



June 3, 2020

The Honorable Andrew R. Wheeler  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

Re: Petition to Initiate a Proceeding to Issue a Procedural Risk Management Rule Under Section 6 of the Toxic Substances Control Act

Dear Administrator Wheeler:

The undersigned trade associations (“Petitioners”) submit this petition pursuant to section 21 of the Toxic Substances Control Act (“TSCA” or “Act”). Petitioners request that the U.S. Environmental Protection Agency (“EPA”) initiate a proceeding for the issuance of a risk management procedural rule under TSCA section 6 as a necessary action to implement the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (“Lautenberg Act”).

On June 22, 2016, the Lautenberg Act was signed into law to amend TSCA and give EPA new authority to evaluate and regulate how existing chemicals are manufactured, processed, distributed, and used. The Petitioners worked for the passage of the Lautenberg Act and have supported EPA’s development and implementation of the new section 6 prioritization and risk evaluation framework. The Petitioners also recognize that EPA staff has put a large amount of work into publishing the section 6 prioritization and risk evaluation framework rules under the TSCA amendments, issuing numerous guidance documents, selecting 50 chemicals for prioritization and risk evaluation, and preparing risk evaluations under demanding deadlines. In particular, the procedural rules for the prioritization and risk evaluation of existing chemicals serve an essential role to guide affected stakeholders through these new processes. Accordingly, this petition seeks a rulemaking to establish a similar degree of procedural consistency, guidance, and transparency for EPA’s risk management process. Petitioners believe that consistent, proper, and successful implementation of the Act will benefit EPA, the general public, and all stakeholders.

In December 2016, EPA repealed the risk management rules that had been issued under TSCA section 6 and become largely outdated with the passage of the Lautenberg Act. These procedural rules, which were located in the Code of Federal Regulations at 40 C.F.R. Part 750, applied to the management of existing chemicals found to present an unreasonable risk. Petitioners respectfully submit that an updated risk management procedural rule is now both necessary and timely. As EPA has yet to complete its initial risk evaluations of the first ten chemical substances, agency resources devoted to future risk management decisions and rulemakings should be available to engage in this endeavor.

If EPA finds that any of the conditions of use for those ten chemicals, or those that follow, present an unreasonable risk, the Administrator must apply requirements to the chemical substance or mixture to the extent necessary so that the chemical substance no longer presents such risk. While this may sound straightforward, it is not. Risk management of chemicals that have been in commerce for many years, by definition, is an exercise laced with options and uncertainties. It requires consistency, transparency, and effective public communication. Procedural guardrails are needed to guide EPA and affected stakeholders so that risk management is consistently applied and appropriately tailored. A

framework rule is needed to establish a central point of reference for all of the requirements and considerations involved in the crafting of a risk management rule that can be found across the various provisions of TSCA in section 6 and elsewhere. In addition to the foregoing considerations, a risk management procedural rule is consistent with your strategic goal as EPA Administrator to provide greater regulatory certainty and improve risk communication to the public.

Petitioners recognize that EPA will need time to draft, propose, and finalize a risk management procedural rule. Under TSCA section 21, the Administrator is required to grant or deny a petition within 90 days. If the petition is granted, TSCA requires the Administrator to promptly commence an appropriate proceeding, in this case in accordance with section 6. Petitioners seek to engage EPA in crafting a rule that is fair, transparent, informed by public comment, and not outcome-determinative. This petition specifically seeks to identify certain essential elements of a risk management framework for chemicals that have been in commerce for many years.

In recent years, some petitioners have used section 21 to try to reorder the priorities of the agency and circumvent the newly minted risk evaluation process; this is not our goal. TSCA's citizens' petitions provision should be used to help EPA achieve the goal of providing the public with confidence that the chemicals they work with, depend on, and use do not present an unreasonable risk and, if they present such a risk, that the government has addressed that risk in manner consistent with one of the enumerated policies of TSCA: "not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of [TSCA] to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."<sup>1</sup> Petitioners share this goal and seek to strengthen the federal program through the adoption of a procedural risk management framework rule.

