

January 25, 2018

Via Docket Submission

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Approaches for Identifying Potential Candidates for Prioritization for
Risk Evaluation under Amended TSCA; Docket Number EPA-HQ-OPPT-2017-
0586

Dear Sir or Madam:

The Ad Hoc Downstream Users Coalition¹ (Downstream Users) supports implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA), and welcome this opportunity to assist the Environmental Protection Agency (EPA) by providing our unique perspective on EPA's "Approaches for Identifying Potential Candidates for Prioritization for Risk Evaluation."² The members of the trade associations that compose the Downstream Users represent well over a thousand companies, including companies that manufacture products and, in some cases, other companies involved in additional portions of the product supply chain.³

¹ The Ad Hoc Downstream Users Coalition include, in alphabetical order, the American Forest & Paper Association (AF&PA), the Motor & Equipment Manufacturers Association (MEMA), the Plastics Industry Association (PLASTICS), the Toy Association and the U.S. Tire Manufacturers Association (USTMA). Each association is a not-for-profit organization serving as a collective voice for their respective members. There are other trade associations that represent companies in the supply chain and downstream users. These comments represent only the views of the aforementioned trade associations.

² The six approaches upon which EPA seeks comment are: (a) the TSCA Work Plan as a Tool; (b) Canada's Chemicals Management Plan; (c) utilizing Safer Chemicals Ingredients List for the low risk classification; (d) the Functional Category Approach, based on Use and Exposure Potential; (e) the Functional Category Approach, based on Chemical Structure and Function; and (f) the Integration of Traditional and New Approaches (see EPA's Discussion document on Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization). EPA also seeks public comment on other analogous regulatory prioritizing processes.

³ AF&PA serves to advance a sustainable U.S. pulp, paper, packaging, and wood products manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative – *Better Practices, Better Plant 2020*. The forest products industry accounts for approximately 4 percent of the total U.S. manufacturing GDP, manufactures approximately \$200 billion in products annually, and employs nearly 900,000 men and women. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 45 states (<http://www.afandpa.org/>)

MEMA represents more than 1,000 members that manufacture motor vehicle systems and component parts for the original equipment and aftermarket segments of the light vehicle and heavy-duty industries. Motor vehicle suppliers provide over 77 percent of the value of a new vehicle and more than 871,000 jobs are directly supported by the

TSCA, as amended, directs EPA to establish a risk-based screening process to designate chemicals as high priority or low priority for risk evaluation (§6(b) (1)). EPA states that the purpose of prioritization is:

to designate a chemical substance as either High-Priority for further risk evaluation of whether the substance may present an unreasonable risk, or Low-Priority for which risk evaluation is not warranted at the time. By December 22, 2019, EPA must have designated at least 20 chemical substances as High-Priority and 20 chemical substances as Low-Priority. TSCA further requires that upon completion of a risk evaluation (other than those requested by a manufacturer), EPA must designate at least one additional High-Priority chemical to take its place, thus ensuring that the EPA's risk evaluation queue always remains full. Prioritization is a priority-setting step. High-Priority designations are not indications of risk and Low-Priority designations are not indications of safety.⁴

These sweeping statutory reforms require EPA to transform the legislation into a practical program for selecting existing substances for prioritization without undermining the intent of the expedited timeframes set by Congress for completing the prioritization and risk evaluation phases.

In developing its prioritization program, it is particularly important that EPA understands and appreciates the unique perspectives of downstream users. The member companies who make up the trade associations in this ad hoc coalition are the face to the average consumer of the process of evaluating "existing" chemicals. The products (containing the substances as to which regulatory risk may be evaluated) are manufactured and/or distributed in commerce by these companies. It is these companies (not the chemical manufacturers) that may be required to reformulate their products if risk is determined or may be contacted by the consumer with questions and concerns. It is their businesses and reputations on the line. These companies do not simply desire, but need, clarity, an efficient, scientifically sound, decision making process that addresses those substances that may present the greatest potential

motor vehicle supplier industry in all 50 states. MEMA represents its members through four divisions: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); Motor & Equipment Remanufacturers Association (MERA); and, Original Equipment Suppliers Association (OESA).

