Environmental Protection Network

(202) 656-6229
environmentalprotectionnetwork.org
info@environmentalprotectionnetwork.org

EPN Comments on EPA's Proposed Rule:
Procedures for Chemical Risk Evaluation
Under the Toxic Substances Control Act (TSCA)
Docket No.: EPA-HQ-OPPT-2023-0496
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The Environmental Protection Network (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

Introduction

The Toxic Substances Control Act (TSCA), as amended in 2016, established an Existing Chemicals Review Program, whereby the agency would select and assess high-priority TSCA-covered chemical substances manufactured, processed, distributed, used, and disposed of in the U.S. and determine under what conditions they could remain in the chain of commerce without imposing unreasonable risks on human health or the environment. This was to be done in three stages: prioritization, risk evaluation, and risk management, with the decisions, policies, and practices for each stage to be codified by formal rulemaking. Generic rules for prioritization and risk evaluation were promulgated in 2017. Risk management rules are chemical-specific and developed on an individual basis.

This proposed rule-making is an updating of the 2017 procedural framework rule for conducting risk evaluations (REs). As the agency states in the Summary of the proposed rule, "EPA has reconsidered the [2017] procedural framework rule for conducting such risk evaluations and determined that certain aspects of that framework should be revised to better align with applicable court decisions and the statutory text, to reflect the Agency's experience implementing the risk evaluation program following enactment of the 2016 TSCA amendments, and to allow for consideration of future scientific advances in the risk evaluation process without need to further amend the Agency's procedural rule."

This updated risk evaluation rule reflects modifications made to existing elements of the 2017 rule, as well as consideration of new elements such as those described in the June 2021 Path Forward statement. Changes are being proposed to definitions as well as steps of the process.

EPN Comments on Proposed Changes

The proposed changes are described in the proposed rule's Unit III. Proposed Amendments.

A. Policy Objectives

EPA envisions that the modifications it is proposing will "(1) better align the TSCA risk evaluation process with the statutory text and structure and Congressional intent, (2) ensure that the risk evaluation process under TSCA is consistent with the best available science and based on the weight of the scientific evidence,

maintains the integrity of Federal decision-making, and upholds the policy in various Executive orders, (3) address the outcome of the Ninth Circuit litigation on the 2017 final rule, (4) apply lessons learned to date to improve the Agency's processes moving forward, and (5) enhance the public's understanding of how EPA expects to carry out subsequent TSCA risk evaluations."

EPN Comments: EPN believes that EPA has largely achieved the goals outlined in the paragraph cited above. If implemented to their fullest, the risk evaluations should be more transparent and understandable for the reader. Importantly, their quality will benefit from the expanded efforts proposed for enhanced stakeholder involvement in their development.

B. General Provisions

1. Applicability of Updated Procedures

EPA intends that all changes to the procedures that are implemented during the rulemaking would be applied to all risk evaluations begun on or after the date of the final rule. For those that may already be underway at the time the final rule goes into effect, EPA would attempt to apply as many of the proposed changes to the extent practicable, taking into consideration the statutory requirements and deadlines.

EPN Comments: A number of the proposed changes (such as those captured in the Path Forward statement) reflect formalization into regulation of principles and practices already articulated and applied, to at least some degree, during the revision of a number of the first ten risk evaluations. Thus, there is precedence for their inclusion, which should facilitate their incorporation into new and ongoing risk evaluations from subsequent lists of priority chemicals.

While EPN is in general agreement with the agency on when the new changes would or would not be applied to upcoming REs, we reserve judgment on the point made about not applying them in all cases where REs are underway, but not yet finished. We could envision circumstances in which exclusion of a key new provision could lead to an underestimation of risk, then leading to inadequate mitigation steps taken. We would argue that adequate protection of human health and the environment outweighs timeliness.

2. Categories of Chemical Substances

EPA is proposing to clarify in the regulatory text at section 702.31(d) that references to single chemical substances also apply to categories of chemical substances. Categories may be created based upon similar structure, similar endpoints, similar MOAs, PK characteristics, etc.

EPN Comments: We agree with EPA on creating categories where appropriate. But, history to date reveals EPA has resisted this approach in cases where others argue the category approach would be more appropriate and, ultimately, more health protective. An early test will be how the phthalate assessment evolves. There are other substances on the second list of 20 priority chemicals that also should be grouped. When that second list of priority candidates was proposed, EPN recommended that in addition to phthalates, other chemicals should be assessed together, specifically 1,1- and 1,2- dichloroethane; ortho- and para-dichlorobenzene. Even as EPA considers reducing to smaller numbers and likely revising the list of chemicals to be assessed in stages over the next few years, they still should establish and maintain categories in the assessment process.

C. Definitions

EPA is proposing changes to a number of definitions codified in the existing regulatory text. These changes include complete deletion, expansion, or modest revision of the definition. Justification for each proposed change has been provided, most of which are intended to bring the definitions into better alignment with existing or updated agency technical and policy guidance.

EPN Comments: EPN supports all of the proposed definitional changes.

D. Technical Corrections and Reorganization

EPA is proposing to make a number of minor updates and corrections and general organizational restructuring. They are summarized in this section of the proposal and captured in the final language of the proposed revised rule.

EPN Comments: EPN finds that the revisions EPA is proposing as minor updates and technical corrections and, perhaps, more importantly, general organizational restructuring, are reasonable and do result in a more orderly presentation of the process steps as well as the draft and final documents associated with each step.

E. Scope of TSCA Risk Evaluations

1. Inclusion of All Conditions of Use

EPA is proposing changes to the regulatory text to make clear that the scope of TSCA risk evaluations will *not* exclude any "conditions of use" (COU). This will remove statements or inferences in the 2017 rule that EPA could pick and choose which COU it would assess in a risk evaluation.

