Environmental Protection Network

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

EPN Comments on EPA's Proposed Rule:
Procedures for Chemical Risk Evaluation Under TSCA
EPA-HQ-OPPT-2025-0260
November 7, 2025

The Environmental Protection Network (EPN) harnesses the expertise of more than 700 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

This proposed rule-making is an update of the 2024 procedural framework rule for conducting risk evaluations of chemicals already in commerce in the U.S. The 2024 rule revised the 2017 procedural framework rule in response to applicable court decisions and the statutory text as well as EPA's experience implementing the risk evaluation program following enactment of the 2016 Toxic Substances Control Act (TSCA) amendments, and to allow for consideration of future scientific advances in the risk evaluation process without need to further amend the procedural rule.

EPN finds that this proposed rule substantially reverts much of the 2024 chemical evaluation procedures to the original 2017 procedures, including reducing the number of conditions of use (COUs) and pathways of exposure considered to less than their full complement when determining whether a substance poses unreasonable risks. Other changes to steps in the process and new definitions of key terms also are being proposed. EPN objects to changes to the 2024 rule because that rule better reflects Congressional intent and statutory requirements. In addition to commenting on the issues raised in the proposed rule, we urge EPA to add a requirement that all risk evaluations must go through a full Science Advisory Committee on Chemicals (SACC) review in a public setting before being finalized.

EPN Comments on Proposed Changes

A. <u>The proposal removes the requirement to consider pathways of exposure regulated by another statute.</u>

The inclusion of all exposure pathways 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."[1] EPA argued that those pathways were already adequately assessed and managed—or could theoretically be assessed and managed—under other EPA statutes and regulatory programs. This exclusion was roundly criticized by many public commenters, including EPN[2], as well as EPA's SACC.

[1] https://www.federalregister.gov/documents/2023/10/30/2023-23428/procedures-for-chemical-risk-evaluation-under-the-toxic-substances-control-act-tsca

[2] See for example https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/05/EPN-Comments-on-Perchloroethylene.pdf; https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/02/EPN-Comments-Carbon-Tetrachloride.pdf; https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019

By not considering exposures to all COUs, as well as those associated with non-TSCA regulated scenarios, EPA grossly underestimates the risk of exposure. The general population is frequently exposed to chemicals through more than one pathway or COU. Historical exclusion of some COUs, as well as exclusion of consideration of exposure pathways where other EPA programs or another regulatory agency had assessed or could assess and regulate the same chemical under other laws, has resulted in an incomplete picture of the chemical's risk profile and has potentially left the workers,consumers, and the general population subject to unacknowledged unreasonable risk, a situation contrary to the 2016 TSCA amendments and stated intent.

TSCA must consider all exposure pathways because it is the only authority that focuses on exposure to a chemical-as-a-whole. The Clean Air Act focuses on air exposures; the Clean Water Act and Safe Drinking Water Act on water exposures; and the Resource Conservation and Recovery Act on exposure from waste disposal. The Occupational Safety and Health Act, administered by the Occupational Safety and Health Administration, focuses on occupational exposures to chemicals in some but not all settings. Furthermore, a worker living near a plant in which he or she works might also be exposed through contaminated wells as well as air emissions from the plant that transcend its boundaries. TSCA is the only place where these aggregate exposures and risks can be assessed.

EPN urges EPA to retain the 2024 requirement to include all exposure pathways, whether or not they are or can be regulated by non-TSCA statutes. When EPA makes an unreasonable risk determination for a chemical, we urge EPA to begin recommending in the risk evaluation whether new or revised regulations under a non-TSCA authority are needed.