PLASTICS is a diverse manufacturing trade association that represents companies who manufacture or otherwise are in the supply chain for plastic products (including material suppliers, processors, equipment & moldmakers, brand owners, and recyclers). These companies employ 965,000 plastics workers nationwide. The PLASTICS provides leadership, guidance and support that will bring about continual improvement in worker safety, environmental and product regulatory performance in the plastics industry, while supporting the use of good science and public policy, and promoting and serving member interests. (<http://www.plasticsindustry.org/>).

The Toy Association is the not-for-profit trade association representing businesses that design, produce, license, and deliver toys and youth entertainment products with 950+ members. The organization has a long history of propelling the health and growth of the toy industry, which has an annual U.S. economic impact of \$107.5 billion.

USTMA is the national trade association for tire manufacturers that produce tires in the U.S. USTMA members operate manufacturing facilities in 19 states, employ nearly 100,000 workers and generate annual sales of more than \$27 billion. (<https://www.ustires.org/>)

⁴ EPA, Prioritizing Existing Chemicals for Risk Evaluation, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation>.

risk. Therefore, given the distinct perspective of downstream users, we ask EPA to give careful consideration to our perspective in implementing TSCA.

To achieve meaningful risk reduction, the prioritization (and eventually the risk evaluation) process must be credible. To be credible, a process needs to be established to facilitate the exchange of information by stakeholders all along the value chain. We support EPA's efforts to seek meaningful information from all stakeholders concerning ways to address the critical task of identifying candidate chemicals for prioritization, and for providing the opportunity to provide these written comments. The associations that represent the downstream user companies desire to work cooperatively with EPA to develop and start implementing expeditiously a workable prioritization process for existing substances. As explained in more detail in these comments, the coalition supports a permanent and predictable "Information Outreach Framework" (Outreach Framework) for companies to provide information expeditiously to inform EPA's decision making under TSCA.

Specifically, we respectfully ask EPA to establish a transparent Outreach Framework process and form for providing information to the agency that enable downstream users to understand the process (and its timing), plan for providing information to EPA, and make other appropriate decisions. 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.

I. DOWNSTREAM USERS ARE A VALUABLE SOURCE OF INFORMATION FOR THE CONDITIONS OF USE OF SUBSTANCES

Under TSCA, downstream users may face requirements to change their ingredients while satisfying consumer expectations on performance, safety, and other characteristics, as well as other non-TSCA regulatory requirements that may apply to the products they produce. Downstream users are an important resource for information on conditions of use.

However, the amount of information now required under TSCA and the consequences of an unreasonable risk finding raise the stakes considerably. While Downstream Users are likely to have more and, in our view, often more reliable and extensive data on conditions of use and potential exposures, we also recognize that there are likely to be areas where there are data gaps. Downstream user trade associations and their member companies may be able to identify any potential data gaps regarding use and exposure to substances under EPA consideration. In such situations, the Outreach Framework also serves as a mechanism to identify and, where appropriate, fill these gaps in a cost-effective, expeditious, and cooperative manner. In short, we may not always have all of the data, but we have an incentive to assist in filling any data gaps.

It is in the best interest of companies up and down the supply chain and companies that use the substances being prioritized in their manufacturing processes (downstream chemical users) to share information on conditions of use and exposure.⁵ Downstream Users members are well-positioned to

⁵ Some information submitted may be confidential business information (CBI), *i.e.*, its disclosure may provide other companies with an advantage in the marketplace. See TSCA § 14, as amended, and EPA's TSCA website, available at: <https://www.epa.gov/tsca-cbi>. Such CBI will be submitted with the appropriate CBI claim, reviewed, and (we anticipate) granted if it satisfies CBI requirements.

provide much of the information that is necessary for appropriate prioritization of which chemicals should undergo a risk evaluation. An improper prioritization methodology is not only cost-ineffective, but delays the regulation of chemicals that truly warrant a more expeditious risk evaluation.

