EDF Comments on

Approaches for Identifying Potential Candidates for Prioritization

for Risk Evaluation Under Amended TSCA

Docket ID: EPA-HQ-OPPT-2017-0586

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on approaches to identifying potential candidate chemicals for prioritization for risk evaluation under the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

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 risk reviews and to provide an accountable means by which EPA decides which chemicals need full risk evaluations and which have ample information at the time of the prioritization decision indicating they can be set aside absent new information. To meet this objective, EDF believes that an effective process for identifying potential candidates for prioritization will:

- not be overly formalized or regimented;
- ensure sufficient information is available or will be developed in a timely manner to inform prioritization, and subsequently risk evaluations, through robust and early use of EPA's section 4, 8 and 11 information-generation and information-gathering authorities;
- proceed at an incremental pace to build trust and gain experience, and preserve balance between high- and low-priority designations; and
- allow EPA to routinely meet deadlines for making priority designations and ultimately completing risk evaluations on high-priority substances.

In light of these objectives, EDF recommends using an augmented TSCA Work Plan approach to identify high-priority candidates and using the Safer Choice Ingredient List (SCIL) as a *starting point* for identifying a comparable number of low-priority candidates. For both recommended approaches, these comments discuss a number of important caveats and additional needs. EDF also offers a number of comments, including some concerns, on the other approaches presented by EPA.

Please find our detailed comments below.

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1. The process for identifying potential candidates for prioritization should not be overly formalized or regimented.

EPA's final prioritization rule appropriately does not establish a prescriptive scoring or ranking process to make prioritization designations of chemicals. As correctly articulated in the agency's response to public comments on the prioritization rule:

> TSCA's mandate for the prioritization procedural rule does not require "sequencing" the universe of chemicals for input into the prioritization pipeline, undertaking some type of quantitative exercise to score or rank individual chemicals, or otherwise lining up large batches of chemicals in a queue to be prioritized.[1]

Likewise, the process for identifying potential candidates for prioritization should not be overly regimented or cumbersome. EDF supports an informal approach that is not codified by rule or in excessively detailed procedures.

Some in industry have argued that EPA's process for identifying potential candidates for prioritization should establish essentially an algorithm that uses specific scoring or ranking schema. EDF strongly disagrees with this approach.

Given the very large number of candidate chemicals (from its work to develop and update the Work Plan, EPA is already aware of over 1,000 chemicals with known hazards[2]) 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 precisely.

The purpose of prioritization and the processes leading to it is *not* to ensure that EPA selects high-priority or low-priority chemicals in their exact order of risk or potential risk, even if such a ranking could be established. Indeed, such an approach would risk putting the cart before the horse, virtually requiring at least a mini-risk evaluation just in order to identify prioritization candidates. This is simply not realistic given the huge data gaps for the great majority of chemicals under TSCA's jurisdiction. Instead, the objective of these processes should be to ensure EPA identifies chemicals for risk evaluation using indicators of potential risk to lend some rational ordering of chemicals to be further 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 potentially pose greater risk than most other chemicals. To develop an algorithm that provides for an exact ordering of chemicals based on potential risk would require an extraordinary investment on EPA's part – one that does not make sense given that EPA is required to conduct risk evaluations on a relatively small number of chemicals at a time.

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[1] U.S. EPA. "'Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA': Response to Public Comments," at p. 2. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0076.

[2] U.S. EPA, Office of Pollution Prevention and Toxics. "TSCA Work Plan Chemicals: Methods Document." February 2012. Available: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

EPA's process for identifying potential candidates for prioritization should also be flexible and allow for the application of new tools and techniques to screen chemicals as those tools become vetted and available. Some of the screening tools available today that EPA is generally referring to as new approach methods (NAMs) 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 retain the ability to utilize new methods where they are appropriate and reliable for the purpose of identifying potential candidates for prioritization.

Furthermore, the argument that industry needs a prescriptive approach to have a predictable planning horizon is not compelling. First, EPA already developed the TSCA Work Plan to identify chemicals meriting further analysis, so industry already knows the first hundred or so chemicals that constitute the pool from which many or most high-priority candidates will be drawn for the foreseeable future. Indeed, the chemicals on the 2014 Work Plan are explicitly identified in the statute as a starting point for the selecting high-priority chemicals into the foreseeable future.[3] Second, the statutorily mandated process even after formal initiation of prioritization is a 9-12 month process, with opportunity for input and comment. No company will be blind-sided by the selection of a chemical as a high-priority.

In sum, as reflected in our comments on EPA's proposed prioritization rule,[4] we fully support EPA's decision not to specify an exact scoring or ranking system in the final prioritization rule, as the most practical, scientifically-sound, and cost-effective approach. EPA should apply the same logic to the process of identifying potential candidates for prioritization and allow itself flexibility and the ability to evolve its process over time. However, EPA should make public both the approach(es) it adopts and identify the potential candidates for prioritization identified through them.

2. Information development, gathering, and transparency

a. EPA needs to use its information authorities *early* to fill information gaps.

Due to tight statutory deadlines, it is *critical* that EPA fully utilize its TSCA authorities beginning before initiation of prioritization to collect and generate information and employ strategies to ensure that sufficient information is available and of sufficient quality.

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

[3] 15 U.S.C. § 2605(b)(2)(B).

[4] EDF Comments on TSCA Procedures for Prioritization of Chemicals for Risk Evaluation Proposed Rule, Comment at pp. 5-7. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

[5] U.S. EPA. "TSCA, as amended by the Frank R. Lautenberg Chemicals Safety for the 21st Century Act: Prioritization Procedural Rule." [Powerpoint] EPA Public Meeting, Presentation by Wendy Cleland-Hamnett, Director, Office of Pollution Prevention and Toxics. August 10, 2016. Available: https://www.epa.gov/sites/production/files/2016-08/documents/prioritization_public_meeting_8.10.16_slides_final_v2.pdf.

of sufficient information under the new law cannot be used as a rationale *not* to ultimately subject all chemicals to prioritization decisions.

Two provisions of the new law are especially worth noting with regard to the need to ensure sufficient information:

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.[6]

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*.[7]

EPA must in particular have at an early stage a considerable amount of information in order to make any low-priority designation. It also must take steps to ensure sufficient information is available to evaluate the risk of high-priority substances, given that, once a chemical is designated as a high priority, a risk evaluation must be completed within the statutory deadlines (section 6(b)(3)(A)), and that chemical's high-priority designation cannot be altered.[8]

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

Due to the information sufficiency requirements coupled with the deadlines set forth by Congress, EPA must generally have all or most of the information it needs to designate a chemical as low-priority or conduct a full risk evaluation (both of 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 information on chemicals at the beginning of the prioritization process, this alone is not likely to provide sufficient information for the great majority of chemicals.

EPA's proposed approaches to identifying potential candidates for prioritization rely heavily on estimation and other modeling as well as high-throughput methods. While these approaches have their

[6] 15 U.S.C. § 2605(b)(1)(B)(ii) (emphasis added).

[7] 15 U.S.C. § 2605(b)(1)(C)(iii) (emphasis added).

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

place, given their significant limitations (see section 7e below), their availability should not be an excuse to avoid acquiring experimental and monitoring information that are needed to make sound low-priority designations, conduct robust risk evaluations, and meet the law's section 26 "best available science" requirements. For example, robust methods to predict most chronic mammalian endpoints (e.g., developmental toxicity, reproductive toxicity, immunotoxicity) are lacking. In order to be prepared to adequately assess the risks posed by high-priority chemicals for these endpoints, EPA may frequently need to mandate testing early in the process. Because the conventional gold-standard studies for these endpoints can take years to conduct, in such cases, EPA needs to mandate testing well before prioritization begins – in order to meet aggressive statutory deadlines.

b. EPA should make full use of its mandatory information authorities to ensure it will have the information needed for prioritization and subsequent risk evaluation.

EPA's Discussion Document does not substantially address the means the agency will use to acquire information needed to identify candidates for prioritization – a conspicuous omission, given that Congress just significantly enhanced the agency's information authorities.

