March 15, 2017

Ms. Sheila Canavan
Mail Code 7405M
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: EPA-HQ-OPPT-2016-0723, EPA-HQ-OPPT-2016-0725, EPA-HQ-OPPT-0732, EPA-HQ-OPPT-2016-0733, EPA-HQ-OPPT-2016-0735, EPA-HQ-OPPT-2016-0736, EPA-HQ-OPPT-0737, EPA-HQ-OPPT-2016-0741, EPA-HQ-OPPT-2016-0742, and EPA-HQ-OPPT-0743

Dear Ms. Canavan:

The American Chemistry Council is pleased to submit these Comments on the U.S. Environmental Protection Agency's Initial 10 Chemicals for Risk Evaluation. ACC supports the reasonable and efficient implementation of the Frank R. Lautenberg Act for the 21st Century (LCSA). ACC believes that as EPA identifies the uses and applications of the first 10 chemicals it has identified for risk evaluation, EPA must use the best available information to identify conditions of use and verify the accuracy of the information it has identified in its Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal documents before proceeding with its risk evaluation scoping exercise. EPA's best source of information on the uses and applications of these substances will likely be chemical manufacturers, processors, and formulators.

ACC encourages EPA to establish ongoing discussions with industry stakeholders throughout the risk evaluation process to ensure it has the most current and relevant information regarding the conditions of use for these chemicals. EPA's risk evaluations should focus on the conditions of use that may present the greatest potential for risks so that the risk evaluations are both protective and practical.

Please let me know if you have any questions regarding these comments. I can be reached at 202-249-6406 or Christina_Franz@americanchemistry.com.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs

AMERICAN CHEMISTRY COUNCIL COMMENTS ON THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S INITIAL 10 CHEMICALS IDENTIFIED FOR RISK EVALUATION

March 15, 2017

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Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to provide comments on EPA's February 14, 2017, Public Meeting on Risk Evaluation Scoping Efforts under TSCA for Ten Chemical Substances (Public Meeting) and the Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal (Preliminary Information) documents. EPA prepared and included these documents in the public docket for each of the initial 10 Work Plan chemicals that EPA identified in December 2016 for risk evaluation under the Toxic Substances Control Act (TSCA), as amended. In particular, EPA is seeking information specifically related to the conditions of use for the 10 chemical substances (i.e., the circumstances as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of).

In the comments that follow, ACC makes the following key points:

- ACC supports reasonable and efficient implementation of the LCSA
- EPA must use the best available information regarding conditions of use
    - EPA must verify the accuracy of the information contained in its Preliminary Information documents
    - EPA must not rely on outdated sources of information without independent verification and substantiation
    - International government and industry organization sources should be consulted
    - EPA must engage stakeholders with the most significant direct knowledge of the conditions of use throughout the risk evaluation process
- EPA should prioritize conditions of use to focus on greatest potential risks so risk evaluations are protective and practical
    - There is no statutory mandate to include all conditions of use in the scope of a risk evaluation under TSCA § 6(b)
    - EPA should exclude certain categories of "uses" during a pre-scope phase prior to scoping, including non-TSCA uses; accidents and misuses; unintentionally added, low exposure, trace quantities; aggregate exposures; and defunct chemical uses
    - EPA should identify conditions of use to be evaluated in its scoping exercise and focus on those that present the greatest potential risk, using the following criteria to set aside those conditions of use that should not move forward from scoping to the more in-depth and refined risk evaluation:
        - Where the margin of exposure in a screening-level risk assessment of a chemical under specific use/exposure scenarios indicates that there is low or no concern
        - Sensitive subpopulations that are not relevant to the conditions of use
        - Where occupational or other exposures are well controlled with current regulatory or risk management measures
        - Certain feedstock uses that are appropriate for early or streamlined review
        - Low or no concern as determined by other competent authorities for same or similar exposures

ACC has long been a strong supporter of and active contributor to TSCA reform efforts, providing concrete proposals and practical solutions to questions debated during the reform process.

ACC is committed to a reasonable and efficient implementation of the LCSA. ACC has become increasingly concerned by some stakeholder comments suggesting that the statute mandates actions not required by the statute (e.g., aggregate risk evaluations) and how EPA should interpret certain provisions in an unwarranted manner that would waste EPA resources (e.g., conditions of use requires EPA to evaluate all conditions of use) in every risk evaluation. These concerns are discussed more fully in the comments below.

I. EPA Must Use the Best Available Information Regarding Conditions of Use

A. EPA Must Verify the Accuracy of the Information Contained in its Preliminary Information Documents

Under the LCSA, EPA must scope the risk evaluations on each of the 10 chemicals by June 19th and then complete those risk evaluations within three years.[1] EPA has indicated it is committed to meeting that deadline. EPA explained at its February 14 Public Meeting that the June deadline to scope these first 10 chemicals is challenging, and, as such, requires it to use information collection or gathering methods that it may not use in the future.[2] Given the tight schedule and the lack of opportunity to comment on draft scoping documents on the initial 10 chemicals, ACC recommends that EPA keep the dockets on the initial 10 substances open to receive information beyond the March 15, 2017, deadline. If the dockets do close, EPA should identify clearly how stakeholders can continue to provide relevant information to the Agency throughout the scoping and risk assessment process.

While tight timeframes and statutory deadlines may require EPA to expedite its information-gathering processes as it identifies the conditions of use for the initial 10 chemicals, these timeframes and deadlines do not justify the use of information that is unreliable, unverified, and unsubstantiated; nor do they obviate the requirement that EPA rely on the best available information. EPA is prudent to solicit comments from manufacturers, processors, distributors, users, and risk management entities of the information contained in the Preliminary Information documents. In the hierarchy of credible sources, industry stakeholders are the most accurate and reliable sources of information EPA has available to it to identify and verify conditions of use.

ACC strongly cautions EPA against relying on unsubstantiated anecdotal information derived from internet sources. Even less reliable are random postings on sites by unknown and unverified persons purporting to use these substances in ways other than as intended. In most cases, no one verifies or approves the content contained in customer reviews/comments on retail websites before they are made public. Information on public websites varies dramatically in reliability and quality and EPA should acknowledge that there is a hierarchy of credible sources when it comes to information on chemical use. EPA should rely only on information sources that are

[1] Frank R. Lautenberg Chemical Safety Act for the 21st Century (LCSA) at 6(b)(2)(A).

[2] Although EPA did not elaborate at the Public Meeting regarding the other information gathering methods it would use beyond this initial 10, ACC presumes EPA will use its TSCA authorities under sections 4 and 8.

credible and verifiable, even if such information is presented after the comment deadline. EPA should not utilize unreliable, unauthenticated information to develop scientific and technical information as a basis for regulatory decision making. Use information provided by industry to a chemical regulatory authority is far more reliable than anonymous postings on websites by unknown sources of dubious accuracy and lacking credibility and unverified sites and sources.[3]

ACC conducted a random review of the information contained in EPA's Preliminary Information documents and identified a number of errors, which are identified in a spreadsheet attached as Appendix A. ACC urges EPA to ensure the accuracy of its data and information through quality control and quality assurance practices. In addition, some ACC members provided information on several specific chemicals that are among the Initial 10 and that information is contained in Appendix B.

B. EPA Must not Rely on Outdated Sources of Information without Independent Verification and Substantiation

EPA has identified the U.S. Department of Health & Human Services *Household Products Database* as a source for identifying conditions of use for the initial 10 chemicals. While the *Household Products Database* is reported to have been updated at some point in the past year or so, these updates were not sufficiently comprehensive. As a result, the EPA cannot assume the database is accurate. ACC believes that the *Household Products Database* and any other sources not regularly kept current should be consulted *only* as a starting point in EPA's inquiry to identify possible uses.