II. EPA SHOULD ESTABLISH AN “INFORMATION OUTREACH FRAMEWORK”

Given the short time frames (prioritization is a 9-12 month process with a deadline of March 2019 for the first 20 high-priority and 20 low-priority chemicals), the ability of Downstream Users to assist in quickly developing a mechanism to obtain sufficient information is essential.⁶ To be consistent with these deadlines, the time EPA takes to select the chemicals it will prioritize should not be any longer, and ideally will be shorter, than the statutory deadlines set by Congress to complete the process. That will mean there is insufficient time for EPA to promulgate a regulation requiring information submission or to develop a myriad of detailed testing orders to gather the information the agency may need in order to identify substances for prioritization. A determination that more information is needed to enter the prioritization process will most likely place a chemical on a separate track for information development.

EPA needs to prioritize approaches that allow for collecting information on exposure scenarios as much as possible. Thus, the Downstream Users urge EPA to adopt at the pre-prioritization stage guidance that creates an Outreach Framework to allow Downstream User companies and their trade associations to provide relevant information to EPA as quickly as possible. This information includes the content of chemicals in products, analysis of exposure scenarios, and calculation of exposure.

In general, the sooner EPA can give notice to stakeholders (particularly Downstream Users) of its intent to prioritize a particular chemical, the better. That way, the regulated community can budget resources and work diligently to gather information the agency needs to move forward in the prioritization process and use this information in corporate internal decision making. 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.

The most efficient method of gathering relevant existing data and obtaining scientifically sound new data is to establish an Outreach Framework that alerts industries as early as possible concerning which chemicals and conditions of use might be subject to review. In this manner, companies and/or their trade associations can provide relevant and scientifically sound exposure information as quickly as feasible. These data would enable EPA and the companies to distinguish among conditions of use that may result in widely different exposure levels.

The Outreach Framework is consistent with EPA’s own TSCA prioritization principle of relying on input from stakeholders to identify potential prioritization candidates.⁷

⁶ EPA, *Prioritizing Existing Chemicals for Risk Evaluation*, available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation#preprioritization>.

⁷ EPA’s Discussion document on Possible Approaches and Tools for Identifying Potential Candidate Chemicals for Prioritization at 11 (December 11, 2017).

III. EPA MUST DEVELOP ITS RISK PRIORITIZATION SCHEME CONSISTENT WITH THE INTENT OF CONGRESS

We provide the following comments on the intent of Congress because we support TSCA. The goal of these comments is to ensure that EPA's implementation addresses the perspective of the Downstream Users. We believe that addressing our perspective is consistent with the intent of Congress.

As a starting point, as Chief Justice Roberts recently emphasized:

In a democracy, the power to make the law rests with those chosen by the people. Our role is more confined – “to say what the law is.” [Citation omitted] A fair reading of legislation demands a fair understanding of the legislative plan. ... If at all possible, we must interpret the Act in a way that is consistent with the ... purpose of the Act], and avoids” an interpretation that would, in effect, destroy the statutory scheme.⁸

When a statute is as complex as TSCA, as amended, the process of determining “what the law says,” is even more important. High priority substances are defined as those that “may present an unreasonable risk of injury to health or the environment because of a potential route of exposure under the conditions of use.” (§6(b)(1)). Low priority substances are those that do not meet the definition of high priority substances under the Act.

The statutory factors to consider in prioritization include (1) The chemical substance's hazard and exposure potential; (2) the chemical substance's persistence and bioaccumulation; (3) potentially exposed or susceptible subpopulations; (4) storage of the chemical substance near significant sources of drinking water; (5) the chemical substance's conditions of use or significant changes in conditions of use; and (6) the chemical substance's production volume or significant changes in production volume. § 6(b) (1) (A).⁹ To determine how best to select which chemicals to prioritize, one must consider the plain meaning of a variety of statutory terms, the context of prioritization in the statutory structure, and the historic use of risk and prioritization in regulatory decision making.

Although the consideration of risk in a risk prioritization process is different, simpler, and less detailed than in a risk calculation performed for a risk evaluation, the risk prioritization process must follow the same overarching statutory principles. EPA must integrate and analyze the weight of all of

⁸ *King v Burwell*, 135 S.Ct. 2480, 2488 (2015), available at https://www.supremecourt.gov/opinions/14pdf/14-114_qol1.pdf. Also see Justice Scalia's direction that EPA must do its best to bear “in mind the ‘fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. *Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2,427, 2,443 (2014) (*UARG v. EPA*).