### **Petitioners**

The Petitioners represent industries and businesses with interests in chemical substances currently undergoing risk evaluations, designated as high-priority chemicals, and on the TSCA Work Plan for Chemical Assessments ("2014 TSCA Work Plan"). These associations and their members significantly contribute to the nation's economy, create millions of domestic jobs, and rely on chemicals every day to serve the American public. As you know, U.S. industries need regulatory certainty to ensure economic success. They rely on essential chemicals with no known replacements, make commercial plans years if not decades in advance, and strive to ensure the protection and safety of their workers, downstream users, the general public, consumers, and the environment. Therefore, while EPA's TSCA section 6 risk management actions will undoubtedly affect chemical manufacturers, Petitioners can envision many situations where such regulations could also have a significant impact on downstream users of such chemicals. Without regulatory certainty, innovation is stifled, job creation erodes, and U.S.-based future investments dry up. The individual Petitioners are listed and introduced in alphabetical order below.

The American Coatings Association ("ACA") is the national nonprofit trade association working to advance the paint and coatings industry and the 287,000 professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals who produce over \$30 billion in paint and coating product shipments. ACA members use and produce chemicals subject to regulation under TSCA.

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the

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<sup>1</sup> 15 U.S.C. § 2601(b)(3).

interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. The Chamber's members include companies in all of the sectors covered by each of the other Petitioners – chemicals, coatings, refiners, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, and electricity, among many others. These companies use chemicals subject to regulation under TSCA.

The National Association of Home Builders of the United States (“NAHB”) is a Washington, D.C.-based trade association that represents more than 140,000 members nationwide who are involved in home building, remodeling, multi-family construction, property management, subcontracting, design, housing finance, building product manufacturing, and other aspects of residential and light commercial construction. NAHB is affiliated with more than 700 state and local home builder associations around the country.

The National Association of Manufacturers (“NAM”) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes \$2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the powerful voice of the manufacturing community, whose members manufacture, and use chemicals subject to EPA's TSCA jurisdiction.

The Toy Association is the not-for-profit trade association that represents more than 1,000 businesses – toy manufacturers, importers, and retailers, as well as toy inventors, designers, and testing labs – who are all involved in bringing safe and fun toys and games for children to market. Toy safety is the top priority for the industry. The Toy Association and its members are leaders in toy safety, dating back to the 1930s, and we place a high value on ongoing programs to ensure safe play. The toy industry is not a producer of chemicals that EPA may seek to regulate, but members may import articles and may be downstream users of materials, such as polymers, which may contain unavoidable trace contaminants of such chemicals at de minimis levels.

### **Background**

On December 2, 1977, shortly after TSCA was initially enacted, EPA issued section 6 risk management framework regulations entitled “Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act.”<sup>2</sup> The agency created those procedures to implement requirements under section 6 for managing chemical substances. Former EPA Administrator Douglas Costle affirmed that section 6 procedural rules were “issued under authority of section 6 of [TSCA].”<sup>3</sup> The rules set forth what information EPA would include in a notice of proposed rulemaking under section 6 and how the agency should handle public comments – many requirements that survived the Lautenberg Act. For example, the prior risk management framework rule required EPA to issue a notice of proposed rulemaking that included a statement with respect to the effects of the chemical substance at issue, as still mandated by section 6(c)(2)(A).<sup>4</sup>

On December 21, 2016, however, EPA concluded that the Lautenberg Act superseded the agency's section 6 risk management framework requirements by rendering them outdated, inefficient,

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<sup>2</sup> “Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act,” 42 Fed. Reg. 61259 (Dec. 2, 1977).

<sup>3</sup> *Id.* at 61260.

<sup>4</sup> *Id.*

and unnecessary.<sup>5</sup> Specifically, because “EPA’s duties under TSCA section 6 have been significantly modified to include specific deadlines and procedures for prioritizing chemicals for risk evaluations, conducting the risk evaluations and promulgating regulations to address unreasonable risks that are identified,” the agency “determined that the procedural regulations in subpart A do not facilitate the efficient administrative process envisioned by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.”<sup>6</sup> Therefore, EPA “remov[ed] the general TSCA section 6 procedural requirements contained in subpart A of 40 CFR part 750.”<sup>7</sup>

That December 2016 action left 40 C.F.R. Part 750 Subpart A reserved for any future procedures for rulemaking under section 6 of TSCA. EPA decided that it needed to make the procedural regulations consistent with the new law. Given the numerous competing statutory deadlines the agency faced at the time, however, EPA understandably passed on the opportunity to update the regulations and explain how the agency generally plans to approach risk management as it continues to implement the Lautenberg Act mandates. This TSCA section 21 petition is now timely and seeks to fill that void.