C. International Government and Industry Organization Sources Should be Consulted

ACC believes there are other sources of chemical use information that may prove significantly more reliable, such as the European Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) database identifying chemical use registrations.[4] Any European use would need to be confirmed as a current use in the United States before it could be relied upon, but EPA should generally consider this information credible.

Another resource for EPA to consult is the Downstream Users of Chemicals Co-ordination Group (DUCC).[5] The DUCC is a platform of European associations representing downstream industries ranging from cosmetics and detergents to aerosols, paints, inks, adhesives, imaging and printing chemicals, construction chemicals, fragrances, and chemical distribution.[6] Since its

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[3] See, e.g., https://www.theguardian.com/technology/2016/dec/04/google-democracy-truth-internet-search-facebook; https://www.theguardian.com/technology/2016/dec/16/google-autocomplete-rightwing-bias-algorithm-political-propaganda; https://www.google.com/insidesearch/howsearchworks/thestory/; https://plato.stanford.edu/entries/ethics-search/

[4] Canada would be an excellent resource as well, although we are not aware that Canada has chemical use information as readily available publicly.

[5] http://www.ducc.eu/Home.aspx

[6] DUCC members include The International Association for Soaps, Detergents and Maintenance Products, the European Council of the Paint, Printing Ink and Artists' Colours Industry, Cosmetics Europe, the European Crop Protection Association, the European Federation for Construction Chemicals, European Aerosol Federation,

creation in 2001, DUCC has been recognized by the EU authorities and other stakeholders as the "common voice" for many users of chemicals. The DUCC has enabled communication both downstream, from registrants to downstream users (DUs) through Exposure Scenarios (ESs), and upstream, from DUs to registrants through the use of sector use maps.

DUs know best how products are manufactured, formulated, and used by their end-users and, therefore, which conditions need to be assessed by registrants in their registration dossiers. Examples of tools developed in this effort are: 1) the Specific Environmental Release Categories (SPERCs), which are factsheets providing information on the operational conditions, risk management measures, and the corresponding release factors to water, air, soil, and waste; and 2) the Specific Consumer Exposure Determinants (SCEDs), which are factsheets developed by some sector organizations to document transparently the way consumers use their products. The SPERCs can be used by registrants to perform an environmental exposure assessment and the SCEDs are expressed in a form that can be used in commonly applied exposure assessment tools.

The DUCC may serve not only as a source of information on current uses of chemicals for EPA, but also as a potential model for U.S. downstream processors and users of chemicals to organize themselves in an efficient and productive manner to streamline communications with EPA regarding the conditions of use of chemicals beyond these initial 10 for risk evaluations under the LCSA.

D. EPA Must Engage Stakeholders with the Most Significant Direct Knowledge of the Conditions of Use throughout the Risk Evaluation Process

EPA has acknowledged publicly that its experience conducting its first risk assessments under its TSCA Work Plan program in 2012 would have benefitted significantly from engagement with industry stakeholders well in advance of conducting the risk assessments.[7] This recognition is, in part, responsible for EPA's modification in 2014 of its risk assessment procedures to include public comment on its Problem Formulation documents (akin to the LCSA scoping documents) before moving ahead with its risk assessments.

In fact, regular discussion with chemical manufacturers, processors, and distributors of the chemicals undergoing evaluation is critical for EPA to gain an accurate understanding of the conditions of use under evaluation. Acquiring the level of understanding necessary to evaluate a chemical accurately under its conditions of use is not a single event. It is certain to require iterative discussion between EPA's risk evaluation teams and industry stakeholders possessing the most relevant knowledge about the particular conditions of use that are included in EPA's scoping process and its subsequent risk evaluation. In the hierarchy of credible sources on the conditions of use, industry stakeholders are in the top tier. EPA may want to consider creating a user group for each chemical evaluated to ensure its understanding of the conditions of use are current and valid.

European Association of Chemical Distributors, the Association of European Adhesive & Sealant Industry, Imaging and Printing Association e.V., and International Fragrance Association.

[7] See, e.g., 80 FR 23545 (April 28, 2015).

II. Prioritize Conditions of Use to Focus on Greatest Potential Risks so Risk Evaluations are Protective and Practical

It is very important that the first 10 (and subsequent) risk evaluations be successful, effective, and completed within the statutory deadline. Therefore, it is important that EPA prioritize the conditions of use it will evaluate and focus on those that present the greatest potential risk to human health and/or the environment.

At the Public Meeting, some stakeholders claimed that EPA is required to examine all conditions of use, all vulnerable subpopulations, aggregate risks, continuing exposures to legacy contamination, intended and actual uses (even misuses), and incidental and cumulative exposures.[8] It was suggested that EPA should not consider current risk management measures in place (e.g., current warning labels, the use of personal protective equipment (PPE)) based on a blanket assertion that people often do not follow risk management requirements or read labels. Notably, EPA is expected to accomplish all these tasks within the statutory deadlines. ACC is concerned that such a comprehensive approach is neither legally required nor practical.

A. <u>There is No Statutory Mandate to Include All Conditions of Use in the Scope of a Risk Evaluation Under TSCA § 6(b)</u>

The LCSA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under certain evaluated circumstances called "conditions of use."[9] Specifically, the statute requires EPA to complete a scoping process before it undertakes a risk evaluation to establish which uses will be evaluated and why. Congress intended the scoping phase as the opportunity to focus the risk evaluation; otherwise, Congress would not have included the step. Indeed, Congress would have stated clearly and unequivocally that EPA must conduct a full risk evaluation on ALL conditions of use identified by EPA, without a scoping or focusing phase, if that is what it intended.

The LCSA includes a definition of condition of use to TSCA: "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[10] Nowhere in the statute does Congress modify "conditions of use" with "all." The plain meaning of the statute does not require EPA to include "all" conditions of use in a risk evaluation. EPA clearly has the discretion to scope the risk evaluation to include and exclude certain uses. EPA cannot apply this discretion in such a manner as to undermine the operation of the entire statute or to make it impossible for EPA to meet its statutory objectives of timeliness and quality. Unquestionably, including all conditions of use in its risk evaluations would have a significant impact on EPA's ability to meet the statutory mandate.

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[8] The LCSA does not require EPA to consider cumulative exposure anywhere in the risk evaluation process. Currently there is not a generally-acceptable approach to inform the scientific methods, inputs, and tools to evaluate cumulative risk. While EPA and other agencies continue to work on guidance in this area, even scientifically robust draft frameworks for the evaluating cumulative exposure risks are non-existent.

[9] §6 (b)(4)(A).

[10] §3(4).

B. EPA Should Exclude Certain Categories of "Uses" During a Pre-Scope Phase Prior to Scoping

Once EPA has received feedback on the conditions of use identified in its Preliminary Information documents, verified the information, and revised the list of conditions of use contained within the Preliminary Information documents, EPA should undertake a pre-scope exercise to exclude from further consideration certain categories of "uses" or exposure scenarios that EPA concludes will not move forward to the scoping phase.[11] The categories of uses and exposure scenarios that should not receive further consideration by EPA under TSCA include the following:

1. **Non-TSCA Uses**

   When TSCA was passed, there was a considerable network of statutes already in place regulating the safety of chemicals. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulates the safety of pesticides; the Consumer Product Safety Act (CPSA), the Consumer Product Safety Improvement Act (CPSIA); the Federal Hazardous Substances Act (FHSA) regulate the safety of consumer products; the Federal Food, Drug and Cosmetics Act (FFDCA) regulates the safety of chemicals in foods, drugs, cosmetics, and medical devices; the Department of Transportation (DOT) regulates the transportation of chemicals under the Hazardous Materials Transportation Act (HMTA); and the Occupational Safety and Health Act (OSHA) regulates chemicals in the workplace, among other laws. TSCA was not intended to replace or supplant these statutes and their regulatory schemes; nor was EPA intended to be the oversight regulator with authority over other agencies.

