have been adequately assessed or that any risks have been effectively managed under TSCA's standards.

EPA offers only a vague claim that EPA "as appropriate, has reviewed, or is in the process of reviewing remaining risks." No specifics as to the status of or timeline for such reviews have been provided, and no indication is made as to when and on what basis such reviews are deemed "appropriate." Nor have the results of any such reviews that have been completed been provided, let alone analyzed in the context of TSCA's requirements.

Drinking water exposures: In seeking to justify its exclusion of drinking water pathways, EPA states:

> EPA's Office of Water has established a Health Advisory level of 35 µg/L (which corresponds to a 1 in ten thousand lifetime cancer risk) for 1,4-Dioxane. (p. 43)

This statement is highly misleading as it misconstrues the context and purpose of Health Advisories. Here is what the Office of Water's own Health Advisory 2018 compilation states:

> HAs [Health Advisories] are intended to protect against *noncancer effects*. The 10^{-4} Cancer Risk level provides information concerning cancer effects.[156]

EPA's own November 2017 Fact Sheet on 1,4-dioxane – never mentioned in the problem formulation – cites the 1,000-fold lower level of 0.35 ug/L that corresponds to EPA's typical cancer risk protection goal for general populations of 10^{-6} (a 1-in-one-million lifetime cancer risk). It also shows that most states have guidelines far below 35 ug/L.[157]

EPA's problem formulation goes on to state:

> 1,4-Dioxane is also currently listed on EPA's Fourth Contaminant Candidate List (CCL 4) and was subject to occurrence monitoring in public water systems under the third Unregulated Contaminants Monitoring Rule (UMCR 3). Under UMCR 3, water systems were monitored for 1,4-dioxane during 2013-2015. Of the 4,915 water systems monitored, 1,077 systems had detections of 1,4-dioxane in at least one sample. None of the systems measured levels greater than the Health Advisory level, *however, 341 systems (6.9%) had results at or above 0.35 µg/L (which corresponds to a 1 in a million-*

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[156] U.S. EPA, *2018 Edition of the Drinking Water Standards and Health Advisories Tables* at p. iii (Mar. 2018), https://www.epa.gov/sites/production/files/2018-03/documents/dwtable2018.pdf (emphasis added).

[157] U.S. EPA, *Technical Fact Sheet 1,4-dioxane* at 3-4 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

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> *lifetime cancer risk).* In accordance with EPA-OW's process, 1,4-dioxane is *currently being evaluated* under the fourth Regulatory Determination process under SDWA.
>
> Hence, because the drinking water exposure pathway for 1,4-dioxane is being addressed under the regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under SDWA, EPA does not plan to include this pathway in the risk evaluation for 1,4-dioxane under TSCA. (p. 43, emphasis added)

This excerpt contains misleading or inaccurate statements or implications. First, by EPA's own admission, the CCL is "a list of *unregulated* contaminants" (p. 43; emphasis added). Numerous additional steps would be needed to actually regulate 1,4-dioxane under SDWA, which have not been taken. The vague statement that the chemical is "currently being evaluated" – with no specification of what outcomes may result or any timeline for further action toward regulation – provides no basis for EPA's assertion that its risks are being "adequately assess[ed] and effectively manage[d]."

Second, EPA again erroneously states that 35 ug/L is the Health Advisory level, and then uses that level to assert there are no exceedances. In fact, as EPA notes, nearly 7% of public water systems – serving 7 million Americans – exceed the risk level representing acceptable risk to the general population.

EPA's decision to ignore such clearly significant levels of exposure and risk, and to refuse to evaluate their contribution to the overall risks of this chemical, is unconscionable.

Ambient water pathways: EPA's problem formulation states: "EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for 1,4-dioxane. ... Currently, only one state (Colorado) includes human health criteria for 1,4-dioxane in their water quality standards and none include aquatic life criteria for 1,4-dioxane. As a result, this pathway will undergo aquatic life risk evaluation under TSCA (see Section 2.5.3.2)." (p. 44)

EPA never indicates that it has also *not* set a recommended water quality criterion for human health for this chemical. Yet inexplicably, it appears EPA plans to exclude ambient water pathways from the risk evaluation of human health risks to the general population. EPA has provided no justification for this exclusion.

In addition, despite EPA's statement (cited above) that "this pathway will undergo aquatic life risk evaluation under TSCA" (p. 44), Appendix E of the problem formulation contradicts that statement, indicating that aquatic species exposure via water will not be subject to any further analysis.

In sum, EPA must analyze these exposure pathways in the risk evaluation in order for it to be consistent with the best available science and reasonably available information.

C. EPA has insufficiently justified many of its decisions not to include known or potential exposures or conduct further analysis, and has prematurely concluded various exposures present no significant risk.

EPA's 1,4-dioxane problem formulation contains many rushes to judgment, with EPA all but concluding there is no unreasonable risk from certain exposures, based on little analysis and with no indication that it intends to revisit those exposures or risks in combination with those it does intend to analyze further. To illustrate, we provide below some specific examples.

Risks to aquatic invertebrates and aquatic plants: With little analysis and based on limited data, EPA asserts that "[m]easured and estimated levels of 1,4-dioxane in the environment are sufficiently below the acute and chronic aquatic COCs [concentrations of concern]," plans no further analysis, and implies it has concluded that any associated risks can be ignored (p. 41). Yet:

- EPA's predicted concentrations in surface water for acute and chronic scenarios are up to 58% and 40% of the COCs, leaving little room for error.
- Elsewhere, EPA acknowledges "[T]here are relatively fewer data available on 1,4-dioxane levels in surface water," (p. 28), indicating a data gap that EPA apparently will do nothing to address.
- EPA implies that its calculations of COCs are conservative at least in part because of its use of assessments factors (pp. 29, 70, 81). The use of such factors is not conservative: They account for *real-world sources of variability as well as database limitations*, and cannot be construed as "safety factors" that yield conservative estimates.[158] As EPA states: "The application of AFs [assessment factors] provides a lower bound effect level that would likely encompass more sensitive species not specifically represented by the available experimental data. AFs are also account for differences in inter- and intra-species variability, as well as laboratory-to-field variability." (p. 70)
- EPA's calculated acute COC is inconsistently reported. In the text, it is listed as 59,800 ppb (p. 35), while in Appendix C it is listed as 20,000 ppb (p. 70). EPA's modeling of surface water concentrations includes assumptions that are not necessarily conservative, despite EPA's claims to the contrary.

For example, EPA points to the surface water modeling assumption that "[w]astewater treatment removal is assumed to be 0% for this exercise" (p. 29); yet its own modeling of wastewater treatment removal efficiency using EPISuite STP module indicates removal rates will be very low, on the order of 2% (p. 24). Far from being a conservative assumption, this use of 0% is a reasonable conclusion based on the available data. Despite a promised "full table of results, see Appendix E" (p. 29), that table provides only EPA's conclusions and none of its analysis.

[158] *See* section 14 of these comments.

EPA's current analysis is incoherent and unexplained. EPA must obtain additional information on exposure through this pathway as well as hazard, and EPA must prepare a scientifically valid analysis of this pathway.

Risks to sediment organisms: EPA states: "While no ecotoxicity studies were available for sediment organisms, the toxicity of 1,4-dioxane to sediment invertebrates is expected to be similar to the toxicity to aquatic invertebrates." (p. 42) EPA provides no basis for this assertion of expected similar toxicity. This is a clear data gap that EPA should have filled, or should now move to fill, rather than resort to such hand-waving to dismiss a potential risk it has not examined.

Occupational exposures: Occupational exposures appear to be the only exposures to 1,4-dioxane EPA will further analyze. But how it will sufficiently do so is far from clear. Below we cite examples of statements that are vague at best as to their intent or implications for EPA's occupational exposure assessment.

EPA states: "EPA will evaluate applicable regulatory and non-regulatory exposure limits." (p. 48) The meaning of this statement is not at all clear; what does it mean that EPA will "evaluate" such limits? Will it do so to determine their adequacy to address risks to workers? What assumptions will EPA make as to their extent of applicability to various exposure sources, or the extent of compliance with them? EPA needs to provide far more detail than it has. See section VI for more on this concern.

EPA states: "For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels." (p. 48) EPA appears to acknowledge that clear exposure data gaps exist, yet avoids any mention of using its authorities to fill the gaps. TSCA Section 4 provides EPA with clear authority to require monitoring or other exposure studies to be conducted, while section 8 provides authority to require reporting of existing studies or data. Yet EPA merely indicates it will review existing models, begging the question as to the adequacy or reliability of the models to address the identified gaps, and what EPA will do if the available models are insufficient.

EPA states: "During distribution, 1,4-dioxane is contained in closed systems (e.g. drums, pails, bottles) so *releases and exposures are not expected*." (p. 37; emphasis added) This blanket assertion is made with absolutely no supporting analysis or data, either documenting the extent to which the identified "closed systems" are actually used, or the extent to which they are in fact "closed" and lead to no releases or exposure whatsoever, as EPA asserts. Even on their face, the examples raise many questions. For example: Are drums or bottles never open? How is a pail a "closed system"?

EPA states: "EPA reviewed the potential for occupational exposures associated with subcategories of conditions of use where a mist may be generated. *EPA determined that most subcategories will not produce a mist during their typical use and, for these, EPA concludes that exposure to 1,4-dioxane would be negligible and does not plan further analysis*." (p. 37, emphasis added) EPA appears to have conducted no analysis, at all, let alone any "further analysis." It provides no supporting analysis or data to support this sweeping assertion. Yet EPA has drawn an apparently final conclusion not to be revisited that exposure is "negligible."

EPA states it will:

> 4) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios. EPA will review potential data sources on engineering controls and personal protective equipment as identified in Table 2-10 to determine their applicability and incorporation into exposure scenarios during risk evaluation." (p. 49)

EPA provides no indication as to how it will "consider and incorporate" such controls or equipment into its exposure scenarios. Myriad questions arise. What assumptions will be made as to their extent of use, their efficacy, etc.? Limitations on the extent of use and the efficacy of workplace controls, especially for PPE, have been illuminated by both OSHA and EPA. EDF discusses this issue at greater length in section 13 of these comments.

EPA's vague and unexplained statements about its planned analyses raise serious concerns and often lack any empirical basis. EPA must analyze occupational exposures based on the best available science, and EPA must use its information authorities to obtain reasonably available information about these exposures.

General population exposures: EPA states that it "does not expect to consider and analyze general population exposures in the risk evaluation for 1,4-dioxane." (p. 49) Yet its own analyses point to the clear potential for such exposures. Below are some examples.

EPA states:

> Indoor air exposures may occur from infiltration from ambient air or emissions from tap water during activities such as showering and bathing. Based on the relatively high water solubility and relatively low Henry's law constant for 1,4-dioxane, EPA expects that volatilization would be low for many indoor uses. However, increased water temperature during bathing and showering can increase volatilization. (p. 31)

In addition to exposure to 1,4-dioxane contaminated tap water used for showering or bathing, use of products containing 1,4-dioxane especially in warm or hot water could also lead to exposures. This would include personal care products like shampoo or soap (some of which may not fall under TSCA jurisdiction) but also various cleaning, laundry or related products that could or would be used in hot or warm water. EPA must analyze exposures to the general population, including exposures through water and products.

EPA states: "1,4-Dioxane has also been detected in landfill leachate (ATSDR, 2012)." (p. 28) Yet it intends to wholly exclude such exposures based on presumed adequate management under federal or state law, absent any analysis demonstrating this. The fact that 1,4-dioxane is present in liquids leaching from landfills suggest that it may be coming from consumer products containing it – yet another demonstration of how arbitrary EPA's decision is to ignore exposures associated with consumer use of products containing the chemical.

36. EPA statements raising questions about the available science identifying health risks are vague and insufficiently supported.

EPA states:

> EPA expects to use these previous analyses [including the IRIS assessment] as a *starting point for identifying key and supporting studies* to inform the human health hazard assessment, including dose-response analysis. (p. 35, emphasis added)

Is EPA planning to use these prior assessments *only* for the purpose of identifying studies? If so, on what basis is it rejecting the hazard assessments themselves? If EPA now believes there are flaws or shortcomings in those earlier assessments, it should clearly identify them and provide the basis for its beliefs.

EPA should not lightly disregard EPA's existing peer-reviewed IRIS assessment for 1,4-dioxane, including the hazard values which the agency has relied on in the past. EPA must identify and explain any decision to deviate from these values, as well as the scientific basis for such deviation.

EPA refers to "key" and "supporting" studies, but the meaning of these descriptors is entirely unclear. EPA must explicitly define the meaning of these terms and their implications with regard to the agency's approach to systematic review and risk evaluation.
EPA states:

> Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that *meet the systematic review data quality criteria* described in the Application of Systematic Review in TSCA Risk Evaluations document (U.S. EPA, 2018a). Data quality evaluation will be performed on key studies identified from the IRIS assessments (U.S. EPA, 2013b, 2010), the *TSCA Work Plan Problem Formulation and Initial Assessment* (U.S. EPA, 2015c) and studies published after 2010 (oral) and 2013 (inhalation) that were captured in the comprehensive literature search. *Hazards identified by studies meeting data quality criteria* will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints. (p. 51, emphases added)

EPA has not explained, either here or in its systematic review document, what it means for data or studies to "meet the systematic review data quality criteria." Moreover, this language suggests EPA will apply its criteria in a black-or-white manner: a study is either in or out. How is this consistent with the statute's requirement that EPA take a weight-of-evidence approach? How is it consistent with the scientific standards in TSCA section 26(h), which require EPA to consider the "extent" or "degree" to which various factors characterize information, methods, models, etc. – which does not support the black-or-white approach EPA appears to intend to apply.

EPA states: "Some data support a non-linear MOA [mode of action] for liver tumorigenesis." (p. 36) Notably, EPA has provided no data and citations to support this contention.

EPA may have in mind work published by Dr. Michael Dourson, who has argued for a non-linear MOA for 1,4-dioxane in work sponsored by PPG Industries, a major user of the chemical.[159] Dourson argued for a far less health-protective standard, about 1000-fold weaker, than the value in EPA's IRIS assessment indicative of an increased cancer risk of 10^{-6}. Scientists employed by the Michigan Department of Environmental Quality[160] and the New Jersey Department of Environmental Protection[161] reviewed Dourson's work on this chemical and found it sorely lacking on scientific grounds. These and other states (including Colorado and Massachusetts) have rejected a non-linear MOA for 1,4-dioxane and have set their standards and guidelines at levels commensurate with the IRIS value.

EPA states: "Human occupational studies into the association between 1,4-dioxane exposure and increased cancer risk are inconclusive because they are limited by small cohort size and a small number of reported cancer cases." (p. 36) EPA has provided no reference to said occupational studies or indicated why they are "inconclusive." Further, EPA appears to have identified a data gap, yet makes no mention of any next step to address the gap. Why not?

37. EPA has not identified all relevant potentially exposed or susceptible subpopulations.

At the end of its section on Human Health Hazards (section 2.4.2.3), EPA states:

> In developing the hazard assessment, *EPA will analyze available data to ascertain whether some human receptor groups may have greater susceptibility than the general population* to the chemical's hazard(s). (p. 36)

In setting the scope of a problem formulation, TSCA requires that EPA identify "potentially exposed or susceptible subpopulations," 15 U.S.C. § 2605(b)(4)(D), including those that "due to ... greater *susceptibility* ... may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12) (emphasis added). This omission of specific subpopulations stands in contrast to the analogous subsection under Human Exposure (p. 32), where EPA identified specific subpopulations that "EPA expects to consider in the risk evaluation due to their greater exposure." This needs to be remedied.

In the analogous section under Human Exposure (p. 32), EPA also should include consumers and adult women who use multiple cosmetics and cleaning products as potentially exposed or susceptible subpopulations, given EPA's prior identification of those subpopulations as particularly likely to be

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[159] Michael Dourson, et al., *Mode of action analysis for liver tumors from oral 1,4-dioxane exposures and evidence-based dose response assessment*, 68:3 REGULATORY TOXICOLOGY & PHARMACOLOGY 387-401 (Apr. 2014), https://www.ncbi.nlm.nih.gov/pubmed/24491968.

[160] *See* Mich. Dep't of Envtl. Quality, Toxics Steering Group, 1,4-Dioxane Subcomm., *Review of a 1,4-Dioxane Presentation by Michael Dourson, Ph.D. on October 8, 2013* (Feb. 2015), https://www.michigan.gov/documents/deq/deq-aqd-toxics-14-DioxaneTSG_Report_2015_487415_7.pdf.

[161] *See* N.J. Dep't of Envtl. Protection, *Response to Public Input on Draft Interim Ground Water Quality Criteria and Draft Interim Practical Quantitation Levels for Eleven Chemicals* at pp. 11-17, https://www.state.nj.us/dep/dsr/supportdocs/11-chemicals-response.pdf.

exposed; see Section 35.A. Workers likely to be using industrial or commercial products contaminated with 1,4-dioxane should also be identified.

38. EPA's problem formulation contains statements relating to confidential business information (CBI) that are or may be inconsistent with its authorities and obligations under TSCA.

EPA states: "EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure." (p. 47) This statement ignores the major changes made to the CBI provisions of TSCA section 14. Companies must substantiate most claims for CBI protection and EPA must review many of them within 90 days of submission of the information. Any claim that does not meet all applicable requirements cannot be protected from disclosure.

Health and safety studies are expressly not eligible for protection as CBI under TSCA, subject only to two very narrow exceptions. *See* 15 U.S.C. § 2613(b)(2). All such information not subject to the exceptions needs to be made public.

Comments on DCM

39. EPA should promptly finalize its proposed ban of DCM in paint strippers.

On May 10, 2018, EPA committed[162] to finalizing its proposed ban on all consumer and commercial uses (except for commercial furniture refinishing) of methylene chloride (also known as dichloromethane, DCM, and hereafter referred to as DCM) in paint and coating removal products. However, in the intervening three months (and counting), the agency has failed to uphold this commitment.

EDF incorporates by reference its comments on EPA's proposed rule to ban DCM for paint and coating removal.[163] EPA's 2014 DCM Work Plan risk assessment (hereafter "DCM risk assessment") and supplemental technical reports make clear that DCM, under the conditions of use subject to the proposed rule, presents an unreasonable risk of injury to the health of workers, consumers, and bystanders. These evaluations reflect the input from numerous and extensive peer reviews, incorporate the best available science, and apply a weight-of-the-scientific-evidence approach.

We urge EPA to promptly send a draft final rule to the Office of Management and Budget (OMB) and then expeditiously finalize this long-overdue ban.

40. EPA has excluded or failed to sufficiently identify and analyze relevant exposure pathways, hazards, and vulnerable subpopulations for DCM.

A. EPA has provided insufficient justification for its exclusion of certain activities from the risk evaluation.

EPA has excluded paint and coating removers, except for those used in commercial furniture refinishing, from the risk evaluation:

> While paint and coating removal falls under the conditions of use for methylene chloride, based on the intention to finalize the rulemaking the scenarios already assessed in the 2014 risk assessment these uses will not be re-evaluated and EPA will rely on the 2014 risk evaluation.

U.S. EPA, Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) at p. 21 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0742-0083.

EDF supports these intentions. However, EPA has placed these conditions of use into Table 2-2 (p. 21), which lists "Categories and Subcategories Determined Not to be Conditions of Use or Otherwise Excluded During Problem Formulation." EPA needs to clarify that the conditions of use subject to the proposed ban remain conditions of use of DCM. First, the ban has not been finalized, and until it has

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[162] News Release, U.S. EPA, EPA Announces Action on Methylene Chloride (May 10, 2018), https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride.

[163] EDF Comments on Regulation of Certain Uses under Toxic Substances Control Act: Methylene Chloride and N-Methylpyrrolidone, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0912.