### **Statutory Authority**

Petitioners submit this petition under TSCA section 21, which permits any person to petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under sections 4, 6, and 8, or an order under sections 4 or 5.<sup>8</sup> The petition must be filed in the principal office of the Administrator and set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal the relevant rule or order.<sup>9</sup> Within 90 days after the filing of a petition, the Administrator must either grant or deny the petition.<sup>10</sup> If the Administrator grants the petition, then the Administrator must “promptly commence an appropriate proceeding” in accordance with section 4, 5, 6, or 8 of TSCA.<sup>11</sup> If the Administrator denies the petition, EPA shall publish in the Federal Register the Administrator’s reasons for the denial.<sup>12</sup>

Petitioners seek a section 6 rule of agency procedure and practice. Even though the Administrative Procedure Act (APA) provides that “rules of agency organization, procedure, or practice” are exempt from notice and comment requirements, Petitioners believe that EPA should publish the requested section 6 risk management procedural rule for notice and comment because the information and opinions supplied by the public will inform the Agency’s views.<sup>13</sup> This approach would be consistent with what the EPA did in December 2016, since that action repealed existing section 6 rules that were deemed largely outdated without precluding the opportunity to issue new ones.<sup>14</sup>

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<sup>5</sup> “Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Amendment,” 81 Fed. Reg. 93633 (Dec. 21, 2016).

<sup>6</sup> *Id.* at 93634.

<sup>7</sup> *Id.* at 93635.

<sup>8</sup> 15 U.S.C. § 2620(a).

<sup>9</sup> *Id.* at § 2620(b)(1).

<sup>10</sup> *Id.* at § 2620(b)(3).

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

<sup>12</sup> *Id.*

<sup>13</sup> 5. U.S.C. § 553(b)(3)(A). This recommendation is consistent with EPA’s approach in its procedural rulemaking entitled, “Modernizing the Administrative Exhaustion Requirement for Permitting Decisions and Streamlining Procedures for Permit Appeals,” 84. Fed. Reg. 66084 (Dec. 3, 2019).

<sup>14</sup> “This action involves revisions of the rules that set out the general rulemaking procedure for EPA under the prior version of TSCA, and the action does not affect the substance of any determinations EPA will make under the

## Risk Management Procedural Rule

Petitioners respectfully request that EPA issue a risk management procedural rule that is consistent with the procedural requirements for risk management in TSCA section 6 and consolidates the related considerations in sections 9 and 18 of the Act. This petition offers a suggested blueprint for designing such a rule that includes all of the features required or implicated by the statute and corresponding regulations.

### I. The Selection of One or More Risk Management Approach(es) Enumerated in Section 6(a) Should Be Guided by a Transparent Process.

TSCA section 6(a) sets forth the scope of a risk management rule for a particular chemical substance or mixture:

If the Administrator determines in accordance with subsection (b)(4)(A) 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, the Administrator shall by rule, and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.<sup>15</sup>

Based on the above, a risk management procedural rule should explain that EPA must first prepare a sensitivity and uncertainty analysis of the risk evaluation inputs so that the full range of scientifically supported estimates of exposure, the range of plausible toxicity factors, and the range of risk estimates are available for consideration by the risk managers for conditions of use found to present an unreasonable risk. Based on this range of risk estimates, EPA shall select from among the seven enumerated risk management approaches in section 6(a) “to the extent necessary” so that the chemical no longer presents an unreasonable risk. The framework should also incorporate procedures to ensure EPA needs to issue such a rule in coordination with section 18 of TSCA and take the additional factors of section 6(c)(2) into consideration, as discussed later in this petition. The risk management options available to EPA include the following:

