Comments of the Ad Hoc Downstream Users Coalition

on the

Initiation of Prioritization Under the Toxic Substances Control Act (TSCA)

Docket Number EPA-HQ-OPPT-2019-0131

June 19, 2019

The Ad Hoc Downstream Users Coalition (Downstream Users) welcomes this opportunity to provide the Environmental Protection Agency (EPA) with our perspective on EPA's initiation of 20 candidates for high priority designation and 20 candidates for low priority designation pursuant to section 6(b)(2)(B) of the Toxic Substances Control Act (TSCA).[1] The trade associations that compose the Downstream Users represent well over a thousand companies, including companies that manufacture products and, in some cases, companies that span the entire value chain.[2] We share some core values on TSCA implementation that include support for a single

[1] 84 Fed. Reg. 10491 (March 21, 2019).

[2] The Ad Hoc Downstream Users Coalition include, in alphabetical order, the American Forest & Paper Association (AF&PA), the Motor and Equipment Manufacturers Association (MEMA), the Plastics Industry Association (PLASTICS), the Toy Association and the US 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.

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 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).

Representing nearly one million workers in the $427 billion U.S. plastics industry, PLASTICS promotes plastics manufacturing, works to make our members and the industry more competitive globally, and advances recycling and the stewardship of resources. Plastics innovations continuously improve products ranging from healthcare and medical devices to building and construction, automotive and packaging. From resin suppliers and

federal approach to preempt redundant, state-by-state regulatory actions. We also share a common interest in providing accurate and current use and exposure information about how the chemicals EPA selects are used in our members' products to inform EPA's prioritization designations and risk evaluations.

We want to recognize the historic nature of the moment, since this marks the first time that EPA is putting prioritization into practice. In particular, we support EPA's description of prioritization as a *process* – one that stakeholders have much to learn from. In the comments that follow, we approach EPA's first foray into prioritization from the complex perspective of those who use, rather than simply manufacture, regulated chemicals. With regard to the emerging nature of the process and the candidate chemicals EPA has identified, we would like to highlight the following points:

- We are committed to effective implementation of the provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which served to update TSCA in 2016, and applaud EPA for continuing to pave the way for meeting TSCA's strict deadlines.

- Our Coalition supports a robust and timely federal approach for chemicals management. We agree that EPA should review all known and reasonably foreseeable conditions of use of a chemical in commerce, make early risk determinations where feasible, and use fit-for-purpose risk evaluations, consistent with best available science.

- Leading up to prioritization, the absence of transparency is making it challenging for industry to understand how best to engage in this process. We seek predictable timeframes for when specific chemicals will be prioritized for review, in large part because our members need time to plan and develop information to submit to EPA. Downstream

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equipment makers to processors, brand owners and the recycling community, we proudly represent all segments of the U.S. plastics industry. For more information on PLASTICS, please visit 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 working to assure safe play, including working to advance safety standards for toys. Our members account for approximately 85% of the North American toy market, and our industry has an annual U.S. economic impact of $107.5 billion.

The U.S. Tire Manufacturers Association (USTMA) is the national trade association for tire manufacturers that produce tires in the U.S. Our 12 member companies operate 56 tire-related manufacturing facilities in 17 states and generate over $27 billion in annual sales. We directly support more than a quarter million tire manufacturing U.S. jobs – totaling almost $20 billion in wages. USTMA advances a sustainable tire manufacturing industry through thought leadership and a commitment to science-based public policy advocacy. Our member company tires make mobility possible. USTMA members are committed to continuous improvement of the performance of our products, worker and consumer safety and environmental stewardship.

Users are an important resource for EPA and the supply chain on conditions of use and exposure. While Downstream Users are likely to have more and, in our view, often more reliable data on conditions of use and potential exposures, we also recognize that there are likely to be areas where there are data gaps that will take resources and planning to address. We support EPA's "Work Plan chemicals first" approach for scheduling chemicals for prioritization in a routine and predictable manner.