⁹ TSCA as amended requires that 50% of all High-Priority designations be drawn from 2014 Update of the TSCA Work Plan. However, aside from these statutory preferences and requirements, EPA has discretion to determine which chemicals to prioritize. EPA, Candidate Selection, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation#preprioritization>.

available information¹⁰ (which includes toxicity, the potentially exposed or susceptible subpopulations, the likely duration, intensity, frequency, number of exposures under the conditions of use of the chemical substance).¹¹ All decisions must be “based on science,” used “in a manner consistent with the best available science,”¹² and based on the weight of the scientific evidence.¹³ 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.”¹⁴ 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.”¹⁵ The statute is “clear that EPA has to make a determination on all conditions of use considered in the scope” of the work/problem formulation in the risk evaluation.¹⁶

EPA faces an admittedly formidable task to apply these principles to the prioritization process. It is not feasible to apply these decision making criteria in the abstract. However, on its face, the science criteria enunciated in TSCA, as amended, were added specifically to modify EPA’s practice¹⁷ and existing

¹⁰ The weight of the evidence is a “systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.” *Id.* at S3518. See House Report at page 33, available at: <https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf>.

¹¹ 15 U.S. Code § 2605 (b)(4) (F).

¹² 15 U.S.C. § 2625 (h).

¹³ 15 U.S.C. § 2625 (i).

¹⁴ Comments of Senator Vitter in the Senate Congressional Record at S3519 (June 7, 2016), <https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf>.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ For example, the 2011 peer review of EPA’s toxicological review of formaldehyde by a National Academy of Science (NAS) points out in detail that EPA had failed to apply properly the weight of the evidence in regulatory contexts. Specifically, it states that there have been persistent “problems encountered with ... [the EPA risk] assessments over the years” which have been “identified by multiple groups.” NAS, Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde at 11 (April 2011) (NAS Formaldehyde Report), available at <http://www.nap.edu/catalog/13142.html> (prepublication copy) (“NAS Formaldehyde Risk Assessment Report”). In fact, sometimes EPA “conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework.” *Id.* at 8. The report urged EPA to use the extensive literature on causal inference, methods for evaluating the strength of evidence of causation, i.e., use of a systematic identification of relevant evidence, criteria for evaluating the strength of evidence, and language for describing the strength of evidence of causation. The NAS Formaldehyde report concluded that evaluating causation must involve “systematic gathering and review of all lines of evidence and classification of the strength of evidence in a uniform and hierarchic structure.” *Id.* Also, the report urged to improve the weight-of-evidence determinations.

case law also cautions against using excessive or too extreme exposure assumptions. Therefore, any of the approaches (particularly use of the Work Plan methodologies) should be re-evaluated in light of these statutory criteria.

IV. COMMENTS ON EPA'S SIX APPROACHES AND RELEVANT ASPECTS OF OTHER RISK PRIORITIZATION PROGRAMS

A. Introduction

The Downstream Users provide these views to improve the process. Downstream Users seek to establish a meaningful working relationship with EPA and to encourage dialogue and exchange of information (i.e., implement an Information Outreach Framework, as discussed in Section II, above). It is particularly important that this process be finalized in a timely manner and that the final process does not result in seemingly never ending review.

B. The TSCA Work Plan As A Tool

The statute requires a preference to include in the Work Plan chemicals that: (1) have persistence and bioaccumulation scores of 3; and (2) are known human carcinogens and have high acute and chronic toxicity. (§ 6(b)(2)(D)). Half of the high priority chemicals must be selected from the TSCA Work Plan.

This Work Plan has undergone multiple updates and changes. As a result, for example, there are transcription and other errors that exist in the Work Plan.¹⁸ In some calculations, the Work Plan uses only the highest calculated value. In some cases, it may not consider the size of the potentially exposed population. The overuse of high end and worst-case assumptions can cumulatively distort priorities, particularly when coupled with incomplete databases (see further discussion of incomplete databases below).

Since TSCA has been amended, the Work Plan should be updated again to correct and update the screening factors to be consistent with the specific statutory criteria (see Section III, above). The updating of the Work Plan should consider 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. Thus, EPA should review the Work Plan to address any errors, update the information used, and consider the new statutory factors.