- Prohibit or otherwise restrict the chemical or limit the amount of the chemical;<sup>16</sup>
- Prohibit or otherwise restrict the chemical for a particular use or a particular use in a concentration in excess of a specified level;<sup>17</sup>
- Require that a chemical or any article containing that chemical be marked with or accompanied by clear and adequate minimum warnings and instructions;<sup>18</sup>
- Require that manufacturers and processors of a chemical make and maintain records of the processes used to manufacture or process the chemical, or monitor or conduct reasonable and necessary tests to assure compliance;
- Prohibit or otherwise regulate any manner or method of commercial use of such chemical;<sup>19</sup> and

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amended TSCA section 6. Accordingly, these revisions fall under the exemption provided in APA section 553(b)(3)(A), and the EPA is not taking comment on this section.” 81 Fed. Reg. at 93633.

<sup>15</sup> 15 U.S.C. § 2605(a).

<sup>16</sup> *Id.* at § 2605(a)(1).

<sup>17</sup> *Id.* at § 2605(a)(2)(A).

<sup>18</sup> *Id.* at § 2605(a)(3).

<sup>19</sup> *Id.* at § 2605(a)(5).

- Prohibit or otherwise regulate any manner or method of disposal of such chemical or any article containing such chemical.<sup>20</sup>

It is necessary to have a risk management procedural rule to organize and direct the agency's use of these diverse options, preferably in a stepwise approach. This list constitutes a broad range of options with which to address any identified unreasonable risk across the workplace, general population, and consumer exposure spectrum – from warning labels to concentration limits to restrictions and use prohibitions in any combination – and, therefore, the number of choices that EPA has at its disposal offers unique flexibility. At the same time, the broad range of possible outcomes imparts a high degree of uncertainty and lack of predictability associated with any given regulatory outcome, unless there is an underlying framework to guide decision making. A risk management framework is needed for stakeholders to understand how EPA will select from among the risk management options and should require the agency to explain why particular options will or will not address the identified unreasonable risk.<sup>21</sup>

Petitioners support a procedural framework for implementing section 6 risk management outcomes to promote the transparency, consistency, and certainty of EPA's risk management decisions. Procedural safeguards are especially necessary to guide the agency and stakeholders when the most restrictive option available, that of prohibiting any manner or method of the commercial use of a particular chemical, is at stake. Accordingly, a risk management framework rule should establish the criteria for proposing when a chemical's use will be prohibited in any manner or method.<sup>22</sup> Prohibiting all manners and methods of the commercial use of a chemical should be selected as an expedient means to eliminate all potential exposure only if (1) all exposures to the chemical present an unreasonable risk and (2) it is not possible to address the unreasonable risk through less drastic options.

With regard to the foregoing, Petitioners recognize, appreciate, and supported the actions of Congress to pass the Lautenberg Act, in part, to render obsolete the holding in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991), and expressly eliminate the statutory provision that maintained any risk management rule must use "the least burdensome requirements." Instead, Congress instructed EPA to issue risk management rules "to the extent necessary so that the chemical substance or mixture no longer presents" an unreasonable risk.<sup>23</sup> This legal standard for risk management seems to require the agency to calculate the reduction in risk that is achieved after various mitigation options are employed and tailor risk management so that it is not unnecessarily overbroad. Petitioner's blueprint suggestions aim to address procedural considerations associated with this legal standard.

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<sup>20</sup> *Id.* at § 2605(a)(6)(A).

<sup>21</sup> EPA previously recommended such an approach in its 2014 "Framework for Human Health Risk Assessment to Inform Decision Making." <https://www.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf>. For example, EPA identified the following considerations for informing risk management decisions: (1) the health protection level provided by each option; (2) the key limitations/uncertainties associated with risk estimates for each option; and (3) other factors such as technologies, costs, social considerations, environmental justice, and sustainability. *See id.* at 47-48. Petitioners cite this document as precedent for the approach we are suggesting, but this reference does not necessarily represent an endorsement of the 2014 framework in its entirety.

<sup>22</sup> In EPA's post-Lautenberg risk management rulemakings to date, Petitioners have observed that the agency has been inclined to impose the most restrictive option – a prohibition on the manufacture and use of a chemical for a particular use – without transparently explaining why a less burdensome option (*e.g.*, a concentration limit) would not have sufficed.

<sup>23</sup> 15 U.S.C. § 2605(a).

