

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Comments of Safer Chemicals Healthy Families on Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act

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Docket ID EPA-HQ-OPPT-2016-0636

Safer Chemicals Healthy Families (SCHF) submits these comments on the Environmental Protection Agency's (EPA's) proposed rule to establish procedures for prioritization of chemicals under the newly enacted Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (LCSA).<sup>1</sup>

SCHF is a coalition of national, state and local organizations committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. SCHF and its members took a leadership role during the LCFA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

LCSA is the first major overhaul of the 1976 Toxic Substances Control (TSCA) and potentially an important step forward in evaluating and reducing the risks of chemicals to health and the environment in the US. If EPA takes forceful and proactive steps to implement the new law, it can deliver significant health and environmental benefits to the American people. However, if EPA rolls back the protections mandated by Congress, the law's promise will not be realized and the threats that chemical risks now pose to our communities and the environment will continue unchecked while the authority of states to protect the public will be put at risk. SCHF will engage constructively with EPA and other stakeholders on an implementation path that maximizes the health and environmental protections of LCSA but will hold EPA accountable if it fails to carry out the law as enacted by Congress.

The following organizations have endorsed and are supporting the SCHF comments:

**Alaska Community Action on Toxics**  
**Breast Cancer Action**  
**Breast Cancer Prevention Partners**  
**Clean and Healthy New York**  
**Earthjustice**  
**Environmental Health Strategy Center**  
**League of Conservation Voters**  
**Learning Disabilities Association of America**  
**Maryland PIRG (Public Interest Research Group)**  
**Physicians for Social Responsibility**  
**Science and Environmental Health Network**  
**U.S. PIRG (Public Interest Research Group)**  
**WE ACT for Environmental Justice**

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<sup>1</sup> 82 Federal Register 4825 (January 17, 2017).

## SUMMARY OF KEY POINTS

**Importance of Prioritization under the LCSA.** Sections 6(b)(1)-(2) of the new law define the principal steps and deadlines in the prioritization process, provide a succinct definition of “high” and “low”-priority chemicals, and specify additional considerations in identifying high-priority chemicals. To implement these provisions, section 6(b)(1)(A) directs EPA to 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 this time.” EPA is obligated to issue a final rule within one year of LCSA’s enactment.

Prioritization is a key stage in an integrated process under the LCSA for (1) identifying chemicals that warrant a full examination of health and environmental risks, (2) conducting comprehensive evaluations to determine if the risks presented by these chemicals are unreasonable, and (3) imposing restrictions on conditions of use where necessary to protect against such risks. Congress set strict deadlines for each stage of this process and structured it so that EPA is obligated to proceed from one stage to the next where warranted by its findings.

The goal of this integrated approach is to remedy the critical weakness of the original law – EPA’s failure to assess and assure the safety of existing chemicals that pose risks of concern to workers, communities, vulnerable populations and consumers. The deadlines and triggers for action in the new law – and its simplified framework for decision-making – were all intended by Congress for one purpose: to accelerate and sustain progress on the many chemicals of concern that had languished without agency scrutiny in the preceding 40 years of TSCA implementation.

**Merits of EPA’s Overall Approach.** EPA’s proposed rule reflects a keen appreciation of the role of prioritization in TSCA’s integrated chemical safety process and the links between prioritization and timely and effective risk evaluation and risk management. EPA has wisely refrained from overloading the proposal with procedures and criteria that would distort the limited purpose of priority setting and add unnecessary resources, time and complexity to prioritization decisions. And EPA has properly recognized that the prioritization process needs to be designed with the goal of assuring that sufficient data on hazard, conditions of use and exposure are available not only to inform designating a chemical as high- or low-priority but also to provide a sound foundation for science-based risk evaluation and risk management for those chemicals identified as high-priority.

We strongly support much of the thinking informing the proposed rule and agree with EPA that:

- ✓ *The bar for high-priority designations is very low and requires a limited showing of potential hazard and exposure. More extensive analysis of potential risks is not necessary or appropriate until the risk evaluation stage.*
- ✓ *The prioritization rule should not codify definitions of scientific terms, a quantitative scoring or ranking system or principles of scientific assessment. These steps would complicate priority setting and are unnecessary to meet the limited goals of prioritization. In any case, EPA has historically used guidance, not rulemaking, to describe how it will use science for decision-making and LCSA provide no indication that EPA should depart from this long-standing practice in its prioritization rule.*

