

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Comments of Safer Chemicals Healthy Families on Initiation of Prioritization for 20 High-Priority and 20 Low-Priority Candidates under Section 6(b)(1) of TSCA

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Docket ID EPA-HQ-OPPT-2019-0131

Safer Chemicals Healthy Families (SCHF), Center for Environmental Health, Earthjustice, Environmental Health Strategy Center, and Natural Resources Defense Council submit these comments on the March 21, 2019 notice of the Environmental Protection Agency (EPA) initiating the prioritization process for 20 candidates for high-priority listing and 20 candidates for low-priority listing under section 6(b)(1) of the Toxic Substances Control Act (TSCA).<sup>1</sup> Our 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. We 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.

The prioritization process in section 6(b)(1) of TSCA is the primary tool in the law for selecting chemicals that will be evaluated to determine whether they present unreasonable risks of injury to human health and the environment. Chemicals found to present unreasonable risks in these evaluations must then be banned or otherwise restricted under section 6(a) as necessary to eliminate such risks. Section 6(b)(2)(B) of TSCA requires EPA to designate at least 20 high-priority and 20 low-priority substances within 3.5 years of enactment of the 2016 TSCA amendments. EPA must then initiate risk evaluations on the high-priority substances; substances designated low-priority are those that EPA can establish do not meet the definition of high-priority chemicals and therefore do not warrant risk evaluations at this time.

Section 6(b)(1)(C) establishes a two-step process for designating substances as high- or low-priority. This process must be completed in no less than 9 months and no longer than 1 year. During the first step, EPA requests submission of relevant information on substances under consideration for high- or low-priority listing and provides 90 days for making these submissions. Then, EPA must propose priority designations for these or other substances, together with all supporting analyses and information, and provide an additional 90 days for comment.

The March 21 notice represents the first of the two steps in the prioritization process. It identifies 20 candidate chemicals for high-priority listing and 20 candidates for low-priority listing and describes the general process by which they were selected and the information sources used for this purpose. According to the notice, the high-priority candidates were all drawn from the 2014 TSCA Work Plan for Chemical Assessments; the low-priority candidates were identified by selecting chemicals on the TSCA Active Inventory previously evaluated for inclusion in EPA's Safer Chemical Ingredients List (SCIL) or by other government reviewers and further screening them for evidence of low hazard.

The March 21 notice does not provide detailed data on hazard and exposure for any of the listing candidates. Nor does it explain how EPA interprets the criteria for high- and low-priority listing in section

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<sup>1</sup> 84 Federal Register 10491

6(b)(1)(B) of TSCA or why the Agency believes the 40 candidate chemicals would meet these criteria. These are tasks that EPA will presumably undertake in the second stage of the prioritization process.

Our comments have a three-fold focus. First, drawing on experience with the initial 10 TSCA risk evaluations, we recommend steps that EPA must take *now* to assure that the next round of evaluations is scientifically sound and based on robust information. Second, we urge EPA to include mercury in the prioritization process because of the importance of a TSCA risk evaluation in meeting US obligations under the Minamata Convention on Mercury. Third, we examine the low-priority listing criteria in the law and offer recommendations for how these criteria should be interpreted and applied, the data necessary for valid low-priority designations and the sufficiency of the information sources EPA has used to identify the 20 low-priority candidate substances. Our goal is to assure a high level of confidence in the safety of chemicals selected as low-priority, including for potentially exposed or susceptible subpopulations and others who may be exposed to these chemicals under their conditions of use.

The principal points in our comments are as follows:

### **High-Priority Listing**

- Despite previous commitments, EPA has failed to evaluate whether the available data on the 20 high-priority candidates are sufficient to conduct robust risk evaluations and, if not, to require testing necessary to fill any data gaps.
- EPA must immediately undertake this data sufficiency analysis and initiate all necessary testing using section 4 authorities so that the 20 upcoming evaluations are based on all reasonably available data on hazard and exposure.
- EPA should establish a systematic process for obtaining existing toxicological and exposure data from industry on the 20 high-priority candidates, including using its section 8(d) reporting authority to obtain unpublished health and safety studies.
- EPA should rely on studies conducted by manufacturers outside the US for prioritization and risk evaluation only if it has access to and independently evaluates all available underlying data and discloses the full studies to the public without material redaction as required by section 14(b) of TSCA.
- In conducting risk evaluations on high-priority substances, EPA should rely on the definitive hazard findings in IRIS assessments, supplemented by additional data that has subsequently become available that inform its evaluation of the weight of the evidence. Such additional data should be assessed using peer reviewed and accepted systematic review methodologies.
- EPA's risk evaluation for formaldehyde under TSCA should be based on its draft IRIS assessment and this assessment should be immediately released for public comment and peer review.

### **Listing Mercury as a High-Priority Substance**

- The United States is a Party to the Minamata Convention on Mercury. The Convention entered into force on August 16, 2017. Under the Convention, the United States has obligations related to reducing mercury use in product manufacturing and in industrial processes.
- Designating mercury as high priority would enable the US to carry out these obligations and also serve the objectives of TSCA.

### **Low-Priority Listing**

- Low-priority listings will only be warranted where sufficient evidence is available to demonstrate the absence of unreasonable risk under all conditions of use.
- To support a low-priority designation, EPA must be in possession of data for all relevant health and ecological endpoints developed using adequate test methodologies.
- The Safer Chemical Ingredients List is a useful source of potential listing candidates, but EPA must independently compile and review available hazard and exposure data on each candidate for listing and consider a broader set of health endpoints and exposure scenarios than those addressed by the SCIL.
- NAMs and data on chemical analogs cannot compensate for the absence of traditional toxicological data except in rare instances and should play a limited role in supporting low-priority designations.

## I. HIGH-PRIORITY LISTING

### A. EPA Has Failed to Evaluate Whether the Available Data on the 20 High-Priority Candidates Are Sufficient to Conduct Robust Risk Evaluations and to Require Testing Necessary to Fill Any Data Gaps

Once EPA's high-priority listings are finalized in December of 2019, the listed chemicals will undergo TSCA risk evaluations. EPA will need to complete these evaluations within three years (with a possible extension of up to six months). To ensure that EPA has the "reasonably available information" that TSCA requires for sound and complete risk evaluations, efforts to develop additional data on a listed chemical's health and environmental effects must begin while a chemical is being considered for prioritization, if not sooner. Yet neither the March 21 notice nor other EPA actions provide any indication that the Agency is systematically identifying data gaps on the 20 listing candidates and taking steps to fill them.

