



**Comments on**  
**Risk Evaluation Procedural Rule**  
**EPA-HQ-OPPT-2016-0400**  
**81 Federal Register 48789-48791 (Tuesday, July 26, 2016)**  
**Submitted August 24, 2016**

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to EPA on the forthcoming risk evaluation rule it is developing, as required under the Lautenberg Act.

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 amounts of public comment;
- allow for EPA to routinely meet deadlines; and
- avoid science policy issues that would be better left to guidance.

Our comments address the following specific points and recommendations:

[1. The risk evaluation rule should be procedural in nature, and the specifics of science policy issues should be left to guidance documents and policy statements.](#)

[2. Close coordination between the prioritization and risk evaluation processes is needed 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.](#)

[b. The timing of the prioritization and risk evaluation processes must be closely coordinated.](#)

[3. The risk evaluation rule should further delineate key definitions.](#)

a. “Intended, known, or reasonably foreseen” conditions of use

b. “Potentially exposed or susceptible subpopulations”

#### 4. Establishing the scope of a risk evaluation

a. EPA should provide a public comment opportunity for risk evaluation scopes.

b. EPA should consider all uses of a chemical and all potentially relevant subpopulations in developing the scope of a risk evaluation, but should have authority to choose a scope that is narrower where fully justified.

c. EPA should have authority to alter the scope of or temporarily bifurcate a risk evaluation under certain circumstances and where fully justified.

d. Scoping decisions for the risk evaluation of a chemical cannot alter the chemical’s prior designation as a high-priority substance.

5. For uses and conditions of use included in the scope of a risk evaluation, EPA should generally assess exposure on an aggregate basis.

#### 6. Third-party draft risk evaluations

a. Third-party draft risk evaluations need to be made publically available with opportunity for public comment.

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

c. Third-party draft risk evaluations should conform to EPA’s guidance.

d. The scope of third-party draft risk evaluations should not determine or limit the scope of EPA’s risk evaluation.

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

#### 7. Industry-requested risk evaluations

a. EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, should always establish the scope of the risk evaluation.

b. 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 it conducts.

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

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

e. 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.

f. EPA should provide public notice of and an opportunity to comment on all industry requests for risk evaluations.

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

9. Principles of systematic review should be incorporated into the TSCA risk evaluation process, but not specified in the rule.

10. EPA needs to take a broad approach to identifying chemicals that are persistent or bioaccumulative.

11. EPA's rule should codify confidential business information (CBI) requirements to maximize public access to the information EPA uses to conduct its risk evaluations.

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

13. Triggers are needed for re-evaluation of a chemical for which a risk evaluation has been completed.

**1. The risk evaluation rule should be procedural in nature, and the specifics of science policy issues should be left to guidance documents and policy statements.**

EDF believes that the final risk evaluation rule should establish 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 science policy issues related to risk evaluation, including those raised in sections 6(b)(4)(F), 26(h), 26(i), and 26(l)(3), are better addressed in guidance documents and policy statements that are more nimble. 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.

**2. Close coordination between the prioritization and risk evaluation processes is needed 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)]

To ensure a smooth and transparent process and transition between prioritization and risk evaluation, EPA needs to clearly define and consistently apply these “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 criteria:

- 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.

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

As already noted, 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.

EDF believes that the needed coordination between the timing of the prioritization and risk evaluation processes would be best achieved 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. Through this strategy, 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.

### **3. The risk evaluation rule should further delineate key definitions.**

#### **a. “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)].

In identifying circumstances that are “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.<sup>1</sup> 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) 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. (While we believe such accidental misuse 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.)

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<sup>1</sup> 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/>.

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<sup>2</sup> and chemical facility spills.<sup>3</sup>

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,<sup>4</sup> 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.

EPA’s risk evaluation rule should consider these factors in addressing how and what EPA will consider to be “intended, known, or reasonably foreseen” conditions of use of a chemical.

### **b. “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.

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<sup>2</sup> “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](http://www.blm.gov/style/medialib/blm/ak/aktest/planning/ne_npra.Par.31802.File.pdf/ne_npra_app_k.pdf).

<sup>3</sup> 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>.

<sup>4</sup> 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%9C-CSPA-Safe-Chemicals>.

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.

**i. The list of example subpopulations provided in the law is not exhaustive.**

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.

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.

EDF recommends that the risk evaluation rule clearly articulate EPA’s authority to include potentially exposed or susceptible subpopulations not explicitly listed in the law.

**ii. EPA needs to establish a process to define relevant subpopulations.**

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, there may be relevant procedural steps that the Agency should address in the rule.



