EDF Comments on

TSCA Procedures for Prioritization of Chemicals for Risk Evaluation

Proposed Rule, Docket EPA-HQ-OPPT-2016-0636

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 prioritization of chemicals for risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

EDF strongly supports most aspects of the EPA's proposed rule implementing the Lautenberg Act's requirement that EPA establish, by rule, "a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time." [TSCA as amended, section 6(b)(1)(A)].

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 our detailed below.

Table of Contents

Overarching points and major provisions of EPA's proposed rule that EDF supports

EDF believes the purpose of prioritization is to provide an orderly, transparent process for EPA to use in working its way through the huge backlog of chemicals needing safety reviews and to provide an accountable means by which EPA decides which chemicals need full risk evaluations and which have ample information indicating they can be set aside at the time of the decision. To do so, the prioritization rule itself should be procedural in nature, setting up basic work flows and processes but avoiding prescribing a specific, detailed methodology. Specifically, an effective prioritization 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 prioritization and subsequently 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.

It is vital that EPA meet its 1-year statutory deadline for promulgating this rule (June 22, 2017), as well as the other "framework" rules governing the processes to be used for inventory notification and risk evaluation. Because these rules establish processes that will require some time 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 do a significant amount of upfront data gathering and review to inform prioritization and subsequent risk evaluation.

1. EPA appropriately proposes a rule that is procedural in nature and avoids specifying science policy issues that are better addressed in guidance and policy statements.

The proposed rule appropriately sets up a process by which chemicals will be prioritized, without specifying science policy or codifying in detail science policy terms in the rule. EDF believes that the final prioritization 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 prioritization, including those raised in sections 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 scientific 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 that could require frequent updating of the

rule to keep pace with the science. Rather, EDF believes the agency should utilize existing guidance, revise existing guidance, or develop new guidance to fulfill this need.

EPA indicates it already relies upon agency guidance for elaborating terms such as "best available science" and "sufficiency of information," and intends to use existing guidance definitions and update them as necessary. EDF fully supports EPA's rationale:

> EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility and responsiveness of the Agency to quickly adapt to and implement changing science. The Agency intends to use existing guidance definitions and to update definitions and guidance as necessary. (p. 4828)

The proposed rule also appropriately recognizes that EPA is not obligated to codify the TSCA section 26 scientific standards in the prioritization rule, and that Congress did not intend for it to do so:

> TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA use certain scientific standards and base those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the prioritization of chemical substances, EPA is not obliged to include them in this proposed rule. By their express terms, these statutory requirements apply to EPA's decisions under TSCA section 6, without the need for regulatory action. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements ''by rule;'' it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions. (p. 4828)

Beyond the arguments presented by the agency cited above, EDF believes that if it had been the intent of Congress for EPA to codify these terms by rule, it would have directed EPA to promulgate rules for all of the processes to which the section 26 provisions apply – including section 5 new chemical reviews, yet it did not do so.

2. EPA's proposed rule provides the appropriate level of detail on the prioritization process and appropriately does not propose an exact scoring or ranking process.

EPA's proposed rule does not – and should not – establish a prescriptive scoring or ranking process the agency would need to follow in order to identify chemicals subject to prioritization. As correctly articulated in the proposed rule: "EPA is not required to select candidates or initiate prioritization pursuant to 40 CFR 702.9 in any ranked or hierarchical order" (§702.7(b)).

Some in industry have argued that EPA's prioritization rule should establish essentially an algorithm that uses specific scoring or ranking schema. Presumably, the desire is to establish a prioritization methodology that another entity could replicate to predict which chemicals are likely to enter the prioritization pipeline. EDF strongly disagrees with this approach.

Given the very large number of candidate chemicals (EPA is already aware of over 1,000 chemicals with known hazard)[1] and the relatively small number of high-priority chemicals to be evaluated at any given time (EPA likely only needs to identify another 10 or so such chemicals in the next couple of years), it would be unnecessarily expensive, time consuming, and of very little public value to define the methodology so finely.

The purpose of the prioritization rule is *not* to ensure that EPA selects high-priority chemicals in their exact order of risk or potential risk. While desirable in the abstract perhaps, this is simply not realistic given the huge data gaps for the great majority of chemicals under TSCA's jurisdiction. Instead, the objective of the prioritization rule should be to ensure EPA identifies chemicals for risk evaluation using potential risk as the metric to determine the approximate order in which chemicals are assessed.

With thousands of chemicals to assess for relative priority, we believe that Congress wanted to ensure EPA focuses its limited resources first on chemicals that are generally expected to be more risky than others. To develop an algorithm that provides the exact order of chemicals based on potential risk would require an extraordinary investment on the part of EPA to develop – one that does not make sense given that EPA is required to assess a relatively small number of chemicals at a time. ***It would also put the cart before the horse, effectively requiring EPA to conduct risk evaluations just to establish the order in which it would then conduct risk evaluations.***

Such a prescriptive approach would require EPA to identify in the rule exactly what models it would use, how such models would be parameterized, and the data sources that would be "fed" into the models. This would be both costly and limiting, as EPA would need to expend significant resources to develop the algorithm and then would need to go through a costly and time-consuming rulemaking process any time one of the elements of the algorithm needed an update due to evolving science or new information.

Given the rapid evolution and development of tools and techniques to screen chemicals, codifying their use in a rule is not a realistic or advisable approach, as they may quickly become obsolete. For example, some of the screening tools available today under the general term "computational toxicology and exposure" are significantly more advanced than they were five – or even two – years ago. We can expect these tools to continue to improve in the coming years. EPA should have the ability to utilize new – and likely more accurate and possibly less expensive – methods for screening and prioritizing

[1] See: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf

chemicals pursuant to this rulemaking without having to undertake additional rulemaking to update the algorithm.

Finally, the argument that industry needs a prescriptive approach to have a predictable planning horizon is not compelling. First, given EPA's original selection process used to identity chemicals on the TSCA Work Plan, industry already knows the first hundred or more chemicals that are likely to be subject to serious consideration for prioritization. Indeed, the roughly 90 chemicals on the 2014 Work Plan are explicitly identified in the statute as a starting point for the first several rounds of selecting high-priority chemicals. The Lautenberg Act requires that not later than 3.5 years after the date of enactment, at least 50% of ongoing risk evaluation are to be drawn from the 2014 update of the TSCA Work Plan [section 6(b)(2)(B)]. Second, the statutorily mandated process after initiation of prioritization is a 9-12 month process. No company will be blind-sided by the selection of a chemical as a high-priority.

In sum, we fully support EPA's proposal not to specify an exact scoring or ranking system in the prioritization rule, as the most practical, scientifically-sound, and cost-effective approach.

As noted above, some in industry have argued for and at times proposed a far more prescriptive approach that we consider unworkable. We have included EDF's earlier critiques of a prescriptive prioritization process proposed by American Chemistry Council in an appendix to these comments.

3. EPA appropriately proposes a "pre-prioritization" stage to gather needed data and meet the statutory requirements of the Lautenberg Act.

a. The need for a pre-prioritization stage

There are currently thousands of chemicals on the market that lack even basic data on their health and environmental impacts.[2,3] While much of the focus of prioritization will initially be on chemicals about which EPA knows a considerable amount, such as many of the Work Plan chemicals,[4] the process established by this rule will also need to accommodate those chemicals for which EPA has much less data.