B. <u>The proposal removes the requirement to include a "no PPE" occupational exposure scenario.</u>

The risk estimates for each COU for the first ten priority chemicals subjected to a risk evaluation included a range of personal protective equipment (PPE) possibilities. For the inhalation route for workers, it was "no PPE" and PPE with Protection Factors of 10 or 50; for occupational non-users (ONUs), no PPE was assumed. For the dermal route applicable to workers, it was "no PPE" and Glove Protection Factors of 5, 10, 25, or 20. Dermal exposure was not assessed in ONUs. Individual unreasonable risk determinations were made for each of these multiple scenarios, for workers, documenting both the assumption that no PPE was employed and, separately, that workers were provided and always used 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 of use of PPE might be credible for employees in larger industrial settings, but was less likely in the smaller businesses that would also be subject to risk management regulations for these chemicals. Public commenters also raised considerable doubt about whether the equipment was always used and maintained even in the larger businesses. 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 should be reserved for the risk mitigation option development, not the risk

/07/EPN-COMMENTS-ON-HBCDDIOXANE.JULY2019.pdf; and https://www.environmentalprotectionnetwork.org/wp-content/uploads/2019/11/Methylene-Chloride-Written-Comments-11_26_19.pdf

evaluation. That is one of the reasons why the 2024 risk evaluation procedures prohibited EPA from "considering exposure reduction based on assumed use of personal protective equipment as part of the risk determination." This approach was implemented when the next batch of risk evaluations was being drafted.

EPN urges EPA to retain the requirement of a "no PPE" scenario in the risk evaluation. It is doubtful that EPA will ever have sufficient information to verify actual and successful PPE use (not merely the existence of a policy that purports to require PPE) over an entire COU. It is critical that the TSCA risk evaluation lets the American people know the risks of a worker not using PPE for the entire duration of his/her work activity throughout their years of employment if PPE is not used. The final risk determination must be made based on the no PPE scenario since there are many known situations where PPE is not required, provided, or used.

C. <u>The proposal removes the requirement to consider all conditions of use.</u>

Pre-2016 risk assessments of existing chemicals often focused on only one or a very few COUs. The COUs were 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. EPA employed this pick-and-choose approach for some priority chemicals evaluated after the 2016 TSCA amendments. An effort to include all COUs was implemented during subsequent rounds of the development of risk evaluations of additional chemicals. Formal public comment and other feedback challenged the tailored approach, pointing out that this is inconsistent with provisions in the amended law to provide adequate protection of human health and the environment. The proposed rule appears to recognize the 2019 court decision that the risk evaluation must consider legacy uses and associated disposal, but does not commit to identifying all COUs in the scoping document.

EPN does not agree that EPA has the authority to exclude COUs from the risk evaluation. It is critical that in the scoping document, EPA identifies all COUs for a substance so the American people will know the full extent of potential exposures. It is also critical that EPA evaluate all COUs for a robust aggregate exposure/risk assessment and possible cumulative exposure/risk assessment.

The proposed rule asks for public comment on several issues related to this new limitation on the COUs subjected to risk evaluation. Public comment is requested on whether a definition of "reasonably foreseen" would enhance the transparency and predictability of EPA's decisions on whether the circumstances of manufacture, processing, distribution in commerce, use, or disposal constitute conditions of use. EPN recommends against such a definition because it is case-specific and is not needed for a chemical that has been in commerce in the U.S. for years.

Public comment is requested on whether EPA should list specific considerations for including COUs in the risk evaluation. EPA suggests that such considerations could include whether reasonable potential exists for exposure to humans or the environment; the extent to which potential risks posed by a chemical impurity can be addressed in risk evaluation for the separate chemical that bears the impurity; and the extent to which risk reduction opportunities are available for the COU. EPN is opposed to including such considerations because TSCA does not permit EPA to exclude identified COUs from risk evaluation on any basis.

Public comment is also requested on whether EPA should promulgate a definition of *de minimis* or insignificant risk. EPN is opposed to such a definition. Any *de minimis* definition would ignore the potential for aggregate risk from multiple COUs and multiple pathways of exposure and would impermissibly grant EPA discretion to exclude identified COUs from evaluation.