Under section 6(b)(4), the goal of risk evaluations is stated in unconditional terms:

"The Administrator shall . . . determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

The burden on EPA to exonerate a chemical at the risk evaluation stage is a high one. As the Senate report explains, the unreasonable risk standard in the new law is one that "ensures, without taking into consideration cost or other non-risk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use . . ." S. Rep. No. 94-698, 114<sup>th</sup> Cong, 1<sup>st</sup> Sess. (2015) at 17. EPA cannot meet this standard by pointing to the absence of data for a particular endpoint. Instead, it must present data affirmatively establishing the absence of risk. The data required to make this demonstration should be sufficient to satisfy EPA risk assessment guidelines for cancer, reproductive and developmental effects and other end-points that define the level of evidence necessary to conclude that a chemical is without adverse effects.<sup>2</sup> As described in the

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<sup>2</sup> See, e.g., EPA 1991. Guidelines for Developmental Toxicity Risk Assessment. Available at [https://www.epa.gov/sites/production/files/2014-11/documents/dev\\_tox.pdf](https://www.epa.gov/sites/production/files/2014-11/documents/dev_tox.pdf); and EPA 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](https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf)

Senate report, evaluations must “look comprehensively at the hazards associated with the chemical,” *id.*, at 2, and thus must include a thorough analysis, informed by comprehensive information, of whether the evidence demonstrates the presence or absence of an unreasonable risk to health or the environment.

**The Importance of an Early Assessment of Data Sufficiency.** Our groups have repeatedly underscored the need to base risk evaluations on adequate information and EPA itself has committed to identify and fill data gaps in advance of prioritization.<sup>3</sup> The importance of these steps was emphasized in the Discussion Document EPA prepared for its December 11, 2017 public meeting on prioritization:

*“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.”*<sup>4</sup>

*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).”*<sup>5</sup>

EPA made similar points in its September 27, 2018 *Working Approach for Identifying Potential Candidate Chemicals for Prioritization* (Working Approach) under TSCA.<sup>6</sup> The Working Approach emphasizes that a selection of chemicals for high-priority listing should be based on 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.”

**EPA’s Obligation to Obtain Reasonably Available Information.** EPA has an obligation to use these or other tools to obtain the information necessary for informed determinations of risk. Under section 26(k) of TSCA, when conducting risk evaluations under section 6, EPA “shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonable available to the Administrator.” EPA’s risk evaluation framework rule defines reasonably

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<sup>3</sup> See 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; and Comments of Safer Chemicals Healthy Families, Natural Resources Defense Council and Earthjustice on Working Approach for Identifying Potential Candidates for Prioritization under Amended TSCA, November 15, 2018, Docket ID EPA-HQ-OPPT-2018-0659.

<sup>4</sup> DISCUSSION DOCUMENT: Possible Approaches and Tools for identifying Potential Candidate Chemicals for Prioritization at 7 (emphasis added).

<sup>5</sup> *Id.* at 11.

<sup>6</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0659-0001>

available information as “information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.” 40 C.F.R §702.33. The preamble to the rule underscores that information that either exists or “can be obtained through testing” is “reasonably available” and that the Agency may be obligated to require “data [to be] generated in response to EPA data gathering, including testing, authorities” to meet its obligation to consider reasonably available information.<sup>7</sup>

**Lessons from PV29.** The dangers of selecting chemicals for risk evaluations without conducting a data adequacy review were painfully evident in EPA’s first draft evaluation, for Pigment Violet 29 (PV29). The December 2018 draft concludes that this chemical does not present an unreasonable risk of injury but bases this sweeping conclusion on limited hazard and exposure information that are inadequate to demonstrate the absence of risk.<sup>8</sup> Comments by SCHF and other groups strongly faulted the draft evaluation for giving PV29 a clean bill of health without a credible scientific basis.<sup>9</sup>

For example, to determine worker and consumer exposure, EPA relied on a single undocumented report of PV29 air concentrations during the manufacture of the chemical. Agency staff then extrapolated this data to *all* downstream industrial and consumer uses on the questionable assumption that manufacturing exposures represent a “worst case” for all exposed populations. In the industrial hygiene community, actual monitoring of individual workers using established measurement protocols is considered the only reliable way to quantify worker exposure levels, but EPA could not point to any monitoring data on PV29.

Similarly, EPA determined that PV29 “presents a low hazard to human health across all routes of exposure” based on a handful of short duration animal studies. However, some of these studies were considered “unreliable” by the very company conducting them while others provide preliminary but suggestive evidence of adverse effects. Moreover, EPA lacked several long-term health effects studies that EPA has historically considered essential to demonstrate the absence of hazard and risk under its risk assessment guidelines and policies.

For example, reliable experimental data on PV29 were available for only 5 of the 15 critical health endpoints that EPA’s [Safer Choice](#) program uses to identify non-hazardous chemical products. Remarkably,

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<sup>7</sup> 82 Fed. Reg. 33726, 33732 (July 20, 2017).

<sup>8</sup> The public process for PV29 risk evaluation has been highly flawed apart from the deficiencies in the evaluation itself. As described below, EPA withheld the 24 industry studies it was relying on from public disclosure on the questionable basis that they required confidential treatment. In the face of strong objections from our groups and others to this lack of transparency, EPA released portions of the studies but withheld others and reopened the public comment period. Now, on the eve of review of the draft evaluation by the Scientific Advisory Committee on Chemicals (SACC), EPA has released a new assessment of worker exposure and risk and extended the comment period again. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0604-0051> Interested parties will have only a few days to review the new assessment and comments will be submitted after the SACC meeting and too late to influence its deliberations.

<sup>9</sup> Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council, and the undersigned groups on EPA’s Draft Risk Evaluation for C.I. Pigment Violet 29 under the Amended Toxic Substances Control Act, January 14, 2019 Docket ID EPA-HQ-OPPT-2018-0604; Supplemental Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council and the Undersigned Groups on EPA’s Draft Risk Evaluation for C.I. Pigment Violet 29 under the Amended Toxic Substances Control Act, May 17, 2019, Docket ID EPA-HQ-OPPT-2018-0604

EPA's determination of "safe" exposure levels was entirely based on a screening study for reproductive and developmental toxicity that [EPA guidelines](#) term "*insufficient by itself to make an estimate of human risk without further studies to confirm and extend the observations.*" Similarly, without any carcinogenicity data, the draft risk evaluation asserted that PV29 is "unlikely to be a carcinogen" – a classification that under [EPA guidelines](#) for assessing cancer risk is only justified where "animal evidence (sic) demonstrates lack of carcinogenic effect in both sexes in well-designed and well-conducted studies in at least two appropriate animal species."

