**Comments of the Environmental Defense Fund on**
**Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act**
**Proposed Rule, EPA–HQ–OPPT–2016–0654**
**82 Federal Register 7562-7580 (Thursday, January 19, 2017)**
**Submitted March 20, 2017**

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on its proposed rule on procedures for conducting risk evaluations of chemical substances under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

EDF strongly supports most aspects of EPA's proposed rule implementing the Lautenberg Act's requirement that EPA establish, by rule, a process to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." [TSCA as amended, section 6(b)(4)(A) and (B)]

However, we do not support several specific aspects of the proposed rule or believe they need to be modified, as detailed in these comments. In addition, there are several provisions we believe need to be added to EPA's rule to be consistent with or meet the requirements of the Lautenberg Act.

Our comments follow, addressing:

- Scope of this rule
- Definitions
- Establishing the scope of a risk evaluation
- EPA-initiated risk evaluations
- Third-party draft risk evaluations
- Industry-requested risk evaluations
- Risk characterization methodologies, guidance and other considerations
- Public information, confidential information and peer review
- Other issues

**TABLE OF CONTENTS**

**OVERARCHING POINTS.....5**

**SCOPE OF THIS RULE .....7**

1. EPA has appropriately proposed a risk evaluation rule that is procedural in nature, and leaves the specifics of science policy issues to guidance documents and policy statements. .....7

a. Codification of the details of science policy requirements in a rule is not practical or sound policy. .....7

b. The law calls on EPA to use its rule to establish a *process* for risk evaluation, not a prescriptive manual for conducting one. .....7

c. The law expressly provides for and calls on EPA to rely on policies, procedures and guidance to carry out the law, but does not call for their specification through this or any other rule. .....8

d. Section 26 science policy requirements apply to a broad range of actions under the Act, including those where there is no requirement to promulgate an underlying rule. .....8

2. EPA needs to do more to coordinate between the prioritization and risk evaluation processes to ensure deadlines are consistently met. .....9

a. EPA should clearly define the points of initiation and completion of the prioritization and risk evaluation processes in the risk evaluation as well as prioritization rules. ..... 9

b. The timing of the prioritization and risk evaluation processes must be closely coordinated. ....10

**DEFINITIONS .....11**

3. In guidance but not the risk evaluation rule, EPA should further delineate what is included in "Intended, known, or reasonably foreseen" conditions of use. .....11

4. EPA's proposal rule has appropriately proposed an inclusive approach to identifying "potentially exposed or susceptible subpopulations." .....13

**ESTABLISHING THE SCOPE OF A RISK EVALUATION .....14**

5. EPA has appropriately proposed to provide a public comment opportunity for risk evaluation scopes, but needs to make it a firm requirement. .....14

6. EPA's conclusion that it must consider all conditions of use of a chemical in the scope of a risk evaluation is acceptable, subject to certain conditions. .....15

7. EDF agrees with EPA's position that the law requires risk evaluations to be conducted and risk determinations to be made on chemical substances as a whole, not on specific conditions of use. ....16

8. EPA's proposal to ''lock down'' the conditions of use included in a risk evaluation at the time of scoping is acceptable, with some conditions. ..... 16

9. The descriptions of the elements of a risk evaluation scope included in EPA's proposed rule are too limiting or ambiguous..... 18

**CONDUCT OF RISK EVALUATIONS ..... 18**

10. EPA's proposal generally to initiate a risk evaluation only when it determines sufficient information is reasonably available to complete the risk evaluation in the allowed timeframe is acceptable, with some conditions. ..... 18

11. EDF agrees that EPA should have authority to temporarily bifurcate a risk evaluation in order to expedite risk management of high-risk conditions of use..... 19

12. EPA should generally assess exposure on an aggregate basis across the conditions of use, and needs to modify its definition of sentinel exposure. ..... 19

13. EPA's proposal to require that all issues on draft risk evaluations must be raised during the public comment period, and cannot serve as a basis for later objections or challenges, is acceptable, with some conditions..... 21

14. EPA needs to provide a 90-day public comment period for draft risk evaluations. ..... 22

15. EPA should make clear that risk determinations are to be based on risk evaluations..... 22

**THIRD-PARTY DRAFT RISK EVALUATIONS ..... 22**

16. Third-party draft risk evaluations need to be made publicly available with opportunity for public comment..... 23

17. EPA should never rely solely or even principally on third-party draft risk evaluations..... 23

18. Third-party draft risk evaluations should conform to EPA's guidance. ..... 23

19. The scope of third-party draft risk evaluations should not determine or limit the scope of EPA's risk evaluation..... 23

20. EPA should specify and adhere to clear deadlines for submission of third-party draft risk evaluations..... 24

**INDUSTRY-REQUESTED RISK EVALUATIONS ..... 24**

21. EPA has appropriately provided that EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, is to establish the scope of the risk evaluation..... 25

22. EPA appropriately proposes that manufacturers requesting risk evaluations demonstrate that there is sufficient information available to complete the risk evaluation for all conditions of use..... 26

23. EPA's rule should make clear that the fees required of a manufacturer making a request for a risk evaluation must be sufficient to cover the full or 50% portion of EPA costs for the *full* risk evaluation EPA conducts. ..... 27

24. EPA has, and should exercise, discretion as to the timing of initiation of industry-requested risk evaluations. ..... 27

25. EPA should not initiate industry-requested risk evaluations until it has received the applicable fees mandated to defray its costs. ..... 28

26. EPA should demonstrate a broad societal benefit in order to give preference to an industry request for a risk evaluation on a chemical that is subject to state restrictions. ..... 29

27. EPA has inappropriately applied its preference criteria for determining whether, and if so, which industry requests for risk evaluations to grant only to those it would consider after meeting the 25% threshold. ..... 30

28. EPA needs to provide public notice of and an opportunity to comment on all industry requests for risk evaluations, not just notice of their receipt, and also needs to make public its decision on each such request and the basis for it. ..... 30

29. EPA must not allow companies to submit information after the close of the comment period when it does not allow other stakeholders to do so. ..... 31

**RISK CHARACTERIZATION METHODOLOGIES, GUIDANCE AND OTHER CONSIDERATIONS ..... 31**

30. EPA should modify its definition of "variability." ..... 31

31. Principles of systematic review should be incorporated into the TSCA risk evaluation process, but details of its application should not be specified in the rule. ..... 32

32. EPA should move away from its margin-of-exposure (MOE) approach for non-cancer effects. ... 33

33. EPA should not codify specific guidance in its risk evaluation rule. ..... 34

34. EPA should exercise caution in relying on models and assumptions rather than using its new data-collecting authorities under the recent TSCA amendments to address data-poor chemicals. ..... 34

35. EPA's rule should avoid assigning greater weight to guideline studies or limiting its use of the published scientific literature in characterizing chemical risks. ..... 35

36. EPA's proposal to formally call for consideration of alternative interpretations of data and analyses is not in TSCA and appears to be at odds with a weight-of-the-scientific-evidence approach. ..... 35

37. EDF supports EPA's decision not to define or specify "weight of the scientific evidence" in its rule. ..... 36

**PUBLIC INFORMATION, CONFIDENTIAL INFORMATION AND PEER REVIEW ..... 36**

38. Full studies considered, included and excluded in the risk evaluation process should be publicly available. ..... 36

39. EPA's rule appropriately codifies the law's confidential business information (CBI) requirements for industry-requested risk evaluations, but needs to broaden their applicability to all CBI claims in information submitted under the rule. ..... 38

40. Peer reviews of EPA risk evaluations need to use procedures to ensure reviewers do not have conflicts of interest. ..... 39

**OTHER ISSUES ..... 39**

41. EPA's proposed authority to revisit a risk determination is acceptable, subject to certain limitations. ..... 39

42. EPA needs to take a broad approach in guidance to evaluating chemical substances that are persistent or bioaccumulative. ..... 40

43. EPA appropriately proposes to be able to conduct risk evaluations of categories of chemical substances, with some clarifications needed. ..... 41

44. EPA's proposed rule inappropriately suggests EPA would not necessarily use already existing information derived from testing on vertebrate animals. ..... 42

## OVERARCHING POINTS

EDF believes that an effective risk evaluation rule will:

- be operable for an extended period of time without frequent revision;
- set forth a transparent process that allows for appropriate opportunities for public comment;
- ensure sufficient information is available in a timely manner to inform risk evaluations;
- allow EPA to routinely meet deadlines for completing risk evaluations; and
- avoid codifying science policy issues that would be better left to guidance and policy statements.

EDF emphasizes the following broad needs for EPA's rule:

*Need for a process that is compatible with reasonably available information and applicable deadlines*: EDF generally agrees with EPA's rationale regarding the need for its risk evaluation process to be compatible with the extent to which information is reasonably available and the need to meet applicable statutory deadlines. We also generally agree that undertaking or requiring extensive information development *during* the risk evaluation process will in many cases not be feasible. (See also comments 10 and 22 below.)

*Need to mandate information development early and often*: However, this reality means that EPA needs to aggressively make use of its information collection and development authorities under sections 4, 8 and 11(c) of TSCA, both prior to and during its prioritization and risk evaluation processes. It is critical that EPA not exclude from these processes chemical substances that could present significant risk merely because it lacks or cannot ensure timely development of information needed to conduct a full

risk evaluation within the allotted timeframes. EDF is concerned that otherwise the processes could be heavily biased toward relatively information-rich chemical substances, which may not be those most warranting risk evaluation. (See also comment 10 below.)

*Need to consider conditions of use*: EDF accepts EPA's conclusion that it must consider all conditions of use of a chemical substance in conducting a risk evaluation, including those that are known, intended and reasonably foreseen. However, EDF believes the law also provides EPA with authority to:

- apply different levels of analysis to different conditions of use in order to inform unreasonable risk determinations for a chemical substance;
- conduct risk evaluations in phases where particular conditions of use clearly present unreasonable risk and expediting risk management is warranted, subject to the conditions that:
    - EPA still completes its RE of all conditions of use within the statutory timelines;
    - EPA's risk determination applies to the chemical substance and not to specific conditions of use; and
    - EPA cannot conclude that a chemical substance does not present unreasonable risk until and unless it determines that no condition of use presents such risk, including for all identified potentially exposed or susceptible subpopulations.

  (See also comments 6, 7 and 11 below.)

*Need to avoid establishing an overly prescriptive process by rule*: As discussed in more detail below, EDF strongly supports EPA's decision not to codify specific scientific policies, procedures and guidance in this rule. To do so would not be consistent with the law and would more generally represent bad policy. EDF also agrees with EPA's proposal not to define in its rule science policy-laden terms such as "weight of the scientific evidence," "best available science," and "unreasonable risk." These concepts are best elaborated on in guidance and policy statements and best understood in the context of specific decisions on chemical substances. (See also comments 1, 31, 33, and 37 below.)

*Need to avoid codifying an interagency process in this rule*: EDF strongly supports EPA's decision not to propose codifying an interagency process in this rule. The executive branch already has the means to ensure appropriate interagency review regarding any aspect of any agency's work, and can adapt and modify these processes at it sees fit. Such processes may evolve over the course of a statute's implementation lifespan, so locking a process into a rule is too rigid an approach.

*Need to promulgate this rule by the statutory deadline of June 22, 2017*: It is vital that EPA meet its 1-year statutory deadline for promulgating this rule, as well as the other "framework" rules governing the processes to be used for inventory notification and prioritization. Because these rules establish processes that will require several years to begin to yield decisions on specific chemicals, delays in promulgating them in final form so that the processes can commence in the timeframe Congress intended will only serve to undermine public confidence in the new law, counter business interests to restore confidence in the chemicals marketplace, and hamper EPA's ability to carry out its new mandates. This is especially the case, given EPA's appropriate recognition in the preamble to this

proposed rule that it will need to initiate measures as soon as possible to drive information development so that sufficient information will be available to inform prioritization and risk evaluation decisions on chemical substances beyond the first 10 substances for which risk evaluations have just commenced.