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been and takes effect, these conditions of use are known conditions of use of DCM. Second, the ban as proposed was not absolute and included certain exemptions. Assuming the final rule retains these, EPA also must take into consideration any exposures remaining from the conditions of use allowed under the exemptions. Third, if EPA finalizes a rule that fails to completely ban consumer and commercial uses of these products (aside from commercial furniture refinishing) as proposed, it will need to consider remaining exposures in the current risk evaluation. Hence, the conditions of use subject to the rule must remain conditions of use in the DCM Problem Formulation.

Additionally, EPA has folded the conditions of use of DCM in paint and coating removal products associated with commercial furniture refinishing into the problem formulation; see Table 2-3, p. 25. This is not appropriate. While EPA deferred extending its ban to such conditions of use while it collected more information on alternatives, it indicated it would then move to propose a rule addressing those conditions of use as well.[164] EPA's 2014 risk assessment for DCM amply demonstrated that such conditions of use present unreasonable risk,[165] so there is no need for EPA to re-evaluate these conditions of use in the present risk evaluation. EPA should instead promptly move to propose a section 6 ban on DCM in paint and coating removal products associated with commercial furniture refinishing. It should be noted that EPA's stated need for more information on alternatives to DCM for these uses involves a *nonrisk factor* that TSCA precludes EPA from considering during the risk evaluation process. *See* 15 U.S.C. § 2605(b)(4)(A).

EPA has also excluded "Extraction solvent for oils, waxes, fats, spices and hops in agricultural chemical manufacturing and food processing" as a condition of use. Its rationale for doing so is that the uses meet the definition of a food additive under section 201 of the Federal Food, Drug, and Cosmetic Act. While it is reasonable to exclude such uses as a condition of use given that they do not meet the definition of a chemical substance under TSCA, EPA can and should consider exposures from such uses as contributing to background exposure that must be accounted for in determining the risk presented by DCM. It is nonsensical for EPA to ignore known background exposures to chemicals when it is charged with evaluating whether a chemical as a whole presents unreasonable risk.

There is clear precedent for accounting for exposures that fall outside those specified by the statute at hand. For example, the EPA's Office of Water routinely uses a Relative Source Contribution factor or a default of 20% of exposure from all sources to account for non-water sources of chemical exposure in establishing its drinking water standards and health advisories.[166] In other words, EPA accounts for non-

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[164] *See* Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

[165] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* at 118-19 (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

[166] U.S. EPA, *2018 Edition of the Drinking Water Standards and Health Advisories* (Mar. 2018), https://www.epa.gov/sites/production/files/2018-03/documents/dwtable2018.pdf.

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water sources of exposure to the chemical even though they derive from exposure sources outside the authority to develop such standards and advisories under the Safe Drinking Water Act.

B. Exposure pathways are inappropriately excluded.

EPA's DCM Problem Formulation is largely irrational and often incoherent, with the agency both: 1) acknowledging many exposures that it later excludes, and 2) choosing to ignore exposure pathways with little or no explanation.

i) Major deficiencies and inconsistencies abound in EPA's assertion that exposures to DCM falling under other legal jurisdictions are adequately managed.

EPA has chosen to exclude all exposures to the general population based on the rationale that other statutes cover such exposures arising through air, water, and land releases. We have explained elsewhere why this is an illegal and unsound approach (see Section 5). However, it is also illogical, as the DCM Problem Formulation itself points to known exposures and potential risks to the general population from such exposures.

EPA explains that DCM is prevalent in environmental media:

> Due to its variety of uses and subsequent release to the environment, methylene chloride is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water, including sources used for drinking water supplies, sediment, soil and food products. (p. 35)

With regards to air, EPA provides the following evidence that DCM contamination in the air is widespread and likely increasing:

- DCM is "moderately persistent and is expected to be subject to atmospheric transport" (p. 33)
- 2,542,146 lbs of DCM was released into the air in 2015 based on Toxic Release Inventory (TRI) data. (p. 34)
- "Ambient air samples worldwide have shown measured levels of methylene chloride... Similarly, air concentrations in the continental U.S. between 2003 and 2014 showed either no trend or increasing levels of methylene chloride." (p. 35)
- "Between 1998 and 2006, >90% of all reported TRI releases of methylene chloride were air releases (U.S. EPA, 2014b) and levels of methylene chloride in the ambient air are widespread and shown to be increasing (Section 2.3.2)." (p. 39)
- "Inhalation serves as the expected primary route of exposure for the general population due to both its high volatility and propensity to be released to air from ongoing commercial and industrial activities." (p. 39)

With regards to water, EPA provides the following evidence that DCM contamination may be widespread in water:

- "Data compiled between 1992 and 2001 from NAWQA showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water (U.S. EPA, 2009)." (p. 36)
- "Methylene chloride was detected in 20% of sediment samples in the STORET database (ATSDR, 2000)." (p. 36)
- "If methylene chloride-contaminated biosolids are released to the environment, including when the biosolids are land applied, methylene chloride will be present mainly in aqueous compartments based on its physical-chemical properties." (p. 53)
- "The general population may ingest methylene chloride via contaminated drinking water, ground water, and/or surface water. Ingestion of contaminated drinking water is expected to be the primary route of oral exposure." (p. 40)

However, EPA excludes such exposures in its Analysis Plan. The agency's rationale – "EPA has determined that the existing regulatory programs and associated analytical processes adequately assess and effectively manage the risks of methylene chloride that may be present in various media pathways (e.g., air, water, land) for the general population" (pp. 65-66) – is in direct contradiction with the explicit statements cited above that the agency expects the general population to be exposed to DCM via air and water.

Further, TSCA requires EPA to give particular attention to "potentially exposed or susceptible subpopulations" when assessing a chemical's risk. These are groups of people that are at greater risk of harm from a chemical due to biological reasons (e.g., children may be more vulnerable) or due to higher exposure (e.g., workers that directly handle the chemical). In the DCM Problem Formulation, EPA appropriately recognizes that people living or working near industrial sites manufacturing, processing, using, or disposing DCM are a "potentially exposed or susceptible subpopulation."

EPA specifically states:

> EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:
>
> ***
>
> - Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites). (p. 40)

The agency goes on to state:

> In summary, in the risk evaluation for methylene chloride, *EPA expects to analyze the following potentially exposed groups of human receptors*: workers, occupational non-users, consumers, bystanders associated with consumer use, and *other groups of*

individuals within the general population who may experience greater exposure. (pp. 41, emphasis added)

Yet, it appears that EPA does *not* in fact intend to evaluate DCM exposure to "individuals within the general population who may experience greater exposure," as the agency plans to ignore all exposures through air, water, and land – the very ways in which these groups of people may be or are exposed to DCM.

EPA must analyze these exposure pathways in order to produce a risk evaluation that is logically coherent and consistent with the best available science and available information establishing that exposure occurs through these pathways.

ii) EPA excludes additional exposure pathways based on insufficient evidence or illogical rationales.

In addition to exclusions on the basis of statutory arguments, EPA has made a number of inappropriate decisions to not further analyze specific exposure pathways or receptors with little or no explanation.

EPA excludes the oral exposure route. For consumers, EPA acknowledges the potential for exposure via hand to mouth behaviors but waves it off by stating that "[t]his exposure pathway will be limited by a combination of dermal absorption and volatilization." (p. 39) The oral exposure pathway for workers is ignored altogether. The absence of any analysis renders these decisions arbitrary and capricious.

EPA excludes exposure to consumers from disposal. EPA's rationale, with no supporting data or analysis, is that the agency, "does not expect exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans." (p. 51) However, EPA then goes on to state that "liquid products may be recaptured in an alternate container following use (e.g. paint scrapings after paint removal as was done in EPA's 2014 risk assessment for methylene chloride paint stripping use)" (p. 51), providing a plausible mechanism by which consumers may be exposed during disposal.

EPA excludes non-occluded dermal exposure to workers with little explanation. In contrast, EPA does intend to consider non-occluded scenarios for consumers. EPA states:

> There is the potential for dermal exposures to methylene chloride in many worker scenarios. Where workers may be exposed to methylene chloride, the OSHA standard requires that workers are protected from contact (e.g. gloves) (29 CFR 1910.1052). EPA's 2014 risk assessment of methylene chloride paint stripping use included the potential dermal exposures to methylene chloride as an area of uncertainty that may underestimate the total exposures (U.S. EPA, 2014b). These dermal exposures would be concurrent with inhalation exposures and the overall contribution of dermal exposure to the total exposure is expected to be small however there may be exceptions for

> occluded scenarios. Occupational non-users are not directly handling methylene chloride; therefore, skin contact with liquid methylene chloride is not expected for occupational non-users and EPA does not expect to further analyze this pathway in the risk evaluation. *EPA expects to further analyze dermal exposures for skin contact with liquids in occluded situations for workers.* (p. 47, emphasis added)
>
> Workers and occupational non-users can have skin contact with methylene chloride vapor concurrently with inhalation exposures. The parameters determining the absorption of methylene chloride vapor are based on the concentration of the vapor, the duration of exposure and absorption. The concentration of the vapor and the duration of exposure are the same for concurrent dermal and inhalation exposures. Therefore, the differences between dermal and inhalation exposures depend on the absorption. The dermal absorption can be estimated from the skin permeation coefficient (0.28 cm/hr for methylene chloride vapor (ATSDR, 2010, 2000)) and exposed skin surface area (on the order of 0.2 m2 (U.S. EPA, 2011a)). The absorption of inhaled vapors can be estimated from the volumetric inhalation rate (approximately 1.25 m3/hr for a person performing light activity (U.S. EPA, 2011a) adjusted by a retention factor such as 0.75. *Based on these parameters the absorption of methylene chloride vapor via skin will be orders of magnitude lower than via inhalation and will not be further analyzed.* (p. 48, emphasis added)

That a smaller relative percentage of exposure to DCM will occur from dermal versus inhalation exposure does not mean that the dermal exposure is irrelevant to evaluating DCM risks in occupational settings. The contribution to DCM exposure from dermal absorption could still be significant. EPA should consider combined exposures to DCM via all pathways across all potential sources of exposure.

Moreover, EPA has not sufficiently justified why EPA will include occluded dermal exposures to workers but not non-occluded dermal exposure. Ostensibly, both exposures scenarios could result in frequent or continuous dermal contact and absorption to DCM, even if occluded exposures would tend to be higher.

EPA's rationale for ignoring non-occluded scenarios appears to be the mere existence of OSHA standard 29 CFR 1910.1052. Yet, in contrast to EPA's assertion that this standard requires use of protective gloves, this standard only requires respiratory protection and never mentions gloves. Thus, EPA's rationale appears to be flatly incorrect. As more accurately described in Appendix A:

> In 1997, OSHA revised an existing occupational safety and health standards [*sic*] for methylene chloride, to include an 8-hour TWA PEL of 25 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1052 App. A). (p. 84)

In sum, EPA's conclusory assertions are insufficient to justify its decisions, and EPA must analyze these pathways and receptors further. When EPA declines to analyze a pathway further, EPA must have

developed and applied a sound, rational basis for assessing the exposure level, supported by scientific evidence. In addition, EPA cannot then effectively ignore the exposure. Rather, EPA still must consider how the exposure may combine with other sources of exposure, so EPA must actually assess the level of exposure from the pathway individually and then consider how it combines with other sources of exposure.

C. EPA has not identified all relevant potentially exposed or susceptible subpopulations.

At the end of its section on Human Health Hazards (section 2.4.2.3), EPA states:

> In developing the hazard assessment, EPA will evaluate available data *to ascertain whether* some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s). (p. 45, emphasis added)

This statement stands in contrast to the analogous subsection under Human Exposure (p. 40), where EPA identified specific subpopulations that "EPA expects to consider in the risk evaluation due to their greater exposure." TSCA requires that EPA identify "potentially exposed or susceptible subpopulations," 15 U.S.C. § 2605(b)(4)(D), including those that "due to *** greater *susceptibility* *** may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12).

Unlike in the exposure section, EPA has not identified any vulnerable populations based on greater susceptibility. This needs to be remedied.

EPA's 2014 DCM risk assessment includes a section on susceptible subpopulations (3.3.2.4), proposing the following as subpopulations that may be more susceptible: smokers who maintain significant constant levels of carboxyhemoglobin; persons with existing cardiovascular disease; people with specific genetic polymorphisms for both GST theta-1 and CYP2E1; and the fetus and infants. EPA provides no rationale for not including at least these subpopulations in the DCM Problem Formulation. Given the evidence before the agency, EPA should identify these groups as relevant potentially susceptible subpopulations.

Further, EPA has deleted without explanation the following paragraph from the earlier DCM Scope under the analogous section:

> The IRIS assessment for methylene chloride indicates that there is some evidence that certain populations may be more susceptible to exposure to methylene chloride and examined lifestage, gender-specific, genetic variation, preexisting health status, lifestyle factors and nutrition status factors (U.S. EPA, 2011). Genetic polymorphisms that impact the enzymes that metabolize methylene chloride may lead to differences in susceptibility of individuals to the effects of methylene chloride and this susceptibility

> was quantified by (U.S. EPA, 2011). There are inadequate chemical-specific data to quantify the degree of differential susceptibility due to other susceptibility factors.[167]

It appears that EPA is going out of its way to avoid consideration of these susceptible subpopulations. They should be restored, along with any other relevant susceptible subpopulations.

41. EPA should rely on its prior hazard assessment in the current risk evaluation, and identify and justify any deviations from it.

EPA should rely heavily on the hazard characterization and dose response analysis done in the DCM risk assessment, which was conducted based on the best available science and has been peer reviewed.

Unfortunately, it appears that EPA plans only to use that assessment to identify relevant studies:

> Methylene chloride has an existing EPA IRIS Assessment (U.S. EPA, 2011b), an ATSDR Toxicological Profile (ATSDR, 2010, 2000), and assessments of the effects of acute exposures in the AEGL (NAC/AEGL, 2008), Spacecraft Maximum Allowable Concentrations (SMAC) for Methylene Chloride (NRC, 1996a) and an acute Recommended Exposure Limit (REL) published by the Office of Environmental Health Hazard Assessment (OEHHA) (OEHHA, 2008); hence, many of the hazards of methylene chloride have been previously compiled and reviewed. *EPA expects to use these previous analyses as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis.* The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for methylene chloride [*Methylene Chloride (CASRN 75-09-2) Bibliography: Supplemental File for the TSCA Scope Document* EPA-HQ-OPPT-2016-0742-0059 (U.S. EPA, 2017a)]. Based on reasonably available information, the following sections describe the potential hazards associated with methylene chloride. (pp. 44-45, emphasis added)

The agency indicates that "many of the hazards of methylene chloride have been previously compiled and reviewed," which was in fact done in the IRIS toxicological review (as well as the ATSDR profile). As described in the IRIS assessment, "[t]his document has been provided for review to EPA scientists, interagency reviewers from other federal agencies and White House offices, and the public, and peer reviewed by independent scientists external to EPA."[168] The IRIS assessment applied a systematic

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[167] U.S. EPA, *Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* at 40 (June 2017), https://www.epa.gov/sites/production/files/2017-06/documents/mecl_scope_06-22-17.pdf.
[168] U.S. EPA, *Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) In Support of Summary Information on the Integrated Risk Information System (IRIS)* at xxii (Nov. 2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0070tr.pdf.

review approach to the identification, consideration, and integration of the scientific literature bearing on the health effects of DCM. EPA relied heavily on the IRIS toxicological review to develop the DCM risk assessment.

In addition to the 2011 IRIS assessment, EPA relied on the AEGL, SMAC, and REL peer-reviewed reports for hazard and dose-response information. Further, the 2014 DCM risk assessment itself underwent a contractor-managed peer review that entailed three convenings of an expert panel during the fall of 2013, culminating in a peer review report.[169]

In describing the IRIS toxicological review and other assessments, EPA stated in the 2014 DCM risk assessment:

> EPA/OPPT used the DCM IRIS assessment as the principal data source for chronic toxicity hazard and dose-response information. The DCM IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for carcinogenic and non-carcinogenic health effects resulting from lifetime exposure to DCM.
>
> The DCM IRIS assessment followed the principles set forth by the various risk assessment guidelines issued by the National Research Council (NRC) and EPA. Primary, peer-reviewed literature identified through September 2011 was systematically reviewed and included where that literature was determined to be critical to the assessment (EPA, 2011c).
>
> In addition, EPA/OPPT used the SMAC, the California acute REL and AEGL technical support documents as the data source for acute toxicity hazard and dose-response information. SMACs and the California acute REL for DCM are derived following the Guidelines for Developing Spacecraft Maximum Allowable Concentrations for Space Station Contaminants (NRC, 1992) and California's Air Toxics Hot Spots Program risk assessment guidelines for acute RELs (OEHHA, 1999), respectively. AEGLs are developed based on the criteria discussed in the Standing Operating Procedures (SOP) for Developing Acute Exposure Guideline Levels for Hazardous Chemicals (NRC, 2001).[170]

Given EPA's multiple, clear statements affirming the scientific rigor of the IRIS toxicological review, its use of other peer reviewed hazard assessments, as well as its decision to rely upon them in its 2014 DCM risk assessment and subsequent TSCA section 6 proposed ban, EPA should continue to rely on these earlier assessments. EPA must identify and explain any decision to deviate from these assessments and clearly identify in its draft risk evaluation any modifications it proposes in hazard

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[169] U.S. EPA Peer Review Panel, *OPPT Methylene Chloride (DCM) Draft Risk Assessment Final Comments of Nine-Member Peer Review Panel* (Dec. 31, 2013), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/oppt-methylene-chloride-dcm-draft-risk-assessment-final.

[170] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* at 66-67 (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

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identification or dose-response characterization, and the scientific basis for them. Any such differences must be based on compelling scientific evidence and explicitly interrogated through the peer review process.

The excerpt from the DCM Problem Formulation cited above refers to "key," "supporting," and "relevant" studies. The meaning of these descriptors is entirely unclear. EPA must explicitly define the meaning of these terms and their implications with regard to the agency's approach to systematic review and risk evaluation.

EDF firmly believes that it is unnecessary – not to mention a waste of time and resources – to re-conduct aspects of the previous risk assessment unless EPA can demonstrate serious shortcomings of the previous assessments. EDF believes that the 2014 hazard assessment meets the best available science requirements and requires only minimal updating to reflect newer information. In particular, EPA has not provided any basis for redoing the dose-response analysis, as EPA suggests it may do on page 68. EPA should not redo the dose-response analysis, barring an exceptional and compelling basis for doing so.

42. EPA ignores important information gaps, and even where they are acknowledged, EPA provides no indication it intends to address them.

EPA has failed to use or signal any intent to use its TSCA section 4 and 8 information authorities, which were expanded under the 2016 TSCA amendments, to fill information gaps.

EPA's DCM Problem Formulation largely ignores information gaps altogether. For example, the 2014 DCM risk assessment identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important information gaps:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures.[171]

Yet the problem formulation does not even mention these data gaps – let alone describe a strategy for acquiring the needed information.

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[171] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* at 115 (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.

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While EPA expressly acknowledges few data gaps in the Problem Formulation, the existence of exposure information gaps is implied through EPA's plan to use surrogate data and models rather than using its information authorities to obtain exposure information on DCM.

With regards to surrogate data, EPA specifically proposes to:

- "Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and chemical and physical properties. Data for solvents that are used in the same types of applications may be considered as surrogate data for methylene chloride. As with methylene chloride, trichloroethylene is used in paints and coatings, in adhesives and sealants, and as solvents for cleaning and degreasing." (p. 60)

- "For several uses including use of adhesives, cleaners, and laundry and dishwashing products, EPA believes that trichloroethylene and other similar solvents may share the same or similar conditions of use and may be considered as surrogates for methylene chloride." (p.63)

While EDF does not oppose including surrogate data when relevant, it should not be the option of first resort or be used as an excuse to fail to actively obtain such data through use of EPA's information authorities.

