

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council and Earthjustice on Working Approach for Identifying Potential Candidates for Prioritization under Amended TSCA

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Safer Chemicals Healthy Families (SCHF), Natural Resources Defense Council and Earthjustice submit these comments on the Environmental Protection Agency (EPA) Working Approach for Identifying Potential Candidate Chemicals for Prioritization (Working Approach) under the Toxic Substances Control Act (TSCA).

Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day. During the legislative process to amend TSCA, we worked hard to maximize public health protections and to assure that EPA has the necessary authority to evaluate and eliminate the risks of unsafe chemicals. We strongly support a proactive approach to implementing the new law that uses the improved tools that Congress gave EPA to deliver significant health and environmental benefits to the American public.

The Working Approach is the latest step in EPA's efforts to develop a framework for designating chemicals as high- and low-priority under section 6(b)(2) of TSCA. EPA convened a public meeting on December 11, 2017 to obtain feedback on its approach to prioritization and then requested written comments. Our organizations participated in the public meeting and amplified our views in our January 25, 2018 comments.¹ We incorporate these comments by reference.

EPA must designate at least 20 high-priority chemicals and 20 low-priority chemicals by the end of 2019 and therefore must begin the formal 9-12 month prioritization process within the next few months. The Working Approach confirms that, in the near term, EPA will rely heavily on the 2014 Work Plan list to identify candidates for high-priority listing. Our groups believe this is the right approach and reflects the strong Congressional focus on Work Plan chemicals in the law.

However, not all Work Plan chemicals warrant prioritization under TSCA, and we have concerns about the factors EPA intends to use to decide which Work Plan chemicals to prioritize. We believe that EPA should not base priority listings on resource and workload considerations but instead should focus principally on the sufficiency of available information for a sound risk evaluation. EPA has also unaccountably failed to mention health and environmental concerns as a factor in selecting Work Plan chemicals for high-priority listing. Consistent with the Administration's principles of cooperative federalism, EPA should also avoid prioritizing chemicals that are being addressed by the states.

While the Working Approach pays lip service to the need for sufficient data before beginning risk evaluations, the reality is that EPA has consistently been unwilling to use its streamlined TSCA

¹ Comments of Safer Chemicals Healthy Families on Possible Approaches for Identifying Potential Candidates for Prioritization under Amended TSCA, January 25, 2018, Docket ID EPA-HQ-OPPT-2017-0586 (Public Meeting Comments).

information collection and development authorities under the new law. If EPA is serious about data-rich risk evaluations, it must establish a credible process for identifying and filling data gaps on Work Plan (and other) chemicals moving forward. The Working Approach, like EPA's earlier prioritization rule, fails to step up to this challenge.

To our disappointment, the Working Approach provides no clarity on how EPA will apply the low-priority listing requirements in the law and what criteria it will use to identify low-priority chemicals. As we have previously shown, TSCA requires EPA to have "information sufficient to establish" that a low-priority candidate lacks the potential for unreasonable risk to health or the environment across its conditions of use. With the fast-approaching deadlines for low-priority listings, the Agency's failure to articulate a legally defensible framework for these decisions is troubling.

The Working Approach also describes a new "binning" process for the 37,000 chemicals on the Active TSCA Inventory that EPA expects to use for prioritization over the long-term in place of the current Work Plan methodology. We believe this binning approach is poorly conceived, unnecessary to implement TSCA and unlikely to produce meaningful, science-based categorizations of chemicals based on potential risk. Based on EPA's own description of binning, it seems like a backdoor mechanism to classify substances as low priority, and exempt them from risk evaluations, without meeting the high bar for low priority designations under the law. The binning process will also be extremely resource-intensive and siphon money and expertise away from programs central to TSCA's mission of protecting public health and the environment.

EPA should reexamine and abandon the binning concept. Rather than screening all chemicals on the Active Inventory, EPA should target chemicals with the greatest potential risk to health and the environment as the initial focus for high-priority listing and risk evaluation. The Work Plan methodology is based on this core concept. We believe an expanded and improved version of the Work Plan process should be sufficient to support prioritization decisions for the foreseeable future and will be far more efficient than the ambitious and costly binning process.