¹⁸ “While the PB score of 2 for 4tOP was transcribed correctly to the Work Plan Tables, the individual score for bioaccumulation was incorrectly transcribed to the Table as being moderate rather than low.” Comments of the Alkylphenols & Ethoxylates Research Council on Proposed Rule: Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act at 5 (March 20, 2017).

C. Canadian Chemicals Management Plan

While each of the potential approaches has advantages and disadvantages, the Downstream Users support several aspects of the Canadian Chemicals Management Plan. The use of an Outreach Framework is consistent with key aspects of Canada's Chemicals Management Plan.¹⁹ The Canadian Chemicals Management Plan was based on strong stakeholder engagement, which began early in the process.²⁰ This early engagement led to buy-in to the approaches considered (and eventually adopted) which resulted in less industry opposition. It also allowed all parties to consider in a meaningful manner non-traditional and group approaches. Importantly, it contains predictable timeframes for when reviews will start and finish. As in the Downstream Users' proposed Outreach Framework, stakeholder engagement in the Canadian Chemical Management Plan 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. The use of streamlined approaches was critical for meeting commitment to assess all priorities within 2020 timelines and "rapidly assessing low priorities with less effort and less time" (i.e., allowed for rapid screening for low volume chemicals).

D. Functional Category Approach, Based on Use and Exposure Potential

Conceptually, the question the Downstream Users have with this approach, is whether EPA has sufficiently accurate information on uses and potential exposure to proceed with this approach. EPA recognizes that an interpretation of TSCA, as amended, that provides "no meaningful limitation" on EPA risk evaluations "could present unmanageable challenges—an outcome that EPA does not expect Congress intended."²¹ The same unmanageable challenges and unintended outcomes (i.e., an interpretation that would, in effect, destroy or severely hamper the statutory scheme) can arise if the risk prioritization scheme relies too heavily on extreme exposure assumptions or over use of maximum values. EPA's models may need to be updated or expanded, and there is a general concern in industry that the agency's use of worst case assumptions leads to overly conservative findings.

The experience of the members of this coalition indicates that there are conditions of use for which data demonstrates there is little exposure, such as where chemicals are inaccessible when they are

¹⁹ Canada's Chemicals Management Plan, Approaches to Prioritization and to Streamlined Assessments, Power Point Presentation by Health Canada and Environment and Climate Change Canada at EPA's December 11, 2017 meeting, available at https://www.epa.gov/sites/production/files/2017-12/documents/us_epa_cmp_deck_-_december_2017_v4.pdf. No one alternative provides the ideal approach to all components of the risk prioritization process, but many of the aspects of the Canadian CMP support recommendations by the Downstream Users.

²⁰ Most, if not all, of these lessons learned are from the Power Point Presentation by Health Canada and Environment and Climate Change Canada at EPA's December 11, 2017 meeting, but the Downstream Users recommendation is based on our own independent understanding of this Plan. Not every aspect of this plan is being endorsed by this comment.

²¹ EPA, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017) (final rule) (Prioritization Final Rule).

a component of an article. However, there will be cases in which EPA has little data on exposure or where data on exposure is generally lacking. This type of information probably will need to be sourced from industry, hence the importance of Information Outreach Framework proposed above.

E. Functional Category Approach, Based on Chemical Structure and Function

It is likely that the chemical manufacturing industry will provide comments on this issue. This approach is outside most Downstream Users area of expertise. However, we submit that EPA should not designate a substance as high priority based solely on Chemical Structure and Function information. Some further basis should be provided, such as consideration of the factors enumerated in the statute and known data, until more experience with these chemical structure and function models is recognized.

F. Integration of Traditional and New Approaches

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.

G. Relevant Aspects of Other Prioritization Programs

While no other prioritization program provides the ideal template for devising a prioritization program (and individual decisions must be evaluated on a case-by-case basis), EPA may want to consider some aspects of several programs in finalizing the prioritization approach. Many programs have worked, in our experience, to provide industry and stakeholders with adequate notice and obtain the data needed in a reasonable timeframe, including the Canadian Chemical Management Plan, the EPA pesticide registration program, and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. EPA could also apply lessons learned from the US-Canadian Regulatory Cooperation Council (RCC) Work Groups on Risk Assessment and particularly the findings of the Work Group on Use, Release and Exposure.

