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Office of Chemical Safety and  
Pollution Prevention

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## **A Working Approach for Identifying Potential Candidate Chemicals for Prioritization**

### **Summary of Public Comments by Topic**

**September 2018**

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## List of Comment Submitters and Organization Abbreviations Used Throughout

Oral comments were received during the December 11, 2017 Public Meeting. Written comments were submitted to the docket following the meeting. <sup>1</sup>

| Abbreviation | Organization  | Name of Submitter            | Type of Comment  |
|--------------|---|------------------------------|------------------|
| AA           | Alliance of Automobile Manufacturers (Auto Alliance)                  | Stacy Tatman                 | Written          |
| AAP          | American Academy of Pediatrics  | Colleen A. Kraft             | Written          |
| ACA          | American Coatings Association   | Raleigh Davis and Riaz Zaman | Written          |
| ACC          | American Chemistry Council  | Sarah Brozena                | Written and oral |
|              |   | Christina Franz              | Oral             |
|              |   | Rick Becker                  | Oral             |
| ACOG         | American College of Obstetricians and Gynecologists                   | Haywood Brown                | Written          |
| AFL-CIO      | American Federation of Labor and Congress of Industrial Organizations | Rebecca L. Reindel           | Written          |
| AFPM         | American Fuel & Petrochemical Manufacturers                           | James Cooper                 | Written and oral |
| AFSCME       | American Federation of State County and Municipal Employees           | Steven Kreisberg             | Written          |
| AMWA         | Association of Metropolitan Water Agencies                            | Diane VanDe Hei              | Written          |
| APERC        | Alkylphenols & Ethoxylates Research Council                           | Barbara S. Losey             | Written and oral |
| API          | American Petroleum Institute  | Uni Blake                    | Written          |
|              |   | Jessica Ryman-Rasmussem      | Oral             |
| AWWA         | American Water Works Association                                      | G. Tracy Mehan, III          | Written          |
| BCI          | Battery Council International   | Jim Anderson                 | Written          |
|              |   | Saskia Mooney                | Oral             |
| BRAG         | Biobased and Renewable Products Advocacy Group                        | Kathleen M. Roberts          | Written          |
| CSPA         | Consumer Specialty Products Association                               | Timothy A. Brown             | Written          |
| CUC          | Chemical Users Coalition  | Lawrence E. Cullen           | Written          |
| DoD          | Department of Defense   | Unattributed                 | Written          |
| DUC          | Downstream Users Coalition  | Unattributed                 | Written          |
| EDF          | Environmental Defense Fund  | Lindsay McCormick            | Written and oral |
|              |   | Rob Stockman                 | Oral             |
|              |   | Richard Denison              | Oral             |
|              |   | Stephanie Schwarz            | Oral             |
| ES           | Endocrine Society   | Angel Nadal                  | Written          |
| EWG          | Environmental Working Group   | Melanie Benesh               | Written and oral |
|              |   | Alexis Temkin                | Oral             |
| -            | Gradient  | Lorenz Rhomberg              | Written and oral |
| GSPI         | Green Science Policy Institute  | Mary Grant                   | Oral             |
| HSUS         | The Humane Society of the United States                               | Catherine Willett            | Written and oral |
| IFRANA       | International Fragrance Association North America                     | Amanda K. Nguyen             | Written          |
| -            | March of Dimes  | Paul E. Jarris               | Written          |
| NABTU        | North America's Building Trades Unions                                | Chris Trahan Cain            | Written          |
| NAMC and NMA | North American Metals Council and National Mining Association         | Kathleen M. Roberts          | Written          |
| NRDC         | Natural Resources Defense Council                                     | Daniel Rosenberg             | Written (2)      |

<sup>1</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control#12/11>

| <b>Abbreviation</b> | <b>Organization</b>   | <b>Name of Submitter</b>                | <b>Type of Comment</b> |
|---------------------|---|---|------------------------|
| PCRM                | Physicians Committee for Responsible Medicine                                   | Esther Haugabrooks and Kristie Sullivan | Written and oral       |
| PETA                | People for the Ethical Treatment of Animals                                     | Joseph Manuppello                       | Written                |
| PLASTICS            | Plastics Industry Association   | Marie Gargas                            | Written                |
| SCHF                | Safer Chemicals Healthy Families et al.   | Elizabeth Hitchcock                     | Written                |
|                     |   | Bob Sussman                             | Oral                   |
| SEHSC               | American Chemistry Council's Silicones Environmental, Health, and Safety Center | Karluss Thomas                          | Written                |
| -                   | Soleil Consulting   | Bill Greggs                             | Oral                   |
| SIRC                | Styrene Information and Research Center   | Ray Ehrlich                             | Written (2)            |
| SOCMA               | Society of Chemical Manufacturers and Affiliates                                | Jared Rothstein                         | Written                |
|                     |   | Robert Helminiak                        | Oral                   |
| SSI                 | Silent Spring Institute   | Jessica Helm and Kathryn Rodgers        | Written                |
| UCB                 | UC Berkeley   | Amy D. Kyle                             | Written                |
| UCSF                | University of California, San Francisco et al.                                  | Veena Singla                            | Written and oral       |
| USCC                | US Chamber of Commerce  | Neil L. Bradley                         | Written                |
| -                   | Unaffiliated  | Dr. Lih Young                           | Written and oral       |
| -                   | N/A   | Anonymous                               | Written (10)           |

## General Considerations for Prioritization

- EPA should not pursue prioritization tools that consider speculative uses for chemicals nor sorting approaches that are strictly “hazard-driven” given current time and resource constraints. *(Lawrence E. Culleen, CUC)*
- EPA should select initial candidates for prioritization that present potential risk concerns and have sufficient data (including exposure and use information) already in EPA’s possession to permit prioritization decisions to be made on the basis of risk, rather than hazard alone. *(Lawrence E. Culleen, CUC; Amanda K. Nguyen, IFRANA)*
- EPA should give chemical hazard priority consideration over exposure estimates when evaluating chemicals for potential prioritization. *(Angel Nadal, ES; Veena Singla, UCSF)*
- In the final approach adopted by EPA, chemical hazard should be given priority over exposure considerations because chemical uses can change over time, thus altering the anticipated exposures. *(Veena Singla, UCSF)*

Response: EPA agrees with the comments that the selection of candidates should be based on both hazard and exposure, as a risk-based approach is required under TSCA. One of EPA’s guiding principles is that the approach to identifying potential candidates for prioritization should be risk-based, and therefore consider hazard and exposure in the prioritization process. EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient for a particular purpose (e.g. sufficient to support a proposed designation that a chemical substance meets the definition of high- or low-priority substance).

- EPA should avoid a bias toward information-rich chemicals. There are currently thousands of chemicals on the market that lack even basic information on their health and environmental impacts. EPA should aggressively use its mandatory authorities to obtain information on chemicals, especially where little information exists, to limit such bias. *(Lindsay McCormick, EDF)*
- Prioritizing data rich chemicals over chemicals which pose greater risks is misguided and not in accordance with law. Chemicals with a large volume of extant data are, by definition, better researched and better understood than other chemicals. This typically means that exposure routes, risks, and health impacts (if any) are already known to industry and regulators, and are likely already well-controlled. *(Jim Anderson, BCI; Saskia Mooney, BCI)*

Response: EPA must keep in mind the statutory deadlines and the numbers of chemicals that must be prioritized and evaluated for risk. Therefore, EPA must balance the need to adhere to TSCA deadlines with chemicals that have sufficient information to perform a risk evaluation. EPA is working with industry to collect additional information, including the range of conditions of use and anticipated exposure pathways.

- EPA should focus its attention and resources on the methods that are most developed and useful for prioritizing chemicals under the specific terms of the revised TSCA – the Work Plan method for high priority substances and the SCIL method for low priority determinations. *(Daniel Rosenberg, NRDC)*

Response: EPA agrees with the commenter and expects to look to the 2014 Update to the TSCA Work Plan, and use chemical reviews from government entities, such as EPA’s Safer Chemical Ingredients List (SCIL), to choose the next chemicals for Prioritization.

- Some of EPA’s “guiding principles” for developing its approach to prioritization (and pre-prioritization) are based on non-risk factors, which is inconsistent with the statute. (*Daniel Rosenberg, NRDC*)
  - Guiding principle 8 seeks to diminish industry’s concern about “stigmatizing” chemicals before they are designated high priority chemicals. This principle is clearly a “non-risk” factor expressly precluded from consideration during the prioritization process. (*Daniel Rosenberg, NRDC*)
- Non-risk factors, including availability of substitutes, should not be considered while identifying potential candidates for prioritization. (*Lindsay McCormick, EDF*)

Response: The commenters are correct that during prioritization and risk evaluation the Agency cannot consider non-risk factors. However, TSCA does not require EPA to develop a pre-prioritization process, so therefore the Agency does not have to follow the statutory requirements for prioritization/risk evaluation. Guiding principle 8 states, “EPA should balance transparency and stakeholder concerns over stigmatization associated with candidate lists. EPA should avoid approaches that could lead to public misperception on risks, while also striving for transparency on how potential high-priority and low-priority candidates are identified.” The goal of this principle was more concerned with EPA’s approach to announcing/communicating a list of candidates for prioritization, and not about how a specific chemical will be evaluated for consideration as a candidate for prioritization.

- Many TSCA chemicals have multiple uses—industrial, commercial and consumer uses. Some categories of uses pose greater potential for exposure than others and there must be a recognition that the risks from many categories of uses are deemed negligible or already well controlled. (*DUC*)
- EPA should utilize a preliminary risk screening statement to communicate as early as justified that some substances under certain conditions of use are unlikely to present a high risk based on existing data. (*DUC*)
- EPA should prioritize candidates with potential risks best addressed by a TSCA regulation, rather than other authorities. If the primary uses underlying perceived risk could be regulated under other industry- or process-specific programs (e.g., air, water, or occupational standards), at the pre-prioritization stage, strong consideration should be given to referring further evaluation and decisions to other EPA program offices in lieu of proceeding under TSCA, which remains a gap-filler statute. This frees TSCA resources to focus on substances of concern for which TSCA may be the only practicable review and control mechanism. (*Ray Ehrlich, SIRC*)
- Pre-prioritization should consider existing regulations as part of the risk or safety projections. (*Ray Ehrlich, SIRC*)

Response: TSCA requires EPA to evaluate a chemical substance “under the conditions of use”. During pre-prioritization EPA is proposing that the complete range of uses must be determined for an effective assessment of the data needs. Additionally, as stated in the prioritization rule, EPA must designate the chemical as high or low priority, not just specific uses. During risk evaluation, EPA will conduct fit for purpose evaluations (taking into consideration existing regulations) and may indicate early that there are uses that are likely to pose less risk than others.

- EPA must prioritize chemicals that could potentially impact drinking water in whatever method(s) it should use during the pre-prioritization process. *(Diane VanDe Hei, AMWA)*

Response: The commenter is correct that during prioritization the Agency must a chemical's storage near significant sources of drinking water, among other criteria. However, TSCA does not require EPA to develop a pre-prioritization process, so therefore the Agency does not have to follow the statutory requirements for prioritization/risk evaluation during pre-prioritization.

- EPA should lean on the more protective and conservative side when prioritizing chemicals. *(Diane VanDe Hei, AMWA)*

Response: During prioritization, EPA must utilize the definitions provided in TSCA for high- and low-priority chemicals. EPA believes these are protective and conservative and adhering to the prioritization rule will ensure that those chemicals that “may present an unreasonable risk” will receive a risk evaluation.

- EPA should implement a hierarchy of controls models when addressing chemical exposure. *(Steven Kreisberg, AFSCME)*
- EPA's approach should effectively and efficiently fulfill the policy and intent of Congress for the risk-based screening process of prioritization described in the statute: *(Ray Ehrlich, SIRC)*

Response: Much of this will be addressed in risk management after a risk evaluation is complete and if unreasonable risks are found.

- EPA should consider potential substitute chemicals that have similar forms and function. Regulating a chemical and not informing the public of a safer alternative can lead to the use of a toxic substitute. *(Steven Kreisberg, AFSCME)*
- Alternatives analysis may be useful during risk management proceedings, but it is an extra-statutory effort and should not be considered in pre-prioritization. *(Ray Ehrlich, SIRC; Kathleen M. Roberts, NAMC and NMA)*

Response: In the prioritization rule, based on comments that substitutes are “non-risk factors” that cannot be considered during prioritization, EPA agreed that the consideration of alternatives is most appropriated considered as part of any risk management rule, rather than during prioritization. However, because pre-prioritization is not required under TSCA, EPA may consider substitutions in the pre-prioritization process of identifying potential candidate chemicals.

- EPA must articulate organizing principles for pre-prioritization. Because TSCA Section 6 implementation must fully implement statutory requirements and goals, those factors must be fundamental to the pre-prioritization process. *(Ray Ehrlich, SIRC)*
  - Pre-prioritization should focus on identifying substances that should be reviewed first in accord with the prioritization goal, and then determining whether available information can support a timely prioritization determination. *(Ray Ehrlich, SIRC)*

Response: EPA believes we are developing a process that does just this. Our long-term approach looks to bin chemicals based on hazard and exposure potential based on available information.

- No existing approach was designed to meet the statutory requirements or longer term policy objectives of the amended TSCA. EPA must develop a new, purpose-built approach. Key elements include the intent to review all chemicals on the TSCA Inventory over an extended period, discretion to determine which “uses” will be reviewed during risk evaluation, the requirement to draw prioritization candidates first from the 2014 Work Plan with preference for chemicals with high persistence and bioaccumulation scores, or are both known human carcinogens and have high chronic and acute toxicity, and the obligation to maintain a certain pace. *(Ray Ehrlich, SIRC)*

Response: EPA agrees with this comment, and has developed a two-pronged approach that addresses both short-term and long-term needs. EPA does plan to review the active chemicals on the TSCA inventory, starting with those on the 2014 Update to the Work Plan.

- The process needs a defined exit or off ramp if the chemical does not appear to be a good prospect for a prioritization rule making. *(Ray Ehrlich, SIRC)*

Response: EPA does not expect the pre-prioritization phase to include a ranked list of chemicals that will come up one-by-one for prioritization, but rather ‘bins’ of chemicals that are candidates for prioritization.

- To be workable, pre-prioritization must not be an exhaustive information search and analysis, but predicated on readily available information and tentative evaluations. *(Ray Ehrlich, SIRC)*
- The pre-prioritization period is a key opportunity for stakeholders to share information and knowledge regarding data, research, and documents on specific chemicals that can enhance the Agency’s capacity to look at forthcoming research and emerging issues rather than continue to reflect on pre-existing work. *(G. Tracy Mehan III, AWWA)*
- If EPA chooses to develop a pre-prioritization phase, the Agency should utilize complete and high-quality data and make all related decisions in a transparent manner. *(Neil L. Bradley, USCC)*

Response: EPA expects that much of the effort associated with pre-prioritization will be determining the information landscape, both quantity and quality of information available, to perform both prioritization as well as risk evaluation on chemicals. What the Agency is looking to avoid is the situation that a chemical enters prioritization only to discover there is insufficient data to perform prioritization and risk evaluation. Therefore, EPA must undertake information gathering during this stage so that transparent decisions can be made. EPA is looking for ways to actively engage

stakeholders to share information and the first step of this is opening a docket for each of the remaining 73 2014 Work Plan chemicals<sup>2</sup>.

- There is agreement with EPA's position that pre-prioritization efforts should focus first on those chemicals listed as "active" on the TSCA Inventory. This allows EPA resources to be properly allocated to those chemicals that are likely in commercial distribution. (*Kathleen M. Roberts, NAMC and NMA; Kathleen M. Roberts, BRAG*)
- Inactive chemicals should be considered as potential candidates for prioritization. (*Lindsay McCormick, EDF; Daniel Rosenberg, NRDC*)
- EPA should focus on the Active portion of the TSCA Inventory when identifying candidates for prioritization. (*James Cooper, AFPM; Raleigh Davis, ACA*) There is agreement with the Agency's assertion that "active chemicals may have a greater potential for exposure," which is clearly outlined in the seventh guiding principle. While there may be rare cases of legacy chemicals posing risks, the Agency has the necessary flexibility and discretion to address those risks. (*James Cooper, AFPM*)

Response: At this time, EPA plans to focus on the active TSCA inventory. EPA believes this is a more effective use of resources, and a more effective strategy to identify those chemicals that may currently pose risk under their conditions of use.

- Pre-prioritization decisions should utilize non-vertebrate animal methods wherever practicable. (*Amanda K. Nguyen, IFRANA*)

Response: Pursuant to TSCA section 4(h), EPA must develop a Strategic Plan to promote the use and development of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing. In the Strategy, released June 22, 2018, EPA states that alternative test methods would be effective tools for the pre-prioritization process, and intends to use these during the long-term approach for binning the active inventory.

- EPA needs an effective communications effort to minimize the potential for stigmatization of chemicals on priority and other lists. This stigmatization can lead to potential market deselection, which can be disruptive to producers and users along the manufacturing supply chain, create advantages for replacement chemicals that have not been fully evaluated for risk or efficacy and, ultimately, cause irreparable damage to companies and supply chains. (*James Cooper, AFPM*)

Response: In an effort to minimize stigmatization of chemicals for the first 20 low and 20 high, EPA intends to choose the first 20 high-priority chemicals from the 2014 Update to the Work Plan, and

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<sup>2</sup> The 2014 Work Plan chemicals list consists of 90 chemicals. With the passage of amended TSCA, EPA was required to select the first 10 chemicals to undergo risk evaluations from the 2014 Update to the TSCA Work Plan. These 10 chemicals were announced on December 16, 2016. TSCA section 6(h) requires EPA to take expedited regulatory action under section 6(a) without a risk evaluation for PBT chemicals from the 2014 Update of the Work Plan Chemicals. Five chemicals meet the requirements of TSCA section 6(h). Manufacturers made requests for two chemicals that are listed in the 2014 Update to the TSCA Work Plan under Section 6(b)(4)(C).

use the SCIL to identify potential low priority chemicals, lists that have existed for many years. When initiating prioritization, EPA must provide a general explanation for why it chose to initiate the process on a chemical substance, which will likely indicate whether EPA expects the chemical to be of high- or low-priority designation. However, EPA will be clear to state that it is only after the risk evaluation is complete, that EPA will make a determination as to whether the chemical presents unreasonable risk.

- The significance of toxicity and exposure over time are quite different. While the intrinsic toxicity of a chemical is not likely to change, the opposite is true for exposure. Many factors can increase or decrease exposure or change the populations that are affected by exposure. EPA needs the ability to escalate management of a chemical that has not changed toxicity but for which exposure has increased or changed. This suggests that only chemicals with low toxicity, persistence, and tendency to bioaccumulate should be considered to be low priority. *(Amy D. Kyle, UC Berkeley)*

Response: EPA will take reasonably available exposure information into account when conducting prioritization.

### Transparency and Public Participation

- EPA should be transparent about the process used to evaluate chemicals for prioritization. *(Angel Nadal, ES; Lindsay McCormick, EDF; Karluss Thomas, SEHSC; Ray Ehrlich, SIRC; Kathleen M. Roberts, BRAG, NAMC and NMA; Stacy Tatman, AA; Sarah Brozena, ACC; Barbara S. Losey, APERC; Chris Trahan Cain, NABTU; Amanda K. Nguyen, IFRANA; James Cooper, AFPM; Lindsay McCormick, EDF; Timothy A. Brown, CSPA; Marie Gargas, PLASTICS; Esther Haugabrooks, PCRM; Daniel Rosenberg, NRDC; Jessica Ryman-Rasmussem, API; Alexis Temkin, EWG; Robert Helminiak, SOCMA)*
  - EPA should make its pre-prioritization working papers available on its website. *(Stacy Tatman, AA)*
  - EPA should incorporate a transparency component in the process with a similar premise to the Public Activities Coordination Tool (PACT) used by the European Chemicals Agency (ECHA). If EPA uses this approach to enhance transparency, the Agency needs to communicate to the public that the substances listed are simply in a review process and are not suspected to be targets of regulatory risk management activities. EPA should also manage the information shared by stakeholders to avoid the misuse of the tool. *(Uni Blake, API; Jessica Ryman-Rasmussem, API)*
- EPA should be transparent about its information needs. *(Jared Rothstein, SOCMA; Marie Gargas, PLASTICS; Lorenz Rhomberg, Gradient)*
  - EPA should ensure that the methods for choosing the prioritization nominees have a clear and publicly stated way to address the information-completeness criteria. *(Lorenz Rhomberg, Gradient)*

Response: In the associated White Paper EPA has described EPA's approach to data sufficiency and collection. In the short term, EPA will look to the 2014 Update to the TSCA Work Plan for high priority candidate chemicals, and use chemical reviews from government entities, such as the Safer

Chemical Ingredients List (SCIL), to choose low priority candidate chemicals for Prioritization. EPA's longer-term approach is intended to provide transparency to the methodology used for chemicals beyond the 2014 Update to the TSCA Work Plan.