EPN Comments: Pre-2016 assessments of existing chemicals often did focus on only one or a very few COUs, presumably chosen because they represented a significant volume of total manufacture and use of a particular substance, possessed a reasonable amount of "readily available information," and appeared to pose high risk to workers and/or consumers. During the early days of implementation of the newly-established Existing Chemicals Review Program in 2016, it appeared that EPA might employ this pick-and-choose approach for some of the first ten chemicals in the queue. Formal public comment and other feedback challenged that approach, pointing out that this would be inconsistent with the provisions in the new law (which EPA now acknowledges) to provide adequate protection of human health and the environment and contradictory to consideration of crafting risk management strategies based upon the "whole chemical approach," espoused as one of the 2021 Path Forward principles.

We heartily support revision of text in the updated rule to state that EPA will assess *all* COUs *all* of the time. This is critical to supporting credible and robust aggregate exposure/risk assessments and cumulative exposure/risk assessments and determination of whether or not the whole chemical approach to risk management will be appropriate and implemented. Historical exclusion of some COUs as well as exclusion of consideration of exposure pathways where EPA or another regulatory agency had or could assess and regulate the same chemical under other laws resulted in an incomplete picture of the chemical's risk profile

and potentially left either the worker and/or general population subject to unreasonable risk, contrary to the updated TSCA statutory language and intent.

Solicitation of public comment on the Scoping document for a chemical chosen for risk evaluation should serve to identify all COUs and other exposure pathways so that the agency can develop a full and credible assessment of that chemical's risk profile.

2. Determination of "Conditions of Use"

While EPA now acknowledges that it should, and will, include all COUs in a risk evaluation, it also asserts that it retains the "authority to exercise judgment in making its determination as to whether a particular circumstance is intended, known, or reasonably foreseen, and therefore falls within the definition of "condition of use" for a particular chemical. As such, for each risk evaluation, EPA has and will continue to undergo a process to determine each chemical's conditions of use, analyzing reasonably available information and applying the facts, Agency expertise and professional judgment on a case-by-case basis."

EPA notes that it "would generally not include within the scope of the risk evaluation exposures associated with future extreme weather events (e.g., hurricanes and wildfires). However, if information reasonably available to the Agency indicated that factors such as rising sea levels or extreme temperatures made worse by climate change were leading to regular and predictable changes in exposures associated with a given condition of use of a chemical substance, EPA would expect to consider those exposures within the scope of the risk evaluation. EPA requests comment on alternative proposals for considering potential climate-related risks." EPN will comment on this specific issue later in this comment document.

EPN Comments: EPN concurs with this point of view and notes that the selection of the COUs for a chemical may also be a subject of public comment on the Scoping document. We also agree with the agency's intent to reconsider past regulatory actions for specific chemicals to determine if those prior actions would continue to be seen as adequately mitigating any determined unreasonable risks.

3. Inclusion of All Exposure Pathways

This issue has been a significant point of contention both before and after TSCA was amended in 2016. It came to a head when, in drafting the first ten risk evaluations, EPA "narrowed the scope of those evaluations by excluding analysis of certain exposures to the general population from releases to air, water and land." It argued that those pathways were already adequately assessed and managed—or could theoretically in the future be assessed and managed—under other EPA statutes and regulatory programs. This exclusion was roundly criticized by many public commenters, including EPN, as well as EPA's Science Advisory Committee on Chemicals (SACC). While no one was recommending that EPA necessarily regulate these ambient exposures under TSCA, they were arguing that these exposures should be aggregated with those resulting from the COUs, as appropriate, for the subpopulation being assessed. Wisely, EPA now no longer interprets TSCA section 6(b)(4)(D) to provide broad discretionary authority to exclude conditions of use or exposure pathways from the scope of TSCA risk evaluations.

EPN Comments: In this proposed rule, EPA is implementing changes to ensure that risk evaluations include *all* relevant exposure pathways. "Specifically, EPA is proposing to explicitly require that each risk

evaluation assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other Federal statutes."

Based upon early attempts to do this in revisions/additions to the first ten chemicals (e.g., 1,4-dioxane), it would appear that EPA may be intending to apply this "all routes of exposure" approach only to the general population. And, based upon the 1,4-dioxane supplemental analysis, which EPN and other commenters found inadequate in several ways, we are not comforted that an "all routes of exposure" approach will be adequately implemented for all relevant affected subpopulations. In our view, in order to credibly describe and quantify potential risks, we recommend several new steps be added to the evaluation process:

1) Exposure data from all relevant routes of exposure to a specific COU should be aggregated *before* making the (un)reasonable risk determination for that individual COU. This was never done for any COU for the first ten chemicals, a criticism EPN leveled virtually every time it submitted comments on those chemicals. The consequence of exclusion of this step was an underestimation of the risks associated with that COU and, perhaps, an incorrect determination of (un)reasonable risk.

2) Exposure data from all relevant pathways and routes of ambient exposure should be aggregated and added to the aggregated exposures from a COU before making a (un)/reasonable risk determination for that COU and/or for the whole chemical. This, too, was never done for any of the first ten chemicals, another criticism EPN leveled virtually every time it submitted comments on those chemicals. This exclusion led to the same consequence as above: an underestimation of the risks associated with that chemical and, perhaps, an incorrect determination of (un)reasonable risk. It needs to be acknowledged that workers/occupational non-users (ONUs) and consumers/bystanders are also members of the general population most of their days/lives when they are not engaged in a COU.