While the available data do not show definitively that PV29 has adverse health effects, they provide no basis to say with confidence that it is not dangerous. Had EPA used its TSCA section 4 authority when it selected PV29 for a risk evaluation nearly three years ago in the fall of 2016, this data vacuum could have been avoided and the congressional mandate fulfilled. A section 4 testing order could have set in motion several studies on health effects as well as additional monitoring of workplace exposure and environmental release. The information generated would now be in hand to inform the ongoing risk evaluation. All of this information was readily obtainable and reasonably available if EPA had chosen to follow the requirements of TSCA and obtain it. EPA should not repeat its PV29 mistakes for the 20 risk evaluations it will soon initiate; it would be irresponsible for EPA to continue its unsupportable refusal to exercise its information gathering authorities as Congress clearly intended—and it is our most vulnerable populations like workers and children who will bear the brunt of the fallout.

**Data Gaps on the 9 Other Risk Evaluation Chemicals.** The health and environmental effects of the other nine chemicals now undergoing risk evaluations are generally better characterized than those of PV29. However, despite the repeated recommendations of SCHF and other groups, EPA likewise made no effort to conduct an early assessment of data gaps for these chemicals and then use its section 4 authorities to fill them. A cursory review of EPA's problem formulations for the 9 chemicals reveals that several substances lack data for critical endpoints like endocrine effects and developmental neurotoxicity<sup>10</sup> and that reliable information on human exposure and environmental release is frequently unavailable. As a result, the draft evaluations that EPA will soon issue will likely be incomplete in important areas. As with PV29, EPA may erroneously classify chemicals as low risk based on untested hypotheses, preliminary data, and sweeping extrapolations from fragmentary information.

**Minimum Data Needed for Robust TSCA Risk Evaluations.** While EPA's March 21 notice identifies the data sources it is using for the 20 high-priority candidates, it fails to describe any process for reviewing the sufficiency of these data for a robust risk evaluation and identifying critical data needs. Although many of the 20 high-priority candidates identified in the March 21 notice have sizable datasets, it is unlikely that they are sufficiently well-characterized for all endpoints that should be examined in a TSCA risk evaluation.

In examining the sufficiency of available data for the 20 chemicals, EPA should determine whether adequate information exists to address the health endpoints identified in EPA's Design for the Environment (DfE) program<sup>11</sup> and the related and widely used chemical assessment protocol

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<sup>10</sup> For example, developmental neurotoxicity data are unavailable for 1,4 dioxane, methylene chloride, trichloroethylene and perchloroethylene.

<sup>11</sup> US EPA (2011) Design for the Environment Alternatives Assessment Criteria for Hazard Evaluation. Available at: [https://www.epa.gov/sites/production/files/2014-01/documents/aa\\_criteria\\_v2.pdf](https://www.epa.gov/sites/production/files/2014-01/documents/aa_criteria_v2.pdf)

GreenScreen.<sup>12</sup> This set of studies is designed for a baseline assessment of chemical safety and represents a group of minimum data requirements for all TSCA priority listings and risk evaluations. Thus, at least the following studies should be conducted using protocols that EPA and other expert bodies have deemed necessary for determinations of risk:

- Acute mammalian toxicity
  - Oral
  - Dermal
  - Inhalation
- Respiratory sensitization
- Skin sensitization
- Eye irritation/ corrosivity
- Skin irritation/ corrosivity
- Carcinogenicity
- Mutagenicity/ genotoxicity
- Reproductive toxicity
- Developmental neurotoxicity
- Neurotoxicity
- Repeated dose toxicity
- Endocrine activity
- Toxicokinetics

Where sufficient data for these endpoints are not available, EPA should use its section 4 authority to require industry to conduct the necessary studies.<sup>13</sup>

**Data Gaps on the 20 High-Priority Candidate Chemicals.** Even without an exhaustive literature review, significant data gaps on the 20 high-priority candidate chemicals are readily identifiable. One example is 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB) (CASRN 1222-05-5), a fragrance that is commonly used in detergents and other consumer and personal care products and has been found in adipose tissue, blood, breast milk, and umbilical cord blood. A 2015 review of HHCB found major data gaps for reproductive toxicity, neurotoxicity, and respiratory sensitization endpoints.<sup>14</sup> Similarly, in its 2014 Work Plan assessment of HHCB's environmental effects, EPA concluded that "[t]he inability to assess potential risks to terrestrial invertebrates and plants is a major uncertainty associated with this assessment."<sup>15</sup> Since EPA identified these data gaps several years ago, it has had ample opportunity to fill them using its section 4 authority, yet has failed to do so.

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<sup>12</sup> Clean Production Action (2018) GreenScreen for Safer Chemicals. Available at:

[https://www.greenscreenchemicals.org/images/ee\\_images/uploads/resources/GS\\_TwoPager\\_July2018.pdf](https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GS_TwoPager_July2018.pdf)

<sup>13</sup> Other studies should also be included such as immunotoxicity. See, e.g., California's Office of Environmental Health Hazard Assessment's list of Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse, available at <https://oehha.ca.gov/media/downloads/risk-assessment//gcregtext011912.pdf>.

<sup>14</sup> <https://www.womensvoices.org/wp-content/uploads/2016/04/1222-05-5-HHCB-aka-Galaxolide-GS-546-v-1-2-Certified-April-2015-3.pdf>

<sup>15</sup> <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0722-0024>

Yet another example of data insufficiency is information on endocrine effects. The Center for Environmental Health (CEH) conducted a literature review of existing studies to identify what is and is not known about the endocrine disruption potential of the 20 high-priority candidates. In total, of the 20 high-priority candidates, 18 currently show evidence that support treating them as an endocrine disrupting compound (EDC). Risk evaluations of these compounds should review this evidence in determining whether they pose unreasonable risks to human health due to the adverse outcomes caused by endocrine disruption. For many of the 20 high-priority compounds, extensive data indicating they are endocrine disruptors is already available, such as the five phthalates. However, further data is necessary for other compounds with less publicly available data (such as p-dichlorobenzene, 1,2-dichloroethane, trans-1,2-dichloroethylene, o-dichlorobenzene, and ethylene dibromide) as studies on these compounds are limited but indicate endocrine activity. For two compounds, 1,1-dichloroethane and phthalic anhydride, no data is publicly available for whether they are or are not EDCs. EPA should use its section 4 authority to require industry to conduct these studies. Tests that should be performed can be found in the Revised Guidance Document 150 on Standardized Test Guidelines for Evaluating Chemicals for Endocrine Disruption from the Organization for Economic Cooperation and Development (OECD), and all studies should perform the tests listed in Conceptual Framework Levels 2-5.