#### **4. Establishing the scope of a risk evaluation**

##### **a. EPA should provide a public comment opportunity for risk evaluation scopes.**

EDF considers the scoping step in the risk evaluation process to be critically important, not only because it defines and communicates the depth and 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 develops for Work Plan chemical risk assessments, which are essentially the same as risk evaluation scopes.<sup>5</sup>

However, it is imperative that the addition of this comment period in no way impinge on EPA's ability to meet its statutory deadlines for completing risk evaluations. See section 2 above on close coordination between the prioritization and risk evaluation processes, as well as section 3.c. in our comments on EPA's prioritization rule, for our recommendations on how EPA can smoothly and efficiently incorporate public comment on scopes into its overall prioritization and risk evaluation processes.

##### **b. EPA should consider all uses of a chemical and all potentially relevant subpopulations in developing the scope of a risk evaluation, but should have authority to choose a scope that is narrower where fully justified.**

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<sup>5</sup> EPA states:

"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>.

The risk evaluation scope delineates all major elements of the evaluation. EPA is to identify “the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider” [section 6(b)(4)(D)]. In deciding what the scope should be, EDF believes EPA needs to examine the full range of each of these parameters for the chemical in question. Only by doing so can there be confidence that EPA has knowledge of and has considered all such uses, etc. And only by doing so can it then make a reasoned decision as to whether there is a sound basis upon which to narrow the scope that EPA actually addresses in the risk evaluation itself.

The statute’s inclusion of the phrase “the Administrator expects to consider” strongly suggests that EPA should be able to exercise its expert judgment and have some leeway in deciding whether to subject all hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations to full risk evaluation. At the same time, EPA needs to provide an explicit and transparent justification for any exclusions. The Agency must fully explain why it has chosen to include and exclude specific uses and populations.

Decisions to exclude certain hazards, exposures, conditions of use or subpopulations from the scope of a risk evaluation, however, should never be based on cost or other non-risk factors. In particular, a lack of information should never be a sufficient reason for excluding a hazard, exposure, condition or use or subpopulation.<sup>6</sup> The statute provides EPA with express and ample authority under section 4 to require testing or data call-ins to obtain the information it needs, and EPA should routinely make use of this authority.

By definition, any use or condition of use of a chemical that is excluded will not undergo a full risk evaluation. As a result, no determination with respect to unreasonable risk of that use or condition of use is warranted; that is, such exclusions *cannot* be characterized as not presenting or not likely to present an unreasonable risk. (It should go without saying that no preemption of state authority under section 18 attaches to any such uses.)

These allowances, limitations and expectations should be made clear in EPA’s risk evaluation rule.

**c. EPA should have authority to alter the scope of or temporarily bifurcate a risk evaluation under certain circumstances and where fully justified.**

EDF recognizes that the risk evaluation process will be a somewhat dynamic one, and that, in the course of conducting one, EPA may develop information or analyses that warrant expanding or contracting the scope of the risk evaluation. The rule should provide EPA with the authority to change the scope of the risk evaluation, but subject to full and transparent justification for any changes.

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<sup>6</sup> 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 assess 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.

Here again, such changes must be science-based and not merely based on lack of information. And any altered scope must promptly be made public, as it has immediate implications for the attendant scope of preemption of an ongoing risk evaluation [see section 18(c)(2)].

There may also be cases where EPA has sufficient information on a subset of uses, subpopulations, etc. to conclude they present an unreasonable risk and complete a risk evaluation, but for others it needs more information. It should be possible in such cases to temporarily bifurcate a risk evaluation pending receipt of the needed information, so that the final risk determinations and needed risk management for the subset with sufficient information are not unnecessarily held back. Three conditions should apply in such cases however:

1. EPA must immediately put in motion mandatory requirements to obtain the needed information on the remaining, uses, subpopulations, etc.
2. The nature of and decision supporting the temporary bifurcation of the risk evaluation must be clearly and publicly explained and justified.
3. The full scope of the risk evaluation must still be completed within the statutory deadlines.

It would not be appropriate, however, for EPA to complete a risk evaluation on only a subset of uses of a chemical for which it finds they do not present an unreasonable risk. That is because such a determination needs to be made considering the risks of *all* uses included within the scope of the assessment. In other words, while one could legitimately conclude that a subset of uses 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 rule governing risk evaluations.

**d. Scoping decisions for the risk evaluation of a chemical cannot alter the chemical's prior designation as a high-priority substance.**

The new law is unambiguous in stating that chemical substances, not particular uses or conditions of use, are to be subject to prioritization [see section 6(b)(1)]. Any chemical substance designated as a high priority must be subjected to a risk evaluation, again under its conditions of use. So, while EPA is to both prioritize and assess the risks of a chemical under its conditions of use, that does *not* mean EPA is to prioritize only certain uses of a chemical.