Where EPA does acknowledge information gaps (see below), it fails to set forth a plan to use its TSCA section 4 and 8 information authorities to fill such gaps. For example:

- Breastmilk as an exposure route: "Methylene chloride and its metabolites have been measured in expired air, blood, urine and breast milk however methylene chloride measurements in human milk have not been quantified and there are no animal studies testing to what extent methylene chloride can pass into milk (ATSDR, 2000)." (p. 36)
    - Given the greater susceptibility of infants to DCM (as their hemoglobin has a higher affinity for carbon monoxide than adult hemoglobin[172]), breastmilk may be an important exposure pathway to consider. In this excerpt, EPA acknowledges that the necessary data do not exist, yet indicates no intent to promulgate a section 4 order or rule to develop such information.

- Acute sediment toxicity studies: "There were no available acute sediment toxicity studies, however, toxicity is expected to be similar to that of aquatic invertebrates when exposed to methylene chloride in sediment pore water." (p. 42)
    - EPA provides no justification for why sediment invertebrates are expected to have a similar toxicity profile as aquatic invertebrates. A sediment toxicity test is a simple

[172] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* at 82 (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf (referencing OEHHA 2001 at https://oehha.ca.gov/media/downloads/air/report/sb2520tac20prioritization.pdf).

protocol that EPA could easily mandate through a section 4 order or rule within the given timeframe.

- Occupational exposures: "For some OSHA data, NAICS codes included with the data will be matched with potentially applicable conditions of use, and data gaps will be identified where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below." (p. 63)
    - Step 2 entails the use of data on surrogate chemicals and Step 3 entails the use of models. No step is indicated that would entail requiring submission or development of the needed data.

EPA should use its information authorities to fill all of these information gaps.

43. The DCM Problem Formulation utilizes assumptions and models that are unclear or not necessarily conservative.

Despite its assertions, EPA uses or suggests it will use non-conservative assumptions at various points in the DCM Problem Formulation. Two examples are provided below.

A. Exposures to terrestrial species.

EPA ignores important pathways of DCM exposure to terrestrial organisms based on unclear and apparently non-conservative assumptions.

EPA initially states, "Terrestrial species populations living near industrial and commercial facilities using methylene chloride may be exposed via multiple routes such as ingestion of surface waters and inhalation of outdoor air." (p. 37)

However, EPA will not further analyze exposure to terrestrial organisms through water, sediment, or migration from biosolids via soil deposition, based on the assertion that "[t]errestrial species exposures to MC in water are orders of magnitude below hazardous concentrations." (Appendix E, pp. 139-140)[173]

Yet EPA has not shown any analysis or calculations and has not provided any citations to data sources to support this statement; it is simply asserted.

Furthermore, EPA has not bothered to calculate acute and chronic concentrations of concern (COC) as it has done in its other problem formulations. EPA explicitly states that it has not applied adjustment factors to the hazard levels listed on pp. 43-44:

> It should be noted that these hazard levels of concern do not account for differences in inter- and intra-species variability, as well as laboratory-to-field variability and are

[173] EPA also excludes exposure to terrestrial organisms from the ambient air pathway based on the inappropriate argument that such exposures are adequately managed by the Clean Air Act (see Section 5.C).

> dependent upon the availability of datasets that can be used to characterize relative sensitivities across multiple species within a given taxa or species group, since the data available for most industrial chemicals are limited. (p. 44)

EPA typically applies a 5x adjustment factor for acute toxicity and 10x for chronic toxicity for ecological receptors to account for such variability, and has done so in other problem formulations.

Finally, while EPA provides several hazard values based on acute exposure and mostly limited to lethality (as opposed to other organism- or population-level effects), EPA has not found or provided any chronic toxicity data for terrestrial organisms other than a NOAEC (only for inhalation, based on concentration in air) for mammals. There are no hazard values at all based on oral exposure to terrestrial organisms – a data gap that EPA fails even to acknowledge.

It is far from clear from the DCM Problem Formulation how EPA managed to conclude that DCM in water is orders of magnitude below concentrations of concern, but it appears the agency did not take a conservative approach in arriving at this conclusion. EPA needs to provide a rational and clear analysis based on the best available science and reasonably available information to support its conclusions, and at this point, it has failed to do so.

B. Occupational exposure via inhalation route.

Under its Analysis Plan, EPA implies that it may rely on U.S. Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL):

> This or other models, including the *assumption of compliance with the OSHA PEL* for methylene chloride, may be explored where models specific to conditions of use are not found. (p. 63, emphasis added)

In general, it makes no sense to default to a standard unless there is strong empirical evidence that workplaces universally comply with the standard. In the case of DCM specifically, there is significant evidence from workplace monitoring studies that levels exceed the current OSHA PEL for DCM of 25 ppm (8-hour time-weighted average).

For example, EPA's proposed section 6 rule to ban DCM in paint and coating removal products explains:

> It is important to note that EPA relied on monitoring data for these occupational exposure estimates. Many air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm; in some industries where paint and coating removal was conducted by immersion in tanks or vats of methylene chloride, air concentrations were measured at above 7,000 milligrams per cubic meter, or 2,016 ppm. Even in industries with lower expected exposures, air concentrations frequently

> were reported in excess of 250 milligrams per cubic meter, or 72 ppm, such as during graffiti removal and automotive refinishing (Ref. 2).[174]

Even these levels may have been an underestimate of DCM exposure. Comments submitted by a former OSHA official to the docket on EPA's proposed section 6 rule on DCM argued that the agency underestimated exposure levels. The commenter provided an OSHA dataset including 12,152 personal air samples OSHA collected on DCM between 1984 and 2016. He summarized the results as follows:

> The data I've provided show that the AVERAGE MeCl2 concentration from 1984 to April 1999 (at which point our 1997 standard took full effect) was about 85 ppm, but the average since then has only dropped to 72 ppm![175]

It makes no sense for EPA to rely on the PEL as a default given the existence of real-world monitoring data demonstrating that it is regularly exceeded.

It also bears mentioning that OSHA's PEL of 25 ppm is itself not health-protective. It was last updated in 1997 – over 20 years ago – and EPA's proposed section 6 rule on DCM and NMP concluded that OSHA's PEL is higher than the levels at which EPA identified unreasonable risk.[176] Furthermore, OSHA itself has indicated[177] that the PEL would be insufficient to protect workers from the risks identified by EPA in the context of paint and coating removal exposures.

As a further indication of the inadequacy of OSHA's PEL, in the course of developing the proposed rule, EPA developed a recommendation for an ECEL as a more current benchmark for workplace exposures; this recommended value (1.3 ppm, 8-hour time weighted average), is nearly 20-fold lower than OSHA's PEL.

44. EPA's problem formulation contains several statements relating to confidential business information (CBI) that are or may be inconsistent with its authorities and obligations under TSCA.

EPA states: "EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure." (p. 59)

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[174] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7477 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

[175] Comment by Dr. Adam M. Finkel on Regulation of Certain Uses under Toxic Substances Control Act: Methylene Chloride and N-Methylpyrrolidone at 3 (May 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0536.

[176] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7470 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

[177] Letter from David Michaels, PhD, MPH, Assistant Secretary, U.S. Dep't of Labor, Occupational Safety & Health Admin., to James J. Jones, Assistant Administrator, U.S. EPA, Office of Chem. Safety & Pollution Prevention (Mar. 31, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0153.

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This statement ignores the major changes made to the CBI provisions of TSCA section 14. Companies must substantiate most claims for CBI protection and EPA must review many of them within 90 days of submission of the information. Any claim that does not meet all applicable requirements cannot be protected from disclosure.

Further, EPA fails to acknowledge that health and safety studies are expressly not eligible for protection as CBI under TSCA, subject only to two very narrow exceptions. *See* 15 U.S.C. § 2613(b)(2). All such information not subject to the exceptions needs to be made public.

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Comments on NMP

45. EPA needs to finalize its proposed ban of NMP in paint and coating removal products and not use the larger ongoing risk evaluation of NMP as a reason for delay.

EDF incorporates by reference its comments on EPA's proposed rule to restrict NMP in paint and coating removal products.[178] EPA's 2015 NMP Work Plan risk assessment (hereafter "NMP risk assessment") and supplemental technical reports make clear that NMP, under the conditions of use subject to the proposed rule, presents an unreasonable risk of adverse developmental outcomes to women of childbearing age from both acute (fetal mortality) and chronic (decreased fetal body weight) NMP exposure. These evaluations reflect the input from numerous and extensive peer reviews, incorporate the best available science, and apply a weight-of-the-scientific-evidence approach.

The Lautenberg Act clearly intended for EPA to move forward to address risks it identified in assessments completed prior to enactment.

Section 26(l)(4) states (emphases added):

> (4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has *published a completed risk assessment prior to the date of enactment* of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator *may publish proposed and final rules under section 6(a)* that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6.

Section 26(p)(3) states (emphasis added):

> (3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE. – *Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule* under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

These provisions of the law make abundantly clear that EPA can proceed to promulgate a rule based on its completed NMP risk assessment and is under no obligation to withdraw its prior risk assessment, risk determination or proposed rule. Indeed, Congress included these provisions for the very purpose of grandfathering-in the Work Plan risk assessments EPA had completed and ensuring its authority to use those assessments as the basis for section 6 risk management rules.

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[178] EDF Comments on Regulation of Certain Uses under Toxic Substances Control Act: Methylene Chloride and N-Methylpyrrolidone, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0912.

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Furthermore, the very high risks EPA has identified for the conditions of use subject to the proposed rule demand that the agency move expeditiously to finalize the rule. It is indefensible for EPA to delay critically needed action on paint stripping products by, as EPA now plans to do, reevaluating those conditions of use in the current risk evaluation. This approach will effectively delay action for years – putting workers', consumers' and the public's health at risk.

EPA needs to expeditiously finalize option 1 of its proposed section 6(a) rule to ban NMP's use in paint stripping products.[179] Then, in the current risk evaluation, it also must take into consideration any exposures remaining from those uses despite that rule due, for example, to any allowed exemptions.

46. EPA should rely on its prior hazard assessment in the current risk evaluation, and identify and justify any deviations from it.

EPA should rely heavily on the hazard characterization and dose response analysis done in the NMP risk assessment, which was conducted based on the best available science and has been peer reviewed.

Unfortunately, it appears that EPA plans only to use that assessment to identify relevant studies:

> EPA expects to evaluate all potential hazards for NMP, using the previous analysis as a starting point for identifying key and supporting studies and including any information found in recent literature. The relevant studies will be evaluated using the data quality criteria provided in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). (p. 10)

U.S. EPA, Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) at p. 10 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0076. Is EPA planning to use its prior assessment *only* for the purpose of identifying "key" studies? If so, on what basis is it rejecting the hazard assessment? If EPA now believes there are flaws or shortcomings in the earlier assessment, it should clearly identify them and provide the basis for its beliefs.

EPA's NMP risk assessment involved a critical consideration of the scientific literature that, among other evidence, included a number of authoritative, peer-reviewed reports such as:

- The Dutch National Institute for Public Health and the Environment (RIVM) Proposal for a Restriction of NMP[180]

[179] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

[180] RIVM (National Institute for Public Health and the Environment (RIVM)), *Annex XV Restriction Report: Proposal for a Restriction, N-Methylpyrrolidone (NMP)* (2013), https://echa.europa.eu/documents/10162/2a5f3a2e-6f9c-08ac-6e44-4e4792b5cba9.

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- Organization for Economic Co-operation and Development (OECD) SIDS Initial Assessment Report[181]

- WHO Concise International Chemical Assessment Document (CICAD) for NMP[182]

- Cal OEHHA Maximum Allowable Dose Levels (MADL) for NMP[183]

The NMP risk assessment itself was peer-reviewed through a contractor-managed peer review process, culminating in a peer review report.[184] In addition, opportunities for public comment were provided upon issuance of the draft risk assessment (Jan – March 2013)[185] and in conjunction with each of the three expert panel meetings.[186]

EDF firmly believes that it is unnecessary – not to mention a waste of time and resources – to re-conduct aspects of the previous risk assessment unless EPA can demonstrate serious shortcomings in the previous assessment. EDF believes that the 2015 hazard assessment meets the best available science requirements and requires only minimal updating to reflect newer information and consideration of susceptible subpopulations (see Section 47.B.i below). In particular, EPA has not provided any basis for redoing the dose-response analysis, as the agency suggests it may do on page 60. EPA should not redo the dose-response analysis, barring an exceptional and compelling basis for doing so.

47. EPA has excluded or failed to sufficiently identify and analyze relevant exposure pathways and vulnerable subpopulations for NMP.

A. Exposure pathways are inappropriately excluded.

EPA's NMP Problem Formulation – Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-

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[181] Organization for Economic Co-operation and Development, *SIDS Initial Assessment Report. 1-Methyl-2-Pyrrolidone* (2007), https://hpvchemicals.oecd.org/UI/handler.axd?id=84daa4ac-feb7-4b5a-9839-206d17914e42.

[182] World Health Organization, *Concise International Chemical Assessment Document (CICAD) 35, N-Methyl-2-Pyrrolidone* (2001), www.who.int/entity/ipcs/publications/cicad/en/cicad35.pdf.

[183] Office of Environmental Health Hazard Assessment, *Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for N-Methypyrrolidone for Dermal and Inhalation Exposures. Reproductive and Cancer Hazard Assessment Section* (2003), https://oehha.ca.gov/media/downloads/proposition-65/chemicals/nmpmadl31403.pdf.

[184] U.S. EPA Peer Review Panel, *OPPT N-Methylpyrrolidone (NMP) Draft Risk Assessment Final Comments of Nine Member Peer Review Panel* (Dec. 2013), https://www.epa.gov/sites/production/files/2015-09/documents/nmp_consolidated_peer_review_comments_december_31_2013.pdf.

[185] Public comment opportunities were available at docket number EPA-HQ-OPPT-2012-0725. *See* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0001.

[186] *Dichloromethane and NMethylpyrrolidone TSCA Chemical Risk Assessment; Notice of Public Meetings and Opportunity to Comment*, 78 Fed Reg. 52525 (Aug. 23, 2013), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0725-0036.

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2016-0743-0076 (hereafter "NMP Problem Formulation") – is largely irrational and often incoherent, with the agency both: 1) acknowledging many exposures that it later excludes, and 2) choosing to ignore exposure pathways with little or no explanation.

i) Major deficiencies and inconsistencies abound in EPA's assertion that exposures to NMP falling under other legal jurisdictions are adequately managed.

EPA has chosen to exclude all exposures to the general population based on the rationale that other statutes cover such exposures to air, water, and land contamination. We have explained elsewhere why this is an illegal and unsound approach (see Section 5). It is also illogical, as the NMP Problem Formulation itself points to potential risks to the general population from such exposures.

For example, EPA acknowledges that:

- "NMP has been detected in industrial landfill leachate;" (p. 33)
- "NMP has been detected in wastewater;" (p. 36)
- "Oral exposure to NMP is expected to be a relevant route of exposure for the general population." (p. 36)

However, such exposures are ultimately excluded in EPA's Analysis Plan. EPA's rationale for excluding oral exposure via drinking water to the general population is the mere existence of the Safe Drinking Water Act. There is no National Primary Drinking Water regulation for NMP; it is only listed on the EPA's fourth Contaminant Candidate List (CCL), which EPA itself describes as a "list of unregulated contaminants." In fact, being placed on the CCL is just the first of a long series of steps that must be taken before it is considered for regulation:

> Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data for evaluation under Regulatory Determination; if sufficient occurrence data is lacking, the contaminant may be considered for monitoring under the Unregulated Contaminant Monitoring Rule. (p. 49)

Such monitoring is required to be considered for regulation:

> EPA must publish a CCL and make Regulatory Determinations to regulate at least five CCL contaminants every 5 years. To regulate a contaminant, EPA must conclude the contaminant may have adverse health effects, *occurs or is substantially likely to occur in public water systems at a level of concern* and that regulation, in the sole judgement of the Administrator, presents a meaningful opportunity for health risk reduction. (p. 49, emphasis added)

Yet EPA argues that this long and uncertain process is a sufficient basis to ignore drinking water exposures to the general population, because "NMP is being addressed under the regular analytical processes used to identify and evaluate drinking water contaminants of potential regulatory concern for

public water systems under SDWA." (p. 49) This statement stands in direct contrast with EPA's statement earlier in the NMP Problem Formulation document acknowledging there are ongoing exposures to the general population from drinking water. Given empirical evidence establishing these ongoing exposures, EPA must analyze exposures to NMP through the drinking water pathway. EPA must analyze exposures through the other pathways as well, for reasons articulated above.

ii) EPA will not further analyze additional exposure pathways based on insufficient evidence or illogical rationales.

EPA has made a number of decisions not to further analyze specific exposure pathways or receptors with little or no explanation.

1) EPA excludes oral exposure for workers with no explanation. Oral exposure is not included as an exposure route for industrial and commercial activities in EPA's conceptual model. (p. 44) While EPA does note that "[I]ncidental ingestion of inhaled NMP (vapor/mist/dust) will be considered as inhalation exposure," (pp. 42, 44) it is unclear why EPA is not evaluating ingestion of NMP from hand-to-mouth or other direct ingestion pathways. EPA's failure to provide a reasoned basis for excluding this exposure pathway is arbitrary and capricious. Notably, EPA does intend to evaluate this exposure route for consumers. (pp. 45, 46)

2) EPA has decided not to further analyze risk to sediment invertebrates or terrestrial organisms (the latter of which EPA notes include soil-dwelling organisms) based on insufficient evidence. EPA has not identified any data on hazards to sediment invertebrates or terrestrial organisms, yet has decided not to further analyze the risk to these organisms because "exposure to soil- or sediment-dwelling organisms is not expected to be significant" – a statement that excludes many types of terrestrial organisms. (p. 38) With respect to soil- or sediment-dwelling organisms, EPA asserts this claim based on the physical-chemical and fate properties of NMP – not any actual exposure monitoring data or even modeling. EPA cites Section 2.3.4 of the problem formulation as providing support for its decision not to further analyze exposure to soil- or sediment-dwelling organisms. (p. 38) Yet Section 2.3.4: 1) does not apply to sediment-dwelling organisms at all, and 2) to the extent that the terrestrial population subsection of section 2.3.4 applies to soil-dwelling organisms, it indicates that they in fact may be exposed to NMP "via multiple routes." (p. 34) If anything, this section suggests that exposure to terrestrial organisms warrants further analysis.

Elsewhere, EPA makes another unsupported assertion for why it will not further analyze the sediment pathway: "NMP toxicity to sediment-dwelling invertebrates is expected to be comparable to that of aquatic invertebrates." (p. 47). But EPA never provides data or analysis to support this expectation, and EPA never explains why it will not further analyze exposures to soil-dwelling organisms. In the end, EPA provides no rationale for declining to analyze risk to terrestrial organisms.

Importantly, exposures cannot be characterized as low absent hazard information. It is certainly possible that NMP is sufficiently toxic to organisms that even "low" levels of exposure pose

> significant risk. EPA must use its information authorities to obtain more information about risks to sediment-dwelling organisms and terrestrial organisms, and EPA must actually evaluate the risks presented to these organisms.
>
> 3) EPA plans not to further analyze exposures to humans from releases to ambient surface water on the basis that a first-tier analysis resulted in a calculated margin of exposure (MOE) for oral, inhalation, and dermal exposure of 338, which exceeded EPA's proposed benchmark MOE of 30, "indicating a low risk concern." (p. 47) But this analysis examines this one pathway in isolation from all others. If EPA were to combine this exposure with those from other pathways resulting from this and other conditions of use the contribution from ambient surface water may very well be significant.

EPA must analyze these pathways and receptors further, or provide a scientifically and logically sound basis for their exclusion, reflecting the best available science and reasonably available information about these exposures and receptors. Where EPA has inadequate information, EPA must use its information authorities to obtain additional information. EPA also must consider how exposures through these pathways combine with other exposures to present an unreasonable risk; EPA cannot simply consider them in isolation and then dismiss them on that basis.

