UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Proposed Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act

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Docket ID EPA-HQ-OPPT-2016-0654

Safer Chemicals Healthy Families (SCHF) submits these comments on the Environmental Protection Agency's (EPA's) proposed rule to establish procedures for chemical risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[1]

SCHF is a coalition of national, state and local organizations committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its partners took a leadership role during the LCFA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

LCSA is the first major overhaul of the 1976 Toxic Substances Control (TSCA) and potentially an important step forward in evaluating and reducing the risks of chemicals to health and the environment in the US. If EPA takes forceful and proactive steps to implement the new law, it can deliver significant health and environmental benefits to the American people. However, if EPA rolls back the protections mandated by Congress, the law's promise will not be realized and the threats that chemical risks now pose to our communities and the environment will continue unchecked while states' authority to protect public health is put at risk. SCHF will engage constructively with EPA and other stakeholders on an implementation path that maximizes the health and environmental protections of the revised TSCA but will hold EPA accountable if it fails to carry out the requirements enacted by Congress.

The following organizations have endorsed and are supporting the SCHF comments

Alaska Community Action on Toxics
Breast Cancer Action
Breast Cancer Prevention Partners
Clean and Healthy New York
Earthjustice
Environmental Health Strategy Center
League of Conservation Voters
Learning Disabilities Association of America
Maryland PIRG (Public Interest Research Group)
Physicians for Social Responsibility
Science and Environmental Health Network
U.S. PIRG (Public Interest Research Group)
WE ACT for Environmental Justice

[1] 82 Federal Register 7562 (January 19, 2017).

SUMMARY OF KEY POINTS

Through LCSA, Congress established a new framework under TSCA section 6(b) for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern identified through the law's prioritization process. This new framework is intended to remedy the weaknesses of the original law by assuring that there is a steady pipeline of risk evaluations on a minimum number of chemicals, that these evaluations address the entire life-cycle of the subject chemicals and that they are completed in accordance with expeditious deadlines.

The law provides that EPA's evaluations must be strictly health-based and must result in a definitive determination whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment, without regard to costs and other non-risk factors. A determination of unreasonable risk then obligates EPA to take action to restrict the chemical under TSCA section 6(a) to the extent necessary to provide protection against the risk, again without regard to cost or other economic considerations. These restrictions must protect all "potentially exposed or susceptible subpopulations" to which the chemical poses an unreasonable risk.

EPA's initial risk evaluations will provide an early test of the effectiveness of the new law. It is therefore critical that they meet Congress' high expectations for public health protection. An important step in that direction, the proposed rule is intended to establish a "process to conduct risk evaluations" as required by TSCA section 6(b)(4)(B). To expedite early implementation, the rule must be finalized by June 22, 2017. Meeting this deadline is critical so that a strong foundation is in place for the initial round of risk evaluations that EPA has initiated under section 6(b)(2)(A) of TSCA.

EPA has correctly determined that the rule should provide a general roadmap for designing and conducting risk evaluations but should not attempt to anticipate and address every aspect of risk assessment methodology that will arise on individual chemicals. As EPA explains:

> "In this proposed rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted. However, EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future."[2]

SCHF supports EPA's decision to keep the rule general and flexible while addressing key issues of policy and procedure and to provide overall direction to its scientists and engineers without prejudging the interpretation and analysis of chemical-specific data. We believe that EPA has accurately captured the four stages of the risk evaluation process – scoping, hazard assessment, exposure assessment and risk characterization – without being overly prescriptive. This approach will encourage the exercise of sound scientific judgment within a transparent overall framework and avoid roadblocks to the timely completion of high-quality evaluations – a central goal of LCSA.

[2] 82 FR at 7567.

We support most aspects of EPA's proposed rule and strongly oppose the changes advocated by industry, which we believe are incompatible with the LCSA and will undermine an efficient and protective risk evaluation process. In several instances, we recommend clarifying the final rule in the preamble.

Our principal recommendations are as follows:

- ✓ *Risk evaluations must address the entire life-cycle and conditions of use of the evaluated chemical. This interpretation is compelled by the broad definition of "conditions of use" in section 3(4) to include all phases of a chemical's life cycle and by the explicit requirement in section 6(b)(4)(A) that a risk evaluation must address "the conditions of use" of the subject chemical.*

- ✓ *EPA must assure that comprehensive information on hazard and exposure is available before a risk evaluation is initiated. This information is best collected or developed through the pre-prioritization process established under EPA's proposed prioritization rule and should be obtained using the expanded data submission authorities in revised TSCA where voluntary submissions are not timely or adequate.*

- ✓ *EPA must apply the definition in TSCA section 3(4) of "conditions of use" broadly and assure that all sources of exposure that may contribute to total risk are considered in its evaluations. For example, where it is "known" or "reasonably foreseen" that a chemical is being used for purposes not identified in labeling or marketing materials or being handled in a manner inconsistent with the practices described in Material Safety Data Sheets (MSDSs), these activities will constitute "conditions of use" as defined in the law. " Similarly, the definition would include the chemical's presence as an impurity or byproduct in waste streams or products, future uses that can be reasonably anticipated, and legacy environmental releases that are contributing to ongoing exposure.*

- ✓ *Aggregate and cumulative exposure assessment must be an essential element of risk evaluations whenever total risk is a function of multiple pathways of exposure or the combined impacts of multiple chemicals of similar toxicity. This approach is consistent with past EPA practice and guidance and inherent in the LCSA emphasis on examining total risk across a chemical's lifecycle and conditions of use and controlling these pathways and uses to the extent necessary to assure that the overall risk is no longer unreasonable.*

- ✓ *EPA lacks authority to "tier" risk evaluations or designate uses as "low risk" at the scoping stage. The scoping process is not intended to make initial judgments about risk and could not realistically perform this function given its limited duration. If uses are dropped from the risk evaluation based on a cursory review at the scoping stage, the risk evaluation itself will be inadequate because critical exposure and hazard information pertaining to these uses will not be considered and their contribution to aggregate exposure and risk will not be taken into account.*

- ✓ *The risk evaluation rule is the wrong vehicle for prescribing the specific elements of scientific decision-making required during risk evaluations. EPA has traditionally issued guidance to elaborate on different aspects of the risk evaluation process. This approach is reaffirmed in LCSA. Guidance is preferable to rulemaking because it can be applied flexibly and revised more readily as scientific understanding changes. To use the risk evaluation rule to codify the complex body of*

risk assessment theory and practice that has evolved over the years is simply not feasible given the 1-year deadline for completing the rule and would run the risk of overturning well-established approaches without thoughtful and careful deliberation. We agree with EPA that terms like "weight-of-the-evidence" and "systematic review" will have evolving and changing meanings and any attempt to define them in EPA's rule would be counterproductive.

- ✓ *Margin of exposure (MOE) approaches have utility in risk evaluations and regulatory decision-making and provide strong support for EPA's determinations of unreasonable risk in its initial section 6(a) rulemakings under TSCA. At the same time, they are often unprotective and improperly fail to take into account low-dose non-cancer effects. Accordingly, EPA's goal should be to use, where practicable, other methods, including probabilistic approaches, which have a stronger science basis and do not understate risk.*

- ✓ *EPA must only accept industry requests for risk evaluations if they cover all conditions of use and contain sufficient information on hazard, use and exposure to support an informed and meaningful evaluation. This approach is well grounded in the LCSA and will protect against industry-initiated risk evaluations that do not further public health and fail to use EPA's limited resources in the public interest. If industry could dictate the scope of requested evaluations, it would be hijacking EPA resources to provide a "clean bill of health" for selected chemical uses while withholding exposure and risk scenarios of greater concern from EPA consideration.*

- ✓ *The term "unreasonable risk" in revised TSCA calls upon EPA to make a combination of policy and scientific judgments that are unique for each chemical and do not warrant codification in EPA's rule. The original version of TSCA did not include a definition of unreasonable risk. While Congress had an opportunity to add such a definition in the LCSA, it choose not to, stipulating only that a determination of unreasonable risk cannot include cost or other non-risk factors. It would unduly limit EPA's discretion to try to capture the many elements of unreasonable risk determinations in a single definition.*