Nor is the law's requirement that EPA assign a priority status to each chemical substance, and not to specific uses or conditions of use of that substance, altered where EPA bases a high-priority designation on only a subset of uses or conditions of use. EPA may well be able to designate a chemical as a high priority based on only certain uses or conditions of use of that chemical.<sup>7</sup>

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<sup>7</sup> In contrast, low-priority designations must be based on consideration of the full range of uses and conditions of use. First, the designation applies to the chemical substance, not particular uses or conditions of use. Second, were EPA not to consider certain uses or conditions of use, an ensuing low-priority designation would be highly

It follows, then, that decisions by EPA to narrow the scope of a risk evaluation to a subset of uses or conditions of use does not mean that the excluded uses or conditions of use are low-priority or do not present an unreasonable risk.

**5. For uses and conditions of use included in the scope of a risk evaluation, EPA should generally assess exposure on an aggregate basis.**

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.”

EDF’s comments on this issue follow.

The desirability of assessing chemicals exposures on an aggregate basis – defined by EPA to “involve the analysis of exposure to a single chemical by multiple pathways and routes of exposure”<sup>8</sup> – 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.<sup>9</sup> 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*.<sup>10</sup>

In contrast, some in industry support EPA assessing exposure based on identification and assessment of one or more “sentinel exposures,” which may be described as “tak[ing] into consideration the most ‘risky’ exposure scenario to simplify the analysis.”<sup>11</sup>

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suspect because of the distinct possibility that the designation might not be warranted had all uses and 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 uses and 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.

<sup>8</sup> US EPA “General Principles for Performing Aggregate Exposure and Risk Assessments for Pesticides.” Last Updated 30 September 2015. Accessed 22 August 2016. <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/general-principles-performing-aggregate-exposure-and>.

<sup>9</sup> 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>.

<sup>10</sup> 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>.

<sup>11</sup> International Council of Chemical Associations. “ICCA Regulatory Toolbox: Guidance on the Introduction or Revision of Legislation on Chemicals Management for Developing Countries.” 2006. <https://www.icca->

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.

We've argued above that EPA should have some latitude to select a subset of uses and conditions of use as the scope of a particular risk evaluation. However, in conducting the risk evaluation, EDF believes EPA should conduct an aggregate exposure assessment across those uses and conditions of use included in the scope. Only if EPA can compellingly demonstrate that another approach fully captures the risk across these uses and conditions of use should it not take the aggregate approach.

## **6. 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."

In developing its risk evaluation rule, EDF believes EPA should address this provision and include the following:

### **a. 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.

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[chem.org/wp-content/uploads/2015/08/ICCA-Regulatory-Toolbox-Guidance-on-Chemicals-Management-for-Developing-Countries.pdf](http://chem.org/wp-content/uploads/2015/08/ICCA-Regulatory-Toolbox-Guidance-on-Chemicals-Management-for-Developing-Countries.pdf).

**b. 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.

**c. 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 in order for them to be considered by the Agency, or at the very least should require the Agency to consider the extent of conformance in deciding what weight should be given to such draft risk evaluations.

**d. 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 either includes all conditions of use of a chemical or fully justifies any exclusions on the same basis as discussed earlier in the comments in reference to EPA risk evaluations.

In any case, even 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.

**e. 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 must be submitted to the Agency in order for it to be considered. We suggest such deadline be no later than 6 months after EPA publishes the scope of a risk evaluation it is conducting.

The submission of third-party draft risk evaluations late 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 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. (EPA should consider establishing a similar deadline for other types of information submitted by third parties in the context of the risk evaluation process.)

## **7. 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 need to be reflected in the EPA risk evaluation rule, including the following:

- Requests can only be made by chemical manufacturers. [see section 6(b)(4)(C)(ii)]
- 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)]
- 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)]
- 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)]
- 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)]
- 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)]
- 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)]
- EPA “shall not expedite or otherwise provide special treatment” to industry-requested risk evaluations. [see section 6(b)(4)(E)(ii)]
- 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)]
- 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)]

Below we elaborate on several of these requirements.

**a. EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, should always 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.

Yet some industry representatives are suggesting 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 risk evaluation rule, EPA should affirm that EPA has sole responsibility and authority to establish the scopes of all risk evaluations it undertakes.

**b. 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 it 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 the 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 risk evaluation rule or its fee rule (or both), 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 comment).



**c. 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 elsewhere in these comments) 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.

In its 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.

**d. 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 EPA initiates on its own – 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 should require receipt of applicable fees prior to initiating such risk evaluations.

**e. 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, EDF believes EPA's 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.

**f. EPA should provide public notice of and an opportunity to comment on all industry requests for risk evaluations.**

While not explicitly called for under the law, EDF believes that EPA's risk evaluation rule should require EPA to make public and provide an opportunity for public comment on all industry requests for risk evaluations. EPA should also promptly make public its decisions regarding such industry requests.

