Comments on

Risk-Based Prioritization Procedural Rule

EPA–HQ–OPPT–2016–0399

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

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.

There is evidence in the record[1] that the intention of the law is for EPA, over time, to work through entire backlog of chemicals in commerce. Thus EPA needs to establish a stable process that can be carried out over many years and even decades, which ultimately reviews the safety of all chemicals in commerce. To do so, the prioritization rule should be procedural in nature, setting up basic work flows and processes needed to carry out prioritization. Our comments raise the following points and recommendations:

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

2. The process established by the prioritization rule should include concrete steps to collect and develop information on chemicals that lack sufficient data on which to base prioritization decisions.

[1] 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

3. Close coordination between the prioritization and risk evaluation processes is needed to ensure deadlines are consistently met.

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

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

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

4. EPA prioritization decisions must apply to chemicals, not to particular uses or conditions of use.

5. Recommendations on factors to be considered when making prioritization decisions

a. Hazard and exposure potential

i. A wide range of data should be used for high-priority designations.

ii. More robust and complete data are needed for low-priority designations than for high-priority designations.

b. "Potentially exposed or susceptible subpopulation"

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

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

c. Conditions of use, volume, and significant changes in either

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

6. The rule should expressly allow and provide criteria for revisiting and revising designations of chemicals as low-priority substances.

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

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

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

EDF believes that the final 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 evidence" should *not* be explicitly defined or expounded on in the rule, which would overly prescribe these science policy issues that are far broader in applicability than just TSCA, are under active debate, and evolve over time as the underlying science changes in a manner could require frequent updating of the rule to keep pace with the science. Rather, the Agency may choose to utilize existing guidance, revise existing guidance, or develop new guidance to fulfill this need.

2. The process established by the prioritization rule should include concrete steps to collect and develop information on chemicals that lack sufficient data on which to base prioritization decisions.

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

Thus, the prioritization process should drive the development of information that either does not currently exist or the Agency does not currently have, by including mechanisms to routinely collect and develop information on chemicals being prioritized. While the Lautenberg Act requires a voluntary 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. The rule should also codify EPA's clear authority to identify

[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

and fill data needs through both section 4 test orders and section 8 data call-ins, and describe how and when EPA will use these mandatory authorities.

For example, 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 call-in, EPA may also choose to use its section 4 order authority to require submission of information at the outset of prioritization. If the requested information already exists, companies could comply with the order simply by providing the data. This parallel strategy may better ensure EPA meets its tight deadlines for prioritization.

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]

Thus, it would behoove the Agency – and companies – to ensure it acquires exposure and hazard data for chemicals it intends to prioritize as early as possible in the process.

[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

3. Close coordination between the prioritization and risk evaluation processes is needed to ensure deadlines are consistently met.

a. EPA should clearly define the points of initiation and completion of the prioritization and risk evaluation processes in the 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." EDF believes the following delineations of the trigger points are required by or supported in the law and would provide for the most efficient overall process:

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

Using these criteria:

- the phrase in section 6(b)(3)(A) "Upon designating a chemical substance as a high-priority substance" means the date of that designation, which also corresponds to the initiation of the risk evaluation; and

- the phrase in section 6(b)(3)(C) "upon the completion of each risk evaluation" means that date of its publication, by which date EPA is to designate at least one new high-priority substance.

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

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

EDF believes that the needed coordination between the timing of the prioritization and risk evaluation processes would be best achieved through use of the annual plan called for in section 26(n). For example, the annual plan could be used to align the number of proposed designations of high-priority chemicals with the number of chemicals for which risk evaluations are expected to be completed in a given year. Through this strategy, EPA can avoid developing either a backlog of high-priority chemicals designated or awaiting designation, or downtime waiting for prioritization designations to be completed that would result in a delay in both initiating new and completing ongoing risk evaluations.

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

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. EDF recommends that the rule make clear EPA's authority to combine public comment periods, where appropriate, to save time and resources without sacrificing the ability of the public to comment. 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.

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.

In our comments on EPA's risk evaluation rule, we argue that stakeholders should be given the opportunity to comment on proposed risk evaluation scopes. If EPA adopts this recommendation, stakeholders would have the opportunity to provide input on three different aspects of 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.

To avoid always having to provide three distinct periods for this public comment and risk unduly delaying the process, EPA could simultaneously take comment on a proposed high-priority designation and the proposed scope of the risk evaluation for that substance.[6]

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.

4. EPA prioritization decisions must apply to chemicals, not to particular uses or conditions of use.

The new law is unambiguous in stating that chemical substances, not particular uses or conditions of use, are to be subject to prioritization [see section 6(b)(1)]. 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.

Nonetheless, a key difference applies to high- vs. low-priority designations. EPA may well be able to designate a chemical as a high priority based on consideration of only certain uses or conditions of use of that chemical. In contrast, low-priority designations must be based on consideration of the full range of uses and 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 uses or conditions of use, an ensuing low-priority designation would be highly suspect because of the distinct possibility that the designation might not be warranted had all uses and conditions of use been considered. None of this negates EPA's authority and mandate to designate chemicals as low-priority where they do not meet the standard for designating them as high-priority – only that such designations must be based on consideration of all uses and conditions of use.

It also follows that uses or 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 risk." Again, it is the chemical that is the object of prioritization. Only the chemical as a whole can be designated low-priority, and unreasonable risk determinations can only be made for uses and conditions of use that are subject to a full risk evaluation.

[6] Another time-saving alternative would be for EPA to propose and take comment on the scope of a risk evaluation at the point when it finalizes a high-priority designation.

