UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Possible Approaches for Identifying Potential Candidates for Prioritization under Amended TSCA

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Safer Chemicals Healthy Families (SCHF), Center for Environmental Health, Environmental Health Strategy Center and Natural Resources Defense Council submit these comments on possible approaches for identifying potential candidates for prioritization under the recently amended Toxic Substances Control Act (TSCA). The comments provide our views on the options presented by the Environmental Protection Agency (EPA) staff at the December 11, 2017 public meeting, building on our statement at the meeting and previous comments during EPA's prioritization rulemaking.

The signatory organizations are national and grassroots groups 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. They took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

Our comments make three critical points:

- **PRE-PRIORITIZATION –** We are disappointed that EPA did not use the December 11 public meeting to identify and request feedback on concrete steps to establish a pre-prioritization screening and information-collection process for candidate chemicals, as it promised in its final prioritization rule. We continue to believe strongly that candidates for prioritization must be carefully screened to assure that EPA has the necessary information for successful risk evaluations; that this screening process needs to begin well in advance of formal prioritization; and that proactive information collection and development using the enhanced tools provided in amended TSCA are critical in "readying" candidate chemicals for high-priority listing and then risk evaluation. We are again submitting our proposal for a step-by-step process to achieve these objectives.

- **RETAINING AND ENHANCING THE WORK PLAN METHODOLOGY --** After reviewing other options presented at the December 11 meeting, we strongly believe that the Work Plan Methodology developed in 2014 should remain the cornerstone of the EPA process to identify potential candidates for high-priority listing. The Work Plan approach was developed after robust public input and was endorsed by Congress in amended TSCA. It provides a sound mechanism for bringing to the fore those chemicals that score highest for hazard and exposure and therefore should be the initial focus of risk evaluations under the new law. At the same time, we believe that the Work Plan process should be improved to better serve the needs of the TSCA program going forward. These improvements should include additional triggers for identifying Step I chemicals so that a larger universe of chemicals can be scored and incorporation of additional data sources to enhance the Step 2 scoring process. Some of the concepts presented by EPA at the December 11 meeting may be helpful in designing these improvements.

- **IDENTIFYING CANDIDATE CHEMICALS THAT MEET THE LAW'S RIGOROUS CRITERIA FOR LOW-PRIORITY LISTING –** Under the law, EPA must be able to demonstrate that low priority chemicals lack potential hazard or potential exposure under all their conditions of use. Only chemicals that meet these rigorous criteria should be screened for low-priority listing. We believe that chemicals receiving the Green Circle label in EPA's Safer Chemicals Ingredient List (SCIL) represent a reasonable starting point for such screening 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.

  More broadly, we are troubled by EPA's desire to list more chemicals as low-priority than the 20 required in the law. Congress was clear that high-priority listings should receive the great bulk of EPA's attention and low-priority listings should be a secondary focus. We strongly oppose elevating the role of low-priority listings in the TSCA program and giving them equal standing to the far more important task of identifying and evaluating the risks of chemicals of concern.

I. EPA MUST FOLLOW-THROUGH ON ITS COMMITMENT TO DEVELOP A PRE-PRIORITIZATION SCREENING AND INFORMATION-COLLECTION PROCESS FOR CANDIDATE CHEMICALS

Although EPA staff at the Agency's December 11 public meeting spoke at length about different conceptual approaches to prioritization, there was no discussion of concrete steps EPA could take to establish and implement a pre-prioritization screening and information-collection process for candidate chemicals. This omission is troubling and disappointing.

The pre-prioritization provisions in EPA's January 17, 2017 proposed prioritization rule were a constructive step forward that our organizations welcomed. When EPA removed these provisions from its final rule, it recognized that "commenters generally supported the concept and importance of pre-prioritization activities" but explained that "the details of implementing pre-prioritization activities were the subject of widely differing, and often irreconcilable views by commenters."[1] EPA promised that it would undertake "further discussions with interested stakeholders" and then finalize a pre-prioritization process through rule amendments or guidance.[2]

We hoped that the December 11 public meeting would provide for the stakeholder discussions EPA promised. Unfortunately, however, EPA offered no new thinking on how to design a pre-prioritization process and identified no options to which stakeholders could respond. EPA is required by the law to list 20 high-priority substances and 20 low-priority substances by the end of 2019 and, as the Agency has recognized, must begin the formal prioritization process in section 6(b)(1)(C) of TSCA later in 2018 in order to meet this deadline. The Agency's lack of progress in creating a procedure for identifying and evaluating candidates for listing will inevitably weaken the quality of the listing decisions to be made in 2019 and leave EPA unprepared to conduct risk evaluations on those chemicals that it lists as high-priority.