4. Comprehensive But Fit-For-Purpose

EPA notes that many of the changes proposed in the rule could lead to risk evaluations that are more comprehensive in scope. The question becomes "how much is enough?" "EPA asserts that the primary purpose of a TSCA risk evaluation is to support regulatory decision making—either to form the basis of a subsequent rulemaking to eliminate identified unreasonable risk under TSCA section 6(a), or to determine that the chemical does not present unreasonable risk and therefore rulemaking is not necessary," a decision to be made within a 3-3.5 year time frame.

EPN Comments: For now, EPN will reserve judgment on whether or not changes in the text of the rule will result in more robust assessments and risk determinations. The proof will emerge when draft scoping documents and risk evaluations for the next set of chemicals are issued for public comment.

5. Additional Efficiencies

Data gathering: Having sufficient data to conduct robust hazard, exposure, and risk assessments is key to successful decision-making. Ideally, a fulsome database would be available prior to, but no later than during, the prioritization phase of the review program.

EPN Comments: EPA has been lax in identifying and requesting any additional information they need from industry in order to conduct credible risk evaluations. We suggest EPA overcome this reticence and make use of all of its data-gathering authorities to get information in a timely manner, consistent with the mandated timelines.

F. Risk Determinations

1. Determinations on the "Chemical Substance"

EPA is proposing to clarify the regulations with respect to the way EPA makes a risk determination at the conclusion of the TSCA risk evaluation process. For the first ten chemicals in the Review Program, the agency determined whether or not exposures to workers/ONUs and consumers/bystanders during each COU resulted in an adequate margin of exposure (MOE). Based upon that outcome, the agency would then make a one-by-one determination that each COU represented a reasonable risk or not.

Going forward, the agency intends to make only a single risk determination for each chemical substance. This, presumably, would be done only after MOE analyses have been performed for each COU. These COU MOE analyses would provide the agency with the information to make the single risk determination and then assist in determining whether or not a specific COU should be prohibited, subjected to risk mitigation measures, or left unchanged.

EPN Comments: EPN is supportive of the agency's proposal to make a risk determination on a chemical substance rather than one-by-one on each COU for that chemical. However, we recommend any new text in a revised rule be very clear that this risk determination will not be made unless and until MOE analyses have been completed for each COU.

2. "Unreasonable Risk" Considerations

As described in the preamble to the 2017 final rule (Ref. 1 at p. 33735), EPA may weigh a variety of factors in determining unreasonable risk including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible subpopulations); the severity of hazard (the nature of the hazard, the irreversibility of hazard); and uncertainties. The proposed rule clarifies that "overburdened communities" may be considered as potentially exposed or susceptible subpopulations within a given risk evaluation. Furthermore, the agency will consider, where relevant, its analyses on aggregate exposures and cumulative risk.

EPN Comments: EPN agrees with the addition of "overburdened communities" to the groups to be considered as affected populations and, thus, the subject of evaluations that will inform the determination of unreasonable risk. And, as stated above, aggregate assessments should be conducted for each route of exposure for those involved in each COU and coupled with relevant aggregate exposures occurring in the ambient environment. Assessments done for the general human population and non-human species should incorporate aggregate ambient exposures in relevant environmental media. Cumulative assessments should be conducted for those chemicals assigned to categories.

G. Risk Evaluation Considerations

1. Occupational Exposure Assumptions

The unreasonable risk determinations for the first ten TSCA chemical risk evaluations incorporated the assumption that workers were provided and always used personal protective equipment (PPE) that achieved the stated assigned protection factor (APF) for respiratory protection, and/or used impervious gloves for dermal protection. Public comments on these risk evaluations revealed that this assumption might be credible for employers in the (larger) industrial settings, but was (far) less likely in the smaller businesses that would also be subject to regulations associated with these chemicals. Doubt was also expressed as to whether the equipment was always used and maintained even in the larger settings. EPA itself noted in some of these early risk evaluations that the assumed use of PPE in a risk determination could lead to an underestimation of the risk to workers, a position that EPN and many others articulated in their comments on the first ten risk evaluations. Some public commenters, as well as parties in litigation, argued that making risk determinations based on assumptions of PPE conflates the risk evaluation and risk management phases and the decision to consider/impose PPE use should be reserved for risk mitigation option development.

In June 2021, the agency announced it would be revisiting the risk determinations for the first ten chemicals to exclude the PPE assumptions from these determinations, shifting consideration of information on use of PPE and other ways industry protects its workers to the risk management process. An example of this shift can be seen in the proposed risk management rule for trichloroethylene, issued for public comment in October 2023.

EPN Comments: EPN is very pleased to see that EPA has made the decision to shift consideration of the use of PPE from the risk evaluation phase to the risk management phase. We were among the many commenters who argued for this shift, believing that, among other factors, it would lessen the likelihood that potential risks to workers would be underestimated and inadequate risk mitigation measures imposed.

2. Aggregate Exposure

Language in the proposed rule states that "Pursuant to TSCA section 6(b)(4)(F)(ii), when conducting a risk evaluation, EPA must "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration." While there is no mandate to conduct aggregate exposure analyses, EPA may conduct aggregate exposure analyses at its discretion. EPA is proposing slight revisions to the definition of aggregate exposure. Aggregate exposure analysis is not only used to assess exposure to an individual, but may also be used to assess exposure for a population, subpopulation, or the environment. Thus, EPA is proposing to strike "to an individual" from the definition, which is consistent with the definition used in General Principles for Performing Aggregate Exposure and Risk Assessments. Additionally, EPA is proposing to strike "single" chemical, as TSCA allows the agency to conduct risk evaluations on categories of chemicals.