D. The proposal eliminates unreasonable risk determinations for the chemical as a whole.

It is critical that EPA evaluate whether or not exposures to workers/ONUs and consumers/bystanders during each individual COU result in an unacceptable margin of exposure (MOE). In addition to calculating the risks from individual COUs, however, EPA must also consider aggregate exposure from multiple COUs. Unreasonable risk determinations should be based upon whether or not the aggregated route exposures (most likely inhalation and dermal) from all the COUs coupled with the aggregate route exposures (inhalation, dermal, and possibly oral) from the concomitant presence of the same substance in the ambient environment reflect an unreasonable risk for non-cancer or cancer effects. Because this unreasonable risk determination must be based on aggregate exposures from all COUs, it would by definition apply to the whole chemical. EPA should not eliminate this whole chemical unreasonable risk determination because making discrete unreasonable risk determinations for each separate COU would ignore aggregate exposures, leading to a potentially significant underestimate of the overall risk of the chemical and the need for risk management to address that risk.

E. The proposed new rule eliminates the requirement to consider aggregate risk.

As noted in Section A above, the general population, workers, and consumers are exposed to chemicals through more than one COU or pathway, including those outside of the regulatory scope of TSCA. The 2024 rule required an aggregate risk assessment, and EPN opposes the deletion of this critically important requirement. In addition, when a class of chemicals is being evaluated such as the phthalates or per- and polyfluoroalkyl substances (PFAS), cumulative exposures should be taken into account, or EPA should state why they could not be taken into account. Cumulative exposures are exposures to different chemicals operating by the same mechanism of action or contributing to the same adverse health effect. Aggregate exposures, discussed above, are exposures to the same chemical through different pathways or routes of exposure or different COUs.

F. The proposal removes "overburdened communities" from the list of susceptible populations.

Overburdened communities are the broadest group of susceptible populations, which also include pregnant women, infants, children, and other members of the general population, including workers and those living in areas where facilities are located. A poignant example of an overburdened community is the area between Baton Rouge and New Orleans along the Mississippi River that is known as "cancer alley," which contains over 200 petrochemical plants and refineries. As of 2012, this area accounted for 25% of the petrochemical production in the United States. By the 1970s, EPA documented serious water and air pollution and rates of cancer caused by air pollution exceeding the limits of acceptable risk. This example points out the importance of examining chemical exposures beyond the fence line of chemical manufacturing and processing facilities for both significant aggregate and cumulative exposures occur here. EPA's TSCA risk evaluations would

be seriously remiss if they did not consider overburdened communities and each risk evaluation should note whether or not such communities exist for each chemical risk evaluation conducted.

G. The proposal requests for definitions of "weight of scientific evidence," "systematic review," and "best available science."

The original 2017 Risk Evaluation Framework rule and its 2024 successor both include a list of regulatory definitions, designed to communicate to the reader some measure of context and understanding as the agency describes its process for evaluating the risk of existing chemical substances under TSCA. The lists were closely aligned, although the definitions for "best available science" and "weight of the scientific evidence" that had been included in the 2017 rule were removed in the 2024 rule. EPA deemed them "unnecessary," stating that "EPA believes codifying definitions for these scientific terms limits the Agency's ability to adapt to the changing science of risk evaluation, as well as the science that informs risk evaluation, and limits the Agency's flexibility to implement and advance novel science." While there is reference to the two terms in TSCA, there is no requirement in the statute to define them by rule.

The 2024 rule also saw some minor, primarily clarifying, modifications to several other definitions which had minimal impact on their intended interpretation, and, thus, they are not the subject of discussion in the proposed revision. However, there are a number of definitions that are subjects of discussion in this proposal, and on which comment is requested.

1. While developing this proposed rule, the agency is reconsidering how best to incorporate the concepts of *best available science* and *weight of the scientific evidence* into the Framework rule. At this time, they are proposing not to develop and codify a definition of *best available science* in 40 CFR 702.33, arguing that much of the 2017 definition is incorporated into 40 CFR 702.37(a) (Evaluation requirements).