[1] 82 Fed. Reg. 33753, 33757 July 20, 2017)
[2] Id.

The goals of pre-prioritization are succinctly stated in the Discussion Document released by EPA before the December 11 public meeting:

> Prior to designating a chemical as a high-priority for risk evaluation, it is important for EPA to ensure the reasonably available information is sufficient to conduct a scientifically robust risk evaluation. In many cases, EPA believes it would be difficult to require the development of necessary chemical substance information, evaluate that information, and incorporate that information into analyses and decisions within the statutory timeframes associated with the prioritization and risk evaluation processes. Therefore, it will be useful for EPA to identify information needs and determine whether any of these needs should be addressed before initiating the prioritization process.[3]
>
> EPA should factor in the need for analyses of candidate's readiness for both prioritization and risk evaluation in order to ensure responsible implementation of TSCA. EPA should identify data needs and actively address those needs before initiating prioritization. This could include voluntary collection of information, sharing information from state and federal partners, and/or utilizing the authorities provided in TSCA sections 4, 8, and 11(c). Once EPA has initiated the prioritization process for a chemical, EPA must issue a final designation as either a high- or low-priority within 12 months. Chemicals designated as high-priority move immediately into risk evaluation with an associated 3 year statutory deadline for completion. In many cases, it could be difficult to require the development of necessary chemical substance information, and to evaluate, and incorporate that information into analyses and decisions within the statutory timeframes of both the prioritization and risk Evaluation processes. Likewise, the scientific underpinnings of a risk evaluation must be strong enough to inform potential future risk management activities.[4]

We strongly agree with EPA that candidates for prioritization must be carefully screened to assure that EPA has the necessary information for successful risk evaluations; that this screening process needs to begin well in advance of formal prioritization; and that proactive information collection and development using the enhanced tools provided in amended TSCA are critical in "readying" candidate chemicals for high-priority listing and then risk evaluation. Having reaffirmed these essential points, however, the Discussion Document then focuses only on possible methodologies for identifying chemicals to be considered for prioritization – ignoring the concrete steps required to screen these chemicals effectively and select the smaller group of substances that will advance to the priority listing and risk evaluation stages.

In our March 17, 2017 comments on EPA's proposed prioritization rule, we outlined the following process to perform these objectives:

1) *Create an initial candidate list* – We suggest a list of 60 chemicals to be culled from the larger universe of chemicals EPA identifies using the Work Plan (or another appropriate) screening methodology. The candidate chemicals would be those scoring highest for exposure and hazard during this screening process, reflecting the goal in EPA's prioritization rule "to select those

[3] DISCUSSION DOCUMENT: Possible Approaches and Tools for identifying Possible Candidate Chemicals for Prioritization at 7.
[4] Id at 11.

chemical substances with the greatest hazard and exposure potential first."[5] Since EPA must designate at least 20 high-priority chemicals every 3.5 years, a candidate list of 60 substances will provide a large enough universe from which EPA can make meaningful selections for prioritization but would not be so large as to over-burden the Agency's information-gathering and analytical capabilities.[6]

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* -- To maximize transparency, EPA should create a docket for each candidate chemical in which relevant studies and other information are collected.

3) *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* -- 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 "roadmap" (or matrix) showing hazard, use and exposure scenarios where data are available and scenarios where data are lacking* -- EPA should develop a standard format for organizing available hazard, use and exposure data for candidate chemicals. Using the information collected in Steps 2 and 3, EPA would populate this matrix for each candidate chemical, indicating elements of hazard and exposure that are well-characterized based on existing information and elements where data is lacking.

5) *Determine data-gaps that need to be filled and issue section 4(a)(2) orders to require industry to develop the necessary information* -- EPA should tailor these requirements to the hazard and exposure profile of the specific chemical and its anticipated data needs for performing a robust risk evaluation.

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 2-5* – With a sufficient data-base on candidate chemicals, EPA should be well-positioned to make

[5] 40 CFR §702.5.