EPN Comments: The proposed modifications to EPA's definitions of aggregate exposure are fine, as far as they go, but are clearly inadequate in the grand scheme of good science. As we articulated above in the section on Inclusion of All Exposure Pathways, we are not convinced that EPA will, in the future, adequately incorporate aggregate exposure assessment principles when attempting to characterize potential

risks to workers/ONUs and consumers/bystanders associated with specific COUs or to these subpopulations or the general population exposed in the ambient environment.

We repeat here our position that, in order to credibly describe and quantify potential risks, several new steps should be added to the evaluation process:

1) Exposure data from all relevant routes of exposure to a specific COU should be aggregated in every case before making the (un)reasonable risk determination for that individual COU. This was never done for any COU for the first ten chemicals, a criticism EPN leveled virtually every time it submitted comments on those chemicals. The consequence of exclusion of this step: it led to an underestimation of the risks associated with that COU and, perhaps, an incorrect determination of (un)reasonable risk.

2) Exposure data from all relevant pathways and routes of ambient exposure should be aggregated and added to the aggregated exposures from a COU, in every case where ambient exposures have been identified, before making a (un)reasonable risk determination for that COU and/or for the whole chemical. This, too, was never done for any of the first ten chemicals, another criticism EPN leveled virtually every time it submitted comments on those chemicals. This exclusion led to the same consequence as above: an underestimation of the risks associated with that chemical and, perhaps, an incorrect determination of (un)reasonable risk. It needs to be acknowledged that workers/ONUs and consumers/bystanders are also members of the general population most of their days/lives when they are not engaged in a COU.

3. Cumulative Risk

EPA currently defines cumulative risk as "an analysis, characterization, and possible quantification of the combined risks to health and/or the environment from multiple agents and/or stressors." To date, the Existing Chemicals Review program has not included a cumulative risk example in implementing the program, but could have with a small number of the chemicals in the first round of ten high-priority chemicals. That may change if/when the agency goes forward with their proposed inclusion of at least three groups of structurally-related chemicals in the next round of risk evaluations: two dichloroethanes, two dichlorobenzenes, and several phthalates.

Consideration of both chemical and non-chemical stressors together are characterized as an evaluation of cumulative impacts. EPA's Office of Research and Development has defined cumulative impacts as the totality of exposures to combinations of chemical and non-chemical stressors and their effects on health, well-being, and quality of life outcomes (Ref. 34) and may or may not include toxicologically defined risk. EPA has not to date considered cumulative impacts in TSCA risk evaluations, but may in the future as appropriate data, methods, and guidance are available.

EPN comments: EPN is comfortable with the definition of cumulative risk that the agency has chosen to use. But, more importantly, EPN urges the agency to proceed with conducting cumulative risk assessments on the three groups of chemicals cited above. Several months ago, EPA issued for comment two documents, one a draft cumulative risk framework, the other the beginning of a cumulative risk approach for the phthalates. We await the issuance of revised versions of these documents in order to see how the agency

responded to the public comments and whether or not the agency is moving forward, using the best available science.

We also need to be mindful that structural similarity is not the only criterion to be used to group chemicals for cumulative risk assessment. Other factors include shared active metabolites and/or shared endpoints of toxicity, especially those with the same or similar modes of action. On that point, when the agency does proceed with the assessment of the two dichloroethanes, we recommend they not only assess those two together but also reexamine some of the volatile chlorinated organic solvents addressed in round one (e.g., trichloroethylene (TCE) and perchloroethylene) for common elements of the criteria cited to determine if and how the group should be enlarged to include any of these because of shared aspects of their hazard profiles.

EPA notes that TSCA "explicitly requires EPA's risk evaluations to consider unreasonable risk to "potentially exposed or susceptible subpopulations," and the statute provides authority to consider non-chemical as well as chemical stressors when identifying these subpopulations.

With regard to the assessment of cumulative impacts, we urge the agency to proceed expeditiously with formulating its cumulative impact approach and for the Existing Chemicals Review program to integrate cumulative impact analysis into *every* chemical risk evaluation, whether it be for a single chemical or a defined group of chemicals, as soon as possible.

4. Potentially Exposed or Susceptible Subpopulations

TSCA requires EPA to evaluate risk to "potentially exposed or susceptible subpopulation[s]" identified as relevant to the risk evaluation under the conditions of use. TSCA defines the term as "a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."
In the proposed updated rule, EPA is interpreting "greater exposure" to potentially include fenceline communities (e.g., those communities in close proximity to facilities emitting air pollutants or living near effluent releases to water) or body burden. It is proposing to add the term "overburdened communities" to the "such as" list cited above.

EPN comments: EPN agrees with the agency's proposal to add overburdened communities to the list of subpopulations that will fall within the scope of an assessment. However, EPN remains concerned about the agency's ability to do that with a high degree of vigor. Last year, EPA submitted for peer review to the SACC and for public comment a document entitled the *Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities*. Many recommendations were made for modifications and additions to assure the technical robustness of the approach. We have yet to see a new version of the tool, so we cannot evaluate the agency's responsiveness to comments or the usefulness of the tool. The agency asserts that it is continuing to develop risk evaluation approaches to help determine risk from all relevant exposure pathways with an emphasis on exposures to overburdened communities, but nothing has been made available to date to enable us to judge progress.

H. Science Policy and Scientific Standards

1. Scientific Guidelines and Procedures

This proposed rule, as does the 2017 final rule, codifies the use of appropriate agency guidance in the development of risk evaluations. It should be emphasized that most of this guidance has been developed as consensus positions for use across EPA so the agency can present a common voice on most of the scientific principles and policies it espouses. On occasion, some modifications may be made to the agency-wide guidance to align with specific mandates in legislation.