EPA should consider including a definition of *best available science* in the Definitions section of the rule. Readers of the rule will want to know how EPA is defining this concept in the context of TSCA and the Existing Chemicals Review program. They should be able to do so easily by consulting the Definitions section, not by having to shuffle through other sections trying to figure out what it might be. However, it should NOT reintroduce the definition that was included in the 2017 rule.

EPA could opt for a definition that is less wordy, but captures the same principles.

Best available science means the application of methods that make the best use of the relevant reasonably available information in conducting a risk evaluation, including methods recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) or other authoritative bodies. Examples of best available science include systematic review, benchmark dose modeling, probabilistic dose-response assessment of non-cancer effects, aggregate exposure assessment, and cumulative risk assessment. Its development relies on both peer involvement and peer review, drawing upon multiple experts across multiple disciplines.

2. EPA is proposing to include a definition for *weight of scientific evidence* as presented in section 2(e) of Executive Order 14303 (Restoring Gold Standard Science).[3] EPA believes that this definition appropriately captures the intention behind TSCA sections 6(b)(4)(F)(v) and 26(i).

The definition EPA proposes to use is:

> *Weight of scientific evidence* means an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data.

EPA chose not to include a definition for weight of the evidence in the 2024, perhaps, in good measure, because NASEM advised EPA that the term is not useful:

> "The committee views weight-of-evidence analysis as a judgment-based process for evaluating the strength of evidence to infer causation. However, it found that the phrase as used in practice has become too vague and is of little scientific use."[4]

> "The phrase *weight of evidence* has become far too vague as used in practice today and thus is of little scientific use. Its use in the literature and by scientific agencies, including EPA, is vague and varied."[5]

Rather than including a definition for weight of the evidence, we recommend EPA include a definition for *strength of the evidence*. As an example, this is the approach that EPA has used historically for determining the human carcinogenic potential of environmental agents.

EPA should adopt this definition for *strength of the evidence*, which was put forth by Tracey Woodruff's team at the University of California, San Francisco:

> "*Strength of the evidence* is a clearly-stated conclusion regarding the level of certainty in a body of evidence developed using rigorous, objective, predefined, transparent methods that minimize bias, consider all relevant studies, and assess the quality of the evidence. In instances where more than one evidence stream is evaluated (e.g., human and animal health effects evidence), strength of evidence is first determined for each evidence stream (i.e., evidence synthesis) separately, and those determinations are then combined for an overall strength of evidence conclusion (i.e., evidence integration). *Strength of the evidence* is expressed by selecting from a pre-specified set of terms such as "high," "medium," or "low;" "sufficient," "limited," or "inadequate;" or "known," "presumed," "suspected," or "not classifiable."[6]

---

[3] 90 FR 22601

[4] NRC. 2014. National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process, page 4.

[5] NRC. 2014. National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process, page 86.

[6] From comments on this proposal's docket submitted by the UCSF Program on Reproductive Health and the Environment (PRHE) and co-signed by numerous scientists, academics, and clinicians.

3. The proposal solicits comments on whether or not a definition for *systematic review* should be added to the rule.

The simple answer is an emphatic "yes."

In December 2021, the Office of Chemical Safety and Pollution Prevention (OCSPP) released a draft, "Systematic Review Protocol" to provide guidance to the Office of Pollution Prevention and Toxics' (OPPT) approach to reviewing and selecting the scientific studies that would be used to develop the chemical risk evaluations in the TSCA Existing Chemicals Program.

At the agency's request, the draft protocol was subjected to peer review by NASEM[7] and the TSCA SACC,[8] as well as public comment.

EPA claims on its Draft Protocol for Systematic Review in TSCA Risk Evaluations webpage that, in response to comments and recommendations made by the NASEM, the TSCA SACC, and the public, it has significantly updated the TSCA systematic review process and developed a systematic review protocol to address NASEM's recommendations. However, it has never issued an updated, final document and a Response to Comments, so it is not possible to discern what changes may have been made.