Consistent with TSCA's requirement for EPA to issue rules "to the extent necessary" to address unreasonable risks associated with an evaluated chemical, Petitioners urge EPA to craft a procedural rule that will ensure risk management regulations will be selectively tailored to identify and address only each condition of use (or perhaps a group of related conditions of use) that presents an unreasonable risk. EPA should anticipate that there will be many times when the agency finds that a chemical both presents an unreasonable risk under some uses while it does not present an unreasonable risk under other uses. This is because the conditions of use of a chemical determine route, duration, and amount of exposure, all of which impact the risk. Where some conditions of use do not present an unreasonable risk, TSCA does not require the application of the least common denominator to prohibit all manner and methods of use. Section 6 risk management rules are not required for all conditions of use within the scope of the risk evaluation. Such rules are not required for those that are found not to present an unreasonable risk. While this point seems apparent – since it would violate TSCA and the intent of Congress for EPA to regulate conditions of use that do not present an unreasonable risk – codifying this approach in a framework rule avoids any misunderstanding.

To accurately inform everyone – from workers to the general public to susceptible subpopulations – the risk management procedural rule must ensure requirements of a risk management rule for a specific chemical will have a clear demarcation and demonstrate that the provisions do not apply to conditions of use that meet the TSCA safety standard by listing those conditions as exempt. Section 6 does not identify how the agency will provide adequate notice to regulated entities and the general public with respect to this important delineation on conditions of use. Publishing final risk management rules in the Federal Register might provide constructive notice, but it does not afford small businesses or the public sufficient notice to know and understand their obligations and the applicability of the regulations if conditions of use that meet the safety standard are not procedurally exempt from a risk management rule.<sup>24</sup>

Moreover, as an overall consideration, mitigation scenarios should be routinely evaluated to ensure that mitigation is employed in a targeted manner that does not extend beyond that which is needed to reduce the unreasonable risk of concern to an acceptable level. For example, TSCA's risk management framework allows EPA to limit the imposition of any restriction or combination of restrictions to a specified geographic area. Even for options such as recordkeeping, it would be important to have rules in place for EPA to explain how that option specifically helps to reduce or eliminate the unreasonable risk. Procedural safeguards are needed so that recordkeeping requirements are not reflexively included in every risk management action even if there is no substantive impact on the risk determination associated with it.

Managing risk necessitates quantified exposures and identifiable endpoint(s) with a toxicity value(s), together with any applicable uncertainty factors, to understand whether one or more of EPA's available risk management options would lower the risk associated with a substance or mixture's condition of use to the extent necessary so that the chemical substance no longer presents an unreasonable risk. In this regard, a risk management procedural rule should recognize and accommodate measured responses for conditions of use where EPA issues a finding of unreasonable risk but notes that the finding is of low to medium confidence. In those cases, further procedural safeguards may be warranted prior to selecting a risk management option, such as the collection of additional

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<sup>24</sup> Petitioners believe it would be helpful for the public to understand the level of PPE that EPA determines to be appropriate for each chemical that has undergone risk evaluation for the conditions of use that both do and do not present an unreasonable risk. For example, EPA could use ChemView or another user-friendly program to provide this information to the public.

information. In other cases, a closely tailored risk mitigation option designed to acknowledge the uncertainty may be warranted.

As part of the procedures envisioned, Petitioners would like to highlight the importance of ensuring that section 6 risk management regulations recognize and are consistent with established Occupational Safety and Health Administration (OSHA) workplace safety requirements, such as the OSHA hazard communication (HazCom) requirements at 29 C.F.R. § 1910.1200 and OSHA worker protection standards at 29 C.F.R. § 1910.132(a) and (d) (requiring employers to “assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). If such hazards are present, or likely to be present, the employer shall . . . select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment”).<sup>25</sup> In cases where EPA finds workplace controls inadequate, EPA has the option of issuing a rule or recommending that OSHA take action to address a finding of unreasonable risk pursuant to sections 6 and 9 of TSCA.