TSCA section 26(k) requires that in carrying out section 6, EPA must consider "[r]easonably available information,"[9] which includes existing information, such as scientific literature, government assessments, and industry studies. But it also includes any information that EPA can reasonably require to be developed or submitted under its broad information authorities. EPA regulations now define "reasonably available information" to mean "information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines … for prioritization."[10] Under this definition, information that EPA can reasonably generate, develop or obtain through the exercise of its information authorities under section 4, 8 and 11 is "reasonably available information." Since EPA must consider "reasonably available information," EPA must exercise those information authorities to inform the prioritization process or provide an explanation, supported by evidence, that EPA's alternative approach will otherwise obtain that reasonably available information. Furthermore, deadlines cannot be an excuse for failing to obtain information relevant to chemicals' conditions of use, hazards, and exposures if EPA intentionally fails to exercise its authorities to obtain needed information early.

TSCA section 4(a)(1)(A) provides EPA with broad authority to require testing for chemicals that may present an unreasonable risk of injury or have significant release or exposure, and EPA should consider using this authority early when there are hazard or release/exposure concerns that could be addressed by information derived from longer-term testing, such as concerns about developmental effects, neurotoxicity, reproductive toxicity, and cancer.[11] This testing authority is not accompanied by deadlines.

[9] 15 U.S.C. § 2625(k).

[10] 40 C.F.R. §§ 702.3, 702.33.

[11] 15 U.S.C. § 2603(a)(1)(A).

TSCA section 4(a)(2)(B) provides EPA with additional authority to require testing when the information is "for the purposes of prioritizing a chemical substance"[12] – which clearly encompasses the identification of candidates for prioritization – though EPA should use that authority mindful of the deadlines for action that accompany it. To require testing "for the purposes of prioritizing a chemical substance" means that establishing the priority of the chemical must be "the reason for which [the testing] is done or created."[13] This provision does not foreclose EPA from ordering such testing prior to initiating the formal prioritization process. EPA should not find a temporal restriction in this general language that is not present.[14]

Nonetheless, EPA should be mindful of the deadline for action that accompanies this section 4(a)(2)(B) authority. TSCA section 4(a)(2)(B)(i) requires that "not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under [section 4(a)(3)(B)], the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance."[15] This requirement does *not* foreclose EPA from requiring long-term testing prior to initiating prioritization, but EPA would need to exercise that authority mindful of the deadlines that accompany the *receipt* of valid information complying with the testing rule, order, or consent agreement. Thus, for longer-term testing, EPA would need to craft its schedule carefully. This testing authority can easily be used for shorter-term testing, such as certain types of exposure monitoring, which can be completed within the timeframes set forth for the formal prioritization process.

If EPA has not already done so in the recent past, when it identifies a candidate for prioritization, EPA must promulgate reasonable regulations under section 8(a) and 8(d) to obtain information about hazards, exposures, and conditions of use for the candidate; EPA should also exercise its authority under section 8(c) to obtain additional information. On a routine basis as part of the process leading up to prioritization, EPA should use these authorities to require companies to submit existing information they have on their chemicals, including information they have already submitted to other governments (e.g., to the European Chemicals Agency (ECHA) under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)).

EPA should issue both section 8 regulations and section 4 orders simultaneously. In the case of section 4 test orders, if the requested information already exists, companies could comply with the order simply by providing such information under the section 8 rule. This parallel strategy will better ensure EPA meets its tight deadlines for prioritization.

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[12] 15 U.S.C. § 2603(a)(2)(B).

[13] OXFORD AMERICAN DICTIONARY 1418 (3d ed. 2010).

[14] *See, e.g.*, *Nat'l Fed'n of Fed. Employees., Local 1309 v. DOI*, 526 U.S. 86, 98 (1999) (finding "ambiguity" in the "general language" that an agency shall negotiate "*for the purposes* of arriving at a collective bargaining agreement" and recognizing that this language left significant discretion to agency to determine "when" such negotiating is required).

[15] 15 U.S.C. § 2603(a)(2)(B)(i).

Finally, EPA should consider using its section 11(c) subpoena authorities when necessary and appropriate.

EDF particularly urges EPA to use its information authorities to obtain more information about the chemicals in the 2014 Work Plan as well as the chemicals identified as "Potential Candidates for Information Gathering" through the Work Plan process.[16] EPA's prior analyses of these chemicals should assist EPA in identifying potential information gaps that need to be addressed as these chemicals are considered for prioritization. In addition, EPA's prioritization regulation provides that EPA will "ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from [the Work Plan] until all substances on the list have been designated."[17] Thus, EPA already knows it will need all reasonably available information on the Work Plan chemicals relatively soon, so EPA should start obtaining it now, conscious of the deadlines that would apply when EPA begins the formal prioritization process. EPA cannot reasonably decline to exercise those authorities now and then later point to the deadlines as an excuse for not obtaining the information.

Additionally, EPA has already identified a number of data gaps through its Integration of Traditional and New Approach Methods, which could serve as the basis for section 4 and/or section 8 rules (see section 7e).

In sum, EPA should first use its section 4, 8, and 11 authorities no later than when EPA identifies a candidate for prioritization, but EPA should also use these authorities when appropriate earlier in the process to assist in its selection of candidates.

b. EPA should avoid a bias toward information-rich chemicals.

There are currently thousands of chemicals on the market that lack even basic information on their health and environmental impacts.[18,19] Information gaps could have a significant impact on the order in which chemicals are subject to prioritization, by forcing EPA to select information-rich chemicals independent of their relative hazard and exposure in order to meet statutory requirements. EDF recognizes that in the short-term, EPA will identify candidates for prioritization that already have a significant amount of information available (such as Work Plan chemicals). This is both reasonable and supported by provisions of the law, e.g., section 6(b)(2)(B).

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[16] U.S. EPA, Office of Pollution Prevention and Toxics. "TSCA Work Plan Chemicals: Methods Document." February 2012. Available: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf. The "Potential Candidates for Information Gathering" are also referenced on p. 13 of the Discussion Document.

[17] 40 C.F.R. § 702.5(b)(2).

[18] 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): 685-95.. Available: http://www.ncbi.nlm.nih.gov/pubmed/19479008.

[19] 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: 159-66. Available: http://www.ncbi.nlm.nih.gov/pubmed/22104386.

However, EDF is concerned about establishing a process intended to work over time that introduces an indefinite bias towards information-rich chemicals. Without EPA mounting aggressive efforts to fill information gaps in advance of prioritization, a bias towards information-rich chemicals could arise whereby EPA would skip over chemicals for which there is either: 1) limited existing information sufficient to raise a red flag but insufficient to conduct a full risk evaluation, or 2) virtually no information. EPA should aggressively use its mandatory authorities to obtain information on chemicals, *especially* where little information exists, to limit such bias.

c. EPA should primarily rely on mandatory information submissions.

EPA should use its mandatory authorities to obtain and generate information early in the process and on a routine basis rather than waiting to see what voluntary information is submitted during candidate selection or the formal information request at the initiation of prioritization.

EDF has several concerns regarding EPA's apparent intent to rely heavily on voluntary information submissions. Unless EPA can demonstrate that it can address these problems with a voluntary approach (and the available evidence establishes that it cannot), it is necessary for EPA to exercise its authorities under the Act.

First, a voluntary call is much less likely to produce all of the necessary information than are rules mandating its submission. A case in point is EPA's voluntary reporting Nanoscale Materials Stewardship Program (NMSP), which yielded little information. EPA has provided no empirical evidence establishing that a voluntary approach will result in EPA obtaining all "reasonably available" information, and there is significant empirical evidence suggesting that it will not.[20]

Second, EPA has not identified any means to ensure that voluntary submissions are complete and accurate. Companies have a vested interest in EPA either not scrutinizing their chemicals or finding that their chemicals are not high-priority. Reliance on voluntary submissions may enable companies to omit information they view as raising concerns about their chemicals – that is, "cherry pick" the information.

To the extent that EPA accepts voluntarily submitted information, it needs to take additional steps to ensure completeness, accuracy, and access to all underlying information.

EDF has commented extensively on these issues in our comments on the section 6(h) PBT chemicals.[21] We incorporate those comments here by reference.

[20] EDF Initial Comments on § 6(h) PBTs under the Toxic Substances Control Act, Comment at pp. 12-13. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0730-0014.

[21] *Id.* at 10-15.

d. EPA must ensure full transparency of the information it uses to identify potential candidates for prioritization.