- Downstream Users support EPA's low priority designations and the continued use of these designations. We think it is critical that EPA's future communications on these chemicals do not cause them to occupy a place of uncertainty and for the agency to avoid statements of implied risk.

- Finally, Downstream Users would like to highlight our appreciation to EPA on its core messaging which recognizes that the selection of a chemical for prioritization or risk evaluation is not a determination of risk or safety.

I. Introduction.

At the outset of these comments, Downstream Users recognize and compliment EPA on its continued efforts to meet the tough deadlines in the 2016 amendments. As called for by statute, by December 2019 EPA has to "ensure that risk evaluations are being conducted on at least 20 high priority substances and that at least 20 chemical substances *have been designated* as low-priority substances." 15 U.S.C. § 2605(b)(2)(B) (emphasis added). As EPA carries out these requirements, Downstream Users thank the agency for consistently emphasizing that the selection of a chemical for prioritization or risk evaluation is not a determination of risk or safety. We support the agency's use of fit-for-purpose risk evaluations and early safety determinations on individual conditions of use overall in the section 6 process. Without these important safeguards, a priority designation for a chemical substance could send the wrong signal to the public long before an actual risk determination is made.

We see the prioritization provisions as establishing an entirely new process, where information is exchanged throughout, and a designation of high or low priority for risk evaluation is made only at the very end of this process. The characterization of TSCA prioritization as a process rather than a pre-determined outcome is supported by the language of the rule, which describes prioritization as a "risk-based screening *process* for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b)" of TSCA. 40 C.F.R. § 702.1 (emphasis added). Prioritization, for purposes of triggering the 9 to 12-month statutory review, begins with the publication of a Federal Register

notice and ends once a subsequent notice is published in the Federal Register announcing a final priority designation. While it bears acknowledging that TSCA requires that the prioritization process lead to one of only two outcomes – a high priority designation or a low priority designation per 15 U.S.C. 2605(b)(1)(B) – such designation is not made at the point EPA initiates this process. Indeed, new information may be brought to bear during the process which could change a proposed designation from low to high or the reverse.

Further to this point, Downstream Users acknowledge the importance of this first comment period in the process since it is expressly intended to allow the public a chance to submit information that will feed into EPA's screening review in the next phase of prioritization. 82 Fed. Reg. at 33755-56.[3] During screening review EPA will review the candidate chemicals against the criteria in TSCA section 6(b)(1)(A) that 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. During the screening stage, EPA may evaluate other risk-based criteria as well, ones that EPA determines to be relevant to the designation of the chemical substance's priority. 40 C.F.R. § 702.9(a). Therefore, even at this early stage, submitted information can materially affect and even change the outcome of the process.

As stakeholders, we expect to gain valuable insights as the process unfolds. A high-priority substance is defined as one which EPA has determined, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure *under the conditions of use*, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA. 40 C.F.R. § 702.1 (emphasis added). In the last step in prioritization, when EPA issues a final designation, the agency expects to make known exactly what condition(s) of use is the primary basis for the priority designation. 40 C.F.R. § 702.11(c). Prior to this, when EPA issues a proposed designation for another 90-day comment period, the agency states that "the supporting documentation for a *proposed* High-Priority Substance designation is likely to foreshadow what will go into a scoping document for risk evaluation." Id. at 33759 (emphasis added). While Downstream Users would like to have as much information sharing by EPA as

[3] As EPA explained in the final rule, the proposed rule specified that EPA would publish the results of the screening review at the initiation of the prioritization process. EPA's final rule shifted the timing of the screening review to occur after the close of this initial 90-day public comment period because commenters expressed strong concerns that the proposed rule did not guarantee any opportunity for public comment prior to the screening review. The shift now allows the public the opportunity to engage in this aspect of the process.

possible from the outset to help us identify information gaps and areas for comment as the process unfolds, the agency's statement underscores the importance for stakeholders to contribute information sooner rather than later and the point that prioritization will chart the course for a chemical and its uses for years to come. Further to this point, it is becoming abundantly clear that the agency intends to obtain the vast bulk of any stakeholder information that will inform EPA's risk evaluations during the prioritization process.