## SCOPE OF THIS RULE[1]

### 1. EPA has appropriately proposed a risk evaluation rule that is procedural in nature, and leaves the specifics of science policy issues to guidance documents and policy statements.

#### a. Codification of the details of science policy requirements in a rule is not practical or sound policy.

EDF agrees with EPA's decision to limit the risk evaluation rule to establishing basic work flows and processes that will be relevant and able to be used years – and even decades – from today. Rulemakings, which are developed through time- and resource-intensive processes, are not appropriate vehicles for tackling significant science policy issues. EDF believes that the details of the science policy issues related to risk evaluation, including those raised in sections 6(b)(4)(F), 26(h), and 26(i), are better addressed in guidance documents and policy statements that are more nimble and, therefore, can adapt to reflect the most current scientific understandings. In particular, the terms "best available science" and "weight of the evidence" should *not* be explicitly defined or expounded on in the rule, which would overly prescribe these science policy issues that are far broader in applicability than just TSCA, are under active debate, and evolve over time as the underlying science changes in a manner could require frequent updating of the rule to keep pace with the science. Rather, the agency may choose to utilize existing guidance, revise existing guidance, or develop new guidance to fulfill this need.

#### b. The law calls on EPA to use its rule to establish a *process* for risk evaluation, not a prescriptive manual for conducting one.

Section 6(b)(4) establishes the requirements for the risk evaluation process and deadlines, including what is to be done by rule, and what is otherwise applicable without being incorporated into a rule. Section 6(b)(4)(B) states: "Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a *process* to conduct risk evaluations in accordance with subparagraph (A)" (emphasis added). The reference in this provision to subparagraph (A) incorporates the purpose of the risk evaluation:

> (A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an

[1] Not be confused with the scope of a risk evaluation, which is discussed later in these comments.

> unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

EPA has directly incorporated references to the other provisions of section 6(b)(4) into its rule, affirming their applicability to risk evaluations conducted pursuant to the rule:

- Section 6(b)(4)(C) at §702.35(a)
- Section 6(b)(4)(D) at §702.39(a)(1) and (c)
- Section 6(b)(4)(E) at §702.37
- Section 6(b)(4)(F) at §702.41(a), §702.39(a)(4) and §702.39(e)(1)

EPA has directly incorporated references to the science policy provisions of section 26(h) and (i) into its rule, also affirming their applicability to risk evaluations conducted pursuant to the rule:

- Section 26(h) at §702.39(a)(4), (b)(4), (c)(3), and (c)(5) and §702.41(b) and (c)
- Section 26(i) at §702.39(a)(4)

Beyond this, any further delineation of these requirements and concepts is not required under the law to be implemented by rule, and for the reasons already discussed, is more appropriately accomplished through guidance documents and policy statements.

**c. The law expressly provides for and calls on EPA to rely on policies, procedures and guidance to carry out the law, but does not call for their specification through this or any other rule.**

Section 26(l)(1) describes the important role that policies, procedures and guidance play in EPA's carrying out of its responsibilities under the law:

> Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

This provision does not require that such policies, procedures and guidance be developed in this or any other rule. EPA's proposed rule acknowledges the need to rely both on existing guidance and to develop new guidance as appropriate. These documents describe in detail how EPA has or will apply the science policy requirements and concepts applicable to risk evaluation.

**d. Section 26 science policy requirements apply to a broad range of actions under the Act, including those where there is no requirement to promulgate an underlying rule.**

Finally, it is important to recognize that the scientific standards in sections 26(h) and (i) apply to *all* science-based decisions under sections 4, 5 and 6; that is, they apply not only to risk evaluations, but to other actions under section 6 (i.e., prioritization and risk management) as well to testing under section 4 and new chemical reviews under section 5. Two points follow from this:

- First, of these areas of applicability, procedural rules are required to be promulgated only for the prioritization and risk evaluation processes under section 6. Clearly Congress did not intend, therefore, that a rule incorporating the requirements was needed in order for them to apply.
- Second, there is no question that the law's scientific standards in sections 26(h) and (i) apply equally to decisions made under all three sections, as no distinction is made among the three in the law. Hence, EPA decisions on new chemicals are to be based on the same scientific standards as those for existing chemicals, and those standards apply to the same degree. EPA must consider the same factors relating to data quality, uncertainty and variability and independent verification when making a decision about a new chemical as it does for an existing chemical decision. Were EPA to specify in detail such standards in the present rule, those specifications would need to apply equally to EPA's reviews of new chemicals under section 5.

**2. EPA needs to do more to coordinate between the prioritization and risk evaluation processes to ensure deadlines are consistently met.**

**a. EPA should clearly define the points of initiation and completion of the prioritization and risk evaluation processes in the risk evaluation as well as prioritization rules.**

The new law ties specific actions and deadlines to the initiation and completion of the prioritization process and the initiation and completion of a risk evaluation. Here are three such key provisions:

> ***Upon designating a chemical substance as a high-priority substance***, the Administrator shall ***initiate a risk evaluation*** on the substance. [section 6(b)(3)(A)]
>
> The Administrator shall designate at least one high-priority substance ***upon the completion of each risk evaluation*** (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)). [section 6(b)(3)(C)]
>
> The Administrator shall, not later than 6 months after the ***initiation of a risk evaluation***, publish the scope of the risk evaluation to be conducted … and, for each designation of a high-priority chemical substance, ensure not less than 12 months between the ***initiation of the prioritization process*** for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance… . [section 6(b)(4)(D)]

EPA's proposed risk evaluation rule also uses these terms, referring specifically to the "initiation of the risk evaluation process" §702.39(c)(6)(ii)), the "initiation of a risk evaluation" (§702.39(c)(6)(iv)(A)), and the "initiation of the prioritization process" (§702.39(c)(6)(iv)(B)). It also refers to the "completion of a risk evaluation" (§702.37(e)(3)(ii)), and the preamble refers to the "completion of the prioritization process" (section III.G., p. 7569). There are many other relevant provisions where variants on this language (i.e., "initiate," "initiated," "complete" or "completed") are used (e.g., at §§702.37(b)(3), 702.37(e)(4), and 702.43(b)(1)).

To ensure these terms are precisely understood, and to facilitate a smooth and transparent process and transition between prioritization and risk evaluation, EPA's prioritization and risk evaluation rules need to clearly define and consistently apply these important "trigger points." EDF believes the following delineations of the trigger points are required by or supported in the law and would provide for the most efficient overall process:

- The date of initiation of the prioritization process should be the date on which EPA identifies a chemical to be subject to prioritization, pursuant to section 6(b)(1)(C).
- The date of completion of the prioritization process should be the date on which EPA publishes the designation of a chemical as a high- or low-priority substance.
- The date of initiation of a risk evaluation should be the date on which EPA publishes the designation of a chemical as a high-priority substance.
- The date of completion of a risk evaluation should be the date on which EPA publishes the final risk evaluation.

Using these definitions:

- the phrase in section 6(b)(3)(A) "Upon designating a chemical substance as a high-priority substance" means the date of that designation, which also corresponds to the initiation of the risk evaluation; and
- the phrase in section 6(b)(3)(C) "upon the completion of each risk evaluation" means that date of its publication, by which date EPA is to designate at least one new high-priority substance.

While EPA's proposed rule is consistent with this approach, the rule needs to specifically define these trigger points lest there be later confusion or contention over them or they be inconsistently applied.

**b. The timing of the prioritization and risk evaluation processes must be closely coordinated.[2]**

Section 6(b)(3)(C) of the new law states: "The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii))." To meet this requirement, EPA will need to have initiated the prioritization process on at least one new substance that will in the end be designated a high-priority substance 9-12 months preceding the completion of each risk evaluation. Thus, coordination will be critical to ensure there are an appropriate number of chemicals in line to be designated high priority for which risk evaluations can be initiated to replace those being completed.

In the preamble to EPA's proposed prioritization rule, EPA describes how it proposes to ensure a timely coordinated process (pp. 4827, 4833),[3] which EDF generally supports. However, such a procedure is not included either in the text of that proposed rule or this one; it needs to be added.

[2] EDF recognizes that the needs described here could be addressed through EPA's prioritization process rule instead of or in addition to this rule.

EDF believes that the needed coordination between the timing of the prioritization and risk evaluation processes would be further facilitated through use of the annual plan called for in section 26(n). For example, the annual plan could be used to align the number of proposed designations of high-priority chemicals with the number of chemicals for which risk evaluations are expected to be completed in a given year, as well as to communicate that alignment to the public.

Through these approaches, EPA can avoid developing either a backlog of high-priority chemicals designated or awaiting designation, or downtime waiting for prioritization designations to be completed that would result in a delay in both initiating new and completing ongoing risk evaluations.

## DEFINITIONS

### 3. In guidance but not the risk evaluation rule, EPA should further delineate what is included in "Intended, known, or reasonably foreseen" conditions of use.

In conducting a risk evaluation, EPA is to address a chemical under its "conditions of use," which TSCA defines as "the circumstances, as determined by the Administrator, under which a chemical substance is *intended, known, or reasonably foreseen* to be manufactured, processed, distributed in commerce, used, or disposed of" [section 3(4), emphasis added].

In identifying circumstances that are "intended," "known" or "reasonably foreseen," EDF believes that EPA needs to interpret these terms relatively broadly to reflect real-world conditions and uses of chemicals, including in products, that are undergoing risk evaluation.

For example, consumers' actual usage of products covers a spectrum often considerably broader than that intended or directed by its producer.[4] The maker of a laundry detergent may call for the use of one capful per load, but many consumers may intentionally or inadvertently use considerably more (or less)

---

[3] EPA states on p. 4833 in the preamble: "In the notice published in the Federal Register finalizing the designation of a new High-Priority Substance, EPA will identify the complete or near-complete risk evaluation that the new High-Priority Substance will replace. So long as the designation occurs within a reasonable time before or after the completion of the risk evaluation, this will satisfy Congress' intent while avoiding unnecessary delay and the logistical challenges that would be associated with more perfectly aligning a High-Priority Substance designation with the completion of a risk evaluation."

[4] Many companies directly study or even quantify the actual use of a product by "real" consumers, through direct observation, "habits and practices" surveys, and analysis of the usage rates through sales data, purchase frequencies, etc. Companies may even use such data to project future sales of products based on rates of usage that differ from the directions the company provides its customers. See, for example, Covey, M. "Spring Cleaning: Scrubbing Deeper with Household Products Purchase Data." InfoScout Blog, 5 April 2016. http://blog.infoscout.co/spring-cleaning-scrubbing-deeper-with-household-products-purchase-data/; and Arizona State University, W.P. Carey School of Business. "Harvesting habits: How marketers can use purchasing cycles to increase sales." 1 October 2012, http://research.wpcarey.asu.edu/marketing/harvesting-habits-how-marketers-can-use-purchasing-cycles-to-increase-sales/.

than directed. In identifying "reasonably foreseen" use of a product and assessing potential risks, EPA should clearly account for such unintended usage.

Consumers may also reasonably be expected to use a product in ways or for purposes that go beyond that strictly intended by the product maker. Use of a product intended to clean bathroom surfaces might, for example, also be used in the kitchen, or a product marketed to clean hubcaps might be used on a barbeque grill. Here again, these "off-label" uses are clearly "reasonably foreseen" and are important to consider because they could alter exposures to a chemical in such a product.