[6] Guiding Principle 8 in EPA's Discussion Document calls for EPA to "balance transparency and stakeholder concerns over the development of lists of candidate chemicals" As EPA elaborates: "The stakeholder feedback received on the proposed prioritization rule indicated concern for stigmatizing large numbers of chemicals, if for example, EPA created and published potential candidate 'lists' without actually putting them into the prioritization/risk evaluation process for some length of time." Id. We disagree strongly that EPA should limit its pre-prioritization activities in order to accommodate industry concerns about "stigmatizing" chemicals and recommend that this Guiding Principle be deleted. The Agency's sole focus in pre-prioritization should be assuring that it has a sound basis for deciding which chemicals should advance to formal prioritization. A candidate list of 60 chemicals, as proposed in the text, would achieve this goal. We hope EPA recognizes that it is impossible to do meaningful evaluation and information collection in advance of prioritization without a candidate list of chemicals on which these activities are conducted. As for the concern about "stigmatization," it should be clear that the candidate list is simply a preliminary step in advance of formal high-priority listing and should not imply any judgment by the Agency about the risks of the listed chemicals. To the extent there is any confusion on this score, EPA is well-equipped to explain the purposes of the candidate list in a way that discourages premature conclusions about chemical risks.

informed and thoughtful high-priority listings and then to conduct comprehensive risk evaluations.

7) *Repopulate the candidate list as chemicals are designated high-priority and enter risk evaluation or are dropped from the list* -- Every chemical designated as high-priority would be replaced by a new candidate chemical which would then be screened using the process described below. Chemicals would also be dropped from the list if, based on screening, they are determined not to be suitable for prioritization at the current time.

We urge EPA to formalize these elements of the pre-prioritization process. It is probably too late to put the entire process in place for use in screening candidate chemicals for the 20 high-priority listings required in late 2019 but EPA should informally complete as many of the steps in the process as possible. This should include identifying data gaps on candidate chemicals and requiring information development to fill these gaps with the goal of informing risk evaluations on the candidate chemicals ultimately designated as high-priority.[7]

II. EPA SHOULD CONTINUE TO RELY ON THE WORK PLAN PROCESS TO IDENTIFY CANDIDATE CHEMICALS FOR PRIORITIZATION BUT SHOULD UPDATE AND IMPROVE THE WORK PLAN METHODOLOGY SO IT BETTER SUPPORTS FUTURE PRIORITIZATION NEEDS UNDER TSCA

The bulk of the Discussion Document and the EPA presentations at the December 11 public meeting are focused not on the screening of candidate chemicals to inform prioritization decisions but on the step that occurs before such screening – identifying a larger universe of chemicals from which candidate chemicals for prioritization can be selected for more intensive review. This is an important part of the overall priority-setting process but probably of less immediate relevance than screening candidate chemicals for listing decisions in 2019.

In the Discussion Document and its presentations at the December 11 meeting, EPA has identified several conceptual approaches that might be used to identify potential prioritization candidates and requested feedback on these options from stakeholders. After reviewing these approaches, we strongly believe that the Work Plan Methodology developed in 2014 should remain the cornerstone of the EPA process but that elements of other options can be used to improve and expand the Work Plan framework so it is better able to support prioritization under TSCA going forward.

Several factors argue for retaining and building on the existing Work Plan Methodology:

- Development of the Work Plan Methodology was a transparent process which included detailed documentation of key elements of EPA's approach and extensive public comment. Since its adoption in 2012, the process has generally worked well to survey the universe of existing chemicals and select chemicals of concern for further scrutiny by the Agency.
- In LCSA, Congress signaled strong support for the Work Plan Methodology by requiring that all of the initial 10 chemicals selected for risk evaluations be drawn from the 2014 Work Plan List

[7] EPA might quickly select candidate chemicals for information collection and development drawing heavily on the 2014 Work Plan List.

and that at least 50 percent of all future risk evaluations be conducted on Work Plan chemicals until the 2014 List is exhausted.[8]

- With the Work Plan driving a large portion of EPA prioritization decisions going forward, switching to a fundamentally different methodology would add confusion and complexity to the prioritization process. It's hard to understand why EPA would want to use its scarce resources and staff time to reinvent the wheel when it can simply build on an accepted and proven process that is readily at hand.[9]

- Section 6(b)(1)(A) of TSCA identifies several factors that EPA must consider during prioritization, including a chemical's hazard and exposure potential, persistence and bioaccumulation, storage near drinking water sources, potentially exposed or susceptible populations, conditions of use and production volume. These factors are codified in EPA's prioritization rule. [10] The Work Plan Methodology captures most of the section 6(b)(1)(A) criteria, thus aligning well with Congressional intent and giving it advantages that other possible methodologies lack.