II. We support the comprehensive identification of the conditions of use in commerce for chemicals during prioritization and early safe use decisions for chemicals designated as high priority for risk evaluation, consistent with best available science.

The chemicals initiated for high priority consideration include seven chlorinated solvents, five phthalate esters, three flame retardants, formaldehyde, a musk fragrance additive, a rubber precursor (1,3-butadiene), a plasticizer precursor (phthalic anhydride), and a flame retardant precursor (ethylene dibromide or EDB).[4] With respect to Downstream Users, in some cases our members do not use these chemicals as direct ingredients, however they may be present in some of our products at very low levels due to incidental contaminants from upstream manufacturing processes. In other cases, association members may be employing candidate high priority chemicals as ingredients in a variety of products. We are working hard to gather information and guide our members on EPA's process. Where we are able to provide comments on individual high priority candidates that represent the collective experience and views of our Coalition we do so below.

As Downstream Users, we think it is important to emphasize that the conditions of use of a chemical along the value chain and for individual uses may vary widely in terms of the potential for human exposure and environmental release. On numerous occasions, EPA has stated that the high priority criteria may be met by a single condition of use. The corollary in most cases is that the same chemical will have uses that do not present an unreasonable risk whatsoever. We ask EPA to ensure that these uses are clearly distinguished from those that may cause a chemical to meet the definition for high priority for risk evaluation.[5] Below, we offer some specific ways in which EPA can make these distinctions.

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[4] Under TSCA, EPA is directed to preferentially select Work Plan chemicals that have persistence and bioaccumulation scores of 3 and are known human carcinogens with high acute and chronic toxicity (§6(b)(2)(D)). The fact that none of the first 20 meet these factors could be viewed as a flaw in the agency's implementation of the Act. Therefore, we urge EPA to turn its attention to these Work Plan chemicals in the next round, consistent with the statute as well as with EPA's own stated goal of focusing this program on substances that may present the greatest potential risk.

[5] The agency has consistently recognized throughout implementation of section 6 that some categories of uses will pose greater potential for exposure than others and that the risks from many categories of use are deemed

First, Downstream Users support the comprehensive identification of the conditions of use for chemicals as early as possible in the prioritization process. While we understand that EPA will only signal which uses are driving a prioritization designation at the end of the process, which is appropriate, the public dockets contain virtually none of the information that EPA would have had to develop already in order to initiate these chemicals for prioritization. The public record does not disclose why these substances were selected or the uses that EPA has identified for them at this stage. We are concerned that the lack of transparency does not provide adequate notice to the public and is inconsistent with best available science practices. We think EPA would receive more, and more meaningful comments at this stage if stakeholders were provided with a better understanding of the information EPA is seeking on the candidate chemicals to fill gaps more quickly.

Second, Downstream Users urge EPA to identify information needs to stakeholders as early in this process as possible. Important information for EPA to have on hand may include the content of chemicals in products, exposure scenario descriptions, knowledge of where a chemical is used in a process, calculations or modeling of exposure, and identified conditions of use. These conditions are determinative of exposure potential 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." Many TSCA chemicals have multiple uses—industrial, commercial and consumer uses, and EPA needs to be able to distinguish among conditions of use that may result in widely different exposure levels. However, gathering these data will take time, particularly when the data are not already readily available. For example, if EPA utilizes an exposure model for a condition of use and our members disagree with the outcome, it is incumbent on us to provide more realistic assumptions to EPA or gather empirical data.