The key points in our comments are as follows:

High-Priority Listing

- The Work Plan list should remain central for the next several rounds of priority setting under TSCA
- EPA must establish a transparent process for identifying and filling data gaps on Work Plan chemicals well in advance of priority listings so that sufficient data are available for risk evaluations
- EPA must commit to using its TSCA authorities to obtain existing information and require testing to fill data gaps on Work Plan chemicals
- The TSCA Systematic Review criteria lack a sound scientific basis and cannot be used to assess the quality of existing information on Work Plan chemicals
- EPA's factors for selecting chemicals for high-priority unaccountably fail to include the level of health and environmental concern of different listing candidates
- Workload and available resources should not be factors that influence prioritization decisions
- Based on principles of cooperative federalism adopted by the Trump Administration, EPA should not list Work Plan chemicals as high-priority if they are being actively addressed by states
- EPA should not categorically exclude inactive substances from high-priority listing

Low-Priority Listing

- EPA must adopt a framework for low-priority listing that includes all the elements of the definition of low-priority substance in TSCA
- While the Safer Chemical Ingredients List (SCIL) is a useful starting point for low-priority listings, the ChAMP and OECD SIDS programs have limited value in identifying listing candidates
- Efforts to develop information to support low-priority listings should occur through a public multi-stakeholder process and utilize TSCA information collection and development authorities
- EPA should exercise caution in designating chemical categories as low-priority

Binning the TSCA Active Inventory

- EPA has failed to explain how the binning process will support the TSCA program or agency priorities generally
- The binning process will not contribute meaningfully to the selection of high-priority chemicals
- The proposed binning approach will be extremely resource-intensive, demanding a major time commitment by EPA scientists and sophisticated automated search tools that do not exist today
- Improving and expanding the Work Plan process is the best way to support TSCA prioritization efforts over the long-term
- The scoring methodology in the proposed binning process lacks a sound scientific foundation and will result in misleading and inaccurate classifications of the risk potential of the binned chemicals

EPA's Near-term Process for High-Priority Listings

1. The Work Plan list should remain central for the next several rounds of priority setting under TSCA

Over the near-term, EPA will rely primarily on the 2014 Work Plan list to identify candidates for high-priority listing. We support this approach. The Work Plan methodology was the result of extensive consultation with stakeholders. The numerous references to the Work Plan list in the law demonstrate that Congress expected it to play an important role in TSCA implementation. Because the Work Plan chemicals have already been screened for exposure and hazard, EPA can limit the resources it devotes to further screening.

Moreover, section 6(b)(2)(B) directs that at least 50 percent of the substances for which risk evaluations are conducted must be drawn from the Work Plan list. This will mean that the list will drive high-priority designations for at least the next 10-15 years until all Work Plan chemicals have been prioritized. To supplement the list, EPA can and should identify non-Work Plan chemicals that raise significant risk issues for potential high-priority listing, but there is no immediate need to replace the Work Plan methodology with a new prioritization framework.

2. EPA must establish a systematic and transparent process for identifying and filling data gaps on Work Plan chemicals in order to make sound prioritization decisions

As EPA recognizes, it must decide which of the 73 remaining Work Plan chemicals it will initially list as high-priority. To that end, the Working Approach identifies factors that the Agency will use for selecting candidates for high-priority listing.

We agree with the Working Approach that a principal factor should be the “sufficiency” of the available hazard and exposure information for conducting a robust risk evaluation. As the Working Approach states, “[i]dentifying information gaps and needs before a chemical enters prioritization is an important component of pre-prioritization and prioritization [and] the Agency has authorities under TSCA sections 4, 8 and 11 to gather information and request data to fill data gaps.” However, as EPA surely realizes, once the prioritization process is underway, there is limited time to develop additional data before the risk evaluation must be initiated; any further testing would necessarily be minimal in scope. Thus, an analysis of data gaps and efforts to fill them must occur *long before* a chemical enters the prioritization process.

EPA could have begun to address data needs for the 73 Work Plan chemicals shortly after the enactment of the new law in 2016 but chose not to do so despite initially proposing in its prioritization rulemaking to establish a pre-prioritization process for information development on listing candidates.² Now, faced with the need to begin selection of 20 high-priority chemicals in early 2019 and finalize these listings by the end of that year, EPA has essentially no ability to require testing or other gap-filling measures on Work Plan chemicals that lack adequate information.