The appropriateness and strength of priority designations is wholly dependent on the information EPA identifies and uses in both the process for identifying potential candidates for prioritization and prioritization itself. It is critical that such information be made publicly available in full (subject only to redaction of confidential information that meets all applicable requirements of TSCA section 14), so that the public understands and can effectively and constructively comment on the proposed prioritization designations made by EPA under section 6(b)(1).

As EDF has explained in prior comments, there are numerous reasons that it is important that the public as well as EPA have access to full health and safety studies submitted by companies, not simply robust or other study summaries.[22] Without access to full studies, the public will be challenged or unable to assess and comment on the quality and relevance of the studies used by the agency, including the extent to which the requirement of section 26(h) and 26(i) are met. Even the best study summaries are incomplete descriptions that do not allow for 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. It is important that EPA obtain the full studies, both so that EPA staff have access and so that EPA can make them publicly available. EPA should make such information public and easily searchable through online portals such as the Health and Environmental Research Online (HERO) database. EDF incorporates by reference and reiterates the points we made in our comments on the proposed prioritization rule regarding access to the full studies.[23]

In identifying potential candidates for prioritization, EDF believes that a large fraction, likely a majority, of the information EPA relies on will constitute health and safety studies. 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.[24]

[22] EDF Comments on Procedures for Prioritization of Chemicals for Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.22. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

[23] *Id.* at 22-24.

[24] 15 U.S.C. § 2602(8).

Health and safety studies 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.

3. EPA should exercise caution in identifying potential candidates for low-priority designations.

a. EPA needs to acknowledge that the law sets a higher evidentiary bar for low-priority designations relative to high-priority designations.

The law specifies that a low-priority designation must be based on *sufficient information* to demonstrate the substance is not high-priority across all of its conditions of use. In contrast, high-priority designations are based on a "*may* present" standard that requires evidence only of "a *potential* hazard and a *potential* route of exposure" – and establishing such potential may be possible after examining only a subset or even a single condition of use of the substance. Hence more extensive and certain information is needed for a low-priority designation, and EPA should select candidates accordingly.

Low-priority candidates should generally be those that are very unlikely to be high-priority, i.e., they exhibit both low hazard and low exposure potential. Otherwise EPA runs the risk of such candidates, upon further examination, being found to be high-priority – which would inadvertently bump up the minimum number of chemicals requiring risk evaluations at any given time.

TSCA makes clear that only chemicals EPA can demonstrate are low-priority across all of their conditions of use can be so designated. This requirement needs to carry over into identifying potential candidates for low-priority designations: EPA should only put forth chemicals for which it has or will have enough information on their full range of conditions of use to find all of those conditions of use are low-priority.

b. EPA should identify only small numbers of chemicals as potential candidates for low-priority, especially initially.

Neither EPA nor the public has experience with the processes leading up to and including prioritization, so EPA should adopt a go-slow approach to identifying potential candidates for low-priority substances that ensures EPA has sufficient time to focus on each candidate and the public has ample opportunity to comment on each.

EPA stated in its Discussion Document that it "should strive to identify more than the statutory-mandated minimum of 20 low-priority chemicals." (p. 11) We urge EPA not to make low-priority designations at a pace that significantly exceeds that for high-priority designations, for several reasons. First, the statute anticipates an approximate balance in the pace at which high- and low-priority designations are made by indicating that EPA should make 20 of each type of finding within three and a half years of enactment (section 6(b)(2)(B)).

Second, if EPA designates significant numbers of low-priority chemicals in a short time frame, it will undermine the ability of public interest stakeholders to meaningfully provide comments and have confidence in the process. For this reason, EPA should place strict limits on the number of low-priority designations undergoing public comment at any given time,[25] and hence EPA should also be identifying relatively few potential candidates for low-priority designations at a time.

And finally, identifying significant numbers of such potential candidates significantly increases the risk that some of these candidates will be designated high-priority, thereby inadvertently bumping up the high-priority/ongoing risk evaluation baseline. EPA acknowledged this risk in its Discussion Document:

> Incorrectly identified potential low-priority candidates that are subsequently designated as high-priority, for example, have the potential to permanently increase the number of ongoing risk evaluations. (p. 11)

Finally, low-priority designations are subject to judicial challenge. Therefore, if EPA inappropriately designates chemicals as low-priority that do not meet the demanding statutory bar, it faces the possibility of judicial challenge and even reversal to high-priority, again risking increasing the overall number of ongoing risk evaluations. This risk is amplified if the agency does not follow a go-slow approach.

c. EPA should not identify categories of chemicals as candidates for low-priority, especially initially.

In comments on the proposed prioritization rule, industry groups argued that EPA should designate whole lists of chemicals as low-priority that are highly troubling, including:

- All chemicals listed as "generally recognized as safe" (GRAS)
- All new chemicals
- All chemicals subject to Significant New Use Rules (SNURs)
- All inactive chemicals
- All low-volume substances

EPA should avoid this approach at all costs if it is to follow the section 26 "best available science" requirements and build public trust. Many of these chemicals may present an unreasonable risk. For example, GRAS chemicals are designated as such under the Federal Food, Drug, and Cosmetic Act with little or no actual independent review.[26] And chemicals subject to SNURs have generally been selected for notification requirements precisely due to potential concerns. Moreover, SNURs only require a manufacturer to notify EPA of a significant new use prior to manufacture; and a SNUR generally cannot

[25] EDF has argued for a cap of proposed low-priority designations undergoing comment at any given time to at most five substances. See EDF Comments on TSCA Procedures for Prioritization of Chemicals for Risk Evaluation Proposed Rule, Comment at p. 15. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

[26] Maricel, M., Neltner, T., and Vogel, S. "We are what we eat: Regulatory gaps in the United States that put our health at risk." *PLoS Biol* (2017) Vol 15(12): e2003578. Available: http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2003578.

do anything to reduce exposure from ongoing uses of the chemical because they by definition are not "new." For these and other reasons, there is simply no basis to argue that chemicals subject to SNURs are sufficiently regulated to eliminate unreasonable risk. If anything, these chemicals should be considered as candidates for high-priority substances.

Furthermore, members of a category may in fact have very different characteristics, and EPA needs to have sufficient information on *each* chemical it designates as a low priority. Any presumed efficiency from considering chemicals as a category withers in the face of statutory requirements for low-priority designations, the ability to judicially challenge such designations, and the potential that individual category members are found not to have sufficient information to support a low-priority designation, which could lead to chemicals (or potentially the entire category) defaulting to high-priority status.

We have particular concern about suggesting that EPA approach chemicals used as intermediates as a category for low-priority designation. First, it cannot be assumed that intermediates are only used in that manner, and the law requires all conditions of use of a chemical to be low priority in order to be so designated. Second, any presumption that intermediates invariably result in low exposure is wholly unwarranted. Workers – a "potentially exposed or susceptible subpopulation" under TSCA – may be exposed to chemical intermediates during manufacture, processing and distribution.[27] Third, chemical intermediates may be present as residuals in final products and hence lead to exposure. Finally, all of the characteristics just described can be highly variable across different chemicals, producers, or even among batches.

To cite a specific example of relevant evidence, EDF recently conducted a project in which people across the U.S. wore, for one week, silicone passive sampling wristbands that can detect over 1,400 chemicals.[28] The wristband of one of our participants detected 3,4-dichlorophenyl isocyanate, a chemical intermediate, which is reportedly used exclusively in chemical manufacturing processes.[29,30]

It is worth reiterating that, even if EPA were to assume or document that a chemical's use as an intermediate results in low exposure, many intermediates have other uses. EPA cannot exclusively consider its use an intermediate without considering potential risk from all other conditions of use. To not do so would be a clear violation of the statute's requirement that EPA consider all conditions of use of a chemical in making a low-priority designation.

Indeed, any approaches involving categories defined based on commonalities in *use* are suspect for the same reasons.

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[27] See e.g., CDC, National Institute for Occupational Safety and Health. "Skin Exposures & Effects." Last visited January 25, 2018. Available: https://www.cdc.gov/niosh/topics/skin/default.html.

[28] EDF, "10 people and the chemicals in their midst." 2017. Available: https://www.edf.org/health/10-americans-and-chemicals-their-midst.

[29] NOAA, CAMEO Chemicals. "Isocyanic Acid, 3,4-dichlorophenyl ester." Available: https://cameochemicals.noaa.gov/chemical/5032.

[30] ECHA. "3,4-dichlorophenyl isocyanate." Available: https://echa.europa.eu/registration-dossier/-/registered-dossier/12087.