EPN Comments: It remains appropriate for the TSCA Risk Evaluation rule to codify and continue to use appropriate agency-wide guidance in the development of risk evaluations to the greatest extent possible.

2. Peer Review

"The Agency remains committed to using peer review in the development of TSCA risk evaluations and any associated methods or approach type documents and proposes to retain the provision to require peer review in the risk evaluation process."

However, EPA is proposing some modifications to the language from the 2017 final rule to provide increased clarity on both the guidance the agency will use to conduct peer review and on what peer review will be conducted. First, the agency proposes removing the reference to specific versions of guidance documents. The 2017 final rule names specifically the EPA Peer Review Handbook 4th Edition 2015 (Ref. 39) and OMB's Information Quality Bulletin for Peer Review (Ref. 40). The agency proposes at § 702.41 to refer instead to "applicable peer review policies, procedures, guidance documents, and methods adopted by EPA and the Office of Management and Budget (OMB) to serve as the guidance for peer review activities."

The actual proposed language is slightly, but not importantly, different;

> "§ 702.41 Peer review.
> EPA expects that peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A), or portions thereof, will be consistent with the applicable peer review policies, procedures, guidance documents, and methods pursuant to guidance promulgated by Office of Management and Budget, EPA, and in accordance with 15 U.S.C. 2625(h) and (i)."

EPN Comments: EPN supports the removal of reference to specific documents in the proposed new text related to § 702.41.

I. Scientific Standards

TSCA Section 26(i) states "the Administrator shall make decisions under sections 4, 5, and 6 based on the weight of scientific evidence" but does not define either "best available science" or "weight of scientific evidence," and there is no requirement in the statute to define them by rule. The proposed 2017 rule did not contain definitions of these two terms. EPA received many comments arguing both for inclusion and exclusion of definitions for these terms and ultimately did codify definitions in the final rule.

EPA is reconsidering that decision and is now proposing to eliminate the currently-codified definitions for "best available science" and "weight of scientific evidence" from the revised regulatory text. EPA believes that codifying a definition of "best available science" and "weight of the scientific evidence" in the Risk Evaluation procedural rule is unnecessary and potentially problematic as it could limit the agency's ability, flexibility, and mandate to incorporate the best available science into TSCA risk evaluations. Flexibility is desirable as it supports the agency's ability to more quickly adopt and implement changing science to ensure that each risk evaluation is fit-for-purpose to the chemical under review. Non-regulatory guidance documents are better suited for the articulation of definitions as they can be updated more quickly and efficiently than can rules.

EPN Comments: EPN concurs with the proposal to remove the definitions for "best available science" and "weight of scientific evidence" from the revised regulatory text for the reasons described.

However, a notable and unacceptable consequence of this deletion, which must be remedied, is the removal of any mention of systematic review protocols from the regulatory language. The preamble to the current proposed rule repeatedly makes mention of "systematic approaches" (or "systemic approach") as substitutes for systematic review, without describing what these systematic approaches consist of or how they would be consistent with TSCA requirements to use the "best available science" and base decisions on the "weight of scientific evidence." The reference to undefined "systematic approaches" is also found in the proposed regulatory text, which is also the only mention of systematic review in the proposed regulatory language: "EPA will apply systematic review and/or systematic approaches to reviewing reasonably available information that are objective, unbiased, and transparent. § 702.37(b)(2)"

Although systematic review protocols are discussed in the preamble, the regulatory language of the current proposal does not include any requirement for, or any mention of, systematic review protocols. The regulatory language concerning systematic review also fails to mention key attributes of systematic review, including "comprehensive" and "consistent," which are critical elements of systematic review previously included in the definition of "weight of scientific evidence" that EPA is proposing to delete from the framework rule. It therefore appears that EPA's current proposal represents a significant retreat from systematic review principles, and thus will result in risk evaluations that are not consistent with the "best available science."

To ensure that its systematic review methods incorporate the best available science, as required by TSCA, we recommend EPA revise the current proposal to restore and/or incorporate basic principles of systematic review into the risk evaluation framework rule. As written, the proposed language will weaken provisions regarding systematic review. Instead, EPA should be strengthening their commitment.

To summarize:

1) By deleting the definition of "weight of scientific evidence" from the regulatory text, EPA would be removing several cornerstones of contemporary risk assessment, including use of a "pre-established protocol" to "comprehensively" and "consistently" identify and evaluate evidence. We recommend EPA restore these key terms to the framework rule. This could be accomplished by revision of the current proposal's regulatory language regarding systematic review (quoted above), found at § 702.37(b)(2), to the following: "EPA will use systematic review methods outlined in a pre-established

chemical-specific protocol to identify, evaluate and integrate all reasonably available relevant information based on the strengths and limitations of the evidence in a manner that is comprehensive, objective, unbiased, transparent and consistent."

2) To correct EPA's practice of omitting or excluding relevant studies, the framework rule should be revised to state that "all relevant evidence" is to be considered in conducting a risk evaluation. This would be incorporated into the § 702.37 "evaluation requirements" and "considerations" for conducting a risk evaluation.

3) We recommend EPA add language to the framework rule to clarify that "a pre-established protocol" means a document specific to each risk evaluation outlining the methods to be used in conducting systematic review for that risk evaluation, including a Population, Exposure, Comparator, and Outcomes (PECO) statement, literature search and screening methods, study quality evaluation methods, data extraction plans, data analysis methods, and methods for evidence synthesis and integration. The revised framework rule should also require that the evaluation-specific protocol is made publicly available before the risk evaluation is conducted.

Lastly, removal of certain definitions from the rule should not be interpreted as relieving the agency from updating the definitions and their implementation on a regular basis to stay current with the state-of-the science. Rather, it should be interpreted as a mandate to be more vigilant in keeping up to date with the science and making sure that this is continually communicated both within and outside of the agency. There are too many examples of still-used agency guidance documents that contain the residues of abandoned scientific principles because their currency has not been maintained.