[2] Judson, R., Richard, A., Dix, D.J., Houck, K., Martin, M., Kavlock, R., Dellarco, V., Henry, T., Holderman, T., Sayre, P., Tan, S., Carpenter, T., Smith, E., "The toxicity data landscape for environmental chemicals." *Environmental Health Perspectives* (2009) Vol 117 (5). http://www.ncbi.nlm.nih.gov/pubmed/19479008.

[3] Egeghy, P.P., Judson, R., Gangwal, S., Mosher, S., Smith, D., Vail, J., Cohen Hubal, E.A., "The exposure data landscape for manufactured chemicals." *Science of The Total Environment* (2012) Vol 414. http://www.ncbi.nlm.nih.gov/pubmed/22104386.

[4] There are Work Plan Chemicals that also lack sufficient data. For example, EPA released a Data Needs Assessment in December 2015 for the Work Plan Chemicals TBB and TBPH concluding that "the toxicological profile and exposure profile for this cluster of chemicals is incomplete and inadequate to develop a TSCA work plan risk assessment." https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0491-0002

In contrast to the prioritization process EPA used to establish its Work Plan, which relied on readily available data and did not seek to determine the priority of chemicals with significant data gaps,[5] a lack of data under the new law cannot be used as a rationale *not* to subject chemicals to prioritization or to make prioritization decisions on the chemicals. Two provisions of the new law are especially worth noting:

Section 6(b)(1)(B)(ii) states:

> The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, *based on information sufficient to establish*, without consideration of costs or other non-risk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance. [emphasis added]

Section 6(b)(1)(C)(iii) provides for a process by which EPA can slightly extend the deadline for a prioritization decision in order to receive or evaluate information required to be submitted – but:

> subject to the limitation that *if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance*. [emphasis added]

Therefore, EPA must have a considerable amount of information on which to base its prioritization designations and subsequently to assess the risk of high-priority substances, as insufficient information cannot be the basis for designating a chemical as low-priority or *not* subjecting a chemical to prioritization. In addition, once a chemical is designated a high priority, a risk evaluation must be completed within the statutory timeframe [section 6(b)(3)(A)], and that chemical's high-priority designation cannot be altered.[6]

Furthermore, under the law, EPA only has 9-12 months between initiating the prioritization process until final designation of a chemical as either high or low-priority [6(b)(1)(C)]. Immediately following this designation, EPA must initiate the risk evaluation process, which in turn has strict deadlines.

Due to the data needs coupled with the deadlines set forth by Congress, we agree with EPA that it must generally have all or most of the data needed to designate a chemical as low-priority or conduct a full risk evaluation – which must address all conditions of use – at the outset of the prioritization process. While the law requires EPA to provide a 90-day period for interested individuals to submit data on chemicals at the beginning of the prioritization process, this alone is likely to be insufficient for the great majority of chemicals.

Given these demands, we fully support EPA's proposed pre-prioritization stage to gather needed data.

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[5] US EPA, EPA Public Meeting Presentation: Prioritization Procedural Rule, August 10, 2016: https://www.epa.gov/sites/production/files/2016-08/documents/prioritization_public_meeting_8.10.16_slides_final_v2.pdf

[6] Section 6(b)(3)(B) provides EPA with authority to redesignate only a low-priority substance, not a high-priority substance.

b. Data gathering during pre-prioritization and limiting bias towards data-rich chemicals

Data gaps could have a significant impact on the order in which chemicals are subject to prioritization, by forcing EPA to select data-rich chemicals independent of their relative hazard and exposure in order to meet statutory requirements.

The pre-prioritization process should be used by EPA to get needed information that either does not currently exist or that EPA does not currently have, by including means to routinely collect and develop information on chemicals being prioritized. EDF strongly encourages EPA to take full advantage of its authorities to require information through sections 4, 8, and 11(c). Section 4 of TSCA provides EPA with express authority to require data for the purpose of informing prioritization decisions [section 4(a)(2)(B)], which could clearly be deployed in pre-prioritization.

On a routine basis as part of the prioritization process, EPA should use these authorities to require companies to submit existing information they have on their chemicals, especially information they have already submitted to other governments (e.g., to ECHA under REACH). Rather than waiting to see what it receives from the voluntary data submission process at the initiation of prioritization (§702.9(e)), EPA should use its authorities to require data submission or generation earlier in the process. In the case of section 4 orders, if the requested information already exists, companies could comply with the order simply by providing such data. This parallel strategy will better ensure EPA meets its tight deadlines for prioritization.

The preamble of this proposed rule appropriately describes EPA's authority to fill data gaps through such means during the pre-prioritization process: "EPA generally expects to use this new authority, as appropriate and necessary, to gather the requisite information prior to initiating prioritization. This could include, as appropriate, TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c), to develop needed information" (p. 4831) and such authority is appropriately noted in §702.5(e) (Consideration of Potential Candidate for Prioritization) and §702.7(f) (Candidate Selection and Screening Review). Such preamble and regulatory language should be retained in the final rule.

In the preamble to its proposed risk evaluation rule (pp. 7572-3), EPA has requested comment on whether it should directly incorporate its TSCA section 8(a) and 8(d) authorities into that rule, to allow EPA to require, by notice in the Federal Register, manufacturers with relevant information to submit that information to EPA for use in a risk evaluation. EDF's comments on that rule strongly support EPA doing so. In the context of this rule, EDF urges EPA to add an analogous provision that would similarly authorize EPA to use its section 8(a) and 8(d) authorities at any stage in the pre-prioritization or prioritization process.

EDF recognizes that in the short-term, EPA will move chemicals through the prioritization process that already have a significant amount of data available (e.g., Work Plan chemicals). Practically speaking, this is a reasonable approach and is supported by provisions of the law, e.g., section 6(b)(2)(B). As noted above, however, EDF is concerned that, without EPA mounting aggressive efforts to fill information gaps in advance of prioritization, a bias towards data-rich chemicals could arise whereby EPA would skip over

chemicals for which there are either: 1) limited existing data sufficient to raise a red flag but insufficient to conduct a full risk evaluation, or 2) virtually no data. Hence, EPA needs to aggressively use its mandatory authorities at the pre-prioritization stage, even as it proceeds with the prioritization process for more data-rich chemicals and with risk evaluations both for the "first 10 chemicals" and subsequent chemicals.

EPA should not, within the context of this rule, inadvertently limit its ability to use these authorities for other purposes in addition to prioritization.

c. Public input on pre-prioritization process

EPA is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization phase. For the reasons outlined above (comment 2), EDF strongly believes pre-prioritization should be a relatively informal process and that the rule should not delineate a detailed pre-prioritization process with specific public listing obligations or provision of opportunities for stakeholder involvement.[7] Specifically, EDF does not believe the process should require EPA to publish lists of chemicals it is screening, justify its selection of those chemicals, or be required to formally propose or take comment on its pre-prioritization process development or on specific chemicals identified through pre-prioritization. We are concerned that these steps would unduly slow down and complicate an already lengthy process that already has numerous formal opportunities for public engagement. Instead, EPA could provide more informal opportunities, such as stakeholder meetings during early stages of implementation, to help inform the process of pre-prioritization.

EDF believes that the first opportunity for formal public engagement on specific chemicals should be at the initiation of prioritization (§702.9).