See section 7 below for additional discussion on EDF's concerns regarding category approaches.

d. EPA should consider requiring a minimum information set for low-priority designations.

In identifying potential candidates for prioritization, EPA should consider whether at least a minimum set of hazard data is available or could be quickly developed, and whether such a set should be required, especially for potential low-priority candidates, given the law's information sufficiency requirement.

Section 4(a)(2)(B)(ii) states that "information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability."[31] However, nothing in this provision or the rest of the statute prohibits EPA from specifying the minimum amount of information sufficient to designate a chemical as low-priority.

One starting point for a minimum data set might be the OECD Screening Information Dataset (SIDS).[32] 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.

EDF provided more extensive comments on the information sufficiency requirement in our comments on the proposed prioritization rule, including a recommendation that EPA consider developing guidance on the types and amount of hazard and exposure information that would be sufficient to make priority designations. EDF incorporates these comments herein by reference.[33]

e. Potential candidates for low-priority designations should have low hazard profiles.

While EPA must consider both hazard and exposure, EPA should place particular emphasis on ensuring that potential candidates identified for low priority have a very low hazard profile. Use and exposure of a chemical can change over time. In fact, one likely consequence of designating a chemical as low-priority is that its use may expand, which would have the perverse impact of increasing risk if the chemical does not have low hazard. Therefore, EPA should focus on low-hazard substances to better ensure that increases in use (which should be considered by EPA to be reasonably foreseen) will not trigger the need to later alter a low-priority designation.

To the extent the Safer Choice Ingredient List (SCIL) includes truly low-hazard chemicals, it may be a good starting point for identifying potential candidates for low-priority substances. However, EDF does not believe that the mere presence of a chemical on SCIL is at all sufficient for designating it as low-priority. See section 7b below.

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[31] 15 U.S.C. § 2603(a)(2)(B)(ii).

[32] OECD. Chapter 2. Data Gathering and Testing: SIDS, the SIDS Plan and the SIDS Dossier. March 2012. Available: http://www.oecd.org/env/ehs/risk-assessment/chapter2datagatheringandtestingsidsthesidsplanandthesidsdossier.htm.

[33] EDF Comments on TSCA Procedures for Prioritization of Chemicals for Risk Evaluation Proposed Rule, Comment at p. 26. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

f. TTC is not a reliable tool for use in chemical prioritization.

The Threshold of Toxicological Concern, or TTC, is a tool that some have advocated for use in prioritization or in risk assessment of chemicals when hazard information is incomplete, including in the context of identifying potential candidates for low-priority. Even advocates for its use note that it would require extensive, reliable information on chemical structural characteristics and chemical exposures, including a robust understanding of how the chemical is metabolized. The TTC approach, as the name implies, is based on the traditional assumption of toxicologists that there is a threshold of exposure below which there is no adverse effect. This assumption has increasingly been questioned by scientific experts,[34] especially in the context of assessing effects on a diverse human population. In addition, the approach is based on the outdated concept that carcinogenicity is the most sensitive health endpoint when compared to non-cancer endpoints (e.g., developmental or reproductive toxicity). The approach is rooted in decades-old toxicity data (which are used to develop the approach's pre-determined decision trees and thresholds) that were generated following testing protocols that do not reflect modern scientific principles and understandings of toxicity, nor real-world chemical exposures in a diverse human population. For example, the approach does not adequately account for factors such as the following:

- Thresholds for health endpoints measured in adult animals do not represent or capture health effects observed in offspring after perinatal exposures.
- Some chemicals exhibit non-monotonic dose-response curves that cannot be addressed using the TTC approach.
- The TTC approach does not account for cumulative exposures from different chemicals or multiple routes of exposure to the same chemical

For these reasons, we do not consider the TTC to be a reliable tool for use in chemical prioritization.

4. EPA must address potentially exposed or susceptible subpopulations in its process for identifying potential candidates for prioritization.

TSCA section 6(b)(1) expressly requires that EPA's prioritization process include consideration of "potentially exposed or susceptible subpopulations," and EPA must designate a substance as a high-priority chemical if it "may present an unreasonable risk of injury to health or the environment … including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]."[35] In turn, section 3(12) of TSCA defines "potentially exposed or susceptible subpopulation" as:

[34] National Research Council. 2009. *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press, pp. 89, chapter 5. Available: https://doi.org/10.17226/12209.

[35] 15 U.S.C. § 2605(b)(1)(A), (b)(1)(B).

> a group of individuals within the general population identified by [EPA] 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.[36]

This provision requires EPA to pay particular attention to impacts to "infants, children, pregnant women, workers, or the elderly."[37] In addition, as EPA recognized in the preamble to the final risk evaluation rule, this term sweeps "broadly," allowing EPA to include "any subpopulation that may be at greater risk due to greater susceptibility or exposure" and to identify "additional subpopulations other than those listed in the statute."[38] The phrase "such as" reveals that the list of examples is not meant to be exclusive.

In implementing this provision, EPA must comply with its environmental justice obligations under the Executive Order (EO) 12,898:

> To the greatest extent practicable and permitted by law, and consistent with the principles set forth in the report on the National Performance Review, each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of the Mariana Islands.[39]

To fulfill the goals of this executive order, EPA has recognized that "it is vital that Agency rule-writers identify and address potentially disproportionate environmental and public health impacts experienced by minority populations, low-income populations, and/or indigenous peoples."[40]

In identifying potential candidates for prioritization, under EO 12,898 EPA must consider whether the chemical substance has a "disproportionately high and adverse human health or environmental effects … on minority populations and low-income populations."[41] If the substance does have such an effect, then logic dictates that EPA should identify that "potentially exposed or susceptible subpopulation … as relevant" and designate the chemical as a high-priority chemical.[42] In addition, when selecting among potential candidates for prioritization, EPA should select potential candidates for high-priority

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[36] 15 U.S.C. § 2602(12).

[37] *Id.*

[38] 82 Fed. Reg. 33,726, 33,732 (July 20, 2017).

[39] 59 Fed. Reg. 7629 (Feb. 16, 1994); *see also Standing Rock Sioux Tribe v. United States Army Corps of Eng'rs*, 255 F. Supp. 3d 101, 136-40 (D.D.C. 2017) (finding that Corps did not comply with environmental justice obligations and relying, in part, on EPA's critiques of the Corps' analysis).

[40] U.S. EPA. "Guidance on Considering Environmental Justice During the Development of Regulatory Actions." May 2015. Available: https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf.

[41] 59 Fed. Reg. at 7629 (February 16, 1994).

[42] 15 U.S.C. § 2605(b)(1)(B).

designation that have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, or indigenous populations. As EPA's *Guidance* explains:

> Consistent with the EO and the Presidential Memorandum accompanying it, the Agency's [environmental justice] policies promote human health and environmental protection by focusing attention and Agency efforts on addressing the types of environmental harms and risks that are prevalent among minority populations, low-income populations, and/or indigenous peoples. EO 12898 and the Agency's [environmental justice] policies … demand that decisions involving the action be informed by a consideration of [environmental justice] issues. Where feasible, regulatory actions should prevent or address and mitigate potential [environmental justice] concerns. [43]

Furthermore, "rule-writers should not only evaluate the distribution of burdens by paying special attention to populations that have historically borne a disproportionate share of environmental harms and risks, but should also evaluate the distribution of the positive environmental and health consequences resulting from their regulatory actions."[44] Given the broad mandate EPA has to consider "potentially exposed or susceptible subpopulations," EPA should use its TSCA authority to consider and address environmental justice concerns when identifying and selecting potential candidates for prioritization. EPA's environmental justice analysis should consider both exposure and susceptibility.

5. Non-risk factors, including availability of substitutes, should not be considered while identifying potential candidates for prioritization.

Through TSCA section 6(b)(1)(A), Congress expressly required EPA to only consider risk-based factors in the prioritization process:

> (A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, ***a 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.[45]

However, EPA's proposed prioritization rule included consideration of chemical substitutes during pre-prioritization: "EPA may also consider the relative hazard and exposure of a potential candidate's substitutes."[46]

At the time, EDF and other stakeholders opposed consideration of substitutes at this early stage. EDF argued that, among other concerns, it constituted a non-risk factor. In finalizing the prioritization rule,

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[43] U.S. EPA. "Guidance on Considering Environmental Justice During the Development of Regulatory Actions," at p. 78. May 2015. Available: https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf.