- ✓ *The proposed rule only addresses CBI protection in the context of industry requests for risk evaluations. However, CBI procedures will be even more important for the remainder of EPA's rule given the large volume of use and exposure information on EPA-initiated evaluations that may be subject to CBI claims. The preamble to the final rule should make clear that, throughout the risk evaluation process, EPA will apply the safeguards against unwarranted CBI claims and mechanisms for increased disclosure that Congress adopted in the LCSA.*

- ✓ *Current EPA peer review policies should apply to risk evaluations. These policies provide appropriate flexibility in selecting the type and level of peer review. In limited cases, peer review may not be required, such as if EPA is simply confirming an assessment of another authoritative body that has already been peer reviewed and there are no new relevant data or information since the earlier assessment. A case in point is where EPA is relying on a chemical assessment completed by the Integrated Risk Information System (IRIS), the International Agency for Research on Cancer, or the National Toxicology Program. However, contrary to suggestions in the proposal preamble, assessments that designate an agent as "low priority" or low/no risk should be subjected to rigorous peer review to avoid the consequences of a "false negative."*

- ✓ *EPA's preamble asks for comments on how other agencies should be consulted during the risk evaluation process. There are many established channels for inter-agency communication, and agencies with relevant information or recommendations will have ample opportunities to bring them to the table. To create a specific consultation mechanism that does not exist today is unnecessarily bureaucratic and will add burdens and delays to the risk evaluation process. We do believe, however, that, in developing risk evaluations, EPA should consult with states, which will often have useful data to share with EPA, and that the scoping document should describe planned consultations with federal and state agencies.*

I. RISK EVALUATIONS SHOULD ADDRESS THE ENTIRE LIFE-CYCLE AND CONDITIONS OF USE OF THE EVALUATED CHEMICAL

EPA has properly concluded that risk evaluations must –

> "encompass **all** manufacture, processing, distribution, use and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. That is to say, a risk evaluation must encompass **all** known, intended and reasonably foreseen activities associated with the chemical substance."[3]

This interpretation is compelled by the broad definition of "conditions of use" in section 3(4) to include all phases of a chemical's life cycle and by the explicit requirement in section 6(b)(4)(A) that a risk evaluation must address "the conditions of use" of the subject chemical. Equally important, as EPA notes, the goal of the evaluation under section 6(b)(4)(A) is to determine whether the "chemical substance" as a whole presents an unreasonable risk, not whether discrete uses present such a risk.[4] This reflects Congress' desire for definitive and comprehensive risk evaluations covering a chemical's entire use and exposure profile, as opposed to partial evaluations that defer unaddressed risks to future resolution.

EPA's comprehensive approach is essential for policy as well as legal reasons. Picking and choosing among a chemical's conditions of use could result in overlooking risk scenarios of significant concern due to resource constraints, political pressures or lack of information. If EPA could meet the statutory deadline for completing evaluations on the basis of a partial characterization of uses, exposure pathways and risks, it would have no obligation under the law to address the remaining risk scenarios, despite their significance. The resulting gap would weaken protection of health and the environment. In some cases, focusing on a subset of uses could even lead to a determination that the chemical does not present an unreasonable risk although a comprehensive evaluation would support a different conclusion. In such cases, the public would erroneously conclude that the chemical is safe.

[3] 82 FR 7565 (emphasis added)

[4] The description of the scoping process in section 6(b)(4)(D) does not, as some have argued, provide discretion for EPA to narrow the scope of risk evaluations. This provision simply requires EPA to enumerate the hazards, exposures and conditions of use it has identified so that it can structure and plan the risk evaluation, provide the public with a clear indication of how it will conducted and give stakeholders an opportunity to identify hazard and exposure scenarios that may be unknown to the Agency. This organizing and public information function does not imply an ability to exclude uses or hazards from the risk evaluation that should be addressed to provide the comprehensive life-cycle assessment that Congress envisioned.

In addition, aggregating exposures across uses – a necessary step to avoid understating risks and identifying and protecting potentially exposed or susceptible subpopulations – cannot be accomplished effectively if some uses are dropped from consideration at the outset of the evaluation. This would mean that pathways that contribute to aggregate exposure would be ignored, and that the evaluation would underestimate total exposure and risk, providing the public with a misleading characterization of the chemical's risks throughout its life cycle.

While the proposal is unambiguous on the need to include all the conditions of use within the scope of the risk evaluation, the preamble surprisingly states that "a use or other activity constitutes a condition of use . . . only if EPA determines that it does" and that "EPA has authority to exercise judgment in making its determination of whether a condition of use is known, intended or reasonably foreseen."[5] We agree that EPA must apply the definition of "conditions of use" to specific circumstances and this will require an examination of the nature of a particular activity to determine whether it meets the statutory definition. However, the term "conditions of use" is clear and unambiguous and EPA lacks discretion to determine that an activity that otherwise meets the definition should be disregarded because EPA wishes to reduce its workload or limit the scope of the evaluation.

II. EPA MUST ASSURE THAT COMPREHENSIVE INFORMATION ON HAZARD AND EXPOSURE IS AVAILABLE BEFORE A RISK EVALUATION IS INITIATED

Essential to any science-based determination of risk is adequate information about hazard and exposure. For comprehensive risk evaluations under TSCA, this necessarily means the ability to characterize the nature, duration and magnitude of exposure for all conditions of use and identify the chemical's health and ecological effects for all end-points and routes of exposure. We are pleased that EPA recognizes that serious data-gaps exist for many of the chemicals that would be candidates for high-priority listing and that a full complement of necessary information should be in hand at the time EPA begins the scoping process for a risk evaluation.

EPA's obligation to affirmatively obtain the hazard and exposure information necessary to inform a risk evaluation is reflected in section 26(k) of revised TSCA, which directs EPA, in implementing sections 4, 5 and 6, to "take into consideration information relating to a chemical substance, including hazard and exposure information, under the conditions of use, that is **reasonably available to the Administrator**" (emphasis added). EPA defines this term in section 702.33 of its proposal as "information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations", underscoring its responsibility to reach out to multiple data sources, both within and outside the government.

As EPA notes in this proposal and explains more fully in its related prioritization rulemaking, the ideal time for filling data gaps is at the pre-prioritization stage, so that the Agency can make an informed priority listing decision and proceed toward a risk evaluation confident that it will have sufficient information to perform a robust examination of hazard, exposure and risk. (Because the initial 10 chemicals selected for risk evaluation did not undergo prioritization and had to be selected shortly after enactment of the LCSA, this information collection phase was not possible. Nonetheless, SCHF has urged that EPA's scoping documents include a road-map for filling data gaps on the 10 chemicals, including

[5] 82 FR 7566.

testing that may not be completed by the 3.5 year deadline but can be used to later reassess EPA's unreasonable risk determination if warranted). [6]

It is not realistic to expect industry to fill data-gaps voluntarily: the track record of industry submission of information on the initial 10 chemicals has been disappointing and very little voluntary testing was conducted under the original TSCA. EPA should therefore plan on using its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law.

For example, section 4 now authorizes EPA to impose testing requirements through orders rather than solely through rulemaking, a cumbersome process. Moreover, under section 4(a)(2), orders or rules can be issued solely to obtain data that EPA deems necessary to "perform a risk evaluation" or "for purposes of prioritizing a chemical substance." These justifications will be present in any case where EPA is reviewing a chemical for prioritization and needs data both to inform a high-priority listing and to conduct a risk evaluation after listing occurs. Thus, for such chemicals, EPA will have a sound basis to require industry to develop new information on the frequency, levels and duration of exposure for the chemical's conditions of use or to perform toxicological testing for a hazard end-point not adequately characterized by the existing literature.

In addition to requiring development of new information, EPA needs to assure it receives all existing information on hazard, use and exposure within industry's possession or control. One mechanism to accomplish this is to add chemicals selected for pre-prioritization to EPA's section 8(d) reporting rule requiring reporting of unpublished "health and safety studies." EPA could also issue new section 8(a) reporting requirements to obtain detailed use and exposure information for chemicals undergoing pre-prioritization.[7] Alternatively, EPA could use its subpoena authority under section 11 to obtain records from individual producers.