Certain "accidental" conditions of use of a chemical, including misuse, may also be "reasonably foreseen." A child's ingestion of a brightly colored detergent "pod" by mistaking it for candy clearly could and should be reasonably foreseen.

Predictable accidental releases of or exposures to a chemical should likely also be considered as "reasonably foreseen." The statute makes explicit reference to one such circumstance: The inclusion of "storage of a chemical near significant sources of drinking water" [section 6(b)(1)(A)] as a criterion for prioritization is clearly based on the reasonable potential for a spill or other unintended release to occur.

While there are practical limits on EPA's ability to consider all accidental situations or so-called upset conditions, it may well be practicable for EPA to include those that are able to be "reasonably foreseen." In other contexts, methods to predict or assign a probability to the likelihood of accidental events occurring have been developed that could serve as models, both for more specifically defining what is to be considered "reasonably foreseeable" in the context of accidental releases and exposures, and in conducting analyses to predict the associated exposures. See these examples in the context of oil spills[5] and chemical facility spills.[6]

Companies, too, may purchase and use a chemical for purposes that go beyond those the chemical manufacturer intends or may even know of. As many in industry have argued,[7] this makes it important for EPA to collect processing and use information from entities in addition to chemical manufacturers, and to use such information in identifying "intended, known, or reasonably foreseen" uses or other activities associated with a given chemical.

---

[5] "Information, Models, and Assumptions Used to Analyze the Effects of Oil Spills." Northeast National Petroleum Reserve, Alaska – Final Amended IAP/EIS. Appendix K. January 2005. http://www.blm.gov/style/medialib/blm/ak/aktest/planning/ne_npra.Par.31802.File.pdf/ne_npra_app_k.pdf.

[6] Meel, A., O'Neill, L.M., Levin, J.H., Seider, W.D., Oktem, U., and Keren, N., "Operational risk assessment of chemical industries by exploiting accident databases." *Journal of Loss Prevention in the Process Industries*. Vol 20, No. 2. March 2007. 113-127. http://www.sciencedirect.com/science/article/pii/S0950423006000714.

[7] For example, the Consumer Specialty Products Association (CSPA) has stated that TSCA needs to "include a means by which EPA can get use and exposure data from companies like those CSPA represents to better assess safety." As quoted in "CSPA Responds to Senator Lautenberg's Introduction of 'Safe Chemicals Act of 2011'", BusinessWire, 14 April 2011. http://www.businesswire.com/news/home/20110414007001/en/CSPA-Responds-Senator-Lautenberg%E2%80%99s-Introduction-%E2%80%9CSafe-Chemicals.

While we believe accidental misuses or releases should be taken into consideration by EPA, we also recognize that not all conceivable use, misuse or abuse of a chemical is reasonable to consider. Intentional abuse of a product, for example, use of a household surface cleanser as a tooth whitener or recreational glue-sniffing, should reasonably be excluded from the scope of uses of a chemical. EPA should consider establishing a "reasonable person test" for elucidating "reasonably foreseen" conditions of use. For example, it could describe a use as reasonably foreseen if a "reasonable person could have foreseen the manner in which a chemical or product would be used."

EPA should consider these factors in developing guidance to address how and what EPA will consider to be "intended, known, or reasonably foreseen" conditions of use of a chemical.

**4. EPA's proposal rule has appropriately proposed an inclusive approach to identifying "potentially exposed or susceptible subpopulations."**

The term "potentially exposed or susceptible subpopulation" appears 20 times in the law, demonstrating Congress' clear intent that EPA protect such subpopulations explicitly through the evaluation and regulation of chemicals. EDF strongly supports this intent.

Section 3(12) of the law defines "potentially exposed or susceptible subpopulation" as:

> a group of individuals within the general population identified by the Administrator 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.

The use of the phrase "such as" preceding the list of potentially exposed or susceptible subpopulations ("infants, children, pregnant women, workers, or the elderly") clearly indicates that the list is demonstrative, and is not an exhaustive list of all such subpopulations that EPA can consider in carrying out the law.

EPA has supplemented this definition in two respects, both of which EDF strongly supports.

First, it has acknowledged that the list of example subpopulations provided in the law is not exhaustive, and has made clear its authority to expand that list as appropriate by including the phrase "including, but not limited to" preceding the examples.

Other examples of such subpopulations that EPA should consider include: fence line communities exposed through the manufacture, processing, distribution or disposal of a chemical; indigenous populations who may be more highly exposed due to dietary sources and habits (e.g., high fish consumption) or other factors; and individuals who may have greater susceptibility due to preexisting disease or genetic factors. This list, too, is not exhaustive. Rather, EPA must identify and address the

potentially exposed or susceptible subpopulation(s) affected by a given chemical on a case-by-case basis, considering the entire lifecycle of the chemical.

Second, EPA's proposed regulatory definition makes clear that such subpopulations may be identified on the basis of "intrinsic" or "acquired" characteristics of a subpopulation or individuals comprising one. This addition is a useful and logical extension of the inclusion in the law's definition of both greater potential for exposure to a chemical and greater potential susceptibility to a chemical's effect.

EPA will need to establish a process it will use to define which subpopulations are relevant for a given chemical. Critical to this process are mechanisms and procedures to obtain needed data on the potential susceptibility or exposure of various subpopulations (e.g., through data call-ins or test orders). For example, reproductive and developmental toxicity data are vital to understand the relevance of prenatal and early life exposures – and thereby ensure protection of infants, children, and the developing fetus.

While EDF believes that the details of these issues should largely be addressed through guidance, the rule should require that EPA's scoping documents clearly describe how the agency identified the relevant subpopulations.

## ESTABLISHING THE SCOPE OF A RISK EVALUATION

### 5. EPA has appropriately proposed to provide a public comment opportunity for risk evaluation scopes, but needs to make it a firm requirement.

EDF considers the scoping step in the risk evaluation process to be critically important, not only because it defines and communicates the breadth of the risk evaluation to be conducted by EPA, but because it also determines the scope of EPA's subsequent risk determination under section 6(b)(4)(A) and, where EPA finds a chemical presents unreasonable risk, the scope of its mandated risk management regulation under section 6(a) and 6(c). Clarity is essential also because the scope of the risk evaluation also dictates the scope of any preemption of state authority that ensues from such risk evaluation and determination or risk management rule [see section 18(a)(1)(B) and sections 18(c)(2) and (3)].

It is vital, therefore, that the rule requires EPA to provide a public notice and comment opportunity for each risk evaluation scope. While not expressly required under the statute, nothing precludes EPA from providing such an opportunity, and it is wholly consistent with the general thrust of the statute toward full transparency of EPA decisions and with EPA's recent practice of providing for public comment on

problem formulations it developed for Work Plan chemical risk assessments, which are essentially the same as risk evaluation scopes.[8]

EDF appreciates, therefore, that its proposal includes reference to a public comment opportunity. However, EPA's proposed rule states: "EPA *generally expects* to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance, and to allow a period of 30 calendar days during which interested persons may submit comment on EPA's draft risk evaluation scope." (§702.39(c)(6)(2)). The phrase "generally expects" suggests that EPA considers both the 3-month and 30-day time periods to be discretionary. EDF strongly disagrees with respect to the latter: we urge EPA to make a firm requirement of the rule that EPA will provide at least 30 days for public comment on draft risk evaluation scopes.

EPA has provided no rationale for proposing that these timeframes would only be its "expectation," though we suspect it is tied to concern over meeting the admittedly tight 6-month statutory deadline for establishing the final scope. For this reason, we consider it reasonable that EPA retain some flexibility as to when within that 6 months it publishes the draft scope, as long as it provides at least 30 days for public comment. We note that 30 days is the shortest time EPA provides for comments and is shorter than the 45 days EPA states in the preamble to this proposed rule on p. 7570 (a typo, we assume), where it states it "proposes to provide" 45 days for public comment.

**6. EPA's conclusion that it must consider all conditions of use of a chemical in the scope of a risk evaluation is acceptable, subject to certain conditions.**

EDF appreciates and finds acceptable EPA's decision that it must consider all conditions of uses of a chemical and all potentially relevant subpopulations within the scope of a risk evaluation. We also note EPA's acknowledgement that other interpretations of the law are possible. In comments EDF filed in August,[9] we argued that while EPA needs to examine the full range of scope parameters, it could retain authority to exclude certain conditions of use from a risk evaluation scope, subject to certain conditions. Subject to those conditions, EPA's current proposal and our earlier one are relatively similar.

---

[8] EPA stated:

> "Based on on-going experience in conducting TSCA Work Plan Chemical assessments and stakeholder feedback, starting in 2015 EPA will publish a problem formulation for each TSCA Work Plan assessment as stand-alone document to facilitate public and stakeholder comment and input prior to conducting further risk analysis. Commensurate with release of a problem formulation document, EPA will open a public docket for receiving comments, data or information from interested stakeholders. EPA believes publishing problem formulations for TSCA Work Plan assessments will increase transparency of EPA's thinking and analysis process, provide opportunity for public/stakeholders to comment on EPA approach and provide additional information/data to supplement or refine assessment approach prior to EPA conducting detailed risk analysis and risk characterization."

See US EPA "Assessments for TSCA Work Plan Chemicals." Last Updated 25 July 2016. Accessed 22 August 2016. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#process.

[9] Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0026.

EDF also believes the law also provides EPA with authority to apply different levels of analysis to different conditions of use in order to inform unreasonable risk determinations for a chemical substance. Decisions to apply lower levels of analysis to, or to require less information for, certain conditions of use, however, need to be fully justified and explained, and should never be based on a lack of information.[10] The statute provides EPA with express and ample authority under sections 4, 8 and 11(c) to require testing or data call-ins to obtain the information it needs, and EPA should routinely make use of this authority.

**7. EDF agrees with EPA's position that the law requires risk evaluations to be conducted and risk determinations to be made on chemical substances as a whole, not on specific conditions of use.**

As EPA discusses in its preambles to its proposed prioritization rule (see p. 4829, section III.B.) and proposed risk evaluation rule (see pp. 7565-6, section II.C.2), the law is unambiguous in stating that chemical substances, not particular conditions of use, are to be subject to prioritization and risk evaluation [see TSCA sections 6(b)(1), 6(b)(4)(A)]. Similarly, EPA cannot apply unreasonable risk determinations to individual conditions of use of a chemical substance; the law is clear that those determinations are to be made for chemical substances as a whole [see sections 6(b)(4)(A), 6(i)].

These requirements and limitations should be made clear in EPA's final risk evaluation rule.

We agree with EPA that it may well be able to designate a chemical as a high priority based on only certain uses or conditions of use of that chemical.[11] Doing so does not alter the law's requirement that EPA conduct a risk evaluation on, and make its risk determination for, the chemical substance, and not only specific conditions of use of that substance.

**8. EPA's proposal to ''lock down'' the conditions of use included in a risk evaluation at the time of scoping is acceptable, with some conditions.**

EDF appreciates the rationale for EPA's proposal to ''lock down'' the conditions of use included in a risk evaluation once a final scope has been established, to avoid having risk evaluations be "moving targets."

[10] This stands in contrast to EPA's past practice in its risk assessments of Work Plan chemicals, where EPA frequently used a lack of information as a reason not to assessment a particular use, hazard, route of exposure, etc. While understandable at the time, given how onerous it was to seek to fill data gaps under the old law, the new law's expanded authority to collect or generate information eliminates this rationale.