   Chemicals with uses regulated by other federal laws and agencies are often referred to as "non-TSCA" uses. For non-TSCA uses of chemicals, such as food additives, Congress has authorized and funded another statutory program administered by another regulatory agency to address those conditions of use. For example, in the case of food additives, the Food and Drug Administration reviews the safety of food additives against a rigorous, risk-based safety standard. EPA should not include these and other "non-TSCA uses" as part of the conditions of use to be considered in a TSCA risk evaluation.

2. **Accidents and Misuses:**

   The statutory definition of "conditions of use" is "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."[12] Including the phrase "…intended, known, or reasonably foreseen" is a limitation on the conditions of use that may be identified and included in the scope of a risk evaluation. If a particular use is not intended, known, or reasonably foreseen, it is not a statutory "condition of use" and cannot be included within the scope of a risk evaluation.

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[11] During the Public Meeting, EPA also expressed interest in information from stakeholders on any alternatives that exist for any of these initial 10 substances. The existence of alternatives is not relevant to whether these initial 10 substances present unreasonable risks in their conditions of use and should not be sought during the risk evaluation. The only time alternatives are relevant is if and when a risk evaluation concludes that a condition of use presents an unreasonable risk and risk management measures are necessary to mitigate the risk.

[12] TSCA §3(4).

The term "intended" is generally well understood to mean intended by the manufacturer and processors. Intention can be demonstrated through an express statement (e.g., a statement to that effect in a premanufacture notice (PMN)) or implied evidence (e.g., marketing materials that imply a potential application for the chemical). The term "known" is often considered a backstop for the term "intended" in that manufacturers may not "intend" or support a particular downstream use for a chemical, but may have actual or imputed knowledge that a chemical is being used in that application.

The definition of "conditions of use" also includes the term "reasonably foreseen." The concept of reasonable foreseeability is also well understood in tort law.[13] Foreseeability is "the determinant for the *limits* of duty under a conventional risk analysis" [emphasis added].[14] Foreseeability is modified by "reasonably," which makes clear that not every conceivable or speculative use is included. Product misuses and illegal uses, and manufacturing that disregards legal and industrial hygiene requirements, are not "reasonable" and therefore are not included in "reasonably foreseen."

The product liability law doctrine of "foreseeable misuse" is described in Sections 2(b) and 2(c) of the Restatement of Torts.[15] The purpose of this doctrine is to allow injured parties an avenue to obtain relief where they have misused a product in a way that the manufacturer either should have or did anticipate. Generally speaking, foreseeable misuses do not include circumstances where the hazard was clear and a person disregarded it anyway (e.g., decided to juggle knives knowing that they are sharp and not intended for juggling); where instructions and warnings are clear and a person disregards them anyway; where a person has the skills, knowledge and training to act prudently and fails to do so.

In short, "reasonable foreseeability" is the boundary where third-party liability ends. Courts seek to predict reasonable and expected conduct under the specific factual circumstances presented. Here, EPA is tasked with making much the same analysis. Reasonably foreseen conduct does not include illegal uses or activities (e.g., should assume that workers adhere to their legal obligations), product misuses, failure to read warning labels, and illegal and improper disposal.[16] Such conditions of use are properly outside the scope of a risk evaluation.

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[13] See, e.g., ANNEXURET, The Concept of Limited Liability, Existing Law and Rationale (Australia), referring to the limiting tests of reasonable foreseeability and proximity, available at http://www.dpc.nsw.gov.au/__data/assets/pdf_file/0012/11406/T.pdf

[14] Tyrus V. Dahl Jr., Strict Products Liability: The Irrelevance of Foreseeability and Related Negligence Concepts, 14 Tulsa L. J. 338, 343 (1978).

[15] Restatement (Third) of Torts: Prod. Liab. §§ 2(b), 2(c) (1998).

[16] Some stakeholders at the Public Meeting asserted that people do not read or follow labelling instructions and therefore EPA should not consider the existence of warning and instruction labels for conditions of use when it conducts its risk evaluations. This unsubstantiated and blanket assertion is without merit. The converse is true: EPA must consider warnings, instructions, and labeling as part of the conditions of use (whether worker exposure or consumer use). For EPA to consider whether particular instructions are disregarded, it must make a fact and *conditions of use* specific inquiry, and have substantial evidence to support such a conclusion. The Agency cannot assume conditions of use based on factually disconnected, general scientific reviews. For that matter, perception and behavioral studies would need to be based on best available science.

Including every conceivable use scenario, regardless of substantiation, likelihood, severity, etc. where someone might misuse or be injured by a chemical substance cannot reasonably be the subject of a TSCA risk evaluation. Indeed, such an approach would ignore the "reasonably" in "reasonably foreseen," which is not consistent with congressional intent that EPA focus on completing risk evaluations in a timely and efficient manner. This approach would result in risk evaluations that are impractical – evaluations that focus on chasing minor, abstract, and even merely hypothetical risks. It undermines the point of scoping the risk evaluation to achieve this purpose, and it is inconsistent with congressional expectations (as described in the Senate Environment and Public Works Committee Report on the approved bill, S. 697, leading up to the LCSA compromise) that misuses are outside the scope of risk evaluations:

> ''Conditions of Use'' is a term used throughout S. 697 to describe the context in which EPA will apply the safety standard in safety assessments and determinations. The term means the ''intended, known, or reasonably foreseeable circumstances'' under which a chemical substance is manufactured, processed, distributed in commerce, used or disposed of. The term is not intended to include ''intentional misuse'' of chemicals."[17]

3. **<u>Exclude Unintentionally Added, Low Exposure, or Trace Quantities</u>:**
There are circumstances where chemicals are present in materials and products in small or trace amounts, but are not intentionally added. The mere presence of trace quantities of unintended impurities or process residues in certain materials and products does not constitute a "condition of use." Although the presence of a chemical byproduct, impurity, or residue might initially be viewed by EPA as "reasonably foreseen," its presence is not due to the "conditions of use" of the chemical, but rather it is present as a result or consequence of the use of some other substance (e.g., a precursor) in the manufacturing process. The presence of substances that do not contribute to the performance of the finished consumer product or impart an attribute that enhances the product user's experience should be beyond the scope of the risk evaluation. Excluding trace chemicals from the scope of a risk evaluation is also consistent with other TSCA regulations that do not require the reporting of the presence of an impurity, byproduct, or process residue.

4. **<u>Exclude Aggregate Exposure from Scoping</u>:**
Some stakeholders at the Public Meeting claimed that EPA is required under the LCSA to consider aggregate exposures when conducting risk evaluations. The LCSA, however, does not support this view. There is only one reference to aggregate risk evaluation in the LCSA and it states that EPA shall "describe *whether* aggregate…exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" (emphasis added).

ACC does not believe that EPA may or should go beyond the intended scope of what should properly be considered in a risk evaluation under the LCSA. For instance, TSCA does not provide EPA authority over pesticides, foods, food additives, drugs, cosmetics, tobacco products, etc. As such, it would be inappropriate for consideration of aggregate exposure to

[17] EPW Report, June 18, 2015.

lead to a risk evaluation of non-TSCA uses and applications. If EPA felt it necessary to consider all those exposures in addition to exposures under TSCA, EPA would by necessity need to enlist all the other federal agencies with authority and expertise over those non-TSCA uses to conduct an inter-agency aggregate risk evaluation.[18]

ACC believes that aggregate exposures should only be considered in a risk evaluation on a case-by-case basis for specific substances when indicated by specific criteria, e.g., low margin of exposure. EPA should commit to including relevant authorities and experts when there are such cases. We expect the need to conduct these consultations to be the exception rather than norm.