4. EPA appropriately proposes that chemical substances, not specific uses or subsets of uses, are to be prioritized.

TSCA as amended by the Lautenberg Act 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)]. So, while EPA is to determine the priority (as well as 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.

EPA's proposed rule is consistent with this requirement, stating that "EPA will designate the priority of a 'chemical substance,' as a whole, under this established process, and will not limit its designation to a specific use or subset of uses of a chemical substance" (p. 4829). EDF fully supports this decision.

It follows that conditions of use EPA did not consider or need to take into account in designating a substance as high-priority are neither low-priority nor determined to "not present an unreasonable

[7] Some in industry are arguing that EPA should promulgate a separate rulemaking process for the pre-prioritization stage. EDF believes this is wholly unneeded that would lead to further delays.

risk." Again, it is the chemical substance that is the object of prioritization decisions as well as risk determinations, which can only be made for chemicals based on consideration of all conditions of use in a full risk evaluation. (See EDF's comments on EPA's proposed risk evaluation rule for more detail.)

Moreover, only the chemical as a whole can be designated a low priority.

5. EPA appropriately sets a higher bar for low-priority than for high-priority designations, including consideration of all conditions of use for the former.

While chemicals substances must be designated as a whole, a key difference applies to high- vs. low-priority designations.

The law defines a high-priority substance as one that:

> the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. [section 6(b)(1)(B)(i)]

In contrast, a low-priority substance is one that:

> the Administrator concludes, *based on information sufficient to establish*, without consideration of costs or other non-risk factors, that such substance does not meet the standard ... for designating a chemical substance a high-priority substance. [section 6(b)(1)(B)(ii); emphasis added]

In other words, a high-priority chemical is one for which a risk evaluation is needed to determine if it presents an unreasonable risk, while a low-priority chemical is one for which a risk evaluation is unnecessary because information is sufficient to determine there is no unreasonable risk without conducting a risk evaluation.

EDF strongly believes that EPA should be able to designate a chemical as a high-priority based on consideration of only certain conditions of use of that chemical. In contrast, low-priority designations must be based on consideration of the full range of conditions of use. This position is further supported by the requirement in section 6(b)(1)(B)(ii) that EPA base a low-priority designation on "information sufficient to establish" that a high-priority designation is not warranted. 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 have been 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 – only that such designations must be based on consideration of all conditions of use.

EPA has appropriately interpreted the statutory language and captured this distinction in the preamble to its proposed rule, indicating that while EPA may base an identification of a potential candidate as high-priority on even a single condition of use, EPA must examine all conditions of use before designating a chemical as low-priority (p. 4830):

> [I]n identifying potential candidates for High-Priority Substance designations, EPA is proposing to seek to identify chemical substances where available information suggests that the chemical substance may present a hazard and that exposure is present under ''one or more conditions of use,'' but where an ''unreasonable risk'' determination cannot be made without a more extensive or complete assessment in a risk evaluation. EPA interprets the statutory definition of a High-Priority Substance … to set a fairly low bar, and EPA expects that a large number of chemical substances will meet this definition. Although EPA will prioritize a ''chemical substance'' as a whole, EPA may base its identification of a potential candidate as a High-Priority Substance, and ultimately the proposed designation, on a single condition of use…
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> Conversely, in identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for ''all conditions of use'' are so low that EPA can confidently set that chemical substance aside without doing further evaluation. By comparison, then, TSCA's definition of Low-Priority Substance … is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-priority Substance standard. Consequently, EPA expects it will be more difficult to support such designations.

EDF fully supports this language and the accompanying provision in the proposed rule under §702.11(d), which codifies this approach.

Some have voiced concerns that the prioritization process should never generate "false positives," where EPA designates a chemical that does *not* pose an unreasonable risk as a high-priority. We argue, however, that any such "overinclusion" of chemicals in the high-priority category is far more acceptable, public health protective, and in line with the intent of the law than a "false negative" designation of a chemical as a low-priority. High-priority substances will always undergo full risk evaluations before any regulatory decision is made, and may be found not to present an unreasonable risk at that point. In contrast, low-priority designations are final agency actions and remain in place until and unless new information arises.

6. EPA appropriately proposes to include "catch all" provisions under §702.5(c) and §702.7(c)

EPA proposes to consider the following factors when considering potential candidates for prioritization (§702.5(c)):

> (1) Persistent, bioaccumulative, and toxic;

(2) Used in children's products;
(3) Used in consumer products;
(4) Detected in human and/or ecological biomonitoring programs;
(5) Potentially of concern for children's health;
(6) High acute and chronic toxicity;
(7) Probable or known carcinogen;
(8) Neurotoxicity; or
(9) Other emerging exposure and hazard concerns to human health or the environment

In the pre-prioritization screening review, EPA proposes to consider the following criteria (§702.7(c)):

(1) The chemical substance's hazard and exposure potential;
(2) The chemical substance's persistence and bioaccumulation;
(3) Potentially exposed or susceptible subpopulations;
(4) Storage of the chemical substance near significant sources of drinking water;
(5) The chemical substance's conditions of use or significant changes in conditions of use;
(6) The chemical substance's production volume or significant changes in production volume; and
(7) Any other risk-based criteria relevant to the designation of the chemical substance's priority, in EPA's discretion.

We support EPA having authority to consider additional hazard and exposure factors beyond those specified in the statute, including through a "catch-all" provision (9 and 7, respectively, in the lists above). As described in the preamble (p. 4830) and consistent with the intent of the law, EPA has broad discretion to decide which chemicals to subject to prioritization. EPA should not be constrained to considering only those risk factors identified in the statute.

7. Additional language and provisions in EPA's proposal that EDF supports.

EDF additionally supports EPA's inclusion of the following language or provisions in the proposed prioritization rule:

- The statute envisions that eventually all substances are to be subject to prioritization[8] (p. 4830)
- The law recognizes the validity of EPA's earlier prioritization done through its Work Plan process (p. 4828)
- Inactive chemicals can be subject to prioritization (p. 4830)
- EPA has broad discretion to decide which chemicals to subject to prioritization and to consider the extent of available information in doing so (pp. 4846, 4830, 4831)

[8] There is evidence in the record that the intention of the law is for EPA, over time, to work through entire backlog of chemicals in commerce. The Statement for the Record submitted by Senate Democrats involved in negotiating the text of the new law states (p. S3516): "While this will take many years, the goal of the legislation is to ensure that all chemicals on the market get such a review. The initial targets for numbers of reviews are relatively low, reflecting current EPA capacity and resources. These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets procedures established and gains experience, these targets can be exceeded in furtherance of the legislation's goals." https://www.congress.gov/congressional-record/2016/06/07/senate-section/article/S3511-1

- In conformance with the law, designation of a high-priority substances is not a final agency action (§702.19)
- Coordination of the timing of the prioritization and risk evaluation processes is addressed, by proposing that simultaneous with the publication of a final designation of a high-priority substance, EPA will identify the risk evaluation completed or near completion that the designated substance will replace (preamble, p. 4833; rule, §702.13(d))
- EPA can prioritize chemical categories, consistent with section 26(c) of the statute (preamble, p. 4830; rule, §702.1(c))
- EPA has authority to revise low-priority designation based on reconsideration of available information, not just new information (p. 4827)
- The rule codifies EPA's statutory authority in section 6(b)(3)(B), and a process, to revise low-priority designations, which specifies, consistent with the statute, that the agency will not revise a final designation of a chemical from high-priority to low-priority (§702.15)
- Costs and other non-risk factors will not be considered in priority designations (preamble, 4832, 4833; rule §702.3, §702.11(b), §702.13(b))

Concerns/Areas for Improvement

8. EDF is concerned about EPA's proposal to "cut off" comments on proposed low-priority designations after the public comment period, but could accept it with some conditions.