- ✓ *High-priority listings must encompass all conditions of use of the listed chemical. Section 6(b)(1)(B) is clear that a high-priority designation covers the chemical as a whole, not subsets of uses or other discrete activities. Limiting a priority listing to specific uses would prejudice the subsequent risk evaluation by removing uses from its scope without the careful assessment of hazard and exposure that the evaluation is intended to provide.*
- ✓ *Low-priority listings will only be warranted where sufficient evidence is available to demonstrate the absence of unreasonable risk under all conditions of use. Low priority chemicals will be perceived as “safe” by users and the general public. Such an aura of safety would be misleading where data to establish the absence of risk is non-existent or incomplete or where some uses cannot in fact be shown to lack the potential for unreasonable risk. To avoid the risk of “false negatives, we strongly urge that the assessments on which low-priority designations are based undergo peer review in accordance with established EPA policies.*

**The Vital Role of pre-Prioritization.** Among the most important aspects of EPA’s proposal is its recognition of the vital role of pre-prioritization in creating a pipeline of listing candidates and assuring sufficient information for risk evaluation and risk management. While many chemicals will meet the low standard for high-priority designation, the new law will be most effective if EPA –

- (1) Has a sound basis for selecting from chemicals meeting the listing criteria those substances that offer the greatest opportunity for risk reduction, and
- (2) Invests its resources in risk evaluation after it has comprehensive hazard, exposure and use information on which to base sound risk-based judgments.

These goals require EPA to create a pipeline of candidate chemicals from which it can make thoughtful selections of high-priority substances. And in view of the tight deadlines for both prioritization and risk evaluation, pre-prioritization offers the best opportunity to collect available information and compel development of new data so that EPA is in a position to conduct a meaningful risk evaluation on chemicals that are designated high-priority.

The candidate list that EPA develops for pre-prioritization should not derive from a numerical scoring process but should be based on screening criteria that incorporate basic indicia of hazard and exposure. *We support the screening criteria in EPA’s proposed rule but believe EPA should add other toxicity and exposure triggers to this list.* These should include literature reports of potential mutagenicity, developmental toxicity, reproductive effects, developmental neurotoxicity, immunotoxicity, endocrine effects and sensitization. Similar triggers should be used for potential ecotoxicity. EPA should also include chemicals listed on one of the many authoritative lists of chemicals of concern (such as the National Toxicology Program (NTP) or International Agency for Research on Cancer (IARC) lists of carcinogens or the Clean Air Act’s list of Hazardous Air Pollutants (HAPs)) and chemicals for which environmental releases have been reported for the Toxic Release Inventory (TRI).

As EPA correctly recognizes, chemicals on the candidate list should be more fully characterized through an information collection process focused on developing a hazard, use and exposure profile for each candidate chemical and identifying “potentially exposed or susceptible subpopulations.” Some of the information needed for this profile may be submitted by industry voluntarily, but EPA

should be prepared to use its mandatory information collection authorities under TSCA to fill remaining data-gaps. This includes section 4 orders requiring new testing or other information development activities, and reporting to obtain existing information under sections 8(a) and 8(d) and subpoenas under section 11.

**Immediate Implementation of the pre-Prioritization Process.** *While the EPA proposal outlines the pre-prioritization process in concept, the process must be operationalized and implemented without delay.* Section 6(b)(2)(C) requires that risk evaluations must be underway on at least 20 high-priority chemicals within 3.5 years of the LCSA date of enactment. Since the formal prioritization process on these chemicals must take 9-12 months, little time remains for initial screening and information collection. To jumpstart these activities, *we strongly recommend that EPA take the following steps:*

- 1) *Create an initial candidate list* – We suggest a list of around 60 chemicals and recommend publishing the list at the same time as finalization of the prioritization rule, if not earlier.
- 2) *Conduct a literature search on chemicals on the candidate list and call for voluntary submission of hazard, exposure and use information by industry and the public* -- These steps should be concurrent with publication of the candidate list and be completed within 3 months.
- 3) *Where necessary based on voluntary industry submissions, add candidate list chemicals to reporting rules under section 8(a) and 8(d) to assure that EPA has all existing hazard, use and exposure information within industry's possession or control* – this step should occur within three months of the completion of Step 2 for chemicals on which EPA determines that mandatory information reporting is necessary.
- 4) *Develop a "roadmap" (or matrix) showing hazard, use and exposure scenarios where data are available and scenarios where data are lacking* -- the roadmap should be complete 45 days after the completion of Step 3.
- 5) *Determine data-gaps that need to be filled and issue section 4(a)(2) orders to require industry to develop the necessary information* -- These steps should be taken within three months of the completion of Step 4. Industry should have an opportunity to commit to develop the information voluntarily or under consent agreements but, absent this commitment, EPA should use section 4 authorities.
- 6) *Initiate the prioritization process on at least 20 candidate chemicals determined to present a strong case for risk evaluation based on information collected or under development under Steps 3 and 4* – This step will need to occur no later than 30 months after LCSA's date of enactment.
- 7) *Repopulate the candidate list as chemicals are designated high-priority and enter risk evaluation* – We recommend that for every chemical designated as high-priority, EPA add 3 chemicals to the candidate list to assure that EPA has a sufficient universe of candidate chemicals to choose among for future high-priority listings and risk evaluations.