[44] *Id.* at 5.

[45] 15 U.S.C. § 2605(b)(1)(A) (emphasis added).

[46] 82 Fed. Reg. 4825 (January 17, 2017).

EPA appropriately removed this reference and explained in its response to comments: "EPA has removed the provision in question from the final rule. EPA agrees that such considerations are best addressed, if at all, as part of a chemical-specific risk management rule."[47]

Despite this, EPA's proposed functional category approaches explicitly include consideration of substitutes. EPA goes as far as to indicate the following benefits from its "Functional Category Approach, based on Use and Exposure Potential":

- "A smoother substitutes transition for industry";
- "Identifying low-priority designations for a given functional use category to help ensure the availability of alternative chemicals, prevent unfortunate substitution and address uncertainty in the marketplace"; and
- "By considering functional use categories, EPA will have more complete information on which to base eventual risk management decisions." (pp. 42-43)

Likewise, EPA explains the benefits of the "Functional Category Approach, based on Chemical Structure and Function" as "provid[ing] a resource for chemical manufacturers and product formulators by increasing the likelihood of the availability of alternative chemicals and helping to address uncertainty in the marketplace." (p. 50)

As EDF argued in our comments on the proposed prioritization rule,[48] consideration of substitutes at this early stage is premature and would clearly constitute consideration of a non-risk factor. For example, such an approach may lead EPA to 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 first chemical. Among the other problems, this approach may foster a system whereby EPA would only consider or give preference to chemicals for high-priority designation that already have substitutes on the market. This approach may also have the perverse effect of stymying innovation towards development of safer alternatives for a risky chemical that initially lacks such substitutes. Moreover, 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 this early stage the full range of conditions of use of the subject chemical or its potential substitutes. Finally, such early consideration of substitutes essentially makes presumptions about ultimate risk management needs well ahead of prioritization and risk evaluation. EDF incorporates by reference and reiterates these and the other points we made in our comments on the proposed prioritization rule.[49]

See further discussion of EPA's functional category approaches in section 7c below.

[47] U.S. EPA. "'Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA': Response to Public Comments." See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0076.

[48] EDF Comments on TSCA Procedures for Prioritization of Chemicals for Risk Evaluation Proposed Rule, Comment at pp. 16-17. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

[49] EDF Comments on TSCA Procedures for Prioritization of Chemicals for Risk Evaluation Proposed Rule, Comment at pp. 16-17. Available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0060.

6. Inactive chemicals should be considered as potential candidates for prioritization.

In the final prioritization rule, EPA appropriately indicated that inactive chemicals can be subject to prioritization:

> Chemicals that are designated as "inactive" pursuant to the Active/Inactive Inventory rule (RIN 2070-AK24) are still chemicals *[sic]* substances on the TSCA Inventory, and therefore subject to prioritization. Nothing in TSCA prohibits EPA from initiating the prioritization process on an "inactive" chemical substance and ultimately from designating the priority of that chemical substance.[50]

However, during the December 11th public stakeholder meeting, EPA suggested that the identification of potential candidates for prioritization would focus on active chemicals. EDF disagrees with such an exclusive focus.

While EDF recognizes that most chemicals that undergo risk evaluation will be active on the Inventory, this certainly should not preclude consideration of inactive chemicals. Certain chemicals – especially those that persist and bioaccumulate – continue to present potential risk despite being inactive.

For example, PBDE flame retardants were largely phased out of use in the mid-2000s due to evidence of health impacts, such as adverse neurological development, and persistence in the environment. However, exposure continues to be widespread. PBDEs can still be found in upholstered furniture, electronic devices such as televisions, and other consumer products still in use or in new imported products. Notably, EPA has never finalized the SNUR that it originally proposed for deca BDE in 2012,[51,52] which would have required people to notify EPA before manufacturing or processing deca BDE. Thus, at present, a person could reintroduce deca BDE for its old uses at any time. One study estimated that flame retardants have been added to hundreds of millions of everyday foam products in the U.S., such as couches and foam baby products.[53] National biomonitoring by the Centers of Disease Control (CDC) demonstrates that most people have PBDEs in their blood and body fat,[54] and a study conducted by UCSF in 2011 demonstrated that 99% of pregnant women have PBDEs in their bodies.[55] CDC describes that:

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[50] 82 Fed. Reg. 33,753 (July 20, 2017).

[51] 77 Fed. Reg. 19,861 (April 2, 2012).

[52] OIRA. "Certain Polybrominated Diphenyletheres; Significant New Use Rule (SNUR) and Test Rule." EPA/OCSPP; RIN: 2070-AJ08. Last visited January 25, 2018. Available: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=2070-AJ08.

[53] Betts, K. S. "Hand-Me-Down Hazard: Flame Retardants in Discarded Foam Products." *Environ Health Perspect* (2015) Vol 123(31): A56-A63. Available: https://ehp.niehs.nih.gov/123-a56/.

[54] CDC, National Biomonitoring Program. "Biomonitoring Summary: Polybrominated Diphenyl Ethers and 2,2',4,4',5,5'-Hexabromobiphenyl (BB-153)." Last visited January 25, 2018. Available: https://www.cdc.gov/biomonitoring/PBDEs_BiomonitoringSummary.html.

[55] Woodruff, T. J., Zota, A. R., and Schwartz, J. M. "Environmental Chemicals in Pregnant Women in the United States: NHANES 2003-2004." *Environ Health Perspect*, (2011) Vol 119(6):878-885. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114826/.

> People can be exposed to PBDEs … by eating contaminated foods, especially those with a high fat content, such as fatty fish. Another source of exposure results from breathing contaminated air or swallowing contaminated dust. Working in industries that make these chemicals or that make, repair, or recycle products containing these chemicals flame retardants can result in exposure.[56]

Exposure to PBDEs continues to result in negative health impacts. A recent systematic review and meta-analysis of the impacts of PBDE exposure in childhood estimated that a 10-fold increase in PBDE exposure was associated with a loss of 3.7 IQ points.[57]

While production of PBDE chemicals in the U.S. has largely ceased, continuing use and disposal of articles containing PBDEs remain sources of exposure to these hazardous chemicals.[58] Evaluation and potential management under TSCA section 6(a) of PBDE chemicals could offer significant public health protection. Such opportunities should not be overlooked simply because these chemicals are not identified on the Inventory as being actively manufactured.

Furthermore, EDF believes that EPA's general approach of ignoring legacy chemical exposures is unlawful. In the context of risk evaluation, EPA has adopted an approach to "conditions of use" that is contrary to law, in part by asserting that it can ignore so-called "legacy uses," "associated disposal," and "legacy disposal."[59] As EDF has explained, there is no legal or logical basis for ignoring legacy uses or associated disposal, and there is also no legal or logical basis for ignoring any conditions of use.[60] EDF incorporates and reiterates the points made in those comments here. With regards to identifying potential candidates for prioritization, EPA should factor in potential risks from legacy uses and associated disposal of materials, articles, and other products containing chemicals, which may result in early prioritization of certain inactive chemicals. Failing to do so would be inconsistent with EPA's requirement to prioritize chemicals based on all conditions of use (section 6(b)(1)(A)).

[56] CDC, National Biomonitoring Program. "Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Biphenyls (PBB) Factsheet." Last visited January 25, 2018. Available: https://www.cdc.gov/biomonitoring/PBDEs_FactSheet.html.

[57] Lam, J., Lanphear, B.P., Bellinger, D., Axelrad, D.A., McPartland, J., Sutton, P., Davidson, L., Daniels, N., Sen, S., and Woodruff, T.J. "Developmental PBDE Exposure and IQ/ADHD in Childhood: A Systematic Review and Meta-analysis." *Environ Health Perspect,* (2017) Vol 125(8): 086001. Available: https://www.ncbi.nlm.nih.gov/pubmed/28799918.

[58] Betts, K. S. "Hand-Me-Down Hazard: Flame Retardants in Discarded Foam Products." *Environ Health Perspect*, (2015) Vol 123(31): A56-A63. Available: https://ehp.niehs.nih.gov/123-a56/.

[59] See 82 Fed. Reg. at 33,729-30.

[60] EDF Comments on Ten Scopes under the Toxic Substances Control Act. See docket: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0107.