EPA should not make this mistake again. Where it concludes that a Work Plan chemical is not ready for high-priority listing because of data gaps, the process of filling these gaps should begin now so that adequate information is available when the chemical is next considered for high-priority listing in 2022. The Working Approach states that “EPA intends to actively begin gathering information for the 73 remaining [Work Plan] chemicals” but does not establish a schedule or process. *We recommend that EPA publish its data gap analyses for the 73 chemicals in mid-2019, seek stakeholder input on filling these gaps and initiate testing or other information development using its TSCA authorities by the end of 2019.*

While EPA has acknowledged the importance of data sufficiency in the abstract, it has failed to develop specific benchmarks for identifying data gaps for chemicals undergoing risk evaluations. Because of this failure, there is no clear framework for defining the minimum information on hazard and exposure EPA requires before it can meaningfully determine a chemical’s risks to health and the environment. This creates a danger that EPA’s determinations of data sufficiency will be arbitrary and err on the side of ignoring data gaps rather than identifying and filling them. *EPA must create a uniform template for organizing available hazard, use and exposure data for candidate chemicals and identifying elements of hazard and exposure that are well-characterized based on existing information and elements where data is lacking.* EPA’s experience with the initial 10 chemicals subject to risk evaluations under the law should

² EPA removed the pre-prioritization provisions in its January 17, 2017 proposal rule from its final rule despite recognizing that “commenters generally supported the concept and importance of pre-prioritization activities.” 82 Fed. Reg. 33753, 33757 July 20, 2017). The Agency promised that it would undertake “further discussions with interested stakeholders” and then finalize a pre-prioritization process through rule amendments or guidance. However, as the Working Approach reflects, it has still not done so.

inform the design of this template, given that data gaps will likely weaken the completeness and quality of several of these evaluations.

3. EPA must commit to using its TSCA authorities to obtain existing information and require testing to fill data gaps on Work Plan chemicals

To date, EPA has not issued a single test rule or order using its streamlined authority under section 4 of TSCA even though section 4(a)(2)(B) of the amended law explicitly allows EPA to “require the development of new information for the purpose of prioritizing a chemical substance under section 6(b).” If EPA is unwilling to use the new tools that Congress provided to increase the amount of testing under TSCA, its professed goal of filling data gaps on the 73 Work Plan chemicals will be irrelevant. EPA must demonstrate a credible commitment to requiring industry to develop information necessary for risk evaluations under section 4 or its determinations of risk under section 6 will continue to be hampered by inadequate data.

The first step in identifying data gaps is a clear process for obtaining all available hazard and exposure data. The Working Approach identifies (pages 11-13) a number of data sources that EPA intends to search. However, these sources consist of the general scientific literature plus a variety of governmental databases. Lacking is any specific process to obtain information from industry beyond encouraging voluntary submissions to the dockets for the 73 chemicals. Our groups have previously recommended adding the Work Plan chemicals to EPA’s TSCA section 8(d) rule (40 CFR Part 716), which would then require submission of all health and safety studies, including exposure as well as hazard data. We continue to believe this is an essential first step in any systematic effort to identify and fill data gaps for the 73 chemicals.

4. The TSCA Systematic Review Criteria lack a sound scientific basis and cannot be used to assess the quality of existing information on Work Plan chemicals

While considerations of data quality should play a role in determining whether available information on a chemical is sufficient to conduct a risk evaluation, we strongly disagree with EPA’s intent (page 13) to base “exclusion of unacceptable data sources . . . on data quality criteria outlined in the *Application for Systematic Review in TSCA Risk Evaluations* EPA document.” As our groups have previously demonstrated, these criteria are out of step with other systematic review approaches used within EPA and across the government and were adopted by the TSCA program without peer review. EPA should either replace them with an established systematic review methodology that reflects mainstream scientific thinking or put them on hold pending careful, independent scrutiny by systematic review experts.

5. EPA’s factors for selecting chemicals for high-priority listing unaccountably fail to include the level of health and environmental concern of different listing candidates

Missing from EPA’s factors for selecting chemicals for high-priority listing is any consideration of the level of health and environmental concern associated with different listing candidates. This omission is unjustified in light of Congress’ emphasis on risk-based decision-making and prioritizing potential threats to health and the environment based on their health and environmental significance.