5. **Exclude Defunct Chemical Uses:**
Consistent with congressional intent, EPA should exclude chemical uses and the limited exposures that may be presented from chemicals that are no longer in commerce and/or undergoing a phase-out (voluntary or otherwise). Indeed, the LCSA as a whole creates a funnel that pushes EPA to distinguish chemicals that are active in commerce from those that are inactive (Inventory Reset); to prioritize active substances as low- or high-priority (further narrowing); and to scope the conditions of use that will be subject to the risk evaluation (narrowing yet again). EPA has a directive from Congress to narrow, not expand, the universe of all potential exposures to those that are most significant in terms of risk – current conditions of use – not obsolete ones.[19]

C. EPA Should Identify Conditions of Use to be Evaluated in its Scoping Exercise and Focus on those that Present the Greatest Potential Risk[20]

Section 6 requires EPA to prepare a scope for each risk evaluation. Each risk evaluation is then limited to its scope. For this requirement to make any sense, it necessarily must mean that Congress intended EPA to have the tools it needs to focus the scope of risk evaluations on certain conditions of use and not others. Otherwise, Congress would not have included a scoping step in the first place. Section 6(b)(4)(D) provides, in part:

> SCOPE. —The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider ....

Notably, this provision requires scoping of those conditions EPA "expects to consider," a clause that would be unnecessary if EPA were directed to simply include "all" conditions of use in a risk evaluation.[21]

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[18] TSCA §9.

[19] Earlier versions of the LCSA would have allowed EPA to prioritize inactive (e.g., legacy chemicals), but that suggestion was not included in the enacted LCSA. EPA could also use its significant new use authority to issue significant new use rules (SNURs) to provide a control over obsolete uses for which EPA has concerns.

[20] The results of EPA's pre-scope and scoping exercise should be made public when EPA releases its scoping document for public comment.

To focus the scope of risk evaluations as it considers the conditions of use, EPA should rely on its existing risk assessment guidance.[22] This guidance directs the agency to define the scope of each risk assessment, including what is to be covered and what is not:

> In general, planning and scoping provides the opportunity for the risk manager(s), risk assessor(s) and others interested in the process to consider the context in which the risk assessment is being conducted and the purpose(s) for which the results will be used. The risk assessment team, in collaboration with the risk managers, also defines what is expected to be covered, considering limitations or constraints (e.g., tools, resources, timing). In this stage, risk assessors and risk managers discuss the risk management options to be considered along with any aspects of the risk assessment design for which there are policy implications. Planning and scoping results in a common understanding of the boundaries for the risk assessment and the process for how it will be conducted. This step also recognizes the potential for the analysis plan to involve qualitative, as well as quantitative aspects.[23]

The LCSA directs EPA to move efficiently through risk evaluations, and to base them on the best available science. We strongly suggest that EPA use the following criteria to set aside those conditions of use that do not belong in the process moving forward from the scoping stage to the more in-depth and refined risk evaluation:

1. **Screening-Level Assessment MOE No Concern**

In its scoping exercise, EPA should conduct a screening-level assessment on conditions of use that are not excluded from further assessment based on other criteria. The schematic below (Figure 1), demonstrates how EPA should use the margin of exposure (MOE) derived from a screening-level risk assessment as a trigger to determine when further evaluation is necessary, i.e., conducting a more refined risk assessment to more accurately quantify potential risks. Depending upon the conservative nature of the screening assessment, it may be appropriate to use a higher or lower MOE (reflected below as "X") to trigger further evaluation. As illustrated below, additional risk management actions should only be considered after a refined assessment has concluded an unreasonable risk exists. EPA should adopt this approach and conduct further refined assessments for conditions of use where the MOE derived from the screening-level assessment falls below the benchmark value of X. Those conditions of use that are above the

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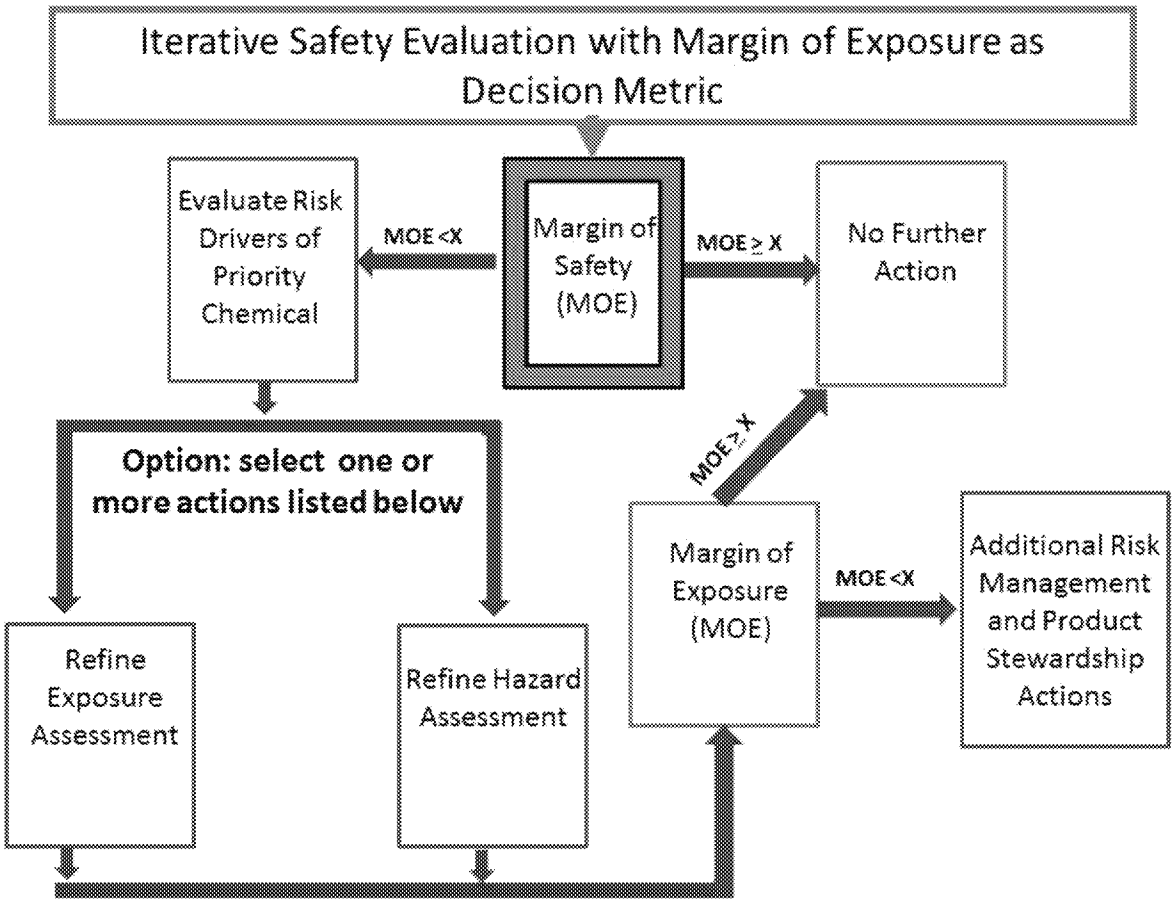
[21] Before LCSA was enacted, EPA published multiple problem formulations under the TSCA Work Plan. EPA explained that its problem formulation documents served as a means to explain the scope of a risk assessment: "A problem formulation and initial assessment document will serve to inform the public and other interested stakeholders about EPA's initial scoping of findings and plan for any further risk assessment. Problem formulation and initial assessment is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined." Many of those completed problem formulations considered limited conditions of use. Like other aspects of the TSCA Work Plan, Congress contemplated that problem formulations from the TSCA Work Plan would serve as the model for EPA actions under the amended TSCA. In this case, the problem formulations were to be the model for the scoping exercise under section 6(b)(4)(D). This is a strong indication that Congress authorized EPA to determine which conditions of use it would evaluate in a risk evaluation by defining the scope appropriately.