It is (past) time to finalize the protocol and, when doing so, to include a TSCA-relevant definition of systematic review and insert it into the Definitions section of the revised rule.

EPA should adopt the following definition of *systematic review*, which is adapted from existing definitions published by the Institute of Medicine[9] and from advice to EPA in the NASEM report on systematic review under TSCA.[10]

> "*Systematic review* is an approach to scientific investigation that that uses explicit scientific methods, pre-specified in an assessment-specific protocol, to identify, select, assess, summarize and integrate all the empirical evidence that meets pre-defined eligibility criteria to answer a specific research question with a clear statement regarding the level of confidence in the conclusion. Systematic reviews use structured, transparent and consistent methods that are aimed at minimizing bias to produce objective and reliable findings to inform decision making."

4. EPA is also requesting comment on how the Agency can apply systematic review methods for TSCA risk evaluations that leverage consideration of systematic review approaches and risk assessments from other EPA offices and authoritative bodies.

---

[7] NASEM, 2021. National Academies of Sciences, Engineering, and Medicine.The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations. Washington, DC: The National Academies Press.
[8] SACC, 2022. TSCA Scientific Advisory Committee on Chemicals. April 2022 SACC Meeting Minutes and Final Report. Washington, D.C.
[9] Institute of Medicine. 2011. Finding What Works in Health Care: Standards for Systematic Reviews, p. 1. https://doi.org/10.17226/13059) and Cochrane (Cochrane Library. About Cochrane Reviews: What is a systematic review? https://www.cochranelibrary.com/about/about-cochrane-reviews)
[10] NASEM. 2021. National Academies of Sciences, Engineering, and Medicine. The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, p.10. https://doi.org/10.17226/25952.

EPA has, in the past, made use of contemporary reviews of a chemical performed by EPA's Office of Research and Development (ORD) or other authoritative bodies such as an individual foreign government (e.g. Health Canada) or a multinational regulatory agency (e.g. European Chemicals Agency) as a resource and time-saving measure when drafting risk evaluations for a handful of substances. This makes sense, in principle. However, what was not always made clear was the process that the other party applied to identify, select, and evaluate the information used in its assessment.

It makes sense to continue considering the integration of others' efforts into a TSCA risk evaluation. But it will require some additional effort and due diligence. First, EPA must finalize its own systematic review approach consistent with the NASEM recommendations for improvement. Then, if another party's chemical assessment seems to be a viable candidate for integration into a TSCA risk evaluation, the agency must have that party share the details of the approach it used to identify, sort, select, and evaluate the information it used so that EPA can determine if the approach met the criteria the agency has determined are required when performing such a review for TSCA purposes. Only if it passes that test should the agency make use of it. Otherwise, it should just be set aside and not used in a risk evaluation.

H. **The proposal limits information submitted by manufacturers requesting an evaluation.**

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 small number of requests have been limited to chemicals included in EPA's pre-Lautenberg 2014 work plan but not yet selected by EPA as high-priority substances for risk evaluation. TSCA section 6(b)(4)(C)(ii) directs EPA to establish the "form . . . manner and . . . criteria" for such requests by rule, which the agency finalized for the first time in its Risk Evaluation Framework rule in 2017.

A number of process changes were made in 2024 based on EPA's experience carrying out the Existing Chemical Review program, including the handling of manufacturers' requests and implementing TSCA section 6(b) in general. Some modifications were made and some new requirements were added. Not all of those changes are finding favor with the current administration. Thus, this second revision to the rule has been drafted for public review and comment.

EPA is requesting comment on all aspects of the changes being proposed to the requirements for manufacturer-requested risk evaluations, but specifically whether the proposed revision to 40 CFR 702.45(a)(8) regarding information known to, or reasonably ascertainable by the manufacturer, or a different standard, is appropriate for manufacturer requests.