*We urge EPA to formalize this pre-prioritization process in parallel with its final rule and implement the process on the timeline described above.*

**Additional Concerns About EPA’s proposal.** SCHF also recommends that:

- ✓ The preamble to the final rule should confirm that EPA will provide for the maximum disclosure of Confidential Business Information (CBI) allowable under the LCSA in order to facilitate informed and productive public participation in the prioritization process.
- ✓ The rule should specify a deadline of 45 days for designating new high-priority chemicals to replace those for which risk evaluations are completed.

**I. EPA HAS CORRECTLY RECOGNIZED THAT HIGH-PRIORITY DESIGNATIONS REQUIRE A LIMITED SHOWING OF POTENTIAL HAZARD AND EXPOSURE AND DO NOT WARRANT EXTENSIVE ANALYSIS**

Industry has argued that EPA should expand the prioritization process to include a system for scoring or ranking chemical substances, a detailed list of the specific hazard and exposure indicators which it will consider in priority designations, and definitions of scientific terms like “weight of evidence” that will inform prioritization decisions. EPA has properly rejected these suggestions, which reflect a misunderstanding of the role of priority setting under the LCSA.

Priority setting is a mechanism for selecting those chemicals that warrant further attention through the risk evaluation and rulemaking process (high-priority chemicals) or do not require such attention because adequate evidence demonstrates a lack of potential for unreasonable risk (low priority chemicals). A high-priority listing should not be confused with a risk evaluation, either in the types of scientific judgments it entails or in the amount of information required to support the listing decision. Nor should such a listing be considered a judgment about the level of risk presented by a chemical since it is merely a preliminary step in subjecting the chemical to scrutiny through the risk evaluation process.

The limited purpose of prioritization is reflected in section 6(b)(1)(B)’s definition of high-priority substances as chemicals that, “without consideration of costs or other nonrisk factors, **may present** an unreasonable risk of injury to health or the environment because of a **potential hazard and a potential route of exposure** under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation” (emphasis added). This is a low standard which simply requires a limited basis for concern about potential toxicity and some reason to believe that humans or the environment may be exposed to the substance.

As court decisions construing similar language in the original law confirm,<sup>2</sup> the showing required to meet these criteria is minimal. For example, preliminary screening data or Structure Activity Relationships (SAR) may suffice to satisfy the hazard prong of the “may present” finding. Similarly, as noted in its preamble, EPA can demonstrate a “potential route of exposure” based on a “single condition of use” that may bring a human or ecological receptor in contact with the chemical.<sup>3</sup> As EPA has underscored, “the statutory structure [indicates] that scientific uncertainty in this process (including as a result of insufficient information) weighs in favor of a High-Priority Designation, as it is merely an interim step

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<sup>2</sup> *Chemical Mfrs. Ass’n v. U.S., EPA*, 859 F.2d 977 (DC Cir. 1988).

<sup>3</sup> 82 FR at 4830.

that assures that the substance will be further evaluated.”<sup>4</sup> As EPA has concluded, it “intends to conserve its resources and the Agency’s deeper analytic efforts for the actual risk evaluation.”<sup>5</sup>

Accordingly, using the prioritization procedural rule to spell out a comprehensive scientific framework for high-priority listings or describe in exhaustive detail the precise information required to support such listings is unnecessary and in fact would defeat the intent of the new law. EPA’s proposal properly tracks closely the statutory definitions of “high-priority” and “low priority” and the considerations for applying these definitions specified in section 6(b)(1)(A).<sup>6</sup> No further elaboration is required.

## **II. INCORPORATING DEFINITIONS OF SCIENTIFIC TERMS AND CODIFYING SCIENTIFIC PRINCIPLES IN THE PRIORITIZATION RULE WOULD BE UNWARRANTED AND COUNTERPRODUCTIVE**

EPA has properly concluded not only that formalizing risk evaluation terms and methodologies is unnecessary to meet the limited goals of prioritization, but also that rulemaking is the wrong vehicle to prescribe how it will use science for decision-making. The Agency’s rationale is presented fully in the preamble to its proposed risk evaluation rule and restated in the prioritization proposal.<sup>7</sup>

As EPA has emphasized in its proposed risk evaluation rule,<sup>8</sup> it has traditionally issued guidance to elaborate on different aspects of the risk evaluation process. Guidance is preferable to rulemaking because it can be applied flexibly and revised more readily as scientific understanding changes. EPA-issued and external guidance documents on different aspects of risk assessment methodology are extremely numerous and have evolved over time through a transparent, peer-reviewed public process that reflects changes in scientific understanding, new data in the scientific literature and input from experts and stakeholders. To use rulemaking to revise or codify this complex body of knowledge, in whole or in part, would require a level of effort and consultation that is simply not feasible given Congress’ 1-year deadline for a final rule and would run the risk of overturning well-established approaches without thoughtful and careful deliberation.