Third, and after careful consideration, Downstream Users generally would prefer that EPA consider the incidental presence of a chemical as an impurity, or non-point sources of aquatic exposure or air emissions associated with the use of these substances, during prioritization and carry these uses forward in any risk evaluations. We think in most cases these uses would be candidates for early and favorable risk evaluations. While we strongly support taking existing authorities into account, regulatory gaps and the benefits of federal management and preemption should figure prominently. In some cases, the existence of a sister statute that governs air or water pollution may be an insufficient basis to exclude a given condition of use; we think the agency's approach needs to be examined case-by-case and do not support a blanket

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negligible or already well controlled. *See generally,* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; Final Rule, 82 Fed. Reg. 33726, 33728 (July 20,2017).

exclusion for such conditions of use as a means to narrow or manage the scope of EPA's review. For example, in the case of formaldehyde, the recent and dedicated rulemaking for composite wood products includes an emission limit that was the product of an extensive risk evaluation. As a result, this use should not trigger the high priority criteria, providing the emission standard is adequately considered. Moreover, we think EPA should be able to reach an early risk determination with respect to this use based on the underlying determination and final rule. Including composite wood products as a condition of use when prioritizing and scoping formaldehyde remains critical so that the agency's final risk management of formaldehyde has preemptive effect for this use. As another example, 1,3-butadiene is a building block in the manufacture of synthetic rubber that many Downstream User companies may subsequently use for their products; such is the case for certain toys and tires. However, in these cases, rubber is the intentionally added component. 1,3-butadiene may not be incorporated directly but may be indirectly present at low levels. Downstream Users generally would favor including impurities as a condition of use in the risk evaluation in exchange for the future benefit associated with the preemptive effect of EPA's review.

Fourth, Downstream Users support EPA's decision to make early safe use determinations and the use of best available science for these determinations. The Coalition understands that risk determinations follow, and are not a part of, the prioritization process. Nevertheless, we want to be sure to address early determinations in our comments because of the regulatory relief that they can provide. The time between initiation of prioritization and the risk evaluation phase is lengthy and can be up to one year. During this period, the public has no signal one way or the other with respect to the outcome. We think early decisions are consistent overall with the steps EPA is taking to address the concern that high priority designations coupled with time could heighten public concerns with risk. This would have negative consequences for any uses of these chemicals, even uses that do not need to be regulated. For this reason, the public should know about the uses that meet TSCA's no unreasonable risk standard as early as possible. Consistent with the desire for early risk determinations, Downstream Users support a "fit-for-purpose" approach to risk evaluation because the conditions of use of these chemicals will vary widely in terms of their potential for exposure. Each use may not require the same level of time and resources to be considered well-evaluated. For example, Canada has established a transparent, tiered, fit-for-purpose hierarchy that it appears to be using largely successfully.

We understand that robust information gathering during this phase will need to play a strong role in the agency's ability to make decisions early in the process. We understand that the amount of information needed in any particular case may depend on the facts of the individual condition of use and the context in which the regulatory statement is presented. However, the agency has explained that information supplied during prioritization and the

designation decision will foreshadow the scope of the risk evaluation for high priority chemicals. This means that EPA should have sufficient information early in the risk evaluation to make early determinations in many cases. In such appropriate circumstances, if EPA deems it has sufficient information, EPA could signal in subsequent documents (such as in the final priority designation or scoping document) that existing data, including risk assessments already performed or published in peer review journals, allow the agency to conclude that a particular condition of use meets the TSCA safety standard.

III. Scheduling that ensures a timely and transparent process for prioritization is a top priority.

Downstream Users would like to take this opportunity to once again express the importance of a timely and transparent process for assessing existing chemicals and that more work needs to be done to make this a reality. We think that to advance federal leadership in chemical regulation through transparency, EPA needs to move ahead with scheduling all 2014 Work Plan chemicals for prioritization to make the process predictable and routine. The schedule should include projected time frames for when work plan chemicals will be reviewed and an off-ramp process for data collection before prioritization begins. We understand this will necessarily involve considerations such as data availability, rationale groupings, and the like.