- EPA should initiate the formation of a working group. The volunteer working group should be convened to develop the oil industry's approach to selecting chemicals for prioritization. The working group may further develop the approach outlined above and develop an implementation strategy that aligns with EPA's amended TSCA implementation. Members of the working group may include EPA representatives, stakeholder organizations (including API) and subject matter experts. *(Uni Blake, API)*

Response: EPA encourages stakeholders to provide comment regarding selection of chemicals and/or approaches.

- When seeking information from stakeholders for prioritization, EPA should accept existing summary formats. Information provided by stakeholders should not require a new format. *(James Cooper, AFPM)*

Response: EPA agrees with this comment, and expects to accept information in existing formats.

- EPA should request voluntary submissions of information to avoid costly rulemaking and to help keep the timing of prioritizations on track. In the event that voluntary submissions are not forthcoming, the Agency can use its authority under Sections 8(a) or 8(d) to collect information it needs to prioritize chemicals. As a last resort, if the Agency still lacks the necessary information, EPA should use its authority under Section 4. *(James Cooper, AFPM)*

Response: EPA agrees with this comment, and as stated in the prioritization rule, EPA expects to use a tiered approach for data gathering. First the Agency expects to review of existing literature and available information. For identified data needs, we expects to issue a voluntary call to the public for relevant information or engage directly with stakeholders, and expects that will be followed as necessary by exercising of EPA's authorities under TSCA to require submission or generation of new data.

- As part of pre-prioritization, EPA should notify stakeholders that it may initiate prioritization for specific chemicals. This will give stakeholders notice and incentive to develop or gather information to voluntarily submit to EPA. This incentive to provide information to EPA is particularly important given the workload and resource constraints. The auto industry has strived to provide useful information to EPA in the past by submitting formal comments, providing requested data information, and attending meetings, and welcomes the opportunity to do so during the pre-prioritization process as well. *(Stacy Tatman, AA)*
- Well-informed selections for prioritization will help prevent unwelcome surprises, both for the regulated community and for EPA. The regulated community could productively gather information in selecting candidate chemicals during pre-prioritization. This will help ensure that EPA's decisions during the prioritization process are well informed and not rushed and that chemicals are not misidentified. *(Stacy Tatman, AA)*
- The pre-prioritization process should encourage dialogue between EPA and industry and should utilize industry sources of information, particularly about the uses and exposures of chemicals.

The process might include Notices in the Federal Register requesting information and a Docket to collect written comments, public meetings and most importantly meetings and direct dialogue with manufacturers, processors and/or users. *(Barbara S. Losey, APERC)*

- EPA should publish for comment the selection process for prioritization that not only includes the criteria and factors it intends to use for decision-making, but also the relative weight given to each factor. When finalized, this approach or algorithm should be open source and reproducible by interested stakeholders. Finally, this algorithm should be evergreen, with regular reviews and updates to account for changing methodologies and data sources. The Agency should document in its pre-prioritization proposal how it will keep the process evergreen. *(James Cooper, AFPM)*
- In general, the sooner EPA can give notice to stakeholders of its intent to prioritize a particular chemical, the better. Gathering data will take time and EPA does not have the resources to perform the testing itself, so will need to rely on data submitted by regulated entities. *(DUC)*
- At a minimum, the pre-prioritization process requires the following elements of stakeholder involvement:
  - EPA should establish a new docket any time it starts to gather information on a chemical or category of chemicals.
  - EPA should alert the public as soon as such a docket is created. This alert should include instructions on how interested persons could submit information on a chemical or chemical category.
  - EPA should promptly make available in each docket all information and analyses EPA has assembled or generated for decision making, as well as any submitted by members of the public with appropriate CBI protection.
  - The dockets should be public, but enable submitters to assert CBI claims.
  - EPA should clarify exactly what information needs it has identified for each chemical or category, and what information would satisfy that need.
  - EPA should assign a responsible Agency official to each docket. *(Amanda K. Nguyen, IFRANA; Robert Helminiak, SOCMA)*
- EPA should develop some kind of public evaluation of chemicals – and their exposures and available data – for those chemicals not yet nominated for prioritization. Making such evaluations public would let stakeholders see where the next prioritization candidates are likely to come from. It would permit and encourage development of needed information to enable a full analysis. *(Lorenz Rhomberg, Gradient)*
- EPA should provide opportunities for stakeholder/public input. *(Amanda K. Nguyen, IFRANA; James Cooper, AFPM; Timothy A. Brown, CSPA; Lawrence E. Culleen, CUC)*
- EPA should communicate clearly about what prioritized chemicals are. *(Stacy Tatman, AA; DUC; Sarah Brozena, ACC; James Cooper, AFPM)*

Response: EPA appreciates stakeholder involvement in this process and looks to continue to develop ways to encourage and continue this collaboration. For the next potential high-priority chemicals, EPA expects to look to the 2014 Work Plan primarily. To gather information from stakeholders, EPA has opened a docket for each of the 73 remaining chemicals and encourages submission of any information, including CBI, that may be useful during prioritization, and risk evaluation if required. EPA may also share information and analysis through these dockets. EPA is in

part choosing chemicals from the 2014 Work Plan in an effort to thwart ‘unwelcome surprises’, as these chemicals are relatively information rich and have been on this list for many years. The long-term approach described in the associated white paper provides transparency as to the information availability and cursory screening. The hope is that with time the Agency will continue to build upon this tool, providing additional transparency regarding subsequent potential candidates for prioritization. EPA is aware of the potential that certain chemicals may be stigmatized and we intend to clearly communicate our findings at each step. EPA intends to be very clear that the identification of potential candidates for prioritization is not a finding of risk.

## Process

- There is support for EPA’s decision to separate the development of the pre-prioritization process from the more formal prioritization process. (*Raleigh Davis, ACA*)
- EPA should consider some way to formalize the pre-prioritization process, since it is not going to be statutorily driven. (*James Cooper, AFPM*)
- Given the Agency’s and the public’s limited experience with pre-prioritization and its central role in defining the Agency’s risk evaluation work flow, the pre-prioritization process should be flexible. (*Ray Ehrlich; Lindsay McCormick, EDF; Timothy A. Brown, CSPA; Bill Greggs, Soleil Consulting*)
  - However, EPA should be intentional and transparent about any changes to procedures and priorities, to encourage planning and avoid the perception of arbitrary action. (*Ray Ehrlich, SIRC; Sarah Brozena, ACC*)
  - EPA is authorized to develop a short term approach to identify potential candidates for the prioritization process now, but the law also requires EPA to update its methodologies, data and information over time. (*Sarah Brozena, ACC*)
  - The process for identifying potential candidates for prioritization should not be overly formalized or regimented. (*Lindsay McCormick, EDF*)

Response: At this time EPA does not intend to undertake rulemaking to formalize pre-prioritization. EPA believes that rulemaking would not provide enough flexibility to implement an effective program. EPA expects to have to balance the need to evaluate potentially risky chemicals, with sufficiency of information, with the rigorous TSCA timelines. EPA believes that rulemaking would create too stringent a process. EPA will be transparent, but for the near-term this will be a learning by doing process. EPA does commit to reevaluating the process in the coming years after we have implemented the program.

- EPA should provide an adequate amount of time between identifying a possible candidate within the pre-prioritization phase and starting the prioritization process. This is particularly important if the Agency intends to rely heavily on information from the public and industry as is stated in the document. (*Diane VanDe Heij, AMWA*)
- All factors to be reviewed in the prioritization and risk evaluation process should be collected during the pre-prioritization phase so that the Agency can ensure there is sufficient data to evaluate the factors effectively before initiating the prioritization process. (*G. Tracy Mehan III, AWWA; Elizabeth Hitchcock, SCHF*)

Response: EPA expects that much of the effort associated with pre-prioritization will be determining the information landscape, both quantity and quality of information available, to perform both

prioritization as well as risk evaluation on chemicals. What the Agency is looking to avoid is the situation that a chemical enters prioritization only to discover there is insufficient data to perform prioritization and risk evaluation. Therefore, EPA must undertake information gathering during this stage so that transparent decisions can be made. Regarding the timing between identifying possible candidates and initiating prioritization, EPA expects pre-prioritization to be an ongoing process of analyzing and collecting information to sort chemicals into bins depending on their potential risk and readiness for prioritization.

- None of the proposed approaches fully explains how an individual chemical within the process would be selected. For example, if EPA uses the TSCA Work Plan as the approach for pre-prioritization, how will the next five or six chemicals be selected from the remaining chemicals on the list? Would they be selected randomly, and if so, by what randomization mechanism? Would staff choose them based on expertise with those chemicals or use patterns? *(Kathleen M. Roberts, NAMC and NMA)*

Response: In the associated White Paper, EPA has presented both a short-term and long-term approach for selecting chemicals to address this comment. The methods presented here would maintain EPA's flexibility and ability to consider the multiple factors addressed in the White Paper.

- One of the perceived failures of old TSCA was the lack of risk evaluation on existing chemicals. To address this issue, EPA should adopt a pre-prioritization approach that assesses whether a candidate chemical has already been reviewed and chemicals that have not undergone any assessment should be among the first candidates to undergo prioritization. *(Kathleen M. Roberts, NAMC and NMA)*
- In addition to Section 5 reviews, EPA should also consider whether the candidate chemical has been evaluated under other regulatory or scientific programs, including the European Union REACH program. *(Kathleen M. Roberts, NAMC and NMA; DUC)*

Response: EPA expects that much of the effort associated with pre-prioritization will be determining the information landscape, both quantity and quality of information available, to perform both prioritization as well as risk evaluation on chemicals, and this would include any previous work by OPPT or others that meets TSCA requirements. What the Agency is looking to avoid is the situation that a chemical enters prioritization only to discover there is insufficient data to perform prioritization and risk evaluation. Due to the rigorous timeframes of TSCA, it will be important to identify those chemicals for which there is sufficient information to conduct risk evaluation, as well as those for which there are gaps. If there are gaps in information, EPA expects to implement a tiered approach to data collection.

### *Criteria*

- EPA should focus its selection criteria on exposure, not production volume. *(Ray Ehrlich, SIRC)*
- The criteria Congress set forth in Lautenberg TSCA Section 6(b) that EPA must consider for prioritization should also guide the pre-prioritization process, including vulnerable populations and exposure potential metrics such as production volume and proximity to drinking water sources. *(Veena Singla, UCSF)*

- The Agency has yet to address critical components of the pre-prioritization process, including the statutory requirement that "storage of chemicals near significant sources of drinking water" be a screening criterion in the prioritization process. (*G. Tracy Mehan III, AWWA*)

Response: In the near term, EPA expects to select the 20 potential high-priority candidate chemicals for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 73 remaining chemicals listed under the 2014 Work Plan. These chemicals may be more suitable for prioritization and risk evaluation than others with respect to available information quantity and quality. In addition to the quantity and quality of the information, EPA expects to consider Agency and inter-agency priorities and overall workload. EPA also acknowledges that due to heightened interest, chemical(s) not on the 2014 Work Plan may be selected for prioritization. For low priority substances, EPA intends to select candidates that have been reviewed by government entities, such as the Safer Chemical Ingredients List (SCIL). EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient to support a proposed designation that a chemical substance meets the definition of a high or low priority substance, and this will include consideration of information and analysis done by others (i.e. Office of Groundwater and Drinking Water) . EPA might consider during pre-prioritization some of the criteria from TSCA section 6(b)(1)(A) (e.g. potentially exposed or susceptible subpopulations, production volume, storage near significant sources of drinking water) to better inform the selection of candidate chemicals for prioritization, as appropriate, for example, to decide if the available data is sufficient to support a high or low priority designation. For Low Priority Substance candidates, quantitative exposure information is often unavailable. In these cases, EPA may use surrogate information, such as production volume rather than direct exposure estimates.

- EPA should clearly define the data needed to make a determination that a chemical does not pose particular hazards—i.e., is not a carcinogen, is not a developmental or reproductive toxicant, etc. EPA’s definition should be informed by, and consistent with, established approaches of other agencies such as the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), and EPA’s own guidelines including the Cancer Guidelines. (*Veena Singla, UCSF*)

Response: EPA believes it is premature at this stage of its implementation of the new statutory program to set overly prescriptive requirements. Accordingly, EPA has not codified a list of specific information sources in the prioritization rulemaking, or otherwise limited the information sources to be used in decision making under TSCA. Also, EPA has declined to publish a bright line rule for “sufficiency” of information. EPA will generally review the reasonably available hazard and exposure information. EPA expects its approach for selecting candidates for prioritization to evolve over time as it develops its expertise selecting chemicals to enter prioritization, and conducting prioritizations, as well as in conducting prioritization and risk evaluations.

- The processes outlined in the Discussion Document do not seem equipped to properly screen UVCB Substances. Given the number of UVCBs on the TSCA Inventory, this exclusion could be problematic and should be addressed. (*Kathleen M. Roberts, NAMC and NMA*)

Response: EPA's long-term goal is to develop a risk-based strategy for selecting candidates for prioritization that integrates data from new approach methodologies (NAMs)<sup>3</sup> and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. This strategy, would consider all chemicals in the active inventory, including UVCBs.

- Legacy uses must be incorporated into any approach for identifying risk evaluation priorities. *(Chris Trahan Cain, NABTU; Lindsay McCormick, EDF)*

Response: EPA has indicated that it will not consider legacy uses as conditions of use (82 FR 33729-33730) during risk evaluation.

- EPA must include imported toxic substances into any approach for identifying risk evaluation priorities. *(Chris Trahan Cain, NABTU)*
- EPA has acted on chemicals with existing OSHA regulations, and existing regulations do not prohibit EPA from taking action where there may be risk. According to Section 9, EPA can designate chemicals as high priority where: 1) other agencies cannot or will not adequately regulate a substance, or 2) the substance is already regulated, albeit ineffectively, by another agency, such as OSHA. *(Rebecca L. Reindel, AFL-CIO)*

Response: EPA appreciates stakeholder comment related to imported substances, and existing OSHA regulations and TSCA section 9 implementation. EPA will consider these comments on a chemical-by-chemical basis during risk evaluation and risk management.

- To evaluate and prioritize chemicals for potential endocrine effects EPA should:
  - (i) Publish studies demonstrating the validity of the proposed ER and AR assays and their ability to predict endocrine effects.
  - (ii) Incorporate models that allow for low-dose effects and NMDR.
  - (iii) Survey the academic literature to identify chemicals with potential effects on the endocrine system, especially for chemicals that may affect pathways not covered by the ER and AR assays. For example, interactions with the progesterone and vitamin D receptors may have deleterious effects. *(Angel Nadal, ES)*

Response: EPA intends to review and evaluate available hazard and exposure data for chemicals, including evidence of endocrine activity as it relate to endpoints such as reproductive and developmental effects.

### *Susceptible Subpopulations*

- EPA must address potentially exposed or susceptible subpopulations in its process for identifying potential candidates for prioritization. *(Lindsay McCormick, EDF; Rebecca L. Reindel, AFL-CIO; Steven Kreisberg, AFSCME; Chris Trahan Cain, NABTU; Paul E. Jarris, March of Dimes; Haywood Brown, AGOC; Colleen A. Kraft, AAP; Amy D. Kyle, UC Berkeley; Alexis Temkin, EWG; Veena Singla, UCSF)*

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<sup>3</sup> The term NAMs was recently introduced to cover any *in vitro*, *in silico*, or *in chemico* technique used to provide data or information for regulatory decision making (ECHA, 2016).

- EPA should clearly articulate specific susceptible subpopulations according to key toxicological or exposure characteristics. When selecting chemicals for prioritization, and in subsequent steps in the prioritization and risk evaluation process, EPA should identify specific subpopulations at risk and clearly explain the toxicological and exposure characteristics that place those subpopulations at risk. *(James Cooper, AFPM)*

Response: EPA agrees with commenters regarding the importance of ensuring protection for potentially exposed and susceptible subpopulations. TSCA mandates that EPA consider “potentially exposed or susceptible subpopulations” during prioritization. While “potentially exposed or susceptible subpopulations” is a new definition to TSCA, EPA has in practice evaluated risk across populations, including infants, children and pregnant women, where appropriate under the conditions of use for a particular chemical substance. EPA intends to continue to consider potentially exposed and susceptible subpopulations during prioritization and risk evaluation, where appropriate under the conditions of use for a particular chemical substance.

- In addition to TSCA, EPA must comply with its environmental justice obligations under the Executive Order (EO) 12,898. EPA’s environmental justice analysis should consider both exposure and susceptibility. *(Lindsay McCormick, EDF)*

Response: EPA agrees with the commenter and in upholding the definition of “potentially exposed or susceptible subpopulations” and the mandate to consider risk (hazard and exposure) EPA must consider exposure and susceptibility during prioritization and risk evaluation.

#### Workers

- EPA must consider potential chemical exposure of susceptible subpopulations, including workers. Occupational exposure should be included in the methodologies used to prioritize chemicals. *(Steven Kreisberg, AFSCME; Chris Trahan Cain, NABTU; Rebecca L. Reindel, AFL-CIO)*
- Given the number of construction workers in this growing industry and the variety of chemicals to which they are exposed, approaches that do not include workplace exposures in the construction industry – even though they may require the collection of new information – would be invalid. *(Chris Trahan Cain, NABTU)*
- EPA must specifically examine chemicals with serious occupational exposures, whether or not they come from the Work Plan. *(Rebecca L. Reindel, AFL-CIO)*
- Lawmakers recognized that OSHA 1) cannot regulate, enforce or compel data from manufacturers, 2) cannot ban a chemical, and 3) has not required substitution with a safer chemical or process; but that EPA can take all of these actions. If EPA determines that a chemical may pose an unreasonable risk to workers, it has a duty to act. LSCA was passed to strengthen, EPA’s role in workplace protections against toxic substances. *(Rebecca L. Reindel, AFL-CIO)*
- Many workers in the U.S. are not covered by the OSH Act. OSHA does not have the capacity and level of authority that EPA has. Congress specifically provided that both EPA and OSHA may regulate a chemical’s use and that action by EPA does not preempt OSHA from taking regulatory action. *(Rebecca L. Reindel, AFL-CIO)*
- EPA should be meeting with worker protection agencies OSHA and NIOSH to exchange information on sources of data, methodologies, criteria documents and other issues, but EPA must ensure the risk is addressed. *(Rebecca L. Reindel, AFL-CIO)*

Response: EPA agrees with commenters regarding the importance of ensuring protection for workers. TSCA mandates that EPA consider “potentially exposed or susceptible subpopulations” during prioritization and risk evaluation. While “potentially exposed or susceptible subpopulations” is a new definition to TSCA, EPA has in practice evaluated risk across populations, including workers. EPA intends to continue to consider occupational exposures during prioritization and risk evaluation, where appropriate under the conditions of use for a particular chemical substance.

EPA recognizes the value of coordinating closely with our Federal partners on matters pertaining to chemical safety, and is committed to continuing to coordinate as the Agency works to implement TSCA, including exchanging information and methodologies with OSHA and NIOSH, and to consider workers during the prioritization and risk evaluation processes. EPA agrees that TSCA provides unique authorities to address worker risks, which complement current OSHA authorities.

TSCA directs EPA to conduct risk evaluations of chemicals designated as high-priority, to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, which depending on the chemical, may include construction and other uses where workers are exposed. During prioritization, and for high-priority chemicals during risk evaluation, EPA intends to consider occupational exposure information to properly evaluate the conditions of use as well as continuing to engage with industry, states, worker groups, and other non-governmental organizations to inform EPA’s understanding of a condition of use. If after risk evaluation EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, TSCA requires EPA to apply one or more of the requirements identified in TSCA section 6(a) to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.