- The Work Plan Methodology is designed to assign scores to chemicals reflecting the relative level of concern they raise based on accepted hazard and exposure considerations that provide an initial indication of potential risk. 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."[11]

While preserving these strengths, the Work Plan Methodology should be improved so it is better positioned to support the identification of prioritization candidates as EPA moves forward to implement the new law. We identify below a number of areas for enhancing the Methodology that we urge EPA to consider adopting:

- Ninety chemicals were on the 2014 Work Plan list. After subtracting the 10 chemicals selected for initial risk evaluations and the 5 chemicals EPA has designated for restriction as PBTs under TSCA section 6(h), only 75 chemicals remain for potential high-priority listing. To adequately support prioritization over the long-term, the Work Plan Methodology needs to be revised so that the Step I criteria, which provide the entry-point into the Work Plan scoring process,

[8] Signifying its comfort with the Work Plan process, the House Report on the TSCA legislation states that "[t]he Committee hopes the Administrator will rely on its TSCA Work Plan Chemicals Methods Document published in February 2012 in identifying PBT candidate substances for listing." H.R Report 114–176, 114 Cong, 1st Sess, June 23, 2015, at 27.

[9] While the Chemical Management Plan (CMP) established by Canada under its Canadian Environmental Protection Act is an interesting example of priority-setting, it is not a workable model for the United States because of the fundamental differences between the US and Canadian chemical management laws and the different universes of chemicals manufactured and used in the two countries. For example, the CMP categorization process did not take into account worker exposures, proximity to significant sources of drinking water, eco-toxicity, or endocrine disruption as a health hazard endpoint. We believe that the Work Plan Methodology, which was devised for use under TSCA and then recognized by Congress when it amended the law, is a far better starting point for prioritization than the CMP.

[10] 40 CFR 702.9.

[11] 82 Fed. Reg. at 33754 (preamble to final prioritization rule).

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)) .[12] Other exposure indicators could include the number of exposed workers and presence in drinking water, surface water or groundwater.[13] 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.[14]

- 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 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 could be accomplished

[12] Information reported under EPA's Chemical Data Reporting (CDR) rule could be helpful in applying these triggers although EPA illogically limited its reliance on CDR submissions in the 2012 Work Plan Methodology. Part III of CDR Form U requires chemical manufacturers to provide information on downstream uses of the chemical, including uses in products for "commercial or consumer use or both." In its Work Plan Methods Document, EPA claimed it could not use the CDR data on consumer uses during Step 1 because Form U combined commercial and consumer uses into one category. However, during the recent regulatory negotiation on inorganic byproducts destined for recycling, both EPA and industry explained that the Form did not differentiate between commercial and consumer uses because companies providing the data lacked the ability to distinguish between the two. Based on this explanation, the best approach under the Work Plan is to treat chemicals for which combined uses were reported in Form Us as having consumer uses for purposes of Step 1 chemical selection. We urge EPA to adopt this approach in future revisions of the Work Plan Methodology.

[13] 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.

[14] Another category that should automatically be selected for screening under Step 1 of the Work Plan process would include chemicals for which the United States has accepted international obligations or for which significant global or regional action has been taken or is expected to be taken. Mercury is a compelling example of such a chemical. Under the Minamata Convention on Mercury, which entered into force on August 16, 2017, the United States has obligations related to reducing mercury use in product manufacturing, and in industrial processes. Discharging these obligations will require action under TSCA and the first step in exercising TSCA authorities is listing mercury as a high-priority substance. Ironically, EPA removed mercury and mercury compounds from the 2014 TSCA Work Plan for Chemical Assessments "because these chemicals are already well characterized" and EPA planned to take additional risk management measures anyway, EPA should reverse this decision and actively screen mercury for high-priority listing under the Work Plan process so it can then use TSCA to fulfill its risk management obligations under the Minamata Convention.

through voluntary data submission and/or application of 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). As EPA suggests in the Discussion Document, the remaining 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 have higher rankings that now meet EPA's criteria for inclusion in the list.

- The Discussion Document suggests the option of using functional categories based on use and exposure characteristics or chemical structure as an organizing tool for identifying potential prioritization candidates. In itself, this approach would not support a meaningful scoring system and could not (and should not) replace the Work Plan Methodology. However, section 26(c)(1) of TSCA allows EPA to apply any provision of TSCA authorizing or requiring action on a chemical substance to an appropriate "category of chemical substances." This term is then defined broadly in section 26(c)(2)(A) to include a group of chemical substances which are similar in "molecular structure," "physical, chemical or biological properties" "use" or other suitable characteristics. Based on these provisions, EPA has authority to designate categories of chemicals as "high-priority" under section 6(b)(1)(B), as expressly recognized in EPA's final prioritization rule.[15] We believe that, where EPA identifies logical functional groupings of chemicals based on use/exposure or chemical structure, they can be scored as "categories" in the Work Plan process using the toxicological profiles of representative category members and the likely aggregate exposure potential of chemicals in the category.[16] If the category ranks high under the Step 2 criteria, it could then be advanced to the pre-prioritization candidate list and, if warranted, listed as high-priority.