Although EPA has strongly underscored the need for comprehensively filling data gaps before initiating risk evaluations, it needs to take the next step and develop a concrete framework and process for information collection on prioritization candidates. In its comments on EPA's proposed prioritization process, SCHF offers it recommendations on how EPA can best create this framework and process at the pre-prioritization stage and apply them to chemicals that are candidates for the next round of high-priority designations and risk evaluations under the law.

To the extent that the data-base available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the

[6] Section 702.45(e) of the proposed risk evaluation rule provides that EPA "may reassess a final unreasonable risk determination at any time based on information available to the Agency." Thus, if new hazard or exposure information that industry is required to develop supports different or more extensive conclusions about a chemical's risks, the risk evaluation for the chemical should be reopened and modified. This should be equally true for evaluations determining that the chemical presents an unreasonable risk and evaluations finding an absence of unreasonable risk.

[7] This rule could require information beyond the limited scope of CDR reporting and apply to both manufacturers/importers and processors.

scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumption or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable. In these situations, the absence of data should be highlighted in the draft scoping document so that interested parties can comment on how a hazard end-point or condition of use lacking data should be addressed in the risk evaluation.

We recommend that EPA recognize in the preamble to the final rule that the absence of data does not mean the absence of risk and commit to prominently identifying in its evaluations any uses, exposure pathways or end-points for which no determinations of risk can be made because of the lack of information.[8]

III. EPA NEEDS TO BROADLY APPLY THE TSCA DEFINITION OF CONDITIONS OF USE AND ASSURE THAT ALL SOURCES OF EXPOSURE THAT MAY CONTRIBUTE TO TOTAL RISK ARE C0NSIDERED IN ITS EVALUATIONS

Neither the proposed rule nor the preamble elaborates on the definition of "conditions of use" or explains how it applies to specific activities that may contribute to overall risk. However, some industry parties have argued – erroneously in our view – that certain exposure scenarios are **not** conditions of use and therefore should **not** be considered in conducting risk evaluations. As explained below, EPA should explicitly reject these arguments in the preamble of its final rule:

Conditions of Use Outside Labeling and Use Descriptions. Several industry groups have claimed that uses of a chemical that are not identified in labeling or marketing materials or are inconsistent with the handling practices described in labeling or Material Safety Data Sheets (MSDSs) are not "conditions of use" because they are not "intended" by the manufacturer or processor. However, section 3(4) defines "conditions of use" to include not just "intended" but "known or reasonably foreseen" activities that occur as a result of manufacture, processing, use, distribution in commerce or disposal of a chemical. This would plainly encompass applications of the chemical not explicitly advertised or identified by the seller but known or reasonably anticipated to occur within a processing or end-use sector, as evidenced by Internet postings, articles in trade or general publications or anecdotal reports by consumers or workers. It would also encompass use of the chemical without safeguards such as ventilation or personal protective equipment when the absence of these safeguards has been reported in the medical or occupational health literature, surveys of work sites or residences or technical bulletins or anecdotal observations by consumers or workers. For several chemicals that EPA is already evaluating such as TCE, PERC, DCM and NMP, solvent or vapor degreasing, paint removal and dry cleaning applications are known to occur at construction job sites, small commercial establishments and homes where the use of personal protective equipment and other precautions is uneven at best and non-existent at worst. To presume that these limitations on exposure are in place and protecting workers and consumers in the

[8] We are uncomfortable with EPA's statement that "all conditions of use will not warrant the same level of evaluation and EPA expects that it may be able to reach conclusions without extensive or quantitative evaluations of risk." 82 FR 7566. This may in fact be true for uses that involve minimal exposure because the chemical is not distributed in commerce and is used only under well characterized processing conditions that are totally enclosed. However, EPA should generally be wary of assuming an absence of exposure based on general processing descriptions or low production volume since experience shows that opportunities for significant releases into the workplace or environment exist even under claimed low exposure conditions.

face of contrary evidence would be to read the terms "known" and "reasonably foreseen" out of the statutory definition of "conditions of use."

Impurities and Byproducts. Some have also suggested that the presence of a chemical in a product or waste stream as an impurity or byproduct does not constitute a condition of use and should not be considered when evaluating the chemical's exposure potential. However, whether or not an impurity or byproduct performs a commercial purpose or is generated intentionally, its existence will generally be "known" or "reasonably foreseen" by the manufacturer and constitute one of the "circumstances under which [the] chemical substances is . . . manufactured, processed, distributed in commerce, used or disposed of." The exposures associated with impurities or byproducts can be significant and their contribution to overall exposure and risk should be accounted for in EPA's risk evaluations.

Future Uses. A chemical's conditions of use should also include future applications, manufacturing or processing conditions and exposure and release pathways that are "reasonably foreseen" based on new product or plant expansion announcements or use scenarios for chemicals with similar characteristics. The LCFA legislative history underscores EPA's responsibility to "consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk" and notes that this "authority and mandate" derives from the LCFA definition of "conditions of use."[9]

Legacy Uses. Legacy environmental releases of a chemical often contribute significantly to current exposure, particularly in communities impacted by groundwater, surface water, drinking water or soil contamination or proximity to waste sites. Such releases would qualify as "conditions of use" under the law because they define the "circumstances under which a chemical substance is . . . known . . . to be disposed of." And even if these releases are best addressed under other laws like CERCLA or RCRA, their incremental contribution to overall exposure by an impacted community or subpopulation is clearly relevant to whether the aggregate risk posed by a chemical is "unreasonable."

Clarifying in the preamble to the final rule that these activities fall within the definition of "conditions of use" is essential to a clear understanding of the scope of EPA risk evaluations by Agency staff, the regulated community and the public.

Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA.

IV. AGGREGATE AND CUMULATIVE EXPOSURE ASSESSMENT SHOULD BE AN ESSENTIAL ELEMENT OF RISK EVALUATIONS WHENEVER TOTAL RISK IS A FUNCTION OF MULTIPLE USES AND PATHWAYS OR THE COMBINED IMPACTS OF MULTIPLE CHEMICALS OF SIMILAR TOXICITY

Determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations is inherent in the new law's focus on the total risk posed by a chemical throughout its life-cycle as distinct from the discrete risk associated with a particular condition of use.

[9] Detailed Analysis and Additional Views of Democratic Senators, June 7, 2016. Congressional Record S3516.

Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity frequency and number of exposures under *the conditions of use* of the chemical substance" (emphasis added). This focus on characterizing exposures across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency and duration of exposures by each population or subpopulation resulting from this combination of pathways.[10]

This approach is commonly described as "aggregate exposure assessment" and EPA has applied it successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[11]

Section 6(b)(4)(F)(ii) of the LCSA provides that, in conducting a risk evaluation, EPA must explain "whether aggregate or sentinel exposures to a chemical under the conditions of use were considered, and the basis for that consideration." In its proposed rule, EPA has provided definitions of "aggregate" and "sentinel" exposure[12] but has not addressed when it intends to apply these two methods of assessment. *We urge EPA to clarify in the preamble to its final rule that it will conduct an aggregate exposure assessment whenever total risk by the general population or a vulnerable subpopulation is a function of the combined exposures resulting from multiple pathways or uses.* This approach is consistent with past EPA practice and guidance and inherent in the LCSA emphasis on examining total risk across a chemical's lifecycle and conditions of use and controlling these pathways and uses to the level necessary to assure that the overall risk is no longer unreasonable.

*The preamble to the final rule should further provide that, at the scoping stage, EPA will identify **all** uses and pathways that contribute to **total** exposure by the general population or significant subpopulations.* In the evaluation itself, EPA would then characterize the magnitude of each use or pathway's contribution to total exposure – quantitatively if possible but qualitatively if not. Based on this characterization, the evaluation would determine whether the chemical presents an unreasonable risk based on the **combination** of uses and pathways, even if in isolation the risk associated with an individual use or pathway may not be unreasonable.

As EPA notes, "sentinel exposure" is a novel concept for the Agency (and many in the scientific community) and has no precedent in existing EPA programs although it is used for other purposes by agencies charged with conducting occupational health and disease surveillance.[13] Insofar as we

[10] We agree with EPA's proposal in section 702.33 to consider "intrinsic" and "acquired" characteristics in identifying "potentially exposed or susceptible subpopulations." It is critical that EPA consider both types because a significant body of science supports that intrinsic and acquired characteristics can contribute to increased susceptibility, as noted by the National Academy of Sciences in *Science and Decisions*.