#### Pregnant Women and Children

- EPA must consider the unique implications for maternal and child health when prioritizing review of chemicals for risk evaluation. This is required by law and protective of public health. *(Paul E. Jarris, March of Dimes; Haywood Brown, AGOC; Colleen A. Kraft, AAP; Amy D. Kyle, UC Berkeley)*
- The approaches do not adequately consider risk for infants, children, and pregnant women. Screening methods that do not reflect consideration of potential hazards or risks for infants, children, and pregnant women cannot be relied upon to “screen out” chemicals. *(Amy D. Kyle, UC Berkeley)*
- Concerns about a chemical’s potential for reproductive toxicity, developmental toxicity, or endocrine disruption should be critical factors in prioritization. *(Colleen A. Kraft, AAP)*
- EPA should expand the risks for health outcomes to include those most relevant to sensitive populations, for pregnant women and children these include: reproductive and developmental endpoints, neurodevelopmental endpoints, neurotoxicity, respiratory endpoints including asthma and lung function, endocrine disruption and thyroid effects, and immune and auto-immune effects. *(Amy D. Kyle, UC Berkeley)*
- EPA should incorporate exposure settings relevant to infants, children, and pregnant women. *(Amy D. Kyle, UC Berkeley)*

Response: EPA agrees with commenters regarding the importance of ensuring protection for infants, children and pregnant women. TSCA mandates that EPA consider “potentially exposed or susceptible subpopulations” during prioritization. While “potentially exposed or susceptible subpopulations” is a new definition to TSCA, EPA has in practice evaluated risk across populations, including infants, children and pregnant women, where appropriate under the conditions of use for a particular chemical substance, and EPA intends to continue this practice during prioritization, and for high-priority chemicals during risk evaluation.

EPA will generally review the reasonably available hazard and exposure information, and evaluate whether that information would be sufficient for prioritization. As part of such a review, EPA would expect to consider the quality, objectivity, utility and integrity of the available information, consistent with the science standards in section 26(h). EPA expects that such information will include descriptions of the conditions of use (e.g. uses at home, schools, child care centers) and endpoints (e.g. reproductive toxicity, developmental toxicity, endocrine disruption, neurodevelopmental endpoints, respiratory endpoints) relevant to “potentially exposed or susceptible subpopulations,” including infants, children and pregnant women.

### **Information and Data Considerations (Filling Data Gaps/Data Adequacy/Data Sufficiency)**

#### *General*

- EPA is cautioned against creating a hard rule that would exclude a chemical solely on the ability to hit a certain data-gathering threshold. A lack of data alone should not automatically be a reason for not prioritizing a chemical if there is a risk to drinking water sources. (*Diane VanDe Hei, AMWA*)

Response: EPA must be mindful of the deadlines for conducting risk evaluations as imposed by TSCA. What the Agency is looking to avoid is the situation that a chemical enters prioritization only to discover there is insufficient data to perform prioritization and risk evaluation. EPA does not intend on creating an information threshold, but expects to determine on a case-by-case basis when information is sufficient.

- The sufficiency-of-data criteria cannot by statute include a required minimum dataset applied across chemicals, so the Agency must step up to the challenge of defining a basis for deciding when available data (and readily obtainable data) will suffice for supporting its decisions, including affirmations of no risk. (*Lorenz Rhomberg, Gradient*)

Response: In the associated White Paper, EPA has presented its approach to evaluate the data landscape of candidate chemicals for prioritization.

- TSCA Section 26(k) requires that in carrying out Section 6, EPA must consider reasonably available information and EPA has now defined reasonably available information to mean information that EPA can possess or reasonably generate, obtain, and synthesize for use, considering the deadlines for prioritization. The deadlines cannot be an excuse for failing to collect information relevant to a chemical’s conditions of use, hazards, and exposures. (*Rob Stockman, EDF*)

Response: In the associated White Paper, EPA has presented its approach to evaluate the data landscape of candidate chemicals for prioritization. In addition, EPA expects to use a tiered approach for data gathering. First the Agency will review the existing literature and other available information. For identified data needs, EPA will issue a voluntary call to the public for relevant information or engage directly with stakeholders, and this will be followed as necessary by the exercising of EPA's authorities under TSCA to require submission or generation of new data.

- EPA should use a risk-based approach to identify potential candidates for prioritization. (*Sarah Brozena, ACC*)

Response: EPA agrees with the comments that the selection of candidates should be based on both hazard and exposure, as a risk-based approach is required under TSCA.

- EPA should identify potential candidates in “batches.” (*Sarah Brozena, ACC*)
  - EPA should consider using a sectoral approach to pre-prioritization. Petroleum substances are unique, and the oil and gas industry has successfully led sectoral programs that have developed information used to assess the safety of petroleum substances. (*Uni Blake, API*)
  - There is support for prioritization and evaluation of categories of chemicals to the extent it facilitates the study of cumulative effects of groups of chemicals. To the extent EPA does group chemicals, EPA should take into consideration the approach outlined in the National Academy of Sciences recommendations on phthalates. (*Melanie Benesh, EWG*)
  - 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. 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. (*Elizabeth Hitchcock, SCHF*)
  - EPA should consider classes of chemicals for prioritization rather than just single chemicals so that a hazardous chemical will not be replaced by a related chemical that is likely also to be hazardous. (*Mary Gant, GSPI*)
- Identifying potential candidate chemicals from chemical categories could be useful in streamlining the process, but this should be a down the road way of thinking about prioritization, in general, and not for initial prioritization. (*Alexis Temkin, EWG*)

Response: EPA appreciates the suggestions provided. In the associated White Paper, EPA has presented its long-term approach to bin chemicals based on hazard and exposure potential based on available information.

- EPA must follow-through on its commitment to develop a pre-prioritization screening and information-collection process for candidate chemicals. EPA has not provided enough detail about how the process will work. (*Elizabeth Hitchcock, SCHF; Amanda K. Nguyen, IFRANA; Daniel Rosenberg, NRDC*)
- EPA failed to define the criteria and methodology by which it would choose which active chemicals from the TSCA Inventory would be included in the pool of candidate chemicals for

prioritization. EPA *did* identify the criteria by which it would narrow the pool into a list of candidate chemicals for prioritization, but it is necessary that the Agency provide additional details as to how it will further narrow that list. (*Neil L. Bradley, USCC*)

Response: The material provided for the meeting was intended to begin public engagement regarding this process. EPA has provided additional detail in the associated White Paper.

- An effective process for identifying potential candidates for prioritization will: not be overly formalized or regimented; ensure sufficient information is available or will be developed in a timely manner to inform prioritization, and subsequently risk evaluations, through robust and early use of EPA's section 4, 8 and 11 information-generation and information-gathering authorities; proceed at an incremental pace to build trust and gain experience, and preserve balance between high- and low-priority designations; and allow EPA to routinely meet deadlines for making priority designations and ultimately completing risk evaluations on high-priority substances. (*Lindsay McCormick, EDF*)

Response: EPA agrees with this commenter, and intends to use the prioritization process for the first 40 chemicals as an opportunity to hone the process.

- EPA should use desirable attributes from the six approaches presented, as well as parts of other approaches that have proven to be transparent, efficient and reproducible. (*James Cooper, AFPM*)
- The Agency should establish a process to ensure that substances do not remain in the candidate pool indefinitely. The Agency should limit a substance's time in the candidate pool to twelve months. EPA should regularly assess the substances to determine which ones are considered for prioritization (high or low) either continuously or in six month intervals. (*Uni Blake, API; Jessica Ryman-Rasmussem, API*)

Response: At this time EPA considers the candidate pool to be the whole of the active inventory.

- Prioritization, including pre-prioritization, and other components of a risk evaluation should immediately incorporate a tiered and targeted approach. Prioritization should be as simple as possible to quickly screen many chemicals to identify only a handful for immediate risk evaluation and those that do not require immediate risk evaluation. (*James Cooper, AFPM*)
- EPA should consider and appropriately weight readily available public information when selecting chemicals for prioritization. (*James Cooper, AFPM*)
- There should be no difference in approaches to identify high priority and low priority substances. (*James Cooper, AFPM*)
- The prioritization process will be strengthened by using the Work Plan framework with some updates, including consideration of susceptible populations, expansion of data sources, addressing data gaps, and giving NAM data indicating hazard or exposure more consideration than data indicating safety. (*Jessica Helm, SSI*)
- The process must be responsive to the pace of change to protect public health. Over the next decade, only dozens of chemicals will be addressed and identified for risk evaluation. (*Amy D. Kyle, UC Berkeley*)
- The Agency should clearly outline, for example, a procedural timeline for determining a chemical candidate's prioritization status, such as 1) gather existing publicly-available and any

voluntarily-submitted information, 2) receive input from international regulatory agencies, 3) use NAMs, and 4) exert testing authority after transparent documentation of information needs. (Esther Haugabrooks, PCRM)

Response: EPA appreciates the comments and, in the associated White Paper, EPA has presented both a short-term and long-term approach for selecting chemicals to address these comments.

### *Best Available Science*

- Any approaches EPA uses must implement TSCA's science policy mandates: rely on the best available science and the weight of the evidence (including robust summaries), which require EPA to incorporate the following principles: (Amanda K. Nguyen, IFRANA)
- All decisions must be "based on science," used "in a manner consistent with the best available science," and based on the weight of the scientific evidence. The conditions of use determine the amount of exposure and, in turn, are "critical to EPA's final determination of whether a chemical is safe or presents an unreasonable risk that must be controlled." (DUC; James Cooper, AFPM)
- EPA must implement TSCA's science policy mandates and that approaches be risk-based (Jared Rothstein, SOCMA; Timothy A. Brown, CSPA), rely on the best available science and the weight of the evidence (including robust summaries), and utilize non-vertebrate animal methods wherever practicable. (Timothy A. Brown, CSPA)
- The funding source of any scientific study should not be considered a factor when using a weight-of-the-evidence approach. EPA should only consider relevant factors such as methods, documentation, sampling, etc. (James Cooper, AFPM)
- EPA should not use IRIS values. The individual components of an IRIS assessment may be useful in a risk evaluation, but none of its final conclusions (e.g., slope factors, dose-response curves, hazard endpoints, etc.) hold up to the science standards of TSCA and are therefore not appropriate for regulatory decision-making. (James Cooper, AFPM)
- Without access to full studies, the public will be challenged or unable to assess and comment on the quality and relevance of the studies used by the Agency. Even the best study summaries are incomplete descriptions that do not allow for an independent examination of study quality and conclusions reached by authors. It is important that EPA obtain the full studies, both so that EPA staff have access and so that EPA can make them publicly available. EPA should make such information public and easily searchable. (Lindsay McCormick, EDF)

Response: EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute, and select candidates with robust data sets for hazard and exposure. Before initiating the prioritization process, EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient and is consistent with the scientific standards of section 26(h) to allow EPA to complete the prioritization process within the statutory deadlines.

While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 from the 2014 Work Plan. In addition to the quantity and

quality of information, EPA will consider Agency priorities and overall workload. EPA acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from new approach methodologies (NAMs) and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology.

### *Data adequacy for hazard evaluation*

- Data sources for hazard rely on IRIS, NTP, and various PBT lists. None of these are appropriate for any screening at all beyond the already well-known toxic chemicals. What is EPA going to do for chemicals that are not already well tested where you need to rely on information that is generated through the TSCA process? Any ranking is only as good as the data inputs and it is incumbent on EPA to get better data for this. *(Amy D. Kyle, UC Berkeley)*

Response: EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient for a particular purpose (e.g., sufficient to support a proposed designation that a chemical substance meets the definition of a High- or Low-Priority Substance). As part of such a review, EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). Hazard information to consider may include but is not limited to study findings on acute toxicity (oral, dermal or inhalation depending on relevant exposure routes) for human health, and acute and chronic ecological toxicity, as well as relevant endpoints of concern such as developmental and reproductive toxicity, neurotoxicity and/or carcinogenicity.

For the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 from the 2014 Work Plan. In the long-term, EPA's goal is to develop a risk-based strategy for selecting both low- and high-priority candidate chemicals for prioritization that integrates data from new approach methodologies (NAMs) and data from traditional studies (e.g., toxicology, exposure science, engineering, fate and transformation sciences), and build on the 2012 TSCA Work Plan methodology.

### *Confidential information*

- EPA must protect CBI and respect industry's right to protect its intellectual property. *(James Cooper, AFPM)*
- Health and safety studies and their underlying information are not eligible for CBI protection from disclosure under TSCA. Both EPA and the public need access to full studies used to identify candidates for prioritization, not simply robust study summaries. *(Lindsay McCormick, EDF)*

Response: EPA recognizes the need for legitimate CBI to be protected from disclosure, and also recognizes the public's interest in maximizing transparency with respect to decisions made during the prioritization and risk evaluation processes. EPA believes the recent amendments to TSCA

appropriately balance these interests, and EPA is committed to implementing those provisions as Congress intended.

### *Need for clarification/transparency*

- None of the approaches provides details as to how a chemical would be assessed for data robustness. EPA needs to provide additional clarity in this area. *(Kathleen M. Roberts, NAMC and NMA)*
- Throughout the discussion document, EPA uses the terms “adequate data”, “sufficient data” and “sufficient information.” EPA should work to clarify what constitutes “sufficient” and “adequate” in these cases. *(Diane VanDe Hei, AMWA)*
- None of EPA’s six suggested approaches for identifying candidate chemicals describes how the Agency would determine whether a chemical being screened had sufficient data references to qualify for a prioritization designation, or how EPA would notify the public of its thinking and invite the public to participate. *(Jared Rothstein, SOCMA)*

Response: EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient for a particular purpose (e.g., sufficient to support a proposed designation that a chemical substance meets the definition of a High- or Low-Priority Substance). As part of such a review, EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). To the extent the information is not currently available or is insufficient, EPA will determine whether and how information can be developed, collected, reviewed and incorporated into analyses and decisions in a timely manner.

EPA continues to seek ways to improve transparency and efficiency in how the Agency carries out activities leading up to prioritization. EPA is committed to meeting its obligations, including those in section 26(j) to make information available to the public relating to its basis for priority designations, including an identification of the information and analysis used. EPA expects to provide for maximum transparency, subject to the limitations in section 14, of the information it uses to make decisions under TSCA.

Furthermore, EPA has previously declined to codify a bright line rule for “sufficiency” of information. As set forth in TSCA 6(b)(1)(C)(iii), if after receiving (or not receiving) relevant information regarding a chemical substance from interested persons and related public comments, the information available to the Agency is insufficient to enable the designation of the chemical substance as a low-priority substance, EPA must designate the chemical substance as a high-priority substance. In this light, EPA has purposefully tried to avoid establishing a threshold for “sufficient information.” The Agency does not wish to create a bright line that could lead to high-priority designations and the initiation of risk evaluations because EPA bound itself to an inflexible “sufficiency” standard.

The Agency will continue to engage with stakeholders as it develops the long-term risk-based strategy and incorporates lessons learned from the selection of candidate chemicals for prioritization, risk evaluation, and risk management.

### *Recommended way to address information needs*

- Whichever method EPA chooses for its prioritization process, the Agency must address procedural and substantive issues including how and when EPA will gather the necessary data on a sufficient number of substances to make prioritization decisions under the chosen method. EPA cannot afford to avoid addressing this issue, even though some stakeholders might prefer that the Agency refrain from using its information gathering authority under Sections 4, 8 and 11 of TSCA. *(Daniel Rosenberg, NRDC)*
- The amended law provides EPA with effective new tools to fill data gaps, but EPA has not provided clear indication of whether and how these tools will be used to support prioritization and risk evaluation. *(Bob Sussman, SCHF)*
- If EPA chooses to develop a Pre-Prioritization phase, it should properly address relevant testing requirements that are included elsewhere in the statute. *(Neil L. Bradley, USCC)*
- It would be beneficial to all stakeholders if the Agency could provide more details on the potential information-gathering activities, both voluntary or under TSCA authority that EPA might utilize to aid in improving the amount of data for prioritization. If EPA provides more transparency into the overall process, affected stakeholders can become more efficient and timely in their data submissions. *(Timothy A. Brown, CSPA)*
- There is clear intent on behalf of the Agency to fulfill its statutory obligations to reduce the conduct of tests using vertebrate animals. However, more information about how it will exert its testing authority when filling information needs for identifying prioritization candidates would be welcome. *(Esther Haugabrooks, PCRM)*

Response: The Agency agrees that there should be a transparent process that both articulates data needs as well as details how the Agency plans to gather information including the use of information gathering authorities under TSCA.

- Section 4(h) is a primary concept that EPA should consider through the process of generating information for all phases of prioritization and should be included in any guiding principles. *(Catherine Willett, HSUS)*

Response: The Agency agrees. The statute requires EPA to take into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information before requesting or adopting a requirement for testing using vertebrate animals. Also, as required by statute, on June 22, 2018 EPA released the final strategic plan to promote the use and development of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing. The Agency will incorporate feedback on this plan throughout the prioritization process.

- EPA should use a tiered approach to address information needs:
  - EPA should first gather reasonably available information, then consider voluntary call-ins for information; then consider use of TSCA Section 8(a) and 8(d) rules. EPA should only consider use of TSCA Section 4 test rules/orders if the Agency concludes that new information is necessary for prioritization purposes.
  - EPA should allow opportunities to iterate: the Agency should release preliminary information (possibly with preliminary priority scores) to give stakeholders an

opportunity to comment and, if needed, to provide additional information to prioritize a potential candidate appropriately. *(Sarah Brozena, ACC)*

Response: The Agency has indicated that as a general matter, EPA intends to use a tiered approach to gather information. EPA will first determine information needs by reviewing existing literature and available information. Secondly, for identified information needs, EPA may issue a voluntary call to the public for relevant information or engage directly with stakeholders. Finally, and as necessary, EPA intends to exercise its authorities under TSCA to require submission or generation of new information.

- The 2012 Work plan identified “Potential Candidates for Information Gathering.” Will EPA share the candidates and/or any new potential candidates to aid in the information-gathering process? *(Timothy A. Brown, CSPA)*
- EDF particularly urges EPA to use its information authorities to obtain more information about the chemicals in the 2014 Work Plan as well as the chemicals identified as “Potential Candidates for Information Gathering” through the Work Plan Process. *(Environmental Defense Fund)*

Response: The Agency is committed to a transparent process and could consider gathering information on chemicals set aside for information gathering purposes as it moves forward. EPA does intend to share the candidates to aid in the information gathering process.