Moreover, different risk management options maybe warranted when a chemical substance is part of a product that is offered at the retail level for use by commercial professionals and by consumers. As EPA recognized in its advance notice of proposed rulemaking, “Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program,” sections 6(a)(2) and (5) of TSCA authorize EPA to issue requirements for a training, certification, and limited access program for professional users of chemicals found to present an unreasonable risk.<sup>26</sup> These requirements could provide EPA with a reasonable option that addresses any unreasonable risks associated with a chemical while still allowing that chemical to be used by trained professionals who understand and protect themselves from those risks. Petitioners respectfully ask EPA to include consideration of such an option in a risk management framework rule. EPA need not prescribe a particular program in the procedural rule, as the agency can make that determination on a case-by-case basis or in another proceeding.

In summary, procedures such as those identified above would provide affected stakeholders and the public with valuable insights into the risk management selection process. An established set of rules and an improved understanding of the agency’s decision process can build public confidence in EPA’s ability to regulate chemicals under TSCA, a goal which these Petitioners support. A procedural framework established through notice and comment rulemaking for implementing section 6 risk management outcomes will promote transparency and consistency in agency decision making and will serve to strengthen the basis for EPA’s risk management decisions.<sup>27</sup>

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<sup>25</sup> OSHA requirements are stand-alone, federal requirements in their own right, which are also enforceable by many states. Reliance on the need for companies to comply with OSHA obligations, together with supporting information in the record of the risk evaluations, should be sufficient to support findings of no unreasonable risk at the risk evaluation stage.

<sup>26</sup> “Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program,” 84 Fed. Reg. 11466, 11467 (March 27, 2019).

<sup>27</sup> This approach would also be consistent with two landmark Executive Orders that govern federal agency regulation. *First*, Executive Order 12866 (Sept. 30, 1993) requires each federal agency to “tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.” <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>. *Second*, Executive Order 13563 (Jan. 18, 2011) similarly requires federal agencies to “tailor [their] regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent

## II. Procedures to Coordinate with Section 18, Codify Section 6(c) Deadlines, and Consider Section 6(c)(2) Effects Associated with Risk Management Rules Are Important.

Beyond the selection of risk management options in section 6(a), TSCA requires risk management rules to be issued in coordination with section 18 of TSCA. Petitioners respectfully submit that adopting a risk management framework rule advances the goals of the Lautenberg Act to establish a strong federal program and a single federal standard for regulated chemicals under section 6. Many aspects of statutory preemption in TSCA that surround the establishment of a single federal standard are self-effectuating and judicially enforceable, such as those in section 18(a), (b), (c), (d) and (e). Nevertheless, procedural rules can ensure that risk management under section 6 is implemented consistent with exclusions made at the risk evaluation scoping phase. In addition, an informed and improved understanding of the process for mandatory and discretionary state waivers may be gained through rulemaking with respect to section 18(h) of TSCA.

Additionally, TSCA section 6(c) contains many important components of a risk management rule. As EPA did with the prioritization and risk evaluation rules, it is necessary to incorporate all of the statutory procedural requirements of section 6(c) into a risk management procedural rule. This would include TSCA's direction that EPA proceed in accordance with section 553 of the APA when prescribing a risk management rule.<sup>28</sup> Moreover, TSCA mandates that EPA "publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule" and "allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available."<sup>29</sup> The final rule must be "based on the matter in the rulemaking record."<sup>30</sup> EPA must also "make and publish with the rule the determination described in subsection (a)."<sup>31</sup> All of these statutory procedural requirements should be incorporated into the risk management procedural rule.

With respect to deadlines, the procedural rule should also incorporate the general requirements for EPA to (1) propose a risk management rule not later than one year after the date on which the final risk evaluation for a particular chemical is published and (2) publish a final rule not later than two years after the date on which the final risk evaluation for a particular chemical is published.<sup>32</sup> EPA's authority to extend those deadlines for not more than two years in the aggregate should be codified in regulations, consistent with similar provisions already in place in the prioritization and risk evaluation framework rules.<sup>33</sup> The agency's ability to extend deadlines is comparatively more complex in the case of risk management, which makes the need for regulatory text heightened. This is because the provision contains a fundamental limitation: EPA may not extend those deadlines for chemicals that are drawn from the 2014 TSCA Work Plan or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification.<sup>34</sup> When providing this justification, EPA must "demonstrate[], following a review of the information reasonably available to the Administrator,

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practicable, the costs of cumulative regulations."