[11] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pd

[12] See proposed section 702.33.

[13] For example, the National Institute for Occupational Health (NIOSH), has adopted the concept of sentinel events as a "warning signal" in occupational medicine that denotes "an event whose occurrence may serve as a

understand EPA's definition of the concept, it envisions that EPA's determination of unreasonable risk would be based on the "plausible maximum exposure to an individual, population (or subpopulation) or the environment to the chemical substance or interest." This may be a reasonable approach if "plausible maximum exposure" is the sum of exposures contributed by all the uses and pathways impacting the individual or population and therefore is a measure of aggregate risk, including to potentially exposed or vulnerable subpopulations. But to the extent that it only includes exposure from a single use or pathway, it would understate risk, except for chemicals with use patterns that do not result in multiple exposures by individuals or populations. *We urge EPA in its final rule to clarify the definition of sentinel exposure assessment, the circumstances in which it might be used and how it might be applied.* The definition might be revised to read as follows:

> Sentinel exposure means the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment, to the chemical substance of interest (or any combination thereof), **demonstrated to be protective of all potentially exposed or susceptible populations and taking into account the combined contribution of all relevant sources and pathways of exposure** (new language highlighted)

Another area requiring clarification is the use of "cumulative exposure" methodologies for TSCA risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[14] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[15]

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warning signal that materials substitution, engineering control, personal protection, or medical care may be required." The implementation of any of these measures would therefore prevent further disease or disability. NIOSH. 2011. Occupational Sentinel Health Events SHE(O) https://www.cdc.gov/niosh/topics/sheo/

[14] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity*. U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[15] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

We recommend that EPA reiterate in the final rule preamble existing Agency policy that cumulative risk will be assessed during evaluations wherever the evidence demonstrates that a defined population or subpopulation is exposed to multiple chemicals that share a common mode of toxicity, or which have common health endpoints, considering where appropriate the contribution of additional non-chemical stressors (e.g., social, economic, and psychological) to the total risk. In this situation, total risk to the relevant population or subpopulation will be a function of combined exposure to these different chemicals and their interaction with each other, which could be additive or synergistic depending on the circumstances. Where the exposed population may be at greater risk because of non-chemical stressors, they must be taken into account in the determination of the cumulative risk.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and/or adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, DCM and NMP) among the initial 10 chemicals EPA has selected for risk evaluations under the LCSA: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. Failure to consider cumulative risk scenarios would result in understatement of these risks and under-protection of exposed populations.

While the LCSA does not directly mention cumulative risk, section 26(c) of TSCA authorizes EPA to implement any provision of the law with respect to "categories," a term broadly defined to allow grouping of chemicals by toxicity, use, exposure pathways or chemical structure. By designating the four solvents (and similarly closely related chemicals in the future) as a category, EPA would be able to align its risk evaluations so they assess cumulative risks across the category in determining if the chemicals pose an unreasonable risk and, if warranted, use these cumulative risks as the basis for risk management under section 6(a).[16] *The preamble to EPA's final rule should recognize the role of conducting integrated evaluations of "categories" of chemicals in these situations.*

V. EPA LACKS AUTHORITY TO "TIER" RISK EVALUATIONS OR DESIGNATE USES AS "LOW RISK" AT THE SCOPING STAGE

At the August 9, 2016 and February 14, 2017 public meetings, industry argued that EPA should adopt a "tiered" approach to risk evaluation, with a "screening level" assessment at the scoping stage and then a more rigorous and comprehensive "full" evaluation for those uses or pathways that warrant closer examination. Uses and exposure pathways that are eliminated at the scoping stage, industry asserted, should be deemed not to present an "unreasonable risk" or treated as "low priority."

These approaches were properly omitted from EPA's January 19 proposal and the Agency should continue to reject them as lacking any basis in the LCSA and as fundamentally unworkable.

To begin with, the scoping process is intended to organize and array the available information on conditions of use, exposure pathways and hazards and to outline a strategy and set of methodologies for analyzing this information. The scoping process is not intended to make initial judgments about risk

[16] As EPA notes in the preamble to its proposal, it seeks to include a clear statement in the regulatory text that "nothing in the proposed rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances." 82 FR 7570.

and could not realistically perform this function in any case. Conducting a preliminary risk analysis – whether for "screening" purposes or otherwise – of the multiple hazards, uses and exposure pathways associated with most high-priority chemicals would be a daunting task that is simply not feasible within the 6 month scoping process. If uses are dropped from the risk evaluation based on a cursory review at the scoping stage, the risk evaluation itself will be inadequate because critical exposure and hazard information pertaining to these uses will not be considered and the contribution of the uses to aggregate exposure and risk will not be taken into account.

Nor is a tiered approach to risk evaluation allowable under the statute. Under section 6(b)(4)(A), a risk evaluation is to be performed for the chemical as a whole, not individual uses. The only mechanism for determining that a chemical or individual conditions of uses do not present an unreasonable risk is completion of a full risk evaluation that meets all the requirements of section 6(b)(4)(F). An informal finding of low risk during the abbreviated scoping process is not a sufficient basis for this determination. Similarly, low priority designation under section 6(b)(1)(4)(ii) is aimed at chemicals, not individual uses, and requires a showing that the chemical lacks the potential for unreasonable risk under **all** its conditions of use. There is no basis to apply the "low priority" label to a specific use based on a limited evaluation during the scoping process, particularly where the remaining uses are known to present risks.

Equally important, the dichotomy industry perceives between "screening" and "full" assessments simply does not exist in practice and is not a useful distinction in the context of implementing the LCSA. The degree of precision and depth of analysis in a risk evaluation depends on the amount and quality of hazard and exposure data available. As noted above, it is EPA's goal to fill critical data-needs at the pre-prioritization stage so that all the information necessary for a risk evaluation is in hand when a chemical enters the scoping process. However, if the available information is incomplete, EPA will need to apply default values and/or make worst case assumptions, as recommended by the National Academy of Sciences (NAS) in *Science and Decisions*[17] and noted in the preamble to the proposed rule.[18] If industry wishes to avoid this outcome, it will have ample motivation to work with EPA at the pre-prioritization stage to identify, develop and submit the data that will support a comprehensive risk evaluation. If it fails to do so and then later seeks to hold EPA to unrealistically stringent analytical standards for "full" evaluations, the responsibility for the absence of data should rest on its shoulders and not on those of the Agency, which is charged with performing the best assessment possible with the data *reasonably available* within the allotted 3.5 year time-frame.[19]

While we generally oppose any tiering or phasing of risk evaluations, we agree with EPA that where a discrete set of uses can be demonstrated to present an unreasonable risk before the full evaluation is completed, it is appropriate for EPA to finalize its risk findings on these uses as soon as possible and to proceed with rulemaking under section 6(a) in order to expedite protection against the risk.[20] EPA's proposed section 6(a) rules for TCE, DCM and NMP are an example of targeting discrete high-risk uses based on partial risk assessments even as EPA undertakes full evaluations of these chemicals under

[17] National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington, DC 2009. *http://www.nap.edu/catalog.php?record_id=12209*.
[18] 82 FR at 7570.
[19] EPA's mandate under Section 26(k) of TSCA is to utilize the scientific information "reasonably available" to the Agency at the time the rulemaking is conducted. Industry recalcitrance in providing chemical data is no longer a justification for EPA regulatory inertia under TSCA.
[20] 82 FR at 7568.

section 6(b). This model may well be applicable to other chemicals that are the subject of ongoing or future risk evaluations. Where it is possible to accelerate health protections, consistent with the law, EPA should always do so.

VI. THE RISK EVALUATION RULE IS THE WRONG VEHICLE FOR PRESCRIBING THE SPECIFIC ELEMENTS OF SCIENTIFIC DECISION-MAKING REQUIRED DURING EVALUATIONS

At the August 9, 2016 public meeting, industry stakeholders advocated using the risk evaluation procedural rule to codify several scientific terms and principles used in risk assessments and to prescribe in the rule itself how these concepts will be applied. EPA's proposal declines to follow these recommendations on the ground that they are "unnecessary and ultimately problematic" and "may inhibit the flexibility of the Agency to quickly adapt and implement changing science."[21] Nevertheless, EPA has requested comments on the pros and cons of codifying scientific principles and definitions in the risk evaluation rule. SCHF continues to believe strongly that this would be a serious mistake and that EPA should retain the approach embodied in its proposal.