[22] Under section 26(p)(2), until EPA completes that guidance, it may continue to use existing guidance.

[23] *Framework for Human Health Risk Assessment to Inform Decision Making,* EPA, April 2014 at 11.

MOE should be determined by EPA not to present an unreasonable risk and this fact should be articulated clearly in the scoping phase.

Figure 1. Using the Margin of Exposure as a Trigger for Further Evaluation.



2. **<u>Only Relevant Sensitive Subpopulations Are Appropriate to Consider in Risk Evaluations</u>**

Some stakeholders maintain that all sensitive subpopulations must be addressed in EPA's risk evaluations. The LCSA requires EPA to consider "potentially exposed or susceptible subpopulations identified *as relevant* to the risk evaluation by the Administrator, under the conditions of use"[24] (emphasis added). Therefore, EPA should only consider those potentially exposed or susceptible subpopulations relevant to the conditions of use that will be the subject of the further-refined risk evaluation.

3. **<u>Occupational Exposures/Exposures Well-Controlled by Current Regulations and Risk Management Measures May Be Appropriate to Exclude</u>**

Although LCSA specifically includes "workers" as a possible category of "potentially exposed or susceptible subpopulation," it does not designate "workers" as a default category. Any

[24] §6(b)(3)(F)(i).

consideration of worker exposure must acknowledge that worker exposures are regulated under the Occupational Safety and Health Act (OSHA). Given that OSHA protocols are designed to regulate risk to worker populations, it should be the unusual case where an unreasonable risk may present to a worker population under conditions of use (e.g., use of controls and personal protective equipment).

Section 9(d) of TSCA requires EPA to consult and coordinate with OSHA "for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements on those subject to [TSCA] and for other purposes." EPA should ensure that this consultation occurs before its risk evaluations are scoped; in cases where worker exposures do not present a significant risk of health impairment under current conditions of use, EPA should decline to include worker populations within the scope of the risk assessment as unduly burdensome and duplicative. This process will reduce the cost, burden, and time required to conduct risk evaluations for the Agency and the regulated community.

Following this consultation, if OSHA agrees that EPA-led risk evaluation considering worker exposures is necessary (and not otherwise duplicative), EPA should describe and make public the process it used to consult with OSHA and the basis for its findings in the scope of the risk evaluation.

4. **Certain Feedstock Uses are Appropriate for Early or Streamlined Review in the Risk Evaluation Process**

There are some feedstock uses where a substance is consumed in the manufacturing process and there is little or no opportunity for exposure. In these cases, any potential exposure is contained within the workplace and is subject to applicable federal regulations. EPA should consider excluding controlled feedstock use that meet specified criteria from further evaluations during the scoping phase.

5. **Low/No Concern as Determined by Other Competent Authorities**

EPA should consider the extent to which other competent authorities have evaluated these 10 substances and their conditions of use. Assuming the exposures are similar, and competent authorities have determined that some or all conditions of use are of low or no concern, EPA should adopt the conclusions of those competent authorities and state clearly that it has determined that the substance does not present an unreasonable risk for the conditions of use impacted. This determination by EPA should be articulated clearly in the scoping document the Agency makes public. If EPA does not accept the conclusion of the competent authority for the conditions of use evaluated, EPA must clearly identify and describe the scientific bases supporting its decision, adhering to the scientific requirements of section 26 of the LCSA.

III. The Risk Evaluations Must be Scientifically Defensible

ACC expects that although these initial 10 substances are undergoing their scoping exercise in advance of EPA finalizing its risk evaluation rule, the actual risk evaluations EPA conducts on the initial 10 will comply with the terms and requirements set forth in the final risk evaluation rule.[25] Section 26 of the LCSA establishes the scientific standards to which EPA must adhere as

it conducts its risk evaluations on the conditions of use identified in the scope of the risk evaluation. ACC is commenting on the specifics of EPA's proposed risk evaluation rule in the context of that rulemaking, but make several key points below regarding the scientific standards required under the LCSA and their application to these initial 10 risk evaluations.

A. EPA Must Use the Best Available Science and Weight of the Scientific Evidence

EPA is required under section 26 of the LCSA to use the best available science and scientific weight of the evidence in its risk evaluations. ACC recommends that EPA define it as follows:

> *Best available science* means information that has been evaluated based on its strengths, limitations, and relevance. EPA relies on the highest quality information. When evaluating best available science, the Agency will consider the peer review of the science; whether the study was conducted in accordance with sound and objective practices; and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science, the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification, and peer review.[26]
>
> *Weight of the evidence* means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.[27]

B. Toxic Release Inventory Information Has Limitations that EPA Must Acknowledge and be Clear How it Intends to Use Should Not Be Used in Risk Evaluations

EPA relied, in part, on available data from the Toxics Release Inventory (TRI) to develop the Preliminary Information documents on manufacturing, processing, distribution, use, and disposal for each of the initial 10 chemicals slated for risk evaluation under the LCSA. Several of these documents include the number of facilities that manufacture, process, or otherwise use the specific chemical and the amount of that chemical released or disposed of on or off site, for each facility.

However, EPA has not described either in the Preliminary Information documents or anywhere else *how* the TRI information on specific chemicals "will inform efforts to develop the scope of the risk evaluation required under section 6(b)(4) of the Toxic Substances Control Act…."[28]

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[26] See 1996 amendments to the Safe Drinking Water Act (SDWA), 42 U.S.C. §300g-1(b)(3)(A,B) and See EPA guidelines available at: https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf.

[27] See Senate Congressional Record, June 7, 2016 at page S3518, available at: https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.

[28] See, Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 1,4 Dioxane, at 2. (available at https://www.epa.gov/sites/production/files/2017-02/documents/14-dioxane.pdf)

TRI release information on chemicals, generally reported in pounds, does not serve as an indicator of potential health impacts posed by chemicals and has significant limitations. As EPA readily acknowledges in its *TRI National Analysis 2015: Releases of Chemicals* that [h]uman health risk resulting from exposure to toxic chemicals are determined by many factors…"[29] These factors include environmental fate, individual exposures, chemical properties, and concentration, none of which are furnished through the TRI. [30] For a chemical to present a risk, there must be a sufficient pathway and exposure, factors that TRI does not address. ACC believes TRI may have a role to play as an element in an overall approach to chemical prioritization, but it is of questionable or little value in risk evaluation, which EPA should acknowledge and explain.

[29] Releases of Chemicals in the 2015 TRI National Analysis, at 32 (available athttps://www.epa.gov/sites/production/files/2017-01/documents/3_tri_na_releases_of_chemicals_ry2015.pdf).
[30] *Id.* at 36.

APPENDIX A

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[3]	Comments
Trichloroethylene								
Electro Blast	Aerosol degreasing	http://procheminc.com/proddocs/ELECTRO%20BLAST%201649%20SDS_1.pdf	Page cannot be found.	Yes	Aerosol safety solvent with blast value	https://procheminc.com/wp-content/uploads/2015/08/ELECTRO-BLAST-1649-SDS.pdf	5/5/2016	Use dossier links to webpage that no longer exists.
ReddyGo	Spot cleaning	http://www.alwilson.com/products/reddygo/ReddyGo%20MSDS.pdf	5/22/2015	Yes	Removes lipstick stains from textiles. For industrial/institutional use only	Matches Use Dossier	Matches Use Dossier	Use dossier cites a different use for the product than what the SDS lists. Company lists a specific industrial application while the Agency cites a more general use.
Carbon Tetrachloride								
Saf-T-Solv™	Carpet Spot Remover	http://www.baneclene.com/msds/saftsolv.pdf	N/A	Yes	Matches Use Dossier	http://blueemporia.aretesw.com/uploads/content3/repos/saftsolv.pdf	2/20/2015	Use dossier directs users to a company publication page, but not a specific SDS. This is problematic because it makes important information harder to find.