- EPA should use a permanent and predictable “Information Outreach Framework” (Outreach Framework) so companies can provide information expeditiously to inform EPA’s decision making under TSCA. This framework should allow electronic data entry through CDX and be linked to particular Federal Register dockets for tracking purposes, and also provide a mechanism for companies to correct errors and supplement with newly discovered information within a reasonable period of time. *(DUC)*
- EPA needs a streamlined, systematic system to ensure there is enough reliable data available to support timely determinations. The Agency must carefully plan and manage data to assure that appropriate information is available to satisfy statutory imperatives to employ best available science and weight of the evidence/systematic review in decision making under TSCA § 26(h), (i), coupled with the short time frames for assembling, developing and assessing data under § 6(b) after formal prioritization commences. For example, a concise spreadsheet describing readily available information on toxicology, exposure and primary uses may be constructive. The goal is to avoid unwarranted risk conclusions (either overly conservative or under protective) based on inadequate data that will not meet statutory requirements. *(Ray Ehrlich, SIRC)*
- Pre-prioritization data collection and assembly procedures should include: (i) Adequate lead time notice of substances of interest to allow industry sectors and value chains to organize to develop and provide relevant information; (ii) Notice of the Agency’s existing database and detailed information on perceived information gaps relevant to fit-for purpose reviews and consistent with systematic review methods; (iii) Points of contact and opportunities for engagement on use assumptions, information gaps, data development plans, existing regulation, and other relevant topics; (iv) Leveraging existing hazard, use and exposure information, including from Chemical Data Reporting, 40 C.F.R. Part 711 (CDR data), and REACH robust study summaries; and (v) Data quality information needs for properly assessing best

available nonguideline study data and information (e.g., use and exposure) from stakeholders in anticipation of weighting and systematic review procedures. *(Ray Ehrlich, SIRC)*

- An adequate and consistent data management framework is needed for the existing chemicals review initiative to be successful. For the Agency to be successful it will require data and studies from industry and stakeholders to fill those data needs. For stakeholders to provide the Agency with useful data, the Agency must, well in advance of the prioritization initiation, clearly articulate the data needs and the standard of data the Agency will use. EPA must establish a system through which stakeholders are able to track what data the Agency already has, what data will be generated by modeling, and what data other stakeholders have submitted. Data gathering and sharing during the pre-prioritization phase should take multiple forms such as open dockets, an annual or biannual stakeholder meeting process, an ad hoc committee, and/or public forums. The Agency must explicitly outline the types and quality of data EPA will accept from stakeholders to use in the prioritization and risk evaluation processes. *(G. Tracy Mehan III, AWWA)*
- EPA should also develop “completeness metrics” that track how many of the desired traits could be assessed based on the available data and provide a public summary characterizing the “completeness of the database” for each chemical. EPA has adopted similar approaches in the past, for instance using published criteria from the HPV, Chemical Assessment and Management Program (ChAMP) and EPA’s Risk Assessment Guidance to evaluate the data adequacy in its brominated phthalates Data Needs Assessment. This information should be made publicly available along with the ultimate priority determination for each chemical. *(Veena Singla, UCSF)*
- In situations where data are lacking, EPA should proactively outline existing data gaps and explicitly state where data are most needed to facilitate the external development and design of studies that will generate these data in a timely manner. *(Veena Singla, UCSF)*
- It is important for the Agency to provide an adequate period between identifying a candidate in the pre-prioritization phase and beginning the prioritization process. There must be a data collection process that fills the information gaps for chemicals in the pre-prioritization phase so that EPA is not forced to select chemicals for prioritization based solely on whether there is adequate data available for the chemical to complete the prioritization, and potentially, risk evaluation phases. *(G. Tracy Mehan III, AWWA)*
- EPA must fill data gaps before initiating prioritization. Regardless of which methodology EPA adopts to prioritize chemicals, it is imperative that EPA takes steps to ensure it has adequate information both to make prioritization decisions (especially if the substance is a candidate for a low-priority designation), and to complete a risk evaluation. *(Melanie Benesh, EWG)*
- EPA should ensure that the data needs of the Agency and the types and quality of data required are explicitly stated when listing a chemical for the pre-prioritization process. This will help to guarantee that the Agency receives the most useful and relevant data from the public and industry. *(Diane VanDe Hei, AMWA)*
- EPA should identify any data gaps and take steps to fill them. EPA should not only consider whether information for a particular data point exists, but also the quality, objectivity, and integrity of the information, and the potential for bias. *(Melanie Benesh, EWG)*

[Response: The Agency agrees with the importance of a transparent process for articulating data needs and information sharing and believes that it is necessary to fill information gaps so that there](#)

is adequate information to make priority designations. The Agency plans to open public docket on the 2014 Work Plan chemicals to facilitate the submission of information and inform the data needs for the Work Plan chemicals not yet under evaluation. For submission of information interested parties could consider using existing templates, e.g., OECD harmonized templates. EPA is also developing a process to ensure there is a consistent approach for articulating data needs for these chemicals, so that it is clear to industry and stakeholders which data is more useful to the Agency.

- Additionally, there is a concern that voluntary submission of information may only include partial information and not the full extent of data. So far there are no guidelines or standards that voluntary submissions will be held to. (*G. Tracy Mehan III, AWWA*)
- EPA should primarily rely on mandatory information submissions. EPA should use its mandatory authorities rather than waiting for voluntary information. A voluntary call is much less likely to produce all of the necessary information than rules mandating its submission. Reliance on voluntary submissions may enable companies to omit information they view as raising concerns about their chemicals. To the extent that EPA accepts voluntarily submitted information, it should take additional steps to ensure completeness, accuracy, and access to all underlying data. (*Lindsay McCormick, EDF*)
- To the extent the Agency seeks voluntary information, it should take steps to review the information for potential bias and ensure that it has received complete information, rather than selective or partial information cherry-picked to present the chemical in the most favorable light. (*Melanie Benesh, EWG*)

Response: For identified data needs the Agency plans on following a tiered approach beginning with data gathering and a voluntary data call and then use of the Agency's TSCA authorities as appropriate. TSCA section 4(h)(1)(A) requires the Agency to take into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information before requesting or adopting a requirement for testing using vertebrate animals. The voluntary data call would be part of tiered approach for collecting existing information. The Agency is also mindful of the timing considerations and plans to include a time frame for voluntary submissions.

Any information that EPA receives, whether submitted voluntarily or through a mandatory data call, is evaluated for quality, relevance or appropriateness to support the Agency's needs. This evaluation includes a consideration of bias.

- A number of commenters urged EPA to use its authority to issue test orders, conduct a broad data call in, and use authorities under sections 4, 8, and 11, and encouraged EPA to use these tools early in the process. (*Veena Singla, UCSF, Amy D. Kyle, UC Berkeley, Lindsay McCormick, EDF; Rob Stockman, EDF, Melanie Benesh, EWG*)
- Two commenters suggested the Agency should avoid requiring testing before a low or high-priority designation has been made. (*Esther Haugabrooks, PCRM, Jared Rothstein, SOCMA*)

Response: The Agency plans to use TSCA sections 4, 8 and 11 as appropriate to gather information. The EPA could use TSCA section 26(a) to obtain information from other agencies. In addition, the Agency could consult with the TSCA Interagency Testing Committee as a way to cooperate with other agencies.

## Testing

- Except in the case of certain high production volume chemicals, these authorities [Section 4] do not permit the Agency to require testing prior to formally initiating the prioritization of a substance for risk evaluation. In TSCA Section 4, there are two authorities by which EPA may require testing. *(Joseph Manuppello, PETA)*

Response: The Agency does not agree that use of TSCA Section 4 authority before prioritization begins is limited to TSCA section 4(a)(1)(A)(ii)(III). The Agency has several information gathering tools it could use under TSCA section 4 during this process. The Agency believes the requirement under TSCA section 4(a)(2) to make a priority designation within 90 days of receipt of the information does not prohibit the Agency from issuing an order before a chemical starts the prioritization process. Cognizant of the timing requirements in both TSCA section 4 and TSCA section 6 the Agency could use its authority under TSCA section 4(a)(2) to issue orders for chemicals that would be entering prioritization process. Additionally, the Agency could use its authority under 4(a)(1)(A)(i) to issue an order, rule or to enter into a consent agreement. Under this section the Agency can make a may present unreasonable risk finding and require testing without making a priority designation for a chemical. This is different from making a “may present unreasonable risk” finding under TSCA section 6(b)(1)(B)(i). Under TSCA section 6(b)(1) the Agency is required to follow a very specific process which includes two opportunities for comment before making a priority designation. The finding in TSCA section 6(b)(1)(B)(i) can only be made after the Agency follows this process. There is another important distinction between section 4 and 6: the basis for the “may present” findings. Under section 4(a)(1), the finding is based on manufacture, processing, distribution in commerce, use or disposal or any combination of those activities. Under section 6(b)(1)(B), the finding is based on “a potential hazard and a potential route of exposure under the conditions of use, including unreasonable risk to potentially exposed or susceptible subpopulation.” Furthermore, the statutory context for interpreting the two provision differs: even if the Agency makes a “may present” finding under TSCA section 4, it does not mean that once the chemical enters prioritization that it will be designated as a high priority. For example, EPA would analyze the “may present” finding under section 6 with the benefit of the information received pursuant to section 4. It is also possible that, under the particular circumstances, after completing the steps in the prioritization process the Agency could reach a different conclusion. Additionally, for chemicals that meet the statutory criteria of being produced and potentially released in substantial quantities or if there is potentially significant exposure the Agency could also consider issuing a rule under 4(a)(1).

## High priority chemicals

- EPA should retain default high-priority status for chemicals with insufficient information. *(Colleen A. Kraft, AAP)*
- Most chemicals will be likely be high-priority due to insufficient data. The definition of high-priority chemical makes clear that EPA does not have to understand all of the risks, or confirm all hazards or exposures before designating a chemical as high-priority. Rather, any chemical that may present an unreasonable risk because of potential hazards or potential exposure should be designated as high-priority. *(Melanie Benesh, EWG)*

Response: EPA did not include a “default-to-high” in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule except for the circumstance

that is explicitly required in 15 U.S.C. 2505(b)(1), which is now described in 40 CFR 702.9(e). EPA expects to be able to determine which priority category each chemical falls into during the prioritization process, and therefore it is not necessary or appropriate to establish priority designations by default (82 FR 33760). To the contrary, the considerations to select chemicals for prioritization are intended to ensure that EPA does not find itself in a situation in which it has insufficient information to make a designation.

- Regardless of approach taken, it is important to provide additional clarification on what may be determined as “sufficient data” to warrant classification of a chemical as high priority. A minimum amount of toxicity information is needed and should be identified before categorizing a chemical as high priority so as to avoid entering into the risk evaluation process without sufficient data to support a valid assessment. *(DoD)*

Response: The comment pertains to prioritization, not to the selection of candidate chemicals for the prioritization process. Please refer to the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final rule (82 FR 33753-33764)* for further information regarding the procedures the Agency will follow to designate a chemical as high-priority during the prioritization process.

- It would be helpful to know the capacity of EPA's evaluation process in order to evaluate how many high-priority chemicals need to be identified per year. *(Catherine Willet, HSUS)*

Response: While EPA should be mindful of its workload and resource constraints, TSCA section 6(b)(2)(B) requires that EPA prioritize at least 20-high and at least 20 low-priority chemicals within 3.5 years of the law's enactment, or by approximately the end of December 2019. TSCA requires that from December 2019 onward EPA have at least 20 ongoing risk evaluations. Section 6(b)(2)(G) requires that EPA completes a risk evaluation for a chemical substance as soon as practicable, but generally no later than 3 years after initiating the risk evaluation. As one risk evaluation is completed another must begin.

## **TSCA Work Plan as a Tool for Identifying Potential Candidates**

### *General Support*

- The Work Plan Methodology developed in 2014 should remain the cornerstone of pre-prioritization. It was developed after robust public input and was endorsed by Congress in amended TSCA. It's 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. *(Elizabeth Hitchcock, SCHF; Bob Sussman, SCHF)*
- EPA should focus resources on gathering information on the Work Plan chemicals while working on a method to prioritize the remaining active TSCA inventory. *(Catherine Willet, HSUS)*
- EPA should rely on the Work Plan as the primary method for selecting high-priority chemicals, at least until further progress on the Work Plan is made, and use other methodologies to complement the Work Plan methodology where appropriate, such as where they can provide additional hazard data for the chemical's conditions of use. *(Daniel Rosenberg, NRDC)*
- The Work Plan provides a sound basis for the selection of the remaining high priority of chemicals: its approach to rank chemicals based on hazard, exposure, and persistence and bioaccumulation is strengthened by its consideration of consumer uses of chemicals that have

high exposure levels. While consideration of consumer exposure is also incorporated into the Functional Category Approach Based on Use and Exposure, the Work Plan provides a more protective approach by also considering hazard. *(Jessica Helm, SSI)*

- EPA should use the Work Plan methodology, with some updates to reflect new requirements. The Work Plan is heavily emphasized in the statute. Given the significant amount of public input that went into developing the Work Plan criteria, and the parallels to the prioritization process under TSCA, the Work Plan criteria offer a logical starting point. Starting with the Work Plan criteria is also consistent with the statute. *(Melanie Benesh, EWG)*
- EPA should not obtain all High-Priority designations from the 2014 Work Plan. There are no issues with achieving an initial rate above 50% but it is suggested that some initial chemicals come from approaches other than that 2014 Work Plan. *(Timothy A. Brown, CSPA)*

Response: EPA appreciates the support for the 2014 Work Plan and the methodology used. The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and for high-priority chemicals risk evaluation; however, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 2014 Work Plan. EPA acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

Before initiating the prioritization process, EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete the prioritization process within the statutory deadlines. To the extent the information is not currently available or is insufficient, EPA expects to determine whether and how information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. EPA retains the discretion to choose not to initiate prioritization for a chemical substance if it identifies critical information deficiencies that may prevent timely completion of a risk evaluation consistent with the scientific standards of section 26(h). EPA believes it is most prudent to identify gaps as early as possible in the process to avoid running afoul of statutory deadlines.

In the long-term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidate chemicals for prioritization that integrates data from NAMs and data from traditional toxicology studies, and build on the 2012 TSCA Work Plan methodology. This approach would allow EPA to go beyond the initial chemicals considered for the Work Plan and consider all chemicals on the active inventory.

### *Concerns with methodology*

- TSCA Work Plan Methodology is more aligned towards identifying candidates for high-priority designation and an alternative mechanism is needed to identify candidates for low-priority designation. EPA should develop an approach that results in the designation of both low- and high-priority chemicals. *(Kathleen Roberts, BRAG; Kathleen M. Roberts, NAMC and NMA)*
  - Toward that end, there is support for re-reviewing those chemical substances that were considered in the 2012 Work Plan review but were excluded because their hazard and/or exposure scores were low, as those chemicals may be candidates for a low priority designation. *(Kathleen M. Roberts, NAMC and NMA)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 2014 Work Plan. EPA expects to look to the SCIL list for the potential low-priority candidate designations. In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. EPA is also developing a parallel strategy to identify potential low-priority chemicals for prioritization. With the integration of traditional toxicology studies and new approach methodologies, EPA will consider those chemicals that were excluded in 2012, as well as other chemicals in the active inventory.

### *Recommended ways to augment the 2014 Work Plan*

- EPA's approach to considering candidate chemicals must consider all of the criteria specified under TSCA Section 6(b)(1)(A) and assess the completeness of the available data. To use appropriately the TSCA Work Plan methodology, EPA must incorporate factors such as storage near significant sources of drinking water and new data, including TSCA Inventory notifications; CDR data; and TRI data. EPA must then determine whether such data are sufficient to allow it to complete the prioritization process within the statutory deadlines. *(Kathleen Roberts, BRAG)*

Response: EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient for a particular purpose (e.g., sufficient to support a proposed designation that a chemical substance meets the definition of a High- or Low-Priority Substance). As part of such review, EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). To the extent the information is not currently available or is insufficient, EPA expects to determine whether and how information can be developed, collected, reviewed and incorporated into analyses and decisions in a timely manner. In addition to the quantity and quality of information, EPA expects to consider Agency and interagency priorities and overall workload. EPA also acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

Please note that TSCA section 6(b)(1)(A) sets considerations for the prioritization process, and not for selecting chemicals for prioritization. EPA might consider during pre-prioritization some of the criteria from TSCA section 6(b)(1)(A) to better inform the selection of candidate chemicals for prioritization, as appropriate, for example, to decide if the data available is sufficient for a high or low priority determination during prioritization.

- EPA should use the TSCA Work Plan as a starting point and strive for greater transparency by making public the specific factors it uses, the weight given to each factor and any assumptions used. (*James Cooper, AFPM*)

Response: EPA continues to seek ways to improve transparency and efficiency in how it carries out activities in determining candidate chemicals for prioritization. EPA is committed to meeting its obligations, including those in section 26(j) to make information available to the public relating to its bases for priority designations, including an identification of the information and analysis used. EPA expects to provide for maximum transparency, subject to the limitations in section 14, regarding the information it uses to make decisions under TSCA.

As explained in the White Paper that presents the working approach for the selection of candidate chemicals for prioritization, EPA expects to consider the quantity and quality of the information, Agency and interagency priorities and overall workload. This approach will evolve as EPA gains experience selecting candidate chemicals for the prioritization, the risk evaluation and the risk management processes.

It is important to note that during prioritization, EPA will fully consider the statutory requirements. As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

Finally, EPA is also planning to open dockets for all 2014 Work Plan chemicals to facilitate receipt of information and transparency.

- The Agency can enhance the methodology by rescreening the larger pool of 345 chemicals identified using updated data sets, integrating new hazard, exposure and bioaccumulation potential information, as well as incorporating data to address components of the prioritization rule. (*G. Tracy Mehan III, AWWA*)

Response: While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 2014 Work Plan. For the long term, EPA's goal is to develop a risk-based strategy for selecting potential high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, building on the 2012 TSCA Work Plan methodology. EPA will consider the larger pool of 345 chemicals along with the other chemicals on the active inventory.

- EPA should look beyond the Office of Water’s Chemical Contaminant List (CCL) when considering potential drinking water risks and contaminants for prioritization. OPPT should work with EPA’s Office of Groundwater and Drinking Water to stay cognizant of emerging contaminants and risks to drinking water as a source of possible high priority chemicals. (*G. Tracy Mehan III, AWWA*)

Response: EPA expects to engage as it always does with other EPA Offices, including the Office of Ground Water and Drinking Water, to identify existing tools and information that could support the implementation of TSCA requirements.

- EPA should augment the TSCA Work Plan approach to incorporate statutory requirements not previously included (or not sufficiently addressed) in the 2012 methodology and integrate new information. EPA should start obtaining information now, conscious of the deadlines that would apply when EPA begins the formal prioritization process. (*Lindsay McCormick, EDF; Rob Stockman, EDF*)
- EPA’s proposed TSCA Work Plan Approach B (and presumably Approach C) includes incorporation of new “high-throughput and *in silico*” data. EPA should also consider any other information that has been developed since the 2014 update (e.g., scientific literature, NHANES biomonitoring, health and environmental information from state governments, other Federal agencies, or manufacturers).
- EPA should make updates and additions to its methods to improve future updates to the rankings, help to identify data gaps to be addressed for prioritization, and initiate a new process to funnel qualifying chemicals into further evaluation to become low-priority chemicals. (*Jessica Helm, SSI*)

Response: The 2014 Work Plan chemical list will not be revised, since, it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. While TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, if needed, risk evaluation; however, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science and approaches have evolved and EPA will identify and review reasonably available information, including any new information during prioritization.

Before initiating the prioritization process, EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete the prioritization process within the statutory deadlines. To the extent the information is not currently available or is insufficient, EPA expects to determine whether and how information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. EPA retains the discretion to choose not to initiate prioritization for a chemical substance if it identifies critical information deficiencies that may prevent timely completion of a risk evaluation consistent with the scientific standards of section 26(h). EPA believes it is most prudent to identify gaps as early as possible in the process to avoid running afoul of statutory deadlines.

In the long-term, EPA’s goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, builds on the 2012 TSCA Work Plan methodology and considers exposures to potential exposed or

susceptible subpopulations. With the integration of traditional toxicology studies and new approach methodologies, EPA will consider those chemicals that were excluded in 2012, as well as other chemicals on the active inventory.

- EPA should update its 5-year old Work Plan methodology and criteria before identifying chemicals as potential high priority candidates that are not on the 2014 Update of the TSCA Work Plan: *(Sarah Brozena, ACC)*

Response: In the long-term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and build on the 2012 TSCA Work Plan methodology. EPA is committed to meeting its obligations, including those in section 26(j) to make information available to the public relating to its bases for priority designations, including an identification of the information and analysis used. EPA expects to provide for maximum transparency, subject to the limitations in section 14, of the information it uses to make decisions under TSCA.

The Agency will continue to engage with stakeholders as it develops the long-term risk-based strategy and incorporates lessons learned from the selection of candidate chemicals for prioritization, risk evaluation, and risk management.

- EPA should develop a mechanism to correct and update data and rankings in the 2014 Work Plan, or develop a subsequent pre-prioritization tracking system. *(Barbara S. Losey, APERC)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, if needed, risk evaluation, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

- Rather than use the methodology of other agencies, EPA should use the information from other agencies (e.g., Canada, REACH) as a data stream to augment the Work Plan. *(Alexis Temkin, EWG)*

Response: EPA's goal is to develop a risk-based strategy for selecting potential high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. This approach would allow EPA to go beyond the initial chemicals considered for the Work Plan and consider all chemicals on the active inventory.

- EPA should not weaken the Work Plan Criteria, especially with regards to PBTs. EPA should actively seek updated data with regards to production volume, toxic releases, hazards and exposure profiles. *(Melanie Benesh, EWG)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule.

TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, for high-priority chemicals risk evaluation; however, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

- EPA should use an updated version of the Work Plan methodology to identify high-priority candidate chemicals. Given the requirement to use a risk-based process for identifying potential high-priority chemicals, EPA cannot avoid using something like the Work Plan methodology. *(Amanda K. Nguyen, IFRANA)*

Response: While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidate chemicals for that EPA must have ongoing by no later than December 2019 prioritization primarily from the 2014 Work Plan. In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology.

The final identification by EPA of a substance as either high-priority or low-priority substance for risk evaluation would be based on the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (40 CFR § 702.1 to 702.17).

- EPA will also need to ensure that its revised methodology is completely objective, rigorous and transparent, so that it leaves no room for invisible exercises of discretion. *(Amanda K. Nguyen, IFRANA)*

Response: EPA continues to seek ways to improve transparency and efficiency in how it carries out activities in determining candidate chemicals for prioritization. EPA is committed to meeting its obligations, including those in section 26(j) to make information available to the public relating to its bases for priority designations, including an identification of the information and analysis used. EPA expects to provide for maximum transparency, subject to the limitations in section 14, regarding the information it uses to make decisions under TSCA.

As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

EPA is also planning to open dockets for all 2014 Work Plan chemicals to facilitate receipt of information and transparency.

- EPA should use Work Plan methodology with these modifications: *(Veena Singla, UCSF)*
  - Improve the existing factors and expand to include all TSCA requirements. EPA could generate a list of chemicals with storage near significant sources of drinking water (including groundwater) and then screen it using the existing Work Plan Methodology.

Alternatively, EPA could screen the current Work Plan list for chemicals stored near significant sources of drinking water, or use some combination of these approaches.

- Also consider:
  - All conditions of use, including reasonably foreseen uses
  - Chemicals with exposure disparities for susceptible populations including children, pregnant women, workers, and communities of color or low socio-economic status
  - Chemicals with conditions of use (manufacturing, processing, use, recycling, disposal) in proximity to communities of color or low socio-economic status
  - Classes or clusters of chemicals, using the chemical categories from the New Chemicals Program as a foundation or considering functional use approaches.
- Add relevant sources (e.g. California Environmental Contaminant and Biomonitoring Program or other state programs).
- Consider “take-home” exposures (when workers track home occupational chemicals, exposing families).
- Consider chemicals of the highest priority to workers, tribes, environmental justice and fence-line communities (those located in proximity to the conditions of use of a chemical). EPA should engage with these groups.

[Response: EPA expects to consider these criteria as it establishes a process for the long-term for determining candidate chemicals for prioritization.](#)

- When evaluating chemicals for further evaluation under the two-step Work Plan pre-prioritization process, the Agency should use a wide range of criteria and data sources in order to consider the risks of as many chemical substances and categories of chemical substances that may pose harm as possible.
  - EPA should expand the toxicity endpoints (e.g., immune, endocrine, cardiovascular, and respiratory systems). EPA should include all the hazard trait lists used by the CA Safer Consumer Products program.
  - EPA should also extend carcinogenic effects to include possible human carcinogens (IARC classification 2B) given the “may pose unreasonable risk” criteria. EPA should expand the current list to include information generated by states, sister federal agencies, and international governments. The US EPA IRIS must also be included.
  - EPA should expand the current factors for preliminary exposure screening beyond children’s products to include general exposure routes (e.g. exposure to chemicals via consumer products in general, furniture, air, water, and other routes).
  - EPA should expand the data sources used to identify human exposures (NHATS, NHEXAS, and TEAM, etc).
  - Caution should be exercised when using biomonitoring data as a source of exposure criteria. Biomonitoring information should be used to positively identify a chemical as having known exposure, but should not be used to exclude chemicals from further classification. *(Daniel Rosenberg, NRDC)*
- The last step in the 2012 Work Plan instructed EPA to consider five factors. The new pre-prioritization process should not include any of those qualitative or black box steps. Every step has to be rigorous and science-based and transparent. *(Robert Helminiak, SOCMA)*

Response: EPA continues to seek ways to improve transparency and efficiency in how the Agency carries out activities leading up to prioritization. EPA is committed to meeting its obligations, including those in section 26(j) to make information available to the public relating to its bases for priority designations, including an identification of the information and analysis used. EPA expects to provide for maximum transparency, subject to the limitations in section 14, of the information it uses to make decisions under TSCA.

As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

EPA is also planning to open dockets for all 2014 Work Plan chemicals to facilitate receipt of information and transparency.

#### Specific to Step 1

- 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, 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. 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. (*Elizabeth Hitchcock, SCHF*)
- For chemicals with missing data in any of the preliminary prioritization (Step 1) criteria, the default assumption should be that the chemical automatically requires additional evaluation. (*Daniel Rosenberg, NRDC*)

Response: In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies. This long-term strategy would allow EPA to fill data gaps for a chemical prior to the chemical entering prioritization. For those chemicals that EPA might still need additional information, the Agency believes that it is necessary to fill information gaps so that there is adequate information to make priority designations. The Agency plans to open public dockets on the 2014 Work Plan chemicals to facilitate the submission of information and inform the data needs for the Work Plan chemicals not yet under evaluation. For submission of information interested parties could consider using templates, e.g., OECD harmonized templates.

The long-term goal is to have a flexible strategy that applies the 2012 Work Plan methodology to a wide range of chemicals, rather than only focusing on those chemicals that were excluded in 2012.

Please note that the final *Procedures for Prioritization of Chemicals For Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR § 702.9) does include the TSCA required criteria and an additional consideration of “other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.”

### Specific to Step 2

- EPA set aside several 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 through voluntary data submission and/or application of the testing and reporting authorities in sections 4 and 8 of TSCA. *(Elizabeth Hitchcock, SCHF)*

Response: The Agency is committed to a transparent process and could consider gathering information on chemicals set aside in 2014 for information gathering purposes (as part of the development of the Work Plan) as it moves forward.

- The chemicals that could not be scored in Step 2 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. *(Elizabeth Hitchcock, SCHF)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, for high-priority chemicals risk evaluation; however, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

In the long term, EPA’s goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies. This long-term strategy would allow EPA to fill data gaps for a chemical prior to the chemical entering prioritization. The long-term goal is to have a flexible strategy that applies the 2012 Work Plan methodology to a wide range of chemicals, rather than only focusing on those chemicals that were excluded in 2012.

- EPA should adjust the scoring approach of ranking chemicals as “high”, “medium” and “low” *(Elizabeth Hitchcock, SCHF; Daniel Rosenberg, NRDC)*
- EPA is encouraged to use a 3-tier labelling approach for pre-prioritization, similar to that used by EPA in Step 2 of the Work Plan method. EPA could use labels other than “high, medium or low” to more clearly describe the intent of placing certain substances on each type of list. For

example: 1. Ready for Prioritization 2. Undergoing Information Collection 3. Future Prioritization. Classifications that are more descriptive of the purpose of the lists could help reduce stigmatization. *(James Cooper, AFPM)*

- EPA should use the results from Step 2 of the Work Plan to select chemicals for prioritization. AFPM acknowledges the efforts of the Agency to narrow the list of candidates for risk evaluations under the Work Plan. To go back and repeat those efforts using similar methodologies would not result in a significantly different list from the 345 substances that EPA already identified. Using the results from Step 2 will enhance transparency and certainty, and will facilitate the efficient collection of necessary information to better focus limited resources of all stakeholders. When selecting candidates for prioritization, however, AFPM expects that the Agency will be more transparent as to what specific factors it has considered and what weight was given to each of those factors. *(James Cooper, AFPM)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, for high-priority chemicals risk evaluation; however, EPA is not bound by the specific findings of the 2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. The long-term goal is to have a flexible strategy that applies the 2012 Work Plan methodology to a wide range of chemicals, rather than only focusing on those chemicals that were excluded in 2012.

#### Selection of chemicals

- EPA should refrain from selecting chemicals that are already well characterized and highly regulated (e.g. mercury and quartz during the 2014 Work Plan update). Also, if a substance is being considered for regulation under an authority other than TSCA, EPA will not be able to determine accurately the conditions of use until the final regulations are promulgated. *(Kathleen Roberts, BRAG)*

Response: Given the timelines set by TSCA, EPA expects to consider the existence and availability of risk-related information on a candidate chemical substance before initiating the prioritization process. As a matter of responsible implementation, EPA retains the discretion to choose not to initiate prioritization for a chemical substance if it identifies critical information deficiencies that may prevent timely completion of a risk evaluation consistent with the scientific standards of section 26(h). However, to the extent the information is not currently available or is insufficient, EPA expects to determine whether and how information can be developed and collected, reviewed, and incorporated into analyses and decisions in a timely manner, thus, avoiding a bias towards well characterized chemicals.

EPA expects to make every effort to factor in existing regulations under statutes other than TSCA. As such, as a chemical goes through prioritization, and if needed risk evaluation and risk management, EPA expects to evaluate the regulatory landscape as appropriate for that phase of the process.

While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 2014 Work Plan. In addition to the quantity and quality of information, EPA expects to consider Agency and interagency priorities and overall workload. EPA acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

- Canada did not start the process by assembling chemicals that were on hazard lists. Rather they started from the full DSL. EPA should consider stepping back from the narrow Work Plan starting point and consider the whole active inventory as it works to identify potential high and low priority candidates. *(Bill Greggs, Soleil Consulting)*

Response: In the long term, EPA's goal is to develop a risk-based strategy for selecting potential high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. With this long-term strategy, EPA would be able to consider all chemicals in the active inventory.

#### Best available science

- EPA is statutorily required to draw at least 50 percent of its high-priority substances from the TSCA 2014 Work Plan until the list is exhausted. As such, any new screening process should reevaluate the potential risk of the Work Plan chemicals to ensure that EPA is utilizing the best available science when moving these candidate chemicals through the prioritization pipeline. Work Plan chemicals must be treated like all other candidates, and undergo reevaluation based on the best available science. *(Jared Rothstein, SOCMA; Robert Helminiak, SOCMA)*
- The TSCA Work Plan should be updated to incorporate advancements in the science that would make it a more effective tool for prioritizing candidates for evaluation. *(Karluss Thomas, SEHSC)*
- The criteria in the TSCA Work Plan Methodology for persistent and/or bioaccumulative chemicals are supported by current science and should be used in the pre-prioritization and prioritization processes. *(Veena Singla, UCSF)*
- EPA should base its prioritization decisions on "best available science." *(Sarah Brozena, ACC)*
- The Work Plan should be updated again to correct and update the screening factors to be consistent with the new statutory requirements (e.g., weight of the evidence, the best available science, and sensitive populations), and EPA should consider the likelihood of actual exposure. Weight of the evidence and the best available science also apply to the considerations for prioritization of impacts on sensitive populations. *(DUC)*

Response: The 2014 Work Plan chemical list will not be revised, since it is the list of chemicals that Congress expects EPA to draw at least 50 percent of its high priority substances from for risk evaluation until the 2014 Work Plan chemical list is exhausted, as explained in the prioritization rule. TSCA requires EPA to evaluate the chemicals on the 2014 Work Plan as part of prioritization and, for high-priority chemicals risk evaluation; however, EPA is not bound by the specific findings of the

2014 Work Plan. EPA recognizes that science approaches have evolved and EPA will identify and review reasonably available information, including any new information, during prioritization.

Before initiating the prioritization process, EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient and is consistent with the scientific standards of section 26(h) to allow EPA to complete the prioritization process within the statutory deadlines.

While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA plans to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 2014 Work Plan. In addition to the quantity and quality of information, EPA expects to consider Agency and interagency priorities and overall workload. EPA acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

In the long term, EPA's goal is to develop a risk-based strategy for selecting high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology.

#### Use of CDR data

- In its methodology for identifying Workplan Chemicals, EPA claimed it could not use the CDR data on consumer uses for risk prioritization purposes because Form U combined the two categories into one. This is an absurd decision. If it is impossible to draw distinctions between the two categories as EPA and industry claim, why can't EPA consider all reported uses as consumer uses for the purpose of priority screening analyses? This is some of the most important data collected on Form U, and to not use it leaves us incredulous. There is hope that this 2012 methodology decision was a one-time mistake in judgment. *(Daniel Rosenberg, NRDC)*

Response: Please note that what EPA stated in the *TSCA Work Plan chemicals: Methods Document* of February 2012 was: "A variety of use information was reviewed to determine whether chemicals were used for consumer, commercial, or industrial purposes. At least two data sources were used to confirm consumer uses. For example, a reported use in EPA's IUR alone was not deemed sufficient to identify a chemical as being in a consumer product. Also note that many chemicals are present in several different product use and functional use categories. All reported uses were considered, and the use with the highest exposure potential informed the prioritization ranking."

- EPA should focus evaluations on chemicals with the most potential for exposure and use CDR to establish exposure rankings. *(Raleigh Davis, ACA)*

Response: While CDR is an important source of exposure-related information, the Agency expects to seek to use other exposure-related information, such as TRI and other data sources listed in the 2012 TSCA Work Plan chemicals methods document.

### Use of GHS criteria and other data sets

- EPA should use GHS health hazard criteria as one factor in the ranking process to the extent that the health hazard classes are aligned with GHS adoption in OSHA's Hazard Communication Standard ("HazCom" standard at 29 CFR 1910.1200). *(Raleigh Davis, ACA)*
- For Phase I and II of the TSCA Workplan Approach, ACA supports consulting data compiled and reviewed by ECHA, Health Canada and lists and data used by other national-level agencies to identify chemicals with known hazard information that have already been screened. International companies would like to see closer collaboration between EPA and these countries, provided EPA evaluate data and analysis for quality and differences in evaluative criteria. *(Raleigh Davis, ACA)*

Response: The U.S. EPA has ongoing efforts with both Canada and ECHA to consult on sharing of information and processes as appropriate, and intends to continue that relationship.

Further, EPA does not believe it would be appropriate to limit its analysis to certain specific data sources. EPA expects to consider all reasonably available information that is consistent with 15 U.S.C. 2625(h) in conducting the screening review, including information identified by commenters. EPA recognizes that these data sources may change over time, and therefore chose to caveat its reliance on those sources to the extent that they are "relevant" and "appropriate" for the task at hand.

- EPA should eliminate reliance on lists compiled by states in the TSCA Workplan Approach. Consulting state-level lists (Washington State's Children's List, used in children's products, and California's Proposition 65 List for reproductive toxicity) is not only unnecessary, but also creates an incentive for states to establish their own chemical regulatory programs and lists, compromising EPA's authority to independently develop consistent national-level requirements. *(Raleigh Davis, ACA)*

Response: TSCA recognizes the authority of the States and only limits specific activities of their own regulatory programs when an action has been taken by the Administrator under TSCA. The use of information collected by States would not compromise EPA's authority to independently develop consistent national-level requirements and might avoid duplication of testing or reporting by industry.

- EPA should include the following hazard endpoints: reproductive and developmental endpoints, neurotoxicity, neurodevelopmental endpoints (or developmental neurotoxicity), respiratory endpoints including asthma and lung function, endocrine disruption, thyroid effects, immune and auto-immune effects. *(Amy D. Kyle, UC Berkeley)*

Response: EPA will generally review the reasonably available hazard and exposure-related information, and evaluate whether that information would be sufficient for a particular purpose (e.g., sufficient to support a proposed designation that a chemical substance meets the definition of a High- or Low-Priority Substance). As part of such a review, EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). Hazard information to consider may include but is not limited to study findings on acute toxicity (oral, dermal or inhalation depending on relevant exposure routes) for

human health, and acute and chronic ecological toxicity, as well as relevant endpoints of concern such as developmental and reproductive toxicity, neurotoxicity and/or carcinogenicity.

- With regard to the exposure data, the screening approach relied on data from the 2006 Inventory Update Rule. Again, this is a poor-quality information source that is also outdated. Any ranking is only as good as the data inputs and it is incumbent on EPA to get better data for this. *(Amy D. Kyle, UC Berkeley)*

Response: EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). With respect to the dated information from the Inventory Update Rule, EPA expects to utilize the 2016 Chemical Data Reporting rule information.

## Low priority chemicals

### *Designating more than the minimum*

- EPA should remain committed to identifying more than the statutory-mandated minimum of 20 low-priority chemicals given the size of the active inventory. *(Jared Rothstein, SOCMA; Kathleen Roberts, BRAG; Kathleen M. Roberts, NAMC and NMA; Timothy A. Brown, CSPA; Esther Haugabrooks, PCRM; Catherine Willet, HSUS; James Cooper, AFPM)*
- EPA, per amended TSCA, should focus its efforts beyond statutory requirements towards identifying more high-priority chemicals, where the potential ramifications to human and environmental health and safety from exposure to these chemicals could be significant. *(Esther Haugabrooks, PCRM; Chris Trahan Cain, NABTU; Veena Singla, UCSF; Elizabeth Hitchcock, SCHF; Daniel Rosenberg, NRDC; Melanie Benesh, EWG; Bob Sussman, SCHF)*
- EPA should continue to consider making preliminary or tentative low-priority designations whenever appropriate, with the understanding that as new information on hazards or exposures is identified, such tentative designations can be updated or removed. *(Lawrence E. Cullen, CUC)*

Response: EPA plans to limit the first round of designations to the statutorily required 20 chemicals. EPA has flexibility for identifying any subsequent low-priority chemical substance candidates beyond the required 20 chemicals. EPA will gain experience through the process leading to designation of 20 low-priority substances. Through that process, EPA expects to: (1) better understand how a chemical's exposure profile and production volume might change after designation; (2) further develop exposure information (including high-throughput approaches to estimate exposure); (3) refine its understanding of the data that would support low-priority designations; and (4) learn how NAMs might be helpful to prioritization. This experience will be useful as EPA designates additional low-priority substances. These additional designations can provide an incentive for use of lower risk chemicals.

### *Process of low-priority designation*

- EPA should identify low-priority substances on a continual basis. *(Kathleen Roberts, BRAG)*

- Initially, EPA should adopt a go-slow approach to identifying potential candidates for low-priority substances that ensures EPA has sufficient time to focus on each candidate and the public has ample opportunity to comment on each because: (*Lindsay McCormick, EDF; Richard Denison, EDF*)

Response: EPA plans to limit the first round of designations to the statutorily required 20 chemicals. EPA has flexibility for identifying any subsequent low-priority chemical substance candidates beyond the required 20 chemicals. EPA will gain experience through the process leading to designation of 20 low-priority substances. Through that process, EPA expects to: (1) better understand how a chemical's exposure profile and production volume might change after designation; (2) further develop exposure information (including high-throughput approaches to estimate exposure); (3) refine its understanding of the data that would support low-priority designations; and (4) learn how NAMs might be helpful to prioritization. This experience will be useful as EPA designates additional low-priority substances. These additional designations can provide an incentive for use of lower risk chemicals.

- Low-priority designations are subject to judicial challenge. If EPA inappropriately designates chemicals as low-priority that do not meet the demanding statutory bar, it faces the possibility of judicial challenge and even reversal to high-priority, again risking increasing the overall number of ongoing risk evaluations. (*Lindsay McCormick, EDF; Richard Denison, EDF*)
- Low priority candidates should generally be those that are very unlikely to be high priority, i.e. they exhibit both low hazard and low exposure potential; otherwise, EPA runs a risk of such candidates being found later to be high priority, which would increase the minimum number of chemicals needing assessment. (*Richard Denison, EDF*)

Response: EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute, and select candidates with robust data sets for hazard and exposure.

Once EPA places a chemical into prioritization, the candidate will be designated as either a high priority substance or low priority substance within 9-12 months. If there is not information sufficient to establish that a chemical meets the low priority substance definition as outlined in the statute, the chemical will be designated as a high priority substance.

As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

### ***Recommendations on identifying candidate chemicals***

- Chemicals which could readily be classified tentatively as lower priority substances include substances that: meet the Polymers Exemption criteria (*Lawrence E. Culleen, CUC; Marie*

*Gargas, PLASTICS*), substances on EPA-recognized lists of lower risk substances such as SCIL, and all substances considered by EPA to be “low risk” inert ingredients which qualify for EPA’s exemption from the pesticide registration requirements. (*Lawrence E. Culleen, CUC*)

- One or more of the Y1– or Y2–flagged polymers would be useful candidates as these have already been determined by EPA to be low-risk. (*Marie Gargas, PLASTICS*)
- Substances that have previously been through the new chemical review process or have been identified as low risk through other regulatory programs should be designated as low priority, unless a change in conditions of use (as indicated by CDR) warrant reexamination. (*James Cooper, AFPM*)
- EPA should consider the findings of regulatory risk evaluation programs in other countries, many of which share the same degree of scientific scrutiny and rigor as TSCA. If domestic conditions of use are different, then the Agency should focus on those specific differences and not concern itself with those already reviewed. (*James Cooper, AFPM*)

Response: EPA has considered the suggested sources of candidates from stakeholders and, in alignment with many of the comments, expects to use the sources with qualities that most closely correspond to the statutory requirements for designation of low priority substances. To identify the first 20 low priority substance candidates, EPA will likely select from chemicals that have been reviewed by a government body, such as those included in the EPA’s Safer Chemical Ingredients List (SCIL). EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute, and will select candidates with robust data sets for hazard and exposure under the conditions of use.