B. Vulnerable subpopulations.

i) Vulnerable subpopulations are inappropriately excluded.

TSCA requires EPA to give particular attention to "potentially exposed or susceptible subpopulations" when assessing a chemical's risks. These are groups of people that are at greater risk of harm from a chemical due to biological reasons (e.g., children who may be more vulnerable) or due to higher exposure (e.g., workers that directly handle the chemical). In the NMP Problem Formulation, EPA appropriately recognizes that people living or working near sites manufacturing, processing, using, or disposing NMP are a "potentially exposed or susceptible subpopulation."

EPA specifically states:

> EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:
>
> ***
>
> - Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites). (p. 37)

The agency goes on to state:

> In summary, in the risk evaluation for NMP, EPA expects to analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use and *other groups of individuals within the general population who may experience greater exposure* (pp. 38-39, emphasis added)

Yet, it appears that EPA does *not* in fact intend to evaluate NMP exposure to "individuals within the general population who may experience greater exposure," as the agency plans to ignore all exposures through air, water, and land – the very ways in which this subpopulation may be exposed to NMP.

EPA's NMP Conceptual Model for Environmental Releases and Wastes (Figure 2-4, p. 52) includes a footnote in the "Receptors" section that states: "Receptors include potentially exposed or susceptible subpopulations." However, every single receptor is greyed out in this conceptual model (indicating that the agency does not intend to further analyze these pathways) – including the general population, and by implication, those subpopulations within the general population living near manufacturing, processing, use or disposal sites. Thus, EPA's conceptual model indicates that EPA intends to ignore the very subpopulations that EPA elsewhere identified as relevant and meriting analysis. EPA's incoherent approach to these subpopulations and exposures is arbitrary and capricious.

It is worth noting that as part of its justification for ignoring the ambient air pathway, EPA cites an analysis from the 2015 NMP risk assessment that predated the 2016 TSCA reforms and hence did not take into consideration the agency's new mandate to identify and evaluate risks to "potentially exposed or susceptible subpopulations." In that earlier assessment, EPA used default exposure factors that are non-specific, and were not appropriate to the susceptible subpopulation of women of childbearing age and children (see Section 47.B.ii below). For example, EPA used an 80-kg body weight (p. 48), while EPA's 2017 Exposure Factors Handbook[187] indicates that the mean weight for women between 16 and <40 years of age ranges from 65.9 – 74.8 kg. If EPA had used a lower body weight in its calculations, it would have derived a lower point of departure (POD). Children have an even lower body weight: for example, infants from birth to <1 month weigh 4.8 kg; toddlers 1 to <2 years old weigh 11.4 kg; and children 6 to <11 years weigh 31.8 kg.

It appears EPA's "first-tier" analysis, which it uses as the basis to exclude ambient air exposures for "Adults and children living near facilities" (p. 126), ignored the most susceptible subpopulations. Moving forward, EPA must take into consideration exposure factors relevant to potentially exposure or susceptible subpopulations, given the new statutory requirement.

ii) EPA has not identified all relevant potentially exposed or susceptible subpopulations.

At the end of its section on Human Health Hazards (section 2.4.2.3), EPA states:

> In developing the hazard assessment, *EPA will analyze available data to ascertain whether some human receptor groups may have greater susceptibility than the general*

[187] U.S. EPA, Exposure Factors Handbook: 2011 Edition at 8-14 (Sept. 2011), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.

population to the chemical's hazard(s). In the previous risk assessment (U.S. EPA, 2015), EPA identified young children and pregnant women as potentially susceptible subpopulations. (p. 41, emphasis added)

In setting the scope of a problem formulation, TSCA requires that EPA identify "potentially exposed or susceptible subpopulations," 15 U.S.C. § 2605(b)(4)(D), including those that "due to *** greater *susceptibility* *** may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture." 15 U.S.C. § 2602(12) (emphasis added).

While EPA acknowledges that its 2015 NMP risk assessment identified concerns specific to young children and pregnant women, EPA has failed to identify such subpopulations as ones that EPA expects to consider due to greater susceptibility in its forthcoming evaluation. Given the evidence EPA cites for reproductive and developmental toxicity, these subpopulations at a minimum need to be identified as potentially exposed or susceptible subpopulations.

This omission of specific subpopulations stands in contrast to the analogous subsection under Human Exposure (p. 37), where EPA identified specific subpopulations that "EPA expects to consider in the risk evaluation due to their greater exposure." This needs to be remedied.

48. EPA ignores important information gaps, and even where others are acknowledged, EPA provides no indication it intends to address them.

EPA has failed to use or signal any intent to use its TSCA section 4 and 8 information authorities, which were expanded under the 2016 TSCA amendments, to fill information gaps.

For example, the 2015 NMP risk assessment identifies a number of important data gaps for both hazard (e.g., neurotoxicity) and exposure (e.g., glove effectiveness for dermal exposure, air monitoring data for inhalation exposure). Pages 95-101 of the 2015 NMP risk assessment[188] detail these data gaps, which are further acknowledged in the NMP proposed section 6 rule.[189] Yet not only has EPA made no attempt to fill these key data gaps, it has not even acknowledged them in the NMP Problem Formulation. EPA should use its information authorities to fill these gaps.

For other data gaps that EPA does acknowledge in the NMP Problem Formulation (e.g., "EPA did not identify water monitoring data for NMP during its review of the national surface water monitoring database," (p. 33), EPA does not describe any strategy for acquiring such data. Instead, EPA indicates it will rely on measured or estimated release data for surrogate chemicals for NMP as well as models (p. 54). While EDF does not oppose including surrogate data when relevant, it should not be the option of

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[188] U.S. EPA, TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripper Use CASRN: 872-50-4 at 95-101 (Mar. 2015), https://www.epa.gov/sites/production/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.

[189] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7519 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

first resort or be used as an excuse to fail to actively pursue such data through its information authorities.

EPA appears adamant on resorting to models and surrogate data even though it has clear authority to require the development of information to fill gaps or resolve discrepancies and uncertainties in the available data. For example, under its Analysis Plan for occupational exposures, EPA states: "Data gaps will be identified where no data are found for specific conditions of use. EPA will attempt to address data gaps identified as described in steps 2 and 3 below." (p. 56) Step 2 entails the use of data on surrogate chemicals and Step 3 entails the use of models. No step is indicated that would entail requiring submission or development of the needed data.

As a result, EPA's decisions in its risk evaluation and any subsequent risk management will be accompanied by unnecessary large degrees of uncertainty. Instead, EPA should rely on its information authorities to obtain additional information.

As described above, EPA has not identified any data on hazards to sediment invertebrates or terrestrial organisms. Here, EPA does not even bother with surrogate data, but claims that "NMP toxicity to sediment-dwelling invertebrates is expected to be comparable to that of aquatic invertebrates." (p. 47) EPA makes this assertion with absolutely no justification. EPA can and should mandate section 4 order or test rules to acquire data on the toxicity of NMP to sediment invertebrates and terrestrial organisms.

Similarly, as described more below, EPA appears to have relatively little information on hazards for aquatic organisms, particularly on chronic hazards, which limits its ability to identify a chronic concentration of concern (COC). EPA should similarly mandate chronic toxicity testing on aquatic organisms.

49. The NMP Problem Formulation demonstrates a lack of conservatism in assumptions and models.

Despite its assertions, EPA uses or suggests it will use non-conservative assumptions throughout the NMP Problem Formulation. Two examples are provided below.

A. Surface water pathway and risk to aquatic species

EPA asserts that its COCs for aquatic effects and its modeled surface water concentrations are "conservative." These statements are inaccurate.

With regards to the acute COC, EPA states:

> The acute COC of 246 µg/L, derived from the experimental aquatic invertebrate endpoint, is used as a *conservative* hazard level for NMP in this problem formulation. (p. 40, emphasis added)

With regards to the chronic COC, EPA states:

> The chronic COC of 1,768 µg/L, derived from the experimental aquatic invertebrate endpoint, is used as the *lower bound* hazard level for NMP in this problem formulation. (p. 40, emphasis added)

First, EPA implies that its calculations of COCs are conservative at least in part because of its use of assessments factors. The use of such factors is not conservative: They account for *real-world sources of variability as well as database limitations*, and cannot be construed as "safety factors" that yield conservative estimates.[190] As EPA states:

> The application of assessment factors is based on established EPA/OPPT methods (U.S. EPA, 2013, 2012d) and were used in this hazard assessment to calculate lower bound effect levels (referred to as the concentration of concern; COC) that would likely encompass more sensitive species not specifically represented by the available experimental data. Also, assessment factors are included in the COC calculation to account for differences in inter- and intraspecies variability, as well as laboratory-to-field variability. (p. 39)

We identify further concerns with these COCs below.

Second, EPA's modeling exercise to identify potential exposure to aquatic species is not as conservative as it suggests. EPA states:

> EPA employed a first-tier screening approach, utilizing readily-available data, modeling tools and conservative assumptions. EPA's Probabilistic Dilution Model (PDM) was used to estimate site-specific surface water concentrations based on the 2015 TRI data for "on-site" NMP releases to surface waters (U.S. EPA, 2007). The reported TRI releases were based on available information including monitoring data, emission factors, mass balance and/or other engineering calculations. The PDM also incorporates wastewater treatment removal efficiency. For this analysis, wastewater treatment removal efficiency was conservatively assumed to be 0%, as the reported NMP water releases were assumed to account for wastewater treatment *a priori*. Further, as the total days of release were not reported in these sources, EPA assumed a range of possible release days (i.e., 12 and 250 days/year) for facilities directly discharging NMP to surface water and 250 days/year for indirect discharges from wastewater treatment plants or Publicly Owned Treatment Works (POTWs) receiving indirect discharges of NMP).
>
> The "high-end" surface water concentrations (i.e., those obtained assuming a low stream flow for the receiving water body) from all PDM runs ranged from 224 µg/L to 0.00005 µg/L, for the acute (i.e., assumed fewer than 20 days of environmental releases per year) and chronic exposure scenario (i.e., more than 20 days of environmental releases per year assumed), respectively. (pp. 33-34)

Yet the modeling makes assumptions that are not conservative:

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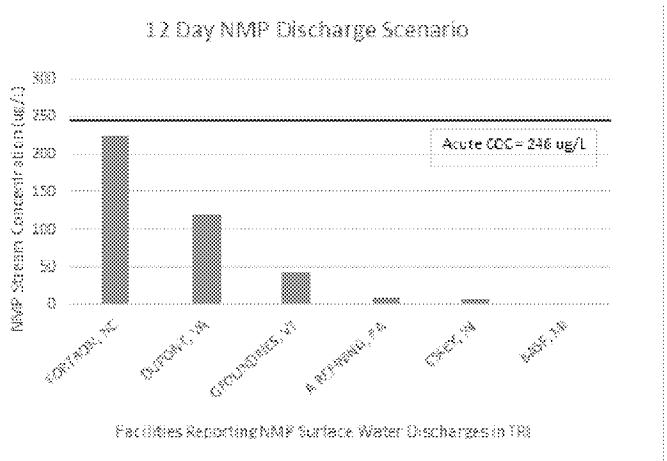
[190] *See* above at Section 14.

- *Days of release*: EPA provides no explanation of how it selected the numbers of release days (12 and 250) per year it used, nor why it selected yet another value – 20 days[191] – as the line between acute and chronic exposures. Given that EPA is using a fixed TRI release value, the best assumption for acute exposure (which might well not be at all conservative) would be to assume the release occurs in a single day. Compared to the 12 or 20 release-day scenarios utilized, this would result in considerably higher acute exposure estimates. Barring any actual data, this would be most appropriate assumption.

- *Sources of exposure*: In modeling surface water concentrations, EPA only considers the 14,092 lb/year of NMP directly and indirectly released to surface water, based on 2015 TRI data. This does not account for the estimated 6,438,594 million pounds released into land based on 2015 TRI data. Elsewhere EPA asserts that, due to its physical chemical properties, NMP will readily partition out of soil into water (e.g., "NMP exhibits high mobility in soil; hence, environmental releases are expected to migrate from soil to ground water," p. 30). How has EPA ruled out that any of the large quantities of NMP released to land do not end up in surface water? The only attempt at a rationale is the speculative statement that "[m]igration of NMP between ground water and surface water has not been documented, but may be mitigated by abiotic and biotic degradation in the water column." (p. 48)

Third, while not as conservative as EPA asserted, its modeling exercise still estimated high-end surface water concentrations at 224 µg/L, based on a facility located in Wilmington, NC (see Table_Apx C-1, p. 91). This value is so close to the acute COC of 246 µg/L that it should compel further data development and analysis beyond EPA's cursory first-tier analysis. *See* Figure Apx C-1 below.

Figure Apx C-1. Estimated Surface Water Concentration for 12-Day NMP Discharge



Fourth, it makes little sense for a chronic COC to be higher than the acute COC (specifically, over 7x higher). Logically, a concentration that causes acute effects should cause at least that same effect when

[191] EPA's invoking of 20 days is curious, as that value appears nowhere else in the document.

a species is subjected to it over a longer period of time. Bizarrely, this disparity in the data is present despite the fact that the chronic and acute values were both derived from testing on water fleas.

In the absence of reliable chronic data (a data gap EPA should use its information authorities to fill), a more conservative estimate would use the lowest acute value (1.23 mg/L) and divide it by an appropriate acute-to-chronic ratio (ACR) – as EPA did in its 1-BP problem formulation – as well as the assessment factor of 10 that EPA used to derive the chronic COC. EPA used an ACR of 10 in its 1-bromopropane Problem Formulation (p. 43); however, a cursory search of the literature indicates that an ACR of at least 100 may be needed to be sufficiently protective for most chemicals.[192] Applying an ACR of 100 and the assessment factor of 10, a more appropriate chronic COC would then be 1.23 µg/L; even using a less conservative ACR of 10 plus an assessment factor of 10, the chronic COC would be 12.3 µg/L.

Nine of the 12 discharging facilities for which EPA reported data (see Table_Apx C-1, p. 91) would exceed a chronic COC of 1.23 µg/L. One facility in Pensacola, FL (PALL CORP), with modeled levels as high as 467.92 µg /L – exceed the chronic COC by a factor of 380.

Of note, EPA's summary on p. 47 only refers to a value of 11 µg/L for the chronic exposure scenario. This is inconsistent with Table APX C-1 (p. 91), which includes a value of 10.75 µg/L (which EPA presumably rounded to 11) for one facility (Wilmington, NC) – but also a number of other concentrations well exceeding this value.

Even using a less conservative chronic COC of 12.3 µg/L, five of the 12 discharging facilities would still exceed the chronic COC, by as much as 38-fold (see Table Apx C-1, p. 91).

EPA relied on its flawed and certainly not conservative analysis to claim "[t]hese values do not exceed the acute and chronic COCs for aquatic organisms (246 µg/L and 1,768 µg/L, respectively) indicating a low risk concern." (p. 47) On this basis EPA indicated it will not further analyze exposures to ecological

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[192] *See* Martin May, et al., *Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels*, 28:1 ENVTL. SCIENCES EUROPE (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044967/; Jan Ahlers, et al., *Acute to chronic ratios in aquatic toxicity - variation across trophic levels and relationship with chemical structure*, 25:11 ENVTL. TOXICOLOGY & CHEMISTRY 2819 (Dec. 2009), 10.1897/05-701R.1. ("For fish, daphnids, and algae, acute to chronic ratios (ACRs) have been determined from experimental data regarding new and existing chemicals. Only test results in accord with the European Union Technical Guidance Document (TGD) and validated by authorities were considered. Whereas the median ACRs of 10.5 (fish), 7.0 (daphnids), and 5.4 (algae) are well below the ACR safety factor of 100 as implied by the TGD, *individual ACRs vary considerably and go up to 4400. The results suggest that a safety factor of 100 is not protective for all chemicals and trophic levels.* Neither a correlation between ACR and baseline toxicity as modeled through the logarithmic octanol-water partition coefficient nor an ACR correlation across trophic levels exists. Narcosis is associated with a preference for a low ACR; nevertheless, low ACRs are frequently obtained for nonnarcotics. Analysis of chemical structures led to the derivation of structural alerts to identify compounds with a significantly increased potential for a high ACR, which may prove to be useful in setting test priorities. *At present, however, life-cycle tests are the only way to conservatively predict long-term toxicity.*") (emphases added).

receptors, including fish, aquatic invertebrates and algae, from NMP release to surface water. EPA later took this conclusion further: "EPA's *conservative* assessment of this exposure scenario predicted NMP surface water concentrations that are well below the hazard benchmarks identified for humans and aquatic organisms." (p. 48, emphasis added)

In contrast to EPA's assertion, the analysis is anything but conservative and is flawed. This pathway certainly warrants additional analysis. EPA should obtain additional information on which to base its COCs and then analyze this pathway further.

B. Occupational exposure via inhalation route

Under its Analysis plan, EPA implies that it may rely in its risk evaluation on the recommended exposure guidelines established by American Industrial Hygiene Association (AIHA) in estimating occupational exposure:

> OSHA has not established any occupational exposure limits for NMP; however, AIHA has adopted a recommended workplace environmental exposure level (WEEL) of 10 ppm based on a time-weighted average (TWA) over an 8-hour workday. EPA will consider the influence of the recommended exposure guidelines in its occupational exposure assessment. (p. 57)

Any assumption of compliance with the WEEL would underestimate exposure. As recommended exposure guidelines are not enforceable, they are unlikely to be routinely followed. For example, the 2015 NMP risk assessment cited a WHO report that found occupational exposures to NMP from paint stripping could be as high as 64 mg/m^3 (or 16 ppm) for an 8-hour time weighted average (TWA) and 280 mg/m^3 (or 69 ppm) for 1 hour peak samples. Further, EPA's Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal estimated consumer exposure to be as high as 540.1 mg/m^3 (or 133.2 ppm) for an 8-hour TWA for one scenario ("Floors, Spray Application in Workshop, Windows Open").[193] These values range from 1.6 to 13.3 times higher than the WEEL.

EPA is charged with evaluating real-world exposures and should not assume compliance with voluntary exposure guidelines.

In addition, the inadequacy of the WEEL as sufficiently protective of worker health is illustrated by the lower exposures called for by others. EPA recommended an existing chemical exposure limit (ECEL) as a

[193] U.S. EPA, *Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal* at 51 (Nov. 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0199.

more current benchmark for workplace exposures;[194,195] this recommended value (20 mg/m^3, or 4.9 ppm, 8-hour time weighted average), is significantly lower than the WEEL. And the California Department of Public Health recently set a PEL of 1 ppm.[196]

50. EPA's proposed tiered assessment for consumer uses raises concerns.

In its Analysis Plan, EPA explains that it intends to use a tiered approach to assess consumer exposure:

> Evaluate consumer exposures to products and articles containing NMP. The 2015 NMP Risk Assessment for Paint Removal Use provides an in-depth characterization of paint removal products, including the NMP content, use patterns and associated exposures that may occur via their use. During risk evaluation, EPA will consider these paint removal uses along with other consumer uses to conduct a first-tier exposure analysis. The results of this analysis will then be used to determine which consumer use scenarios may need a more refined exposure assessment. In addition to the comparison of consumer exposure scenarios to each other, the associated exposure estimates for each scenario will also be compared to the hazard benchmarks identified for dermal and inhalation exposure. Based on the results of this evaluation, EPA may consider a subset of consumer use scenarios for a more extensive analysis. (p. 58)

TSCA requires EPA to "conduct risk evaluations *** to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment *** *under the conditions of use*." TSCA § 6(b)(4)(A) (emphasis added). EPA must analyze all consumer uses in order to know whether the use itself presents risk.