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[3]	Comments
FOSTER 60-38	Coating	http://fosterproducts.com/docHandler.aspx?docid=11d0c75d-4540-4795-826e-4b6698483866	Page cannot be found.	N/A	Matches Use Dossier	http://fosterproducts.com/product/foster-60-38/	5/7/2015	Use dossier links to webpage that no longer exists.
LOCTITE® H4720/H4710™ Structural Adhesive Speedbonder Part A	Adhesive	http://www.rshughes.com/wm/p/wm-asis/e769b70dd3388fab28bce0693d18e75cd5c10c10.pdf?uf	10/16/2012	No	Structural adhesive	http://hybris.cms.henkel.com/henkel/msdspdf?matnr=1264965&country=US&language=EN	9/24/2015	Use dossier links to an earlier SDS that is not hosted on the company page. Use dossier also mischaracterizes
Zip Patch Adhesive Spray Activator	Adhesive	http://www.chemical-concepts.com/media/downloads/1275/11500%20msds.pdf	1/15/2011	No	Matches Use Dossier	http://www.devcon.com/prodfiles/pdfs/sku_msds_66.pdf	8/10/2015	Use dossier links to an earlier SDS that is not hosted on the company page.
MA 310 Adhesive	Adhesive	http://www.jamestowndistributors.com/userportal/pdfs/MSDS/Plexus/MSDS_MA-310_301146.pdf	12/15/2009	No	Matches Use Dossier	http://www.actiocms.com/VIEW_MSDS/view_language_kits2.cfm?edit_msds_id=7078&dbname=production&language=1&format=16&CFID=28670312&CFTOKEN=526e5c0328a59dec-9ECB2979-B198-517B-E33559EA4723ECFB	8/14/2015	Use dossier links to an earlier SDS that is not hosted on the company page.
Pigment Violet 29								

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[2]	Comments
Professional Water Color Tube, 14ml, Perylene Violet	Watercolor paint	http://d4of2brjuv1jo.cloudfront.net/assetfiles/3b66a55d-9f40-4008-af19-ab034c5ef82aSAFETY%20DATA%20SHEET-12251-1-1.pdf	10/6/2015	No	Fine art painting	http://colart.s3.amazonaws.com/assetfiles/3b66a55d-9f40-4008-af19-ab034c5ef82aSAFETY%20DATA%20SHEET-12251-1-1.pdf	10/6/2015	Use dossier links to current SDS, but not hosted by the company. Use dossier also lists a different use than the SDS.
Methylene Chloride								
JAD Developer – Aerosol	Liquid developer for use with red and fluorescent penetrants. Usually applied by aerosol or using a compressed airgun to give thin and uniform coverage before being given adequate time to develop.	http://www.johnsonandallen.co.uk/media/files/SDS_JAD-DEVELOPER-AEROSOL_201216.pdf	N/A	Yes, but specific link redirects to a page not found	For use in the Dye Penetrant Inspection Process	http://www.johnsonandallen.co.uk/media/files/SDS_JAD-DEVELOPER-AEROSOL_130217.pdf	2/13/2017	Use dossier links to a page that no longer exists. Use dossier lists a different use than the company SDS.
N-Methylpyrolidone								
KBS RustSeal	Rust preventative	https://www.winzerusa.com/ecat/msds/891_1802_7.pdf	8/19/2014	No	See comments.	Use dossier lists to an SDS not hosted on the company page. Company SDS are available on request.		
3M Sky Restore by Elixair Cured Sealant Remover	Sealant remover	http://www.unionesadhesivas.com/wp-content/uploads/2014/06/MSDS-3M-SkyRestore.pdf	1/31/2014	No	Matches Use Dossier	http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSuUn_zu8l00xmxtGnYtvnv70k17zHvu9lxtD7SSSSSS--	1/13/2014	Use dossier links to an earlier SDS that is not hosted on the company page.

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[2]	Comments
Vara HD Spar Varnish Semi-Gloss VA	Top coat/varnish	http://www.homedepot.com/catalog/pdfImages/c5/c59d2d20-deaa-476a-894e-c7befda3a539.pdf	5/11/2015	No	Topcoat/varathane	http://www.rustoleum.com/MSDS/ENGLISH/266321.pdf	5/14/2015	Use dossier links to an earlier SDS not hosted on the company page.
Dioxane								
Masterlife SRA 20	Concrete Shrinkage-Reducing Admixture	https://ehs.cranesville.com/msds.pdfs/MSDS(M067).pdf	1/20/2015	No	Matches Use Dossier	http://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/AdmixBulkGallon/doc4/BASF/PRD/30606195/.pdf?urn=urn:documentum:ProductBase_EU:09007af88034bb95.pdf	10/24/2016	Use dossier links to an earlier SDS not hosted on the company page.
Free Tag 300000 Count ECL	DNA Amplification	https://www.mesoscale.com/%7E/media/files/msds/msd%20product%20sds/sds-3-3026-020003-msd%20free%20tag%20300000%20ecl%20usa.pdf	2/24/2014	Yes	Matches Use Dossier	https://www.mesoscale.com/~/media/files/msds/msd%20product%20sds/sds-3-3051-020011-sector%20imager%20preventive%20maintenance%20pm%20kit usa.pdf	2/28/2015	Use dossier links to an earlier SDS.
Golden Acrylic Flow Release	Additive for Acrylic Artist Paint	http://www.dick-blick.com/msds/DBH_SDS_006280014.pdf	11/22/2013	No	Matches Use Dossier	http://www.goldenpaints.com/pdf_viewer?file=http://www.goldenpaints.com/admin/image/get_assets/afr-sds-040116.pdf	11/22/2013	Use dossier links to an SDS not hosted by the company page.

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[2]	Comments
Chapco Safe-Set 7	Adhesive	http://www.buildsite.com/pdf/chapco/Safe-Set-7-SDS-1131330.pdf	8/16/2013	No	Matches Use Dossier	http://chapco-adhesive.com/assets/products/msds/SS%207%20SDS.pdf	12/30/2015	Use dossier links to an older SDS not hosted on the company page.
Starfire Purefleet Extreme HD ELC	Anti-freeze/coolant	http://www.supremeoilcompany.com/StarFire_files/Starfire%20Purefleet%20Extreme%20HD%20ELC_SDS.pdf	12/8/2014	No	Matches Use Dossier	http://www.starfire1.com/Documents/Package%20Antifreeze/Starfire%20Purefleet%20Extreme%20HD%20ELC_SDS.pdf	1/8/2016	Use dossier links to an older SDS not hosted on the company page.
Adflex Q 100 F	Polypropylene Copolymer	https://www.pharosproject.net/uploads/files/sources/49/1406049943.pdf	3/29/2013	No	Matches Use Dossier	http://msds.lyondelli.com/ehswww/lyondell/e/result/report.jsp?P_LANGU=E&P_SYS=2&P_SSN=1799&P_REP=00000000000000000006&P_RES=515	4/23/2015	Use dossier links to an older SDS not hosted on the company page.
Masterkure CC 1315	Sealant	http://www.bondedmaterials.net/assets/sds/basf_kure_1315.pdf	5/12/2016	No	Matches Use Dossier	http://worldaccount.basf.com/wa/msds/showpdf/36574200_15132751_-44	5/12/2016	Use dossier links to an older SDS not hosted on the company page.
Bromopropane								
Triagen	Industrial metal cleaner	http://www.ecolink.com/wp-content/uploads/triagen-a_msds		No	Matches Use Dossier	https://ecolink.com/wp-content/uploads/triagen-a_msds.pdf	6/6/2007	Use dossier links to an older SDS.