J. Process for EPA Revisions to Scope or Risk Evaluation Documents

EPA is proposing some new procedures and criteria for whether and how EPA would endeavor to revise or supplement final scope documents, draft, or final risk evaluations. Unlike the 2017 final rule, this rule proposes criteria and procedures that would serve the law's purpose to move chemicals more efficiently through the process within the statutory deadlines, and allow the agency to move on to evaluating other high-priority substances without compromising content quality or stakeholder participation in document development.

Efficiencies proposed include:

- Earlier implementation of a tiered data collection strategy to better inform data needs for prioritization and risk evaluation candidates
- Publication of the final scope within the draft risk evaluation, rather than separately before the draft risk evaluation is completed.
- Refraining from re-issuing draft risk evaluations in a second draft form, unless major significant changes were made. The changes would be documented and highlighted only in a final risk evaluation.

This rule proposes a general practice for how and when to revisit final risk evaluations, and certain exceptions to that practice. Unlike the resource-draining and timeline-disrupting situation with the first ten chemicals, re-issuing draft risk evaluations would now be expected to be an infrequent occurrence. On those

(hopefully) rare occasions on which revision is warranted, the proposed rule will require EPA to follow the same process and requirements for TSCA that all risk evaluations must follow, including publication of a new draft and final risk evaluation, solicitation of public comment, and, as appropriate, peer review.

EPN Comments: EPN finds that the proposed process for revisions to the scope or risk evaluation documents should increase the efficiency and pace for document development, while preserving their scientific integrity and opportunities for stakeholder involvement.

K. Process and Requirements for Manufacturer-Requested Risk Evaluations

TSCA section 6(b)(4)(C)(ii) allows a manufacturer or group of manufacturers to request that the agency conduct a risk evaluation of a chemical substance (or category of substances) that they manufacture. To date, the requests have been limited to chemicals identified in the 2014 work plan, but not selected by EPA as high-priority substances for risk evaluation. EPA is proposing some modifications to increase clarity and to better position the agency to carry out manufacturer-requested risk evaluations (MRREs) moving forward. Some of these modifications will apply to agency actions, others to the requester(s).

The 2017 final rule allows requests to contain information relevant only to conditions of use of the chemical that are of interest to the requesting manufacturer. EPA must make a go or no-go decision on a very short timeline. If EPA would like to include additional COUs in the risk evaluation, it must do the work of identifying and collecting the data to cover those additional COUs. The current process also provides that upon granting the request, EPA will initiate the risk evaluation, triggering the start of the three-year statutory deadline to complete the activity. Based upon the agency's experience with several manufacturers' requests, it has become clear that the current process is unrealistic. In general, EPA believes that the process and timeframes for reviewing incoming MRRE requests should be more in line with the process and timeframes that precede EPA-initiated risk evaluations.

Several key changes are being proposed to address the challenges identified in responding to the several manufacturer's requests submitted to EPA since the 2017 rule was promulgated. They include:

1) Submission of MRRE. The current rule allows one or more manufacturers to request a risk evaluation. Multiple submissions on the same chemical were submitted but handled separately, resulting in duplication of effort on the part of the agency.

Going forward, the agency expects to treat a group/consortium as a single entity for purposes of any regulatory determinations with regard to the requests, fee payments, and other general communication regarding the MRRE request and/or the risk evaluation. Joint submitters must designate a single point of contact for agency engagement, and are otherwise collectively responsible for providing complete and sufficient information to the agency to support the risk evaluation.

2) Scope of Request

Currently, the rule allows manufacturers to request a risk evaluation on particular conditions of use of interest, leaving the agency with the heavy burden of identifying the remaining conditions of use.

EPA is proposing that manufacturers only be permitted to make requests for evaluations of entire chemical substances, not individual COUs or subsets of COUs. This is consistent with EPA's stated objective to make risk determinations on the whole chemical, not COU-by-COU.

3) Contents of the Request

As a general matter, EPA believes that the requesting manufacturer(s) should bear the primary burden of providing EPA with all information necessary to conduct a risk evaluation on their chemical substance(s). This is consistent with Congressional sentiment expressed in section 2 of TSCA, and so, EPA is proposing changes that would require more fulsome information as part of the request by the manufacturer(s). This would include a listing of all of the chemical's conditions of use, and all information known to or reasonably ascertainable by the requesting manufacturer(s) that supports the identification of those circumstances.

EPA is also proposing that incoming requests include "all information known to or reasonably ascertainable by the requesting manufacturer on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s)." This would relieve EPA of the burden of identifying the remaining conditions of use and also locating and reviewing available literature to quickly determine whether there is sufficient information to carry out a risk evaluation.

Acknowledging that the requesting manufacturer(s) may not be in a position to provide the agency with all the information necessary to complete the risk evaluation, EPA is also proposing a process to use its information collection authorities under TSCA section 4 (require manufacturers (including importers) or processors to test chemicals and report their findings), section 8 (require reporting on chemical manufacturing, processing, and use, or require the submission of unpublished chemical health and safety information from manufacturers (including importers), processors, or distributors), or section 11 (ability to inspect facilities where chemicals are manufactured, processed, stored, or held before or after their distribution in commerce) to fill in the gaps.