**While EPA has wasted valuable time, it is not too late to conduct a comprehensive data sufficiency analysis of the 20 candidate chemicals. This should be a high priority as EPA proceeds with the prioritization process.**

**B. EPA Should Establish a Systematic Process for Obtaining Existing Toxicological and Exposure Data from Industry on the 20 High-Priority Candidates, including Using its Section 8(d) Reporting Authority to Obtain Unpublished Health and Safety Studies and Expanding Reporting under the CDR Rule**

Although identifying the data sources EPA has searched, the March 21 notice provides no indication of a systematic process to obtain information from industry beyond reviewing previous submissions on the 20 high-priority candidates under the Comprehensive Data Reporting (CDR) rule.<sup>16</sup> This is a significant omission given both the possibility that industry is in possession of unpublished toxicology and human health studies and the considerable information on occupational exposure and environmental release in industry files. The CDR rule and other mandatory TSCA reporting requirements do not call for the submission of this information. If industry voluntarily provides such information selectively or (as in the case of PV29) in summary form with no documentation, the quality and credibility of the EPA risk evaluations will suffer.

We recommend that, for each of the 20 candidate high-priority chemicals, EPA issue an information request to all manufacturers and processors specifying the toxicological and exposure information necessary for TSCA risk evaluations, with a focus on the data needed to evaluate risks to potentially exposed or susceptible subpopulations. The Agency should also develop a standardized format for submitting this information.

Because industry may not fully comply with this voluntary request, EPA should put in place mandatory reporting mechanisms as a backstop. For example, EPA should add the 20 chemicals to its TSCA section

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<sup>16</sup> 84 Fed. Reg. at 10493.



8(d) rule (40 CFR Part 716). This rule requires manufacturers, processors and distributors to report “health and safety studies” on listed chemicals. The rule defines “health and safety study” broadly to include studies of health and environmental effects as well as of human exposure and environmental release.<sup>17</sup> Reporting under the rule would be particularly useful to capture information on exposure and release: the definition of health and safety study explicitly includes “[a]ssessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies” and “[m]onitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.”<sup>18</sup> This is a critical area of analysis in TSCA risk evaluations and one where EPA may receive limited and undocumented information unless it uses its reporting authority.

40 CFR § 716.105 provides an expeditious mechanism for adding chemicals to the section 8(d) health and safety data reporting rule. EPA should use this mechanism to subject the 20 high-priority candidates to reporting immediately.

Another essential step is to expand the scope of CDR reporting (40 CFR Part 711) for high-priority listing candidates. Because EPA needs more comprehensive use and exposure information on these chemicals to support risk evaluations, the reporting threshold should be lowered from 25,000 pounds of a chemical substance at any single site to 2500 pounds or even less for particular chemicals. For these chemicals, EPA should also add a processor reporting component to the CDR rule, so it obtains accurate and complete information on downstream conditions of use and exposure. These revisions should be made as part of the ongoing rulemaking to modify the CDR rule, so they are implemented for the 2020 reporting cycle.<sup>19</sup>

In particular instances, these expanded reporting requirements may not be sufficient to provide sufficient information for TSCA risk evaluations. In these cases, EPA should use its subpoena authority under TSCA section 11 to obtain more information from individual manufacturers and processors.

**C. EPA Should Rely on Studies Conducted by Manufacturers Outside the US Only If It Has Access to and Independently Evaluates All Available Underlying Data and Discloses the Full Studies to the Public Under Section 14(b) of TSCA**

The March 21 notice indicates that information on some of the 20 high-priority candidates is available from assessments by other countries. EPA does not provide further details but is likely referring to assessments conducted under the REACH program and industry-generated studies in REACH dossiers described in ECHA “robust summaries.” While these industry studies can contribute useful information to TSCA risk evaluations, it is critical that EPA obtain and independently evaluate the studies themselves and not rely on industry-generated summaries that may not faithfully reflect the study findings. In addition, EPA must treat these studies and underlying data as “health and safety studies” for purposes of section 14(b)(2)(A) of TSCA, which expressly prohibits EPA from withholding such studies as

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<sup>17</sup> 40 CFR § 716.3.

<sup>18</sup> Id. For example, section 8(d) requirements might encompass exposure monitoring data collected by employers – whether required by OSHA or developed voluntarily – which must be retained for 30 years under OSHA regulations. 29 C.F.R. 1910.1020(D)(7)(ii).

<sup>19</sup> 84 Fed. Reg. 17692 (April 25, 2019). We are separately submitting these recommendations to the CDR rulemaking docket.

confidential business information (CBI). As this provision recognizes, disclosure of the data underlying the Agency's risk evaluations is legally required and necessary to protect the public's right to know the health and environmental effects of chemicals to which it is exposed and to comment meaningfully on EPA's proposed determinations of risk.

Under no circumstances should EPA repeat its unlawful and irresponsible treatment of REACH studies on PV29 that were submitted by European manufacturers for use in the Agency's risk evaluation of this substance. Because the data owners demanded confidentiality, EPA initially disclosed to the public only ECHA summaries but not actual studies. After strong objections to this lack of transparency by our groups and members of Congress, EPA belatedly released some, but not all, of the studies and continued to withhold critical data claimed by industry to comprise CBI. These actions violated TSCA and undermined the public's ability to comment on the draft PV29 evaluation. In the future, EPA should follow a uniform policy of disclosing these industry studies to the public as required by TSCA. If companies will not agree to disclosure of the studies, EPA should require testing under section 4 of TSCA so there is no doubt about public access to the data under section 14 of TSCA.