- The Discussion Document also proposes the option of identifying prioritization candidates based on New Approach Methods (NAMs),[17] which it defines as in vitro, in silico, or in chemico techniques that can provide information on a chemical's hazard or exposure potential.[18] These techniques include high-throughput screening using computational toxicology models based on chemical structure and bioactivity; "read-across" models for applying data on structurally similar compounds to characterize hazards of the substance of interest; modeling techniques for predicting exposure pathways and making quantitative exposure estimates; and QSAR modeling to predict environmental half-life and bio-accumulation factors.

[15] 82 Fed. Reg. 33756.
[16] To be clear, scoring would not be based on chemical structure alone but on hazard data on chemicals within the category. Similarly, we would oppose using chemical structure alone as a basis for identifying categories as candidates for low-priority listing.
[17] NAMs are also described as alternative test methods (ATMs), a term that is used in section 4(b) of TSCA and may be preferable to NAMs, an Agency-generated term with no statutory basis.
[18] Discussion Document at 53-54.

We do not believe that NAMs are sufficiently advanced and scientifically reliable to provide a stand-alone tool for scoring potential candidates for high-priority listing.[19] Nor do we believe they can validly be used as a basis to designate substances as low-priority.[20] However, we do agree with EPA that 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. Accomplishing this will require careful adjustments in the Work Plan scoring methodology. The Discussion Document identifies five different approaches to scoring chemicals using NAMs in combination with other data sources.[21] Further analysis of these options to devise an optimum scoring system must have stakeholder input from a wide range of viewpoints (NGOs, academics, sister agencies, industry, etc.).

EPA's current scoring approach of ranking chemicals as "high", "medium" and "low" for three different attributes should be replaced by one which assigns numerical scores in each area (plus other areas added to the Step 2 scoring methodology) and then sums these scores to determine a composite overall score for the chemical. This approach will more accurately reflect gradations among chemicals looking at the totality of relevant risk factors and 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 high toxicity and/or exposure that warrant further screening for possible prioritization.

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

The Discussion Document and EPA presentations on December 11 also address how best to identify candidates for low-priority listing under section 6(b)(1) (B)(ii) of TSCA. Any discussion of this topic must start with the statutory requirements for low-priority listing.

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."

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."

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[19] NAMs have several severe limitations that demonstrate the need for additional research and development prior to their sole use (i.e., without the inclusion of existing, whole animal, ecosystem, and/or epidemiologic data) under the amended TSCA. We thus object to Guiding Principle 6 in the Discussion Document, which seems to endorse the notion that, standing alone, high throughput approaches may be an acceptable screen for hazard and exposure.

[20] A key concern is that the limitations of these tools severely diminish the capacity of high-throughput systems to accurately identify all chemicals with potential toxicity, Because of the high incidence of false negatives, NAMs could not support a conclusion that a chemical lacks the potential for unreasonable risk, the prerequisite for low-priority listing under the law.

[21] Id at 54-60.

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. As Congress recognized, 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. This message would be misleading and irresponsible where comprehensive hazard and exposure information for all uses is unavailable or where there is evidence that some uses of the chemical may indeed present unreasonable risks.

EPA underscored these aspects of low priority listing in its proposed prioritization rule:

> "[I]in 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."[22]

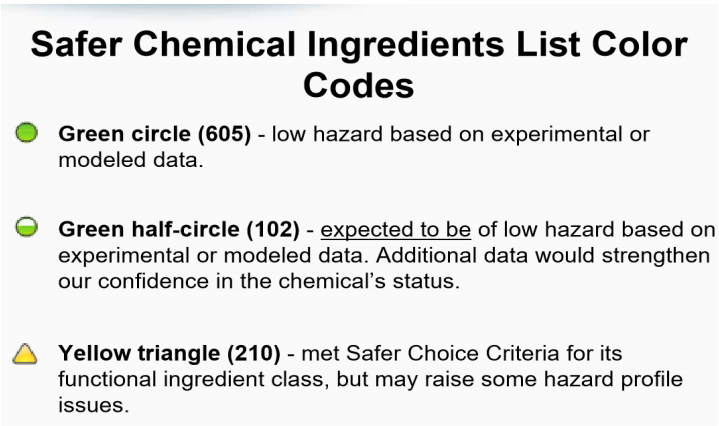
If EPA proposes a chemical for low-priority listing but is unable to finalize the listing because it cannot meet the rigorous standards in the law, then the chemical will automatically be designated high-priority under section 6(B)(1)(C)(iii). In the Guiding Principles in its Discussion Document, EPA notes this requirement and cautions that "[i]ncorrectly identified low priority candidates that are subsequently designated as high-priority" can greatly add to its workload by "permanently increase[ing] the number of ongoing risk devaluations."[23]