4) EPA Process for Reviewing Requests

EPA is proposing a number of changes to how the agency will review MRREs, given the reality that the current process simply does not allow enough time for thoughtful review of requests and consideration of potential information needs.

a. *Notice of Receipt*. EPA will provide the public with notice within 15 days that a MRRE has been received,
b. *Initial Review for Completeness*. EPA will then begin reviewing the request and supporting information against the requirements in the proposed rule to determine whether or not the request appears complete. Decisions on acceptance or rejection will be facilitated.
c. *Public Notice and Comment*. In those where EPA determines a request to be complete, EPA will submit a notice of receipt of the MRRE for publication in the Federal Register within 90 days, open a docket and provide a 60-day public comment period.
d. *Secondary Review for Suffic*iency. At the start of the public comment period, EPA would begin conducting a more in-depth review of the request to determine whether there truly is sufficient information to support a reasoned evaluation on the chemical substance(s). EPA's review during this period would encompass both the information provided with the request and any additional relevant

information that may be uniquely available to EPA. EPA's review for sufficiency will be completed within 90 days from the end of the public comment period. For requests determined not to be supported by sufficient information during this period, EPA will reject the request—informing both the requester(s) and the public of its decision. Requesters will have an opportunity to re-submit a request once supplemented to fill the identified information gaps.

e. *Grant*. For requests determined to be supported by sufficient information, EPA will proceed with granting the request and continuing the review process. There may be occasions where EPA becomes aware of critical information needs later in the process. As such, the proposed rule specifically reserves the right for EPA to identify additional information needs for the risk evaluation at any time, including after granting the MRRE request.
f. *Publication of Draft Conditions of Use and Request for Information.* EPA will next publish a notice in the Federal Register that sets out, in draft form, the agency's preliminary determination on the chemical's conditions of use, taking into account information provided in the MRRE request. This notice will request relevant information from the public, and provide no less than a 60-day public comment period. Within 90 days following the close of the public comment period, and depending on the nature of comments received, EPA will either initiate the risk evaluation or notify the requesting manufacturer of any additional information needed.
g. *Initiation of Risk Evaluation*. Upon initiation of the MRRE, EPA will notify the manufacturer that the MRRE has been initiated, and will also keep the public apprised of the status through updates to its website.
h. *Identification of Information Needs*. Where additional information needs are identified at any time before the MRRE has been granted, the proposed rule provides a clear process for supplementation and resubmittal of the request. Where a manufacturer chooses to provide the necessary information, EPA will set a reasonable amount of time for the requesting manufacturer to provide that information to EPA. Upon receipt of the new information, EPA will review the information within 90 days and determine whether or not it satisfies the identified need—again providing notice to the requesting manufacturer of its determination, and keeping the public apprised of the status of the MRRE on its website. EPA would further endeavor, to the extent possible, to make the supplemental information publicly available in the docket.
i. *Unfulfilled Information Needs.* EPA is proposing procedures in the proposed rule that account for a scenario in which information needs are not met, and the agency is simply unable to complete the risk evaluation. The proposed rule at § 702.45(g) contemplates that EPA can deem the MRRE request to be constructively withdrawn even in the absence of a request to withdraw. Any fees to be collected or refunded would be determined in accordance with this proposed rule and the TSCA fee provisions in 40 CFR 700.45.

Unit IV. Requests for Comment

EPA requested comment on all aspects of the proposed rule as discussed in Unit III. EPN has provided comments on Unit III above. In Unit IV, the agency is soliciting feedback from the public on specific issues which are summarized in this section. They are:

1. EPA requests comment on how the agency could consider potential climate-related risks in a risk evaluation.

EPN Comments: TSCA, as is true of other laws EPA has been designated to implement, contains no language that either mandates or, at a minimum, explicitly provides the discretionary authority to integrate climate-related factors into the risk assessment and risk management decision-making processes. We have seen attempts by other agency programs which were ridiculed as over-reach and soundly rebuffed in the courts (e.g., the Clean Power Plan). That doesn't mean that EPA should give up and not seek to determine whether or not exposure to evolving climate factors can alter human or ecosystem responses to exposure to chemicals in the environment. Information on these potential interactions is sparse and inadequate to make judgments. So, perhaps, the place to start is to revisit existing studies/data with an eye on re-reviewing them from a different perspective and conducting new studies which incorporate climate-related information into the equation.

For instance, heat stress is known to have adverse effects on human health. So, one might design an epidemiology study which compares the health outcomes of a study population divided into four subgroups, two of which are known to be exposed to one or more chemicals under evaluation, one of which resides and works in a heat-manageable environment and one of which resides and works in a heat-stressed environment. The other two groups would not have been exposed to one or more of the same chemicals but are split based upon whether or not they live and work in a heat-stressed environment.

Another approach might be to conduct a study, over a time span of several years, to determine whether and how the environmental fate profile of a chemical in the environment changes as the climate changes—again, heat might be a/the major stimulus.

2. EPA requests comment on the proposed approach of publishing a draft scope during the prioritization process when it is clear that the chemical undergoing the prioritization process will be designated as a high-priority chemical.

EPN Comments: The mantra should be "The sooner, the better." The agency is proposing modifications to the existing chemical review that will result in a more efficient, timely, and robust (that is, more chemicals evaluated) production process. Integrating certain multiple steps once conducted individually into fewer is desirable and doable without compromising the integrity of the process. The proposed approach described above is a sensible step and will enhance, not detract from, the integrity of the process.

3. EPA requests public comment on the proposed elimination of the definitions of best available science and weight of scientific evidence, the need for such definitions, and the utility of definitions as the state of science evolves.

EPN Comments: EPA is proposing to remove the definitions of the two terms from the text of the revised rule, thus nullifying their codification in the rule. That does not mean it is abandoning the definition or use of either term, but transferring deliberation on them to non-regulatory guidance documents which support the risk evaluation process. EPA asserts that this shift will provide it with greater flexibility to update these definitions so as to stay current as the science evolves over time. We agree with this proposed action, subject to assurance that the discussion of systematic review is retained, as recommended above.