This requirement is important for overall transparency of the EPA risk evaluation program and its priorities, and provides 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).

**8. 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 make those studies publicly available in full.

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.<sup>12</sup> The HERO database is also used to house and organize studies used in the development of Integrated Science Assessments (ISA)<sup>13</sup> and Provisional Peer Reviewed Toxicity Values (PPRTV).<sup>14</sup>

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<sup>12</sup> 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.

<sup>13</sup> US EPA, "Integrated Science Assessments." Last Updated 16 May 2016. Accessed 23 August 2016. <https://www.epa.gov/isa>.

<sup>14</sup> US EPA, "Provisional Peer Reviewed Toxicity Values for Superfund (PPRTV)." Accessed 23 August 2016. [https://hhpprtv.ornl.gov/quickview/pprtv\\_papers.php](https://hhpprtv.ornl.gov/quickview/pprtv_papers.php).

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.

As already mentioned, information used to develop the scope and conduct risk evaluations should be made available in full, meaning that the public should 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 the quality of a study and its treatment in a weight of 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, as systematic review practices are more fully integrated into risk evaluations, access to full studies will be required, 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.

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

EDF applauds EPA’s interest in and efforts to increasingly integrate systematic review practices into its risk evaluations, as EPA indicated during the stakeholder meeting on the risk evaluation rule held on August 9, 2016. Systematic review has increasingly been the practice of human health hazard assessments conducted by the 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 principle of transparency inherent and manifested in the practice of systematic review supports 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. To that end, the structure and transparency of

literature searches and study inclusion and exclusion criteria and decisions that are core elements of systematic reviews are directly applicable.

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.<sup>15</sup>

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 evidence” approaches.

In developing and applying systematic review to TSCA risk evaluations, we encourage the Agency to look to the National Toxicology Program’s Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration<sup>16</sup> and the Navigation Guide methodology led by researchers at UCSF.<sup>17</sup>

While we strongly urge EPA to integrate systematic review 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 rules are the appropriate vehicles 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.

#### **10. EPA needs to take a broad approach to identifying chemicals 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 section 6(b)(4)(F).

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<sup>15</sup> 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>.

<sup>16</sup> 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](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf).

<sup>17</sup> 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>.

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).<sup>18</sup> 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.<sup>19</sup> 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.”<sup>20</sup>

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.

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<sup>18</sup> 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>.

<sup>19</sup> 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 Polyfluoroalkyl Substances (PFAS).” Last Updated 12 August 2016. Accessed 22 August 2016. <https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas>.

<sup>20</sup> 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>.

**11. EPA’s rule should codify confidential business information (CBI) requirements to maximize public access to the information EPA uses to conduct its risk evaluations.**

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 confidential business information (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 rule, EPA should make clear that these requirements are to be applied rigorously and in a manner that maximizes public access to the information EPA uses to conduct its risk evaluations.

**12. 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 its draft risk evaluations to peer review, in addition to public comment. EPA’s risk evaluation rule should address and identify the circumstances under which EPA will do so. The rule should also describe the procedures and requirements EPA will follow to ensure that individuals with conflicts of interest or an appearance of impartiality are generally excluded from peer review panels. These procedures and requirements should be consistent with those called for under other federal requirements, including EPA’s peer review handbook.<sup>21</sup>

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<sup>21</sup> See US EPA, “Peer Review Handbook 4<sup>th</sup> Edition”, (2015). <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>.

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,<sup>22</sup> should EPA indicate it would employ such peer reviews.

**13. Triggers are needed for re-evaluation of a chemical for which a risk evaluation has been completed.**

While not expressly addressed in the law, EPA’s risk evaluation rule should include express authority for EPA to undertake a new, or update an existing, risk evaluation on a chemical subsequent to completion of a risk evaluation, and it should describe under what circumstances EPA would consider doing so.

Such authority is clearly needed. Production or use of a chemical is likely to change over time, as may other changes in 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 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 serve as “triggers” for a re-evaluation.

EDF appreciates the opportunity to provide these comments to the Agency as it develops this important procedural rule.

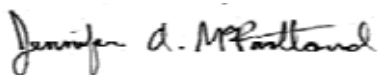
Sincerely,



Richard A. Denison, Ph.D.  
Lead Senior Scientist



Lindsay A. McCormick  
Research Analyst



Jennifer McPartland, Ph.D.  
Senior Scientist



Jonathan J. Choi  
High Meadows Fellow

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<sup>22</sup> 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](http://blogs.edf.org/health/files/2016/08/EDF-EPA-COI-recommendations-letter-final-20131120_with-attachments.pdf).