[11] In contrast, low-priority designations must be based on consideration of the full range of conditions of use of a chemical substance. First, the designation applies to the chemical substance, not particular conditions of use. Second, were EPA not to consider certain conditions of use, an ensuing low-priority designation would be highly suspect because of the distinct possibility that the designation might not be warranted had all conditions of use been considered. None of this negates EPA's authority and mandate to designate chemicals as low-priority where they do not meet the standard for designating them as high-priority [see section 6(b)(1)(B)(ii)] – only that such designations must be based on consideration of all conditions of use. This position is further supported by that provision's requirement that EPA base a low-priority designation on "information sufficient to establish" that a high-priority designation is not warranted.

Industry interests in particular have a long history of using public input opportunities to delay forward progress on chemical reviews and regulations. Setting a firm scope is also important because the scope of a risk evaluation also determines the scope of any preemption of state authority that ensues, so clarity and certainty in this regard is important to all concerned.

However, if EPA is also to require that any issues or comments not provided during the public comment period on draft scopes cannot be a basis for raising an objection or challenge later (as it has proposed in §702.39(c)(6)(iii)), several conditions must be included:

- A minimum 30-day public comment period must be made mandatory (see comment 5 above).
- EPA must retain full authority (as it has proposed in §702.45(c)) to subject a chemical substance to a new risk evaluation and determination based on a review of available information.[12]
- The scope, including all hazards, exposures, conditions of use or potentially exposed or susceptible subpopulations, must be thoroughly described both upon finalization of the scope and in the risk evaluation itself.
- EPA must include a clear statement that any hazards, exposures, conditions of use or potentially exposed or susceptible subpopulations not described in the scope, whether ongoing or future, are:
    - outside of the scope of the risk evaluation;
    - not subject to any risk determination reached by the agency; and
    - not subject to any preemption of state authority pursuant to section 18.
- All information on which EPA has relied, including full copies of all studies, must be readily publicly accessible.[13]

EPA's preamble states (p. 7570): "Note that EPA is not proposing to preclude parties from raising newly discovered information, or from raising issues that could not have been fairly raised during this comment period. Rather, EPA seeks merely to prevent parties from delaying the risk evaluation by withholding information or by providing it piecemeal." However, these exceptions for newly discovered information and issues that could not have been fairly raised during the comment period are ambiguous at best and create loopholes that could be used to get around the intent of this entire provision.

Rather than providing for such potentially broad exceptions, EDF strongly urges EPA instead to restrict stakeholders from submitting any new information (other than that required by law, e.g., substantial risk notices under TSCA section 8(e)) unless they have provided EPA with prior notification, by a date certain, that they are developing new information; we propose no later than 90 days after EPA's designation of a chemical substance as a high priority.

[12] However, see a critical limitation to this authority we discuss in comment 41 below.
[13] See also our comment 38 below.

**9. The descriptions of the elements of a risk evaluation scope included in EPA's proposed rule are too limiting or ambiguous.**

In §702.39(c)(1)-(3), EPA describes the elements to be included in a risk evaluation scope. Language used therein, however, is narrower than that used in the law or otherwise too limiting or ambiguous.

In (c)(1), EPA's phrase "EPA will identify those uses that constitute the conditions of use ..." appears to limit the provision only to chemical uses, which is only one aspects of "condition of use." EPA should reword this simply to read "EPA will identify the conditions of use ... ." Similarly, the second sentence should begin: "Those conditions of use ... ."

In (c)(2), EPA uses the phrase "the exposed individuals and populations," which differs in several ways from the term defined in the statute and in EPA's proposed rule in §702.33. EPA should instead use the term "potentially exposed or susceptible subpopulation." EPA's reference to "ecological characteristics" is also unclear, including why such consideration would be limited to the environment. If EPA is referring to environmental fate and transport parameters (e.g., biodegradability, partitioning, etc.), it should use these more well-understood terms or be somewhat more specific. Either way, this provision should be clarified and expanded to include biological fate and transport parameters.

In (c)(3), the phrase "combination of" is ambiguous, as it implies EPA would only consider the listed items in combination. EPA should simply delete "combination of."

**CONDUCT OF RISK EVALUATIONS**

**10. EPA's proposal generally to initiate a risk evaluation only when it determines sufficient information is reasonably available to complete the risk evaluation in the allowed timeframe is acceptable, with some conditions.**

EDF generally supports the need for EPA to consider the extent of information that is or will be reasonably available on a chemical substance prior to initiating a risk evaluation, and EPA's inclusion in its proposed prioritization rule of a pre-prioritization stage to help ensure this. However, EPA must do more at that stage than use it to set aside chemical substances for which sufficient information does not exist. As already discussed, EPA needs to aggressively make use of its information collection and development authorities under sections 4, 8 and 11(c) of TSCA in order to ensure there will be sufficient information on a chemical that initially lacks it. This issue is discussed at greater length in EDF's comments on EPA's proposed prioritization rule.

In the preamble to this rule, in discussing manufacturer-requested risk evaluations, EPA has requested comment on how it should use its information-gathering authorities (pp. 7573-4). We agree with EPA on the need to use these authorities early in the risk evaluation process (or even preceding it; see EDF's

comments on EPA's prioritization rule), as essential to ensuring sufficient information is available to conduct risk evaluations. We strongly support EPA's suggestion to incorporate its TSCA section 8(a) and 8(d) authorities directly into this rule in the "Information and Information Sources" provision in §702.39(b), and to make them available for use in conducting all risk evaluations, not just those requested by manufacturers.

**11. EDF agrees that EPA should have authority to temporarily bifurcate a risk evaluation in order to expedite risk management of high-risk conditions of use.**

EDF agrees with EPA that there may be cases where EPA has sufficient information on a subset of uses, subpopulations, etc., to conclude a chemical substance presents an unreasonable risk even in advance of completing the full risk evaluation of the substance (p. 7568 and §702.39(a)(6)). We agree that EPA has authority and that it is sound policy for EPA in such cases to temporarily bifurcate a risk evaluation, so that needed risk management for the subset is not delayed until the full risk evaluation is completed. Three conditions should apply in such cases however:

- EPA must still complete its risk evaluation of the chemical substance for all conditions of use within the statutory timelines, as EPA proposes in §702.39(a)(6);
- EPA's ultimate risk determination applies to the chemical substance and not to specific conditions of use, as EPA has stated in its preamble (p. 7565); and
- EPA cannot conclude that a chemical substance does not present an unreasonable risk until and unless it determines that no condition of use presents such risk, including for all identified potentially exposed or susceptible subpopulations (not stated in the text of the proposed rule).

To elaborate on the third of these, it would never be appropriate for EPA to expedite a risk evaluation on only a subset of uses of a chemical substance in order to then find they do not present an unreasonable risk. Such a determination can only be made after evaluating the risks of *all* conditions of use. In other words, while one could legitimately conclude that a subset of uses means a chemical substance presents an unreasonable risk even in advance of a full evaluation of all uses, the converse is not true.

These allowances and expectations should be made clear in the final rule governing risk evaluations.

**12. EPA should generally assess exposure on an aggregate basis across the conditions of use, and needs to modify its definition of sentinel exposure.**

Section 6(b)(4)(F)(ii) requires EPA, in conducting a risk evaluation, to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration."

The desirability of assessing chemical exposures on an aggregate basis – defined by EPA to be "the combined exposures to an individual from a single chemical substance across multiple routes and across

multiple pathways" – is clear. The approach was expressly included by Congress in the 1996 Food Quality Protection Act as a required consideration for EPA in conducting risk assessments of pesticides. EPA has developed extensive guidance to that end.[14] Assessing exposure on an aggregate basis is also a core concept in the National Academy of Sciences' seminal 2009 report, *Science and Decisions: Advancing Risk Assessment*.[15]

In contrast, some in industry support EPA assessing exposure based on identification and assessment of one or more "sentinel exposures," which EPA describes as "the exposure(s) of greatest significance, which may be the maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof)." (§702.33)

In EDF's view, given the diversity of use of many industrial chemicals, there is a compelling need to assess risk in a manner that reflects real-world exposures experienced by a diverse human population, including a range of subpopulations, as well as to the environment. Such diversity of use makes it likely, or certainly reasonably foreseeable, for individuals to be exposed to a given chemical from multiple sources, with the overall risk they face arising from the sum of those exposures. This is a strong argument for taking an aggregate approach; it also makes it difficult to imagine how a sentinel approach would be possible or sufficiently protective.

Consistent with comment 11 above, however, EPA needs to be able to determine that a chemical presents an unreasonable risk based on a single condition of use or a subset of all conditions of use without first having to aggregate exposures, so that it can expedite risk management of such condition(s) of use. As it subsequently completes its full risk evaluation of the chemical substance for all conditions of use, however, an aggregate approach is again likely to be warranted.

In sum, in conducting risk evaluations, EDF believes EPA should generally conduct an aggregate exposure assessment across the conditions of use. Only if EPA can compellingly demonstrate that another approach fully captures the risk across these conditions of use, or it needs to expedite action on a subset of conditions of use, should it not take the aggregate approach.

With respect to sentinel exposure, EPA has proposed to define this term as "the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof)."

EDF takes serious issue with the agency's equating of exposures of "greatest significance" as those exposures associated with "maximum plausible exposure." The significance of an exposure is not

[14] US EPA, Office of Pesticide Programs. "General Principles for Performing Aggregate Exposure and Risk Assessments." 28 November 2001. https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf.

[15] National Research Council, Committee on Improving Risk Analysis Approaches Used by the U.S. EPA; Board on Environmental Studies and Toxicology, Division on Earth and Life Sciences. "Science and Decisions: Advancing Risk Assessment." 2009. http://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

determined only by the magnitude of the exposure, but by a host of factors, including notably the timing of such exposures. For example, for a developmental toxicant, the exposures of greatest significance will almost certainly be those that occur *in utero* or during early childhood even if such exposures are lower than those experienced during adulthood. Similarly, chronic low-dose exposures may be more significant in terms of characterizing chemical risk than an acute maximum dose exposure. EDF strongly recommends that the agency rewrite its definition of sentinel exposure to be one that more accurately reflects current scientific understanding of what types of exposures, across different sub-populations may be of the greatest significance in terms of human health risk, including risks to potentially exposed or susceptible subpopulations.

**13. EPA's proposal to require that all issues on draft risk evaluations must be raised during the public comment period, and cannot serve as a basis for later objections or challenges, is acceptable, with some conditions.**

EDF appreciates the rationale for EPA's proposal to require stakeholders to raise all relevant issues relating to a draft risk evaluation during the public comment period, to avoid having risk evaluations be "moving targets." Industry interests in particular have a long history of using public input opportunities to delay forward progress on chemical reviews and regulations.

However, if EPA is also to require that any issues not provided during the public comment period on draft risk evaluations cannot be a basis for raising an objection or challenge later (as it has proposed in §702.45(a)(2)), several conditions must be included:

- A minimum 90--day public comment period must be provided; see comment 14 below.
- EPA must retain full authority (as it has proposed in §702.45(c)) to subject a chemical substance to a new risk evaluation and determination based on a review of available information.[16]
- The draft risk evaluation must clearly and thoroughly describe all hazards, exposures, conditions of use or potentially exposed or susceptible subpopulations evaluated.
- All information on which EPA has relied, including full copies of all studies, must be readily publicly accessible.[17]

In the context of draft scopes, EPA's preamble states (p. 7570): "Note that EPA is not proposing to preclude parties from raising newly discovered information, or from raising issues that could not have been fairly raised during this comment period. Rather, EPA seeks merely to prevent parties from delaying the risk evaluation by withholding information or by providing it piecemeal." It is not clear whether EPA intends to take the same approach at this stage of the risk evaluation process. However, as noted in comment 8 above, such exceptions are ambiguous at best and create loopholes the could be used to get around the intent of this entire provision.

[16] However, see a critical limitation to this authority we discuss in comment 41 below.
[17] See also our comment 38 below.