Industry has also proposed that the prioritization rule incorporate and prescribe how EPA will implement the general “principles” for using science in decision-making set out in section 26(h) of the Act. However, these principles are not absolute requirements; EPA must “consider” them “as applicable.” The principles are also straightforward, self-executing and generally consistent with current agency practice, so there would be no added benefit to restating them in rule language. As EPA points out in its preamble,<sup>9</sup> the lack of any indication in section 26(h) that its science principles would be subject to further elaboration in rulemaking is in direct contrast to the many provisions of LCSA

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<sup>4</sup> 82 FR at 4832.

<sup>5</sup> 82 FR at 4829.

<sup>6</sup> As noted in the proposal, these consideration include: (1) The chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume.

<sup>7</sup> SCHF’s comments on the risk evaluation proposal address these issues at greater length and are incorporated by reference.

<sup>8</sup> 82 Federal Register 7562, 7570 (January 19, 2017).

<sup>9</sup> 82 FR at 4828.

requiring rulemaking and supports EPA's position that these principles should not be codified in its risk evaluation and prioritization rules.

### **III. HIGH-PRIORITY LISTINGS MUST ENCOMPASS ALL CONDITIONS OF USE OF THE LISTED CHEMICAL AND CANNOT BE LIMITED TO SPECIFIC USES**

Industry has suggested that EPA target high-priority listings at particular uses. EPA has properly concluded that this approach would be contrary to the letter and intent of the LCSEA.<sup>10</sup>

Section 6(b)(1)(B) is clear that a high-priority designation covers the chemical as a whole under its conditions of use, not subsets of uses or other discrete activities. Moreover, since the goal of prioritization is to select chemicals for risk evaluation, limiting a priority listing to specific uses would prejudice the evaluation by removing non-listed uses from its scope without the careful assessment of hazard and exposure that the evaluation is intended to provide. This would undermine EPA's determination in its risk evaluation rulemaking that TSCA requires a comprehensive examination of **all** conditions of use during evaluations.<sup>11</sup> Obviously, if all uses must be addressed in the evaluation, it would be illogical and counterproductive to restrict the high-priority designation that is the basis for the evaluation to some uses but exclude others.

### **IV. LOW-PRIORITY LISTINGS WILL ONLY BE WARRANTED WHERE SUFFICIENT EVIDENCE IS AVAILABLE TO DEMONSTRATE THE ABSENCE OF UNREASONABLE RISK UNDER ALL CONDITIONS OF USE**

Section 6(b)(1)(B)(ii) authorizes a substance to be listed as low-priority –

“if the Administrator concludes, based on information sufficient to establish, . . . that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.”

Under this definition, since the prerequisite for high-priority listing is a determination that a chemical “may present an unreasonable risk”, a chemical will qualify as low priority only if it can be demonstrated to lack the potential for unreasonable risk. Moreover, this determination cannot be made in the absence of data. Rather, EPA must have “information sufficient to establish” the lack of potential for unreasonable risk. This will require data adequate to characterize the hazard and exposure potential of the chemical for the range of pathways and toxicological endpoints. Finally, like high-priority designations, low priority listings apply to the chemical as a whole, not specific uses, and thus must be based on a finding of no unreasonable risk across all the conditions of use. Demonstrating the absence of unreasonable risk for all activities that fit the definition of “conditions of use” is essential because low priority chemicals will not be subject to risk evaluations and will be perceived as “safe” by users and the general public. Such an aura of safety would be misleading and indeed irresponsible where data to establish the absence of risk is non-existent or incomplete or where some uses cannot in fact be shown to lack the potential for unreasonable risk.

EPA has properly recognized these aspects of low-priority designations and underscored the high burden of proof that they must meet:

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<sup>10</sup> 82 FR 4829

<sup>11</sup> 82 FR at 7565—66.

“[I]n identifying potential candidates for Low-Priority Substance designation, EPA is proposing that it will seek to identify chemical substances where the information indicates that hazard and exposure potential for “all conditions of use” are so low that EPA can confidently set that chemical substance aside without doing further evaluation. By comparison, then, TSCA’s definition of Low-Priority Substance ( “. . . based on sufficient information, such *substance* does not meet the standard for [. . .] a high-priority substance . . . ” ) is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-Priority Substance standard. Consequently, EPA expects it will be more difficult to support such designations. Unlike High-Priority Substances, EPA will not be able to designate a chemical substance as a Low-Priority Substance without first looking at all of the conditions of use.”<sup>12</sup>

SCHF strongly supports this approach.<sup>13</sup> We also urge EPA to confirm in the preamble of its rule that low priority designations will be subject to current peer review policies, as stated in the OMB Peer Review Bulletin<sup>14</sup> and the EPA Peer Review Handbook, 4th Edition (2015).<sup>15</sup> The determination that a chemical lacks any potential for unreasonable risk may raise significant scientific issues and the consequences of erroneously reaching such a conclusion could be serious for consumers and communities who rely on EPA’s expert judgment. Peer review would provide an essential safeguard against unwarranted “false negatives.”