The Downstream Users believe that there are existing (often quite thorough) risk evaluations and assessments performed by the European Union, other nations (e.g., the Danish EPA), and in the peer reviewed literature. Historically, EPA has performed new redundant and resource-intensive risk evaluations or risk assessments rather than reviewing existing non-EPA risk evaluations to determine whether they are adequate. EPA could expedite its risk evaluation process by reviewing existing risk assessments to determine if they are adequate to make high priority, low risk findings, a determination that a chemical does not present an unreasonable risk, or a more limited preliminary risk screening statement.

V. **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**

The statute evidences a Congressional intent to support a robust (but measured) federal approach to the regulation of chemicals. Providing more risk information earlier in the process will allow EPA to fulfill its role and give clearer risk communication to the markets and the public. EPA's risk evaluation rule explicitly states that:

EPA may complete its evaluation of the chemical substance under specific conditions of use or categories of conditions of use at any point **following the issuance of the final scope document**, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use. EPA will follow all of the requirements and procedures in this Subpart when it conducts its evaluation of the chemical substance under any individual or specific conditions of use.²² (Emphasis added)

The Downstream Users endorse EPA making the determination that a chemical does not present an unreasonable risk as early in the process as possible. Risk designations (or communications) earlier in the process will assist implementation of the statute. Low-Priority Substances already:

are taken out of consideration for further assessment. This gives the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent, and provides some insight into which chemical substances are likely not to need additional evaluation and risk management under TSCA.²³

As a practical matter, the information gathering efforts necessary to identify high priority and low priority substances may also identify information (even prior to the issuance of a final scoping document) that allows EPA to identify substances which under certain conditions of use have a remote likelihood of presenting an unreasonable risk. In such appropriate circumstances, nothing in the statute prevents EPA from issuing a preliminary risk screening statement (i.e., a summary of current intent based on existing information).

This preliminary risk screening statement will not be a final safety determination on the use but could simply state which uses are of concern. Such a statement will provide the Downstream Users useful direction on which conditions of use to focus resources.

These preliminary risk screening statements will benefit downstream users by providing early certainty for both users and regulators by allowing them to focus their limited resources on the conditions

²² Id. at 33,751.

²³ Id. at 33,755.

of use of a particular substance that may present the greatest risk. For example, EPA could make a statement that existing data (including risk assessments already performed or published in peer review journals) make it unlikely that there is exposure. The amount of evidence and documentation should depend upon the facts of the individual condition of use and the legal consequences of the regulatory statement.

We encourage EPA to carefully consider the manner in which the agency communicates the prioritization process to the public. EPA must describe the prioritization process in a clear manner to ensure the prioritization process does not create potential concern about a specific use of a chemical substance before the risk evaluation process is complete. An uninformed, overly broad communication concerning the risk or an untimely delay in providing an accurate and balanced risk communication has the real potential to adversely impact companies and generally provide misleading signals to the public. These early and preliminary risk determinations increase the likelihood that the public is provided clear information in a timely manner that a chemical substance is safe for certain intended conditions of use and is more cost-effective. Such an early determination will lessen ambiguity in the market place.

VI. CONCLUSION

In closing, the prioritization process directly impacts the companies represented by the Downstream Users. It is in the interest of our members companies that TSCA be implemented efficiently and in a manner that is credible. Our comments are intended to make the process better. The Downstream Users view EPA's task in developing a prioritization system as being able to employ criteria and methods that allow EPA to decide how to select which substances it will review systematically, expeditiously and transparently.

The Downstream Users offer to work with EPA in implementing an Information Outreach Framework to assist EPA. Downstream users need clarity, an expeditious timeframe for decisions, and a scientifically sound, decision making process. We support much of what EPA has done. But a more transparent process that explains the basis for EPA's decisions will benefit our member companies and the public.

Thank you for the opportunity to submit these comments. For questions or additional information please contact Sarah Amick at the U.S. Tire Manufacturers Association, Ex. 6 and samick@ustires.org.

Respectfully submitted,

American Forest & Paper Association
Plastics Industry Association
Motor & Equipment Manufacturers Association
Toy Association, Inc.
U.S. Tire Manufacturers Association