Rather than providing for such potentially broad exceptions, EDF urges EPA instead to restrict stakeholders from submitting any new information (other than that required by law, e.g., substantial risk notices under TSCA section 8(e)) unless they have provided EPA with prior notification, by a date certain, that they are developing new information; we propose no later than the end of the comment period on the draft scope of a risk evaluation.

Finally, see our comment 29 below regarding inequitable allowance for manufacturers to provide new information late in the risk evaluation for risk evaluations they have requested.

**14. EPA needs to provide a 90-day public comment period for draft risk evaluations.**

The law requires that EPA provide no less than 30 days for public comment on draft risk evaluations (TSCA section 6(b)(4)(H)). EPA has proposed the same in §702.45(a)(1). Nonetheless, EDF considers such a minimum period to be much too short to allow for adequate review of documents as complex and typically lengthy as are risk evaluations.

EDF urges that EPA specify in its final rule a 90-day comment period. We recognize the need for EPA to stay on schedule given statutory deadlines for completing risk evaluations, but believe that period of 3-3.5 years is sufficient in length to allow for 90 days for public comment. EDF would also support EPA making the length of this comment period firm and not subject to extension, barring a case where EPA has not provided access to all information required and needed to provide meaningful comments on a draft risk evaluation.

**15. EPA should make clear that risk determinations are to be based on risk evaluations.**

TSCA Section 6(b)(4)(A) makes clear that risk determinations are to be based on the risk evaluations EPA conducts. §702.43 states that EPA will make unreasonable risk determinations – but does so without any mention of risk evaluations. The section never states that such determinations are to be based on the risk evaluations conducted pursuant to this subpart (Subpart B). While it may be obvious, the rule needs to state the basis on which EPA will make such a determination, lest it leave open the suggestion that it could be made on a different basis.

**THIRD-PARTY DRAFT RISK EVALUATIONS**

The new law anticipates that "interested persons" may wish to develop their own "draft risk evaluations" and submit them to EPA for its consideration [section 26(l)(5)]. That provision requires EPA to develop guidance to assist such persons in doing so, which is to address information quality and the process to be followed in developing such draft risk evaluations. The provision also states that such draft risk evaluations "shall be considered by the Administrator."

Beyond noting this provision of the law in its preamble, EPA has not addressed this issue in its proposed rule. While the details are best addressed in the guidance EPA is required to develop, EDF believes EPA's rule needs to specify how it will consider third-party risk evaluations, which our points here address.

**16. Third-party draft risk evaluations need to be made publicly available with opportunity for public comment.**

Because EPA is required to consider such draft risk evaluations, EDF believes they need to be made publicly available promptly upon receipt by EPA and that EPA should solicit and be required to consider public comments on them, including the extent of their conformance with EPA's guidance and their adequacy for consideration by the Administrator. EPA's rule should specify these requirements.

**17. EPA should never rely solely or even principally on third-party draft risk evaluations.**

EPA's rule should require that EPA always conduct its own risk evaluations and that it cannot solely or heavily rely on a third-party draft risk evaluation in making decisions on whether to conduct or in conducting its own risk evaluation. This is critical to ensure full independence of EPA from any third party that may have a vested interest in the outcome of EPA's risk evaluations or its decision whether or not to conduct one.

**18. Third-party draft risk evaluations should conform to EPA's guidance.**

EPA's rule should require that third-party draft risk evaluations conform to EPA's guidance for such drafts required under TSCA section 26(l)(5) in order for them to be considered by the agency. Failing that, at the very least the rule should require the agency to consider the extent of conformance to the guidance in deciding what weight should be given to such draft risk evaluations.

In any case, the rule should make clear that the scientific standards established in the statute, including those in sections 26(h) and (i), fully apply to third-party risk evaluations – whether with respect to EPA's acceptance of such a document or the weight given to it.

**19. The scope of third-party draft risk evaluations should not determine or limit the scope of EPA's risk evaluation.**

In general, EDF believes that third-party draft risk evaluations should be required to conform to the same requirements EPA must meet for its own risk evaluations; that includes establishment of a scope that includes all conditions of use of a chemical substance.

If a third party submits a draft risk evaluation with a more limited scope, that should not be used to limit or alter the scope of EPA's own risk evaluation.

**20. EPA should specify and adhere to clear deadlines for submission of third-party draft risk evaluations.**

EPA's rule should establish a deadline, within its risk evaluation process, by which any third-party draft risk evaluations on chemical substances for which EPA is conducting or has indicated it intends to conduct a risk evaluation must be submitted to the agency in order to be considered. We propose that such deadline should coincide with the end of the comment period for the draft scope of a risk evaluation EPA is conducting.

The submission of third-party draft risk evaluations later in EPA's risk evaluation process would likely be disruptive, lead to delays affecting EPA's ability to complete its risk evaluations on time, and be prone to abuse. Experience in other chemical assessment programs such as IRIS amply demonstrates these concerns, where stakeholders with a vested interest in the outcome of an IRIS assessment have frequently submitted new studies, models or other information, or requested IRIS to delay its assessments to wait for such information they were developing. This dynamic has been a major contributor to the chronic delays in completion of IRIS assessments.

It should be noted that such stakeholders, along with others, will have ample opportunity to comment on EPA's own proposed risk evaluations as part of the process. But it is vital for efficiency that third parties wishing to provide draft risk evaluations they wish EPA to consider provide that information to EPA early in the risk evaluation process.

**INDUSTRY-REQUESTED RISK EVALUATIONS**

The new law provides a means by which a manufacturer of a chemical can request EPA to conduct a risk evaluation on that chemical [see section 6(b)(4)(C)(ii)]. The provision has or is subject to a number of important conditions and limitations that are reflected in EPA's proposed risk evaluation rule and need to be retained. Below is a list, with an indication of where it has been included in EPA's proposed rule:

- Requests can only be made by chemical manufacturers. [see section 6(b)(4)(C)(ii)]
    - Included in §702.37(b)
- Requests can only be made for a risk evaluation to be conducted on a chemical that the manufacturer making the request manufactures. [see section 6(b)(4)(C)(ii)]
    - Included in §702.37(b); more than one manufacturer of a chemical may join a request
- Industry requests for risk evaluations are to be made "in a form and manner and using criteria EPA prescribes in its risk evaluation rule." [see section 6(b)(4)(C)(ii)]
    - Included in §702.37(a), (b)(3)-(5)
- Such risk evaluations are to be conducted in accordance with all applicable requirements of the law [e.g., those in section 6(b)(4)(F)] and in EPA's risk evaluation rule. [see section 6(b)(4)(C)]
    - Included in §702.37(e)(4)(ii), (e)(5)-(6)

- The requirements EPA must follow in establishing the scope of a risk evaluation do not differentiate between the scope of a risk evaluation EPA initiates on its own versus one for industry-requested risk evaluations. [see section 6(b)(4)(D)]
    - Included in §702.37(e)(6)
- The number of such requests granted by EPA shall not be fewer than 25% (assuming a sufficient number of requests are received), and not more than 50% of the number of chemicals undergoing risk evaluations that EPA initiates on its own. Hence, if EPA has 20 risk evaluations ongoing that it has initiated on its own, the number of industry-requested risk evaluations that could be ongoing at the same time would be 5-10 (assuming at least 5 industry requests had been received). [see section 6(b)(4)(E)(i)]
    - Included in §702.37(e)(4)(ii)
- All industry requests are subject to the payment of fees [see section 6(b)(4)(E)(ii)]:
    - a fee that is sufficient to defray EPA's full costs to conduct a risk evaluation requested by a manufacturer, except that
    - if the chemical for which the request is made is listed on the 2014 update to EPA's Work Plan, the fee shall be sufficient to defray 50% of EPA's costs to conduct the risk evaluation. [see section 26(b)(4)(D)]
    - Included in §702.37(f) [but see comments 23 and 25 below; details pending EPA's pending fee rule]
- EPA "shall not expedite or otherwise provide special treatment" to industry-requested risk evaluations. [see section 6(b)(4)(E)(ii)]
    - Included in §702.37(e)(7)
- In deciding whether to grant an industry request for a risk evaluation, EPA is to give preference to requests for chemicals where EPA "determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment." [see section 6(b)(4)(E)(iii)]
    - Included in §702.37(e)(5) [but see comments 26 and 27 below]
- The deadlines and public notice and comment requirements applicable to EPA-initiated risk evaluations also apply to industry-requested risk evaluations. [see section 6(b)(4)(G) and (H)]
    - Included in §702.35(a)

Below we elaborate on several of these requirements, as well as several additional requirements EPA has included in its proposed rule.

**21. EPA has appropriately provided that EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, is to establish the scope of the risk evaluation.**

The new law's allowance for companies to request and pay for risk evaluations was intended to expand the number of chemicals being reviewed and provide companies with some ability to have a risk evaluation done on a chemical sooner than would otherwise be the case through the normal prioritization process. It was never intended, nor does the law allow, for the conduct of risk evaluations

undertaken in response to industry requests to deviate in any manner from those EPA initiates on its own.

Some industry representatives have suggested that EPA can and should conduct risk evaluations only on conditions of use requested by manufacturers. This is clearly disallowed by the law.

Sections 6(b)(4)(C) and (F) make clear that both EPA-initiated and industry-requested risk evaluations are to conform to the same requirements, including that they both be conducted "in accordance with the rule" EPA is to promulgate to govern its conduct of risk evaluations. Nor does the provision of the law establishing requirements for the scope of risk evaluations [section 6(b)(4)(D)] make any distinction between the scopes of EPA-initiated and industry-requested risk evaluations.

In its final risk evaluation rule, EPA should affirm that EPA has sole responsibility and authority to establish the scopes of all risk evaluations it undertakes.

**22. EPA appropriately proposes that manufacturers requesting risk evaluations demonstrate that there is sufficient information available to complete the risk evaluation for all conditions of use.**

As noted above, the law makes clear that both EPA-initiated and industry-requested risk evaluations are to conform to the same requirements. Consistent with EPA's proposal that it will generally conduct risk evaluations only when it determines sufficient information is reasonably available to complete the risk evaluation in the allowed timeframe, EDF strongly supports EPA's proposal in §702.37(a) to require the same of industry requestors of risk evaluations. Indeed, because such chemicals will not have gone through the prioritization process and its associated opportunities for EPA to collect or require the development of information, it will be especially important to require requesters to demonstrate the sufficiency of the information that they are providing or is otherwise reasonably available to EPA.

We also agree with two other requirements EPA proposes to impose on requestors:

- A legally binding and enforceable certification that the information provided is accurate and complete (§702.37(b)(5)). EPA must avoid a situation in which a requestor only provides some of the available information on a chemical substance, e.g., only that information suggestive of low risk, and omitting other information.
- A firm commitment to provide EPA upon request any information referenced but not provided initially by the requestor (§702.37(b)(4)). This requirement should be further enhanced as follows:
    - To ensure such information is promptly provided, EPA's rule should specify a deadline for submission of the requested information that is no longer than 15 days after the request. Any longer than that could risk delaying EPA's risk evaluation and would call into question whether the information was in fact reasonably available.
    - The certification should include a statement that the requestor has rights to the information provided or cited and that it is not subject to any restrictions on EPA's

ability to use and make publicly available the information. Experience under the European Union's REACH Regulation necessitates this, given that companies have frequently claimed that existing information submitted to meet REACH requirements cannot be provided to EPA for its use or be made public, due to inter-company agreements limiting use of or access to the information.

As noted in comment 38, EPA needs to provide public access to all studies and other information used in the risk evaluation, including those provided by or cited by the requestor.