Some areas being proposed for modification that pertain to manufacturers' requests may also be relevant to agency-executed risk evaluations. Thus, any modifications made for one set of risk evaluations must be compatible with any made for the other.

1. Limiting scope of COUs for inclusion in a risk evaluation

The agency's current proposal to revise the rule includes narrowing the scope of information that the manufacturer(s) would be obligated to provide to the agency when making a request for the agency to conduct a risk evaluation for its/their chemical(s). If implemented, the agency would be

obligated to evaluate a chemical or category of chemicals based only on the set of COUs that the requester(s) identify.

EPN believes that no risk evaluation should be conducted unless it addresses *all* existing COUs, while continuing to make unreasonable risk evaluations on each and every COU individually and on all of those combinations of COUs for concomitant (aggregate) exposure scenarios. To do otherwise is certain to result in flawed conclusions about, and, undoubtedly, significant underestimates of, the potential risks associated with exposure to the chemical in the aggregate, which reflects a more realistic situation and which provides an enhanced opportunity to protect public health and the environment, key elements of EPA's stated mission. The risk determination should therefore be based on the risks posed by the whole chemical.

2. Responsibilities for collecting information on COUs

The 2024 final rule requires the manufacturer(s) to provide all information "known to or reasonably ascertainable by" the requesting manufacturer(s) regarding a chemical substance's (or category of substances') COUs, hazards, and exposures. As EPA notes in the preamble of the proposed rule, 40 CFR 702.43(a)(8) defines the phrase "known to or reasonably ascertainable by" as including all information in the requesting manufacturer's possession or control, as well as information obtained through a thorough search of publicly available information, a reasonable inquiry within the requester's entire organization, and a reasonable inquiry outside of the requester's organization, including suppliers and downstream users. This outside inquiry is expected to extend beyond parties within the manufacturer(s)' personal chain of commerce. In addition, 40 CFR 702.43(e)(7) provides that, should EPA determine that additional information is needed to carry out the risk evaluation, the requester has three options: to provide the requested information, withdraw the risk evaluation request, or ask that EPA use its authorities under TSCA sections 4, 8, and 11 to obtain the information because the information needed is not reasonably ascertainable to the requester.

EPN believes that the manufacturers' information requirements with regard to the range of COUs contained in the current rule (that is, to provide information on *all* COUs, not just those associated with the manufacturer(s), its/their suppliers and customers) are appropriate and should not be scaled back in any revision of the rule.

Consistent with this opinion, EPN believes EPA should *not* delete the phrase "EPA will not exclude conditions of use from the scope of the risk evaluation" from 40 CFR 702.37(a)(4), as is proposed.

The burden of information collection should be shared between the agency and the requester(s) in a more balanced way than was the case in the original 2017 rule or as envisioned in the current proposal. The 2024 rule language reflects a better balance, although it may not be fully equal. It should be highlighted that a granted request provides the significant benefit to the requester(s) of jumping ahead in the queue. And as noted above, the requester(s) can always ask EPA to use its authorities under TSCA to obtain the information to fill the data gaps that the requester could/did not identify, even after exercising due diligence in an attempt to do so. If EPA uses its TSCA authorities to develop or request additional information from the manufacturer(s) or the public, no decision on granting or rejecting the manufacturer's request should be made until the agency has had the opportunity to judge the information's completeness, as is current practice. Within 90 days following the close of the period during which EPA requests comment on a draft set of COUs and solicits additional information from the public, EPA must determine whether further information is

needed to carry out the risk evaluation and notify the requesting manufacturer(s) of its decision. If EPA determines that no further information is necessary, EPA is obligated to immediately initiate the risk evaluation, triggering the statutory three-year timeline for completion of the evaluation.