6. Workload and resources should not be factors that influence prioritization decisions

At the same time, we disagree with EPA that work load and available resources should influence the choice of substances for high-priority listing and risk evaluation, and in any event, the law does not allow it. The criteria for high-priority designation in section 6(b)(1)(B) of the law do not include work load and resource considerations. Moreover, the law's minimum number of high-priority listings and time-frame for conducting risk evaluations were based on a careful analysis of EPA resources and the Agency's judgment that it could handle the resulting workload within the statutory deadlines. Section 26(b) of TSCA further augments EPA's resources by directing it to collect fees from manufacturers to cover the costs of risk evaluations. EPA recently promulgated an implementing rule under this provision that sets fee payments at a level commensurate with estimated risk evaluation costs. For all these reasons, there is no need or justification to select chemicals for high-priority listing on the basis of cost and resource savings, an approach that could screen out chemicals that are strong candidates for listing because of potential risks to health and the environment.

7. Based on principles of cooperative federalism adopted by the Trump Administration, EPA should not list Work Plan chemicals as high-priority if they are being actively addressed by states

The Working Approach identifies (page 7) EPA and other Executive Branch priorities as a factor in selecting Work Plan chemicals for high-priority listing. It does not, however, address the role of state priorities in listing decisions.

Many states have active chemical management programs and either have restricted Work Plan chemicals or are in the process of evaluating their risks and considering measures to address them. There will be less need for TSCA risk evaluations and rulemakings when state efforts to protect against health or environment risks are ongoing. Instead of duplicating state risk reduction initiatives, EPA can most effectively leverage its resources by focusing on chemicals that are not receiving attention at the state level.

EPA leadership in the Trump Administration has embraced principles of "cooperative federalism," a concept that entails greater deference to the state role in environmental protection and a stronger recognition of the need for federal and state agencies to work in harmony. As stated on EPA's Website:

EPA is embracing cooperative federalism and working collaboratively with states, local government, and tribes to implement laws that protect human health and the environment ... EPA is more efficient and more effective in its protection of human health and the environment when it works together with states and tribes and engages local communities from a foundation of trust, transparency, and collaboration.³

Because risk evaluations on high-priority chemicals would trigger "pause" preemption of state programs under section 18(b) of the law, states working on chemicals under laws that restrict manufacturing, processing, and distribution in commerce of a chemical could be blocked from pursuing further regulation if a chemical is listed as high-priority under section 6(b). This would undermine the federal-state partnership that the Trump EPA has sought to foster and frustrate state-based solutions to

³ <https://www.epa.gov/home/cooperative-federalism-epa>

environmental challenges that cooperative federalism seeks to encourage. EPA should therefore refrain from listing as high-priority Work Plan or other chemicals that are being addressed by states.

8. EPA should not categorically exclude inactive substances from high-priority listing

The Working Approach indicates (page 7) that, in identifying listing candidates that are not on the Work Plan list, EPA only plans to consider chemicals on the TSCA Active Inventory. This limitation is unnecessary and could well exclude substances that should be addressed during the TSCA risk evaluation process. While the new law required reporting of active substances under section 8(b) and directed EPA to list these substances in a special section of the Inventory, it consciously chose to include inactive substances in the law's prioritization and risk evaluation provisions under section 6(b). The legislative history demonstrates that Congress recognized that substances that had not been manufactured or processed for the previous 10 years might nonetheless have ongoing uses and remain in the environment and thus could be a source of present and future human exposure and environmental release. EPA's approach would unjustifiably preclude the resulting risks from being evaluated under section 6(b) and reduced, if necessary, through rulemaking under section 6(a).

EPA's Framework for Low-Priority Chemical Selection

The law requires EPA to designate at least 20 low-priority chemicals by December of 2019. Accordingly, EPA must initiate the prioritization process in early 2019 at the latest, leaving only a few months to identify the 20+ candidate chemicals to be proposed for low-priority listing.

Given these impending deadlines, it is troubling that the Working Approach contains few details on the criteria and process EPA will use for low-priority listings. These subjects were addressed at length at EPA's December 11, 2017 public meeting on prioritization approaches and in follow-up comments, but the Working Approach fails to resolve the many issues raised.

1. EPA must explain how it will apply the statutory definition of low-priority substance

Of greatest concern is the lack of clarity on how EPA will apply the definition of "low-priority substances" in section 6(b)(1)(B)(ii) of the law. This provision 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."