**23. EPA's rule should make clear that the fees required of a manufacturer making a request for a risk evaluation must be sufficient to cover the full or 50% portion of EPA costs for the *full* risk evaluation EPA conducts.**

Some industry representatives have raised the possibility that the fees EPA imposes to cover the full or 50% portion of costs it incurs in conducting industry-requested risk evaluations should only apply to EPA costs for the portion of the scope of the risk evaluation corresponding to the requestor's portion of manufacture of the chemical in question. Here again, there simply is no basis for such an approach in the law. Section 26(b)(4)(D) provides no such allowance, and rather requires that, "[i]n setting fees under this section, the Administrator shall ... establish the fee at a level sufficient to defray the full costs [or 50 percent of the costs] to the Administrator of conducting the risk evaluation." This requirement applies regardless of whether or not the requesting manufacturer manufactures the chemical for only a subset of the conditions of use included in the scope of the risk evaluation.

In its final risk evaluation rule as well as in its forthcoming fee rule, EPA should affirm this requirement that fees collected for industry-requested risk evaluations be sufficient to cover all or a 50% portion of its costs to conduct the risk evaluation, the scope of which is to be established by EPA, not the requesting manufacturer (per our preceding comments 21 and 22).

**24. EPA has, and should exercise, discretion as to the timing of initiation of industry-requested risk evaluations.**

EPA can and should time the initiation of industry-requested risk evaluations so as to ensure that the conduct of such risk evaluations does not disrupt or interfere with EPA's conduct of or ability to meet applicable deadlines for risk evaluations it initiates on its own.

The law requires that "[u]pon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance" [see section 6(b)(3)(A)]. This provision (as we note in comment 2 above) effectively defines the point of initiation of a risk evaluation as the point of designation of a substance as a high-priority substance.

In contrast, no such trigger event is designated in the law to govern the precise point at which industry-requested risk evaluations are to be initiated. (While in principle industry could request a risk evaluation

on a high-priority substance, this will likely never happen, because EPA is already required to conduct risk evaluations on all high-priority chemicals; the only effect of such a request would be to trigger payment of a fee by the requesting manufacturer.)

A key concern over the allowance for industry-requested risk evaluations is that they not impede risk evaluations EPA initiates on its own, which are to be selected based on risk concerns and should be the higher priority. Congress' decision not to specify a date or other event to trigger initiation of an industry-requested risk evaluation, in contrast to those EPA initiates on high-priority substances, supports our view that EPA has discretion as to the timing of initiation of industry-requested risk evaluations, and that it should exercise that discretion to time the initiation of such risk evaluations so as to minimize any delay or disruption in conducting risk evaluations on high-priority substances.

For chemicals already on EPA's Work Plan, industry requests for risk evaluations are to be "granted at the discretion of the Administrator" [see section 6(b)(4)(E)(iv)(II)]. In such cases, EPA has discretion both as to whether or not to accept such a request and the timing of initiation of any risk evaluation for such a request it grants. Here again, EPA can and should exercise this discretion to ensure it retains full capacity to initiate, conduct and complete on time those risk evaluations it chooses to initiate on its own.

EPA's proposed rule states that EPA will make a determination within 9 months of the end of the public comment period on industry requests for risk evaluations, as to whether the request meets all applicable requirements and the risk evaluation should proceed (see §702.37(e)(4)). Even where EPA makes a positive determination, for the reasons cited above, EPA should be able to exercise discretion and retain flexibility as to exactly when such a risk evaluation is to be initiated.

In its final risk evaluation rule, EDF urges EPA to affirm the discretion it has under the law over the granting of industry-requested risk evaluations and the timing of their initiation, and articulate the desired purpose of exercising it – to manage overall workflow and not impede progress on the risk evaluations on high-priority substances.

**25. EPA should not initiate industry-requested risk evaluations until it has received the applicable fees mandated to defray its costs.**

Congress intended that EPA conduct risk evaluations requested by industry only subject to the payment of fees sufficient to defray all or 50% of its costs to conduct such risk evaluations. The fee provision is a clear acknowledgment by Congress that additional resources would be needed in order for EPA to conduct industry-requested risk evaluations. Coupled with the concern that EPA's conduct of such risk evaluations not interfere with risk evaluations of high-priority substances – a concern reflected in multiple provisions in the law that limit or condition industry-requested risk evaluations [see sections 6(b)(4)(C) and (E)] – it only makes sense that EPA not initiate such risk evaluations until it receives the requisite fees.

To ensure it is developing and sustaining the capacity (including sufficient personnel, contractors, etc.) required to conduct such risk evaluations, EPA will need to be able to budget and plan prospectively – which in turn requires, or would at least be aided substantially, by having received the fees prior to initiating the requested risk evaluations.

EPA's risk evaluation rule includes a provision establishing that manufacturers must pay fees to support risk evaluations they request (see §702.37(f)), but both in the final rule and in the upcoming fee rule, EPA should require receipt of applicable fees prior to initiating such risk evaluations.

**26. EPA should demonstrate a broad societal benefit in order to give preference to an industry request for a risk evaluation on a chemical that is subject to state restrictions.**

Section 6(b)(4)(E)(iii) states that, in deciding whether to grant industry requests for risk evaluations, EPA is to "give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment."

EDF considers this provision as a call to EPA to demonstrate that there will be a significant benefit to its acting on a chemical at a national level, when that chemical is already subject to restrictions at the state level. That benefit may be an economic, health or environmental benefit. While one such anticipated economic benefit is reducing an undue burden on interstate commerce, it might also be a positive impact on health or the environment resulting from extending protections against exposure to a risky chemical to the full U.S. population, where extending those protections would be significantly more beneficial than those already resulting from the state restrictions.

In order to give preference to an industry risk evaluation for such a chemical on the basis of Section 6(b)(4)(E)(iii), EDF believes EPA's final risk evaluation rule should require EPA to articulate and demonstrate a clear broader benefit to acting on that chemical at a national level, and any such economic benefit should extend beyond a potential economic benefit of its action on companies making or using the chemical in question.

EPA's proposed rule, in addition to codifying the preference criterion in Section 6(b)(4)(E)(iii), would also give preference "to requests where EPA estimates there may be relatively high exposure(s) and/or hazard(s) under one or more conditions of use" (see §702.37(e)(5)(ii)). EDF strongly supports this additional criterion and considers it wholly consistent with the law's intent that EPA conducts risk evaluations first on chemicals presenting the greatest potential risk.

Finally, §702.37(e)(5)(iii) provides a third catch-all criterion: "Any other factor EPA determines to be relevant." This criterion is far too vague and could lead to the granting of industry requests on virtually any grounds, even ones far afield from the purposes of the law. EPA should either delete this criterion, which has no basis in the law itself, or at least restrict it to "risk-based" factors.

**27. EPA has inappropriately applied its preference criteria for determining whether, and if so, which industry requests for risk evaluations to grant only to those it would consider after meeting the 25% threshold.**

§702.37(e)(5) states (second emphasis added):

> (5) *Preferences*. In conformance with 40 CFR 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals *in excess of the 25% threshold* in paragraph (e)(4)(ii) of this section, EPA will give preference to requests for risk evaluations on chemical substances:
>
> (i) That demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment.
>
> (ii) EPA will also give preference to requests where EPA has determined there are relatively high estimates of hazard and/or exposure for the chemical substance.
>
> (iii) Any other factor EPA determines to be relevant.[18]

The wording is not clear as to whether the modifying phrase "in excess of the 25% threshold" applies both to TSCA Work Plan and non-TSCA Work Plan chemicals. Regardless, the law makes clear the criteria are to apply to *all* industry requests, not just those above the 25% threshold. Section 6(b)(4)(E)(iii) makes no distinction between requests up to vs. those exceeding the 25% threshold. EPA needs to modify its rule accordingly, by striking the phrase "in excess of the 25% threshold in paragraph (e)(4)(ii) of this section" from §702.37(e)(5).

**28. EPA needs to provide public notice of and an opportunity to comment on all industry requests for risk evaluations, not just notice of their receipt, and also needs to make public its decision on each such request and the basis for it.**

EDF strongly supports EPA's proposal to make public and provide an opportunity for public comment on all industry requests for risk evaluations. However, the actual provision – §702.37(e)(5) – only states EPA will publish "the receipt of the request," not the request itself. We expect this is inadvertent, as the provision goes on to state EPA's solicitation of "[i]n particular, comments identifying any information gaps in the request (e.g., any conditions of use not identified in the request)" – something the public would not be able to comment on without seeing the request itself. Equally germane would be public comments on whether or not EPA should grant or give preference to the request.

In addition to making industry requests for risk evaluations public, EPA should also promptly make public its decisions regarding such industry requests and the bases for them.

[18] See the last paragraph in our comment 26 regarding this catch-all provision.

These requirements are important for overall transparency of the EPA risk evaluation program and its priorities, and would provide public access to information that is directly germane to the required reporting and planning requirements the agency must meet pursuant to sections 26(m) and (n).

**29. EPA must not allow companies to submit information after the close of the comment period when it does not allow other stakeholders to do so.**

As discussed above in comment 13, EPA has proposed that stakeholders must raise all relevant matters and issues during the public comment period for risk evaluations; see §702.45(a)(2). However, in §702.37(e)(3)(ii), EPA's proposed rule states (emphases added):

> (ii) At any point *prior to the completion of a risk evaluation* conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) *and 40 CFR 702.37, or other information that has the potential to change EPA's evaluation of the risk of the chemical substance*. Such information must be submitted within 30 calendar days of discovery.

EDF agrees, of course, with the requirement that manufacturers promptly submit so-called "substantial risk" notices as required under TSCA section 8(e). However, the proposal to extend this provision to any information required under "40 CFR 702.37, or other information that has the potential to change EPA's evaluation of the risk of the chemical substance" is far too broad and could effectively undermine the requirement in §702.45(a)(2) and its purpose. As drafted, §702.37(e)(3)(ii) could create an enormous inequity by which manufacturers could continue to provide new information until the very end of the risk evaluation process for risk evaluations they have requested, while all other stakeholders would be precluded from doing so.

EDF strongly opposes the broad reach of §702.37(e)(3)(ii), and urges that EPA limit it only to "substantial risk" notices as required under TSCA section 8(e). If broadened beyond those notices, it should be limited *only* to other information that would make it more likely that EPA would reach an unreasonable risk determination for the chemical substance – although we then do not see a rationale for precluding other stakeholders from also providing that type of information.

**RISK CHARACTERIZATION METHODOLOGIES, GUIDANCE AND OTHER CONSIDERATIONS**

**30. EPA should modify its definition of "variability."**

EPA has defined variability to mean, "… the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population" (§702.33).

EDF urges the Agency to modify this definition to reflect the fact that "variability" in a population is not always "inherent" or "natural" or otherwise intrinsic, but may also be extrinsic or acquired. As noted in a 2013 paper by Zeise et al.[19]:

> A large array of possible health outcomes is of concern for such assessments [human health risk assessments for chemicals], and many sources of variation can influence the severity and frequency of the adverse effects at different exposure levels. These sources may be intrinsic (e.g., heritable traits, life stage, aging), or extrinsic, exogenous, and acquired (e.g., background health conditions, co-occurring chemical exposures, food and nutrition status, psychosocial stressors). Interactions between inherent and extrinsic factors create the large range of biological variation exhibited in response to a chemical exposure (NRC 2009). Given that biological variability in susceptibility is context-dependent, so too is the extent to which it needs to be described and quantified to inform any particular environmental decision.

**31. Principles of systematic review should be incorporated into the TSCA risk evaluation process, but details of its application should not be specified in the rule.**

EDF supports EPA's interest in and efforts to increasingly integrate systematic review[20] practices into its risk evaluations. EPA has discussed this issue in the preamble of its proposed risk evaluation rule (p. 7564) and has requested comment on whether regulatory text should be included (p. 7572).