EDF is sympathetic in general to EPA's rationale for "cutting off" comments in order not to have to deal with incoming information or arguments while it is trying to make a final decision. But EPA's proposal (p. 4833, §702.11(f)) to constrain the ability of a stakeholder to challenge a final EPA designation of a chemical as a low priority because it had not necessarily raised all conceivable arguments or issues during the comment period could pose too high a burden on stakeholders likely to question or oppose such a designation, who are typically less well-resourced than those would support a proposed low-priority designation.

To be clear, EDF is not supportive of applying the comment stricture to high-priority designations.[9] In that case, were EPA to change a proposed high-priority designation of a chemical to a final low-priority designation, challenging that final decision would be subject to unacceptable constraints, in our view.

EDF could only accept this provision restricting stakeholder engagement on proposed low-priority designations if several essential conditions are met:

- The comment stricture must, as EPA has proposed (§702.11(f)), apply only to ***proposed***, not final, low-priority designations. It would be unacceptable to so constrain a stakeholder in the case where EPA changed a proposed high-priority designation of a chemical to a final low-priority designation.
- EPA must cap the number of proposed low-priority designations undergoing comment at any given time to at most five substances. This would ensure that the process could not be overloaded with proposed low-priority designations so as to compromise the ability of less well-resourced stakeholders (e.g., NGOs, states) to comment on each such designation within the comment period.
- EPA must retain in the final rule its proposal to authorize EPA to revise a final low-priority designation at any time based on information available to it (§702.15). (See also comment 9 below.)

[9] EPA's argument for why it has proposed to impose this stricture only on proposed low-priority designations is as follows:

> By contrast, designation of a chemical substance as a High-Priority Substance is not final agency action. The statute mandates additional opportunities for public input during the risk evaluation process, and EPA does not consider it appropriate to restrict the public's ability to comment during these subsequent processes based on this early phase proceeding. (p. 4833)

This rationale has two problems. First, in its proposed risk evaluation rule, EPA has proposed similar cut-offs for two decision steps that also are not final agency actions: scoping decisions and risk evaluations. Second, applying the comment stricture to proposed high-priority designations would not constrain a stakeholder's ability to comment at later stages in the process, i.e., on a draft scope of a risk evaluation or a draft risk evaluation, only on its ability to object later to the final decision EPA made on an initially proposed high-priority designation.

9. EPA's proposed process to revisit low-priority designations is appropriate, but should include additional steps.

Consistent with the law [section 6(b)(3)(B)], EPA's proposed prioritization rule includes authority for EPA to "revise a final designation of chemical substance from Low-Priority to High-Priority Substance at any time based on information available to the Agency" and establishes a process in the rule for such revisions (§702.15).

EDF recommends that in promulgating the final rule, EPA add a provision that allows any person to request that EPA revisit a final low-priority designation, and a requirement that EPA respond to the request in a timely manner.

EPA should consider further describing, in guidance but not in this rule, under what circumstances EPA would consider revisiting a final low-priority designation. 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 (e.g., a substantial change in the use pattern of a chemical), that would serve as "triggers" warranting EPA revisiting and potentially revising a low-priority designation.

10. EDF does not support EPA's proposal to consider substitutes in the pre-prioritization process.

EPA proposes that it may consider potential substitutes for a chemical substance in the pre-prioritization process: "EPA may also consider the relative hazard and exposure of a potential candidate's substitutes" (§702.7(b)), Candidate Selection and Screening Review). While EDF shares EPA's concern about wanting to avoid so-called regrettable substitutions, EDF is very concerned about EPA including this criterion at an early stage (e.g., pre-prioritization), for a number of reasons.

First, this provision suggests or would allow that EPA could choose to advance or not to advance a chemical into the prioritization process based on information not about the substance, but about chemicals that might substitute for that chemical. To be specific, EPA could, based on consideration of this factor, choose to put one chemical into prioritization over another that has greater risk potential, simply because substitute (and potentially less risky) chemicals are thought to be available for the chemical with lower risk potential. Moreover, this decision-making would be happening well before EPA has considered and identified the full range of uses of a chemical, years before a risk evaluation would be completed if it was deemed a high priority, and even more years ahead of any risk management that might be imposed if it was deemed to present unreasonable risk.

Second, how is EPA at that early stage to have any ability to know for which uses of the chemical a possible substitute might or might not be appropriate and feasible, let alone what risks such uses may present? EPA certainly could not reliably be taking into consideration at that point the full range of conditions of use of the subject chemical or its potential substitutes. Moreover, such early consideration of substitutes essentially makes presumptions about ultimate risk management needs well ahead of prioritization and risk evaluation.

Third, such considerations could be used to decide to, or not to, advance a chemical to prioritization independent of its own risk potential. They prematurely assume:

- that substitutes for the chemical may be needed, when the questions of the availability of a substitute and whether it is necessary (e.g., whether a use is critical or not) would depend on factors expressly to be considered and accounted for under the statute during risk management, not during a stage taking place years earlier and that precedes the earliest stage of chemical review provided for in the statute; and
- that ultimate risk management, if needed, should be based on a chemical-for-chemical substitution approach rather than on other options such as elimination, product redesign, etc..

Fourth, EDF is concerned that such considerations could readily come close to or cross the line into consideration of non-risk factors, which the statute precludes EPA from considering until risk management.

Finally, the approach would seem to ignore or discount the potential for EPA actions taken to prioritize and review a chemical to incentivize the market to develop safer alternatives for a chemical that initially lacks them. Conversely, it may have the perverse effect of allowing higher-risk chemicals, with no alternatives, to remain on the market for a longer period of time.

For these reasons, EDF opposes EPA's proposed inclusion of the relative hazard and exposure of a potential candidate's substitutes as a pre-prioritization criterion in §702.7(b).

As an alternative approach, in cases where EPA has concerns about two or more chemicals that may be substitutes for one another, EPA may want to consider a category approach, as it has done, for example, with the flame retardant clusters in its Work Plan assessments,[10] through which it could advance prioritization and risk evaluation of the category (as provided for under §702.1(c)) so as to be able to consider the relative risks of chemicals that can be substituted for one another.

11. Consideration of "significant changes" in conditions of use should not be restricted to revisiting a priority designation.

Section 6(b)(1)(A) states (emphasis added):

> The process to designate the priority of chemical substances shall include a consideration … the conditions of use or *significant changes in the conditions of use* of the chemical substance, and the volume or *significant changes in the volume* of the chemical substance manufactured or processed. [emphases added]

This provision clearly establishes a requirement that EPA consider, in making *initial* prioritization decisions, significant changes in conditions of use and volume. This consideration is particularly

[10] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

important, as such changes over time can alter exposure potential to the general population and may lead to exposures to additional relevant potentially exposed or susceptible subpopulations. For example, if data collected in the past two cycles of reporting under EPA's Chemical Data Reporting rule showed a significant increase in production volume of a chemical, or identified new uses of a chemical, such changes might well warrant elevation of the priority assigned to it.