As we noted in January 25, 2018 comments following the December 2017 public meeting, the prerequisite for high-priority listing under section 6(b)(1)(B)(i) is a determination that a chemical "may present an unreasonable risk" because of "a potential hazard and a potential route of exposure." Thus, a chemical will qualify as low priority only if it can be demonstrated to *lack the potential for unreasonable risk – i.e. because it lacks potential hazards or a potential route of exposure*. As with high-priority listings, this demonstration must reflect the circumstances of "potentially exposed or susceptible populations" as well as the general population. Moreover, the absence of potential hazard or a route of exposure cannot be assumed where hazard and exposure data are unavailable. EPA must instead have "information sufficient to establish" that the chemical lacks these characteristics. This will require the

Agency to create a record adequate to assess the hazard and exposure potential of the chemical for all relevant exposure 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 “conditions of use” as defined in TSCA section 3(4) is essential because low-priority listings will remove a chemical from the TSCA risk evaluation and management program and convey the message to users of the chemical and the general public that EPA considers the chemical “safe” for all purposes.⁴

The Working Approach acknowledges (page 16) that “TSCA requires high-priority substance designation to be based on sufficient information [and] EPA will ensure designations are based on an adequate quantity and quality of information.” EPA also says that it “intended to select candidate low priority substances with robust data-sets for hazard and exposure, with respect to the range of the substances’ conditions of use.”

These statements are helpful, but they leave many questions unanswered and highlight the need for greater clarity on the analysis EPA will conduct to demonstrate that a substance meets the low-priority definition. For example, EPA should clearly define what constitutes “sufficient information” for a low priority designation. This definition should include a list of end-points and other relevant chemical characteristics, such as physical/chemical properties, human health and environmental hazards, magnitude and routes of exposure, conditions of use and effects on potentially exposed or susceptible subpopulations, together with a description of the information necessary for each characteristic to support a determination of no unreasonable risk. In identifying such information, EPA should draw on the hazard assessment methodologies of other agencies such as the National Toxicology Program (NTP)⁵ and the International Agency for Research on Cancer (IARC)⁶ and EPA’s own risk assessment guidelines, including those for carcinogenicity⁷ and other end-points.

2. EPA should not select low-priority listing candidates from data sources that are of limited value in meeting the statutory definition of low-priority substance

The Working Approach (page 15) identifies EPA’s Safer Chemical Ingredients List (SCIL) as a useful source of low-priority listing candidates, based on its “low concern SAFER CHOICE criteria for both human health and ecological toxicity end-points” and its recognition that SCIL chemicals are “relatively rich” in information on hazards and conditions of use. As noted in our January 25, 2018 comments, our groups agree that chemicals receiving the SCIL Green Circle label represent a reasonable starting point for

⁴ Once a chemical is listed as low-priority following an evaluation of its conditions of use, EPA should be notified of new uses that are introduced since they may not fall within the justification for the listing and could be a basis for rescinding the listing and, under some circumstances, further evaluation of the chemical’s uses. A SNUR might be one way to track new uses of low-priority chemicals.

⁵ National Toxicology Program, Office of Health Assessment and Translation. 2015. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. Available from: https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf

⁶ IARC (International Agency for Research on Cancer). 2006. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble. Available: <http://monographs.iarc.fr/ENG/Preamble/index.php>

⁷ U.S. Environmental Protection Agency, 2005. Guidelines for Carcinogen Risk Assessment. Available from: https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

identifying low-priority chemicals, although additional evaluation of the uses, hazards and exposure profiles of these chemicals will be required to determine whether they in fact qualify for low-priority listing under the law.

However, we are more skeptical of the value of relying on evaluations performed for EPA's Chemical Assessment Management Program (ChAMP) and Organization for Economic and Cooperative Development (OECD) Screening Information Data Sets (SIDS) assessment documents. These sources do not closely track the TSCA definition of low-priority substance and in many cases provide limited data on hazard, exposure and risk. Because they cover hundreds of chemicals, considerable effort will be necessary to home in on a subset of low concern chemicals and, once identified, these chemicals will require considerably more analysis to determine whether they are appropriate candidates for low-priority listing. For the time being, the use of the SCIL as a starting point, with further review of available information on individual chemicals, should generally be sufficient to meet the minimum low priority listing requirements in the law.

3. Efforts to develop information to support low-priority listings should occur through a public multi-stakeholder process and utilize TSCA information collection and development authorities

The Working Approach (page 16) indicates that industry stakeholders "may wish to volunteer to sponsor the development of information that could be used by EPA to identify candidates that may be designated as low-priority chemicals" and that Agency may encourage "an enhanced stakeholder role in designation of additional substances."