Role of Guidance in Establishing Risk Evaluation Procedures. EPA has traditionally issued guidance to elaborate on different aspects of the risk evaluation process. Guidance is preferable to rulemaking because it can be applied flexibly and revised more readily as scientific understanding changes. EPA-issued and external guidance documents on different aspects of risk assessment methodology are extremely numerous, as the lengthy list in the proposal rule demonstrates.[22] They have evolved over time through a transparent, peer-reviewed public process that reflects changes in scientific understanding, new data in the scientific literature and input from experts and stakeholders. To use this rulemaking to revise or codify this complex body of knowledge, in whole or in part, would require a level of effort and consultation that is simply not feasible given the 1-year deadline for completing the rule and would run the risk of overturning well-established approaches without thoughtful and careful deliberation. To be sure, improvements in EPA risk assessment practices should be encouraged and there are many aspects of current EPA guidance that could benefit from updating. However, these are tasks best performed through the guidance development process, not a procedural rulemaking conducted on an expedited schedule.[23]

The apparent premise behind the industry recommendations is that Congress was unhappy with EPA's approach to risk assessment and demanded significant changes in EPA practices in the LCSA. While such sentiments may have been expressed by some members of Congress and in early bill language, they are not reflected in the LCSA as enacted. The law does instruct EPA to use certain scientific principles in the risk evaluation process, but they are relatively few in number and represent well-established tenets of

[21] 82 FR at 7572.

[22] 82 FR at 7574. EPA also notes that a compendium of existing Agency guidance related to risk assessments is maintained at *https://www.epa.gov/risk/risk-assessment-guidelines, a* compendium of guidance, databases and models used for assessing pesticide risks is available at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks*, and information about available predictive models and tools for assessing chemicals under TSCA can be found at *https://www.epa.gov/tsca-screening-tools*.

[23] As EPA suggests, there is value in identifying the guidances on which EPA intends to rely in the draft scoping documents and soliciting comments on whether these and/or other guidances from EPA or elsewhere are most appropriate to address the risks of the chemical at hand. 82 FR at 7573.

risk assessment that EPA has been applying for years. And the law conspicuously does **not** direct EPA to use rulemaking in order to codify these or other aspects of risk assessment methodology. Indeed, section 26(l) creates a timeline for issuing and reviewing "policies, procedures and guidance" to implement sections 4, 5 and 6, including "procedures for assessing and determining risk," but makes no reference to using rulemaking for this purpose.

Weight of the Evidence. A case in point is the term "weight of the evidence"(WoE), which EPA is required to describe in its evaluation when making findings about hazards and exposure under section 6(b)(4)(F)(v). As EPA details in the preamble to the proposal, it has utilized a WoE approach for many years and there are many discussions of how to make WoE determinations in EPA guidance documents and reports from independent bodies like NAS. At the same time, there is no cookbook approach to a WOE analysis, as NAS cautioned in its landmark report *Science and Decisions*:

> "because scientific evidence used in WOE evaluations varies greatly among chemicals and other hazardous agents in type, quantity, and quality, it is not possible to describe the WoE evaluation in other than relatively general terms. It is thus not unexpected that WoE judgments' in particular cases can vary among experts and that consensus is sometimes difficult to achieve."[24]

More recently, the National Research Council 2014 report on the *Review of EPA's Integrated Risk Information System (IRIS) Process* found that the phrase WoE has become "far too vague as used in practice and thus of is of little scientific use."[25] The committee compared various definitions of WoE, including seemingly simplistic balancing equations with hazard on one side and evidence on the other to more intricate "systematic review" processes with pre-established protocols and comprehensive inclusion of a variety of data sources. These definitions each proved unsatisfactory to the committee, with the committee recommending the term "evidence integration" as a more appropriate and useful term for the data integration step involved in IRIS assessments. While TSCA itself incorporates the WoE terminology, these concerns strongly argue against codifying its meaning in a regulatory definition.

Systematic Review. In an effort to be transparent, the preamble to the proposed rule provides a useful overview of the steps EPA intends to take in a WoE analysis. This overview is informative, particularly in its description of how EPA will conduct a "systematic review" of the different studies and other information on chemicals subject to a risk evaluation. EPA notes that:

> "The National Toxicology Program of the National Institute of Environmental Health Sciences has developed a tool called "systematic review" to assist in WoE evaluations particularly for hazard identification (*https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html*). This tool uses a defined set of processes to identify, select, critically assess, and synthesize evidence to arrive at a hazard conclusion for a chemical. It is designed to enhance transparency and informs scientific judgments. The evidence synthesis step involves considering factors that decrease confidence in the body of evidence for a particular health endpoint (*e.g.* risk of bias, inconsistencies across studies, imprecision) as well as factors that increase confidence (*e.g.* magnitude of the effect, residual confounding, consistency). By evaluating study design (*e.g.,*

[24] See note 15.

[25] National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/18764.

consistent with study guidelines issued by OECD, and test guidelines issued by the Office of Chemical Safety and Pollution Prevention), and study quality (*e.g.,* studies that comply with Good Laboratory Practices (GLP) like those applicable generally (*https://www.federalregister.gov/documents/2016/08/24/2016-19875/good-laboratory-practice-for-nonclinical-laboratory-studies*) and those issued by EPA for studies submitted under TSCA and FIFRA (*https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program*)), and integrating negative data (and consideration of the quality of those data), the confidence in hazard conclusions can be increased."[26]

While SCHF appreciates the systematic review approach as described by NIEHS, the critical evaluation of studies and other information pertaining to a chemical's health and environments should not be a mechanical "check the box" exercise in which rigid criteria are applied to accept some studies and reject others. Systematic review is a tool to inform scientific judgment, not replace it. Thus, we oppose codifying in EPA's rule either a systematic review protocol or a fixed definition of WoE.

Data Quality. We are also concerned that, while properly recognizing the role of data quality considerations, EPA's discussion of WoE and systematic review appears to elevate studies that are conducted according to OECD guidelines, EPA test guidelines, and Good Laboratory Practices (GLP). However, Guideline and GLP studies – mostly sponsored by industry to meet regulatory requirements -- don't necessarily use modern methods for evaluating chemicals and aren't designed to grapple with the problems of low-dose exposures, complex and systemic endocrine effects, behavioral or learning effects, metabolic perturbations, or upstream effects that inform predictive toxicology. Over-reliance on GLP and Guideline studies will bias against academic studies, including those funded by government agencies. EPA should establish protocols that outline the criteria by which scientific evidence will be evaluated for internal and external validity, including outlining a process by which non peer-reviewed studies (such as GLP and Guideline studies) will undergo independent peer-review.

Science Consideration in Section 26(h). Industry has also proposed that the risk evaluation rule incorporate and prescribe how EPA will implement the general "principles" for using science in decision-making set out in section 26(h) of the Act. However, these principles are not absolute requirements; EPA must "consider" them "as applicable." The principles are also straightforward, self-executing and generally consistent with current agency practice, so there would be no added benefit to restating them in rule language.

The industry points to section 26(h) to claim that Congress was deeply concerned about EPA's failure to use "good science" and sought to compel far-reaching changes in the Agency's approach to risk assessment. However, this claim is refuted by the history of the LCSA's development and the final legislative text. The Senate bill contained detailed directives on the use of science and risk assessment under TSCA and mandated that EPA incorporate these directives in rules and guidance by a fixed deadline. No comparable provisions were included in the House bill. LCSA as enacted moved toward the House approach by greatly streamlining and adding flexibility to section 26(h) and deleting any obligation to implement its provisions through rulemaking.[27] As EPA points out in its preamble,[28] the

[26] 82 FR 7584.