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[3]	Comments
76334 High Tech Electronic Cleaner	Not Specified	http://www.chemcas.com/msds_archive/part2/cas/gf_msds/osborn_com---76334.asp	Not specified	No	Electronics Cleaner	http://www.osborn.com/media/msds/pdf/76334.pdf	5/14/2015	Use dossier links to an older SDS not hosted on the company page. Use dossier also states a different use than the company SDS.
Tetrachloroethylene								
Zep-Erase Aero DZ	Vandal mark remover	http://associatedfuelsystems.com/wp-content/uploads/2014/05/Zep-Erase-Aerosol-SDS.pdf	7/10/2015	No	Specialty cleaner and remover	https://sds.zepinc.com/ehswww/zep/result/direct_link.jsp?P_LANGU=E&P_SYS=2&P_SSN=11337&C001=MSDS&C002=US&C003=E&C013=031101&C123=SDS*	2/20/2017	Use dossier links to an older SDS not hosted on the company page. Use dossier also states a different use than the company SDS.
Flush Monkey	Solvent	http://encoreindustrial.com/wp-content/uploads/2016/01/Flush-Monkey-2016.pdf	N/A	Yes. See comments.	Not listed	http://encoreindustrial.com/wp-content/uploads/2016/01/I-130-Flush-Monkey-SDS.pdf	3/23/2015	Use dossier links to a product information page with preliminary health and safety information, but not a full SDS.
NAPA Mac's Brake and Brake Parts Cleaner	Automotive - Brake cleaner	http://ebpaving.com/wp-content/uploads/2013/09/Macs-Brake.pdf	11/12/2009	No	Not listed	http://s7d9.scene7.com/is/content/GenuinePartsCompany/716659pdf?PDF	7/31/2015	Use dossier links to an older SDS not hosted on the company page. Use dossier also states a different use than the company SDS.
Non TSCA Uses								

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[1]	Comments
TexasLash Mascara	Mascara	http://www.cargocosmetics.com/texaslash-mascara.html	Date not listed. See Comments.	Yes. See comments.	N/A	N/A	N/A	EPA links to a product page, not an SDS. Company page does not have SDS's. Product listed not under TSCA uses
5 Second Stop Fungus Nail Treatment	Fungus nail treatment	http://www.5secondnail.com/ https://www.amazon.com/Second-Nail-Stop-Fungus-Treatment/dp/B001KYQG3U#customerReviews	Date not listed. See comments.	Yes. See comments.	N/A	N/A	N/A	EPA links to a product page and an online retail page selling the product, not an SDS. Product listed not under TSCA uses.

***Columns A-E represent information from EPA use dossier**
***Columns G-J represent information from manufacturer's SDS found via internet search**
[1]Indicates last revision date found on the SDS accessed by link from EPA

TRADE NAME	Use of the Product	EPA link to references, SDS or other industry info	Link Date[1]	EPA Reference Link to Company's Site?	Company SDS Stated Use of the Product	Company's Site[2]	Link Date2[3]	Comments

[2]Indicates link to SDS from manufacturer's site

[3]Indicates last revision date found on the SDS accessed by link from manufacturer's site

APPENDIX B: Chemical Specific Information on Initial 10

ACC members are responding to the Preliminary Information documents EPA has in each of the dockets on the initial 10 chemicals in various ways: some will submit comments and information individually to the docket; others may provide information in a confidential business information (CBI) submission; and others may submit information through a downstream trade organization if they are a chemical user. Information provided below was received regarding several, but not all of the initial 10 chemicals.

Information Provided by Company X Regarding 1,4-Dioxane

Product Category	Market	Article	Max Concentration (% by weight)
Adhesive/Sealant Removers	Commercial	N	9.00E-06
Adhesives & Sealants	Commercial	N	8.01E-07
Automotive	Commercial	N	2.81E-05
Cleaners	Commercial	N	1.38E-03
Coating Removal	Commercial	N	1.50E-03
Coatings	Commercial	N	3.03E-03
Fire Protection	Commercial	N	6.00E-03
Inks	Commercial	N	5.10E-06
Processing/Application Aid	Commercial	N	1.55E-05
Vehicle Care/Refinishing	Commercial	N	8.00E-05
Adhesive/Sealant Removers	Consumer	N	9.00E-06
Adhesives & Sealants	Consumer	N	1.50E-05
Cleaners	Consumer	N	5.50E-03
Coating Removal	Consumer	N	3.52E-06
Coatings	Consumer	N	2.06E-07
Home Improvement/DIY	Consumer	N	4.97E-03
Inks	Consumer	N	2.00E-02
Vehicle Care/Refinishing	Consumer	N	6.25E-04
Abrasives	Industrial	N	8.80E-05
Adhesives & Sealants	Industrial	N	1.91E-03
Fabric Care	Industrial	N	4.40E-05
Insulation	Industrial	N	2.78E-02
Odor Inhibitor	Industrial	N	6.60E-05
Polymer Additive	Industrial	N	6.50E-05
Cleaners	Commercial	Y	4.29E-06
Commercial Graphics	Commercial	Y	1.60E-05
Electronics Components	Commercial	Y	2.00E-06
Fire Protection	Commercial	Y	1.96E-06

Product Category	Market	Article	Max Concentration (% by weight)
Sorbents	Commercial	Y	2.51E-04
Abrasives	Consumer	Y	2.47E-07
Adhesives & Sealants	Consumer	Y	2.19E-03
Adhesives & Sealants	Industrial	Y	6.00E-03
Automotive	Industrial	Y	1.66E-04

Semi-Finished/Intermediate Materials	Market	Article	Max Concentration (% by weight)
	Industrial	N	5.00E-02
	Industrial	Y	3.70E-03

1,4-dioxane is present in these products as a byproduct and not intentionally added. Given the uncertainty whether 1,4-dioxane is actually present and the wide variety of products and markets reflected in the list above, it is impractical to provide exposure scenarios. In addition, since 1,4-dioxane is present only in trace amounts, exposure and release controls for these materials will be dictated by the intentional ingredients present in higher concentrations.

1,4-dioxane may be present as an unintended trace impurity at concentrations less than 0.003% by weight in a limited number of industrial products with chlorinated ingredients, based on information provided by Company X's raw material suppliers. Company X has not verified by analytical testing that carbon tetrachloride is actually present in those products and regards this concentration as a worst-case assumption.

Information Provided by Company X Regarding Pigment Violet 29:

Pigment Violet 29 is just one component in the overall pigment mixtures purchased as raw materials and appears in low concentrations in the following products:

1. **License plate paints.** These paints are used primarily for the alphanumerics on license plates. The maximum concentration in the ink is 0.23% by weight, although concentrations are typically much lower than this.
2. **Reflective sheeting for traffic signs.** These are article products, and Pigment Violet 29 is present at a maximum concentration of 0.003% by weight.
3. **Commercial graphics films.** These are also article products, and the pigment is compounded into the polymer (typically vinyl) film, so there is little potential for exposure. The maximum concentration is 0.091% by weight.
4. **Automotive striping tapes.** These are article products used in decorative striping on vehicles. Use of this product is decreasing in the U.S. The ink is printed onto the surface of the tape. The maximum concentration is 0.08% by weight.

***Information Provided by Company X Regarding NMP*:**

NMP is a solvent with characteristics that are useful in several industrial processing operations. NMP has a relatively high boiling point, is non-explosive, and is water soluble.

- NMP is used as a coalescing aid in antistatic applications. By allowing particles to coalesce into a more continuous film, NMP enhances antistatic performance by a factor of ten or more compared to solutions without NMP. These processes typically use about 0.5% NMP by weight.

- NMP is used to control the viscosity of urethane coatings in the process of making aqueous dispersions. Typical aqueous urethane dispersions contain between 5 and 15% NMP.

- NMP is capable of dissolving difficult polymers. This makes it ideal for applications such as dissolving polyester oligomers at an elevated temperature and then precipitating them to form polyester beads. High concentrations of NMP may be necessary, depending on the specific application.