Proactive efforts by industry to fill data gaps can be valuable and could provide information useful in applying the statutory criteria for low-priority substances (or in laying the groundwork for evaluating the risks of high-priority substances). However, it is critical to avoid hidden understandings between EPA and industry about the data that EPA would deem sufficient to designate a chemical low-priority. Thus, all stakeholders should have the ability to participate in the identification of data needs to support designation and the studies that should be conducted to meet these needs. Moreover, TSCA section 4 tools – either test rules, testing orders or testing consent agreements -- should be the vehicle for information development to assure accountability and data quality and provide the public with a seat at the table.

4. EPA should exercise caution in designating chemical categories as low-priority

The Working Approach (page 16) raises the possibility that EPA may designate entire categories of chemicals as low-priority. In order to do so, EPA would need to have "information sufficient to establish" that all chemicals within the category lack the potential for unreasonable risk under their conditions of use. Because of the potential for judicial review of low-priority listings, which the statute makes available, EPA may choose to forego listing categories as low-priority and avoid the large commitment of resources that such listings will require.

EPA's Long-term Approach to Prioritization: Binning the TSCA Inventory

Looking beyond near-term prioritization needs, the Working Approach outlines (pages 16-29) an ambitious "longer-term, risk-based approach for parsing the chemicals on the TSCA Active Inventory

that are not currently on the TSCA Work Plan into bins” using a scoring system based on indicators of relative hazard, exposure and data sufficiency. We believe this approach is poorly conceived, unnecessary to implement TSCA and unlikely to produce meaningful, science-based categorizations of chemicals based on potential risk. EPA should thus reexamine and abandon the binning concept.

1. EPA has failed to explain how the binning process will support the TSCA program or agency priorities generally

EPA indicates (page 16) that the binning approach “can be used to inform multiple activities and priorities throughout EPA” but it does not identify what they are. There is no explanation, for example, of how the air, waste and water programs might use the binning scores to carry out their regulatory responsibilities – i.e. how these scores might guide implementation of the air toxics program or the management of hazardous and solid waste. Likewise, EPA does not identify the benefits of binning – which is not required by the law – to meet its obligations under TSCA. In fact, EPA concedes (page 17) that “its purpose is not to identify a list of high-priority candidates [or] to signal that EPA has concerns with particular categories of chemicals” and acknowledges (page 25) that “neither a chemical’s score nor the bin in which it is placed would determine whether a chemical is a good candidate for prioritization or whether it will be selected for prioritization.”

The only purpose for the binning system provided in the Working Approach (page 17) is to “identify a portion of the Active Inventory that can be set aside as not containing candidates for high-priority designation.” But a clear goal of TSCA is to conduct risk evaluations on all chemical substances except low-priority substances, “for which risk evaluations are not warranted.” The criteria for identifying these substances are specified in section 6(b)(1)(B)(ii) and, as discussed above, they set a high bar that requires information sufficient to demonstrate an absence of unreasonable risk under the chemical’s conditions of use. The scores EPA proposes to assign to chemicals during binning will be highly preliminary and imprecise given major data limitations and uncertainties and the potential for false negatives. EPA itself cautions that “the score is intended to . . . allow EPA to loosely group chemicals into pools of potential candidates for further evaluation.”

2. The binning process will not contribute meaningfully to the selection of high-priority chemicals

Given these severe constraints, the binning system will simply not provide a sound basis to “set aside” chemicals that do not warrant high-priority listing. To the extent that it purports to perform this purpose as EPA claims, it will circumvent the exclusive mechanism Congress provided to designate low-priority chemicals. EPA has no authority to make *de facto* low-priority designations in the guise of setting aside candidates for high-priority listing, whether it does so through rules, guidance or a prioritization scoring system.

EPA also asserts (page 17) that, by screening out large numbers of chemicals from consideration for high-priority listing, the Agency “can focus on chemicals that are most likely to meet the statutory standard of high-priority chemicals.” However, the bar for high-priority listing is very low under the law, requiring only a finding that “the chemical 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.” A large number of chemicals (including many that EPA seeks to “set aside” under the binning process) will easily satisfy the standard.