We have raised concerns throughout these comments about EPA's decision "not to further analyze" exposure pathways based on limited data and questionable assumptions. The same concern applies prospectively. In its first-tier assessment of consumer uses, EPA needs to have a robust scientific basis for deciding not to further refine the exposure analysis for a particular condition of use, including sufficient information as well as justified and documented assumptions. If EPA does not have empirical data (after using its authorities to obtain it), it should use reasonable worst-case assumptions to assure that the first-tier analysis is adequately conservative. Failing to conduct a robust exposure analysis would be inconsistent with the best available science requirement under TSCA section 26(h).

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[194] Memorandum from Chris Brinkerhoff, et al., US EPA Risk Assessment Div., to Niva Kramek, U.S. EPA Chemical Control Div., Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP (Jan. 6, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0238.

[195] Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7532 (proposed Jan. 19, 2017), https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0231.

[196] Cal. Dep't of Pub. Health, N-Methylpyrrolidone (NMP) (June 2014), https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/HESIS/CDPH%20Document%20Library/nmp.pdf.

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51. EPA's problem formulation contains statements relating to confidential business information (CBI) that are or may be inconsistent with its authorities and obligations under TSCA.

First, EPA states: "EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure." (p. 53) This statement ignores the major changes made to the CBI provisions of TSCA section 14. Companies must substantiate most claims for CBI protection and EPA must review many of them within 90 days of submission of the information. Any claim that does not meet all applicable requirements cannot be protected from disclosure.

EPA later makes an even more absolute statement in the context of human health studies:

> Human health studies will be evaluated using the evaluation strategies laid out in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Human and animal data will be identified and included as described in the inclusion and exclusion criteria in Appendix G. *** Further, ***EPA will consider any relevant CBI in a manner that protects the confidentiality of the information from public disclosure***. (p. 59, emphasis added)

Health and safety studies are expressly not eligible for protection as CBI under TSCA, subject only to two very narrow exceptions. *See* 15 U.S.C. § 2613(b)(2). All such information not subject to the exceptions needs to be made public.

Comments on Perchloroethylene

52. EPA has unreasonably excluded from the risk evaluation certain exposures to perchloroethylene on the basis of other environmental statutes.

As discussed earlier in these comments (see Section 5), EPA unreasonably excluded exposures to perchloroethylene through air, drinking water, ambient water, biosolids, and disposal pathways. EPA should not exclude those exposures, for the reasons given above.

For additional reasons, EPA's decision to exclude certain exposures is illegal and arbitrary and capricious. For instance, even though EPA excludes exposures through air because of the Clean Air Act, EPA states that the "[g]eneral population inhalation exposure to perchloroethylene in air may result from industrial manufacturing and processing plant fugitive and stack emissions." U.S. EPA, Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) at p. 46 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0080. EPA must analyze this exposure. Additionally, even though EPA excludes exposures through drinking water because of the Safe Drinking Water Act, EPA states that the general population may ingest perchloroethylene through drinking water, which "enters water supplies through industrial and commercial wastewater and liquid waste streams, sewage sludge land application, wet deposition (rain) and leaching from contaminated soils." (p. 46) EPA has provided no coherent rationale for excluding this exposure.

In particular, EPA needs to consider all reasonably available information and accurately describe "the magnitude of the exposure of human beings to the chemical substance" based on this risk evaluation. 15 U.S.C. § 2605(c)(2)(A)(i). EPA will be unable to fulfill these duties if it excludes some exposures from its analysis. To the extent EPA lacks information on these exposures, EPA should use its information authorities to address the information gaps.

53. EPA has provided insufficient justification for its decision to conduct no further analysis on a number of exposure pathways.

Occupational Exposures: EPA states that it will do no further analysis on any exposures to workers and Occupational Non-users (ONU) during the distribution of bulk shipments of perchloroethylene or the distribution of formulated products with perchloroethylene. (p. 147) The only reason provided is that "[e]xposure will only occur in the event of spills." (p. 147) Exposure from spills, even if infrequent (and EPA does not even suggest spills are infrequent), still contributes to overall exposure and should be included in the risk evaluation. In addition, distribution includes storage, transfer and transport of perchloroethylene, each of which can entail routine as well as accidental releases through, for example, fugitive emissions, venting, etc.

For numerous worker and ONU exposures, EPA states that it will do no further analysis on mists as an exposure pathway because "mist generation not expected." (pp. 143-56) EPA has provided no explanation, analysis or citation to evidence to support this expectation.

EPA also plans to do no further analysis on dermal exposures from liquid to ONU because "[d]ermal exposure is expected to be primarily to workers directly involved in working with the chemical." (pp. 143-56) TSCA provides no basis for limiting EPA's risk consideration only to intentional exposures, nor to focus only on persons "primarily" exposed.

Consumer Exposures: EPA must analyze all exposures to consumers and bystanders. EPA states that it will not further evaluate the oral pathway for consumers because such exposure "will be limited by a combination of dermal absorption and volatilization." (p. 57) EPA points to no data or analysis supporting this conclusion, and even if this exposure is limited, it will add to the total exposure level. EPA needs to evaluate the oral pathway for consumers. In particular, as EPA acknowledged "[i]nfants and young children may also be exposed to perchloroethylene via mouthing of treated products and articles (e.g., spot treatment of carpets; dry cleaned blanket)." (p. 46) Given the greater likelihood of oral exposure for infants and young children, EPA must analyze these potential exposures.

EPA also states that because bystanders are not directly handling perchloroethylene, "inhalation exposure to mists *** are not expected for bystanders," (p. 46), but this statement does not make sense. A bystander could easily inhale mists even if she is not personally handling the perchloroethylene. EPA points to no evidence supporting this statement. It lacks a factual or rational basis.

EPA states that it will not analyze exposure to consumers from disposal of consumer products because it is anticipated that most products will be disposed of in original containers. (p. 57) Does EPA have any evidence supporting this assumption? And even if disposed of in original containers, does EPA have a plan to evaluate the exposures that eventually flow from this disposal? The problem formulation fails to address these important questions.

When setting forth inclusion criteria for data sources for exposures to consumers and ecological receptors, EPA appears to limit its analysis to sources involving "non-closed systems," thus excluding all sources from "closed systems." (p. 164) EPA has not explained, let alone provided measurable criteria for, what qualifies as a "closed system" for these purposes; EPA should not exclude these data sources on this basis unless the data source reliably confirms that there are no (i.e., zero) exposures to consumers and ecological receptors.

54. EPA should analyze all reasonably available information about the hazards associated with perchloroethylene.

For the reasons articulated earlier in these comments (see Section 1), EPA must consider all reasonably available information about a chemical's hazards when preparing a risk evaluation. *See* 15 U.S.C. § 2625(k). EPA's problem formulation for perchloroethylene suggests that EPA will fail to consider all reasonably available information about both health and environmental hazards.

EPA's plan to analyze human health hazards states that EPA does not plan to evaluate "case reports and series or ecological studies for endpoints that appear to be less severe endpoints (e.g., nausea)." (p. 74) EPA has provided no basis for ignoring this reasonably available information about hazard. It has no basis in the statute. Accurately evaluating the risk presented by a chemical requires consideration of the numerous hazards it presents, and Congress contemplated that, based on the risk evaluation, EPA would be able to describe "the effects of the chemical substance or mixture on health." 15 U.S.C. § 2605(c)(2)(A). Nothing in the statutory text suggests that EPA can ignore certain effects just because they are less severe. Moreover, "less severe" presents an unclear standard for application. How severe does an endpoint need to be for EPA to consider it? EPA needs to fulfill its statutory duty and consider this reasonably available information about hazard.

EPA's plan to analyze environmental hazards appears to potentially be limited to analyzing hazards to aquatic species. (pp. 74-75) EPA needs also to consider hazards to terrestrial species and other ecological receptors. As EPA acknowledges elsewhere in the problem formulation: "Terrestrial species populations living near industrial and commercial facilities using perchloroethylene may be exposed via multiple routes such as ingestion of surface waters and inhalation of outdoor air. As described in Section 2.3.3, perchloroethylene is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water." (p. 43); *see also* (p. 40) ("Perchloroethylene has been found in *** terrestrial organisms."). Alternatively, it may be that EPA intends to analyze hazard to terrestrial species, but it is not clear that EPA has sufficient information to evaluate those hazards. If EPA lacks sufficient information to characterize the hazards presented to non-aquatic ecological receptors, then EPA should use its information authorities to obtain the reasonably available information regarding these hazards.

55. EPA should analyze the risks to the general population, children, infants, pregnant women, women and men of child-bearing age, and those residing in buildings where dry cleaning occurs.

EPA states that it will not analyze general population exposures to perchloroethylene because EPA considers its existing regulatory programs sufficient. (p. 73) EPA's approach is illegal for the reasons given earlier in these comments (see Section 5). In addition, the reasonably available information establishes that the general population experiences significant exposures to perchloroethylene, and it is irrational to ignore those exposures in light of this evidence. "A subset of National Health and Nutrition Examination Survey (NHANES) data (1999-2000) reported in Lin et al. (2008) show the presence of perchloroethylene in 77% of human blood samples from non-smoking U.S. adults." (p. 42) Perchloroethylene also is a common contaminant in air, soil, surface water, and drinking water, and EPA cannot ignore those exposures which are occurring under its existing regulatory regimes.

Similarly, EPA has identified reproductive/developmental toxicity as a hazard presented by perchloroethylene, and EPA must therefore consider infants, children, pregnant women, and women and men of childbearing age as potentially susceptible subpopulations. (p. 52) "Studies of tetrachloroethylene exposure in humans have evaluated several reproductive outcomes including effects on menstrual disorders, semen quality, fertility, time to pregnancy, and risk of adverse pregnancy outcomes including spontaneous abortion, low birth weight or gestational age, birth anomalies, and

stillbirth (U.S. EPA, 2012e). Data from animal studies identified various manifestations of developmental toxicity." (p. 52)

Given EPA's findings about developmental and reproductive toxicity, infants, children, pregnant women, and women and men of childbearing age are potentially susceptible subpopulations for perchloroethylene under TSCA § 3(12). 15 U.S.C. § 2602(12). TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to *** greater susceptibility *** may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." (p. 52) Due to the hazards presented by perchloroethylene, these subpopulations are at greater risk of adverse health effects. There can be no question that each of them is a "relevant" subpopulation for this evaluation.

EPA did not commit to analyzing risks to these subpopulations, despite recognizing these hazards. EPA stated that the available data are "insufficient to allow for a quantitative assessment of the impact of susceptibility on risk." (p. 53) EPA should use its information authorities to generate and obtain the necessary information to prepare the required analysis.

Moreover, available data indicate that a particularly exposed subpopulation would include those residing in buildings where dry cleaning is carried out. "[S]ampling (over 100 samples) of air in six residential apartments in two buildings where dry cleaning was carried out on the ground floor revealed tetrachloroethene concentrations ranging from 50 to 6100 $\mu g/m^3$, with means ranging from 358 to 2408 $\mu g/m^3$." (p. 38) EPA needs to analyze risks to this subpopulation as well due to its greater exposure.

56. EPA should use its information authorities to fill information gaps revealed by the perchloroethylene problem formulation.

In a number of places, EPA appears to use models, surrogate chemicals, or other estimates instead of measured data. EPA should use its various information authorities to obtain actual measured data on perchloroethylene instead of relying so extensively on estimated information. In addition, in places EPA suggests that available information is insufficient for certain portions of the analysis. EPA needs to use its information authorities to fill those information gaps.

EPA's analysis of environmental fate appears to rely overwhelmingly on EPI Suite and other models, not measured evidence. (pp. 35-37) EPA notes that "the literature review is currently underway through the systematic review process," (p. 35) but elsewhere (p. 160), EPA suggests that "environmental fate data will not be further evaluated." EPA should obtain and rely on needed measured data, and EPA should not exclude environmental fate data from its systematic review or its further analysis in the risk evaluation.

EPA also appears to intend to rely heavily on models for both occupational and consumer exposures, but instead EPA should rely on its information authorities to obtain measured information on these exposures. EPA states that: "If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be

estimated using EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality." (pp. 66-67) Similarly, EPA states that it may use information for surrogate chemicals. (p. 66) Rather than shift immediately to models and surrogates, EPA should use its information authorities to obtain or generate the necessary high-quality studies. EPA's statement in its response to comments (EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA p.13, *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0051) that available information is sufficient for the risk evaluations cannot be reconciled with EPA's repeated acknowledgement that it may have to rely on models and surrogates in the absence of measured data.

Similarly, EPA stated that "Perchloroethylene specific formulation processes were not identified so EPA will rely on [Emission Scenario Documents (ESDs), Generic Scenarios (GS)]." (p. 108) EPA could obtain this information by exercising its information authorities, and EPA should do so.

It would be particularly appropriate for EPA to use its information authorities to obtain information about the scenarios where EPA was not able to identify applicable Emission Scenario Documents (ESDs), Generic Scenarios (GS), or release scenarios. (pp. 66-67) "EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including use of perchloroethylene as an intermediate, recycling of perchloroethylene, use of perchloroethylene as an industrial processing aid, and use of perchloroethylene in commercial carpet cleaning." (pp. 66-67) EPA needs to use its information authorities to fill these information gaps. In particular, EPA needs accurate information about recycling processes because, according to the TRI data cited in the problem formulation, over 46 million pounds of perchloroethylene are recycled per year, representing over 71% of total waste managed. (p. 39)

As explained earlier in these comments (see Section 6), EPA should not assume that all occupational exposures meet the existing regulatory limits for perchloroethylene. Among other things, the exposure information reveals that some exposures exceed the regulatory and non-regulatory exposure limits identified by EPA. *E.g.*, *compare* (p. 123) (showing maximum 8-hr TWA Concentration of 390 ppm), *with* (p. 44) (describing various regulatory exposure limits well below those levels).

Moreover, EPA indicates that it "was not able to identify occupational exposure scenarios corresponding to several conditions of use due generally to a lack of understanding of those conditions of use (e.g., use of perchloroethylene metal and stone polishes). EPA will perform targeted research to understand those uses which may inform identification of occupational exposure scenarios." (p. 71) EPA must ensure that it has sufficient information to analyze these exposure scenarios, and should use its information authorities to do so.

EPA should also use its information authorities to determine the extent to which exposure occurs through the consumption of fish. EPA acknowledges that the EU Risk Assessment indicates that perchloroethylene may be present in fish, (p. 47), and given widespread contamination of surface water, this source of exposure should be examined. EPA states "EPA does not anticipate fish ingestion to be a significant general population exposure pathway, as perchloroethylene has a low bioaccumulation

potential in aquatic organisms," (p. 47), but given there is evidence to the contrary, EPA must assess the available information to see if the factual record supports this "anticipation."

57. EPA must identify and explain any deviations from its previous assessments of perchloroethylene.

EPA states in the problem formulation:

> Perchloroethylene has an existing EPA IRIS Assessment U.S. EPA (2012e) and a draft ATSDR Toxicological Profile (ATSDR, 2014); hence, many of the hazards of perchloroethylene have been previously compiled. EPA expects to use these previous analyses as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. (p. 51)

EPA identifies two previous assessments of perchloroethylene: the IRIS 2012 toxicological review and the 2014 ATSDR toxicological review. The agency further indicates that many of perchloroethylene's hazards were compiled in the ATSDR profile and IRIS toxicological review. Both documents were peer reviewed by independent scientists. EPA has previously relied heavily on IRIS toxicological reviews to develop subsequent risk assessments.

Given EPA's clear indications of the scientific rigor of IRIS toxicological reviews as well as its decision to rely upon them, EPA must identify, explain and justify any deviations from the earlier review in its draft risk evaluation in terms of hazard identification and dose-response characterization. Any differences must be based on compelling scientific evidence and explicitly interrogated through the peer review process.

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Comments on Trichloroethylene

58. EPA should finalize its proposed bans of TCE under TSCA immediately and not use the larger ongoing risk evaluation of TCE as a reason for delay.

EDF incorporates by reference its comments on EPA's proposed rules to ban TCE for use in vapor degreasing, aerosol degreasing, and spot cleaning in dry cleaning facilities.[197,198] EPA's 2014 risk assessment and supplemental technical reports make clear that TCE, under the conditions of use subject to the proposed rules, presents an unreasonable risk of injury to health of workers, occupational bystanders, and consumers. These evaluations reflect input from numerous and extensive peer reviews, incorporate the best available science, and apply a weight-of-the-scientific-evidence approach.

The Lautenberg Act clearly intended for EPA to move forward to address risks it identified in assessments completed prior to enactment.

Section 26(l)(4) states (emphases added):

> (4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has *published a completed risk assessment prior to the date of enactment* of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator *may publish proposed and final rules under section 6(a)* that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6.

Section 26(p)(3) states (emphasis added):

> (3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE. – *Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule* under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

These provisions of the law make abundantly clear that EPA can proceed to promulgate a rule based on its completed TCE Work Plan risk assessment and is under no obligation to withdraw its prior risk assessment, risk determination or proposed rule. Indeed, Congress included these provisions for the very purpose of grandfathering-in the Work Plan risk assessments EPA had completed and ensuring its authority to use those assessments as the basis for section 6 risk management rules.

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[197] EDF Comments on Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a) (May 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0696.
[198] EDF Comments on Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a) (Mar. 16, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0172.

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It is indefensible for EPA to delay critically needed action on TCE, as EPA now plans to do, reevaluating those conditions of use in the current risk evaluation. This approach will effectively delay action for years, putting public health at risk. EPA needs to expeditiously finalize its proposed bans of these high-risk uses of TCE, while taking into consideration any exposures remaining from those conditions of use due, for example to allowed exemptions.

59. EPA's apparent intent to deviate from longstanding agency-wide guidance on assessing risks for developmental toxicity lacks scientific justification.

EPA states in the problem formulation document:

> Based on initial screening, EPA plans to analyze the hazards of TCE identified in the scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. *For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios.* This means that it is unlikely that every hazard identified in the scope document will be considered for every exposure scenario.

U.S. EPA, Problem Formulation of the Risk Evaluation for Trichloroethylene at p. 39 (emphasis added) (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0737-0083. EPA's proposal here is deeply concerning, and suggests that the agency plans to ignore its own established guidance[199] on the evaluation of chemical hazards and risks. With regard to TCE, EPA's 2011 Integrated Risk Information System (IRIS) assessment[200] correctly identified fetal cardiac malformation, a developmental toxicity effect, as the most sensitive endpoint and supported by multiple lines of evidence—epidemiological, laboratory animal, metabolism, and mechanistic studies. EPA OCSPP reaffirmed this conclusion in its 2014 TCE work plan risk assessment.[201] The TCE problem formulation introduces the possibility that EPA may exclude developmental toxicity as an acute effect—a decision that would not only be odds with EPA's past assessments, proposed regulations, and guidance but also at odds with applying a health-protective approach to chemical risk evaluation.

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[199] *See* U.S. EPA, *Guidelines for Developmental Toxicity Risk Assessment* (Dec. 1991), https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.

[200] U.S. EPA, *Toxicological Review of Trichloroethylene (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS)* (Sept. 2011), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

[201] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses* (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

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As described in EPA's proposed section 6 TCE rules[202,203] and in the 2014 TCE risk assessment, EPA relied on developmental endpoints for assessing health risks of TCE resulting from acute exposure. This is in alignment with EPA's longstanding agency-wide guidance, Guidelines for Developmental Toxicity Risk Assessment,[204] which indicates that even a single exposure to a chemical within a critical window of development may produce adverse developmental effects. For example, EPA's proposed section 6 TCE rule, Trichloroethylene (TCE) Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), states:

> As indicated in the TCE risk assessment, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy presumes that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (Ref. 5). This is the case with cardiac malformation. EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional developmental studies of TCE metabolites (Appendix N) (Ref. 2). EPA based its acute risk assessment on the most sensitive health endpoint (*i.e.,* fetal heart malformations) representing the most sensitive human life stage (*i.e.,* the developing fetus) (Ref. 2).[205]

As a general matter, EDF strongly recommends that EPA follow this established EPA risk assessment practice, and include developmental toxicity effects in its assessment of acute exposure from chemicals. In the case of TCE, EDF strongly recommends that the agency include fetal cardiac malformations in its assessment of acute effects in addition to its assessment of chronic effects. EPA has provided no basis for deviating from this practice in its problem formulation, and to do so would deviate from using the best available science as required under TSCA.