#### **V. EPA HAS CORRECTLY RECOGNIZED THE VITAL ROLE OF PRE-PRIORITIZATION IN CREATING A PIPELINE OF LISTING CANDIDATES AND ASSURING SUFFICIENT INFORMATION FOR RISK EVALUATION AND RISK MANAGEMENT**

As EPA correctly notes, pre-prioritization is a necessary first step in priority setting and fulfills the statutory directive to “establish a risk-based screening process” to support the selection of chemicals for risk evaluation. The pre-prioritization phase is – in EPA’s words – intended to “narrow the pool of potential candidates and identify a single chemical (or category of chemical substances) to screen against the statutory [listing] criteria.”<sup>16</sup>

While many chemicals will meet the low standard for high-priority designation, the new law will be most effective if EPA –

- 1) Has a sound basis for selecting from chemicals meeting the listing criteria those substances that offer the greatest opportunity for risk reduction, and
- 2) Invests its resources in risk evaluation where it has comprehensive hazard, exposure and use information on which to base sound risk-based judgments.

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<sup>12</sup> 82 FR at 4830.

<sup>13</sup> An additional reason why EPA should assure that it is on sound footing in proposing a low priority listing is that, under section 6(b)(1)(C)(iii), a proposed low priority designation will default to a high-priority designation if, after seeking additional information, EPA concludes that the information in hand is insufficient to justify a low priority listing. This could force EPA into risk evaluations on chemicals which lack a strong risk case for the investment of resources required to carry out such evaluations.

<sup>14</sup> OMB. 2004. Memorandum for Heads of Departments and Agencies, *Final Information Quality Bulletin for Peer Review*. <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>

<sup>15</sup> EPA 2015. Peer Review Handbook 4<sup>th</sup> Edition. <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>

<sup>16</sup> 82 FR at 4826.



These goals require EPA to create a pipeline of candidate chemicals from which it can thoughtfully and carefully choose a sufficient number of high-priority substances to meet the law's minimum requirements. And they also require EPA to create a process by which it can collect available information and compel development of new data on candidate chemicals in order to fill data-gaps that would prevent it from conducting a meaningful risk evaluation.

As EPA observes,<sup>17</sup> because a risk evaluation must be completed in no more than 3.5 years under section 6(b)(4)(G), the Agency's ability to require new studies or even collect and analyze existing information will be severely constrained once the evaluation is initiated. Similarly, section 6(b)(1)(C) requires EPA to complete priority designation in no more than 12 months after initiating the process – again too little time for meaningful data development. Thus, EPA must use the pre-prioritization process to assure sufficient lead time for generating information to both inform priority setting and, if warranted, lay the groundwork to conduct a comprehensive risk evaluation.

EPA's list of candidate chemicals should not be expansive in scope. By the same token, the list should be sufficiently large so that EPA has a reasonable ability to make periodic selections of high-priority substances that not only meet the statutory criteria but warrant the commitment of resources to risk evaluation based on the level of concern and availability of adequate data. Developing this list should not involve a numerical scoring process but should be based on screening criteria that incorporate basic indicia of hazard and exposure. Using the TSCA Workplan methodology as a starting point, section 702.5(c) of the proposal identifies the following screening criteria:

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

*We support these criteria but believe EPA they should be fleshed out by clarifying that they encompass other, more specific indices of toxicity and exposure.* <sup>18</sup> These should include literature reports of potential mutagenicity, developmental toxicity, reproductive effects, developmental neurotoxicity, immunotoxicity, endocrine effects and sensitization. Similar triggers might be used for potential

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<sup>17</sup> 82 FR at 4831.

<sup>18</sup> EPA's preamble asks for comment on whether the availability of substitutes should be taken into account during this phase of the prioritization process. 82 FR at 4831. We believe this would be inappropriate. Substitution considerations are not relevant to any aspect of prioritization; in fact, section 6(b)(1)(B) provides that high- and low-priority designations must be made "without consideration of costs or other non-risk factors." Moreover, moving from prioritization to a risk management rule under section 6(a) will be a lengthy process, 6-8 years in duration, providing ample time for industry to invest in developing and evaluating substitutes. Thus, judgments about substitutability that EPA might make at the time of prioritization will likely be irrelevant when EPA must consider this issue in the context of section 6(a) rulemaking.