Hence, EDF disagrees with EPA's interpretation and discussion of "significant changes in conditions of use" in the preamble of the proposed rule:

> EPA interprets ''significant changes in'' conditions of use to have relevance primarily in the context of revising a priority designation. With respect to an initial prioritization decision, any changes in use that have occurred in the past would already be captured by the concept of ''conditions of use,'' as defined in TSCA section 3. (p. 4826)

First, we disagree that "significant changes in conditions of use" is sufficiently encompassed by the term "conditions of use." Second, the language appears to limit EPA's consideration of "significant changes to conditions of use" to its revisiting of a priority designation and not in making initial priority designations. This is clearly disallowed by the law.

EPA's statement in the preamble is not consistent with the regulatory text: Consideration of "[t]he chemical substance's conditions of use or *significant changes in conditions of use*" (emphasis added) is codified as a consideration in the screening review process (§702.7(c)).

In promulgating the final rule, EPA should remove the conflicting language in its preamble. Separate from the rule, EPA should consider developing guidance that defines what would constitute a significant change in volume or use, and describes procedures EPA will use to identify such changes – in pre-prioritization, prioritization, or revision of a low-priority designation. In defining significant changes, the agency may want to consider quantitative measures, such as a specific percentage increase (or decrease) in production volume of a chemical, as well as qualitative measures, such as identification of a new use in children's products. EDF encourages EPA to routinely consider changes in volume or use, for example, through review of data reported under its Chemical Data Reporting (CDR) rule.

EDF further notes that, while not discussed in any detail in the proposed rule, the law is clear that conditions of use, including for the purpose of prioritization, must include "reasonably foreseen uses." [TSCA section 3(4)]. In our comments on EPA's proposed risk evaluation rule (comment 3), EDF recommended that EPA develop guidance to address what EPA will consider to be reasonably foreseen conditions of use of a chemical.

Finally, EDF believes that a nanoscale form of a chemical substance would certainly constitute a condition of use of that substance. EPA should clearly consider, therefore, hazard and exposure potential of nanoscale forms, along with the bulk form, of any substance being prioritized or evaluated.

12. Additional detail is needed 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 prioritization as well as risk evaluation 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" in both the prioritization and risk evaluation rules. 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.

While EPA's proposed rule is consistent with this approach (and indeed the first two triggers above are appropriately described in the preamble[11]), EDF urges that EPA specifically define these trigger points in the text of the rule, 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.

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),[12] 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.

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.

[11] "EPA is proposing in this rule that initiation of the prioritization begins upon publication of a notice in the Federal Register that identifies a chemical substance for prioritization and provides the results of the screening review. The process is complete upon publication of a notice in the Federal Register announcing a final priority designation." (p. 4829)

[12] EPA states 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" (p. 4833).

13. EPA should articulate in the rule its authority to combine public comment periods.

We appreciate EPA's concerns about staying on schedule and meeting statutory deadlines. Given these concerns, we recommend that EPA articulate its authority in the final rule to combine public comment periods, to save time and resources without sacrificing the ability of the public to comment.

EDF believes that public comment is critical and must be provided for. However, because the process of taking and responding to public comment can be time- and resource-intensive, too many distinct comment periods may lead to delays and missed deadlines. Under the proposed rules, stakeholders will have the opportunity to provide input at three different points in the process before EPA publishes a draft risk evaluation: 1) the request for information on a chemical being prioritized, 2) the proposed high- or low-priority designation, and 3) the proposed risk evaluation scope. While the law specifies certain EPA actions or decisions for which opportunity for public comment is required, nothing precludes EPA from taking comment on more than one decision or action at the same time to avoid always having to provide three distinct periods for this public comment and risk unduly delaying the process.

This strategy may be particularly prudent or needed during the prioritization process, where EPA only has 9-12 months to make a priority designation and must include two 90-day public input opportunities. EPA may in some cases be able to combine the 90-day period for responding to EPA requests for information on a chemical being prioritized with the 90-day public comment period on its proposed high- or low-priority designation. Alternatively, EPA could simultaneously take comment on a proposed high-priority designation and the proposed scope of the risk evaluation for that substance, which would provide the agency with additional time to conduct the risk evaluation itself within the statutory deadlines.

These approaches would likely be most appropriate where EPA already believes it has sufficient information to make a high-priority designation, as with many of the Work Plan chemicals.

14. EPA needs to specify how it will decide whether or not it is necessary to determine the priority of a newly activated chemical.

Section 8(b)(5)(B)(iii)(IV) requires EPA to determine the priority (high or low) of a newly activated chemical "as the Administrator determines to be necessary."

This rule and EPA's inventory rule need to specify how EPA will make this determination, including the process and timeframe under which EPA will do so. EDF believes the same criteria should apply as EPA will use for prioritization decisions for already active chemicals, in order to ensure a level playing field.

15. Use of the Safer Choice Ingredient List ("SCIL") list should only be a starting point for identifying low-priority substances.

As discussed on p. 4830 of the preamble to this proposed rule, EDF agrees with EPA that the Safer Choice "SCIL" list can be considered a starting point for identifying potential low-priority candidates. However, EDF does not believe that the presence of a chemical on the SCIL list is at all sufficient for designating it as low-priority. Chemicals on the SCIL have been screened through specific criteria that do not require having sufficient data to meet the TSCA's stringent low-priority standard.

For example, the Safer Choice surfactant functional class criteria focus mainly on key[13] environmental fate and ecological toxicity endpoints, and not human health endpoints.[14] A much more comprehensive evaluation is necessary to meet the statute's low-priority designation.

16. Work Plan chemicals should nearly always be designated high-priority.

The preamble of the proposed rule indicates that "it is premature to presume that [Work Plan] chemicals will necessarily be prioritized as High-Priority Substances" (p. 4831). While EDF recognizes that, other than the first 10 substances already identified pursuant to TSCA section 6(b)(2)(A), all chemicals will need to go through the same prioritization process, EDF believes that it should be an extremely rare case that a chemical identified on the 2014 EPA Work Plan would not qualify as a high-priority chemical – barring errors in the Work Plan itself or underlying studies.

EDF believes that the strong presumption of the law is that the Work Plan is effectively a list of high-priority substances, as it requires that at least 50% of ongoing risk evaluation are to be drawn from the 2014 update of the TSCA Work Plan within 3.5 years of enactment [section 6(b)(2)(B)].

We therefore recommend this language is removed in any text accompanying the final prioritization rule, as it may inadvertently set an expectation that Work Plan chemicals would routinely not be designated as high-priority.

17. Full studies used to make prioritization designations should be publicly available.

The appropriateness and strength of priority designations is wholly dependent on the information identified and used. It is critical that such information be made publicly available in full so that the public

[13] As explained by the Safer Choice program, "Within these "functional classes," many ingredients share similar toxicological and environmental fate characteristics. As a result, Safer Choice focuses its review of formulation ingredients on the *key* (environmental and human health) characteristics of concern within a functional class. This approach allows formulators to use those ingredients with the lowest hazard in their functional class, while still formulating high-performing products." Available at: https://www.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients

[14] See: https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants

understands and can effectively and constructively comment on the prioritization designations made by EPA under section 6(b)(1). Therefore, the rule should expressly require that information EPA uses to make priority designations be available to the public in full. Similarly, persons submitting information to inform the prioritization process or commenting on proposed priority designations 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.