[https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/eo12866/eo13563\\_01182011.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/eo12866/eo13563_01182011.pdf).

<sup>28</sup> *Id.* at § 2605(c)(3).

<sup>29</sup> *Id.* at §§ 2605(c)(3)(A) and (B).

<sup>30</sup> *Id.* at § 2605(c)(3)(C).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at §§ 2605(c)(1)(A) and (B).

<sup>33</sup> *Id.* at § 2605(c)(1)(C). See also 40 C.F.R. § 702.1(d) ("Prioritization timeframe") and 40 C.F.R. §702.49(b)(2) ("Final risk evaluation").

<sup>34</sup> *Id.*

that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.”<sup>35</sup>

Petitioners ask EPA to consider and recognize that the risk evaluations for the first ten chemicals are all drawn from the 2014 TSCA Work Plan, as are the 20 high-priority chemicals that follow. It seems both reasonable and prudent to consider the possibility of a future in which the agency, for any number of reasons, may be unable to complete all of the risk management rules associated with the risk evaluations within the two-year deadline. Therefore, a procedural framework should identify the factors that EPA will consistently consider, with an appropriate level of flexibility, to demonstrate the adequate justification needed to avail itself of the extension for these chemicals.

As previously noted, section 6(a) expressly directs EPA to issue risk management rules in accordance with section 6(c)(2), which requires EPA to issue a statement of effects.<sup>36</sup> TSCA’s requirement that EPA publish this statement of effects provides transparency into the agency’s cost-benefit calculations when deciding on a particular approach for risk management of a chemical.<sup>37</sup> In a proposed or final risk management rule, EPA must publish this statement based on reasonably available information with respect to:

- The effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
- The effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
- The benefits of the chemical substance or mixture for various uses; and
- The reasonably ascertainable economic consequences of the rule, including consideration of
  - The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
  - The costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
  - The cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.<sup>38</sup>

Importantly, TSCA requires the Administrator to “factor in, to the extent practicable,” the considerations listed above in accordance with section 6(a).<sup>39</sup> Codifying the requirements of section 6(c)(2) into a procedural rule would ensure that EPA gives due consideration to these effects, while providing affected stakeholders and the public with a clear understanding of the information these statements consistently need to contain. The procedural rule should also specifically require the Administrator to explain how these considerations were factored in to a specific proposed or final risk management rule.

Based on the considerations above, TSCA additionally calls upon the EPA Administrator to take into account alternatives when “deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action.”<sup>40</sup> Specifically, the Administrator must also “consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the

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<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at § 2605(a).

<sup>37</sup> *Id.* at § 2605(c)(2)(A).

<sup>38</sup> *Id.* at §§ 2605(c)(2)(A)(i)-(iv).

<sup>39</sup> *Id.* at § 2605(c)(2)(B).

<sup>40</sup> *Id.* at § 2605(c)(2)(C).

environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.”<sup>41</sup> Many downstream users of the initial ten chemicals and other 2014 TSCA Work Plan chemicals do not have reasonably available substitutes available to them. Incorporating a procedure to implement this requirement into the risk management procedural rule would promote a better understanding of the process EPA will undertake and the substitutes that are actually – not theoretically – reasonably available. Stakeholders will gain an improved understanding of the process and the opportunity to submit relevant, helpful information to the agency. The agency would have the opportunity to provide helpful directions in a rule to inform, guide, and support this consideration.

In the risk management procedural rule, EPA also needs to develop a statutorily consistent, logical approach to the exemptions for replacement parts and articles permitted under TSCA sections 6(c)(2)(D) and (E):

(D) Replacement parts

(i) In general

The Administrator *shall exempt* replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), *unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.*

\* \* \*

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator *shall apply* such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).<sup>42</sup>

As explained in public comments submitted to the agency, EPA’s prior interpretation of these provisions is mistaken and contrary to the plain reading of the statutory text.<sup>43</sup> Petitioners respectfully submit that the above provisions forbid EPA from enacting any prohibitions and restrictions on articles and replacement parts, unless an EPA risk evaluation has been conducted and has found that either the replacement part contributes significantly to an identified unreasonable risk or regulation of an article is necessary to address an unreasonable risk.