ecotoxicity. EPA should also include chemicals listed on one of the many authoritative lists of chemicals of concern (such as the NTP or IARC lists of carcinogens or the Clean Air Act's list of Hazardous Air Pollutants) and chemicals for which environmental releases have been reported for the Toxic Release Inventory (TRI). Classes of chemicals with similar uses and/or structures might also be added based on indicators of toxicity or exposure for a chemical within the class.<sup>19</sup>

*We recommend that EPA clarify in the preamble to the final rule these additional triggers for hazard or exposure will be considered in applying EPA's screening criteria.*<sup>20</sup>

As section 702.5(d) of the proposed rule indicates, chemicals on the candidate list should be more fully characterized through an information collection process focused on developing a hazard, use and exposure profile for each candidate chemical and identifying "potentially exposed or susceptible subpopulations." Some of the information needed for this profile may be submitted by industry voluntarily, but EPA needs to recognize that the track record of industry submission of information has already been disappointing under the LCSA and very little voluntary testing was conducted under the original TSCA. As section 720.5(e) of the proposal acknowledges, EPA should therefore be prepared to use its mandatory information collection authorities under TSCA to fill data-gaps.

Fortunately, the LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to impose testing requirements through orders rather than solely through rulemaking, a cumbersome process. Moreover, under section 4(a)(2), orders or rules can be issued solely to obtain data that EPA deems necessary to "perform a risk evaluation" or "for purposes of prioritizing a chemical substance."<sup>21</sup> These justifications will be present in any case where EPA is screening a chemical for prioritization and needs data both to inform a high-priority listing and to conduct a risk evaluation after listing occurs. Thus, for such chemicals, EPA will have a sound basis to require industry to develop new information on the frequency, levels and duration of exposure for the chemical's conditions of use or to perform toxicological testing for a hazard end-point not adequately characterized by the existing literature.

In addition to requiring development of new information, EPA needs to assure it receives all existing information on hazard, use and exposure within industry's possession or control. One mechanism to

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<sup>19</sup> Section 702.1(c) of the proposed rule recognizes that categories of chemicals can be listed a high-priority under TSCA section 26(c).

<sup>20</sup> While the rule should identify the screening criteria EPA intends to use to determine candidate chemicals, it should not codify the Workplan methodology (or any other screening protocol) by which EPA scores and ranks candidate chemicals. How EPA selects chemicals for high-priority listing from the candidate list should be left to Agency discretion.

<sup>21</sup> While the best time to use these authorities is at the pre-prioritization stage, there may be instances where, after initiating prioritization, EPA determines that there are still gaps in available data that militate against directly proceeding with risk evaluation. EPA's preamble appears to suggest that the only permitted outcomes of the prioritization process are high- and low-priority listings. 82 FR 4831. This is true once EPA has proposed one of these two designations. However, as the first step in the prioritization process, section 6(b)(1)(C)(i) requires EPA to seek information without actually proposing a high or low-priority listing. This step would have little or no purpose if EPA could not rethink whether to propose a listing based on the information submitted.

accomplish this is to add chemicals selected for pre-prioritization to EPA's section 8(d) reporting rule (40 CFR Part 716) requiring reporting of unpublished "health and safety studies." As in the past, this could be done by amending the rule so that selection of a candidate chemical for prioritization automatically triggers section 8(d) obligations, avoiding the need for additional chemical-specific rulemaking.<sup>22</sup> EPA could also issue new section 8(a) reporting requirements to obtain detailed use and exposure information for chemicals undergoing pre-prioritization.<sup>23</sup> Alternatively, EPA could use its subpoena authority under section 11 to obtain records from individual manufacturers, processors and users.

## **VI. EPA MUST IMMEDIATELY IMPLEMENT THE PRE-PRIORITIZATION PROCESS BY CREATING A PIPELINE OF CANDIDATE CHEMICALS AND INITIATING INFORMATION COLLECTION ACTIVITIES ON THEM**

While the EPA proposal outlines the pre-prioritization process in concept, the process must be operationalized and implemented without delay. Section 6(b)(2)(C) requires that risk evaluations must be underway on at least 20 high-priority chemicals (in addition to the first 10 chemicals already selected for risk evaluation under section 6(b)(2)(A)) within 3.5 years of the LCSA date of enactment. Since the formal prioritization process on these chemicals must take 9-12 months, little time remains for initial screening and information collection. *To jumpstart these activities, we strongly recommend that EPA take the following steps:*<sup>24</sup>

- 1) *Create an initial candidate list* – We suggest a list of 60 chemicals and recommend publishing the list at the same time as finalization of the prioritization rule, if not earlier. Several Workplan chemicals should be on the list, since TSCA section 6(b)(2)(B) requires at least 50 percent of initial risk evaluations must be drawn from the Workplan list, giving preference to those chemicals which score high for persistence and bio-accumulation or are known human carcinogens and have high acute and chronic toxicity. Additional non-Workplan chemicals should also be included on the candidate list based on the screening criteria described above.
- 2) *Conduct a literature search on chemicals on the candidate list and call for voluntary submission of hazard, exposure and use information by industry and the public* -- These steps should be concurrent with publication of the candidate list and be completed within 3 months. They will provide an opportunity for all stakeholders to engage in and contribute to the pre-prioritization process. In addition to providing information, stakeholders will be able to comment on data-needs and information gaps. To maximize transparency, EPA should create a docket for each candidate chemical. In the case of