To reprise, EPA's current proposal is all about scaling back. It argues that no manufacturer should be obligated to pursue the collection of information on COUs that they, their suppliers, and their customers are not directly engaged in. This change is said to be made, in part, in the name of efficiency, when it is likely to have quite the opposite effect.

3. Nuances of proposed revisions to language in the proposed rule

As discussed above, EPA is proposing to revise 40 CFR 702.45(e) to limit manufacturer information obligations to information about the identified COUs, and to clarify the decisions EPA will make regarding request completeness and the result of the request. In general, EPA will grant requests that are complete and that provide sufficient information to permit EPA to complete a risk evaluation on the identified COUs.

EPN does not agree with this proposed revision of this text, given the agency's proposed definition/interpretation of "intended." As EPN argued above, "intended" COUs should not encompass only those which the requester(s), their suppliers, and their customers are directly engaged in, but rather to include all other COUs which the requester(s) should be obligated to identify following a reasonable level of effort searching outside of their immediate sphere.

The agency proposal claims that to narrow the number of COUs to be evaluated would lead to greater efficiency. That may be true in the abstract because fewer COUs analyses would be required, theoretically saving some time and resources. However, the tradeoff is potentially quite sinister because an incomplete assessment of a chemical's potential risks results in a tangible, negative impact on the level of protection of public health and the environment. Further, the greater number of COUs excluded from analysis, the greater the impact.

4. Allowable one-year delay

The proposal states that, to the extent that EPA lacks other information needed to perform a comprehensive risk evaluation on the chemical substance, such as information about other conditions of use, revised paragraph (e)(7) would require EPA to develop a strategy to obtain the information and would permit EPA to delay initiation of the risk evaluation on the chemical substance for up to one year in order to obtain the information using available TSCA authorities.

EPN has no objection to the proposed language in this section. However, based upon past practices in developing previous risk evaluations, TSCA information-gathering tools have been used sparingly. Not openly acknowledged, but it appears that EPA has chosen not to request any information that would likely take a year or more to develop, even when the data gap is substantial and could make a difference in the assessment. The agency has attempted to manage this situation by employing a range of work-arounds in most cases, using surrogate data, models, and/or a variety of computational tools.

5. Withdrawal of request and payment of fees

EPA is proposing to revise the text in Section G (related to withdrawal of a request) and Section K (related to payment of fees) to clarify that manufacturer requests that are withdrawn before the request is granted do not incur fees.

This proposed change may appear reasonable on its face until one considers the level of effort that EPA may have already expended up until the point in time the withdrawal request is made. Coupled with the proposed shift in responsibility for identifying COUs not directly attributable to the requester(s), its/their suppliers or customers, agency resource expenditure could be significant before the decision point to grant (or deny) a request is reached.

EPN does not agree with the proposal of a blanket no-fee policy if a request is withdrawn before the request is granted. Rather, a structured, pro-rated fee schedule should be developed, informed by the level of effort the agency has expended to that point.

I. <u>The proposal requests comment on the date when new procedures apply.</u>

The proposed rule states that when finalized, the new risk evaluation procedures will apply to all risk evaluations initiated on or after the date of the final rule and to risk evaluations that are in process, but not yet finalized, as of the date of the final rule. EPA asks for public comment on whether the new procedures should apply to evaluations initiated prior to the effective date of the rule and whether it should apply retroactively to already finalized risk evaluations.

EPN opposes application of these less protective risk evaluation procedures to any evaluations completed or initiated before the date of the final rule. If the final rule is similar to the proposed rule in narrowing the conditions of use and pathways of exposure considered in risk evaluations, it will be litigated and potentially struck down by the courts. EPA's entire rationale for undertaking the third rulemaking in eight years on existing chemical risk evaluation procedures is to speed up the evaluation of 20 or more chemicals each year. Application of these less protective procedures to older risk evaluations would create a backlog of evaluations, depriving the American people of any near-term reduction in risks from chemicals with known toxicity. Furthermore, it would be an inappropriate expenditure of monetary and staffing resources.