**D. EPA Should Not Revisit Definitive Findings in IRIS Assessments Unless There Are New Data That Inform the IRIS Evaluation of the Weight of the Evidence and These Data Should be Evaluated Using a Peer Reviewed, Valid Systematic Review Methodology**

14 of the 20 high-priority candidates identified in the March 21 notice have been assessed under the EPA Integrated Risk Information System (IRIS).<sup>20</sup> The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS). The IRIS program recently received a favorable review from the NAS.<sup>21</sup>

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the "best available science," a requirement under section 26(h) of TSCA for all science-based decisions under the law. Reopening IRIS findings would harm the public by prolonging uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation. To revisit IRIS findings would also be

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<sup>20</sup> The 14 chemicals with IRIS assessments are: p-Dichlorobenzene (1,4-dichlorobenzene); 1,2-Dichloroethane; trans-1,2-Dichloroethylene; o-Dichlorobenzene; 1,1,2-Trichloroethane; 1,2-Dichloropropane; 1,1-Dichloroethane; Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester); Butyl benzyl phthalate (BBP) - 1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester; Di-ethylhexyl phthalate (DEHP) - (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester); Ethylene dibromide; 1,3-Butadiene; Formaldehyde; and Phthalic anhydride.

<sup>21</sup> National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.

inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget constraints and is straining to manage its TSCA workload.

For some IRIS assessments performed several years ago, significant new data have subsequently become available. However, this should not be an open-ended basis to reopen previous IRIS hazard findings. Rather, to update and incorporate new evidence, the new data should be reviewed, in consultation with scientists in the IRIS program, to assess whether they might inform the previous IRIS determination of the weight of the evidence for particular endpoints. This review should be conducted using one of four existing empirically-based systematic review methodologies listed below. Having been peer-reviewed, validated, demonstrated in case studies and recommended for chemical evaluations by the NAS,<sup>22</sup> these are the best available science for systematic review:

- Navigation Guide: Woodruff TJ, Sutton P. *The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes*. Environ Health Perspect. 2014;122(10):1007-1014. doi:10.1289/ehp.1307175.
- OHAT: National Toxicology Program Office of Health Assessment and Translation. *Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration*. National Institute of Environmental Health Sciences; 2015
- Integrated Risk Information System (IRIS): National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25086>.
- International Agency for Research on Cancer (IARC): Revised Preamble for the IARC Monographs: Modernized and transparent evidence synthesis for cancer hazard identification. January 2019. <https://monographs.iarc.fr/preamble-to-the-iarc-monographs/>

Unfortunately, EPA is following a much more questionable approach in the 10 ongoing risk evaluations. Under this approach, *all* studies on IRIS-assessed chemicals are being reviewed using the “study quality” scoring system in EPA’s TSCA systematic review document and other as-yet unidentified protocols for reviewing study relevance and weight.<sup>23</sup> This process necessarily involves revisiting the interpretation of

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<sup>22</sup> The National Academies of Sciences. *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals*. Washington, D.C.: National Academies Press; 2017.

<sup>23</sup> Typical is this description of EPA’s approach in the problem formulation for asbestos, the subject of a comprehensive IRIS assessment:

EPA expects to consider and analyze human health hazards as follows:

1) Included human health studies will be reviewed using the evaluation strategies laid out in the Application of Systematic Review in TSCA Risk Evaluations (U.S. EPA, 2018).

- Studies will be evaluated using specific data evaluation criteria.
- Study results will be extracted and presented in evidence tables by cancer endpoint.

2) Evaluate the weight of the scientific evidence of human health hazard data.

- EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

studies already evaluated in IRIS, potentially making different judgments about their quality and relevance and modifying overall IRIS determinations of the “best available science” and “weight of the evidence.” Moreover, these judgments are being driven by a deeply flawed and unscientific method for reviewing studies – currently under review by the NAS and not otherwise peer-reviewed -- that would result in less defensible conclusions than peer-reviewed IRIS assessments.<sup>24</sup>

While TSCA section 26(h) establishes “scientific standards” for science-based decisions under section 6 and other provisions, these standards are general and flexible and do not materially change long-standing criteria used by agencies and the scientific community to assess the reliability, relevance and completeness of scientific evidence. The TSCA standards are consistent with the data review methodologies used by IRIS, other EPA programs and expert organizations like NTP and provide no justification for questioning science judgments and study interpretations made in the IRIS process. We will comment on how EPA has used IRIS assessments in the context of individual draft evaluations but strongly object to EPA’s overall approach and oppose its application to the next 20 risk evaluations EPA will conduct.

**E. EPA’s Risk Evaluation for Formaldehyde Under TSCA Should be Based on the Draft IRIS Assessment and This Assessment should be Immediately Released for Public Comment and Peer Review**

Formaldehyde, one of the 20 high-priority candidates, is the subject of a draft IRIS assessment that has not been released for public comment and peer review. EPA Assistant Administrator Dunn has [stated](#) that “the work done for IRIS will inform the TSCA process” on formaldehyde but has provided no indication that TSCA staff will rely on this work or that the Agency will publicly release either the IRIS draft or OPPT’s analysis of the key IRIS conclusions. Continued suppression of the draft IRIS assessment would depart from the Assistant Administrator’s recent [declaration](#) that “[e]nsuring greater public transparency of chemical information is a top priority, and the EPA is actively working to achieve this across all areas of TSCA implementation.”

Formaldehyde is a chemical of high concern. It has been linked to several types of cancer and other adverse health effects and has multiple uses with the potential for widespread consumer and worker exposure. Protecting public health from formaldehyde exposure has been critical to the missions of several EPA offices for many years. To meet this agency-wide need, formaldehyde has been a priority of the IRIS program since 1997 and IRIS scientists have devoted thousands of hours to reviewing and analyzing its voluminous database.

An earlier IRIS assessment of formaldehyde was reviewed by the NAS in 2011. Following that review, EPA began revising the assessment in response to the NAS recommendations. A new draft assessment was reportedly completed over 18 months ago and reaffirmed previous conclusions by IRIS and other expert bodies that exposure to formaldehyde is causally linked to nasal cancers and leukemias, as well

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- Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route.

3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical’s hazard(s) than the general population.

Problem Formulation of the Risk Evaluation for Asbestos, at 51-52.

<sup>24</sup> See comments on the TSCA Systematic Review guidance from SCHF, NRDC, and UCSF-PRHE to Docket EPA-HQ-OPPT-2018-0210

as other adverse effects. EPA then prepared to release the draft for public comment and peer review by the NAS. However, these efforts were blocked by senior EPA management and work on the assessment was abandoned. A [March 4 Government Accountability Office \(GAO\) report](#) raised concerns about this decision, yet EPA has never explained why it opposes public comment and peer review of a definitive draft report by its leading scientists that is directly relevant to its public health protection responsibilities.