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<sup>22</sup> EPA added such an automatic triggering mechanism to its model rule for chemicals designated for testing consideration by the Interagency Testing Committee (ITC). See 40 CFR 716.105(b). Under this provision, reporting requirements for these chemicals become effective 30 days after the ITC designation.

<sup>23</sup> SCHF believes that the level of use and exposure information necessary for candidate chemicals will be more extensive than the elements of the Chemical Data Reporting (CDR) rule and that EPA should develop a template for section 8(a) reporting on candidate chemicals that is broader and more detailed in scope than CDR requirements. Unlike the CDR rule, such a rule could apply to both manufacturers/importers and processors

<sup>24</sup> We offer these recommendations in response to the statement in EPA's preamble that "it is requesting comment on whether and how EPA should solicit additional input at the pre-prioritization stage." 82 FR at 4832.

Workplan chemicals that have already been screened, EPA may be able to conserve resources by avoiding further literature reviews.

- 3) *Where necessary based on voluntary industry submissions, add candidate list chemicals to reporting rules under section 8(a) and 8(d) to assure that EPA has all existing hazard, use and exposure information within industry's possession or control* – this step should occur within three months of the completion of Step 2 where EPA concludes that voluntarily submitted information is insufficient. As discussed above, concurrent with the final prioritization rule, EPA should lay the groundwork for using section 8 authorities by amending its existing section 8(d) rule to provide an automatic triggering mechanism for candidate list chemicals and proposing a new section 8(a) rule with a similar triggering mechanism.
- 4) *Develop a "road map" (or matrix) describing available information on each candidate chemical and identifying data-gaps.* EPA should develop a template for organizing available hazard, use and exposure data for candidate chemicals. Using the information collected in Steps 2 and 3, EPA would populate the template for each candidate chemical, indicating elements of hazard and exposure that are well characterized based on existing information and elements where data is lacking. This step would be taken 45 days after completion of Step 3.
- 5) *Determine hazard and exposure information necessary for a complete data-set on the candidate chemical and issue section 4(a)(2) orders to require industry to develop the necessary information --* This step should be taken within three months of the completion of Step 4. Industry should have an opportunity to commit to develop the information voluntarily or under consent agreements but, absent this commitment, EPA should use section 4 authorities.
- 6) *Initiate the prioritization process on at least 20 candidate chemicals determined to present a strong case for risk evaluation based on information collected or under development under Steps 3, 4 and 5* – This step will need to occur no later than 30 months after LCSA's date of enactment so that final high-priority designations and the initiation of risk evaluations can occur no later than 3.5 years from the LCSA enactment date. With an ample database on candidate chemicals and the input it receives during the two comment periods required during the prioritization process, EPA should be well positioned to make informed and thoughtful high-priority listings.
- 7) *Repopulate the candidate list as chemicals are designated high-priority and enter risk evaluation* – We recommend that for every chemical designated as high-priority, EPA add 3 chemicals to the candidate list to assure that EPA has a sufficient universe of candidate chemicals to choose among for future high-priority listings and risk evaluations. As chemicals are added to the list, they should undergo Steps 2-4 as described above.

*We urge EPA to formalize these elements of the pre-prioritization process in parallel with publication of its final rule and implement the process on the timeline described above. Failure to move ahead promptly will jeopardize EPA's ability to make timely and sound listing decisions on the next 20 chemicals that must undergo risk evaluations.*

## VII. EPA SHOULD COMMIT THAT, IN IMPLEMENTING THE PRIORITIZATION PROCESS, IT WILL ASSURE THE MAXIMUM DISCLOSURE OF CBI ALLOWABLE UNDER THE LCSA

As EPA emphasizes, there will be multiple opportunities for information submission during the pre-prioritization and prioritization phases. In order to have a sound basis for risk evaluation, the Agency aspires to use these stages of the process to obtain full information on the chemical's conditions of use throughout its life cycle and the resulting levels and pathways of exposure. Much of this information is in the possession of industry; it is to be expected that large portions of industry's submissions will be claimed as Confidential Business Information (CBI) that must be withheld from disclosure.