Toward this end, the agency should provide for easy online access to studies used to make priority designations. 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.[15] The HERO database is also used to house and organize studies used in the development of Integrated Science Assessments (ISA)[16] and Provisional Peer Reviewed Toxicity Values (PPRTV).[17]

We strongly recommend that the agency leverage the HERO database for both prioritization and 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 revisiting or updating of prioritization decisions and 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 EPA's judgment, and crucially, to assess and comment on the quality of the studies used by the agency. 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 do not 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.

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[15] 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.

[16] See US EPA, "Integrated Science Assessments." Last Updated 16 May 2016. Accessed 23 August 2016. https://www.epa.gov/isa.

[17] See US EPA, "Provisional Peer Reviewed Toxicity Values for Superfund (PPRTV)." Accessed 23 August 2016. https://hhpprtv.ornl.gov/quickview/pprtv_papers.php.

In sum, EDF strongly recommends that the rule require ready public access to full studies used to make priority designations.

18. EPA's rule should codify confidential business information (CBI) requirements to maximize public access to the information EPA uses to make prioritization decisions.

With respect to prioritization decisions made under section 6(b), we note that section 26(j)(5) of the new law states:

> Subject to section 14, the Administrator shall make available to the public each designation of a chemical substance under section 6(b), *along with an identification of the information, analysis, and basis used to make the designations*. [emphasis added]

In making its prioritization decisions, EDF believes that a large fraction, likely a majority, 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 the proposed rule, EPA has not included a requirement that those submitting information to the agency and asserting CBI claims must meet all applicable requirements of the law , including providing upfront substantiations for all CBI claims other than those specified in TSCA section 14(c)(2).[18] These requirements may be particularly salient for the information collection process detailed in §702.9.

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 make its prioritization decisions.

[18] 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.

19. EPA should include in its rule a section on "publically available information," analogous to the risk evaluation rule.

EPA should add a section to the final rule addressing "publically available information," analogous to section §702.47 in the proposed risk evaluation rule (see also comment 11 above).

20. EPA should include a definition of "potentially exposed or susceptible subpopulations" in the rule.

EPA should include a definition of "potentially exposed or susceptible subpopulation" in the prioritization rule and should use the same definition that is in the proposed risk evaluation rule (§702.330), adapted as appropriate. For more detail, see EDF's comments on the risk evaluation rule (comment 4).

21. The rule should specify that the Federal Register notices for both the proposed and final designations will include "information, analysis, and basis used to make the designation."

The final rule should specify that the Federal Register notices for the final designation will include "information, analysis, and basis used to make the designation." This requirement of the law is specified in the proposed rule with regards to the Federal Register publication for the proposed designation (p. 4836), but not the final designation. While TSCA section 6(b)(C)(ii) only specifies that these items be made available for the proposed designation, section 26(j)(5) clearly indicates that they shall also be made available to the public for "each designation of a chemical substance under section 6(b)." This information will be particularly important for cases where the final designation differs from the proposed designation.

22. EPA needs to revise the preamble text on preferences to be given to 2014 Work Plan chemicals to be consistent with the statute.

The preamble text appears to limit EPA to giving preference, in selecting and screening candidate substances, to 2014 Work Plan chemicals that *both* have a persistence and bioaccumulation (P&B) score of 3 and are known carcinogens and have high acute/chronic toxicity (pp. 4827, 4831). TSCA Section 26(b)(2)(D) clearly indicates, however, that preference should be given to chemicals with either set of characteristics, not both. The proposed rule language itself, at §702.7(a)(1), is consistent with the law.

Items for Guidance

23. EPA should consider developing guidance on the types and amount of hazard and exposure data sufficient to designate chemicals as high- and low-priority.

As described above, EPA appropriately articulates in the proposed rule that a higher bar must be met to designate a chemical as low-priority compared to high-priority: "EPA is proposing to require a default-to-high in all cases in which insufficient information exists to designate the chemical as a Low-Priority Substance at both the proposed and final designation" (p. 4828). The proposed rule appropriately does not seek to specify in detail the specific types of hazard data to be considered.

We urge EPA to develop guidance, outside the rule, on the types and amounts of data to be considered and in particular to specify the minimum requirements for what would constitute "sufficient information" to designate a chemical as low-priority.[19]

While EPA cannot require the up-front development of a minimum information set for prioritization purposes [section 4(a)(2)(B)(ii)], there is nothing in the statute that prohibits EPA from specifying the minimum amount of information that would be sufficient to designate a chemical as low-priority. Without such a minimum, EPA risks equating absence of evidence of harm with absence of (potential) harm.

The minimum amount of information required to designate a chemical as low-priority might, however, vary (e.g., depending on the nature of the chemical's uses), and EPA should retain some discretion to identify the relevant minimum dataset for a given chemical.

In prioritizing a chemical as high priority, EDF believes that EPA can and should use a wide range of types of data to identify "a potential hazard and a potential route of exposure." These could include in vitro tests for hazard, structural similarities to chemicals with known hazard, monitoring data, and exposure modeling. While we recognize that there needs to be some consideration of plausibility in determining that there is a potential route of exposure, we maintain that many types of information could be used to meet this plausibility test.

[19] One starting point might be the OECD Screening Information Dataset (SIDS). The SIDS was developed as the minimum information necessary to conduct a screening-level risk assessment, and is well short of what would be needed to inform a full risk evaluation under the new law. (OECD, 2012. Chapter 2. Data Gathering and Testing: SIDS, the SIDS Plan and the SIDS Dossier. http://www.oecd.org/env/ehs/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm)

24. EPA needs to take a broad approach in guidance to identifying chemical substances that are persistent or bioaccumulative.

In prioritizing chemicals, the new law requires EPA to consider the extent to which chemicals are persistent or bioaccumulate in the environment or organisms [TSCA section 6(b)(1)(A)], which has been codified in the proposed rule (§702.5(c)).

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).[20] 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.[21] 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."[22]

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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[20] 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.

[21] 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.

[22] 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.

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Appendix: 2011 EDF Blogs on ACC Prioritization Tool

1. ACC's chemical prioritization tool: Helpful, but flawed and off the mark for EPA to use without TSCA reform

Available: http://blogs.edf.org/health/2011/09/20/acc%E2%80%99s-chemical-prioritization-tool-helpful-but-flawed-and-off-the-mark-for-epa-to-use-without-tsca-reform/

By RICHARD DENISON | BIO | Published: SEPTEMBER 20, 2011

Richard Denison, Ph.D., is a Senior Scientist.
As I noted in my last post, the American Chemistry Council (ACC) issued its own "prioritization tool" in anticipation of the Environmental Protection Agency's (EPA) public meetings to get input on the approach it will use to identify additional chemicals of concern under its Enhanced Chemicals Management Program.

In the context of TSCA reform, various actors in the industry have long called for prioritization, often saying they support EPA's ability to get off to a quick start on identifying chemicals for further work – only to propose schemes that are more likely to do the opposite.

ACC itself has over time come off as a bit schizophrenic on prioritization, apparently being for it before they were against it. ACC's release of its tool puts it squarely back in the pro-prioritization camp, but just what is it proposing? My sense is it's after something quite different from what EPA proposes, and frankly, different from what EPA is currently capable of deploying, given its limited authority and resources under TSCA. In this sense, ACC's proposal is more relevant in the context of TSCA reform, where we presumably would have an EPA with a mandate to review all chemicals in commerce, the authority to readily get the data it needs, and the resources required to execute the kind of comprehensive prioritization scheme ACC proposes.