- Some UVCB substances, particularly biobased substances, may serve as a source for potential low-priority candidates. For instance, if a UVCB substance, such as “fatty acids, canola-oil, Me esters,” is designated as low-priority under the prioritization rule, EPA should consider similar UVCB substances from similar sources, such as fatty acid methyl esters from coconut oil, tall oil, or walnut oil, to be potential candidates for low-priority designations. EPA can make assumptions about the range of composition of a UVCB substance that can serve to bind the “worst case” composition and inform a reasoned evaluation of the hazard and risk of such a substance. (*Kathleen Roberts, BRAG*)

Response: For the first 20 candidates for low priority designation, EPA intends to select candidate chemicals with discretely defined CAS numbers to ensure the agency has the most accurate and representative supporting information for a chemical. Many UVCBs and other chemicals that do not have a discretely defined structure are associated with data that might not describe the full range of structures represented by a given CAS number. EPA will develop expertise through this first round of prioritization that will inform a longer-term approach.

- EPA should not identify categories of chemicals as candidates for low-priority. (*Lindsay McCormick, EDF; Richard Denison, EDF*)
- EPA should not use an approach that targets chemicals used as intermediates as a category for low-priority designation because: (*Lindsay McCormick, EDF; Richard Denison, EDF*)

Response: EPA will develop expertise through the first round of prioritization and will likely identify individual, discrete substances for this first round. However, in the future, EPA could consider

categories, as stated in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764) preamble: “TSCA section 26 provides EPA with authority to take action on categories of chemical substances.” Furthermore, “...should EPA determine to prioritize a category of chemical substances, EPA would describe the basis for such a determination in the Federal Register notice published to initiate prioritization” and “EPA will provide an explanation of the rationale for initiating the process on the chemical substance, thus ensuring the public has notice and an opportunity to comment on any decision to prioritize a category of chemical substances.”

- While EPA must consider both hazard and exposure, EPA should place particular emphasis on ensuring that potential candidates identified for low priority have a very low hazard profile. (*Lindsay McCormick, EDF*)
- EPA should be cautious not to equate low exposures with low risks. Low exposure alone should not be the basis for designating a chemical as low priority. In some cases, particularly with regards to endocrine disrupting chemicals, low-dose exposures to a chemical can be just as dangerous as—or more dangerous than—high-dose exposures. (*Melanie Benesh, EWG*)

Response: EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute, and will select candidates with robust data sets for hazard and exposure under the conditions of use. As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

- The Agency should consider function, use condition, and low exposure based on relevant occupational exposure limits as a primary consideration for the selection of low priority candidate chemicals. (*Jessica Ryman-Rasmussem, API*)

Response: EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute, and will select candidates with robust data sets for hazard and exposure under each chemical’s conditions of use. As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA will also consider the potential for worker and children’s exposure during the prioritization process and will use the information that is most relevant to the statutory considerations in 6(b)(1)(A). Also, EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

### *Threshold of information*

- Amended TSCA requires a stronger threshold for EPA to make the determination of a low priority substance than it does for a high priority substance, and only with adequate evidence to do so. *(Rebecca L. Reindel, AFL-CIO; Lindsay McCormick, EDF; Richard Denison, EDF)*
- The law very clearly intends all chemicals to be considered high priority unless EPA has sufficient evidence to determine they are not. LSCA requires EPA to assess the risk on the basis of health impacts “without consideration of cost and other non-risk factors.” The risks of concern, explained in the statute, are to people, not to chemical companies and employers. *(Rebecca L. Reindel, AFL-CIO)*

Response: EPA is mindful of the statutory requirements for designating low priority substances and will initiate chemicals into prioritization that have sufficient information to be designated. EPA is committed to designating chemicals that the Agency is confident can be authoritatively designated. EPA must keep in mind the statutory deadlines and the numbers of chemicals that must be moved through prioritization. The law does not anticipate any moment during this process when the Agency can stop to collect additional information. Therefore, EPA must balance the need to adhere to TSCA deadlines with chemicals that have sufficient information for designation as low priority substance. In the associated White Paper EPA has described EPA’s approach to data sufficiency and collection.

The considerations in Section 6(b)(1)(A) will be factors, among others, that EPA will weigh during prioritization. Please note that TSCA section 6(b)(1)(A) sets considerations for the prioritization process, and not for selecting chemicals for prioritization. EPA might consider during the selection of candidate chemicals for prioritization some of the criteria from TSCA section 6(b)(1)(A) to better inform the selection of candidate chemicals for prioritization; however, EPA is not bound by those criteria when selecting candidate chemicals for prioritization.

- EPA should clearly define what constitutes “sufficient information” for evaluation to make a low priority designation. *(Veena Singla, UCSF; Lindsay McCormick, EDF; Bob Sussman, SCHF)*
  - This definition should include a list of traits deemed important to assess, such physical characteristics, health outcomes, effects on potentially exposed or susceptible subpopulations, etc., and a discussion of how these traits will be evaluated to determine whether “sufficient information” is available. *(Veena Singla, UCSF)*
  - EPA should consider requiring a minimum information set for low-priority designations. Nothing in Section 4(a)(2)(B)(ii) or the rest of the statute prohibits EPA from specifying the minimum amount of information sufficient to designate a chemical as low-priority. One starting point for a minimum data set might be the OECD SIDS. *(Lindsay McCormick, EDF; Richard Denison, EDF)*

Response: EPA has declined to publish a bright line rule for “sufficiency” of information. EPA will generally review the reasonably available hazard and exposure information on a case-by-case basis. In the associated White Paper EPA has described EPA’s approach to data sufficiency and collection. The data required to make a low priority determination will vary with a chemical’s hazard, and its exposure across the range of conditions of use. As explained in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764), EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to

initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

- EPA can be protective without requiring a minimum dataset. The statute is very clear that there are no minimum datasets. (*James Cooper, AFPM*)
- The low-priority designation for substances cannot be limited to substances that EPA finds have low hazard to health and ecotoxicity. EPA should also seek out substances that may have an identifiable hazard, but have conditions of use such that the reasonably foreseeable release and exposure scenarios do not present unreasonable risk to potentially exposed and susceptible subpopulations. (*Kathleen Roberts, BRAG*)
- 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. (*Elizabeth Hitchcock, SCHF*)

Response: EPA will base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute and select candidates with robust data sets for hazard and exposure under the conditions of use. In the associated White Paper EPA has described its approach to data sufficiency and collection.

- 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. (*Elizabeth Hitchcock, SCHF; Richard Denison, EDF*) 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, for both susceptible subpopulations and 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. (*Elizabeth Hitchcock, SCHF*)
- 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. 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, which would be misleading and irresponsible. (*Elizabeth Hitchcock, SCHF*)
- To the extent data are missing about particular endpoints, exposures, or susceptible populations, EPA would not have “sufficient” information to make a low-priority designation. Given significant data gaps, it follows that most chemicals will not meet the information requirements to be designated “low-priority.” (*Melanie Benesh, EWG*)

Response: The commenters describe considerations for low priority designations during prioritization. However, TSCA does not require EPA to develop a process for selecting candidate chemicals for prioritization, so therefore the Agency does not have to follow the statutory

requirements for prioritization/risk evaluation during pre-prioritization. EPA intends to assess hazard and exposure potential under known, intended, or reasonably foreseen conditions of use.

## SCIL

- EPA's plan to use SCIL as a source for identifying low priority chemicals is sound since the TSCA Workplan is more likely to produce high priority chemicals. (*G. Tracy Mehan III, AWWA*)
- Green circle SCIL chemicals are an appropriate starting place for identifying potential low-priority chemicals. (*Veena Singla, UCSF; Elizabeth Hitchcock, SCHF et al; Daniel Rosenberg, NRDC; Timothy Brown, CSPA; Lindsay McCormick, EDF*)
- EPA should exclude half green circle and yellow triangle chemicals because they are unlikely to meet EPA's high bar for low-priority definition. (*Elizabeth Hitchcock, SCHF et al; Melanie Benesh, EWG; Lindsay McCormick, EDF*)

Response: EPA appreciates stakeholder comments on the value of SCIL as a starting point to identify candidates for prioritization. To identify the first 20 Low Priority Substance candidates, EPA intends to draw from chemicals that have been reviewed by a government body, such as on the Safer Chemical Ingredients List (SCIL). EPA will likely focus on chemicals with full-green circle SCIL listings. This approach would be consistent with the Agency's approach of selecting candidates with robust data sets for hazard and exposure under the conditions of use.

- SCIL is a valid way to identify potential low priority chemicals; however, care should be taken to make sure the evaluation is risk-based and not be treated as 'testing needed.' (*Catherine Willet, HSUS*)
- SCIL should not be used as a stand-alone source of potential candidates for prioritization because it is not risk-based. (*Sarah Brozena, ACC*)
- SCIL is a starting point for identifying candidates for low-priority designation. Substances with low hazards are not likely to present an unreasonable risk. The LCSA makes clear that prioritization activities must be based on risk and not just hazard, so EPA should also identify chemicals that are suitable for a low-priority designation based on low exposure potential. (*James Cooper, AFPM*)

Response: EPA intends to base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute and select candidates with robust data sets for hazard and exposure under the conditions of use. In the associated White Paper EPA has described its approach to data sufficiency and collection.

- SCIL should be treated as a starting point only. A more robust evaluation of SCIL chemicals will be needed to meet the strict statutory requirements for low-priority designation, including all conditions of use and storage near drinking water sources which is not accounted for in the SCIL criteria. (*Melanie Benesh, EWG; Lindsay McCormick, EDF*)
- In order to meet the statute's requirements, EPA will need to evaluate all conditions of use, including reasonably foreseen uses, and additional hazard endpoints. (*Veena Singla, UCSF; Elizabeth Hitchcock, SCHF et al; Daniel Rosenberg, NRDC; Stephanie Schwarz, EDF*)
- EPA would need to integrate hazard, exposure and use data (including for potentially exposed or susceptible subpopulations) in a comprehensive assessment document providing "information

sufficient to establish” the absence of unreasonable risk, as the statute requires. *(Elizabeth Hitchcock, SCHF et al)*

Response: EPA intends to select candidates with robust data sets for hazard and exposure under the chemical’s conditions of use. In the associated White Paper EPA has described its approach to data sufficiency and collection.

Please note that TSCA section 6(b)(1)(A) sets considerations for the prioritization process, and not for selecting chemicals for prioritization. EPA might consider during the selection of candidate chemicals for prioritization some of the criteria from TSCA section 6(b)(1)(A) to better inform the selection of candidate chemicals for prioritization. The *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764) describes how EPA will consider section 6(b)(1)(a). In addition, the Final rule also indicates that EPA intends to foster a dialogue with stakeholders by publishing a notice explaining why it chose to initiate the prioritization process on the chemical substance and seek relevant information from the public. EPA also intends to publish a proposed priority designation along with an identification of the information, analysis, and basis used to support the proposed designations and provide a comment period on the proposed designation.

- Notably missing from the Safer Choice Master Criteria is endocrine activity, which should be evaluated using the Tiered Protocol for Endocrine Disruption (TiPED) or equivalent. *(Veena Singla, UCSF)*

Response: EPA intends to select candidates with data sets the are adequately robust to support prioritization determinations. These data sets will include hazard and exposure information across a chemical’s conditions of use. EPA intends to consider endocrine activity as part of the prioritization process. EPA will review and evaluate available data for chemicals, including evidence of endocrine activity, and use a weight of evidence approach to determine potential adverse outcomes on apical endpoints, such as reproductive and developmental effects.

Endocrine-related effects continue to be an area of rapidly evolving science. Validation of test methods and guidance for interpretation of data for endocrine activity is ongoing in EPA’s Endocrine Disruptor Screening Program.

- The SCIL list should be evaluated and refined to allow for the equal inclusion of all authoritative lists. The Master Criteria should be expanded to include several GHS criteria (including skin corrosion, eye irritation and corrosion, single dose toxicity, and respiratory irritation) and endpoints evaluated by the California Department of Toxic Substance Control (DTSC) in the Safer Consumer Products program. Toxicity thresholds across multiple endpoints should be expanded to be more protective of human health. Environmental toxicity and fate should be expanded significantly to assess potential impacts of SCIL chemicals on ecosystems and the environment. *(Daniel Rosenberg, NRDC)*
- EPA should expand its search for potential low-priority substances beyond SCIL. EPA’s approach to identifying potential low-priority candidates could apply the Safer Choice program’s low-concern criteria to a broader range of chemicals. *(Kathleen Roberts, BRAG)*

Response: To identify the first 20 low priority substance candidates, EPA intends to draw from chemicals that have been reviewed by a government body, such as the Safer Chemical Ingredients List (SCIL). These reviews contain information on hazard, conditions of use, and exposure that will be useful in designation. EPA will learn through the process of designating the first 20 low priority substances and evaluating stakeholder comments on those designations. This learning will inform our long-term approach for designating additional low priority substances.

- EPA should target the half green circle chemicals for data generation because they currently have data gaps. EPA should exclude yellow triangle chemicals since they do not meet the criteria for low priority chemicals. *(Veena Singla, UCSF)*

Response: EPA agrees that half-green circle chemicals could be an opportunity for stakeholders to provide supporting information or generate additional data.

- EPA has a mandate to consider production volume in prioritization (Section 6(b)(1)(A)); however, the statutory context of this mandate should lead EPA toward looking at *low* production volume chemicals as potential candidates for low-priority designations since they are likely to result in lower exposure – versus *high* production volume chemicals as EPA as proposed. *(Lindsay McCormick, EDF; Stephanie Schwarz, EDF)*

Response: In choosing chemicals for designation, EPA intends to assess the hazard and exposure potential under known, intended, or reasonably foreseen conditions of use.

- SCIL has value in providing direction to how to find “not-as-bad” substances. It is based on a comparative structure but does not provide any absolute level of protection to the public. In some use classes, the “safer” products may still be either known toxics or untested substances. So, as a general matter, it cannot be used to identify low-priority chemicals. There may be some areas in the program where EPA can establish a pattern of data that demonstrate that the chemicals are truly low priority. *(Amy D. Kyle)*

Response: EPA intends to base its selection of candidate chemicals on the best available science, consistent with section 26(h) of the statute and select candidates with robust data sets for hazard and exposure under the conditions of use. EPA intends to assemble information beyond that used to justify SCIL listing to support prioritization. In the associated White Paper EPA has described its approach to data sufficiency and collection.

- EPA should consider SCIL chemicals for which the conditions of use are limited solely to those encompassed in the product categories that SCIL covers. Selecting SCIL chemicals which are used in products and applications beyond those covered by SCIL would re-open the data gaps unless their safety in all of the other products and applications has been fully assessed and found to be safer. *(Daniel Rosenberg, NRDC)*

Response: EPA intends to identify and evaluate the conditions of use for a given chemical beyond SCIL.

- For some functional use categories, SCIL only applies a subset of TSCA relevant criteria. For example, for surfactants, EPA has only considered eco-toxicity and has not examined human health endpoints. These critical limitations are given minimal attention in EPA's document and the Agency will need to address them before considering use of SCIL (*Stephanie Schwarz, EDF*)

Response: EPA intends to select candidates with robust data sets for hazard and exposure under the conditions of use, beyond the functional class criteria. The master criteria currently incorporate GHS criteria and are aligned with EPA's New Chemical Program. The criteria may be found here: [https://www.epa.gov/sites/production/files/2013-12/documents/dfe\\_master\\_criteria\\_safer\\_ingredients\\_v2\\_1.pdf](https://www.epa.gov/sites/production/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf).

### Functional Category Approaches

- While it's unclear that either functional category approach would be appropriate for prioritization, EPA could use functional category based on use, exposure and structure to inform prioritization decisions. (*Catherine Willet, HSUS*)
- Grouping chemicals by structure, functional use, or exposure potential is an approach that should be approached with caution. It could lead to scenarios where high priority chemicals are falsely classified into low priority designations because the group of chemicals as a whole is considered low priority, as well as the inverse occurring. (*G. Tracy Mehan III, AWWA*)
- EPA should be applauded in offering approaches that focus on functional use, but several concerns arise:
  - If data-poor chemicals are excluded from pre-prioritization screening within a functional category, but all the other chemicals are screened and potentially receive high priority designations, the data-poor chemical could gain a commercial advantage within that function simply because it was not screened.
  - A number of factors to be assessed under the functional category approaches (e.g., number of workers or volume of chemical used per function) are reporting elements under the Chemical Data Reporting (CDR) rule that often have severely conflated values due to duplicative reporting among CDR submitters. (*Kathleen M. Roberts, NAMC and NMA*)
- Any category approach used by EPA should be science-based. EPA must be transparent when it contemplates category approaches to prioritization so that stakeholders can fully understand all the factors leading to EPA's consideration of a category of chemicals for prioritizing for risk evaluations. Public consultation is recommended in the pre-prioritization stage when EPA is specifically considering the use of chemical categories. (*Barbara S. Losey, APERC*)
- EPA should not use the two functional category approaches because they are not risk based. (*Sarah Brozena, ACC; Veena Singla, UCSF et. al.*)
  - Uses of chemicals can and do rapidly change which would render a prioritization relying solely on current uses inaccurate (*Veena Singla, UCSF et. al.*)
  - The benefits to public health, especially for the most vulnerable, are not clear. (*Veena Singla, UCSF et. al.*)
  - Both approaches, especially the functional category approach based on chemical structure and function, appear to consider factors related to the viability of alternatives

to high priority chemicals, a non-risk factor which TSCA 6(b) explicitly prohibits. (*Veena Singla, UCSF et. al.*)

- These approaches would not support a meaningful scoring system and could not (and should not) replace the Work Plan Methodology. (*Elizabeth Hitchcock, SCHF*)
- The emphasis EPA has placed on these two category approaches for identifying chemical substitutes is neither appropriate nor complies with the law's requirement that the prioritization process be risk-based (section 6(b)(1)(A)). (*Lindsay McCormick, EDF*)
- IFRANA does not understand the two proposed functional category approaches. Most important, we do not see how these approaches can be considered risk-based. (*Amanda K. Nguyen, IFRANA*)
- EPA's presentations on these two approaches were not entirely clear, and functional categorization doesn't seem to add any value. (*Amy D. Kyle, UC Berkeley*)
- The functional category approaches are more useful for pre-prioritization than for the prioritization process itself. (*Lorenz Rhomberg, Gradient*)

Response: EPA appreciates the comments and does not expect to use the functional use approaches presented at the December 11, 2017 meeting as the basis for selecting candidate chemicals for prioritization. However, EPA might still consider chemical structure, functional use and other chemical characteristics to identify relevant hazard or exposure data of candidate chemicals.