60. EPA's problem formulation raises concerns regarding the agency's approach to the evaluation of fetal cardiac malformations.

In the "Human Health Hazards" section of the Analysis Plan, EPA states:

> The final TSCA Work Plan Chemical Risk Assessment of TCE (U.S. EPA, 2014c) included an assessment of fetal cardiac malformations. EPA will use the systematic review approach (U.S. EPA, 2018) to re-evaluate key studies in this assessment as well as more recent information on this endpoint. of mechanistic data as part of EPA's reevaluation of key

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[202] Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91595, 91599 (proposed Dec. 16, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0001.
[203] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432, 7435, 7439 (proposed Jan. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001.
[204] U.S. EPA, *Guidelines for Developmental Toxicity Risk Assessment* at 4, 45 (Dec. 1991), https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf.
[205] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a), 82 Fed. Reg. 7432, 7439 (proposed Jan. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001.

> studies. [*sic*] Mechanistic data related to all other endpoints will be identified as "Supplemental Information." (p. 68)

In response to EDF's request for a correction of the typo in this excerpt, EPA indicated the excerpt should read as follows:

> The final TSCA Work Plan Chemical Risk Assessment of TCE (U.S. EPA, 2014c) included an assessment of fetal cardiac malformations. EPA will use the systematic review approach (U.S. EPA, 2018) to re-evaluate key studies in this assessment as well as more recent information on this endpoint. ~~of mechanistic data as part of EPA's reevaluation of key studies.~~ Mechanistic data related to all other endpoints will be identified as "Supplemental Information. [206]
>
> [AND]
>
> Mechanistic data related to developmental toxicity in general is included in the PECO statement for our systematic review. Mechanistic data for non-developmental toxicity will be considered supplemental for the time being.[207]

EPA indicates in its *Application of Systematic Review in TSCA Risk Evaluations* document (hereafter "TSCA Systematic Review document"):[208]

> EPA/OPPT plans to prioritize the evaluation of mechanistic evidence instead of evaluating all of the identified evidence upfront. This approach has the advantage of conducting a focused review of those mechanistic studies that are most relevant to the hazards under evaluation. The prioritization approach is generally initiated during the data screening step. For example, many of the human health PECOs [Populations Exposures Comparators and Outcomes] for the first ten TSCA risk evaluation [*sic*] excluded mechanistic evidence during full text screening. Excluding the mechanistic evidence during full text screening does not mean that the data cannot be accessed later. The assessor can eventually mine the database of mechanistic references when specific questions or hypotheses arise related to the chemical's MOA [mode of action]/AOP [adverse outcome pathway].[209]

Taken together, these excerpts suggest EPA intends to treat the scientific evidence for fetal cardiac malformations and for developmental toxicity generally differently than it will other endpoints. Yet it provides no rationale for doing so. EPA has not explained why it is treating mechanistic data pertaining to fetal cardiac malformations and developmental toxicity differently from all other endpoints. Such a decision in the absence of a scientific explanation is inappropriate especially within a systematic review

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[206] Personal communication from Niva Kramek (EPA) to Jennifer McPartland (July 12, 2018).
[207] Personal communication from Keith Jacobs (EPA) to Jennifer McPartland (July 12, 2018).
[208] U.S. EPA, *Application of Systematic Review in TSCA Risk Evaluations* (May 2018), https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.
[209] *Id.* at 172.

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framework, and more broadly serves to highlight the serious problems that arise from the absence of a protocol.[210] EPA's unreasoned dissimilar treatment of similar information is arbitrary and capricious.

61. EPA has failed to describe how it will evaluate non-quantitative data for contribution to weight of evidence, and qualitative endpoints that are not appropriate for dose-response assessment.

In describing how it expects to analyze TCE's human health hazards, EPA states: "Non-quantitative data will also be evaluated for contribution to weight of evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment." (p. 69). EPA provides no further explanation.

EPA fails to describe how it intends to evaluate non-quantitative data for contribution to weight of evidence, or for qualitative endpoints that are not appropriate for dose-response assessment. EPA's TSCA Systematic Review document also fails to provide this detail.

62. EPA statements calling for reevaluating the available science pointing to TCE health risks are vague and insufficiently supported, with no clear next step identified.

In the problem formulation EPA states:

> Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that *meet the systematic review data quality criteria* described in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018) document. Data quality evaluation will be performed on key studies identified from the Integrated Risk Information System (IRIS) Toxicological Review of TCE (U.S. EPA, 2011c), the final TSCA Work Plan Chemical Risk Assessment of TCE (U.S. EPA, 2014c) and studies published after 2010 that were captured in the comprehensive literature search conducted by the Agency for TCE [Tricholoroethylene (79-01-6) Bibliography: Supplemental File for the TSCA Scope Document; (EPA-HQ-OPPT-2016-0737; U.S. EPA, 2017g)]. Hazards identified by studies *meeting data quality criteria* will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints. (p. 69, emphases added)

EPA has not explained, either here or in its TSCA Systematic Review document, what it means for data or studies to "meet the systematic review data quality criteria." EPA has also not explained what it means by "key studies," including how they will be identified from the IRIS toxicological review, Work Plan Chemical Risk Assessment, and post-2010 literature review and how they will be used in the risk evaluation.

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[210] *See* EDF Comments on Application of Systematic Review in TSCA Risk Evaluation, https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0210 (to be posted in the docket link provided).

63. EPA should rely on its prior hazard assessment in the current risk evaluation, and identify and justify any deviations from it.

EPA states in the problem formulation:

> TCE has an existing EPA IRIS Assessment (U.S. EPA, 2011c) and an ATSDR Toxicological Profile (ATSDR, 2014a); hence, many of the hazards of TCE have been previously compiled and systematically reviewed. Furthermore, EPA previously reviewed data/information on health effects endpoints, identified hazards and conducted dose-response analysis in the TSCA Work Plan Chemical Risk Assessment of TCE (U.S. EPA, 2014c). EPA has relied heavily on these comprehensive reviews in preparing this problem formulation. EPA expects to use these previous analyses *as a starting point for identifying key and supporting studies* to inform the human health hazard assessment, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the Application of Systematic Review in TSCA Risk Evaluations document (U.S. EPA, 2018). (p. 44, emphasis added)

The agency indicates that "many of the hazards of TCE have been previously compiled and systematically reviewed," which was in fact done in the ATSDR profile and the IRIS toxicological review. EPA should heavily rely on its IRIS assessment, which is based on the best available science and has been peer reviewed. As noted in EPA's Work Plan assessment, EPA relied heavily on the IRIS toxicological review to develop the Work Plan assessment. In describing the IRIS toxicological review, EPA stated in the Work Plan Assessment:

> The assessment uses the hazard and dose-response information published in the final toxicological review that the U.S. EPA's Integrated Risk Information System (IRIS) published in 2011 (EPA, 2011e). The TCE IRIS assessment used a weight-of-evidence approach, the latest scientific information and physiologically-based pharmacokinetic (PBPK) modeling to develop hazard and dose-response assessments for TCE's carcinogenic and non-carcinogenic health effects resulting from lifetime inhalation and oral exposures. In addition to relying on the latest scientific information, the TCE IRIS assessment underwent several levels of peer review including agency review, science consultation on the draft assessment with other federal agencies and the Executive Office of the President, public comment, external peer review by the EPA's Science Advisory Board (SAB) in 2002, scientific consultation by the U.S. National Academy of Sciences (NAS) in 2006, external peer review of the revised draft assessment by the EPA's Science Advisory Board (SAB) in January 2011, followed by final internal agency review and EPA-led science discussion on the final draft.[211]

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[211] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses* at 20-21 (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

Given EPA's multiple, clear statements affirming the scientific rigor of the IRIS toxicological review as well as its decision to rely upon it in its 2014 Work Plan Assessment[212] and subsequent TSCA section 6 proposed bans, EDF firmly believes that it is unnecessary – not to mention a waste of time and resources – to re-conduct aspects of the agency's previous hazard identification and dose-response characterization unless EPA can demonstrate serious shortcomings in the previous assessment. Further, EPA must identify and explain any decision to deviate from the previous IRIS assessment and clearly identify in its draft risk evaluation any modifications it proposes in hazard identification and dose-response characterization, and the scientific justification for them. Any such differences must be based on compelling scientific evidence and explicitly interrogated through the peer review process.

The excerpt from the problem formulation refers to "key," "supporting," and "relevant" studies. The meaning of these descriptors is entirely unclear. EPA must explicitly define the meaning of these terms and their implications with regard to the agency's approach to systematic review and risk evaluation.

64. EPA fails to acknowledge its previous physiologically-based pharmacokinetic (PBPK) analysis described extensively in its peer-reviewed 2014 Work Plan Chemical Assessment.

In the "Human Health Hazards" section of the Analysis Plan in the problem formulation, EPA states:

> EPA will evaluate whether the available physiologically-based pharmacokinetic (PBPK) and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by body weight$^{3/4}$ ($BW^{3/4}$) scaling in accordance with (U.S. EPA, 2011b), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with (U.S. EPA, 1994). (p. 69-70).

EPA fails entirely to acknowledge the route-to-route analysis performed as part of the 2014 Work Plan Assessment that was extensively peer reviewed. As noted in the Work Plan Assessment:

> PBPK model—route-to-route extrapolation: PBPK-derived hazard values were based on PODs from either inhalation or oral studies. The TCE PBPK model used interspecies and route-to route extrapolation approaches to convert both the inhalation and oral PODs to human internal doses. Then, the model estimated the human equivalent concentrations needed to produce the human internal doses. Since the PBPK model was

[212] It bears emphasis that extensive peer reviews were undertaken for the IRIS toxicological reviews and 2014 Work Plan assessment. *See* EDF Comments on Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a) at 4, 26 (May 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0696; EDF Comments on Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a) at 4, 20 (Mar. 16, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0172.

used, the uncertainties associated with using oral studies for inhalation exposures were minimized.[213]

EDF recommends that EPA use its previous PBPK route-to-route extrapolation approach. Any decision to deviate from the agency's previous PBPK modeling approaches should require a compelling, scientifically-based justification based on empirical evidence.

65. EPA must use its information authorities under TSCA to address areas where there is insufficient information to evaluate risks.

The problem formulation identifies numerous information gaps in evaluating TCE's risks. Examples of such gaps are listed below.

- Table 2-3, *Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation*, includes a category "other uses" within the "industrial/commercial/consumer use" lifecycle stage. Appendix B.1.3.10 describes this "other uses" category as follows:

  > Based on products identified in EPA's Use Document, [EPA-HQ-OPPT-2016-0737-0003 (U.S. EPA, 2017c)], a variety of other uses may exist for TCE, including use in hoof polish, pepper spray and as a toner aide. It is unclear at this time the total volume of TCE used in any of these applications. EPA has not identified any information to further refine the use of TCE in these products at this time; more information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process. (p. 108)

  Here EPA acknowledges a significant lack of information regarding the "other uses" category of conditions of use. Even still, EPA intends not to use any of its information authorities under TSCA sections 4 and 8 to address these information gaps. Instead, EPA indicates that it will attempt to fill them through an expanded literature search for which there is no assurance EPA will obtain the information it needs. EPA provides no discussion of what action it will take to obtain necessary information if the expanded literature search proves inadequate. Moreover, a decision by EPA to wait to use its information authorities until after the literature search is completed is inefficient and may not provide enough time for EPA to obtain and integrate information into its risk evaluations.

- On page 34 EPA states: "Compared with other environmental media, there is a relative lack of nationally representative monitoring data on levels of TCE in ambient soil." Here again, EPA has identified an information gap that it should fill using its information authorities under TSCA.

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[213] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses* at 122-23 (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

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- On page 45 EPA states:

> Limited epidemiological data do not support an association between TCE exposure and allergic respiratory sensitization or asthma; however, there is strong human evidence for severe skin sensitization resulting in dermatitis, mucosal lesions and often systemic effects such as hepatitis. Skin sensitization tests on rodents corroborate the contact allergenicity potential of TCE and its metabolites along with the resulting immune-mediated hepatitis (U.S. EPA, 2011c)."

Here EPA appears to be relying on acknowledged limited data to assert a lack of association between exposure and allergic respiratory sensitization or asthma. This is especially problematically given observed linkages between skin sensitization and respiratory sensitization for chemicals.[214] EPA should use its information authorities to obtain additional information about TCE exposure and allergic respiratory sensitization and asthma.

- On page 60 EPA states:

> EPA was not able to identify release scenarios corresponding to several conditions of use, including recycling of TCE, commercial carpet cleaning, and as an industrial process solvent. EPA will perform additional targeted research to understand those conditions of use, which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use.

Here again, EPA acknowledges significant information gaps regarding release scenarios from several conditions of use of TCE. Even still, the agency intends not to use any of its information authorities under TSCA sections 4 and 8. Instead, EPA indicates that it will attempt to fill these information gaps through "additional targeted research" on various conditions of use and applicable models and associated parameters. The meaning of "additional targeted research" is entirely unclear. EPA should define what "additional targeted research" means as a general matter, and immediately initiate use of its information authorities to obtain information necessary to identify the missing release scenarios.

- On page 63 EPA states:

> EPA has identified Emission Scenario Documents (ESDs) from the Organization for Economic Co-operation and Development (OECD) and EPA Generic Scenarios

[214] European Chemicals Agency, Guidance on Information Requirements and Chemical Safety Assessment Chp. R.7a: Endpoint specific guidance (Jul. 2017), https://protect-us.mimecast.com/s/IzjeCpYzmDhnE3g3SPVakj?domain=echa.europa.eu.

> (GS's) corresponding to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on Metalworking Fluids, and the GS for textile finishing are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs and GSs corresponding to several conditions of use, including manufacture of TCE, use of TCE as an intermediate, recycling of TCE, and commercial carpet cleaning. EPA may conduct industry outreach efforts or perform supplemental, targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA will consider inhalation exposure to vapor and mist models in the Chemical Screening Tool for Exposure and Environmental Releases (ChemSTEER) Tool that are routinely used for assessing new chemicals. EPA may also need to perform targeted research to identify applicable models that EPA could use to estimate exposures for certain conditions of use.

EPA must obtain emission information it explicitly acknowledges is lacking for "several conditions of use." EPA indicates it "may conduct industry outreach efforts"—a hardly convincing indication that EPA will actually pursue outreach and that also disregards its information authorities under TSCA. Again, the meaning of "targeted research" is entirely opaque and must be explained.

- In describing its analysis plan for occupational exposure on page 64, EPA states: "EPA anticipates that existing EPA/OPPT dermal exposure models would not be suitable for quantifying dermal exposure to highly volatile chemicals such as TCE."

  If EPA does not have sufficient information on dermal exposure whether through measured or modeled data, it must obtain such information. EPA's indication that dermal exposure models may not be suitable for quantifying dermal exposure is confusing and concerning given the agency's quantification of dermal absorption in early sections of the problem formulation (see for example p. 47). EPA indicates that its exposure models are not suitable and yet provides specific absorption percentages using a specific model, IHSkinPerm. This is entirely incongruent. EPA must obtain sufficient information to accurately assess dermal exposure.

- On pages 64 and 65 EPA states:

> EPA was not able to identify occupational exposure scenarios corresponding to several conditions of use due generally to a lack of understanding of those conditions of use. EPA will perform targeted research to understand those uses which may inform identification of occupational exposure scenarios and analyze those uses identified.

This is yet another example of EPA not using its information authorities while explicitly acknowledging significant information gaps regarding occupational exposures.

66. EPA goes out of its way to avoid using its information authorities in numerous instances.

Throughout the problem formulation EPA goes out of it way to avoid using its information authorities. Examples of such instances are listed below.

- On page 58 EPA states:

> While EPA has conducted a comprehensive search for reasonably available data as described in the Scope for TCE (EPA-HQ-OPPT-2016-0737-0057; U.S. EPA, 2017d), EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during the risk evaluation. EPA will continue to consider new information submitted by the public.

  Rather than relying solely on voluntary submissions—an approach that has proven insufficient in the past[215]—EPA should use its information authorities to obtain necessary information on conditions of use, exposures, hazards, and potentially exposed or susceptible subpopulations.

- On page 59 under the environmental releases section of the analysis plan, EPA states:

> EPA has reviewed key release data sources including the Toxics Release Inventory (TRI). EPA will continue to review relevant data sources as identified in Table_Apx B-4 during risk evaluation. EPA will match identified data to applicable conditions of use and identify data gaps when no data are found. Additionally, for conditions of use where no published release data are available, EPA may use a variety of methods including the application of conservative release estimation approaches and assumptions in the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER).

  EPA indicates it will "use a variety of methods" to gather data "where no published release data are available" and uses the ChemSTEER model as the only example of such a method. Again, EPA provides no indication it will use its information authorities even where information gaps exist.

67. EPA is not evaluating potentially exposed or susceptible subpopulations as required under the law.

In the problem formulation EPA identifies potentially exposed or susceptible subpopulations but will not be considering them in the risk evaluation as required under the law. Specifically EPA indicates

[215] *See* section 8; *see also* EDF Comments on § 6(h) PBTs under the Toxic Substances Control Act at 10-13 (Jan. 12, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0730-0014.

widespread contamination of TCE in soil and groundwater but will not consider the risks to subpopulations that may be affected by such contamination in the risk evaluation. On pages 33 and 34 EPA notes widespread TCE contamination:

> While the primary fate of TCE released to surface waters or surface soils is volatilization, TCE is more persistent in air and ground water, where it is commonly detected through national and state-level monitoring efforts. TCE is frequently found at Superfund sites as a contaminant in soil and ground water TCE has been detected in ambient air across the United States.

Yet notably absent from EPA's list of potentially exposed or susceptible subpopulations in section 2.3.5.4 are subpopulations that live in proximity to such sources of TCE contamination. EPA's apparent decision to ignore these subpopulations is entirely inconsistent with requirements under TSCA. EPA must include these subpopulations in its risk evaluation of TCE.

68. TCE exposures to terrestrial organisms can occur through multiple pathways of exposure.

EPA is ignoring important pathways of TCE exposures to terrestrial organisms. EPA states:

> Exposure to terrestrial organisms is expected to be low since physical chemical properties do not support an exposure pathway through water and soil pathways to these organisms. The partition of TCE into sediments is very low. Furthermore, the primary fate of TCE released to surface waters or surface soils is volatilization. (p. 35)

This statement ignores entirely TCE exposures to terrestrial organisms through air, which is a primary pathway of exposure to TCE. EPA establishes the case for this throughout the problem formulation document. For example in section 2.2.3, Presence in the Environment and Biota, EPA notes, "TCE is more persistent in the air and ground water, where it is commonly detected through national and state-level monitoring efforts" and "TCE has been detected in ambient air across the United States, though ambient levels vary by location and proximity to industrial activities." (pg. 33)

Additionally, EPA is ignoring exposures to terrestrial organisms that may occur from contaminated water and soil.

EPA must comprehensively consider all routes of exposure to terrestrial organisms in its risk evaluation of TCE given its widespread detection throughout the environment including at contaminated sites.

69. EPA repeatedly only references aquatic plants when describing its approach to evaluating aquatic species.

Throughout the problem formulation document, EPA repeatedly parenthetically references aquatic plants only in "i.e." statements relating to ecological exposures to aquatic species via contaminated surface water. For example:

> EPA expects to analyze aquatic species (i.e., aquatic plants) exposed via contaminated surface water. There are no national recommended water quality criteria for the

> protection of aquatic life for TCE and as a result EPA does not believe that TCE exposure to aquatic organisms in surface water has been adequately assessed. (p. 53)

In doing so, EPA suggests that it will only consider aquatic plants and no other aquatic species in its evaluation of aquatic species exposed via contaminated surface water. EPA must comprehensively consider all relevant aquatic organisms in its assessment of such exposures. If this is unintentional, EPA should change all relevant "i.e." references to "e.g." references. If it is intentional, EPA needs to revise its proposed approach to evaluating aquatic species to include all relevant aquatic species, which extend well beyond aquatic plants.