More importantly, it is unnecessary to screen and score the 37,000 chemicals on the Active Inventory in order to identify a smaller universe of chemicals that are strong candidates for priority listing and risk evaluation. As the Work Plan methodology demonstrates, EPA can define this universe by identifying a finite group of chemicals with indicia of hazard and exposure and then winnowing this list further to select a subset of chemicals that score highest in these categories. These chemicals would then become the pool from which EPA selects high-priority substances. Although not a formal “ranking” system, this approach enables risk-based comparisons between chemicals and thus contributes to the “primary objective of the [prioritization] process ... to guide the Agency towards identifying the High-Priority Substances that have the greatest hazard and exposure potential first.”⁸

3. Improving and expanding the Work Plan process is the best way to support TSCA prioritization efforts over the long-term

In our January 25, 2018 comments,⁹ we urged EPA to refine the Work Plan methodology and expand its criteria for selecting chemicals for scoring so that it could support high-priority listing decisions well into the future, after the current Work Plan list has been prioritized. Our principal recommendations were as follows:

- EPA should revise the Step I criteria, which provide the entry-point into the Work Plan scoring process, to capture a larger universe of chemicals. This can be accomplished by adding to the list of toxicity and exposure triggers used to select chemicals during Step 1. For example, EPA could select chemicals on the basis of additional hazard end-points, such as chronic toxicity, acute toxicity, neurotoxicity, immunotoxicity, and endocrine effects. It could also add triggers based on reported eco-toxicity values. On the exposure side, additional triggers might include production volume, use across multiple industrial and commercial sectors and storage near drinking water sources (all of which correspond to the criteria in section 6 (b)(1)(A)). Other exposure indicators could include the number of exposed workers and presence in drinking water, surface water or groundwater.¹⁰ Step 1 could also automatically include chemicals subject to Toxic Release Inventory (TRI) reporting, listed as Hazardous Air Pollutants (HAPs) under the Clean Air Act, designated as RCRA hazardous wastes, classified as hazardous substances under CERCLA, included in the ATSDR Neurotoxicants List, or contained in the NTP OHAT reproductive and developmental toxicants list. It should also include chemicals for which the United States has accepted international obligations or significant global or regional action has been taken or is expected to be taken.
- After winnowing the Step 1 list of 1235 chemicals to a universe of 345 substances, EPA set aside several additional substances because they could not be scored in Step 2 for exposure or hazard as a result of insufficient data. These substances were identified separately as “Potential Candidates for Information Gathering” so that they would not be removed from further consideration given other indicators of concern under the Step 1 criteria. Systematically

⁸ 82 Fed. Reg. at 33754 (preamble to final prioritization rule).

⁹ Public Meeting Comments, at pages 5-9.

¹⁰ EPA should also expand the data sources used to identify human exposures. Such sources might include California Prop. 65, National Human Adipose Tissue Survey (NHATS), National Human Exposure Assessment Survey (NHEXAS), Total Exposure Assessment Methodology (TEAM), the NIH Hazardous Substances Data Bank, and the Danish Consumer Product Studies.

developing information sufficient for hazard and exposure scoring would allow this group of chemicals to be evaluated in Step 2 of the Work Plan process, increasing the pool of potential prioritization candidates. This information collection should be accomplished through the testing and reporting authorities in sections 4 and 8 of TSCA.

- The final Work Plan list released in 2014 consisted of chemicals in the Step 2 universe that could be scored based on available data **and** were ranked “high” in two of three categories (hazard, exposure and PBT properties). To add additional substances, the remaining Step 2 chemicals could be re-scored using up-to-date data sources. With the benefit of additional information, the revised scores would be more current and robust. Chemicals that previously did not qualify for the Work Plan list might now have higher rankings based on new information and might therefore meet EPA’s criteria for inclusion in the list.
- The current Work Plan scoring approach of ranking chemicals as “high”, “medium” and “low” for three different attributes could be replaced by one which assigns ratings in each area (plus other areas added to the Step 2 methodology) and then sums these ratings to determine a composite overall rating for the chemical. This approach will more accurately reflect gradations among chemicals by looking at the totality of relevant risk factors. It would accordingly avoid an artificial distinction between the highest-ranking chemicals (i.e. those selected for the Work Plan list) and other chemicals with lower rankings but indicators of significant toxicity and/or exposure that warrant further screening for possible prioritization.

These adjustments to the Work Plan methodology can be accomplished efficiently and would then provide the Agency with a screening process for high-priority chemicals that would meet the long-term needs of the TSCA program. By contrast, the proposed binning approach will be extremely resource-intensive, demanding a major time commitment by EPA scientists and sophisticated automated search tools that do not exist today. There is no justification for such a long-term commitment of time, money and expertise when a superior, cost-effective alternative is available. As EPA well knows and often points out, the resources available to meet the many requirements of the new law are constrained, and it is indefensible to divert these resources from programs for the protection of health and the environment to a costly and questionable binning exercise that is unnecessary to meet the law’s objectives and appears to be intended to circumvent the law’s definitions of high- and low-priority and legal requirements for prioritization.