7. Specific comments on EPA's proposed approaches

a. TSCA Work Plan

EDF generally supports EPA's TSCA Work Plan approach for identifying potential candidates for high-priority designations. Moving forward, EDF recommends that EPA augment the TSCA Work Plan approach to incorporate statutory requirements not previously included (or not sufficiently addressed) in the 2012 methodology and integrate new information (similar to EPA's TSCA Work Plan Approach C). Updated criteria should include, but not necessarily be limited to, additional criteria specific to particular potentially exposed and susceptible subpopulations (e.g., worker exposures, early-life exposures), storage near significant sources of drinking water, and changes in production volume and use patterns. EPA's proposed TSCA Work Plan Approach B (and presumably Approach C) includes incorporation of new "high-throughput and *in silico"* data. (pp. 22-23) While EDF supports the incorporation of new information, EPA should also consider any other information that has been developed since the 2014 update (e.g., scientific literature, NHANES biomonitoring, health and environmental information from state governments, other Federal agencies, or manufacturers).

One area of particular need is that EPA should improve its methodology for consideration of potential exposure to children. As described in the Work Plan Methods Document,[61] EPA considered exposure to children only if the chemical was expected to be used in children's products, based on review of the 2006 Inventory Update Reporting (IUR) – which is now quite outdated and should be updated using the latest Chemical Data Reporting (CDR) information – and several other databases. There are a number of limitations to this approach. First, these data on use in children's products are based on limited sources of information. For example, CDR reporting (previously IUR) is limited to manufacturers, who typically have limited knowledge about whether or how their chemicals are used in products intended for use by children; such information need only be reported to the extent it is known or reasonably ascertainable by the manufacturer. CDR reporting is subject to volume thresholds and has many exemptions that mean it does not capture information from all manufacturers of all active chemicals.

Second, even if a product is not intended for use by children, it very well may be used by them. Children are also often subject to exposures as bystanders even if they are not themselves using a product. Finally, accidental exposures must be considered. For example, many children are accidentally consuming laundry detergent pods. According to the American Association of Poison Control Centers, there were nearly 12,000 cases of laundry detergent pod exposure in children five years old and younger reported to poison centers in 2014.[62] According to Consumer Reports, based on information it obtained through a FOIA request to Consumer Product Safety Commission, there were eight reported deaths, two

[61] U.S. EPA, Office of Pollution Prevention and Toxics. "TSCA Work Plan Chemicals: Methods Document," at p. 3. February 2012. Available: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

[62] AAPCC. "AAPCC Position Statement on Single-Load Liquid Laundry Packets." Available: https://aapcc.s3.amazonaws.com/files/library/AAPCC_Laundry_Packet_Position_Statement.pdf.

children and six adults with cognitive impairment, between 2012 and 2017.[63] Where known or otherwise reasonably foreseeable, such exposures should be considered.

Third, much of children's chemical exposure is likely to come from environmental sources such as contaminated water, air, soil, and dust – which was not captured through the Work Plan methodology. For example, chemicals likely to contaminate house dust, where young children could be more highly exposed due to their increased intake of air per unit body weight as well as crawling and mouthing behaviors,[64] warrant further scrutiny.

And finally, an approach that relies on use in children's products completely ignores prenatal exposures, which can be as or even more detrimental than exposure during childhood.[65] EPA's own framework for assessing health risks to children applies a lifestage approach, including preconception and prenatal exposures: "Assessing potential health risks to children as a result of their environmental exposure to toxicants includes considering risk from exposure before conception, during the prenatal period, and through childhood and adolescence."[66]

We also recommend that EPA re-examine the criteria used to exclude certain chemicals from the Work Plan. In particular, a number of chemicals were excluded in 2012 because, at the time, they were subject to ongoing Action Plans. EPA's rationale for excluding these chemicals was that "they had been recently reviewed and are already being addressed."[67] However, most of the actions proposed under the Action Plans were never finalized and are no longer being pursued. For example, while SNURs were contemplated through the Action Plan or even formally proposed for six of the Action Plan chemicals or chemical groups (benzidine-based substances, DnPP (phthalate), short-chain chlorinated paraffins, TDI, MDI, and PBDEs), only one SNUR was finalized (benzidine-based substances).[68,69]

We recognize that the chemicals subject to five of the Action Plans were added back into the Work Plan in 2014. However, the other five were not and for at least three of these – PFCs, MDI and TDI – EDF believes this decision should be revisited, especially given that many of the contemplated actions that

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[63] Janeway, K. "Liquid Laundry Detergent Pods Pose Lethal Risk for Adults with Dementia." Consumer reports. June 15, 2017. Available: https://www.consumerreports.org/laundry-cleaning/liquid-laundry-detergent-pods-pose-lethal-risk/.

[64] ATSDR, Environmental Health and Medicine Education. "Principles of Pediatric Environmental Health: Why are Children Often Especially Susceptible to the Adverse Effects of Environmental Toxicants?" Last visited January 25, 2018. Available: https://www.atsdr.cdc.gov/csem/csem.asp?csem=27&po=3.

[65] Bellinger, D. "Prenatal Exposure to Environmental Chemicals and Children's Neurodevelopment: An Update." S*afety and Health at Work* (2013) Vol 4(1): 1-11. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601292/.

[66] U.S., EPA, Office of Research and Development. "A Framework for Assessing Health Risks of Environmental Exposures to Children," at p. 2-3. September 2006. Available: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158363.

[67] U.S. EPA, Office of Pollution Prevention and Toxics. "TSCA Work Plan Chemicals: Methods Document," at p. 5. February 2012. Available: https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf. https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

[68] U.S. EPA. "Action Plan Fact Sheet." April 2011. Available: https://www.epa.gov/sites/production/files/2014-11/documents/overview.pdf.

[69] U.S. EPA. "Risk Management for Benzidine Dyes." Last visited January 25, 2018. Available: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-benzidine-dyes.

were to have been taken under the Action Plans have faltered. In addition, the Lautenberg Act gives EPA greater authority to require testing of and to regulate chemicals than EPA had when it crafted those Action Plans. EDF believes that these chemicals may be good candidates for early high-priority prioritization.

After updating the criteria and compiling additional information, EPA should re-screen the existing 2014 Work Plan chemicals against the updated criteria in order to determine whether some chemicals are elevated in priority as a result. This is a logical first step, as at least 50% of ongoing risk evaluations must be drawn from the 2014 update of the TSCA Work Plan (section 6(b)(2)(B)) under EPA's own regulations. Subsequently, EPA may want to consider incorporating the updated criteria and new information into a new iteration of the Step 1 screening that led to its identification of the 1,235 chemicals in the 2012 Work Plan process. It could then screen the identified chemicals against the Step 2 criteria (updated as appropriate) to see which of those chemicals are elevated and could become potential candidates for high-priority designations.

Finally, EPA needs to preserve the flexibility to identify potential candidates for high-priority designations that are not necessarily elevated through the established methodology. For example, GenX, DuPont's C6 replacement for C8-perflourinated compounds, entered the market through EPA's New Chemicals program. Since that time, there have been growing concerns about its environmental persistence, bioaccumulation potential, and its health effects. Just one indication of these concerns is that DuPont has filed 16 section 8(e) substantial risk reports to EPA on GenX since 2006.[70] Rather than attempt to develop a prescriptive system whereby EPA would seek to be able to predict all future concerns chemicals may present, EPA should preserve flexibility to identify candidates based on new information and through new approaches. (EPA should of course incorporate section 8(e) substantial risk reports it receives for all chemicals into its methodology, if it has not already done so.)

b. Canadian Categorization and Chemicals Management Plan

EPA has proposed the Canadian Categorization and Chemicals Management Plan processes as an approach to identifying potential candidates for high and low priority designations under TSCA. However, Canada's processes have a number of aspects that are misaligned with TSCA requirements and considerations for prioritization.

First, the Canadian Environmental Protection Act (CEPA) required Health Canada to sort through 23,000 substances on the Domestic Substances List (DSL) to identify ("categorize in") chemicals meeting certain criteria indicative of potential risk in just seven years (1999 to 2006).[71] Unlike prioritization under TSCA, Canada's categorization exercise was intended only to identify chemicals of potentially high concern, *not* to also identify chemicals of low concern. In addition, because of the Canadian law's aggressive

[70] Lerner, S. "A Chemical Shell Game: How DuPont Concealed the Dangers of the New Teflon Toxin." *The Intercept*. March 3, 2016. Available: https://theintercept.com/2016/03/03/how-dupont-concealed-the-dangers-of-the-new-teflon-toxin/.