In addition to these industrial applications, NMP has characteristics that are useful in certain products. For example, NMP's polarity allows moisture to migrate through sealer formulations to enhance curing. Company X uses NMP in the following product categories:

Product Category	Market	NMP Concentration (% by weight)
Adhesives	Industrial/Commercial	< 5
Automotive Seam Sealers	Commercial	< 1.5
Fire Protection Sealants	Commercial	< 0.5
Protective Clear Coatings	Commercial	< 14

Representative product Safety Data Sheets (SDSs), Technical Data Sheets, and product bulletins are included with these comments. The SDSs describe the safe handling and disposal of these products, and the Technical Data Sheets and product bulletins describe the uses of these products.

Information Provided by Company Y Regarding NMP:

Company Y uses NMP for two different product types. In the first product type, it is used as a solvent in industrial coatings. The products are batch manufactured in an enclosed process. The process vents to a carbon absorber, and workers use full face respirators when handling NMP. It is stored on site in tote bins. Final product is shipped in drums and totes. No waste is generated in the manufacture of the industrial coatings.

In the second product type, the NMP is a solvent for a component which is used to make adhesives. The NMP content in the component is 30-50%. The metering of the component into the blend vessel may be done using open containers. During the compounding process, the blend vessel is closed. The blend vessel may be vented to the atmosphere during off-loading. The NMP bearing component is stored in 55 gallon closed head drums. The final formulations contain <0.1% NMP.

Information Provided by Company X Regarding Methylene Chloride:

Company X utilizes methylene chloride as a solvent in certain nonflammable industrial adhesive products. These products are used to bond a variety of substrates in manufacturing operations where nonflammable or high temperature-resistant adhesives are desired. Methylene chloride content in these products varies between 40 and 90% by weight.

These industrial adhesives are distributed to industrial users in handheld aerosol cans, in larger aerosol cylinders, or in bulk pails or drums. Handheld aerosol cans allow for spray application of adhesives when small amounts are required. Aerosol cylinders require specialized equipment to spray the adhesive, but allow for larger amounts to be used. Bulk adhesive in pails or drums allows users to brush or roll the product onto substrates.

In 2016, Company X processed approximately 690,000 lbs. of methylene chloride into industrial adhesive products. The majority (67%) of this amount was packaged in aerosol cylinders; bulk drums/pails and aerosol cans accounted for 29% and 4% of the total, respectively.

Representative product Safety Data Sheets (SDSs), Technical Data Sheets, and a cylinder spray adhesive user guide are included with these comments. The SDSs describe the safe handling and disposal of these products, and the Technical Data Sheets and cylinder spray adhesive user guide describe the uses of these products.

Information Provided by Company Y Regarding Methylene Chloride

Company Y uses methylene chloride as part of a solvent mixture to manufacture polycarbonate and polycarbonate copolymers in a continuous process. The NAICS code would be 325211. The methylene chloride is introduced in the beginning of the process as a liquid and remains within the totally enclosed process until it is flashed off the product. It is recovered on site, stored, and reintroduced into the process. Methylene chloride is stored in a nitrogen padded storage tank to minimize emissions. The tank is vented to the control device (incinerator). The pellets contain a 0-2 ppm methylene chloride as an unintentional impurity. The pellets are shipped in bags, boxes, and railcars to industrial and commercial companies. There are no consumer applications for the pellets. Finished articles manufactured from the pellets do not contain any methylene chloride.

Information Provided by Company X Regarding Carbon Tetrachloride:

Company X clarifies wishes to clarify that its former product containing carbon tetrachloride was discontinued in 2012, and that carbon tetrachloride was present only as a residual impurity from another chlorinated ingredient.

Company X maintains an Environmental, Health, and Safety Standard that prohibits intentional use of carbon tetrachloride and other highly ozone-depleting chemicals in all its products, raw materials, process aids, and manufacturing processes worldwide. Among Company X's active products, carbon tetrachloride may be present as an unintended trace impurity at concentrations less than 0.003% by weight in a limited number of industrial products with chlorinated ingredients, based on information provided by Company X's raw material suppliers. Company X has not verified by analytical testing that carbon tetrachloride is actually present in those products and regards this concentration as a worst-case assumption.

The vast majority of the methylene chloride is recovered onsite. However, any process and tank vents are treated thru on site incineration. Company Y has state NSR and federal Title V air permits. Any solid waste generated is disposed at a RCRA permitted incinerator or waste recovery.

Company Y complies with the requirements of the OSHA methylene chloride Standard. The process is fully enclosed to minimize emissions. Company Y uses local exhaust ventilation as needed, and all personnel are required to wear personal protective equipment.
Company Y also uses methylene chloride to clean process equipment used in the manufacture of polyurethane foam and polycarbonate sheets.

Information Provided by ACC's Plastics Food Service Packaging Group Regarding HBCD:

(1) HBCD is not added to any polystyrene food service manufactured in the U.S. (comments submitted to EPA Feb 13, 2017). No flame retardants of any kind are used in any food contact applications under the auspices of the U.S. Federal Food and Drug Administration (FDA)
(2) Polymeric foodservice, including polystyrene, is regulated in the U.S. by the Federal Food and Drug Administration. http://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.177&rgn=div5
    a. As noted above in these comments, non-TSCA uses regulated by FDA should not be included in the scope of the risk evaluation.
(3) Nearly all of polystyrene food service manufactured in the U.S. is made from virgin polystyrene resin (some recycled content included in manufacture of polystyrene foam egg cartons). HBCD is not added to virgin, food grade polystyrene.
    a. It is not added because HBCD, a flame retardant, serves no purpose in this application, which does not need to be flame retarded.
    b. It is not added because FDA regulations do not allow it to be added.
    c. FDA regulations also cover polystyrene food service made from recycled polystyrene. These applications must be approved through process that reviews the source of the feedstock and manufacturing processes to ensure polymeric integrity. FDA's only approvals for use of recycled polystyrene to make food grade polystyrene have been from foodservice http://www.accessdata.fda.gov/scripts/fdcc/?set=RecycledPlastics
(4) The vast majority of polystyrene foodservice is manufactured in the U.S., not imported. In fact, [99.9%] of all polystyrene foodservice is manufactured domestically, and only [.1%] is imported. This is to be expected, particularly with expanded polystyrene, which is made by "puffing" the polystyrene to fill it with air. Expanded polystyrene (e.g., coffee cups) is expensive to ship because it takes up so much volume for its weight.
(5) Reference to a Republic of Korea study detecting HBCD in food-related polystyrene products as "Potential Uses Based on Current International Uses of HBCD)
    a. Korean "FDA" requirements, like the U.S., also do not approve the presence of flame retardants in food contact packaging – Korea Food Additives Code (http://www.mfds.go.kr/fa/ebook/egongjeon_intro.jsp) and Korea Food and Agricultural Import Regulations and Standards (https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricu

ltural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Seoul_Korea%20-%20Republic%20of_12-29-2015.pdf)

b. The Korean study appears to be an extraordinary outlier, possibly attributable to contamination of the recycling stream in that country. However, even considering that study, the likelihood of recycled products with an HBCD entering the U.S. is extremely small.
c. According to the Korea Foam-Styrene EPS Recycling Association (KFRA) (http://epsrecycling.org/global-recycling-access/korea) and their sustainability programs (http://epsrecycling.org/sustainability), recycled EPS (expanded polystyrene) is used in both closed-loop and open-loop processes to make a variety of applications from recycled-content foam packaging to durable goods and innovative new building products. These recycled products are used primary in Korea and Asia – it is unlikely the recycled material (even if it allegedly contained some HBCD in Korea) would be imported to US.
d. If EPA has a concern about this isolated study, it should refer the study to FDA for follow up and enforcement.