[27] Significantly, as noted above, section 26(l) contemplates that EPA will issue "policies, procedures and guidance" required for implementation of the Act and references "procedures for assessing and determining risk under this Title," but does not mention using rulemaking for this purpose. Moreover, this provision gives EPA discretion to

lack of any indication in section 26(h) that its science principles would be subject to further elaboration in rulemaking is in direct contrast to the many provisions of LCSA requiring rulemaking and supports EPA's position that these principles should not be included in its risk evaluation rule. [29] Moreover, while EPA has not incorporated the section 26(h) principles in its proposed rule, section 702.41(b) confirms that EPA risk characterizations will, as appropriate, address issues of uncertainty, variability and data quality -- considerations also identified in section 26(h).

Fit for Purpose. The phrase "fit for purpose" does not appear in the revised TSCA. EPA notes, however, that "it is proposing to require that the components of its risk evaluations will be 'fit for purpose.'"[30] EPA has not defined this vague term in its proposal. However, EPA's *Framework for Human Health Risk Assessment to Inform Decisionmaking* describes the "fit for purpose" approach as a way to target risk evaluations toward the risk management options of greatest interest to the agency.[31] This approach is at odds with revised TSCA, which requires the Agency to comprehensively evaluate conditions of use and aggregate exposures to potentially exposed or susceptible subpopulations, in order to have the strongest possible scientific basis for choosing among the risk management options available under section 6(a). Any narrowing of the evaluation based on a prejudgment of the restrictions that are most appropriate for the chemical would be contrary to the law's clear dividing line between risk evaluation and regulation.

EPA's preamble does describe one application of the "fit for purpose" concept: "All conditions of use will not warrant the same level of evaluation, and EPA expects it may be able to reach conclusions without extensive or quantitative evaluations of risk . . . {for] lower volume or less dispersive uses."[32] We agree that it may be possible to scale the level of analysis in a risk evaluation to take into account gradations in potential exposure. But this must be done very carefully and thoughtfully. If EPA believes that certain exposure and use scenarios are indicative of low risk, it must clearly document the data and assumptions used to draw conclusions about these scenarios. Even low volume or seemingly contained uses can result in exposures or releases of concern in light of the physical-chemical properties, persistence and hazard profile of the chemical. And while a given use may have limited exposure potential in isolation, it could be more significant when combined with the contributions of numerous other "low risk" uses.

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identify "any" policies, procedures and guidance it deems "necessary," but does not prescribe when and for what purpose EPA should use these tools.

[28] 82 FR 7565

[29] We also agree with EPA that the statute does not require the animal testing provisions in section 4(h) to be implemented by rule. Nor would it make sense for EPA to do so, since they address policies that are evolving and will continue to evolve. For example, the bulk of the "animal-testing" provisions of section 4(h) pertains to a Strategic Plan to reduce testing on vertebrate animals, the first version of which is not even due to be produced by EPA under the statute until June 2018 and for which EPA must submit updates and goals for future implementation strategies to Congress every five years.

[30] 82 FR at 7566.

[31] According to the Framework: "The overarching questions in addressing 'fit for purpose' are the following: Does the assessment inform choices among risk management options? Will the risk assessment need to be changed or expanded to discriminate between risk management options?" Office of the Science Advisor, EPA, Framework for Human Health Risk Assessment to Inform Decisionmaking at 4 (2014), available at https://www.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf

[32] Id. We are not sure that EPA's example is in fact an appropriate application of the "fit for purpose" principle.

In the preamble to the final rule, EPA should explain more fully when and how it will dispense with "extensive or quantitative evaluations of risk" for particular conditions of use and what steps it will take to document the assumptions and analysis underlying these choices. It should also clarify that "fit for purpose" has little or no role in TSCA risk evaluations.

VII. EPA SHOULD ONLY ACCEPT INDUSTRY REQUESTS FOR RISK EVALUATIONS IF THEY COVER ALL CONDITIONS OF USE AND CONTAIN SUFFICIENT INFORMATION ON USE AND EXPOSURE TO SUPPORT AN EVAUATION

TSCA section 6(b)(4)(C)(ii) provides that EPA's risk evaluation rule must prescribe the "form and manner" of manufacturer requests for risk evaluations and establish the "criteria" that these requests must meet. These issues are addressed in section 702.37 of the proposed rule. We believe that EPA's approach in this provision is well grounded in the LCSA and will protect against industry-initiated risk evaluations that do not further public health and fail to use EPA's limited resources in the public interest.

First, we agree with section 702.37(e)(6), which provides that industry-initiated risk evaluations conducted by EPA should address "all the conditions of use of the chemical substance" subject to the evaluation. The requirement to include "the conditions of use" in risk evaluations in TSCA section 6(b)(4) does not differentiate between those initiated by industry requests and those triggered by EPA itself. Having concluded in this rulemaking that risk evaluations should provide a comprehensive determination of risk across a chemical's entire life-cycle, there is no logical reason why industry-initiated evaluations should be subject to a narrower approach. Indeed, were EPA to apply such an approach, industry could hijack EPA resources to provide a "clean bill of health" for selected chemical uses while withholding exposure and risk scenarios of greater concern from EPA consideration. This would result in a distorted and incomplete picture of the chemical's safety that would serve the manufacturer's commercial objectives while ignoring the broader public interest.

Second, we agree with section 702.37(a), under which EPA would only grant a manufacturer request if it "includes or references all the information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 . . . " EPA has made clear elsewhere in its proposal that it will initiate risk evaluations only where the available data-base is sufficient to fully characterize the hazard and exposure profile of the chemical across its conditions of use and life-cycle.[33] For chemicals undergoing risk evaluations following a high-priority listing, the Agency intends to use its TSCA information development and collection authorities at the pre-prioritization stage to assure that it possesses adequate information to support the evaluation. However, given that there will no prioritization process for chemicals subject to industry requests, the manufacturer should bear the burden of demonstrating the availability of sufficient data to conduct the evaluation (including a description of potentially exposed or susceptible subpopulations), and EPA should reject for consideration all requests that do not meet this burden.

For EPA to itself assume the burden of producing sufficient information to support the evaluation would be inefficient and unfair, since the chemical in question will not be one that the Agency has affirmatively prioritized for a risk evaluation and its limited resources are best devoted to substances meeting the

[33] 82 FR 7570.

LCSA's criteria for high-priority listing. For these reasons, we support section 702.37(b)'s list of minimum required information that manufacturer requests should contain and agree that requests lacking this information should be rejected as incomplete and invalid, as provided in section 702.37(e)(1).

Third, if EPA does deem an industry request complete, we agree that, as provided in section 702.37(e)(2), EPA should announce receipt of the request in the Federal Register and provide a public comment period. This would enable other manufacturers and the public to submit information on the use, exposure and hazard profile of the chemical and express their views on whether the available information is sufficient to support a comprehensive risk evaluation across the chemical's conditions of use.[34] As EPA proposes, a period of 90 days following the close of the comment period is appropriate to review the comments and make a final determination whether the manufacturer has met its burden of providing sufficient information to justify conducting the evaluation.

Fourth, as EPA recognizes, once a request meets its criteria, the Agency is required to initiate an evaluation unless, per TSCA section 6(b)(4)(E), the number of industry-requested evaluations initiated at any given time represents at least 25 percent of the risk evaluations underway on high-priority substances. Once this threshold is met, EPA has discretion whether to initiate additional industry-requested evaluations, subject to an upper limit of no more than 50% of the number of evaluations underway on high-priority substances.[35] We agree that, in exercising this discretion and prioritizing among industry requests, EPA should not only consider the scope of state regulation of the chemical as provided in TSCA section 6(b)(4)(E)(iii) but the level of potential hazard and exposure associated with the chemical and other risk-related factors.

Finally, EPA should clarify that, once it makes a final determination that industry has met the criteria and other requirements in its rule, the deadlines for completing the scoping process in TSCA section 6(b)(4)(D) and then finalizing the risk evaluation itself in section 6(b)(4)(G) shall apply.