Continued suppression of the draft IRIS report would enable the TSCA program to produce a more favorable assessment of formaldehyde's health effects without informing the public of the IRIS determinations and how and why OPPT has reached different conclusions. This would be contrary to EPA's responsibilities under TSCA Section 26(h) and (i) to use all relevant scientific information "in a manner consistent with the best available science" and to base its decisions under TSCA section 6 on "the weight of the scientific evidence." Should the TSCA risk evaluation exonerate formaldehyde from the serious health effects found in the IRIS draft, the credibility of the TSCA program would be irreparably damaged and its risk determinations for this chemical would be legally compromised.

Rather than pursuing this untenable course, EPA should immediately release the draft IRIS assessment for public comment and submit it to the NAS for peer review. If TSCA scientists have questions or concerns about the scientific basis for the IRIS findings, they can be framed for public comment and reflected in the charge for NAS review. The public comments and NAS guidance that EPA receives could then inform how it uses the IRIS determinations in the TSCA risk evaluation and avoid an open-ended reanalysis of the formaldehyde database that fails to leverage the extensive work NAS has already done. If these steps occur early in the risk evaluation process, they will conserve EPA resources and enhance the credibility of its ultimate evaluation – which otherwise will be fatally compromised by persistent questions about EPA's commitment to transparency and scientific integrity.

## II. LISTING MERCURY AND ITS COMPOUNDS AS HIGH-PRIORITY SUBSTANCES

The United States is a Party to the Minamata Convention on Mercury. The Convention entered into force on August 16, 2017. Under the Convention, the United States has obligations related to reducing mercury use in product manufacturing and in industrial processes. For example, under Article 4 of the Convention, the United States must reduce mercury use in the manufacture of switches and relays,<sup>25</sup> and under Article 5 of the Convention take measures to phase out mercury use in the production of polyurethane "as fast as possible."<sup>26</sup> Moreover, the United States has obligations to discourage new mercury product types<sup>27</sup> and discourage new uses of mercury in manufacturing processes,<sup>28</sup> and has reporting obligations related to each of these control measures.<sup>29</sup> Exercising these responsibilities requires actions under various provisions of TSCA.

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<sup>25</sup> See

[http://www.mercuryconvention.org/Portals/11/documents/submissions/USA%20declaration\\_Art%204%20para%202.pdf](http://www.mercuryconvention.org/Portals/11/documents/submissions/USA%20declaration_Art%204%20para%202.pdf), p. 5.

<sup>26</sup> See Minamata Convention on Mercury, Annex B, Part II.

<sup>27</sup> See Article 4, Paragraph 6.

<sup>28</sup> See Article 5, Paragraph 7.

<sup>29</sup> See Article 21.

Nonetheless, EPA removed mercury and mercury compounds from the 2014 TSCA Work Plan for Chemical Assessments. At that time, the Agency maintained that “their hazards are already well characterized”<sup>30</sup> and that EPA planned to take additional risk management measures anyway, both because of the high hazard these chemicals present and because of the government’s Minamata Convention on Mercury obligations.<sup>31</sup>

This decision to remove mercury and mercury compounds from the 2014 Workplan was made before the 2016 TSCA revisions were enacted. Now, under the current TSCA statutory scheme, EPA must designate mercury as a high-priority chemical, conduct a risk evaluation under TSCA section 6(b) and determine that it presents an unreasonable risk of injury to health or the environment, before taking the necessary regulatory actions under TSCA section 6(a). Accordingly, in its comments on EPA’s prioritization framework rules, NRDC emphasized the need to prioritize mercury and other chemicals covered by binding international agreements as high-priority substances under TSCA where implementing action under TSCA is necessary to carry out US responsibilities under these agreements. EPA concurred, as reflected in the Response to Comment document on the final rule:

Comment: One commenter (0054) suggested that EPA consider its international obligations in selecting a chemical for prioritization, as achieving compliance with these obligations may necessitate prioritization of a particular chemical substance under TSCA.

EPA Response: EPA agrees that it should take into consideration relevant international actions, such as multilateral environmental agreements, global and regional partnerships, and bilateral or international commitments. EPA is of the view that it should give particular attention to those chemicals for which the United States has accepted international obligations and to chemicals for which significant global or regional action has been taken or is expected to be taken.

There is a compelling basis to select mercury and mercury compounds for high-priority designation and risk evaluation under TSCA at this time. Even apart from the Minamata Convention, mercury is already a priority of EPA and other federal agencies. EPA’s mercury activities under the TMDL program,<sup>32</sup> and the recent work of EPA and US Customs to improve the tracking of mercury and mercury compound trading within North America, are indicative of the importance of mercury within the federal government.<sup>33</sup> The federal government has also enacted a mercury export ban,<sup>34</sup> mandated the construction of a facility to permanently sequester mercury in lieu of placing the mercury in commerce, and records/publicizes

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<sup>30</sup> See e.g., <https://www.epa.gov/mercury/health-effects-exposures-mercury>.

<sup>31</sup> See [https://www.epa.gov/sites/production/files/2015-01/documents/tsca\\_work\\_plan\\_chemicals\\_2014\\_update\\_final.pdf](https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update_final.pdf), p. 7.

<sup>32</sup> See <https://www.epa.gov/tmdl/impaired-waters-and-mercury>.

<sup>33</sup> See <http://www3.cec.org/islandora/en/item/11769-enhancing-alignment-north-american-trade-statistics-elemental-mercury-and-en.pdf>.

<sup>34</sup> See <https://www.epa.gov/mercury/questions-and-answers-mercury-export-ban-act-meba-2008>.

mercury fish consumption advisories.<sup>35</sup> Strong support for addressing mercury is also evident from state agencies.<sup>36</sup>

In addition, the science underlying the risks posed by mercury is extraordinarily strong and substantial.<sup>37</sup> As EPA indicated in the 2014 Workplan Update, mercury and mercury compounds are already “well characterized.” And under TSCA as revised, a separate and detailed supply, use, and trade reporting system is now in place, under final rules published by EPA on June 27, 2018.<sup>38</sup> These rules will require the electronic submission of data from both mercury (and mercury compound) manufacturers and processors by July 1, 2019.<sup>39</sup> Accordingly, approximately six months before EPA’s final prioritization decisions are made (by the end of December 2019), the Agency will have a mercury-specific database that includes information for identifying conditions of use and potential exposure scenarios.<sup>40</sup> Based upon these data, the Agency is required to issue an inventory of mercury supply, trade, and use by April 1, 2020, which would further inform EPA’s scoping and risk evaluation processes following the priority designation.