Systematic review has increasingly been the practice of human health hazard assessments conducted by the National Toxicology Program and EPA's IRIS program. Several principles and elements of systematic review are directly relevant to provisions under the new TSCA, including provisions relating to the development of information and scientific issues related to risk evaluations in sections 6(b)(4) and 26(h), (i), and (l)(3).

The principles of transparency, objectivity, and consistency inherent and manifested in the practice of systematic review support our comments herein. In particular, as already noted, we strongly urge that EPA include in its risk evaluation rule requirements that EPA clearly communicate what information is considered and ultimately used to develop the scope and to conduct risk evaluations. In meeting these requirements in the context of specific risk evaluations, EPA should be transparent in describing how it has identified relevant information, assessed study quality, and synthesized the body of evidence to reach conclusions regarding risk. To that end, the structure and transparency of literature searches and study inclusion and exclusion criteria and related decisions that are core elements of systematic reviews are directly applicable.

---

[19] Available at https://ehp.niehs.nih.gov/1205687/.

[20] The preamble of the proposed rule notes, "The National Toxicology Program of the National Institutes of Environmental Health Sciences has developed a tool called "systematic review" to assist in Wo# evaluations particularly for hazard identification." (p. 7564) We note that while the NTP has been a leader in recent efforts to apply systematic review in the context of environmental health, systematic review itself has been in use for decades, most notably in the clinical sciences.

We have expressed concern over the lack of such transparency in the Problem Formulation and Data Needs Assessment and Problem Formulation and Initial Assessment documents developed for the various Work Plan flame retardant chemical clusters. These documents did not provide an adequate description of the approach EPA used to search the broader literature, or the approach it used to identify, compile, evaluate, and select studies for inclusion.[21]

We urge that other aspects of systematic review, namely specification of considerations used to evaluate study quality and the overall strength of the evidence for identifying chemical hazard and risk, also become common practice in the conduct of risk evaluations under the new TSCA; such factors are already arguably invoked in requirements in section 26(h) and (i) that EPA use the "best available science" and "weight-of-the-scientific-evidence" approaches.

In developing and applying systematic review, or aspects of it, to TSCA risk evaluations, we encourage the agency to continue to look to the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration[22] and the Navigation Guide methodology led by researchers at UCSF.[23]

While we strongly urge EPA to integrate systematic review methodologies into its risk evaluations, we do not believe that its risk evaluation rule should specify these or other scientific details of how risk evaluations are to be conducted. As noted above, EDF does not believe that this rule is the appropriate vehicle for specifying scientific aspects of how risk evaluations are to be conducted, but rather are better addressed in guidance documents and policy statements that are more nimble.

**32. EPA should move away from its margin-of-exposure (MOE) approach for non-cancer effects.**

While, as indicated in comment 33, EDF does not support codifying specific methods in this rule, as a matter of practice in conducting risk evaluations, and in developing future or modifying existing guidance, EDF strongly urges the agency to move away from the application of a default threshold approach (e.g., margin-of-exposure approach) to evaluations of risk for non-cancer effects, as articulated and strongly recommended in the 2009 National Academy of Sciences report, Science and Decisions: Advancing Risk Assessment. There is strong evidence against continuing to make the assumption that for non-cancer endpoints there is a threshold level of exposure below which no adverse effect occurs across the population. As documented in the 2009 NAS report, this assumption is

[21] See, for example, EDF comments on an EPA data needs assessment, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0491-0013; and EDF comments on an EPA initial assessment, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0068-0015.

[22] National Toxicology Program, Office of Health Assessment and Translation, "Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration." 9 January 2015. https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf.

[23] Clinical Practice & Policy: Navigation Guide; An Evidence-Based Medicine Methodology to Bridge the Gap Between Clinical and Environmental Health Sciences, at http://prhe.ucsf.edu/prhe/navigationguide.html.

particularly unwarranted when assessing risks to a highly diverse human population. The NAS committee stated:

> Historically, dose-response assessments at EPA have been conducted differently for cancer and noncancer effects, and the methods have been criticized for not providing the most useful results. Consequently, noncancer effects have been underemphasized, especially in cost-benefit analyses. A consistent approach to risk assessment for cancer and noncancer effects is scientifically feasible and needs to be implemented" (Page 8).

**33. EPA should not codify specific guidance in its risk evaluation rule.**

EDF strongly agrees that EPA should not codify any specific guidance, method, or model for risk evaluation into the final rule. Such guidance needs to be adaptable in order for risk evaluations conducted by the agency to reflect the best available science. Current-day guidance documents, models, and methods are not same as they were 10 or 20 years ago and will not be the same 10 or 20 years from now as our understanding of chemical risk as well as the underlying data types and tools available for chemical risk evaluations evolve. Locking in specific guidance documents, methods, and tools runs a high risk of making agency risk evaluations irrelevant and outdated in the future, and, as a result, out of step with the intent and language of the law that EPA use the best available science.

**34. EPA should exercise caution in relying on models and assumptions rather than using its new data-collecting authorities under the recent TSCA amendments to address data-poor chemicals.**

In §702.39(a)(5), the proposed rule indicates that:

> To the extent a determination as to the level of risk presented by a condition of use can be made, for example, by the use of accepted science policies (e.g., default assumptions or uncertainty factors), and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the use(s).

EDF appreciates the purpose and value of using estimates and uncertainty factors in the absence of measured data, as is often the case for TSCA chemicals. However, in the context of conducting robust risk evaluations, we advise that the agency not to limit itself to relying on them exclusively as a first-order approach to filling in information gaps. The reforms made to TSCA intentionally and explicitly gave EPA new authorities to require the development of data on chemicals, and EPA should be aggressively using these authorities as early in the review process as possible.

Furthermore, toward applying the best available science, the agency should continuously review whether current science policies, models, and screening methodologies reflect the most up-to-date science and provide for health-protective outcomes in consideration of the often data-poor, or data-lacking chemicals to which they are applied.

**35. EPA's rule should avoid assigning greater weight to guideline studies or limiting its use of the published scientific literature in characterizing chemical risks.**

EDF is deeply concerned about the agency's overly constrained characterization of the meaning of study design and quality in the preamble to the proposed rule. This approach jeopardizes EPA's ability to use the best available science, by potentially limiting it to, or giving greater weight to, guideline studies typically used for regulatory purposes, and excluding large swaths of the scientific literature that can provide important information relevant to evaluating a chemical's risks.

This concern is best exemplified on p. 7564, where the preamble to the proposed rule indicates:

> By evaluating study design (e.g., consistent with study guidelines issued by OECD, and test guidelines issued by the Office of Chemical Safety and Pollution Prevention), and study quality (e.g., studies that comply with Good Laboratory Practices (GLP) like those applicable generally applicable generally (*https://www.federalregister.gov/documents/2016/08/24/2016-19875/good-laboratory-practicefor-nonclinical-laboratory-studies*) and those issued by EPA for studies submitted under TSCA and FIFRA (*https://www.epa.gov/compliance/good-laboratory-practices-standards-compliancemonitoring-program*)… .

While guideline studies and studies that comport with good laboratory practices have their value, they are certainly not the only meaningful sources of information relevant to evaluating chemical risks, nor are they gold standards against which to judge the merit of the design and quality of any study. We caution the agency to be mindful as to how study design and quality are characterized in the final rule.

**36. EPA's proposal to formally call for consideration of alternative interpretations of data and analyses is not in TSCA and appears to be at odds with a weight-of-the-scientific-evidence approach.**

The proposed rule at §702.41(b)(3) provides that: "If appropriate and relevant, a discussion of alternative interpretations of the data and analyses will be included." It is not clear how this aligns with a weight-of-the-scientific-evidence approach, which is inherently designed to provide for a defined conclusion of risk, taking into consideration the body of evidence available to evaluate chemical risk. We understand that uncertainties may exist, or assumptions may be used, in the course of a risk evaluation, but these are fundamentally considered and integrated into weight-of-the-scientific-evidence approach to reach a conclusion regarding chemical risk, and should be transparent.

Formally requiring consideration of alternative interpretations would seem to work at odds with the purpose of applying a weight-of-the-scientific-evidence approach, and has been abused in the past to cast doubt and slow action on risks of great societal concern (e.g., lung cancer and secondhand tobacco

smoke[24]). We are concerned about this novel concept being incorporated into EPA's risk evaluation rule, which is not invoked anywhere in the law. EDF recommends that it be removed from the final rule.

**37. EDF supports EPA's decision not to define or specify "weight of the scientific evidence" in its rule.**

Implementation of weight of the scientific evidence is itself a scientific exercise, which may evolve or be refined overtime as greater knowledge and experience related to evidence integration is gained. Indeed, the emergence of systematic review in the field of environmental health, in part as a response to challenges associated with wholly expert-opinion based reviews, provides a recent prime example of how application of weight of the scientific evidence is evolving. Similarly, the advent of the rapidly growing and dynamic field of predictive toxicology has a role in the conduct of weight-of-the-scientific-evidence evaluations, a role that has yet to be fully refined and will evolve as greater experience is gained in its application to risk evaluation.

While certain principles related to weight of the scientific evidence are inviolable (e.g., transparency and objectivity), the agency is best served by maintaining flexibility in the specific execution of weight-of-the-scientific evidence in order to ensure that its application of it is, and remains, commensurate with the best available science.

**PUBLIC INFORMATION, CONFIDENTIAL INFORMATION AND PEER REVIEW**

**38. Full studies considered, included and excluded in the risk evaluation process should be publicly available.**

The appropriateness and strength of conclusions drawn in risk evaluations is wholly dependent on the information identified and used, beginning from the point of determining the risk evaluation scope. It is critical that such information be made publicly available in full so that the public understands and can effectively and constructively comment on the scope, analysis, and conclusions of proposed risk evaluations developed by EPA under section 6(b)(4)(A) or submitted to the agency by interested persons under section 26(l)(5).

Therefore, the rule should expressly require that information EPA, and by extension third parties, use both to determine the scope and conduct a risk evaluation should be available to the public in full. Similarly, persons commenting on draft risk evaluations should be required to provide full copies of any studies not already publicly available to which they refer in their comments, and EPA should provide public access to those studies in full.

[24] See, e.g., D. Michaels (2008) *Doubt is their Product: How Industry's Assault on Science Threatens Your Health*, Oxford University Press, New York, NY, Chapter 7.

Toward this end, the agency should provide for easy online access to studies considered, included, and excluded in determining the scope and in conducting risk evaluations. EPA has effectively done this in other parts of the agency, most notably in the IRIS program where the agency is using the Health and Environmental Research Online (HERO) database to collect, organize, and publicly display the information identified and ultimately used to conduct its human health hazard assessments.[25] The HERO database is also used to house and organize studies used in the development of Integrated Science Assessments (ISA)[26] and Provisional Peer Reviewed Toxicity Values (PPRTV).[27]

We strongly recommend that the agency leverage the HERO database for risk evaluations under TSCA, because of its display and query features and the opportunity to build a centralized repository of current information that can be drawn upon for multiple agency needs and that enables efficiencies in future updating of risk evaluations.

It is important that the public have access to full studies, not simply robust or other study summaries. Without access to full studies, the public will be challenged or unable to ascertain and comment on decisions to include or exclude a study, and crucially, to assess and comment on whether the agency has used the best available science and on its treatment of reasonably available information in a weight-of-the-scientific-evidence approach—considerations that are mandated by the law in sections 26(h) and (i).