[71] Canadian Environmental Protection ACT (CEPA), 1999. Available: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/canadian-environmental-protection-act-1999/part-1.html.

timeline, Canadian officials had to make do with whatever information they already had or could develop rapidly through predictive models.

Many chemicals reviewed by Canada were not "categorized in" because the available information was too uncertain or lacking altogether. No attempts were made to fill data gaps.

As a result, despite what the chemical industry frequently asserts, chemicals not found to meet the categorization criteria *cannot* be characterized as affirmatively low-priority. Given that TSCA now gives EPA strong information generation authorities and requires that low-priority designations be based on sufficient information to affirmatively determine that the chemicals are not high-priority, adopting Canada's approach to identify potential candidates for prioritization would not be at all appropriate.

Second, by law Canada's Categorization process specifically targeted chemicals that were deemed either: 1) to have the greatest potential for human exposure, or 2) to be inherently toxic and either persistent or bioaccumulative (or both). If applied under TSCA, this categorization process would bias the pool of potential high-priority chemicals in a manner that would miss key chemicals of concern, such as those posing significant exposure potential for workers, a vulnerable sub-population explicitly identified in the law, where the affected population may be relatively small, and chemicals that may not be persistent or bioaccumulative but are sufficiently toxic or exhibit sufficient exposure to potentially pose significant risks.

More generally, Canada has a population that is only 11% that of the U.S., and has less than 1.5% of the global market in chemicals,[72] with a significant majority of those chemicals imported rather than domestically manufactured[73] – which makes mandating testing a more significant logistical and political challenge. Given these stark contrasts with U.S. chemicals economy, we do not see why EPA should regard the Canadian system to be an appropriate model.

c. Safer Choice Ingredient List (SCIL)

EDF supports utilizing the SCIL as a *starting point* for identifying potential candidates for low-priority designation. However, EDF does not believe that the presence of a chemical on the SCIL list alone is at all sufficient for designating it as low-priority. Rather, the SCIL list may help EPA identify a select number of candidates, which would need to undergo a much more robust evaluation to determine whether they meet the strict statutory requirements for low-priority designations. Such a robust evaluation would consider, among other things, whether sufficient information exists on all conditions of use and hazard endpoints, what vulnerable subpopulations may be exposed, and whether there are potential environmental releases, including whether storage occurs near significant sources of drinking water.

[72] CEFIC Fact & Figures 2017. "World chemical sales: geographic breakdown," (p. 5) and "Chemical sales by country: top 10," (p. 6). Available: http://fr.zone-secure.net/13451/451623/#page=5.

[73] Government of Canada. "Chemicals and chemical products (Total)." Last visited January 25, 2017. Available: https://www.ic.gc.ca/eic/site/chemicals-chimiques.nsf/eng/bt01270.html#trade.

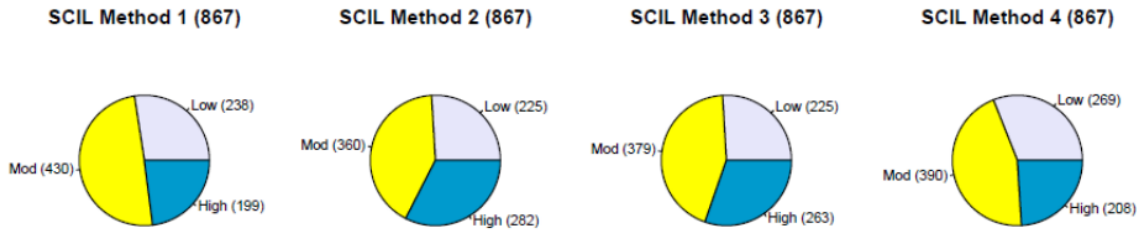
Any approach involving the use of the SCIL as a starting point must acknowledge and address a number of limitations.

First, while SCIL serves important, beneficial goals, it was developed considering "conditions of use" only in a very narrow context, primarily use as ingredients in cleaning products. In contrast, TSCA requires that all conditions of use of a chemical be determined to be low priority in order for the chemical to be so designated.

Second, chemicals on the SCIL have been screened through specific criteria that do not require having sufficient data to meet TSCA's stringent low-priority standard. For at least some functional use categories, SCIL only applies a subset of TSCA-relevant criteria. For example, for surfactants (the functional use category with the most SCIL chemicals), EPA has only considered ecotoxicity[74] and has not examined human health endpoints.[75]

These critical limitations, which are given minimal attention in EPA's Discussion Document, will need to be addressed by EPA before considering use of SCIL as a means to identify potential candidates for low-priority substances.

Further, some SCIL chemicals are known to exhibit hazardous properties. This is understandable in the context of a voluntary certification program that focuses on identifying "best-in-class" chemicals, where non-hazardous or very low-hazard alternatives may not be available for certain functional classes, but it should clearly preclude such chemicals from receiving low-priority designations. The presence of such hazard properties is exemplified by EPA's application of its web-based tool integrating traditional methods and NAM to prioritize SCIL chemicals. The analysis demonstrates that across four methods, a sizeable fraction of SCIL chemicals were categorized into moderate and high bins (hazard/bioactivity-to-exposure ratio). Only 225-269 (26-31%) of the 867 SCIL chemicals fell into the low bin in this analysis. These low-bin chemicals may be a good place for EPA to start.



EPA Discussion Document: Possible Approaches and Tools for Identifying Potential Candidates Chemicals for Prioritization. Appendix 1, p. 61.

[74] U.S., EPA, Safer Choice. "Safer Choice Criteria for Surfactants." Available: https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants.

[75] 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." See: U.S. EPA, Safer Choice. "Safer Choice Master Criteria for Safer Chemical Ingredients." Last visited January 25, 2018. Available: https://www.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients.

However, even within the low bin, EDF strongly believes that only those chemicals that are classified as "full green circles" should serve as a starting point for identifying potential candidates for low-priority, (though many of these are so designated based on modeled rather than measured information). Half green circles are only "expected to be of low hazard," indicating that there is insufficient information, and yellow triangles have "some hazard profile issues." Both of these sets should be excluded from consideration, barring additional information demonstrating low hazard.

Finally, EPA has proposed in its Discussion Document to focus on high-production volume chemicals under its SCIL approach, claiming that that "[d]esignating chemicals with high production volumes may maximize the benefits of chemical prioritization." (p. 35) While it is clear how this approach would benefit industry, it is not at all clear how this approach would benefit human health and the environment, and EPA has offered no such reasoning. The agency does have a mandate to consider production volume in prioritization (section 6(b)(1)(A)); however, the statutory context of this mandate should lead EPA in the opposite direction than it appears to be heading. It should lead toward looking at *low* production volume chemicals as potential candidates for low-priority designations, because they are likely to result in lower exposure. EPA has not offered any statutory basis to completely flip the presumption relating to the production volume criterion.

d. Functional category approaches

EPA has proposed two functional category approaches, one based on use and exposure potential and the other based on structure and function.

It is unclear from the Discussion Document whether EPA's functional category approach intends to move whole functional categories through the prioritization process, particularly with respect to the structure and function approach. EDF strongly urges EPA not to move large numbers of chemicals through the prioritization process for the reasons described in section 3c above.

Furthermore, use- or function-based categories, by definition, do not encompass all conditions of use. EDF does not see how these approaches would work and comport with the law except for their possible use exclusively as an initial, purely organizational step.

As described in section 5 above, EDF believes that the emphasis EPA has placed on these two category approaches for identifying chemical substitutes is neither appropriate nor complies with the law's requirement that the prioritization process be risk-based (section 6(b)(1)(A)).

i. Functional Category Approach, based on Use and Exposure Potential

EDF has specific concerns with the EPA's proposed 4-step process to tier functional categories of chemicals based on exposure potential. In the first step, EPA proposes to assign highest priority to functional categories with the greatest exposure potential. Exposure to vulnerable subpopulations isn't proposed to be addressed until step 2, where additional exposure factors are considered. However, even here EPA is proposing that two or more exposure factors be triggered in order to shift the tier

assigned to a product category in step 1. This scheme unacceptably downplays exposure to vulnerable subpopulations, which by itself should drive a higher ranking.