We support EPA on its "Work Plan chemicals first" approach. It makes sense to Downstream Users to start with this list, because EPA is required to have at least 50% of its risk evaluations be on Work Plan chemicals (cite), the list itself has been out in public for several years, and the agency already has been evaluating many of the chemicals on this list for years. Moreover, we think that EPA can choose to focus on this list almost exclusively, with adjustments if needed, because Congress directed the agency to make prioritization decisions for all the Work Plan chemicals. As a result, it is not a matter of if, but when, EPA will review each chemical on the Work Plan. For these reasons, we support EPA's approach.

In general, the sooner EPA can give notice to stakeholders (particularly Downstream Users) of its intent to consider a chemical as a candidate for prioritization, the better. This way, the regulated community can budget resources and work diligently to gather information that can inform agency decision making. It is particularly important that the process be for a set period of time and does not result in seemingly never-ending review of any particular chemical. The time EPA takes to review each Work Plan chemical for initiation should not take any longer, and ideally will be shorter, than the statutory deadlines set by Congress to complete the entire prioritization process. The potential outcomes of the candidate screening process could be either a decision to prioritize the chemical or the off-ramp issuance of a "notice of deficient information". The latter determination will provide time to collect information the agency deems

necessary to put the substance forward into prioritization. We view an off ramp for data gathering as particularly important for allowing the agency to move efficiently through groups of binned Work Plan chemicals for the same kind of determinations.

Downstream Users do not view scheduling the 2014 Work Plan chemicals for prioritization as a unique or unreasonable request, because all of the other existing chemical evaluation programs we are aware of, as implemented in the European Union, Canada and Korea, have published schedules for when dossiers are due and/or reviews are expected to take place. Scheduling will build confidence, predictability, and a sense of deliberate routine throughout the broader stakeholder community, including the states, in relying on EPA's process to produce timely chemical reviews. Other 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, Authorization and Restriction of Chemicals (REACH) regulation. All of these processes came about in part based on early stakeholder engagement, which led to greater acceptance and understanding of the processes that were eventually adopted. Stakeholder engagement in these programs has continued to be essential for developing information necessary for agency decision making. These approaches demonstrate the benefits of predicable timeframes for when screening reviews will start and finish and routine announcements on the need for information from industry.

Concurrent with the foregoing, we also support EPA's vision for the long-term to "bin" all of the other chemicals on the TSCA Inventory for prioritization and we support the agency's previously proposed "notice of deficient information" approach for this group as well. We believe there are several possible groups for low priority consideration. Chemicals that are on the TSCA Inventory based on EPA's review of a premanufacture notification (PMN) should be lower in priority in relation to chemicals that have never undergone PMN review. EPA's low risk findings in relation to the polymer exemption could be the basis for low priority binning of many polymer listings on the Inventory that would otherwise qualify for the exemption. Other candidates for low-priority binning include additional chemicals beyond those EPA has identified in this round that are predominantly used in food or other non-TSCA applications, and possibly certain low volume chemicals as well. Open consideration of ways to streamline the process is needed, and we encourage EPA to foster these discussions.

III. Downstream Users see utility in continuing to make low priority designations.

The chemicals EPA has initiated for low priority consideration include Gluconic acid and five derivatives widely used in food and pharma applications, propylene glycol and six derivatives

used in polymer manufacturing, one solvent (3-methoxybutyl acetate), and certain additional cosmetic and polymer ingredients (e.g., 1,2-Hexanediol). As we already noted, however, the EPA docket did not contain information that would help us understand the uses of these chemicals that fall under TSCA's jurisdiction. We take note of the requirement in TSCA that a low priority designation must be based on ''information sufficient to establish'' that a chemical substance meets the definition. 15 U.S.C. § 2605(b)(1)(B)(ii). To ensure this condition can be met, we think it would be important for EPA to identify and articulate the known conditions of use for the low priority candidates at the proposed designation stage, along with the information the agency provided on the other safety determinations that have been made for them.