Even the best study summaries are incomplete descriptions that disallow an independent examination of study quality and conclusions reached by authors. Common examples of such conclusions include, "findings were not statistically significant," "findings are within the range of historical controls," and "effects observed were non-linear [and therefore biologically questionable or irrelevant]." Divorced from the details of the actual design and results of a study, it is impossible to evaluate the appropriateness of such conclusions.

Finally, systematic review practices require access to full studies, as details of study design and results are necessary elements of consistently determining study quality and ultimately evidence integration.

In sum, EDF strongly recommends that the rule require ready public access to full studies used to develop the scope and to conduct risk evaluations.

[25] For studies published in the peer-reviewed literature and hence already publicly accessible, HERO provides full references and access to the study abstracts, which EDF believes provides sufficient public access to such published studies.
[26] US EPA, "Integrated Science Assessments." Last Updated 16 May 2016. Accessed 23 August 2016. https://www.epa.gov/isa.
[27] US EPA, "Provisional Peer Reviewed Toxicity Values for Superfund (PPRTV)." Accessed 23 August 2016. https://hhpprtv.ornl.gov/quickview/pprtv_papers.php.

**39. EPA's rule appropriately codifies the law's confidential business information (CBI) requirements for industry-requested risk evaluations, but needs to broaden their applicability to all CBI claims in information submitted under the rule.**

EPA has appropriately proposed in §702.37(d) to require companies requesting risk evaluations to meet all applicable requirements of the law when submitting requests and associated information to EPA, including providing upfront substantiations for all CBI claims other than those specified in TSCA section 14(c)(2).[28]

However, numerous other aspects of this rule may entail submission of information containing CBI claims. EPA must broaden §702.37(d) to encompass all such claims.

With respect to risk evaluations made under section 6(b), we note that section 6(b)(4)(H) requires draft and final risk evaluations to be made public. In addition, 26(j) of the new law states that all determinations and findings are to be made public, subject to section 14.

In conducting risk evaluations, EDF believes that a large fraction of the information EPA relies on will constitute health and safety studies or underlying information. TSCA's definition of this term in section 3(8) is very broad and includes information on chemical hazards, fate and exposures as well as the results of any testing EPA requests or requires:

> The term ''health and safety study'' means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

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

In addition, any CBI claims for other types of information EPA obtains under TSCA are subject to the assertion, certification, substantiation, review, and expiration requirements of section 14.

In its final rule, EPA should make clear that these requirements, including those applicable to EPA as well as CBI claimants, are to be applied rigorously and in a manner that maximizes public access to the information EPA uses to conduct its risk evaluations.

[28] EPA published a clarification of the law's substantiation requirements in a Federal Register notice published on January 19, 2017. That notice clearly states, based on extensive supporting analysis, that all CBI claims other than those for information delineated in section 14(c)(2) must be substantiated at the time they are asserted. 82 Fed. Reg. 6522. Available at https://www.federalregister.gov/documents/2017/01/19/2017-01235/statutory-requirements-for-substantiation-of-confidential-business-information-cbi-claims-under-the.

**40. Peer reviews of EPA risk evaluations need to use procedures to ensure reviewers do not have conflicts of interest.**

EDF anticipates that EPA will typically subject many but not all of its draft risk evaluations to peer review, in addition to public comment. The preamble to EPA's proposed risk evaluation rule addresses and identifies the circumstances under which EPA will do so; EDF generally agrees with EPA's proposed approach.

As an initial matter, EPA's regulatory text at §702.41(c) is not fully consistent with its discussion of peer review in the preamble. The regulatory text states that "Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A)," implying it will always occur. Yet EPA has noted in its preamble discussion (p. 7573) that only some risk evaluations will require or warrant peer review. EPA should make its regulatory text consistent.

The final rule should ensure that procedures and requirements EPA will follow are sufficient to ensure that individuals with conflicts of interest or an appearance of impartiality are excluded from peer review panels, subject only to the very narrow exceptions current provided. These procedures and requirements should be consistent with those called for under other federal requirements, including EPA's peer review handbook, which EPA's proposed rule cites in at §702.41(c).[29]

We urge EPA to consider the recommendations EDF provided in our 2012 comments on EPA's peer reviews plans for its Work Plan chemical risk assessments (available here), as well our recommendations for contractor-managed peer reviews,[30] should EPA decide to employ such peer reviews.

**OTHER ISSUES**

**41. EPA's proposed authority to revisit a risk determination is acceptable, subject to certain limitations.**

While not expressly addressed in the law, EPA's proposed risk evaluation rule includes authority for EPA to "reassess an unreasonable risk determination based on a review of available information" (§702.45(c)).

[29] See US EPA, "Peer Review Handbook 4th Edition", (2015). https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.

[30] See Richard Denison and Rachel Shaffer, Environmental Defense Fund, "Letter to Dr. Glenn Paulson." 20 November 2013. http://blogs.edf.org/health/files/2016/08/EDF-EPA-COI-recommendations-letter-final-20131120_with-attachments.pdf.

We support EPA having this authority, but strongly believe it should only be able to be exercised following a final agency action, lest it be used as a means of delaying that action. Specifically, the redetermination authority should be provided to EPA once EPA either issues an order as required where it determines a chemical substance does not present an unreasonable risk (pursuant to TSCA section 6(i)(1) and §702.45(d)), or promulgates a final section 6(a) rule after determining a chemical substance presents an unreasonable risk (pursuant to TSCA section 6(a) and 6(i)(1) and §702.45(c)).

The law is clear that if EPA determines that a chemical substance presents an unreasonable risk, it must promulgate a risk management rule pursuant to section 6(a); see TSCA section 6(c)(1). The law is equally clear that a determination by EPA that a chemical substance presents an unreasonable risk is not a final agency action until the requisite risk management rule is promulgated pursuant to section 6(a); see TSCA section 6(i)(2). Providing a means for EPA to "reassess an unreasonable risk determination" at any time prior to a final agency action would undermine a core intent of the law.

Authority to revisit a prior determination is clearly warranted. Production or use of a chemical is likely to change over time, as may other aspects of the chemical's conditions of use that could alter exposure to the substance or which subpopulations may be exposed. In addition, new information on exposures as well as on the hazards and environmental and biological fate, transport and other properties of a chemical may emerge over time. Advancements in science or chemical testing relating to chemical hazards and exposures may emerge that warrant integration into risk evaluations.

EPA's rule should provide a process by which a person may request EPA to undertake a redetermination and a requirement that EPA promptly make such requests public and promptly respond to that request and explain its decision.

EPA should consider further describing, in guidance but not in this rule, under what circumstances EPA would consider revisiting a prior final determination. EPA should identify specific events (e.g., receipt of a notice under section 8(e) that indicates a substantial risk) as well as general criteria (a substantial change in the use pattern of a chemical), that would serve as "triggers" for considering the need for a redetermination.

**42. EPA needs to take a broad approach in guidance to evaluating chemical substances that are persistent or bioaccumulative.**

In conducting risk evaluations on chemicals, the new law requires EPA to consider various aspects of chemicals' hazards and exposures that will need to reflect the extent to which chemicals are persistent or bioaccumulate in the environment or organisms; see TSCA section 6(b)(4)(F).

Traditionally, EPA has used relatively narrow criteria and information to define and assess such chemical characteristics. The approach has largely assumed that chemicals are released to aquatic media, remain in the water column, and are taken up by aquatic organisms such as fish, free-swimming invertebrates

or algae. For bioaccumulation, accumulation of hydrophobic substances in fat tissue is typically assumed.

Yet a large and growing body of scientific research demonstrates the need to broaden these assumptions and tests for these chemical characteristics. For example, some chemicals can be taken up directly from air and bioaccumulate through food webs in air-breathing terrestrial animals (including humans).[31] Some chemicals, such as PFOA and related perfluorinated compounds, do not meet typical criteria for bioaccumulation that only assess uptake from water into fish and accumulation in fatty tissues. Yet PFOA does have bioaccumulative properties, as it binds to blood proteins and builds up in blood rather than fatty tissue or organs.[32] With respect to persistence, some chemicals that do not meet current test criteria or technical specifications for persistence nevertheless can result in chronic exposures because of the nature of their use and release; such chemicals have been termed "pervasive due to continuous release."[33]

Hence, in evaluating chemicals that may present an unreasonable risk, EPA needs to consider the best available science and think beyond the incomplete and more limited criteria and testing methods typically relied on to assess persistence and bioaccumulation.

Note, however, that EDF does not believe such issues should be addressed in the rule, but rather through guidance.

**43. EPA appropriately proposes to be able to conduct risk evaluations of categories of chemical substances, with some clarifications needed.**

EDF supports EPA's proposed authority in 702.39(a)(3) to conduct a risk evaluation on a category of chemical substances. Two small changes should be made to the regulatory text, however. In the phrase "may consider the hazards and exposures associated with the category of chemical substances, and the populations likely to be exposed":

- "may" should be changed to "shall." If EPA is conducting the evaluation on the category, these considerations should not be optional.

[31] See, for example, Kelly, B., Ikonomou, M.G., Blaire, J.D., Morin, A.E., Gobas, F.A.P.C., "Food Web–Specific Biomagnification of Persistent Organic Pollutants." *Science*. 13 July 2007. Vol 317. Issue 5835. pp 236-239. http://science.sciencemag.org/content/317/5835/236.

[32] See, for example, Seals, B., Bartell, S.M., and Steenland K., "Accumulation and Clearance of Perfluorooctanoic Acid (PFOA) in Current and Former Residents of an Exposed Community." *Environmental Health Perspectives*. 2011. Vol 119. No 1. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3018490/ and US EPA "Research on Per- and Polyflouroalykyl Substances (PFAS)." Last Updated 12 August 2016. Accessed 22 August 2016. https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas.

[33] United Nations Environment Programme/Global Environment Facility (UNEP/GEF) project cited in "Phase Out Persistent, Bioaccumulative, or Highly Toxic Chemicals," Background Paper #2, Louisville Charter, August 2005, available at http://www.comingcleaninc.org/louisville-charter/2-phase-out-toxic-chemicals.

- the phrase "the populations likely to be exposed," EPA should use the term defined in the law: "potentially exposed or susceptible subpopulations."

**44. EPA's proposed rule inappropriately suggests EPA would not necessarily use already existing information derived from testing on vertebrate animals.**

In §702.39(b)(5), EPA states: "Where appropriate, to the extent practicable, and scientifically justified, EPA will use information generated without the use of testing on vertebrates in performing risk evaluation." This wording suggests that EPA would not utilize even pre-existing information derived from prior testing on vertebrates where viable information from non-vertebrate tests is available.

Such a requirement or approach is not consistent with the law. All of the references in the law that address reducing testing using vertebrate animals refer to *new testing*, not to the use of existing information derived from testing on vertebrate animals. See sections 4(a)(3) and 4(h). In fact section 4(h)(1)(A) requires EPA to take into consideration just such existing information (emphases added):

> (h) REDUCTION OF TESTING ON VERTEBRATES.—
>
> (1) IN GENERAL.—The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures under this title, by—
>
> (A) *prior to making a request or adopting a requirement for testing using vertebrate animals*, and in accordance with subsection (a)(3), *taking into consideration*, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—
>
> (i) *toxicity information*;

§702.39(b)(5) of EPA's rule needs to be redrafted to make clear EPA can and should use existing information derived from testing on vertebrates. Such information can be considered alongside any viable information developed through the use of non-vertebrate testing methods. A suggested rewrite of this provision would be:

> "Where appropriate, to the extent practicable, and scientifically justified, EPA will *require the development of* information generated without the use of testing on vertebrates in performing risk evaluation."

EDF appreciates the opportunity to provide these comments to the agency as it finalizes this important procedural rule.