But setting that disconnect aside for the moment, let's delve a bit deeper into the ACC proposal on its own merits.

ACC's proposal is welcome in several ways: First, it's substantive and specific (which I haven't always been able to say about what ACC has offered in the past). It's so much easier to start working toward common ground when you know where the other guy is coming from.

Second, there are some refreshing elements and acknowledgments:

- ACC at least implicitly notes (p. 2) that there are gaps in available hazard data for many chemicals – and that a chemical with such gaps should be elevated in priority to a high ranking. (Unfortunately, ACC makes no such provision for what is arguably an even larger knowledge gap for chemicals: data on use and exposure. This is one of several ways in which ACC's tool over-relies on limited exposure information.)
- Chemicals with multiple uses would be assigned the overall exposure ranking corresponding to the use with the greatest potential exposure (p. 5) – an appropriately conservative approach. (Unfortunately, this is not the approach ACC uses in other cases; more below).

- ACC rightly criticizes at some length (p. 9) EPA's reliance on presence in children's products as insufficiently indicative of kids' exposure – noting, for example, that products used in the home but not by children may well lead to higher exposures. (Unfortunately, it relegates children's exposure potential to a second-tier consideration in prioritization.)
- ACC appropriately proposes using production volume (p. 6) as one of several surrogate measures of exposure – a bit ironic, given how much the industry railed against the European Union's REACH Regulation for doing the same. (Unfortunately, ACC reserves its "high" ranking for those few chemicals annually produced at the staggeringly high level of 100 million pounds per year – *that's 100 times higher than the level EPA has designated as a high production volume (HPV) chemical*.)
- ACC proposes that EPA be able to use its professional judgment (p. 1) in certain aspects of prioritization – though it then appears to limit that allowance to hazard ranking (*not* exposure ranking!) and second-tier considerations. (And as we'll see below, little evidence of such flexibility is evident in the details of ACC's proposal.)

There are also a number of quite problematic aspects of ACC's proposal:

Overly rigid rules applied in lockstep

For an organization that has frequently asserted that the greatest strength of TSCA has been its *flexibility*, ACC has produced a remarkably rigid tool for prioritization. With calculator-like precision, neatly-assigned little numbers get tallied up in the ACC tool: Each element gets a numeric score, which are then added up and banded to yield crisp overall scores, which are finally assigned to high-, medium- and low- priority status. But the real world is not quite so reducible to simple arithmetic.

ACC's tool demands EPA use certain "rules" in the name of sound science and consistency:
The "equal basis" rule: Most prominent among these rules is that "the hazard and exposure elements should be applicable across all substances being evaluated" (p. 10), "rather than just those information elements available only for subsets of chemicals" (p. 1).

By this sleight of hand, ACC manages to rule out any types of information that may indicate a hazard or exposure of high concern unless it has been measured across basically all chemicals subject to prioritization. This rule may well help to explain ACC's relegation to a second-tier consideration any direct evidence of human or environmental exposure – e.g., biomonitoring and environmental release and media monitoring data – because such data aren't collected for all chemicals. ACC instead would have EPA resort to extremely narrow and rigid definitions and measurements of persistence and bioaccumulation potential even where direct real-world exposure data exist (more on this below).

The lockstep application of this rule would have EPA ignore a chemical like perfluorooctanoic acid (PFOA) because it accumulates in blood rather than in fat tissue – the latter being the only kind of data that are available for many if not most chemicals and to which ACC restricts its bioaccumulation criterion.

ACC's rule would also have EPA ignore other chemicals with unique or uncommon properties simply because either most chemicals haven't been examined for those properties or because those properties actually distinguish certain chemicals from most others. An example of the former might be a chemical deemed of concern because it is known to disrupt expression of a particular gene, while an example of the latter would be virtually all nanomaterials with unique size-dependent behavior that only shows up at the nanoscale.

High hazard and high exposure: A second such rigid rule in ACC's tool is that only chemicals for which high hazard *and* high exposure can be demonstrated warrant high priority. While such chemicals certainly merit prioritization, applying this as a hard-and-fast rule is overly limiting of professional judgment.

I noted in my last post that ACC invokes the Canadian approach to categorization to support its tool. But ACC fails to point out that the criteria Canada used to screen its inventory included *separate* criteria for hazard and exposure, and any chemical meeting either advanced to the next stage.

Given the large gaps in hazard and exposure data for many chemicals, it's simply shortsighted to automatically set aside as low priority any chemical for which evidence of both high hazard and high exposure is lacking – without any regard for how high the hazard *or* exposure might be. A potent developmental toxicant for which there is uncertainty about the extent to which pregnant women or infants are exposed may well warrant prioritization; likewise for a chemical released to the environment that is highly bioaccumulative and where there is suggestive but not definitive evidence of serious hazard.

This need is especially acute given that one of the key actions to be taken on chemicals that are prioritized is to get more information on their hazards, uses and exposures – a step that would be forgone if a high-hazard or high-exposure chemical were set aside indefinitely.

Over-relying on exposure information – appropriately called the "weakest link" in risk assessment – to relegate high-hazard chemicals to low priority is especially problematic – a topic on which I have blogged at some length earlier.

Persistent and bioaccumulative: A third rigid rule relates both to how ACC defines these P and B properties, and how ACC would only assign high priority to chemicals that are both P and B. Here again, ACC's invoking of Canada as the ideal approach fails to acknowledge that that country's criteria included chemicals that, in addition to being toxic, were found to be persistent *or* bioaccumulative.

ACC's tool uses extremely narrow definitions of P and B, presumably due in part to the "equal basis" rationale that more data exist from tests based on the narrow definitions. The B definition, for example, assumes that the only means by which chemicals bioaccumulate is by being taken up from water into the fat tissue of aquatic organisms. Yet bioaccumulation can occur in other tissues (e.g., blood, bone) and by other routes, for example, through food-web uptake and accumulation by air-breathing animals.

Many chemicals that may not qualify as P or B using ACC's narrow definitions are for all intents and purposes persistent or bioaccumulative. This is often the case for chemicals that are frequently or even continuously released into the environment or to which people are routinely exposed. Bisphenol A is not P or B, yet shows up in the bodies of more than 90% of the American population. Why? Because exposure to it is ubiquitous and ongoing, it's being replaced as fast as it's being eliminated. It makes no sense for EPA to be required to ignore that fact.

There's every reason to consider the data on P and B that ACC proposes be used – but there's also every reason not to stop there. Especially if data from biomonitoring and monitoring of environmental releases and media reveal direct evidence of persistence, EPA can and should consider this information in making prioritization decisions. Yet ACC's tool would relegate such data to at best second-class status.

Consistent use of the least conservative classification values
For toxicity, ACC proposes that EPA rely on classification criteria developed under the Globally Harmonized System (GHS) for Classification and Labeling (p. 1).