VIII. THE TERM "UNREASONABLE RISK" CALLS UPON EPA TO MAKE A COMBINATION OF POLICY AND SCIENTIFIC JUDGMENTS THAT ARE UNIQUE FOR EACH CHEMICAL AND DO NOT WARRANT CODIFICATION IN EPA'S RULE

The end-point of risk evaluations under section 6(b) is a determination whether the chemical presents an "unreasonable risk of injury to heath and the environment." EPA's preamble discusses the elements of this determination in general terms but the proposal itself does not include a definition of "unreasonable risk." EPA seeks comments on whether such a definition should be included in its final rule.[36]

The original version of TSCA did not include a definition of unreasonable risk. While Congress had an opportunity to add such a definition in the LCSA, it choose not to, stipulating only that a determination

[34] At the start of the comment period, the Agency might also add the chemical to its section 8(a) and 8(d) reporting rules so it has been the benefit of unpublished information (including from other manufacturers who did not join in the request for a risk evaluation) when it makes a final decision whether to proceed with the evaluation and, if so, to initiate the scoping process.

[35] Under section 6(b)(4)(E)(iv), this limit does not apply to chemicals on the EPA Workplan list. However, in all other respects, industry requests for evaluations of these chemicals must comply with the information and other requirements in EPA's rule.

[36] 82 FR at 7566.

of unreasonable risk cannot include cost or other non-risk factors. As EPA notes in its preamble, a number of factors are commonly used to make risk-based judgments, including the nature, irreversibility and severity of the hazard, the size of the exposed population, the levels, frequency and duration of exposure and uncertainties in the evidence of hazard and exposure. In addition to these scientific issues, policy considerations are important in weighing the seriousness of a risk. This would include, for example, cancer risk levels that EPA and other agencies have traditionally deemed unacceptable, safety factors and other benchmarks that regulators have developed to determine the acceptability of non-cancer risks (including developmental and reproductive toxicity, neurotoxicity and other serious health effects). Since potentially exposed or susceptible subpopulations must be protected against unreasonable risk, special factors that apply to these groups would need to be applied as well. Moreover, as science evolves, new standards for judging the acceptability of risks will be developed and change how EPA and other agencies make risk-based decisions.

There is no fixed formula for weighing these scientific and policy considerations (or others that may be relevant); each chemical will require a unique set of judgments. It would unduly limit EPA's discretion to try to capture the many elements of unreasonable risk determinations in a single definition. Such a definition should not be included in EPA's final rule.

IX. WHILE THE MOE APPROACH HAS BEEN APPLIED SUCCESSFULLY IN SOME SITUATIONS, IT IS LESS PROTECTIVE AND SCIENTIFICALLY SOUND THAN NON-THRESHOLD APPROACHES FOR NON-CANCER END-POINTS

EPA's preamble requests comments on the strengths and weaknesses of using a Margin of Exposure (MOE) approach in TSCA risk evaluations and whether there are other approaches that might better suit the goals of such evaluations.[37]

EPA has traditionally used MOE analysis for evaluating chemical risks from non-cancer health effects. Its calculated MOEs played an important role in the Workplan risk assessments it conducted under the old law on trichloroethylene (TCE) and other chemicals and are now part of the unreasonable risk determinations included in EPA's recent proposed rules for these chemicals under section 6(a) of TSCA. While these MOEs may be insufficiently conservative and protective, there is no doubt that they provide a strong basis for concluding that the uses targeted in the EPA rulemakings present serious and unacceptably great risks under well-established agency benchmarks.[38] Indeed, the MOEs may understate the risks.

However, MOEs have certain limitations compared to other approaches. They do not provide a quantifiable risk estimate and are difficult for stakeholders to understand. They also assume without basis that there is a 'safe' exposure level below which negligible or no health effects will occur (a "threshold" of response) and thus underestimate risks. Newer science is finding many examples of chemicals that increase the risk of various non-cancer health effects -- such as reproductive harm and neurological effects -- at low doses, without any scientifically identifiable threshold.[39] To yield the most

[37] 82 FR at 7572.

[38] 81 FR 91592, 91603 (Dec. 16, 2016) (TCE proposed rule).

Grandjean P, Bellinger D, Bergman A, et al. 2008. The Faroes Statement: Human Health Effects Of Developmental Exposure To Chemicals In Our Environment. Basic Clin Pharmacol Toxicol. 102(2):73-5; Grandjean P, Landrigan PJ.

accurate and useful information for decision-making, the NAS in *Science and Decisions* recommends calculations of probabilistic risk distributions for cancer and non-cancer effects using a spectrum of evidence from humans, animals, mechanistic and other relevant studies.[40] These probabilistic risk distributions, incorporating variability of responses in the population (including sensitive subpopulations) and any existing uncertainty in the data available, provide a more accurate way to quantify the risk associated with a particular level of exposure, including central tendency/ average and high-end exposures.[41]

In sum, EPA should clarify in the preamble to the final rule that while MOEs have utility in risk evaluations and regulatory decision-making, they are often unprotective and improperly fail to take into account low-dose non-cancer effects. Accordingly, EPA's goal should be to use, where practicable, other methods, including probabilistic approaches, which have a stronger science basis and do not understate risk.

X. THE PREAMBLE TO EPA'S RISK EVALUATION RULE SHOULD CLARIFY HOW EPA WILL ASSURE THE MAXIMUM DISCLOSURE OF CBI ALLOWABLE UNDER THE LCSA

As EPA repeatedly emphasizes, risk evaluations cannot be conducted effectively without full information on the chemical's conditions of use throughout its life cycle and the resulting levels and pathways of exposure. Much of this information is in the possession of industry; it is to be expected that large portions of industry's submissions will be claimed as Confidential Business Information (CBI), which must be withheld from disclosure.

The proposed rule only addresses CBI protection in the context of industry requests for risk evaluations.[42] However, CBI procedures will be even more important for the remainder of EPA's rule given the large volume of use and exposure information on EPA-initiated evaluations that may be subject to CBI claims. It is therefore critical that EPA recognize in the preamble to the final rule that the law's general CBI requirements apply to all aspects of the risk evaluation process and that EPA will assure that it follows all the safeguards against unwarranted CBI claims and mechanisms for increased disclosure that Congress adopted in the LCSA. There will be a high level of public interest in EPA risk evaluations. Access to the use and exposure information that forms the basis for these evaluations will be invaluable for informed public participation in the evaluation process.

We recommend that EPA confirm in the final rule preamble (as do the CBI provisions in the rule text relating to industry requests for risk evaluations) that CBI claims must be substantiated at the time they are asserted (e.g. "upfront"). Such substantiation is required under section 14(c)(3) for all CBI claims except for those specifically exempt under paragraph (c)(2). The obligation to provide upfront substantiation was explicitly reaffirmed by EPA in its Federal Register notice of January 19, 2017 (82 FR 6522).

2006. Developmental neurotoxicity of industrial chemicals. Lancet. 16;368(9553):2167-78;Grandjean P, Landrigan PJ. Neurobehavioural effects of developmental toxicity. 701 Lancet Neurol. 2014, 13, (3), 330-338

[40] *Science and Decisions,* pp.135-9

[41] Science and Decisions Ch. 5

[42] Section 702.37(d).

In addition, EPA's preamble should clearly state that certain information cannot be claimed CBI under TSCA section 14(b)(3). This provision defines "information not protected from disclosure" to include:

> "(A) *any general information* describing the manufacturing volumes, expressed as specific aggregated volumes or . . . in ranges; or
>
> "(B) *a general description* of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . . " (emphasis added).

Much of the use and exposure information submitted on chemicals subject to risk evaluations will fall within these disclosure requirements because it describes processes used in manufacturing and processing in broad terms or characterize uses and related exposures using commonly accepted descriptors and ranges and percentages rather than specific values. As EPA has concluded in reference to the Chemical Data Reporting (CDR) rule, "general use and process information . . . is not the type of specific information referenced in TSCA § 14(c)(2)" and thus should fall under section 14(b)(3).[43]

Alternatively, TSCA section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." EPA risk evaluations under section 6(b)(2) of TSCA represent a "proceeding" under LCSA. And information submitted by industry on chemicals selected for risk evaluations is clearly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks associated with such chemicals. *EPA should therefore make a determination that section 14(d)(7) applies to risk evaluations and that all or most exposure, use and hazard information pertaining to these evaluations is "relevant" and therefore not protected from disclosure*.