In sum, EPA should recognize that mercury and mercury compounds are a candidate for high-priority listing and risk evaluation because EPA can only carry out the US government’s obligations as a Party to the Minamata Convention on Mercury by applying the TSCA prioritization and risk evaluation process to these substances, and because they fully meet TSCA’S criteria for high-priority chemicals.

### III. LOW-PRIORITY LISTING

The March 21 notice outlines the winnowing process EPA used to select from the TSCA Active Inventory a smaller universe of chemicals warranting evaluation for potential low-priority designation. As described in the notice, EPA’s goal was to identify a subset of Inventory-listed substances that are “best suited” for possible low-priority listing “based on low toxicity, across a range of endpoints.”<sup>41</sup> According to the Agency, the 20 substances for which it has initiated prioritization have a “comprehensive data set

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<sup>35</sup> See <https://www.epa.gov/sites/production/files/2015-06/documents/technical-factsheet-2011.pdf>.

<sup>36</sup> See e.g., ECOS Resolution 16-2 at <https://www.ecos.org/documents/resolution-16-2-reducing-mercury-in-the-environment/>, and <http://www.newmoa.org/prevention/mercury/imerc/about.cfm>.

<sup>37</sup> See <http://www.who.int/mediacentre/factsheets/fs361/en/>; [http://cwm.unitar.org/cwmplatformscms/site/assets/files/1254/mercury\\_timetoact.pdf](http://cwm.unitar.org/cwmplatformscms/site/assets/files/1254/mercury_timetoact.pdf); [https://www.nrdc.org/sites/default/files/hea\\_15062401a.pdf](https://www.nrdc.org/sites/default/files/hea_15062401a.pdf). See also footnote 6.

<sup>38</sup> See 83 FR 30054-77 (June 27, 2018).

<sup>39</sup> See 40 CFR 713.17, as published at 83 FR 30076-77 (June 27, 2018).

<sup>40</sup> In petitions for review currently pending before the United States Court of Appeals for the Second Circuit, NRDC and the State of Vermont are challenging several exemptions to the mercury reporting rule promulgated by EPA. See *Natural Resources Defense Council, Inc. v. United States Environmental Protection Agency, et al.* (Case No. 18-2121); *State of Vermont v. United States Environmental Protection Agency, et al.* (Case No. 18-2670). Those exceptions, NRDC and Vermont contend, unlawfully exempt from reporting (1) manufacturers and importers of mercury-added products in which the mercury is in a component of the larger product; and (2) manufacturers and importers of mercury already reporting to the EPA’s Chemical Data Reporting database. Although NRDC and Vermont believe the mercury reporting rule’s exceptions are unlawful under TSCA, the rule will contribute to the quantity and quality of information available to EPA, regardless of whether the exceptions are upheld. A successful outcome in the litigation will further strengthen the available data on mercury supply and uses.

<sup>41</sup> 84 Fed. Reg. 10495.



demonstrating lower hazard, based on an internationally accepted set of low-concern thresholds for a broad range of end-points, and in view of [their] known, intended and reasonably foreseen uses.”<sup>42</sup>

EPA’s approach leaves many issues unresolved. For example, EPA does not identify the “internationally accepted set of low-concern thresholds” with which it has determined “lower hazard” substances, the “range of endpoints” that it has used to define a “comprehensive data set” or the role of use and exposure in evaluating whether candidate chemicals are low risk.<sup>43</sup> In the next stage of the prioritization process, we look forward to reviewing a fuller description of EPA’s methodology and the detailed hazard and exposure analysis it has performed on specific low-priority listing candidates.

Below, we provide our understanding of the framework TSCA establishes for designating low-priority substances and our recommendations on applying this framework, and then comment on data sources and tools for making the low-priority designation described in the March 21 notice.

#### **A. 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.”

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 hazard or a potential route of exposure.*<sup>44</sup> 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.

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<sup>42</sup> 84 Fed. Reg- 10496-98.

<sup>43</sup> EPA says that it does “not expect estimated exposures to alter the assessment” supporting low-priority listing but does not explain this surprising statement. Under the statutory definition of low-priority substance, exposure levels would only be irrelevant where the absence of any hazard has been demonstrated for all endpoints. However, EPA’s reference to “lower hazard” and “low concern thresholds” seems to recognize that some low-priority candidates have demonstrated toxicity, albeit at high concentrations. In this event, the statutory definition would call for evidence that there is no “potential route of exposure,” as discussed below.

<sup>44</sup> The March 21 notice asserts that a “final designation of a Low Priority substance does not require a finding of no or low risk.” 84 Fed. Reg. at 10492. This cannot be squared with the statutory definition which defines low-priority substances as those which do not meet the criteria for high-priority listing, i.e. because they lack the potential for unreasonable risk. It is hard to understand how a chemical could meet the statutory definition unless it does not present a risk.



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 potential for 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]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>45</sup>

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).

#### **B. To Support a Low-Priority Designation, EPA Must be in Possession of Data for a Broad Range of Health and Ecological Endpoints Developed Using Adequate Test Methodologies**

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 lack of hazard or absence of exposure. If available data demonstrate the lack of hazard for all relevant endpoints as defined by DfE, GreenScreen or other authoritative sources, an assessment of potential exposure may be unnecessary. However, where there is evidence of toxicity for one or more endpoints, EPA must be able to demonstrate the absence of a potential route of exposure that could create a risk of harm for that endpoint. As noted above, where one or more conditions of use could create such a risk, then the substance will not qualify for low-priority listing under the statute. Thus, EPA’s application of the low-priority definition must take into account all the listing candidate’s conditions of use (known, intended, and reasonably foreseen) as defined in section 3(4) of TSCA.

While EPA has recognized that low-priority designations require a “set of high-quality data relevant” to an “internationally accepted list of endpoints,”<sup>46</sup> it needs to identify these endpoints specifically and define the types of studies it deems necessary to establish the absence of hazard for each endpoint.

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<sup>45</sup> 82 Federal Register 4825, 4830 (January 17, 2017).