(Now, I simply must stop here for a moment to flag a statement in ACC's document (p. 2) that I can only hope is an inadvertent – if gross –misstatement. ACC claims that "GHS classification information is *readily available for all substances*, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements." But GHS does not require any company to generate any data where it doesn't already exist; it simply provides a means of classifying already available data. Because GHS provides criteria for dozens of different endpoints, I can imagine that most chemicals will have *some* data for *some* endpoints for which GHS provides classification criteria. But it is simply untrue that companies have data for all such endpoints. A very small number of chemicals have been tested for carcinogenicity, for example, yet GHS provides criteria for this endpoint.)

But back to ACC's tool: I generally support ACC's proposal that EPA rely on GHS criteria, but with two caveats: First, GHS does not include every endpoint of concern, and its use should not limit EPA's ability to consider other health or environmental endpoints.

Second, GHS' cutoff values must be used faithfully – and here, ACC fails badly.

ACC's Table 2 (p. 3) lists what it says are cutoff values for repeat dose toxicity test data. But the table neglects to specify the corresponding test duration or to note that the cutoff values depend on the duration of the repeat dose test. Instead, ACC uses the least conservative values – those corresponding to the less commonly used 90-day test duration. Applying ACC's cutoff values to data from the much more commonly used 28-day repeat dose test would relegate what GHS would classify as a high-toxicity chemical to a lower ranking. See Table 6, p. 17, in this EPA document summarizing the GHS repeat dose criteria.

This is not the only case in which ACC has selected the least conservative cutoff values:

- *Persistence*: ACC's tool would designate any chemical with a degradation half-life in water, soil or sediment of less than 180 days as "non-persistent" (p. 7). Yet EPA's own PBT criteria, also used in the New Chemicals Program, would classify chemicals with half-lives all the way down to 16 days as at least moderately persistent! Here are EPA's criteria (from Table 12, p. 23 in this EPA document):
    - > 180 days half-life = Very highly persistent
    - 60-180 days half-life = Highly persistent
    - 16-59 days half-life = Moderately persistent

- *Bioaccumulation*: ACC's tool would only designate a chemical as bioaccumulative if its fish bioaccumulation factor (BAF) or bioconcentration factor (BCF) exceeded 5,000 (p. 7). Yet here again, EPA's own PBT criteria, also used in the New Chemicals Program, would classify chemicals with BAF or BCF values all the way down to 100 to be at least moderately bioaccumulative! Here are EPA's criteria (from Table 13, p. 24 in this EPA document):
    - >5000 BAF/BCF = Very highly bioaccumulative
    - 1,000-5,000 BAF/BCF = Highly bioaccumulative
    - 100-1,000 BAF/BCF = Moderately bioaccumulative

ACC's tool fails on two counts: Not only does it use the least conservative values, which would relegate many P and B chemicals to low priority. It also takes two critical chemical properties that manifest themselves along a broad continuum, and assigns a *single* bright line – when all authoritative bodies have explicitly acknowledged the continuous nature of such properties by designating multiple classification categories, ranging from very high to low or very low.

Over-relying on limited exposure information and discounting evidence of hazard

In several subtle ways, ACC's tool reflects its longstanding tendencies to over-rely on limited exposure information and discount evidence of hazard:

- The tool collapses its health hazard and environmental hazard rankings into a single score (albeit the higher of the two), whereas it combines scores for its three exposure elements. This means that a chemical that harms both people and other organisms only gets counted once, while a chemical that is low-volume and used only as an intermediate and is not P or B gets credit for being of low concern for all three attributes.
- The tool's scale for hazard runs from only 1-4, whereas its exposure scale runs from 1-5. Because these scores ultimately get combined, it's that much harder for a high-hazard chemical to get a high overall ranking than it is for a low-exposure ranking to get a low overall ranking.
- High-exposure scenarios that occur in industrial and commercial settings get discounted (Table 3, p. 5). Only chemicals with consumer exposure get a high ranking; this means that even if large numbers of workers are exposed to a very high-hazard chemical, that chemical automatically gets assigned a lower exposure priority. Again, this approach is too rigid: EPA needs to be able to elevate in priority a chemical where the risk to a subset of the population is disproportionately high.

Conclusion

While ACC's tool has some serious flaws and is not something that EPA has the authority or resources to utilize under current TSCA, ACC has put forth a serious proposal for prioritization that should help to raise the level of debate over this critical issue in TSCA reform.

2. Expansion of my critique of the ACC tool's persistence and bioaccumulation criteria

Available: http://blogs.edf.org/health/2011/09/29/expansion-of-my-critique-of-the-acc-tools-persistence-and-bioaccumulation-criteria/

By RICHARD DENISON | BIO | Published: SEPTEMBER 29, 2011

Richard Denison, Ph.D., is a Senior Scientist.

I want to clarify and expand on the discussion in my last post on ACC's selection of criteria for persistence (P) and bioaccumulation (B). The bottom line remains the same: *ACC selected the least conservative values proposed by any authoritative body for these parameters*.

I want here to give a fuller picture of available P and B criteria. It should be noted that there can be multiple types of measures of both P and B, but so as not to overly complicate the discussion, and for comparative purposes, I'm focusing here on:

- Values for transformation half-lives for P
- Values for fish bioaccumulation factors (BAF) or fish bioconcentration factors (BCF) for B

As a reminder, here's what ACC proposed for these values:

- Half-life < 180 days = non-persistent
- BAF/BCF > 5,000 = bioaccumulative

So how do those compare to cut-offs established by authoritative bodies?

Globally Harmonized System (GHS):

- For P, GHS doesn't use transformation half-life values.
- For B, GHS indicates that a fish BCF < 500 is "considered as indicative of a low level of bioconcentration."

EPA's New Chemicals Program (policy for PBTs) and Toxics Release Inventory (TRI) PBT definitions:

- For P:
    - a half-life > 60 days in water is deemed persistent and triggers imposition of testing requirements and controls via a consent order (if B and T criteria are also met)
    - a half-life > 180 days is deemed highly persistent and triggers a presumptive ban unless demonstrated to be incorrect (if B and T criteria are also met)
- For B:
    - a fish BAF/BCF > 1,000 is deemed bioaccumulative and triggers imposition of testing requirements and controls via a consent order (if P and T criteria are also met)
    - a fish BAF/BCF > 5,000 is deemed highly bioaccumulative and triggers a presumptive ban unless demonstrated to be incorrect (if P and T criteria are also met)

EPA's Design for Environment (DfE) Program: These are the values that I cited in my last post; they were developed by DfE staff in consultation with other EPA experts and consideration of relevant literature. They were designed to provide greater granularity in P and B rankings to reflect the continuous nature of these chemical properties.

EU REACH Regulation Annex XIII:

- For P:

    - a half-life > 40 days in fresh water is deemed persistent
    - a half-life > 60 days in fresh water is deemed very persistent (vP)
- For B:
    - a fish BAF/BCF > 2,000 is deemed bioaccumulative
    - a fish BAF/BCF > 5,000 is deemed very bioaccumulative (vB)

Finally, it's worth noting that the Stockholm Convention on Persistent Organic Pollutants (POPs) also has criteria to identify P and B for chemicals for which ***international bans on production and use are warranted*** (when they also meet toxicity criteria) – which of course goes far beyond mere criteria for prioritizing chemicals for further scrutiny. Here are the POPs criteria:

- For P: a half-life > 60 days in fresh water
- For B: a fish BAF/BCF > 5,000

It's clear that ACC's P and B cut-off values are those representing the most extreme level of concern for these parameters across a range of authoritative U.S. and international bodies.