Downstream Users support EPA's effort to discharge its initial mandate with the first 20 chemicals selected for low priority review.[6] It is not clear to us that EPA will continue to make low priority designations after the first required 20, but we encourage the agency to persevere. Section 6(b)(2)(B) requires EPA to "ensure" that no later than three and one-half years after June 22, 2016, "at least 20 chemical substances have been designated as low-priority substances." Once the 20 low priority designation milestone is met, section 6(b)(2)(C) instructs that EPA "shall continue to designate priority substances and conduct risk evaluations . . . at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines" of the statute. However, subsection (C) does not specify the "priority substances" EPA needs to continue to designate in this sentence as either high or low. This provision in not entirely silent on this point however, since the continued need for these designations is closely linked to making sure EPA keeps to its deadlines for completing risk evaluations. It therefore appears that Congress' instructions in this subsection seem limited to high priority designations only. But, if TSCA does not require EPA to designate additional low priority chemicals, at a minimum the agency has discretion to continue to make these designations. We participated in the legislative process as part of the AAI Coalition, and from that standpoint we don't think Congress intended for EPA to ultimately limit the number of low priority designations under TSCA to a mere 20 chemicals out of the 43,000 active chemicals on the TSCA Inventory. That would leave EPA with 42,980 high priority chemicals for risk evaluation.

EPA can and should continue to make low priority designations when it makes sense even though we recognize that the identification and defense of low priority candidates may present a high hurdle. Since these designations are final agency actions with no preemptive effect, ensuring that the likelihood of state action stays low will turn on the quality and thoroughness of EPA's determinations. We understand that data gathered through this comment period could

[6] While the toxicology and prior assessments for these chemicals are encouraging, it is possible that the agency could fall short of this objective if only one of the 20 does not meet the necessary criteria.

add to EPA's high priority chemical workload unexpectedly if the information demonstrates that the candidate chemical does not qualify as low priority. On the other hand, we see the following benefits associated with these designations:

- Well-conducted low priority designations may help restore confidence in TSCA and by process of elimination, can help EPA plan, manage and balance its workload.

- EPA should not be faced with conducting multi-year, in-depth risk evaluations on every chemical on the TSCA Inventory because for some chemicals this is simply not needed.

- We view the use of these designations as consistent with public health principles and good government, in that existing chemicals that truly present a greater potential for risk due to hazard and exposure will be reviewed earlier in time than those that are on balance less likely to cause harm.

- As noted, low priority designations could aid in future commercial selection of these ingredients.

When making low priority designations, we ask EPA to avoid creating a misunderstanding about what a low priority designation is and is not. Low priority designations need to be clearly identified as such so that they do not occupy a place of uncertainty and are not associated with statement of implied risk. A designation of low priority requires EPA to only reach the conclusion that the substance does not meet the standard for designating the chemical as a high priority because as outlined in the Lautenberg Act (15 U.S.C. § 2605(b)(1)(B)(ii)), a low priority designation is simply any substance and its uses that do not meet the high priority designation. Any conclusions beyond this or which depart from this finding go beyond the agency's stated authority. Because EPA is directed to reach a specific conclusion – that the criteria nested in the high priority definition are not met – we respectfully ask the agency to respect the rule of law and stay closely on task with the determination it is required to make.

Precisely because the high priority criteria are used to reach a low priority designation, a low priority designation does not require EPA to establish zero risk. By rule, a low-priority substance is defined as "a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance." 40 C.F.R. § 702.3. This means EPA has to find that none of the conditions of use, as determined by the Administrator, cause the chemical substance to present an unreasonable risk. As a result, in any given case, it is reasonable to expect a

chemical designated as low priority to have uses that present low or no risk. On the other hand, it would be unreasonable to tolerate the presence of an elevated or significant risk for any single use of the chemical and in that case, a low priority determination would be unlikely. When making a low priority designation, we ask EPA to consider describing a low priority chemical as "a chemical for which EPA finds no compelling evidence that the chemical is likely, without consideration of cost or other non-risk factors, to present a significant risk to health or the environment if a risk assessment were to be conducted." Alternatively, we ask EPA to describe a low priority conclusion as one in which "EPA finds, without consideration of cost or other non-risk factors, that there is no compelling evidence that the substance may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations."