<sup>46</sup> 84 Fed. Reg. 10495

The well-recognized health endpoints (described above on page 7) that must be well-characterized to support an acceptable risk evaluation on high-priority chemicals under TSCA are the same endpoints for which adequate data must be available to inform low-priority listing decisions under the law. In defining the minimum amount of data necessary to address each endpoint, EPA should draw on the hazard assessment methodologies of other agencies such as the National Toxicology Program (NTP)<sup>47</sup> and the International Agency for Research on Cancer (IARC)<sup>48</sup> and EPA's own risk assessment guidelines, including those for carcinogenicity, reproductive and developmental effects and other endpoints. We strongly encourage EPA to fully describe the endpoints and related testing methodologies on which it will rely in the upcoming Federal Register notice proposing specific substances for low-priority listing.

**C. The Safer Chemicals Ingredients List is a Useful Source of Potential Listing Candidates but EPA Must Itself Independently Compile and Review Available Hazard and Exposure Data on Each Candidate for Listing**

The March 21 notice indicates that EPA initially identified potential low-priority candidates by focusing on “chemicals that had been evaluated by a government body like the U.S. EPA or an OECD member nation.” As explained by the Agency:

“EPA’s Safer Chemicals Ingredients List (SCIL) and Chemical Assessment Management Program (ChAMP), as well as the OECD Screening Information Data Sets, served as sources of government-evaluated chemicals.”<sup>49</sup>

While it is reasonable to focus on previously evaluated chemicals in narrowing the universe of low-priority candidates, these evaluations cannot in themselves demonstrate that a substance meets the TSCA criteria for low-priority designation. Rather, EPA must itself independently compile and review available hazard and exposure data on each candidate for listing.

Of the three sources of listing candidates identified in the March 21 notice, we believe the most useful is EPA’s Safer Chemical Ingredients 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 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. EPA correctly notes that most SCIL-listed chemicals are “relatively rich in data on hazard.”<sup>50</sup> Chemicals on SCIL are assigned one of three geocodes reflecting their hazard profile and available data:

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<sup>47</sup> 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](https://ntp.niehs.nih.gov/ntp/ohat/pubs/handbookjan2015_508.pdf)

<sup>48</sup> 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>

<sup>49</sup> 84 Fed. Reg. 10495

<sup>50</sup> Id.

## Safer Chemical Ingredients List Color Codes

-  **Green circle (605)** - low hazard based on experimental or modeled data.
-  **Green half-circle (102)** - expected to be of low hazard based on experimental or modeled data. Additional data would strengthen our confidence in the chemical's status.
-  **Yellow triangle (210)** - met Safer Choice Criteria for its functional ingredient class, but may raise some hazard profile issues.

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.

While warranting consideration for low-priority listing, Green Circle chemicals will require further evaluation 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 was evaluated for the SCIL listing. EPA would also need to review the adequacy of the data on which the Green Circle designation was based and potentially examine additional hazard endpoints not addressed for the SCIL listing – such as neurobehavioral and functional endpoints, which were critical to identifying the low-dose long-term impacts of developmental neurotoxicants such as lead and mercury. EPA staff with the SCIL program also emphasize these data gaps and information needs.<sup>51</sup> . More detailed exposure data will likely be required as well, including for potentially exposed or susceptible subpopulations. Finally, EPA would need to integrate hazard, exposure and use data and determine whether, as a whole, these data provide “information sufficient to establish” the absence of potential unreasonable risk, as the statute requires for low-priority designation.

We do not support relying on the two other sources EPA has used to identify low-priority listing candidates -- 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 comport with the TSCA definition of low-priority substance and in many cases provide limited data on hazard, exposure and risk. Thus, they would not support low-priority listing under TSCA. While EPA has emphasized that several of the 20 candidate chemicals have been determined to be “low priority for further work” in SIDS initial assessment reports, this determination cannot be equated with a finding that these chemicals *lack potential hazards or a potential route of exposure*, as TSCA requires for low-priority designation.

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<sup>51</sup> EPA. Approaches to Identifying Potential Candidate Chemicals for Prioritization: EPA’s Safer Chemical Ingredients List (SCIL). PowerPoint presentation by Clive Davies and Lauren Sweet. December 11, 2017. [https://www.epa.gov/sites/production/files/2017-12/documents/session\\_3\\_-\\_prioritization-scil\\_v11.pdf](https://www.epa.gov/sites/production/files/2017-12/documents/session_3_-_prioritization-scil_v11.pdf)

**D. NAMs and Data on Chemical Analogs Cannot Compensate for the Absence of Traditional Toxicological Data Except in Rare Instances and Should Play a Limited Role in Supporting Low-Priority Designations**

Finally, EPA has indicated that, in the absence of data from experimental animal studies on candidate chemicals, it may “use alternative means or new approach methods (NAMs) to obtain relevant data” or “consider closely related, analogous chemicals, or analogs, and use data from these chemicals to demonstrate” that the candidate meets the TSCA low-priority criteria.<sup>52</sup> EPA should be extremely cautious in using these approaches to compensate for the absence of experimental data on a relevant endpoint.

In general, NAMs are not sufficiently advanced and scientifically reliable to provide a stand-alone tool for TSCA risk determinations: under section 4(h)(2) of TSCA, these methods can substitute for traditional animal toxicology studies only if they “provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances.”

Similarly, while there are limited circumstances where data on analogs can characterize the effects of an untested chemical with a high level of confidence, there are many other situations where extrapolation from analog data involves considerable uncertainty, and testing on the compound of interest is necessary to provide reliable information for risk evaluation purposes. Since designation of a chemical as low-priority under TSCA connotes the absence of public health concern and the law requires “information sufficient to establish” the lack of potential for hazard or a potential route of exposure, reliance on analog data will only be justified where these data are highly likely to be predictive of the health and environmental effects of the low-priority candidate. Finally, for any chemical where EPA proposes an extrapolation from analog data, EPA must provide sufficient information to evaluate the suitability of the analogue and its relevance for the chemical at issue.

**Conclusion**

We appreciate this opportunity to comment on EPA’s March 21 notice initiating prioritization for 20 high-priority and 20 low-priority chemicals under section 6(b) of TSCA.

If you have any questions, please contact Bob Sussman, SCHF counsel, at [bobsussman1@comcast.net](mailto:bobsussman1@comcast.net).

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<sup>52</sup> 84 Fed. Reg. 10495.

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