4. The elements of the proposed scoring process lack a sound scientific foundation and will result in misleading and inaccurate classifications of the risk potential of the binned chemicals

The seven bins proposed by EPA would categorize Active Inventory chemicals on the basis of potential risk and information availability. Chemicals with the greatest potential risk would be assigned to Bins 1-3; those with lower risks would be placed in Bins 4-7. While EPA acknowledges that a chemical’s bin classification is not “determinative,” the reality is that it will be seen by stakeholders and the public as an EPA “judgment” about the chemical’s safety and public health and environmental footprint. There is a significant likelihood, however, that the scores that drive bin classification will be highly imprecise and will not reliably capture chemical characteristics indicative of potential risk. For example:

- The use of a hazard-to-exposure ratio score assumes that reported adverse effects of a chemical have thresholds, but this will likely not be the case for carcinogens and, increasingly, non-cancer effects like endocrine disruption and developmental toxicity, where the science is pointing toward the absence of a threshold for particular chemicals and end-points. As the National Academy of Sciences (NAS) has concluded, on a population-wide basis we should assume there is *not* a threshold for carcinogens or non-carcinogens absent compelling evidence for a specific chemical.¹¹ To design a risk-based scoring system around a default assumption of a threshold for all chemicals is thus in conflict with TSCA's requirement to use the best available science in implementing the law.
- In any case, for most of the chemicals on the Active Inventory, available exposure data will be sparse or non-existent and any hazard-to-exposure ratio score will be largely an exercise in guesswork. Although EPA intends to model exposure potential based on properties such as volatility, these provide at best rough approximations of real-world exposure and are no substitute for information on actual use conditions and exposure levels.
- The genotoxicity component of the scoring system assumes a genotoxic mechanism of carcinogenicity but there are many known carcinogens that lack genotoxic activity. Chemicals that are potential carcinogens but operate by an epigenetic mechanism would thus be overlooked under EPA's approach. Moreover, a full tiered battery of mutagenicity assays is generally considered necessary to reliably assess mutagenic potential, but it is very doubtful that this level of data will be available for the great majority of substances on the Active Inventory. Flagging these chemicals for further research would not in itself overcome the imprecision of a genotoxicity score based on one or two *in vitro* assays.
- The heavy reliance on New Approach Methods (NAMs) in the proposed scoring system in the absence of data from recognized test systems is problematic. We do not believe that NAMs are sufficiently advanced and scientifically reliable to provide a stand-alone tool for scoring chemicals as potentially low-risk. However, we do agree that, used properly, NAMs can be combined with other information to provide further insight into toxicity, exposure or PBT potential and in this manner provide a more robust basis for scoring candidate chemicals. Thus, we would favor including NAM-derived predictions in the Work Plan scoring process as strengthening evidence of hazard or exposure potential.
- Scores for exposure by potentially susceptible subpopulations – a group requiring special consideration during TSCA priority-setting and risk evaluation – would be based solely on exposure by children. No score would be assigned to reflect exposure by other vulnerable groups, such as pregnant women, workers or the elderly. This falls far short of what is necessary to meet one of the central mandates of the revised law: to ensure protection of these susceptible populations.

These limitations, coupled with the likely absence of sufficient data for nearly all of the 37,000 chemicals to be scored, will make the scores used for binning of limited predictive value in judgments about potential risk and thus greatly reduce their utility for prioritization and other risk-based decisions under

¹¹ Science and Decisions: Advancing Risk Assessment (National Research Council, 2009)

TSCA. While the scoring system may be designed to capture information availability, EPA admits that these scores will be based on a simplistic and automated screening process that will be at best a crude guide to data needs. Moreover, given EPA's abject failure to date to use its TSCA authorities to fill data-gaps on Work Plan chemicals and other high-priority candidates for testing, it is unrealistic to expect any systematic or sustained effort to develop data on the thousands of Active Inventory chemicals that lack adequate information.

We appreciate the opportunity to comment on the Working Approach.

Please contact SCHF counsel Bob Sussman at bobsussman1@comcast.net with any questions.

Respectfully submitted,

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