70. EPA must include exposures to the general population in its risk evaluation of TCE.

EPA has erroneously proposed to ignore exposures to the general population from TCE. For example,

> EPA does not plan to consider and analyze general population exposures in the risk evaluation for TCE. EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of TCE that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes. (p. 63)

EPA's decision to exclude exposures to the general population is unscientific, not health-protective, and illegal. EPA must include the general population in its assessment of TCE, particularly given known inhalation exposures via ambient air and ingestion.[216]

71. EPA's exclusion of non-occluded dermal exposures to workers lacks rationale and is inconsistent with its approach to including occluded dermal exposures.

In describing its approach to evaluating occupational dermal exposures to TCE, EPA states:

> Exposures to skin that are instantaneous would be expected to evaporate before significant dermal exposure would occur based on the physical chemical properties including the vapor pressure, water solubility, and log Kow (the estimate from IHSkinPerm, a mathematical tool for estimating dermal absorption, is 0.8% absorption and 99.2% volatilization). Exposure that occurs as a deposition over time or a repeated exposure that maintains a thin layer of liquid TCE would have greater absorption (the estimate from IHSkinPerm for an 8-hr exposure is 1.6% absorption and 98.4% volatilization). In both instantaneous or repeated exposure scenarios, the dermal exposures to liquid TCE would be concurrent with inhalation exposures and overall the contribution of dermal exposure to the total exposure is relatively small. This is in

[216] U.S. EPA, *Sources, Emission and Exposure to Trichloroethylene (TCE) and Related Chemicals* at 23-26 (Mar. 2001), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=4824.

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> agreement with the NIOSH skin notation profile for TCE, which estimates a low hazard potential by dermal absorption for systemic effects when inhalation and dermal exposures are concurrent (NIOSH, 2017). Therefore, it is not anticipated that dermal absorption will be significant for the majority of occupational exposure scenarios; thus, non-occluded dermal exposure scenarios will not be analyzed for workers. Based on the 2017 NIOSH Skin Notation Profile for TCE, TCE is associated with systemic and direct (i.e., irritation) effects, as well as sensitization. An occluded exposure scenario, wherein liquid TCE is not able to evaporate readily, may have dermal exposures that significantly contribute to the total exposure or effects on the skin (e.g., dermal sensitization). An example of such an occluded scenario includes TCE being trapped under a worker's glove during occupational activities, thus preventing the rapid volatilization that generally inhibits dermal absorption. Therefore, occluded dermal exposure scenarios will be analyzed for workers. (p. 47)

That a smaller relative percentage of exposure to TCE is expected from dermal versus inhalation exposure does not mean that the dermal exposure is irrelevant to evaluating TCE risks in occupational settings. The contribution of TCE exposure from dermal absorption could be a significant source of exposure in a comprehensive evaluation of TCE's risks. Indeed, in EPA's 2014 Work Plan Assessment, the agency noted:

> Rapid absorption through the skin has been shown by both vapor and liquid TCE contact with the skin. EPA (2011e) summarized several volunteer studies in which both TCE liquid and vapors were shown to be absorbed in humans via the dermal route. Following exposures of between 20 and 30 minutes, absorption was rapid, with peak TCE levels in expired air occurring within 15 minutes (liquid) and 30 minutes (vapor).[217]

EPA should consider combined exposures to TCE via all pathways across all potential sources of exposure.

Moreover, it is not clear why EPA will include occluded dermal exposures to workers but not non-occluded dermal exposure that "maintains a thin layer of liquid." Ostensibly, both exposures scenarios result in continuous dermal contact and absorption of TCE.

72. EPA's approach to evaluating consumer dermal exposure to TCE is problematic and points to inconsistencies in how EPA plans to evaluate dermal occupational exposures.

In describing its approach to evaluating consumer dermal exposures to TCE, EPA states:

> Conceptual model for consumers, dermal exposure: "There is potential for dermal exposures to TCE from consumer uses. As described in section 2.5.1, TCE in direct

[217] U.S. EPA, *TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses* at 72 (June 2014), https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

> contact with skin would be expected to evaporate before significant dermal absorption could occur. Based on TCE's physical chemical properties, including the vapor pressure, water solubility and log KOW, only 0.8% is expected to be absorbed dermally after instantaneous exposure and only 1.6% of TCE is expected to be absorbed dermally after an 8-hour duration of continual deposition. Furthermore, dermal exposures to liquid TCE are expected to be concurrent with inhalation exposures, which reflect the preponderance of overall exposure from a particular use or activity for most consumer exposure scenarios. Therefore, non-occluded dermal exposure scenarios will not be analyzed for systemic effects for users. However, dermal sensitization will still be considered for these scenarios. There may also be certain scenarios with a higher dermal exposure potential, for example, an occluded scenario where liquid TCE is not able to evaporate readily such as a user holding a rag soaked with liquid TCE against their palm during a cleaning activity. Therefore, occluded dermal exposure scenarios will be evaluated for both systemic effects and sensitization and non-occluded scenarios will only be evaluated for sensitization. In scenarios involving exposure to TCE vapor, inhalation and dermal exposures would also be concurrent, with predominate exposure from inhalation. A dermal to inhalation uptake ratio of around 0.1% for vapor to skin scenarios is predicted using IHSkinPerm. Therefore, only the inhalation exposures will be analyzed in these cases. (p. 50)

As with dermal occupational exposure, EPA's invoking of the relatively smaller percentage of dermal exposure from TCE when compared to inhalation exposure as a basis for excluding most non-occluded dermal exposure scenarios is arbitrary and not a basis for deeming such exposure to be irrelevant to evaluating TCE risks to consumers.

For consumer exposures, EPA is proposing not to examine non-occluded dermal exposure for systemic effects but to include such exposures for sensitization. This decision is inconsistent with EPA's approach to occupational dermal exposures where it does not plan to examine non-occluded dermal exposures for either skin sensitization or systemic effects.

For both occupational and consumer exposures, EPA should include non-occluded and occluded dermal exposure in its risk evaluation for all relevant endpoints.

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Comments on Pigment Violet 29

73. EPA's decision not to further analyze any condition of use for Pigment Violet 29, based on presumed low hazard and exposure potential, is unsupported.

Unlike most of the other problem formulations, EPA does not intend to exclude any conditions of use from the risk evaluation, but EPA also states that it does not plan to conduct further analysis on any condition of use of Pigment Violet 29:

> EPA determined as part of problem formulation that it is not necessary to conduct further analysis on the exposure pathways that were identified in the C.I. Pigment Violet 29 scope document (U.S. EPA, 2017c) and that remain in the risk evaluation.****EPA expects to be able to reach conclusions about particular hazards or exposure pathways without extensive evaluation and plans to conduct no further analysis on those hazards or exposure pathways in order to allow EPA to focus the Agency's resources on more extensive or quantitative analyses. As discussed below, EPA preliminarily determined that there are no environmental release and waste pathways for the environment or general populations that EPA plans to further analyze in the risk evaluation.

U.S. EPA, Problem Formulation of the Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline- 1,3,8,10(2H,9H)-tetrone) at pp. 29-30 (May 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0048.

EPA's decision to not further analyze any condition of use for Pigment Violet 29 is not supported based on the limited hazard and exposure information available. More broadly, the problem formulation strongly signals the agency's intent to find that Pigment Violet 29 does not present risks to humans or the environment. Before any risk conclusions can be reached, EPA must obtain significantly more hazard and exposure information on Pigment Violet 29 and integrate such information into a comprehensive evaluation of risk.

EDF recommends that EPA immediately use its information authorities under TSCA to fill information gaps to ensure that the agency has sufficient information to perform a comprehensive and robust risk evaluation of Pigment Violet 29 based on the best available science. As EDF has previously explained, EPA must use its authorities under TSCA §§ 4 and 8 to obtain additional information. EDF incorporates and reiterates those points here as well. EDF Comments on Ten Scopes under the Toxic Substances Control Act pp.11-15, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0069. As particularly relevant here, EPA must use these information authorities because TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

In turn, TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* Here, much additional information is necessary to prepare a risk evaluation for Pigment Violet 29, and EPA must use its authority to fill these information gaps. Congress expressly gave EPA broader testing authority to fill information gaps when preparing risk evaluations, and EPA cannot ignore that authority when it so clearly lacks information necessary for an adequate risk evaluation.

A. The evidence base for Pigment Violet 29 is severely lacking.

In total EPA is relying on three main sources of information for Pigment Violet 29: 1) REACH registration materials, 2) an FDA food additive petition, and 3) estimated data from EPA's EPI Suite program. The majority of the limited information on Pigment Violet 29 comes from the REACH registration materials.

Information available through these sources is captured in the problem formulation appendices C (Physical and Chemical Properties), D (Environmental Fate Studies), E (Environmental Hazard Study Summaries), and F (Human Health Hazard Study Summaries). An overview of the available information is provided in the table below alongside initial concerns raised by the limited information.

Information Type	Number of Studies	Study types	Initial Concerns
Physical and Chemical Properties (Appendix C)[218]	6	OECD 102 (melting point); OECD 104 (vapor pressure); OECD 105 (water solubility); OECD 109 (density); octanol/water coefficient; solubility in n-octanol	
Environmental Fate (Appendix D)[219]	3	OECD 301 F (Biodegradability); OECD 305 (Bioaccumulation);	No reference or explanation provided for hydrolysis half-life value of "stable." All other endpoints estimated from EPI

[218] Appendix C lists six physical and chemical properties. Five of these are included in Table 2-1 (p. 14). The sixth, solubility in n-octanol, is included in text on page 14. The text indicates that the solubility in n-octanol is 0.07 mg/mL whereas Appendix C indicates this value as < 0.07 mg/mL. This discrepancy must be corrected.

[219] Appendix D lists three environmental fate studies (OECD 301F, OECD 305, and OECD 209). The results from 301F are included in Table 2-4 (p. 22). Results from OECD 305 and OECD 209 are not included in Table 2-4. It is not clear why results from OECD 209 are not included in Table 2-4. OECD 305 data are

		OECD 209 (Activated sludge, respiration inhibition test)	Suite which is inappropriate for dyes.
Ecological hazards (Appendix E1 to E3)	3	OECD 201 (Acute aquatic plant toxicity in Duckweed); OECD 202 (Acute freshwater vertebrate study in zebrafish); OECD 203 (acute fresh water invertebrate study in Dapnhia magna)	The ecological evidence base is limited only to studies in aquatic species, and even then only for acute effects. There are no studies of terrestrial organisms. There are no chronic toxicity studies or long-term ecological studies.
Human health hazards - Acute (Appendix F-1)[220]	3	OECD-401 (acute oral single dose in Sprague-Dawley rat); OECD-403 (acute inhalation in Wistar rat); OECD-402 (acute dermal in Sprague-Dawley rat)	Only one acute study is available for each route of exposure. Outdated OECD guideline study for acute oral toxicity.
Human health hazards – Chronic/Repeated dose (Appendix F-2)	0	n/a	No chronic or repeated-dose studies available to examine potential chronic effects.
Human Health Hazard – Reproductive and Developmental Toxicity (Appendix F-3)	1	OECD-421 (Reproductive/developmental screening via gavage in Wistar rats)	

presumably absent from Table 2-4 because the "result" provided in Appendix D is "no bioaccumulation from the 8-weeks bioaccumulation study" as likely gleaned from a study summary (not the full study). Beneath Table 2-4 EPA indicates it has received full studies for OECD 301F and OECD 209 (p. 22). EPA has not appeared to request the full study for OECD 305 and it should. Table 2-4 includes additional environmental fate values (indirect photodegradation, hydrolysis half-life, soil organic carbon:water partition coefficient) all estimated using EPI SUITE.

[220] Appendix F-1 lists three acute toxicity studies (OECD 401, 402, and 403). OECD 402 and OECD 403 are not included in the list of full study reports in EPA's possession (p. 28). EPA must obtain full study reports on these and any other studies it obtains or seeks. On page 28, EPA also lists two non-guideline acute toxicity studies: intraperitoneal study in rats and inhalation toxicity study in rats. These are not reflected in Appendix F-1 and should be.

Skin Irritation and Sensitization	5	OECD-404 (occlusive skin irritation in 2 Weiber Wiener rabbit studies); OECD-405 (eye irritation in 2 rabbit studies); OECD-429 (Skin sensitization LLNA in Male CBA/Ca mouse)	
Genotoxicity and Cancer studies	2	Salmonella typhimrium; Chinese hamster lung fibroblasts	

The evidence base for Pigment Violet 29 hazards is completely inadequate. In fact, it does not even fulfill the OECD Screening Information Data Set (SIDS)[221]—"the minimum amount of data that is required for making an initial hazard assessment of chemicals."[222] Notably absent from the existing information are a repeated-dose or chronic toxicity study. Indeed, there are no chronic studies of Pigment Violet 29 available for ecological or human receptors. EPA does not speak at all to the complete absence of studies evaluating effects resulting from mammalian repeated-dose or chronic exposure studies.

With respect to the absence of data for chronic ecological hazard, EPA notes:

> No studies were identified that characterized the effects of chronic exposure of C.I. Pigment Violet 29 to aquatic species, or the effects to terrestrial species. As a result of uncertainties inherent in extrapolating between acute and chronic exposure regimes and dissimilar environmental receptors, multiple lines of evidence were considered to evaluate the potential for hazards under chronic aquatic exposure conditions and to terrestrial organisms. (p. 27)

However, there is no further discussion in the problem formulation of how EPA plans to consider potential chronic hazards. And what "multiple lines of evidence" EPA is referring to is entirely unclear.

Astoundingly, EPA concludes: "A preliminary review of these study summaries indicates that C.I. Pigment Violet 29 presents a low hazard to human health and environmental receptors." (p. 8) Given the dearth of available information, EPA has certainly not established the low hazard potential of Pigment Violet 29 for ecological or human receptors.

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[221] Organisation for Economic Co-operation and Development, Manual for the Assessment of Chemicals, Chp. 2 Data Gathering (Mar. 2012), http://www.oecd.org/chemicalsafety/testing/49944183.pdf.

[222] CHAPTER 2. DATA GATHERING AND TESTING: SIDS, THE SIDS PLAN AND THE SIDS DOSSIER, http://www.oecd.org/chemicalsafety/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm (last visited Aug. 14, 2018).

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Additionally, with the exception of hydrolysis half-life and biodegradation, all environmental fate endpoints—also required under OECD SIDS—are estimated using EPI Suite, which EPA itself warns is questionable for dyes. Specifically, footnote b in Table 2-4 notes with respect to estimated EPI Suite data: "There are limited pigment data in the EPI Suite training set, therefore values should be used with caution." (p. 22) With respect to hydrolysis half-life, Table 2-4 simply indicates "stable" with no reference or explanation provided. EPA has not established that it is considering the best science available by relying on modeling based on an admittedly limited data set and failing to obtain additional testing information that is reasonably available.

EPA must immediately use its section 4 and 8 information authorities to fill the significant information gaps associated with Pigment Violet 29.

B. Despite obvious information gaps, EPA shockingly chooses to exclude information on analogs from its review.

In describing existing human health studies available on Pigment Violet 29, EPA notes, "Additional study summaries were identified in the ECHA database, but these were found to be conducted on analogous chemicals, so these studies were not requested at this time." (p. 28) EPA's decision to ignore such studies is both irrational and contradictory. Given the extremely limited evidence base for Pigment Violet 29, EPA should have at least sought out already available and potentially relevant information on analogs. Notably, EPA routinely uses data from analogs to review new and existing chemicals.[223] Indeed, EPA references information associated with analogs in the other sections of the problem formulation. For example, EPA references information on an analog, perylene, in a discussion of potential carcinogenicity (p. 29). The agency's decision to exclude information on analogs for Pigment Violet 29 contradicts standard EPA practice and lacks justification, especially for such a data-poor chemical.

Coupled with its lack of any intent to use its TSCA information authorities to fill gaps, EPA is indicating little interest in basing its decisions about this chemical on anything even approaching the best available science. EPA should include relevant information on appropriate analogs in its review of Pigment Violet 29 while simultaneously using its information gathering authorities under TSCA sections 4 and 8.

74. EPA repeatedly cites low exposure potential as a basis for not further analyzing Pigment Violet 29 despite the meager information available on exposure.

EPA states: "Human exposure to C.I. Pigment Violet 29 through occupational (Figure 2-2), consumer (Figure 2-3) or general population (Figure 2-4) activities and uses is possible, but exposures via all routes (oral, dermal, and inhalation) are expected to be low when physical-chemical properties are considered." (p. 24)

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[223] ABOUT USING PREDICTIVE MODELS AND TOOLS TO ASSESS CHEMICALS UNDER TSCA, https://www.epa.gov/tsca-screening-tools/about-using-predictive-models-and-tools-assess-chemicals-under-tsca (last visited Aug. 14, 2018).

Through this single, sweeping statement EPA declares there is no significant exposure to Pigment Violet 29. A deeper review of EPA's support for this statement reveals glaring holes.

A. Occupational exposures during manufacture.

EPA dismisses occupational exposure during manufacture using a series of weak or otherwise problematic arguments discussed below.

EPA states:

> Workers may be exposed via inhalation and dermal routes. However, absorption via inhalation pathways is expected to be low due to low water solubility and dermal absorption is estimated to be negligible for the neat material (because it is a solid of high molecular weight), and poor absorption in solution (based on high molecular weight and low solubility). (p. 24)

This statement ignores entirely the potential for exposure via inhalation to the neat substance, appearing to exclusively focus on inhalation of Pigment Violet 29 in solution. Elsewhere, EPA attempts to address this issue in a discussion of inhalation exposure from industrial and commercial activities and uses:

> Air emissions are typically relevant for volatile and/or dusty materials and since C.I. Pigment Violet 29 is not volatile, the vapor pathway is not relevant.****Also dust handling systems are in place at the manufacturing facility where the dried powder is added or discharged from the equipment and 99.5% of dust is captured in baghouses. The resulting dust and bags are handled as contaminated industrial waste and sent to a licensed waste handler for disposal. Absorption of C.I. Pigment Violet 29 via inhalation is also expected to be negligible based on low water solubility. Inhalation monitoring has shown that exposure was about 0.5 mg/m^3 over a 12-hr work shift (Mott, 2017a). Due to the low potential for inhalation exposure and low potential absorption and low inhalation toxicity, this pathway will not be further analyzed in the risk evaluation. (p. 30)

EPA relies on Pigment Violet 29's low vapor pressure to dismiss one pathway of inhalation exposure (i.e., volatilization) through air emissions. But EPA appears to ignore the concerns raised by Pigment Violet 29's low water solubility. Multiple studies reveal that inhalation of poorly soluble particles can lead to significant health impacts, including chronic pulmonary inflammation, pulmonary fibrosis, and lung

tumors.[224,225,226] EPA's argument that absorption via inhalation is expected to be negligible because of low water solubility is highly problematic and discordant with current scientific understanding.

Unable to rely on physical chemical properties of Pigment Violet 29 to dismiss inhalation exposures to the substance when present as a dusty material, EPA relies on two personal communications about air concentrations and industrial hygiene controls (Mott, 2017a and Mott, 2017b). EPA relies on these personal communications, from one employee of what EPA states is the only U.S. manufacturer of the chemical, to dismiss all concern for occupational exposure. The content of these personal communications is not even publicly available.[227] Nor is there any mention made of the inherent conflict of interest that this personal communicator has in minimizing any concerns over exposure to the chemical his company makes. Yet EPA relies on this sole source to draw sweeping conclusions that all potential workplace exposures are negligible.