Finally, for any information related to risk evaluations to which these grounds for disclosure may not apply, EPA should expeditiously review and determine the adequacy of the submitter's substantiation of its CBI claims under section 14(g)(1), which requires the Agency to approve or deny CBI claims within 90 days of receipt. While this review deadline applies to 25 percent of CBI claims (except for chemical identity), EPA is not barred from reviewing **all** claims within 90 days where there is justification to do so; such justification would clearly exist for information being considered in risk evaluations. In addition, EPA may be evaluating information covered by CBI claims that have never been substantiated; an example might be information reported to the Agency before the LCSA's enactment. *EPA should commit to immediately require substantiation of such information under section 14(f)(1)(C), which authorizes this step where EPA concludes that "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6."*

XI. CURRENT EPA PEER REVIEW POLICIES SHOULD APPLY TO RISK EVALUATIONS

[43] Q&As relating to CBI under amended TSCA posted on EPA Website, response to Q.7., at https://www.epa.gov/tsca-cbi/general-qs-and-relating-cbi-under-tsca-amended-frank-r-lautenberg-chemical-safety-21st. Although the Q&A related to whether CDR reports are the type of "specific" processing and use information for which substantiation of CBI claims is not required under section 14(c)(2), EPA's conclusion that this provision does not apply necessarily means the CDR-reported processing and use information is "general" and thus cannot be withheld from disclosure under section 14(b)(3).

Over the years, EPA and OMB have provided extensive guidance on when peer review is needed for science documents used for decision-making and what procedures should be used to conduct peer review where it is warranted. Section 702.41(c) of the proposed rule incorporates existing peer review guidance by reference and provides that it will provide the basis for peer review activities for TSCA risk evaluations. SCHF supports this straightforward approach but wishes to address several aspects of peer review that are flagged for comment in the proposal preamble.

The LCSA and existing guidelines provide the Agency with some flexibility in selecting the type and level of peer review that is appropriate for different situations, as discussed in the preamble to the OMB Peer Review Bulletin[44] and the EPA Peer Review Handbook, 4th Edition (2015).[45] Peer review mechanisms can include internal review by EPA staff not involved with the scientific product under review, inter-agency review, or review by external parties outside federal agencies. The latter category of review may include review by a special panel of experts selected by EPA or by a formal external body such as the EPA Science Advisory Board (SAB) or a committee of the National Academy of Sciences. The key considerations in choosing the appropriate peer review mechanism will be whether the evaluation raises novel, unresolved and difficult scientific issues, whether the regulatory decisions that will be based on the evaluation will have significant and widespread impacts, and whether these decisions are of interest to the public, including affected communities, subpopulations and individuals.

Science documents that entail the straightforward application of established methods for hazard and exposure assessment may not need a full external public peer review by a committee. However, once such a hazard assessment is incorporated into a risk evaluation that characterizes the nature and extent of the risk, that evaluation *should* undergo peer review. Moreover, where general scientific issues common to multiple evaluations are presented, they might more efficiently be reviewed by the new Science Advisory Committee on Chemicals established under the LCSA rather than submitted to a specially formed peer review panel for a specific chemical. In this event, it would need to be clear that the goal is only to gather scientific or technical feedback, that participating individuals on the Committee are free of actual or potential financial conflicts and competing interests, and that there is not an appearance of bias or lack of impartiality.

Peer review should be unnecessary where an EPA hazard assessment is simply confirming an earlier peer reviewed assessment conducted by an authoritative body such as the International Agency for Research on Cancer (IARC), the NIEHS National Toxicology Program (NTP) or by EPA itself and no new relevant data or information has become available since the earlier assessment that should now be considered. However, once such a hazard assessment is incorporated into a risk evaluation, the risk-related analysis and conclusions in the evaluation *should* undergo peer review.

A case in point is where EPA has already assessed a chemical under the Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment and extensive peer review. Where EPA is conducting a TSCA evaluation of a chemical

[44] OMB. 2004. Memorandum for Heads of Departments and Agencies, *Final Information Quality Bulletin for Peer Review*. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

[45] EPA 2015. Peer Review Handbook 4th Edition. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015

that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science at the time it was conducted. Not only should EPA not have to reinvent the wheel, but further peer review should be unnecessary. *EPA should clarify the role of IRIS assessments in TSCA risk evaluations in the preamble of its final rule*.

Risk evaluations that downgrade previous hazard classifications of a chemical or reach a conclusion of low-priority or no unreasonable risk are often in most need of public comment and transparent rigorous peer review. SCHF therefore strongly disagrees with EPA that "there will be individual circumstances where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions on the same information, such that the Agency could determine that peer review is not necessary for that chemical risk evaluation."[46] This fails to consider the potential public health implications of erroneously declaring chemicals low priority or low or no risk. In fact, the potential health and environmental impacts of making an error in such an assessment – that is, a "false negative" – could be very serious and could be averted if there is peer review.

EPA needs to be mindful that the revised TSCA imposes a firm 3.5 year deadline for completing risk evaluations and there is a similarly strict deadline for rules restricting chemicals shown to present unreasonable risks. The decision to seek peer review – and the type of peer review process required – should take into account and respect these deadlines. To the greatest extent possible, EPA should design the mode of review and frame the issues to be addressed in a manner that avoids delay. And as EPA notes, the charge for the reviewers should not include policy issues, which are within EPA's sole domain, but only questions of science.

XII. EPA SHOULD NOT C0DIFY A PROCESS FOR INTER-AGENCY COLLABORATION ON RISK EVALUATIONS BUT SHOULD BETTER EXPLAIN HOW IT INTENDS TO CONSULT WITH STATE AGENCIES

EPA's preamble asks for comments on how other agencies should be consulted during the risk evaluation process.[47] There are many established channels for inter-agency communication and agencies with relevant information or recommendations will have ample opportunities to bring their views to the attention of EPA. To create a specific consultation mechanism that does not exist today is unnecessarily bureaucratic and will add burdens and delays to the risk evaluation. EPA should continue to rely on existing coordination procedures. Nonetheless, it would be useful for EPA's scoping document to describe which agencies it will be consulting on the risk evaluation and what mechanisms will be used for this consultation. This will enable stakeholders to better understand the information that other agencies will be contributing and to interact with them where it might be helpful.

EPA should also include state agencies as potential partners for interagency consultation. State agencies can provide valuable information on multiple aspects of a risk evaluation, including conditions of use, potentially exposed or susceptible subpopulations, and exposures. A number of states including

[46] 82 FR 7573
[47] 82 FR 7573

Washington[48], Vermont[49] and Maine[50] have laws requiring reporting of certain hazardous chemicals used in products. The Massachusetts Toxics Use Reduction Act (TURA) requires Massachusetts companies that use large quantities of specific toxic chemicals to evaluate and plan for pollution prevention opportunities, implement them if practical, and annually measure and report the results.[51] Cal/EPA implements a number of relevant state programs, including California's landmark right-to-know law on hazardous chemicals in products, known as "Proposition 65[52]," as well as the Safer Consumer Products Program.[53] The California Department of Public Health[54] Safe Cosmetics Program, Occupational Health and Evaluation program and others could also be valuable sources. Other states doubtless have programs and data like these, and more, that can inform EPA's evaluations*. EPA should outline in the preamble to the final rule the general steps it will take to consult with state agencies and provide additional details on these steps in individual scoping documents.*

CONCLUSION

We appreciate the opportunity to comment on EPA's proposed process for risk evaluations under amended TSCA and urge EPA to issue a sound and flexible final rule that establishes a strong foundation for science-based and protective risk evaluations under the new law.

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[48] WA Children's Safe Product Act: http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/

[49] VT Chemical Disclosure Program for Children's Products: http://healthvermont.gov/environment/children/chemicals-childrens-products

[50] ME Safer Chemicals in Children's Products: http://www.maine.gov/dep/safechem/

[51] http://www.mass.gov/eea/agencies/massdep/toxics/tur/

[52] CA Safe Drinking Water and Toxic Enforcement Act of 1986: https://oehha.ca.gov/proposition-65

[53] CA Safer Consumer Products Program: http://www.dtsc.ca.gov/SCP/index.cfm

[54] CA Department of Public Health, Occupational Health Branch Programs: https://www.cdph.ca.gov/programs/ohb/Pages/Programs.aspx