In light of the statutory requirements for listing, the process EPA establishes for identifying low-priority candidates should be focused on chemicals with well-documented hazard and exposure profiles and strong evidence of either low toxicity or an absence of exposure. One possible starting point for identifying such chemicals is EPA's Safer Chemicals Ingredient List (SCIL). This list is an outgrowth of EPA's Safer Choice program and is intended to provide a supportable basis for formulating products that

[22] 82 Federal Register 4825, 4830 (January 17, 2017).
[23] Discussion Document, at 11.

bear the Safer Choice Label. SCIL-listed chemicals are those that EPA has determined are among the safest within their functional classes based on measured and estimated data by hazard endpoint. To make these determinations, EPA has developed hazard criteria for a range of human health, eco-toxicity and environmental fate endpoints. SCIL-listed chemicals are used in products with high consumer and worker exposure and include high-production volume substances.

Chemicals on SCIL are assigned one of three geocodes reflecting their hazard profile and available data:



We believe that only Green Circle chemicals are appropriate for consideration for low-priority listing. Green Half-Circle and Yellow Triangle chemicals should be excluded because either lack of data or affirmative evidence of hazard indicates that they would not meet the TSCA low-priority definition. [24]

While warranting consideration for low-priority listing, Green Circle chemicals will require further screening before EPA can be confident that they will meet the TSCA listing criteria. For example, EPA would need to evaluate all conditions of use, given that only a subset of uses were evaluated for the SCIL listing. EPA would also need to evaluate additional hazard endpoints beyond those included in the Safer Choice Master Criteria. More detailed exposure data may be required as well, including for potentially exposed or susceptible subpopulations. Of highest importance, EPA would need to integrate hazard, exposure and use data in a comprehensive assessment document providing "information sufficient to establish" the absence of unreasonable risk, as the statute requires.

Guiding Principle 5 in EPA's Discussion Document is that the Agency "should strive to identify more than statutory-mandated minimum of 20 low-priority chemicals." We do not support this Guiding Principle. The statute does not preclude additional low-priority listings beyond the minimum of 20 chemicals required in section 6(b)(2)(B) of TSCA. However, before EPA goes down this path, it must be mindful of resource constraints and the larger goals of the amended law. As the preceding discussion underscores, developing a record sufficient to meet the TSCA criteria for low-priority listing will be resource-intensive and challenging and proposed listings which are not adequately justified may prompt litigation as well as the designation of more chemicals as high-priority than the Agency has the bandwidth to address.

[24] For similar reasons, we do not believe that substances classified as "low concern" under the Canadian chemicals law represent a good starting point for identifying low-priority listing candidates.

Moreover, Congress' greater emphasis on high-priority than low-priority listings demonstrates that the former should be EPA's principal focus and the latter should be a secondary area of activity. [25] It would turn TSCA on its head if EPA were to elevate the role of low-priority listings so they have equal standing to the far more important task of evaluating the risks of chemicals of concern and restricting exposure where warranted by findings of unreasonable risks. TSCA was amended in 2016 because of EPA's lackluster record in assessing and regulating existing chemicals and the high-priority listing mechanism was included in the amended law to increase the pace of action on unsafe chemicals. EPA should not undermine this goal by redeploying scarce resources for the purpose of increasing low-priority listings.

We appreciate this opportunity to comment on prioritization issues under TSCA. If you have any questions, please contact Bob Sussman, SCHF counsel, at bobsussman1@comcast.net.

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[25] The clearest evidence of the predominant role of high-priority listings under the law is in section 6(b)(2)(B) of TSCA, which only requires a one-time listing of 20 low-priority substances but places on EPA the obligation of assuring that at least 20 risk evaluations on high-priority substances are underway at any time, thus requiring EPA to list at least 20 high-priority substances every 3 years.