At this stage, we have not identified any of these chemicals as critical ingredients in our products. Nevertheless, they represent potential candidate ingredients for future products, and we think a low priority designation could aid their commercial selection in the future. Again, how EPA characterizes a low priority determination is important to the Downstream User community. State action on these chemicals is not precluded by these determinations, which are final agency actions challengeable in court. This make a compelling case for EPA to effectively communicate the lower relative need for a risk evaluation for these chemicals and build public confidence in these decisions.

IV. <u>We thank EPA for communicating through this action that the selection of a chemical for prioritization or risk evaluation is not a determination of risk or safety.</u>

When it comes to selecting chemicals to prioritize for risk evaluation that have been in U.S. commerce for many years, Downstream Users have a unique stake and perspective. 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 or retailers with questions and concerns. It is their businesses and reputations on the line. These companies do not simply desire, but need, clarity and an efficient, scientifically sound, decision-making process that addresses those substances that may present the greatest potential risk. Therefore, given the distinct viewpoint of downstream users, we ask EPA to consider our perspective in implementing TSCA.

As a practical matter, this means that our member companies and the public greatly benefit from consistent messaging that selecting chemicals for prioritization does not include a determination of risk or safety. For example, in this action on page 10492 of the Federal Register, EPA specifies that *"[i]nitiation of prioritization for substances as High Priority candidates is not a finding of risk. Rather, when prioritization is complete, for those chemicals designated as high, the Agency will have evidence that this substance may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use."* Thank you, EPA, for continuing to communicate the deliberative nature of this process and TSCA's emphasis on the use of best available science. We can't emphasize the importance of these points enough. Please keep helping us send this message. Because conditions of use are a central focus for information exchange from the earliest stages of this program, it will remain important for EPA to consistently emphasize the preliminary nature of either type of priority initiation and designation in communications in the Federal Register, in agency guidance, in agency presentations and meetings, and on EPA's website.

V. Conclusion.

We appreciate the opportunity to call attention to the need for a better process leading up to prioritization and the importance of safe use determinations following prioritization. During prioritization of these chemicals, we look forward to a continued exchange of information in this process. Downstream Users would appreciate EPA's adoption of these specific, proactive procedures to help to reduce concerns by consumers and the potential for adverse commercial effects related to premature product deselection or substitution decisions, including:

- Use the "Work Plan chemicals first" approach and issue a public schedule of when these chemicals will be initiated for prioritization;

- Engage in further stakeholder discussions on EPA's vision for the long-term to "bin" all of the other chemicals on the TSCA Inventory for prioritization;

- Comprehensively identify the known conditions of use for chemicals as early as possible in the prioritization process, such as at the initiation stage. Since the changes in the statute emphasize that chemicals are to be evaluated based on their conditions of use, it is insufficient for EPA to identify candidates for prioritization based on solely on chemical identity and toxicology information. Exposure is an equally critical component of these decisions;

- Take every opportunity to clearly distinguish uses that are safe from those that are driving a high priority determination. Beyond early use identification, another way in which EPA can build the ability to make these distinctions is to explain its information needs as early as possible;

- Consider the incidental presence of a chemical as an impurity, or non-point sources of aquatic exposure or air emissions associated with the use of these substances, during prioritization and carry these uses forward in any risk evaluations. We think in most cases these uses would be candidates for early and favorable risk evaluations, which we support; and

- Provide a focused and robust message on low priority designations which clearly identify low priority chemicals as such, so that they do not occupy a place of uncertainty and are not associated with statements of implied risk.

Thank you in advance for your consideration of these requests.

Respectfully submitted,

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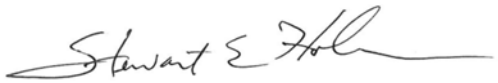

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