The proposed rule does not address CBI protection. However, there will be a high level of public interest in all stages of prioritization. Access to the use and exposure information that is considered during this process will be invaluable for informed public participation. *It is therefore critical that EPA commit that the CBI requirements it implements under the final rule will reflect the full safeguards against unwarranted CBI claims and mechanisms for increased disclosure that Congress adopted in the LCSA.*

We recommend that, in the preamble to the final rule, EPA make clear that CBI claims must be substantiated at the time they are asserted (e.g. "upfront"). Such substantiation is required under section 14(c)(3) for all CBI claims except for those specifically exempt under paragraph (c)(2). The obligation to provide upfront substantiation was explicitly reaffirmed by EPA in its Federal Register notice of January 19, 2017 (82 FR 6522).

In addition, EPA's preamble should clearly state that certain information cannot be claimed CBI under TSCA section 14(b)(3). This provision defines "information not protected from disclosure" to include:

*"(A) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . in ranges; or*

*"(B) a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ." (emphasis added).*

Much of the use and exposure information submitted during prioritization will fall within these disclosure requirements because it describes processes used in manufacturing and processing in broad terms or characterize uses and related exposures using commonly accepted descriptors and ranges and percentages rather than specific values. As EPA has concluded in reference to the Chemical Data Reporting (CDR) rule, "general use and process information . . . is not the type of specific information referenced in TSCA § 14(c)(2)" and thus should fall under section 14(b)(3).<sup>25</sup>

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<sup>25</sup> Q&As relating to CBI under amended TSCA posted on EPA Website, response to Q.7., at <https://www.epa.gov/tsca-cbi/general-qs-and-relating-cbi-under-tsca-amended-frank-r-lautenberg-chemical-safety-21st>. Although the Q&A related to whether CDR reports are the type of "specific" processing and use information for which substantiation of CBI claims is not required under section 14(c)(2), EPA's conclusion that this provision does not apply necessarily means the CDR-reported processing and use information is "general" and thus cannot be withheld from disclosure under section 14(b)(3).

Alternatively, TSCA section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she “determines that disclosure is relevant in a proceeding under this Act.” Prioritization under section 6(b)(1) of TSCA represents a “proceeding” (or set of “proceedings”) under LCSEA. And use and exposure information submitted by industry on chemicals under consideration for high- or low-priority listing is clearly “relevant” to this proceeding (or proceedings). EPA should therefore make a determination that section 14(d)(7) applies to the prioritization process and that all or most exposure, use and hazard information pertaining to prioritization is “relevant” and therefore not protected from disclosure.

Finally, for any information related to prioritization to which these grounds for disclosure may not apply, EPA should expeditiously review and determine the adequacy of the submitter’s substantiation of its CBI claims under section 14(g)(1), which requires the Agency to approve or deny CBI claims within 90 days of receipt. While this review deadline applies to 25 percent of CBI claims (except for chemical identity), EPA is not barred from reviewing all claims within 90 days where there is justification to do so; such a justification would clearly exist for information being considered during prioritization. In addition, EPA may be evaluating information covered by CBI claims that have never been substantiated; an example might be information reported to the Agency before the LCSEA’s enactment. EPA should immediately require substantiation of such information under section 14(f)(1)(C), which authorizes this step where EPA concludes that “disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6.” This would obviously be the case for information submitted during prioritization, since it is closely connected to the risk evaluation process.

#### **VIII. EPA SHOULD SPECIFY A DEADLINE OF 45 DAYS FOR DESIGNATING NEW HIGH-PRIORITY CHEMICALS TO REPLACE THOSE FOR WHICH RISK EVALUATIONS ARE COMPLETED**

Under TSCA section 6(b)(3)(C), EPA must designate at least one new high-priority substance upon completing a risk evaluation on an existing high-priority substance or one of the 10 chemicals selected for risk evaluation under section 6(b)(2)(A) without prioritization. This requirement serves the important function of maintaining risk evaluation activity at a constant level over time, thereby preventing the number of substances subject to evaluation from declining. While we are pleased that the proposal preamble addresses repopulation of the high-priority list, we are concerned that there is no provision in the rule itself addressing this process. In addition, we are troubled by the preamble statement that “the timing for the completion of the risk evaluation and/or the prioritization process is difficult to predict” and, accordingly, EPA will simply assure that the new designation occurs “within a reasonable time before or after the completion of the risk evaluation.”<sup>26</sup> While there may be some timing uncertainty, the law in fact prescribes clear deadlines for completing the prioritization process and finalizing risk evaluations. A vague “reasonable time” requirement would create a risk of unnecessary delay in repopulating the priority list and could slow down the timely initiation of risk evaluations. *We strongly recommend that this imprecise requirement be replaced by a clear deadline of 45 days from risk evaluation completion to the designation of a new high-priority substance.*

#### **CONCLUSION**

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<sup>26</sup> 82 FR at 4833.

We appreciate the opportunity to comment on this important step in implementing LCSA and urge EPA to develop a final prioritization rule that provides a strong and effective foundation for priority setting.

Respectfully submitted,

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