Also, EPA asserts in Step 1 that "many industrial and commercial operations will have overarching health and safety procedures to minimize exposures." (p. 39) EPA cannot casually assert this blanket statement without sufficient evidence that demonstrates for each specific chemical that such measures are in place, fully complied with, and actually demonstrated to be effective, across all actors in the supply chain. Given that section 6(b)(1)(A) of the new law mandates EPA to consider in the prioritization process potential risks to potentially exposed or susceptible subpopulations – which explicitly includes workers – EPA cannot make sweeping assumptions that have the effect of deprioritizing worker exposures in identifying potential candidates for prioritization, as it is proposing to do here.

ii. Functional Category Approach, based on Chemical Structure and Function

EDF opposes EPA's proposed structure and function category approach. This proposed approach would use predictive models to identify clusters of structurally and functionally related chemicals within which there may be varying toxicities. From our understanding, the impetus behind this methodology is to identify potential candidates for both high-and low-priority substances within a single functional class.

This proposed approach is problematic for two reasons. First, it appears to be motivated by a desire to identify safer alternatives, which for the reasons described in section 5 above, EDF strongly believes is inappropriate to consider during the process of identifying candidates for prioritization.

Second, this proposed methodology relies on relative risk within a narrow category, rather than following the broad mandate to identify high- and low-priority substances called for under the law. Under this proposed approach, EPA could designate a chemical as low-priority that could present significantly greater risk than many other chemicals – based only on the narrow ranking of a small number of chemicals within a category. This is hardly the "worst-first" approach to evaluating chemical's risks that Congress intended. For example, EPA could identify a preservative with significant risk potential as a low priority only because it has lower risk potential than other preservatives in the category. Such a chemical should not be considered low priority simply because it might be a preferable substitute to others in the category.

e. Integration of Traditional and New Approaches

EDF believes that NAMs have a role in the process of identifying potential candidates for prioritization, given the large number of chemicals with limited information that EPA will need to sort through over the long term. However, such methods also have significant limitations. NAMs are not currently available for all potential modes of toxicity across diverse human and ecological populations, including those arguably of greatest concern, such as developmental toxicity. Indeed, a November 2017 report by the European Chemicals Agency (ECHA), *Non-animal approaches: Current status of regulatory applicability under the REACH, CLP and Biocidal Products regulations*, highlights such limitations, noting:

> For higher-tier endpoints, specific non-animal approaches that could directly replace vertebrate animal tests are not yet available and not foreseen in the near or even medium-term future, and adaptations are currently the main approaches to reduce the need for new animal testing. In spite of very active ongoing research in the area of non-animal approaches, approaches capable of replacing animal testing for complex endpoints are not yet available. Also the nature of such future approaches cannot be established yet. Furthermore, they may not provide the same level of information on the toxicity of substances as the current animal studies, for instance in terms of dose/concentration-response relationship and adverse effects.[76]

Additionally, NAM approaches face key technological hurdles, including challenges with metabolic competency and chemical solubility in high-throughput *in vitro* testing assays.

In general, NAMs have a number of well-established limitations from biological, chemical, and technological standpoints. As such, EPA should be transparent about how these limitations bear on any use of NAMs for any purposes under TSCA, including use in identifying candidates for prioritization. Among other details, the agency should describe which NAMs were considered and used or not used (and why); assumptions made in their application and in the interpretation of results; associated uncertainties and limitations; information gaps that remain following the use of NAMs; and how remaining information gaps have been addressed or otherwise considered. For example, NAM Method 5 excludes dermal and inhalation exposure, and thereby underestimates actual exposure. To the extent EPA considers applying NAM Method 5, it should explicitly identify these limitations and describe the implications for the candidate selection process.

The use of NAMs at early stages should not discourage the agency from aggressively utilizing its mandatory authorities to generate or obtain the information that will ultimately be needed for prioritization and risk evaluation.

Russell Thomas's presentation at the December 11th stakeholder meeting included a list of caveats applicable to EPA's proposed approach to the use of NAMs:[77]

1. Ongoing data cleaning and curation
2. Ecological hazard endpoints currently limited to acute and chronic aquatic toxicity
3. No quantitative estimates for occupational exposure
4. No respiratory sensitizer data in current database
5. No experimentally measured persistence and bioaccumulation data in current database
6. Limited media and chemical coverage for quantitative ecological exposure

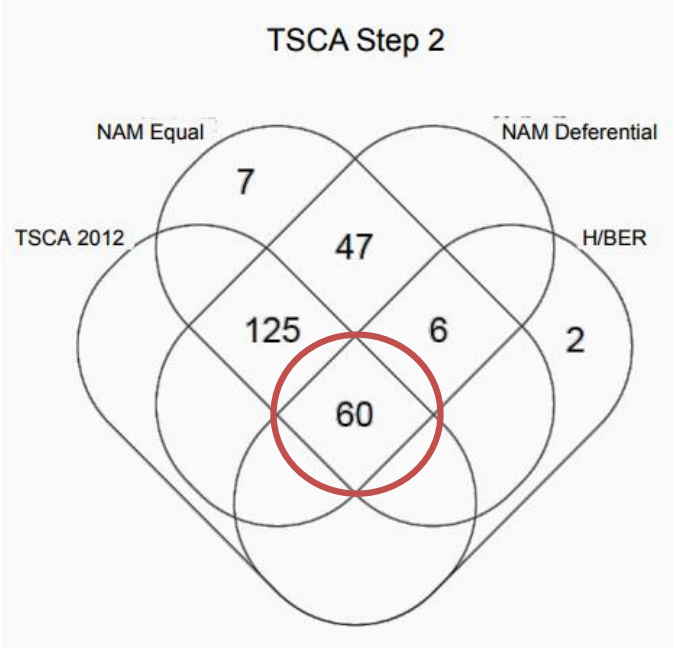
[76] ECHA. "Non-animal approaches: Current status of regulatory applicability under the REACH, CLP and Biocidal Products regulations." November 2017. Available: https://echa.europa.eu/documents/10162/22931011/non_animal_approcches_en.pdf/87ebb68f-2038-f597-fc33-f4003e9e7d7d.

[77] U.S. EPA, Office of Research and Development. "Approaches to Identifying Potential Candidate Chemicals for Prioritization: Integration of Traditional and New Approach Methods." [Powerpoint] EPA Public Stakeholder Meeting, Presentation by Russell S. Thomas. December 11, 2017. Available: https://www.epa.gov/sites/production/files/2017-12/documents/session_6_-_tsca_preprioritization_tool_public_meeting_dec_2017_final2.pdf. See slide 18.

7. Scoring criteria in this approach do not account for Safer Choice use restrictions (e.g., strong acids as pH modifiers), or some SCIL criteria (e.g., rate of biodegradation to mitigate aquatic toxicity)

Most of these listed caveats represent information gaps (items 2-6). EDF strongly recommends that EPA use these as a starting point for promulgating section 4 testing rules and/or section 8 data call ins.

Thomas' presentation also highlighted the significant overlap in the chemicals assigned to the "high" bin across the different methodologies using traditional methods (TSCA 2012) and incorporating NAM (NAM Equal, NAM Deferential, and H/BER). In particular, there are 60 chemicals that were categorized into the high bin across these four methodologies:



Thomas, Russell. "Approaches to Identifying Potential Candidate Chemicals for Prioritization: Integration of Traditional and New Approach Methods." Powerpoint presentation, U.S. EPA Stakeholder meeting, December 11, 2017. (Slide 15).

EDF encourages EPA to move forward with these 60 chemicals as potential candidates for high priority, coupled with the augmented Work Plan approach we discussed earlier (section 7a of these comments). As a starting point, EPA could overlay these 60 chemicals with those on the 2014 Work Plan. Any overlapping chemicals would likely be good candidates for the next round of high-priority substances that need to be identified and subject to initiation of risk evaluations by December 2019. To the extent that the agency considers candidates for high-priority substances beyond the 2014 Work Plan, we recommend that the agency also look to any of these 60 chemicals not on the 2014 Work Plan as a starting point. Furthermore, if EPA updates the Step 2 TSCA 2012 list (e.g., through re-running Step 1 of the Work Plan with updated criteria and new information, as described in section 7a above), the NAM analysis should be re-run with the updated list to reflect such changes.

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