Environmental Defense Fund Questions for

Public Meeting 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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Process

1. Does EPA envision a step prior to the formal prioritization process whereby it will publicly identify potential candidates?
2. By 3.5 years after enactment, EPA must be conducting risk evaluations on at least 20 high-priority chemicals and have designated at least 20 low-priority chemicals.
    a. What does EPA mean by the statement "EPA should strive to identify more than the statutory-mandated minimum of 20 low-priority chemicals"? Does EPA envision significantly exceeding the statutory threshold for low-priority designations? If so, what is its rationale for doing so, given that the statute appears to seek an approximate balance in the pace at which high- and low-priority designations are made?
    b. Neither EPA nor the public has experience with the processes leading up to and including prioritization, so EDF believes EPA should adopt an approach to identifying candidates for low-priority substances that ensures that EPA has sufficient time to focus on each decision and the public has ample opportunity to comment on each candidate chemical. What steps does EPA plan to take to ensure that its identification of candidates for low-priority chemicals proceeds in a manner that is manageable and fair for both the agency and the public?

Filling data gaps

3. How will EPA proactively use its enhanced information-gathering authorities under the revised TSCA in identifying potential candidates for prioritization in order to ensure both timely and sufficient information exists on which to base prioritization decisions and conduct robust risk evaluations within the statutory deadlines? Please explain how EPA will utilize its section 4, 8, and 11(c) authorities.
4. What are EPA's plans to obtain relevant information companies have submitted to other jurisdictions (e.g., submission of data to ECHA under REACH)?
5. How will EPA ensure that data received from companies for the purpose of informing prioritization is complete and accurate, and does not omit information a company may view as raising concerns about one of its chemicals? In particular, if the agency seeks voluntary submission of information during this phase, how will it ensure its quality and completeness (e.g., avoid submission of "cherry picked" or otherwise selective or partial information)?

6. While EPA may reasonably focus on information-rich chemicals initially, how will EPA ensure that the process of identifying chemicals for prioritization does not indefinitely skew toward or excessively lead to selection of relatively information-rich chemicals as candidates for prioritization and risk evaluation?
7. How will EPA address/acquire information in the candidate identification process that will be needed to identify the full range of conditions of use that must be considered in making prioritization decisions?
    a. How will EPA utilize TSCA Section 4's explicit authorization for EPA to require the generation and submission of exposure-relevant information on chemicals?
    b. Under what circumstances will the agency mandate exposure monitoring or similar studies to be conducted?
8. The statute defines low-priority substances as follows: "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 nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance." (emphasis added) (TSCA 6(b)(1)(B)(ii)). In its prioritization rule, EPA chose not to define what "sufficiency" of information meant. Will it do so by guidance? How will EPA ensure the sufficiency of information on which to identify candidates for low-priority designations?

CBI/transparency

9. Health and safety studies and their underlying data are not eligible for CBI protection from disclosure under TSCA. How will such studies and data submitted through the process for identification of candidates for prioritization be shared with the public?
10. Will EPA commit to requiring submission of full studies for use in identifying chemicals for prioritization? And will it commit to making such studies publicly available?

Approach-specific comments

<u>TSCA Work Plan</u>

11. Under the Work Plan process, EPA identified a subset of chemicals as "Potential Candidates for Information Gathering." One of EPA's proposed approaches would integrate high-throughput screening and *in silico* data, in part to identify data gaps/errors and opportunities to generate data. However, it is unclear how the agency intends to fill such identified data gaps. Would EPA integrate section 8 data call-ins and section 4 test rules into such a system?

<u>Canada's Chemicals Management Plan</u>

12. Does EPA consider the Canadian model appropriate for the US, given that Canada – with a population that is only 11% that of the US – has only about 2% of the global market in chemicals,

and the great majority of those chemicals are imported rather than domestically manufactured? If so, why?

13. The vast majority of chemicals reviewed by Canada under its chemicals management plan lacked sufficient information to prioritize. This was the case even with respect to the ability to develop estimated or modeled data. Canada lacked the capacity to require testing to fill these huge gaps, in part because of the factors just described: a small share of the global market, mainly imports. In contrast, the new TSCA provides EPA with enhanced authority to require companies to test their chemicals and other data generation and collection authorities. Given these major differences between the two systems, how would EPA modify the Canadian model to account for major data gaps with respect to selecting candidates for the prioritization process?

Safer Chemicals Ingredient List (SCIL)

14. In EPA's discussion of potential use of SCIL as a source of candidates for low priority designations, EPA appears to downplay or fails to mention some significant limitations to SCIL. First, SCIL was developed for use in a very narrow context, specifically for chemicals primarily used 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. This extends to the full lifecycle of a chemical, not just the product use phase that is the main focus of SCIL listings. Second, 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 chemicals), EPA has only considered ecotoxicity and has not examined human health endpoints. Why are these critical limitations given short shrift in EPA's document, and how does EPA propose to address them before considering use of SCIL as a means to identify low priority chemicals?
15. Under the SCIL approach for identifying potential low-priority chemical candidates, EPA is proposing to focus on high production volume chemicals, claiming that "[d]esignating chemicals with high production volumes may maximize the benefits of chemical prioritization." While it is clear how this approach would benefit industry, how does the agency believe it would benefit human health and the environment? How would this approach aid in identifying those chemicals with the lowest exposure/hazard profile? The agency does have a mandate to consider production volume in prioritization; however, this mandate arguably would lead EPA toward designating *low* production volume chemicals as low priority, because they are likely to result in lower exposure. What is the statutory basis for EPA to completely flip the presumption relating to this production volume criterion?

Functional category approaches

16. Is it EPA's intent to designate categories of chemicals as candidates for high priority and/or low priority, as opposed to individual chemical substances? If so:
    a. How would EPA address the situation where some chemicals in a category are proposed to be designated as high priority and some as low priority? Or the situation where some chemicals have sufficient information for prioritization and others do not?

b. EPA has proposed as one approach to look at chemicals based on use/exposure categories. How would this work, given that EPA will need to look at all conditions of use to designate a chemical as low-priority? How would this process allow EPA to identify and consider all conditions of use?

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EDF appreciates the opportunity to provide questions and looks forward to hearing EPA's responses.