4. EPA requests comments on the proposed changes to the process of a manufacturer requested risk evaluation. In regards to cost, while the costs to EPA would be reflected in the final invoice to the requesting manufacturer, EPA is seeking comment on, to the extent that test orders are issued to

support a MRRE, whether the entire test order fee should also be directed to the requesting manufacturer, even where the order is also issued to another entity. Additionally, EPA requests specific comment on the burden estimate of a manufacturer requested risk evaluation, including the assumptions used in estimating the burden (e.g., number of requests EPA expects).

EPN Comments: (We have summarized those proposed changes above, primarily to assist our review team as we developed our comments on the proposed rule). Our summary judgment is that we support all of the modifications that EPA has proposed to make in the process of a manufacturer requested risk evaluation.

In regards to cost, specifically with regard to testing orders, we believe the entire test order fee should also be directed to the requesting manufacturer, even where the order is also issued to another entity. The other entity will be performing the work for the manufacturer's benefit, so it should be the one to figure out whether a cost-sharing agreement would be appropriate and how it would be designed. We have no comments on the burden estimate of a manufacturer-requested risk evaluation.

5. EPA requests comment on general approaches or best practices for improving engagement with small entities. Early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical is critical for the agency to be able to accurately identify and characterize that chemical's conditions of use for consideration in the risk evaluation, EPA is seeking comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities.

EPN Comments: We have no comments on this topic.

6. EPA requests public comment on how the agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits derived from the risk evaluation process.

EPN Comments: Existing chemical exposure limits (ECELs) and unreasonable risk determinations should be derived and summarized in both the draft and final versions of the risk evaluation for each chemical undergoing review.

For the first ten chemicals, exposure estimates for each COU were derived and summarized in Section 2 of each risk evaluation, but no existing chemical exposure limits (ECELs) were established at that time. The term never appeared in any risk evaluation. Risk determinations for each COU were presented in Section 5 of each risk evaluation.

Going forward, we recommend the agency continue to derive exposure estimates for each COU. These should presume aggregate exposure by all routes directly related to a worker/ONU or consumer/bystander COU (most often inhalation and dermal, rarely oral) coupled with aggregate exposures from air, water, and soil sources, as identified in the ambient environment. These estimates should be summarized in Section 2 and documented in greater detail in an appendix to the risk evaluation.

We first became acquainted with the term "existing chemical exposure limits (ECEL)" in the proposed Methylene chloride risk management rule and again in the proposed TCE risk management rule. In neither case was there a substantive discussion of how an ECEL is determined—e.g. solely risk-based or are

additional factors considered?, candidate data sources and selection (empirical or modeled?), application in a scientifically credible mathematical formula, value/necessity of having analytical capabilities to identify LOD, LOQ, etc.

When, where, and how should the issue of ECELs be addressed in the future? Since the ECEL is an 8-hour occupational inhalation exposure limit, they would apply only to worker/ONU COUs. We offer several alternatives to consider:

1) Calculate ECELs for all aggregated exposure scenarios in all worker/ONU COUs. Summarize the findings in section 2 of the risk evaluation and prepare a more detailed discussion of their derivation as an appendix to the risk evaluation.

2) Calculate ECELs only for aggregated exposure scenarios in worker/ONU COUs for which an unreasonable risk determination has been made. Summarize the findings in Section 2 of the risk evaluation and prepare a more detailed discussion of their derivation as an appendix to the risk evaluation.

3) Calculate ECELs for all aggregated exposure scenarios in all worker/ONU COUs. Summarize the findings in the proposed risk management rule and prepare a more detailed discussion of their derivation as a support document to the proposed rule to be placed in the docket for the rule.

4) Calculate ECELs only for aggregated exposure scenarios in worker/ONU COUs for which an unreasonable risk determination has been made. Summarize the findings in the proposed risk management rule and prepare a more detailed discussion of their derivation as a support document to the proposed rule to be placed in the docket for the rule.

A factor to consider when deciding between Options 1/2 or 3/4 is whether or not the agency finds it desirable to have this information on hand before or after it makes a summary risk determination on the chemical under evaluation.

A factor to consider when deciding between Options 1 or 2 or Options 3 or 4 is the level of resources the agency is willing/able to allocate to ECEL derivation. Options 2 and 4 likely will require fewer resources as it is assumed that at least a few of the COUs will be determined to not present unreasonable risk or present an unreasonable and are proposed for immediate/near-term prohibition of future use in a proposed risk management plan. Neither would require a workplace chemical protection program (WCPP) of which ECELs are a component. The unknown is how many resources would have to be expended on ECEL derivation later if, after public comment on a proposed rule, the agency determines that one or more uses needn't be prohibited after all and can be preserved without imposition of risk mitigation measures.

Pivoting to the discussion of risk determination, going forward, they should continue to be presented for each COU in Section 5 of the risk evaluation. As posited earlier, they should be based upon whether or not the aggregated route exposures (most likely only inhalation and dermal) from the COU coupled with the aggregated route exposures (inhalation, dermal, and perhaps, oral) from the concomitant presence in the ambient environment reflect acceptable or unacceptable risk determinations for MOEs non-cancer effects or risk estimates for cancer effects. Once these individual COU risk determinations have been established, the risk determination for the chemical can be made. Both of these actions should be presented in Section 5.

The individual COUs can be presented in table form, but the decision logic for making the (whole) chemical risk determination requires extensive articulation of the decision logic applied to reach a conclusion. If additional, more detailed information is thought desirable, it can be captured in an appendix to the risk evaluation.