EPA is relying entirely on this personal communication (Mott 2017a) as the basis to assume the air concentration of Pigment Violet 29 in manufacturing facilities is 0.5 mg/m^3 and then uses this value to dismiss any concern about occupational exposures to the neat substance via inhalation. It is entirely unclear how this value was derived and whether it represents the best available science. It is worth noting the uncertainty around this value the first time EPA cites it: "The information indicates a workplace air concentration of 0.5 mg/m^3 over a 12-hour shift (Mott, 2017a). *It is not clear if the monitoring result was for C.I. Pigment Violet 29 or for total dust.*" (p. 24, emphasis added) (When the same data are cited six pages later in the problem formulation, EPA drops this caveat entirely; see p. 30.)

EPA also relies on Mott, 2017a for a flimsy defense for why oral and dermal exposures are not expected during manufacture of Pigment Violet 29.

With regard to oral exposure EPA states:

> Oral contact is not a relevant pathway for workers manufacturing C.I. Pigment Violet 29 since eating is not allowed in the production and laboratory work areas and proper personal

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[224] Eileen D. Kuempel, et al., *Human and Animal Evidence Supports Lower Occupational Exposure Limits for Poorly-Soluble Respirable Particles*, 58:9 THE ANNALS OF OCCUPATIONAL HYGIENE 1205 (Nov. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618468/.

[225] Oberdörster G., *Lung particle overload: implications for occupational exposures to particles*, 21:1 REGULATORY TOXICOLOGY & PHARMACOLOGY 123 (Feb. 1995), https://www.ncbi.nlm.nih.gov/pubmed/7784625.

[226] Mike Jayjock, *Inhaled Insoluble Particles are more than a Nuisance*, HUMAN HEALTH RISK ASSESSMENT TO CHEMICALS (June 22, 2014), http://jayjock-associates.blogspot.com/2014/06/inhaled-insoluble-particles-are-more.html.

[227] EDF's search of the Pigment Violet 29 problem formulation docket for Mott 2017a and Mott 2017b yielded nothing; the only related item is a document noting that a February 13, 2017 meeting was held between EPA and representatives of BASF, SOCMA, GL+PC, Avanti, CPMA, and Sun Chemical (Robert Mott). Stakeholder Meeting with CPMA – February 13, 2017, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0026.

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protective equipment (PPE) are expected to be worn at the sole C.I. Pigment Violet 29 US manufacturing facility (Mott, 2017a)." (p. 25)

This assumes oral exposure would only occur if workers eat contaminated food, as well as 100% compliance with the no-eating policy. No information is provided on the type of PPE used and whether it could be sufficiently protective; EPA simply asserts that the equipment and its use are "proper." EPA needs to more closely assess the potential for oral exposure via pathways beyond ingestion of contaminated food, and perform baseline risk evaluation of Pigment Violet 29 in the absence of PPE. *See* Section 13.

With regard to dermal exposure EPA states: "The domestic manufacturer of C.I. Pigment Violet 29 also indicates that workers in production and laboratory areas at their facility wear long sleeves and gloves to prevent dermal exposure (Mott, 2017a)." Again, EPA must perform baseline risk evaluation of Pigment Violet 29 in the absence of PPE. *See* Section 13.

EPA then repeatedly cites a second personal communication from the same individual. The citation provided for Mott, 2017b is "Mott, RC. (2017b). Personal communication between Dr. Robert C. Mott (Sun Chemical Corporation) and Alie Muneer (EPA) regarding release of PV29 to Cooper River [Personal Communication]." As noted earlier, and as is the case with Mott 2017a, Mott 2017b is not publicly available.

EPA uses Mott 2017b to support its assertion of low occupational exposure potential during manufacture. Specifically, EPA states that "[D]ust handling systems are in place at the manufacturing facility that capture dust in baghouses. The efficiency rate is greater than 99.5% (Mott, 2017b; Sun Chemical, 2017b)." (p. 22) No document corresponding to "Sun Chemical, 2017b" is included in the docket.

It would seem that EPA is relying entirely on non-public personal communications (Mott 2017b, Sun Chemical, 2017b) as the basis to assume a 99.5% efficiency rate of dust handling systems. It is entirely unclear how this value was derived and whether it represents the best available science. And, as with PPE, EPA must also evaluate risks in the absence of dust-handling engineering controls.

EPA also cites Mott, 2017b to support an assertion of limited releases to the environment. (p. 24)

EPA must immediately make public the details of the Mott 2017a, Mott 2017b, and all other personal communications relevant to the problem formulation in the docket. EPA's reliance on these personal communications to assert limited exposure to workers (or occupational bystanders) and the environment is highly questionable given the lack of information provided, the inappropriateness of evaluating risk only assuming universal use and efficacy of industrial hygiene controls, and admitted uncertainty in the exposure values obtained.

EPA has authority to require the very types of information, e.g., workplace and environmental monitoring data, on which it here has instead relied on unverified information from a potentially

conflicted source that it has not made public. There is no basis for EPA not to use such authorities, and without doing so the agency is failing to rely on the best available science.

On this point, EPA repeatedly claims that there is only one domestic manufacturer of Pigment Violet 29 (*e.g.*, pp. 22, 24, 25). But EPA acknowledges that it is aware of at least one importer of Pigment Violent 29 importing the chemical below the Chemical Data Reporting (CDR) threshold (p.18) and that there could be additional manufacturers or importers operating below the CDR threshold. Using its authorities under TSCA § 8, EPA could obtain a more definitive and complete understanding of whether and where this chemical is manufactured (including imported) in the United States. This information is reasonably available information, and EPA should use its authorities to obtain it.

B. Occupational exposures to downstream processors and users.

With regard to occupational exposures to downstream processors and users under Section 2.3.5.1 EPA states:

> For downstream processors and users, worker exposure via inhalation through particulates that deposit in the upper respiratory tract or oral routes such as incidental ingestion of C.I. Pigment Violet 29 residue on hands is possible. These exposures are possible during handling solids and spray application of coatings containing C.I. Pigment Violet 29. However, oral and inhalation exposures to downstream processors and users are likely to be limited due to the use of PPEs and negligible oral absorption due to low water solubility [(BASF, 2017), (Sun Chemical, 2017d), (CPMA, 2017a)].
>
> EPA reviewed available Safety Data Sheets (SDSs) for C.I. Pigment Violet 29. The SDSs recommend the use of personal protective equipment to minimize exposure, including the use of chemical-resistant protective gloves and safety glasses with side-shields or a face shield if a splashing hazard exists. It also recommends adequate ventilation when handling C.I. Pigment Violet 29 [(BASF, 2017), (Sun Chemical, 2017d), (Sun Chemical, 2017c)]. (p. 25)

This is incredibly weak evidence on which to base an assertion of limited occupational exposure to downstream processors and users. Basically, EPA has assumed PPE is universally used because companies have told EPA it is or recommend it in their SDSs, and EPA then concludes that oral and inhalation exposures are negligible without any data or analysis as to the actual extent of use, the efficacy, etc., of the PPE. There is absolutely no indication that EPA knows even what type of PPE is being used across various downstream users, nor the extent to which PPE is being consistently and appropriately used. More broadly, as discussed above for manufacturing workers, exposures and risks must also be evaluated in the absence of PPE.

C. Consumer exposures.

With regard to consumer exposures to Pigment Violet 29, EPA states:

> Consumer exposures via oral and dermal routes are expected to be limited based on physical-chemical properties of C.I. Pigment Violet 29. Oral ingestion is expected to be negligible due to the low water solubility (see Table 2-1; 0.01 mg/L) and dermal absorption is estimated to be negligible for the neat material (because it is a solid of high molecular weight) and poor absorption in liquid (based on high molecular weight and low solubility). (p.25)

EPA fails to substantiate its assertion that "consumer exposures associated with identified consumer uses are expected to be limited." Further, EPA's use of Pigment Violet 29's physical chemical properties to assert limited dermal permeation is not supported. A *in silico* model designed to predict the skin sensitization of chemicals, CADRE-SS, [228] indicates that Pigment Violet 29 is at the threshold between a moderate and low skin permeation rate. Additionally, there are examples of dermal permeation by chemicals with greater molecular weights than that of Pigment Violet 29.[229] This evidence indicates that dermal permeation may be higher than EPA suggests for Pigment Violet 29, and that EPA inappropriately relies on molecular weight to assert low skin permeability.

As a general matter, skin permeability cannot be used as an indicator of skin sensitization. There is no direct relationship between skin sensitization and permeability; it is possible for chemicals with low dermal permeability to be skin sensitizers.[230]

Appendix F-4 lists a single skin sensitization study for Pigment Violet 29 with a result simply of "negative." EPA must gather additional information on both dermal permeation and skin sensitization for Pigment Violet 29.

75. EPA must provide access to full studies and other relevant information it has obtained.

EPA indicates that it "has reviewed the robust study summaries of physical/chemical properties, environmental fate, human health hazard and environmental hazard studies in these databases, (summarized in Appendix C- Appendix F) and obtained the full study reports from the data owners for in-depth review." (p. 8) In conformance with TSCA section 14(b)(2), EPA must promptly make these full health and safety studies publicly available immediately. For Pigment Violet 29 this includes the full studies obtained from the ECHA database and the full studies from the FDA Food Additives Petition (FAP) 8B4626 submitted by BASF. These studies do not appear to be included in the EPA dockets associated with Pigment Violet 29.

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[228] Jakub Kostal & Adelina Voutchkova-Kostal, *CADRE-SS, an* in Silico *Tool for Predicting Skin Sensitization Potential Based on Modeling of Molecular Interactions*, 29:1 CHEMICAL RESEARCH IN TOXICOLOGY 58 (Jan. 2016), https://www.ncbi.nlm.nih.gov/pubmed/26650775

[229] Taravat Ghafourian & Shadi Fooladi, *The effect of structural QSAR parameters on skin penetration*, 217:1-2 INTERNATIONAL JOURNAL OF PHARMACEUTICS 1 (Apr. 2001), https://www.ncbi.nlm.nih.gov/pubmed/11292537

[230] Vinicius M. Alves, et al., *Predicting chemically-induced skin reactions. Part II: QSAR models of skin permeability and the relationships between skin permeability and skin sensitization*, 284:2 TOXICOLOGY AND APPLIED PHARMACOLOGY 273 (Apr. 2015), https://www.ncbi.nlm.nih.gov/pubmed/11292537

As a general matter, EPA should obtain and make public full studies of any robust summaries it obtains on chemicals undergoing risk evaluation. It is not sufficient that EPA rely on or provide to the public only robust study summaries.

More broadly, EPA has relied on a substantial amount of industry-provided information, much of which is not publicly available—for example, personal communications, information submitted as part of a food additives petition, and information related to conditions of use apparently gathered during a September 15, 2017, meeting "with several representatives from trade associations." (p. 15) EPA must make all information pertaining to Pigment Violet 29 publicly available in the docket.

76. Environmental release information is insufficient or absent.

EPA repeatedly cites non-public personal communications or EPI Suite-modeled environmental fate information as its basis for ruling out significant environmental release. These sources are of questionable reliability.

EPA again relies on Mott, 2017b for information regarding yield loss during manufacturer (p. 22), dust handling systems efficiency rates (p. 22), and transfer of lost yield to an on-site aboveground biological wastewater treatment system (p. 23) As discussed in Section 74.A, Mott, 2017b is a personal communication that EPA has not made publicly available. Its reliability, and the extent to which it reflects the best available science, is entirely uncertain.

With regard to releases from downstream processors, EPA indicates the following:

> No data pertaining to environmental releases from the twenty downstream industrial facilities that process C.I. Pigment Violet 29 into plastics, paints and coatings were identified. These uses account for 10% of the total production volume. However, CPMA indicated that all of these facilities are subject to EPA and state regulations resulting in limiting releases to air, water, and land of materials to the environment.
>
> Exposure and releases are possible when handling concentrated C.I. Pigment Violet 29 but once it is encapsulated in plastics or paint resins, it is not expected to leach out [21 CFR 178.3297, (BASF, 1998a)]. (p. 23)
>
> AND
>
> As outlined above, physical-chemical and fate properties as well as engineering controls limiting manufacturing (the largest use) releases are expected to result in limited exposure to water and sediment, groundwater via biosolids, landfill leaching, and air. It is estimated that less than one pound per day of C.I. Pigment Violet 29 is being released as the overall total of the National Pollutant Discharge Elimination System (NPDES)-permitted total suspended solids (TSS) discharges from the sole US manufacturer (Mott, 2017b). Because volumes used by downstream users are markedly less than the manufacturer (less than 5% each), it is expected that there will be minimal releases to water and sediment, groundwater via biosolids, landfill leaching, and air.

Where releases do occur, they are expected to result in limited environmental exposures. Specifically, releases of C.I. Pigment Violet 29 to water and sediment could occur during the wastewater treatment process following manufacturing/processing through possible releases of TSS, but these releases and corresponding aquatic exposures are expected to be limited since the high sorption of this chemical to organic matter (Log Koc = 5.0; see Table 2-4) will result in the vast majority of C.I. Pigment Violet 29 being captured as sludge in wastewater treatment facilities which is subsequently disposed of via incineration or landfill disposal. Similarly, the strong sorption properties would be expected to limit exposure via migration to groundwater from C.I. Pigment Violet 29 disposed of in landfills or applied via biosolids. (p. 24)

AND

Although the persistence and tendency to sorb to sediment means that there is the potential for entry into the aquatic food web, available data indicate that the BAF is low so uptake and bioaccumulation is likely to be limited. (p. 23-24)

These excerpts raise a number of concerns:

- EPA readily admits that is has no information on potential releases from downstream users. Instead EPA simply indicates that "CPMA [an industry trade association] indicated that all of these [downstream] facilities are subject to EPA and state regulations resulting in limiting releases to air, water, and land of materials to the environment." (p. 23) EPA doesn't even suggest that it has evaluated whether CPMA's statement is true and further, if so, the extent to which these EPA and state regulations are actually effective in limiting release.
- In a single sentence, EPA indicates that release of Pigment Violet 29 is possible from downstream users and then pivots to the expectation that the substance will not leach out of plastics or paint resins. For neither of these two distinct issues, however, has EPA addressed the need to obtain actual information on release potential during processing.
- EPA relies on Mott, 2017b for its only estimate of release of Pigment Violet 29 though surface discharge. As discussed in Section 74.A, this is a personal communication that is not publicly available and is of questionable reliability.
- EPA relies on environmental fate information (Log Koc) to dismiss aquatic exposures even though, as discussed in Section 73.A, EPA itself indicates that values derived from EPI Suite for dye chemicals should be used with caution. In fact the only environmental fate endpoint derived with measured data is biodegradability; the result of which indicates that Pigment Violet 29 is highly persistent. It is also worth noting that on pages 23-24 EPA indicates that it "did not find any environmental monitoring data (e.g., presence in air, soil, sediment, surface water, or biota)***[nor] biomonitoring data for C.I. Pigment Violet 29 (U.S. EPA, 2017a)." Absence of data does not support a finding of absence of the presence of the chemical in the environment or people.
- EPA relies on environmental fate data (BAF) to support an assertion that entry of Pigment Violet 29 into the aquatic food web will be limited. However, again, EPA is using a BAF derived from EPI Suite that is not reliable for Pigment Violet 29.

77. EPA's review of a residual, naphthalimide, is entirely inadequate and raises major red flags for EPA's treatment of residuals, by-products, and degradation products in future risk evaluations.

In the problem formulation, EPA identifies naphthalimide as a residual of C.I. Pigment Violet 29 as manufactured. The totality of the agency's brief discussion is as follows:

> There are no known by-products or degradation products resulting from the manufacture of C.I. Pigment Violet 29. There is a residual amount of naphthalimide, the starting material used in the fusion, at approximately 1% (Sun Chemical, 2017a). Per robust study summary reports from the ECHA Database, the hazard profile of naphthalimide is low for human health and environmental receptors (ECHA, 2017a). Based on the minimal amount of naphthalimide released from manufacturing and low hazard, EPA will not conduct any further analysis of the naphthalimide residual associated with C.I. Pigment Violet 29 production. (p. 14)

This is an entirely inadequate review of the potential risks associated with naphthalimide, based solely on industry information provided to and not evaluated by ECHA. (See Section 8.B) It certainly does not represent use of best available science. EPA must conduct a much more extensive review of the extent of presence and the potential risks of naphthalimide before reaching a decision to do no further analysis.

The implications of EPA's dismissal of any need to evaluate the naphthalimide residual are significant. EPA has indicated elsewhere that it will not analyze exposures and risks of chemicals only present incidentally (e.g., as an impurity or byproduct) (e.g., see 1,4-dioxane problem formulation at 18) when preparing risk evaluations, suggesting that the appropriate time for such evaluation may be when the parent substance is undergoing risk evaluation.[231] EDF strongly disagrees that EPA can disregard a chemical's presence as an impurity or byproduct when evaluating the chemical, and our concerns are only affirmed and increased by EPA's cursory dismissal of the naphthalimide residual associated with Pigment Violet 29.

78. EPA's discussion of waste handling, treatment and disposal is lacking.

With regard to waste handling, treatment and disposal EPA states:

> Releases of C.I. Pigment Violet 29 from recycling of used papers and plastic articles containing C.I. Pigment Violet 29 is possible. However, due to its low water solubility and high sorption to particulates and biosolids, most C.I. Pigment Violet 29 in aqueous waste streams is expected to be captured in the waste water treatment systems. As a result of the lack of exposure expected to result from this pathway, EPA plans no further analysis of this pathway for workers or occupational non-users in the risk evaluation. Figure 2-3 in the C.I. Pigment Violet 29 Scope Document presented the possible

[231] Problem Formulation of the Risk Evaluation for 1,4-Dioxane at 18, *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064.

> exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of C.I. Pigment Violet 29 (U.S. EPA, 2017c). Due to these releases, pathways and routes of exposure, EPA has concluded no further analysis of these pathways is warranted, as indicated in Figure 2-3. (p. 31)

EPA has not provided any actual evidence that Pigment Violet 29 will be captured in wastewater treatment systems. Information related to wastewater treatment included in the problem formulation appears to be primarily, if not exclusively, from the Mott, 2017b personal communication reference (see for example section 2.3.4 on page 24 and section 2.5.2.2 on page 33). Moreover, the high sorption to particles and biosolids is based on EPI Suite data that is not reliable for Pigment Violet 29.

79. EPA heavily relies on information received by ECHA and FDA to assert low exposure and hazard potential, yet it has not reviewed the corresponding full studies it has apparently has received and they are not publicly available.

EPA states:

> The analysis plan for C.I. Pigment Violet 29 therefore consists of evaluating the study reports received by the Agency to ensure that the studies are scientifically sound and the results are consistent with EPA's preliminary review of the robust summaries in the ECHA database and the FDA Food Additive Petition (FAP) 8B4626 for C.I. Pigment Violet 29 (BASF, 1998a). If the review of these study reports indicates that the results are not scientifically sound or consistent with the robust summary reports, EPA may conduct additional analysis in developing the Draft Risk Evaluation for C.I. Pigment Violet 29, which may include changes to the pathways analyzed. (p. 8)

Remarkably, EPA relies heavily on robust summaries received by ECHA and FDA from industry to conclude in the problem formulation that EPA will not further analyze any Pigment Violet 29 condition of use without even yet having reviewed the corresponding full studies EPA apparently has obtained—studies that are not publicly available. Instead, EPA indicates that it plans to review the full studies, at some point after publishing the problem formulation, to ascertain whether the robust summaries are reliable and consistent with the full studies. If concerns arise, EPA indicates that it "may conduct additional analysis." EPA seems to be indicating that it may also choose to do nothing at all.

The premature decision not to further analyze any condition of use is nothing less than shocking, as is EPA's indication that it may still do nothing even if the full studies call into question the robust study summaries EPA has relied on to develop the problem formulation, and on which it bases its premature decision. These decisions do not reflect a best available science approach to conducting risk evaluations.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.