### *Use and exposure potential*

#### General support

- EPA should adopt this approach with consideration for: (i) lessons learned from Canada's experience and how they evolved. (ii) exposure information for conditions of use. (iii) If elements from the strategy to identify Work Plan chemicals is used it should be updated with new information to reduce uncertainty to the extent possible. (iv) use of SCIL to augment prioritization, with inclusion of exposure information. (*DoD*)

#### Concerns

- A caveat for this approach is that it may let a high hazard chemical without a category to not be selected early. The discussion document states "EPA does not expect that the path forward will necessarily entail choosing one single approach, but rather may include a number of differing approaches and tools, or components of differing approaches and tools, that could work in tandem." With this in mind, could this methodology be combined with one or more other methods in order to ensure that high hazard chemicals are not overlooked within the pre-prioritization process? (*Diane VanDe Hei, AMWA*)
- Chemicals that may come into contact with drinking water sources should be placed into highest tier of prioritization if EPA moves forward with this option. (*Diane VanDe Hei, AMWA*)
- The successful implementation of this approach would require a significant level of stakeholder input at nearly every step of the process, and likely result in delays. Relying on CDR data may result in inaccurate classification of categories since double-counting often occurs for some data, particularly the volume reported and the number of exposed workers. (*Kathleen Roberts, BRAG*)

- Given the statutory mandate that the prioritization process be risk-based and consider all conditions of use, this approach will not provide an efficient route to identifying candidates for prioritization. *(Kathleen Roberts, BRAG)*
- It's unclear whether EPA has sufficiently accurate information on uses and potential exposure to proceed with this approach. Unmanageable challenges and unintended outcomes arise if the risk prioritization scheme relies too heavily on extreme exposure assumptions or over use of maximum values. *(DUC)*
- This option does not provide a clear, transparent or robust process that meets the statutory requirements. It may provide information on high priority categories due to exposure potential for vulnerable populations, but it is not effective for identifying low priority chemicals because these assumptions may mask real-world conditions that increase risk. *(Daniel Rosenberg, NRDC)*
- The functional use approach is a valid method to generally categorize potential exposures, but there should be a distinction between chemicals used in a controlled industrial setting and those used in consumer and commercial settings. *(James Cooper, AFPM)*
- Given that section 6(b)(1)(A) of the new law mandates EPA to consider in the prioritization process potential risks to potentially exposed or susceptible subpopulations – which explicitly includes workers – EPA cannot make sweeping assumptions that have the effect of deprioritizing worker exposures in identifying potential candidates for prioritization, as it is proposing to do here. *(Lindsay McCormick, EDF)*
- EPA should be cautious in its use of this approach. Many chemicals can be categorized into multiple functional-use classes. This approach may strain the resources which EPA has at its disposal by needing to evaluate the same chemical which does not have a high hazard potential or high exposure multiple times. Further, by focusing on exposure potentials related to a functional use category, chemicals with a high hazard profile may be passed over due to low exposure potential in a particular use for chemicals that have a comparable lower hazard profile that have higher exposure potentials. *(Timothy Brown, CSPA)*
- In step two of its process for tiering, EPA is proposing that two or more exposure factors are required to modify the product category tiering from step one. This unacceptably downplays exposure to vulnerable subpopulations, which by itself should drive a higher ranking. *(Stephanie Schwarz, EDF)*
- EPA asserts in step one that many industrial and commercial operations will have overarching health and safety procedures to minimize exposures. EPA cannot make such a blanket statement without sufficient evidence of adoption and compliance across all actors in the supply chain. *(Stephanie Schwarz, EDF)*

Response: EPA appreciates the comments and does not expect to use the functional use approaches presented at the December 11, 2017 meeting as the basis for selecting candidate chemicals for prioritization. However, EPA might still consider chemical functional use and other chemical characteristics to identify relevant hazard or exposure data of candidate chemicals.

EPA also appreciates the comments regarding the shortcomings of this methodology (e.g. robust consideration of potentially exposed or susceptible subpopulations, accuracy of the information, comparison between industrial and commercial and consumer uses, etc.), and will consider these comments as the Agency develops a long-term risk based strategy for selecting candidates for prioritization.

## *Chemical structure and function*

### General support

- EPA should use the Functional Category Approach (based on chemical structure and function) to streamline the pre-prioritization process. *(Raleigh Davis, ACA)*
  - EPA already uses similar technology that this approach would require in its New Chemicals Review Program. *(Raleigh Davis, ACA)*
  - This approach would allow EPA to rank large numbers of chemicals more efficiently.
  - Ultimately; however, final selection and any subsequent regulatory actions must be based on appropriate, scientifically valid, information. *(Raleigh Davis, ACA)*
  - This approach relies heavily on publicly available information. As such, EPA should open the process to public comment to make the evaluations more robust. *(Raleigh Davis, ACA)*

### Not supportive

- The availability of substitutes is a non-risk factor that should not be part of the prioritization process. It is relevant only when considering risk management measures. *(Sarah Brozena, ACC; Barbara S. Losey, APERC; Melanie Benesh, EWG; Lindsay McCormick, EDF)*
- This proposed methodology relies on relative risk within a narrow category, rather than following the broad mandate to identify high- and low-priority substances called for under the law. *(Lindsay McCormick, EDF)*
- The functional category approach is useful for *predicting toxicity ranges*, but EPA should not attempt to identify *uses* by way of molecular structure. This approach is a complicated process that does not fit well into the Work Plan approach. There is no value in trying to determine uses based on molecular structure as a component of any pre-prioritization approach. *(James Cooper, AFPM)*
- EPA should not rely on structure and function for designating low priority chemicals *(Daniel Rosenberg, NRDC)*

### Concerns with approach / recommended ways to modify

- Successful implementation of this approach would require significant stakeholder support. Industry would need to assist EPA in the refinement of the functional use categories and the identification and verification of potential alternative chemicals. Such substantial industry participation is likely to result in delays. Relying on CDR data may result in inaccurate classification of categories. The use of models to build and classify the functional categories will diminish the efficiency of the pre-prioritization process and would be resource-intensive. *(Kathleen Roberts, BRAG)*
- Categories of chemical substances must be carefully considered, scientifically based and subject to specific opportunities for public comment. Section 2625(c) of TSCA provides EPA with authority to take action on categories of chemical substances. *(Barbara Losey, APERC)*
- EPA should not designate a substance as high priority based solely on chemical structure and function. Some further basis should be provided, such as consideration of the factors enumerated in the statute and known data. *(DUC)*
- Structure-function categories may be useful for designating high-priority chemicals. Increasingly sophisticated screening methods of thousands of chemicals and publicly accessible

toxicogenomics data collected on hundreds of chemicals are being used to generate molecular information that is potentially useful to support predictive toxicity modeling. *(Daniel Rosenberg, NRDC)*

- EPA should be cautious in its use of a functional category approach based on chemical structure and function. Slight modifications in structure can have profound effects on the health and environmental assessment of an individual chemical. Further, many chemicals have multiple functionalities – while understanding that a single use might have a higher potential impact for a population or subpopulation, the number of possible uses for a single chemical might strain EPA’s resources. EPA also might not have complete data for all chemicals used in a particular usage, missing critical chemicals that should be reviewed before others. *(Timothy Brown, CSPA)*

Response: Based on the weight of stakeholder comment, the Agency does not expect to use the function use approaches proposed approach as presented in the December 11, 2017 meeting as the basis for selecting candidate chemicals for prioritization. However, EPA might still consider chemical structure, functional use and other chemical characteristics to identify relevant hazard or exposure data of candidate chemicals.

## Canada’s Chemicals Management Plan

### *General Support of CMP (or Elements of CMP)*

- EPA should continue to consider how to apply the methods used by Canada for its Chemical Management Plan in the Agency’s efforts to update the Work Plan lists. *(Lawrence E. Culleen, CUC)*
- There is support for the use of a prioritization approach modeled from Canada’s Chemical Management Plan (CMP). There are a number of lessons that could be readily adapted for TSCA. For example, consideration of exposure of ecological receptors and use of weight of evidence are important during prioritization. Another benefit would be the ability of EPA scientists to confer regularly with their colleagues at Health and Environment Canada regarding the prioritization process, data needs, incorporating new tools and techniques as they become available, and practical implementation of the prioritization process. *(Karluss Thomas, SEHSC)*
- The Agency is commended for incorporating international prioritization efforts and encouraged to continue consideration of efforts from other international regulatory bodies regarding prioritization of chemicals. Canada’s approach could be extremely useful for the Agency to model and encourage the incorporation of relevant elements. *(Esther Haugabrooks, PCRM)*
- EPA can and should adopt and adapt the Canadian approach and apply it as the chief means of identifying potential candidate chemicals (and chemical categories) for low-priority designation. *(Amanda K. Nguyen, IFRANA)*
- EPA should adapt the CMP to conduct a similar exercise for chemicals in U.S. commerce. *(Jared Rothstein, SOCMA)*
- The Canadian CMP was based on strong stakeholder engagement, which began early in the process. This early engagement led to buy-in to the approaches considered (and eventually adopted) which resulted in less industry opposition. Stakeholder engagement played an essential role in developing information, gathering approaches and developing strategies. This approach confirms the benefits of obtaining evidence from industry and sharing preliminary decisions. *(DUC)*

- The benefit of the Canadian process is that it looks at everything – it is a good basis for discussion on chemicals. It does not rank them strictly, but categorizes them, identifies possible data gaps, starts stakeholder conversations about them, and tries to elicit information. *(Lorenz Rhomberg, Gradient)*
- There are currently approximately 8,500 chemicals on the U.S. active list that Canada set aside for further prioritization and evaluation. EPA should not reinvent the wheel when it has an opportunity to leverage the work of Canada and use those 8,500 as a starting point for identifying potential low priority candidates. That said, Canada's categorization was conducted 10-15 years ago and there may be new information on some of the chemicals. EPA should evaluate whether Canada's conclusions are still valid and the current uses and exposures in the U.S. are consistent. *(Christina Franz, ACC)*

*Recommended ways to modify CMP (and apply best practices and lessons learned)*

- The approach provides best practices: (i) importance of a risk-based approach since less than 10% of substances identified as priority based on ecological hazard turned out to be of low concern when exposure was considered; (ii) periodic review of finished assessment to identify how to further refine the process; (iii) following a similar approach to screen chemicals of low known or potential exposure and application of the Threshold of Toxicological Concern. EPA is already adopting: development of NMs and engagement of stakeholders. *(Catherine Willet, HSUS)*
- EPA should refer to the low-priority findings from the CMP screening assessments to identify chemicals that might also be likewise designated as low-priority. *(Kathleen Roberts, BRAG)*
- EPA should implement rapid screening tools to assess substances expected to be low-priority. Similar to the Government of Canada's approach, any chemical that is flagged during the rapid screening as appearing to present a potential unreasonable risk can be further assessed by other means. *(Kathleen Roberts, BRAG)*
- EPA should implement a process for collating and incorporating newly available data on a regular basis and for providing stakeholder input on such information, similar to the identification of risk assessment priorities (IRAP) approach that the Government of Canada implemented. *(Kathleen Roberts, BRAG)*
- The legislative mandates governing CMP differ from those under TSCA. As a result, the CMP process did not screen candidate chemicals against all of the criteria and considerations specified in TSCA Section 6(b)(1)(A). In using the CMP process, EPA will need to develop mechanisms to integrate the required data and fill data gaps where possible. *(Kathleen Roberts, BRAG)*
- EPA should employ a systematic, risk-based approach to identify potential candidates for prioritization that considers hazard and exposure information on each chemical at each step of the process. However, EPA should go one step further than Canada and integrate hazard and exposure information to achieve a true risk basis for prioritization. *(Sarah Brozena, ACC)*
- EPA should fully consider the lessons learned from Canada's Chemical Management Plan (CMP). There are differences between TSCA and CEPA, as well as differences in US and Canadian commerce. However, there is enough consistency in scientific principles and general approaches to risk evaluation that EPA can learn from the experience of Canada. Lessons learned include: *(James Cooper, AFPM)*

- EPA should use information available from Health Canada in evaluating the revised TSCA Inventory. EPA can identify chemicals that are both “active” on the revised TSCA Inventory and listed on Canada’s DSL (Domestic Substances List) of 23,000 chemicals. EPA can refer to Health Canada’s screening and categorization of these 23,000 chemicals for persistence, bioaccumulation and toxicity, as part of EPA’s pre-prioritization screening process. *(Raleigh Davis, ACA)*
- The Canadian Chemicals Management Plan allows for stakeholder involvement in the initial evaluation of existing chemicals. It makes no sense for EPA to reinvent the wheel when data has already been submitted and used by Canada, Europe as well as other regions around the world. By assessing currently available toxicity data in existence in other countries, the EPA can be more efficient and better utilize its resources in determining which chemicals are chosen for a full assessment. Broader examination and consideration of otherwise available data would be consistent with the essence of the Lautenberg Act as a whole in evaluating as many potential concerns as possible. CSPA encourages continued international partnerships such as the U.S.-Canada Regulatory Cooperation Council. *(Timothy A. Brown, CSPA)*

### *Not Supportive*

- The Canadian model of chemical prioritization would not be sufficient to meet the statutory requirements of TSCA, and therefore is not an appropriate method for EPA to use. *(G. Tracy Mehan III, AWWA)*
- EPA should not adopt the Canada CMP approach for pre-prioritization. The CMP prioritization process did not include discriminatory functions for metals and the screening mechanism set up for organics did not work well for metals. Instead, an advisory expert group had to be formed to assist with interpreting the CMP regulations for metals and other inorganics. *(Kathleen M. Roberts, NAMC and NMA)*
- Canada’s processes have a number of aspects that are misaligned with TSCA requirements and considerations for prioritization. First, CEPA required Health Canada to sort through 23,000 substances on the Domestic Substances List (DSL) to identify (“categorize in”) chemicals meeting certain criteria indicative of potential risk in just seven years (1999 to 2006). Unlike prioritization under TSCA, Canada’s categorization exercise was intended only to identify chemicals of potentially high concern, not to also identify chemicals of low concern. *(Lindsay McCormick, EDF; Stephanie Schwarz, EDF)*
- While Canada’s chemical management plan should be seen as a potential source of data for EPA, it would not be appropriate for EPA to adopt Canada’s chemical management plan. EPA has not verified whether the Canadian process meets the specific requirements of the statute and the prioritization rule. Additionally, the Canadian process exempts workers. Furthermore, there are differences between Canada and the U.S. (e.g. Canada has a much smaller population than the U.S. and has a much smaller share of the global chemical market; many of the chemicals reviewed in Canada lacked sufficient data and the Agency lacked the authority to request additional data). Given these significant differences in demographics, market share, statutory requirements, and data collection authority, the Canadian chemical management plan is likely not a good model for EPA to adopt. *(Melanie Benesh, EWG)*
- The Canadian approach was not adequately transparent is not an appropriate model. *(Amy D. Kyle, UC Berkeley)*

- The Canada CMP approach is best used to augment other approaches, and is not sufficient on its own as a basis for low-priority designation. While it may offer useful lessons and a potential starting point for inquiry, a chemical rated as a lower priority in the Canadian program may not meet the statutory standard for a low-priority designation under TSCA. *(Daniel Rosenberg, NRDC)*
- Canada has a population that is only 11 percent that of the U.S. and has only about 2 percent of the global market in chemical with the great majority of those chemicals imported, rather than domestically manufactured. Given the sharp contrasts with U.S. chemicals economy, it does not make sense to use this model. *(Stephanie Schwarz, EDF)*

Response: The U.S. EPA and Canada have a history of working cooperatively on chemical evaluations and EPA intends to continue that relationship, including appropriate sharing of information.

Canada operates under a different legislative construct, and their efforts to categorize all substances on their Domestic Substances List (DSL) were undertaken in that context. Under the Canadian Environmental Protection Act 1999 (CEPA), Health Canada and Environment Canada worked together to sort through approximately 23,000 substances on their DSL to determine what chemicals should get further attention. Specifically, Environment Canada's review during this process was limited to identifying chemicals that were persistent, bioaccumulative and inherently toxic to the environment. Health Canada's review was limited to identifying chemicals that had the greatest potential for human exposure and inherently toxic to humans. Chemicals that met these criteria (~4000) were placed in a priority sequence for further review. The Government of Canada uses this list, completed in 2006, to focus resources on chemicals with the highest hazard and greatest potential for exposure.

Contrast this process with EPA's task under TSCA: to prioritize all chemical substances on the TSCA inventory as either High-Priority Substances (for which risk evaluations begin immediately, and are subject to a 3-year statutory deadline) or Low-Priority Substances (a final agency action to set aside the chemical, subject to judicial review). Additionally, the criteria for categorizing chemicals is not comparable. TSCA defines a "High-Priority Substance" as one that "may present an unreasonable risk" based on a potential hazard and a potential route of exposure. A "Low-Priority Substance" under TSCA is a chemical for which there is "information sufficient to establish" that the chemical doesn't meet the High-Priority standard. Canada's review was explicitly limited to identifying PBTs (for the environment), and toxic chemicals with the "greatest" exposures (for human health). In other words, the ~19,000 chemicals that Canada temporarily set aside under CEPA did not undergo the equivalent of a TSCA Low-Priority designation.

## **Integration of Traditional and New Approach Methods**

### *General support*

- In the near-term, integration of NAMs should be done with careful consideration and should be flexible, depending on context. With increasing confidence in the approaches, NAM could be used for prioritization and risk evaluation. *(Catherine Willet, HSUS)*

- EPA should develop an approach that uses high-throughput screening and QSAR modeling during prioritization for filling information gaps that arise in traditional toxicology data. Candidate chemicals under consideration could be refined and filtered by the amount of data available for a chemical's hazard and exposure potential, improving the certainty of priority designations. Employing an open and interactive screening process that allows for stakeholder input should minimize complications that arise from the evaluation of candidates with unique chemistries. *(Jared Rothstein, SOCMA)*
- In the Integration of Traditional and New Approach Methods [NAMs], the Agency demonstrates that it is poised to use non-animal NAMs in making regulatory decisions. At the meeting, EPA indicated that this approach has already been further developed since the preparation of the discussion document including the addition of acute toxicity and ecotoxicity data. This is a major advance in transforming toxicology from an observational science based on evaluating apical endpoints in animals to a predictive science based on evaluating perturbations in biological pathways in cells, preferably of human origin. *(Joseph Manuppello, PETA)*
- The final EPA approach should integrate older approaches with new scientific screening methods. *(Kathleen M. Roberts, NAMC and NMA)*
- It is clear that HTP and other alternative methods are the only way that efficient prioritization can be accomplished. Continued use of these approaches will reinforce the Agency's commitment to move away from the default regulatory reliance on traditional in vivo methods and encourage increased use of NAMs for regulatory decisions. *(Esther Haugabrooks, PCRM)*
- Hazard characterization of petroleum substances by Tox21 assays is challenging, therefore, novel approaches are required. *(Uni Blake, API)*
- CSPA supports identification of methods and approaches to facilitate high throughput screening and prioritization, such as SHEDS-HT. It is also critical that these models rely upon exposure models and use scenarios that are reflective of current uses in commerce. *(Timothy A. Brown, CSPA)*
- Expanding the biological coverage of new assessment methodologies is a research priority. Building scientific confidence in NAMs is critical to ensure acceptance by all stakeholders. *(Rick Becker, ACC)*

Response: In the long-term, EPA's goal is to develop a risk-based strategy for parsing the TSCA active inventory into bins that can be used to inform priorities within the TSCA program. The bins are intended to reflect both important components such as hazard, exposure, persistence, and bioaccumulation as well as information availability. The long-term strategy builds on the TSCA 2012 Work Plan methodology and incorporates objectives identified for integrating NAMs in the Canadian Chemicals Management Plan (CMP)<sup>4</sup>. The use of NAMs is critically important to bin the thousands of chemicals on the active TSCA inventory. In the current long-term strategy, NAMs are integrated to fill gaps when traditional testing information are not available. EPA also acknowledges the need to work closely with stakeholders in order to build scientific confidence and acceptance of the use of NAMs. As scientific confidence in NAMs is established through the process outlined in the EPA's

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<sup>4</sup>Chemicals Management Plan Science Committee Objectives Paper for Integrating New Approach Methods (<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=172614CE-1>).

Strategic Plan to Promote the Development and Implementation of Alternative Test Methods<sup>5</sup>, NAMs may be accepted as alternatives to, or eventually replace, certain traditional tests.