5. Recommendations on factors to be considered when making prioritization decisions

Section 6(b)(1)(A) of the law clearly lays out a number of factors EPA is to consider in prioritizing chemicals:

> The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), 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.

EDF believes that these factors should also be considered when deciding which chemicals to move into the prioritization pipeline and in determining if a low-priority designation needs to be revised (discussed in a later section of these comments below).

Similarly, EPA is to identify a chemical as high-priority if it "may present an unreasonable risk of injury to health or the environment because of *a potential hazard and a potential route of exposure*" [section 6(b)(1)(B)(i)].

Below we elaborate on several of these factors.

a. Hazard and exposure potential

i. A wide range of data should be used for high-priority designations.

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" in prioritizing a chemical as high priority. EDF urges EPA to clearly articulate in the prioritization rule its authority to use a variety of data types, including *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.

ii. More robust and complete data are needed for low-priority designations than for high-priority designations.

It is EDF's position that more data are required to make a low-priority designation than a high-priority designation.

The law defines high-priority substances as those 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, low-priority substances are those 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, low-priority substances are those for which there is a significant basis to conclude that they do not meet the criteria for high-priority substances – that is, there need to be sufficient data to determine that a substance is *not* a high priority. By basic principle, less information is needed to demonstrate a positive (i.e., evidence that a chemical meets a criterion warranting a high-priority designation) than a negative (i.e., evidence sufficient to show that none of the criteria for a high-priority designation are met).

To meet this higher bar with respect to hazard, EDF proposes that a chemical should generally not be designated low-priority unless EPA has at least a screening-level data set, such as the OECD Screening Information Dataset (SIDS),[7] that does not indicate potential hazard. 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; hence, it is appropriate for use at the prioritization step in the process.

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 requiring minimum information as a basis for designating a chemical low-priority. Without such a minimum, EPA risks equating *absence of evidence* of harm with absence of (potential) harm.

[7] 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

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.

Some in industry have voiced concerns that the prioritization process will generate "false positives," where EPA designates a chemical that does *not* pose an unreasonable risk as a high priority. We argue, however, that any "overinclusion" of chemicals in the high-priority category is far more acceptable 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.

b. "Potentially exposed or susceptible subpopulation"

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

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

> a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

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

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

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

EDF recommends that the prioritization rule clearly articulate EPA's authority to make prioritization decisions based on potentially exposed or susceptible subpopulations not explicitly listed in the law.

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

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

While EDF believes that the details of these issues should largely be addressed through guidance, there may be relevant procedural steps that the Agency should address in the rule.

c. Conditions of use, volume, and significant changes in either

In prioritizing chemicals, EPA is to consider the conditions of use, volume, and significant changes in either. The latter is particularly important to consider, as such changes over time can alter exposure potential to the general population and may lead to new relevant potentially exposed or susceptible subpopulations. As noted above, significant changes in volume and use may also be relevant both when deciding whether to move a chemical into the prioritization pipeline and in deciding whether to revisit a low-priority designation. 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.

In the prioritization rule, EPA should both define what constitutes a significant change in volume or use as well as develop procedures to identify such changes. In defining significant changes, the Agency may want to consider quantitative measures, such as a specific percent increase (or decrease) volume triggers, as well as qualitative measures, such as a new use in children's products.

Prioritization applies to chemicals under their conditions of use. That in turn requires EPA to consider their "intended, known, or reasonably foreseen to be manufactured, processed, distribution in commerce, used, or disposed of" [section 3(4)]. EDF commented extensively on defining these terms in our Risk Evaluation Rule comments and refers EPA to those for consideration here.

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

In prioritizing chemicals, the new law expressly requires EPA to consider the extent to which chemicals are persistent or bioaccumulate in the environment or organisms; see section 6(b)(1)(A).

Traditionally, EPA has used relatively narrow criteria and information to define 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).[8] Some chemicals, such as PFOA and related perfluorinated compounds, do not meet typical criteria for bioaccumulation that only assess update 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.[9] 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." [10]

6. The rule should expressly allow and provide criteria for revisiting and revising designations of chemicals as low-priority substances.

Section 6(b)(3)(B) states that EPA "may revise the designation of a low-priority substance based on information made available to the Administrator." EPA's prioritization rule should include express authority for EPA to revisit and where warranted revise a low-priority designation, and it should describe under what circumstances EPA would do so.

Such authority is clearly needed. As noted earlier, production or use of a chemical is likely to change over time, as may other aspects of the chemical's conditions of use that could alter exposure to the substance or which subpopulations may be exposed. In addition, new information on exposures as well as on the hazards and environmental and biological fate, transport and other properties of a chemical may emerge over time. Advancements in science or chemical testing relating to chemical hazards and exposures may emerge that warrant reconsideration.

[8] 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.

[9] 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.

[10] 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.

EPA's rule should identify specific events (e.g., receipt of a notice under section 8(e) that indicates a significant risk) as well as general criteria (a substantial change in the use pattern of a chemical) to serve as "triggers" that would warrant revisiting and potentially revising a low-priority designation.

7. 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 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 make those studies publicly available 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.[11] The HERO database is also used to house and organize studies used in the development of Integrated Science Assessments (ISA)[12] and Provisional Peer Reviewed Toxicity Values (PPRTV).[13]

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.

As already mentioned, information used to make priority designations should be made available in full, meaning that the public should have access to full studies, not simply robust or other study summaries.

[11] 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.

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

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

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.

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.

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

8. 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. EPA should

apply these requirements rigorously and in a manner that maximizes public access to the information EPA uses to make its prioritization decisions.

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

Sincerely,

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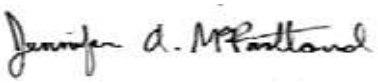

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