### *Recommended ways to enhance approach*

- HTP screening assays offer a rapid and cost-effective route to analyzing potential candidate substances. To ensure accurate and reliable results, such assays must undergo rigorous, formal validation before being used. EPA is urged to clarify the criteria for assessing new HTP assays and specify that it will provide an opportunity for public comment on the proposed assay prior to implementing it in the pre-prioritization process. *(Kathleen Roberts, BRAG)*
- EPA's ORD is strongly encouraged to continue improving the tools for making EPA's approach to prioritization easier and more risk- and science-based. It is imperative that EPA implement procedures to foster direct collaboration of scientists in ORD with scientists in OPPT to ensure these new scientific approaches are fit-for-purpose within the context of the risk-based decisions required under TSCA. *(Sarah Brozena, ACC)*
- The Work Plan utilizes a qualitative method for ranking exposure with an algorithm that combines information on use type, general population and environmental exposure and releases. Rather than that indirect method for ranking, it would far preferable to use a quantitative method. If NAM exposure tools, such as SEEM and SHEDS-HT can provide scientifically sound, appropriately health-protective consumer, environmental and worker exposure estimates, it would improve this part of the process. *(Sarah Brozena, ACC)*
- EPA may use its order authority to request additional data generated by validated high-throughput technology to generate an array of screening-level information for data-poor chemicals. Validated screening techniques may assist in closing data gaps for a spectrum of endpoints, deciding whether to consider related chemicals as a category, and identifying new areas of potential concern where additional testing may be warranted. *(Melanie Benesh, EWG)*
- New approach methods may only be appropriate for certain chemicals or certain types of chemicals and not others. Correlation between testing methodologies needs to be adequately investigated before the adoption of new approach methods can be relied on to fill data gaps and ensure new approach methods are not used prematurely. *(Melanie Benesh, EWG)*
- There is support for the inclusion of endocrine activity endpoints as suggested, but note that limiting these endpoints to estrogenic and androgenic (or antiestrogenic and anti-androgenic) activities is a poor representation of the vast biological pathways regulated by the endocrine system—including but not limited to thyroid, neuroendocrine and metabolic effects—and that continued work should be done to validate and include these additional endpoints in new approach methods. *(Melanie Benesh, EWG)*
- EPA has already identified a number of data gaps through its Integration of Traditional and New Approach Methods, which could serve as the basis for section 4 and/or section 8 rules. *(Lindsay McCormick, EDF)*

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<sup>5</sup>Alternative Test Methods and Strategies to Reduce Vertebrate Animal Testing in TSCA (<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>).

- CSPA supports identification of methods and approaches to facilitate high throughput screening and prioritization, such as SHEDS-HT. It is also critical that these models rely upon exposure models and use scenarios that are reflective of current uses in commerce. *(Timothy A. Brown, CSPA)*
- Expanding the biological coverage of new assessment methodologies is a research priority. Building scientific confidence in NAMs is critical to ensure acceptance by all stakeholders. *(Rick Becker, ACC)*

Response: EPA appreciates the recommendations on how to enhance this approach. In the development of the long-term strategy, ORD and OCSPP worked closely together to develop a risk-based approach for parsing the TSCA active inventory into bins that can be used to inform priorities within the TSCA program. The risk-based strategy would consider both hazard and exposure-related information and integrates NAMs to fill gaps when traditional testing information are not available. For the exposure component, EPA intends to use quantitative exposure modeling approaches such as SEEM that incorporate information on chemical uses.

An important part of the long-term approach includes implementation of EPA's Strategic Plan to Promote the Development and Implementation of Alternative Test Methods where a variety of weight-of-evidence approaches are considered for using and integrating NAMs for use in decision making. As part of this strategy, EPA intends to work closely with stakeholders to enhance collaborative efforts for identifying research needs for building confidence in NAMs specifically for TSCA.

### *Concerns with approach*

- Applying Method 5 to prioritization would likely be inconsistent with the statutory criteria, particularly with regards to potentially exposed or susceptible populations. *(Melanie Benesh, EWG)*
- NAM data alone should not be used to designate a chemical as low-priority as this is not consistent with the statute's requirement for "sufficient information." A hazard classification is never made based on high-throughput or other kinds of NAM data alone. EPA should continue to follow this established scientific practice. *(Veena Singla, UCSF)*
- NAMs are not sufficiently advanced and scientifically reliable to provide a stand-alone tool for scoring potential candidates for high-priority listing. Nor do we believe they can validly be used as a basis to designate substances as low-priority. 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. 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.). *(Elizabeth Hitchcock, SCHF)*
- There are severe limitations that demonstrate the need for additional research and development prior to the sole use of ATMs—particularly for identifying low toxicity or exposure. *(Daniel Rosenberg, NRDC)*

- NAMs may be of value, but each must stand on its own scientific merits. This approach should be viewed as a set of tools that could be used to augment EPA's TSCA Work Plan Method, but care must be taken to ensure transparency and scientific validity when using any of the tools. The web-based tool should be made available for public comment before it is used as part of a regulatory program. *(James Cooper, AFPM)*
- NAMs have a role in the process of identifying potential candidates for prioritization, given the large number of chemicals with limited information that EPA will need to sort through. However, such methods also have significant limitations. NAMs are not currently available for all potential modes of toxicity across diverse human and ecological populations, including those arguably of greatest concern, such as developmental toxicity. *(Lindsay McCormick, EDF)*
- Data generated from NAM approaches should be considered supportive, but lack of data should not be considered a measure of safety. *(Jessica Helm, SSI)*

Response: EPA appreciates the comments related to the importance of the use of NAMs, along with the concerns related to potential limitations in the use of NAMs for prioritization. EPA's goal is to develop risk-based strategy for parsing the TSCA active inventory into bins that can be used to inform priorities within the TSCA program. The long-term strategy builds on the TSCA 2012 Work Plan methodology and considers important components such as hazard, exposure, susceptible populations, persistence, and bioaccumulation. In order to bin the thousands of chemicals on the active inventory, the long-term strategy intends to integrate NAMs to fill gaps when traditional testing information are not available. The binning process is intended only to reflect the synthesis of a substantial volume of information and to allow EPA to loosely group chemicals into pools of potential candidates for further evaluation. This process would inform EPA's decision, but would not be determinative. Expert review of the substances within the bins would be an integral part of the process.

An important part of the long-term approach includes implementation of EPA's Strategic Plan to Promote the Development and Implementation of Alternative Test Methods where a variety of weight-of-evidence approaches are considered for using and integrating NAMs for use in decision making. As part of this strategy, EPA is actively working to address many of the technical limitations associated with NAMs (e.g., metabolic competence, solubility) and intends to work closely with stakeholders to establish scientific relevance, reliability and confidence of NAMs, specifically for TSCA. Section 4(h)(2)(F) also requires the EPA to prioritize and carry out performance assessment, validation, and translational studies to accelerate the development of NAMs (to the extent consistent with available resources and the Administrator's other responsibilities under TSCA). EPA views its domestic collaborations with ICCVAM and NICEATM, its international engagement with OECD, and its working with stakeholders and the public as helping to meet this requirement.

*More information/clarification from EPA needed*

- This approach seems similar in some regards to the Canadian Chemical Management Plan. EPA should put in writing what this means in detail so interested parties, such as the Downstream Users, can understand how it affects their operations and how they need to use it for internal planning purposes. *(DUC)*

- What alternative methods are deemed valid and fit-for-purpose of identifying potential candidates for prioritization now? To support implementation commencing in June 2018, can EPA indicate those NAMs for which it has sufficient scientific confidence in as being qualified equivalent or better than traditional methods? And in future expansion of this approach, what other NAM endpoints and approaches might be included for both hazard and exposure screening? *(Sarah Brozena, ACC)*

Response: The long-term strategy builds on both the TSCA 2012 Work Plan methodology and incorporates objectives identified for integrating NAMs in the Canadian Chemicals Management Plan (CMP). An important part of the long-term approach includes implementation of EPA's Strategic Plan to Promote the Development and Implementation of Alternative Test Methods which provides both a list of acceptable NAMs, as well as the criteria for considering scientific reliability and relevance of NAMs within the TSCA program. The list of NAMs included in the final Strategic Plan is not meant to be exhaustive, but more representative of possible NAMs. EPA will consider methods and strategies not included in this list if they meet the criteria described in the Strategy. EPA expects that the decision context for an individual NAM may change over time as confidence in different tests may evolve based on data, experiences, and retrospective analyses.

## Other methods

### *General*

- The following process is recommended:
  - Create an initial candidate list of 60 chemicals using the Work Plan (or another appropriate) screening methodology. The candidate chemicals would be those scoring highest for exposure and hazard.
  - Conduct literature search of the candidate list chemicals 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.
  - 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. Amend section 8(d) and 8(a) rules to provide an automatic triggering mechanism for candidate list chemicals.
  - Develop a "roadmap" (or matrix) showing hazard, use and exposure scenarios where data are available and scenarios where data are lacking for each candidate chemical.
  - Determine data-gaps that need to be filled and issue section 4(a)(2) orders to require development of the necessary information.
  - 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.
  - Repopulate the candidate list. Every high-priority chemical would be replaced by a new candidate chemical to be screened. Chemicals could drop from the list if, based on screening, they are determined not to be suitable for prioritization at the current time. *(Elizabeth Hitchcock, SCHF)*

- The most pragmatic and efficient approach is for EPA to update its TSCA Work Plan methodology (both the methodology and its underlying data and information) and to integrate within it (in its updated form) certain practical aspects of Canada’s Chemical Management Plan (CMP) approach. If the New Approach Methods are currently ready for use, EPA OPPT should work with EPA ORD to integrate these approaches into the updates to the Work Plan methodology as appropriate. If these currently are not quite ready for these purposes, EPA should update its approach with them when they are ready and use them in a future round of identifying potential candidates for prioritization. *(Sarah Brozena, ACC)*
- EPA should consider a variety of regulatory approaches when creating its process to identify chemicals for prioritization. Of the six approaches listed by the Agency, only two are established regulatory approaches to select chemicals for prioritization: EPA’s Work Plan Methodology and the approach used under Canada’s Chemical Management Plan (CMP). There may be components of other regulatory approaches not found on the list that could be of value. EPA should not limit itself by only looking at its current approach and that used by Canada. *(James Cooper, AFPM)*
- EPA needs to preserve the flexibility to identify potential candidates for high-priority designations that are not necessarily elevated through the established methodology. Rather than attempt to develop a prescriptive system whereby EPA would seek to be able to predict all future concerns chemicals may present, EPA should preserve flexibility to identify candidates based on new information and through new approaches. (EPA should of course incorporate section 8(e) substantial risk reports it receives for all chemicals into its methodology, if it has not already done so.) *(Lindsay McCormick, EDF)*
- The pre-prioritization process should provide a clear definition of a “use type” and exposure from “chemical intermediates” in the Work Plan methodology and/or in a successor methodology. *(Barbara S. Losey, APERC)*

Response: EPA appreciates the recommendations provided on how to move forward with the selection of high-priority candidates for prioritization. While EPA develops a process to select candidate chemicals for prioritization, for the near term, EPA expects to select the 20 potential high-priority candidates for prioritization that EPA must have ongoing by no later than December 2019 primarily from the 73 remaining chemicals listed under the 2014 Work Plan. EPA acknowledges that due to heightened interest, another chemical(s) not on the 2014 Work Plan may be selected for prioritization.

EPA would expect to consider the quality, objectivity, utility, and integrity of the available information, consistent with the science standards in section 26(h). To the extent the information is not currently available or is insufficient, EPA expects to determine whether and how information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner. In addition to the quantity and quality of the information, EPA expects to consider Agency and interagency priorities and overall workload.

EPA doesn’t intend to update the 2014 Work Plan chemicals or “repopulate” a candidate list. Rather, EPA expects that the long-term risk-based strategy would allow selection of high-priority candidates for prioritization that integrates data from NAMs and data from traditional toxicology studies, and builds on the 2012 TSCA Work Plan methodology. EPA will learn through the process of designating

the first 20 low priority substances and evaluating stakeholder comments on those designations. This learning will inform our long- term approach for designating additional low priority substances.

As explained in the White Paper that presents the planned approach for the selection of candidate chemicals for the 20 high-priority and 20 low-priority designations and the long term risk-based strategy, EPA expects that this approach will evolve as EPA gains experience selecting candidate chemicals for the prioritization, the risk evaluation and the risk management processes.

EPA expects that the long-term plan will preserve flexibility in the risk-based strategy to identify candidates for prioritization in order to incorporate new information and new scientific developments.

### *RISK21*

- Using a relative risk framework like RISK21, chemical substances can be screened and mapped according to known information about potential hazard and exposure and bounded by uncertainty. In this way, substances with higher or lower priority can be readily identified and the uncertainty facilitates the gathering of information that most likely decreases the uncertainty about the risk. (The comment includes a detailed description of RISK21). (*Catherine Willet, HSUS*)
- The Agency should consider incorporating elements of International Life Sciences Institute's Health and Environmental Sciences Institute (ILSI HESI) Risk21 project and tool in addition to its own tools. EPA should also use its past work, including the TSCA Work Plan Chemicals list, from which to draw, as well as data generated under other regulatory programs such as the EU REACH program. (*Esther Haugabrooks, PCRM*)

Response: EPA appreciates the suggestions regarding the use of specific methodologies, and will consider these comments as the Agency develops a long-term risk based strategy for selecting candidates for prioritization. As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence.

Further, EPA fully supports the development and use of approaches that reduce the use of animals in chemical safety testing. Section 4 of TSCA mandates that EPA develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing. As such, the Agency must take decisive steps to move scientifically sound non-animal tests into chemicals-related decision making.

### *Threshold of Toxicological Concern tool*

- EPA should consider adopting Thresholds of Toxicological Concern (TTC), which is a NAM used as a screening tool for safety assessment of chemicals when hazard data are incomplete and human exposure can be estimated. In addition, EPA should leverage the activities underway to develop Eco-TTC values<sup>16</sup> and internal TTC values. (*Sarah Brozena, ACC; Rick Becker, ACC*)
- The Threshold of Toxicological Concern (TTC) is not a reliable tool for use in chemical prioritization. The approach is rooted in decades-old toxicity data that were generated following

testing protocols that do not reflect modern scientific principles and understandings of toxicity, nor real-world chemical exposures in a diverse human population. (*Lindsay McCormick, EDF*)

Response: EPA appreciates the suggestions regarding the use of specific methodologies, and will consider these comments as the Agency develops a long-term risk based strategy for selecting candidates for prioritization. As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence.

Further, EPA fully supports the development and use of approaches that reduce the use of animals in chemical safety testing. Section 4 of TSCA mandates that EPA develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing. As such, the Agency must take decisive steps to move scientifically sound non-animal tests into chemicals-related decision making.

#### *Targeted Risk Assessment (TRA) model*

- EPA should consider using the European Centre for Ecotoxicology and Toxicology of Chemicals' (ECETOC) Targeted Risk Assessment (TRA) model for exposure ranking. The TRA is a targeted screening approach to risk assessment that includes Tier 1 health-protective screening approaches for developing exposure estimates. (*Sarah Brozena, ACC*)

Response: EPA appreciates the suggestions regarding the use of specific methodologies, and will consider these comments as the Agency develops a long-term risk based strategy for selecting candidates for prioritization. As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence.

Further, EPA fully supports the development and use of approaches that reduce the use of animals in chemical safety testing. Section 4 of TSCA mandates that EPA develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing. As such, the Agency must take decisive steps to move scientifically sound non-animal tests into chemicals-related decision making.

#### *Petroleum substances*

- API supports a tiered approach for petroleum substances. Tier I: Data acquisition. Identify the petroleum substances based on the reset TSCA Inventory. Tier II: Classify petroleum substances using a heat map or similar approach by likelihood of exposure and functional use as variables. Suggested categories based on functional uses as defined by CDR and OECD. For example: (i) Step one - describe the functional use, e.g.: "Fuels and related products" with three sub-categories: a) cooking and heating fuels, b) vehicular and appliance fuels, and c) fuel additives; Intermediates found only on site; and Petroleum substances with widespread use. (ii) Step two - describe exposures, e.g.: High, medium or low likelihood of exposure. Results may further be classified substances by next action, e.g.: "further evaluation needed" (see Tier III), "medium

priority” (may be assessed later), and “no need for further evaluation as unlikely to pose a risk to health or environment.” Tier III: Screening assessment. (For substances under "further evaluation needed"). Substances are screened based on pre-identified criteria (e.g., PBTs, CMRs, reproductive toxicants). Data that may be used: category approach of the HPV Program, hazard testing from the VCCEP, TSCA Section 4 ECAs, and the Section 211(b) Tier 1 Fuel and Fuel Additives Hazard Characterization Program. Tier 4: Identify chemicals for prioritization. Develop specific criteria to select chemicals for prioritization. For example, RISK21 tool’s output (customized using the same parameters used to select chemicals for prioritization). (*Uni Blake, API*)

Response: EPA appreciates the suggestions regarding the use of specific methodologies, and will consider these comments as the Agency develops a long-term risk based strategy for selecting candidates for prioritization. As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence.

Further, EPA fully supports the development and use of approaches that reduce the use of animals in chemical safety testing. Section 4 of TSCA mandates that EPA develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing. As such, the Agency must take decisive steps to move scientifically sound non-animal tests into chemicals-related decision making.

Additionally, while EPA has decided not to use the functional use approaches presented at the December 11, 2017 meeting as the basis for selecting candidate chemicals for prioritization, EPA might still consider chemical structure, functional use and other chemical characteristics to identify relevant hazard or exposure data of candidate chemicals.

## Specific Chemicals

- EPA should prioritize the following chemicals: (*Colleen A. Kraft, AAP*) [*Comment provides detailed reasons.*]
  - Flame retardants
    - Organohalogen flame retardants
    - PDBEs
  - Perfluoroalkyl substances (PFAS)
  - PFOA
  - Phthalates
- EPA should designate mercury as a high priority chemical. (*Daniel Rosenberg, NRDC*)
- EPA should always consider as high priority: carcinogens as classified by IARC, NTP, EPA, and California EPA and chemicals identified as high priorities under REACH (Substances of Very High Concern). (*Melanie Benesh, EWG*)
- EPA should also use as basis for potential high-priority candidates the European Commission’s priority list of endocrine-disrupting chemicals, the European Union’s (EU) Globally Harmonized System of Classification and Labelling of Chemicals hazard and toxicity classifications, the Association of Occupational and Environmental Clinicians’ Exposure Code List for asthma-causing

substances, and the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Value (TLV). *(Melanie Benesh, EWG)*

- EPA should exclude the following chemicals from consideration for prioritization:
  - Polymers, due to their inherent safety. *(Marie Gargas, PLASTICS)*
  - Substances used primarily as polymer additives, because becoming entrained into a polymer matrix generally prevents all exposure to or risk from the substance. *(Marie Gargas, PLASTICS)*

Response: EPA appreciates the comments and will consider the suggestions for potential candidates for prioritization.

- Most, if not all chemicals, used by the paint and coatings industry – and chemicals in many other industries - are controlled in processes and cause little to no exposure to downstream users and/or consumers. This is especially true for paints and coatings, where chemicals are bound in a matrix with no exposure potential. For more accurate exposure information, EPA should allow industry to provide perspective on assumed exposures as part of the pre-prioritization process. *(Raleigh Davis, ACA)*

Response: EPA encourages industries to submit any information they think may help EPA prioritize and evaluate chemicals.

- EPA should consider that petroleum substances have separate management programs under the European Chemicals Agency (ECHA) and the Canadian Chemicals Management Plan (CMP). *(Uni Blake, API)*

Response: EPA must follow chemical evaluation and management as mandated under TSCA.

- None of the approaches reviewed take into account the inherent differences between metal substances and organic substances. The screening approaches used to assess persistence and bioaccumulation for organic chemical substances are not appropriate for metals and metal substances. Rather, metals need to be screened and assessed based on bioavailability. *(Kathleen M. Roberts, NAMC and NMA)*

Response: The Agency expects to adjust screening and assessment on a chemical-by-chemical basis to best capture the chemical's characteristics. EPA intends to follow the requirements of TSCA section 6(b)(2)(E) to use during prioritization and risk evaluation of metals the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

- If EPA has received an 8(e) substantial risk submission for a chemical, that chemical should always be considered high priority. *(Melanie Benesh, EWG)*

Response: EPA must complete the prioritization process, as described in the *Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act* Final rule (82 FR 33753-33764) to determine if a chemical is high- or low-priority.

- When EPA removed the data rich chemical “mercury compounds” from the 2014 Work Plan, it explained that “their hazards are already well characterized and the Agency has an existing risk reduction effort in place....” The Agency should apply this well-reasoned approach to other data-rich, highly-regulated chemicals when evaluating potential prioritization candidates under TSCA.  
*(Jim Anderson, BCI)*

Response: EPA intends, as it did with the first 10 chemicals for risk evaluation, to evaluate existing regulatory activities on a chemical-by-chemical basis during the risk evaluation process.