In other words, the exemption for replacement parts orders EPA to exempt replacement parts in any and all risk management rules (*i.e.*, “*The Administrator shall exempt replacement parts. . .*”). The statute provides only one exception: if the Administrator finds such replacement parts contribute

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<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at §§ 2605(c)(D) and (E) (emphasis added).

<sup>43</sup> Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 84 Fed. Reg. 36728, 36746 (July 29, 2019); Public Comment RIN 2070-AK34.

significantly to the risk identified in a risk evaluation conducted under section (b)(4)(A), then EPA may find that the exemption does not apply. EPA can, therefore, apply its section 6(a) authority over replacement parts *only if* there is an unreasonable risk finding pursuant to a risk evaluation *and* that evaluation finds such replacement parts contribute significantly to the identified risk.

EPA's risk management framework rule should also codify the statutory definitions of "complex consumer goods" and "complex durable goods," which are terms used in the exemption for replacement parts.<sup>44</sup> It would be helpful if EPA further defined or explained what it understands the phrase "impracticable to redesign or replace" to mean in the context of the definition of "complex consumer good."<sup>45</sup>

Similarly, the exemption for articles gives EPA the authority to apply prohibitions and restrictions on articles *only to the extent necessary* to address risks identified in a risk evaluation under section (b)(4)(A). This exemption bounds EPA's authority to regulate articles. The agency can apply its section 6(a) authority over articles *only if* there is an unreasonable risk finding pursuant to a risk evaluation *and* regulating the article is necessary to address that risk. The TSCA article exemption, in particular, is a necessary bulwark to protect those who manufacture, sell, or use articles containing restricted chemicals from unforeseen and unintentional liability, especially when many entities are unable to know the de minimis chemical composition of their products. This interpretation could have wide-ranging impacts, including in TSCA section 21 petition proceedings.

Finally, Petitioners respectfully ask EPA to consider and affirm the agency's express authority under section 6(b) to exempt de minimis levels of regulated chemicals as part of risk management with respect to mixtures and imported articles. As the implementation of EPA's TSCA Fees Rule for risk evaluations has brought to light, accounting for *de minimis* levels of every chemical in mixtures and imported articles is difficult and time-consuming. Risk management will, therefore, need to be closely coordinated to reflect agency decisions on *de minimis* levels that are made at the scoping and findings phases of risk evaluation. Petitioners understand the provision on articles in the Lautenberg Act was contemplated with these harmonized chemical risk communication and management precepts in mind – to ensure that this class of products not divert attention from more likely exposures and higher concentrations that potentially may warrant more serious consideration.<sup>46</sup>

There is precedent for establishing and maintaining an exemption for de minimis levels of chemicals during risk management in related sections of TSCA and in other chemical regulatory programs administered by EPA. For example, the de minimis provisions of the TSCA section 12 export notification rule provide that "no notice of export is required for the export of a chemical substance or mixture for which export notification is otherwise required, where such chemical substance or mixture is present in a concentration of less than 1% (by weight or volume)" and that "[n]o notice of export is required for the export of a chemical substance or mixture that is a known or potential human carcinogen where such chemical substance or mixture is present in a concentration of less than 0.1% (by

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<sup>44</sup> 15 U.S.C. §§ 2605(c)(2)(D)(ii)(I) and (II).

<sup>45</sup> *Id.* at § 2605(c)(2)(D)(ii)(I).

<sup>46</sup> The TSCA section 12(b) export notification rules provide that "[n]o notice of export will be required for articles . . . unless the Agency so requires in the context of individual section 5, 6, or 7 actions." 40 C.F.R. § 707.60(b). Under TRI, 40 C.F.R. §372.38(b) provides that "if a toxic chemical is present in an article at a covered facility, a person is not required to consider the quantity of the toxic chemical present in such article when determining whether an applicable threshold has been met . . . or determining the amount of release to be reported." Similarly, the import of a chemical substance "as part of an article" is not subject to Chemical Data Reporting (CDR) per 40 C.F.R. § 711.10(b).

weight or volume).<sup>47</sup> This rule also provides in subsection (e) that “[a]ny person who would be prohibited by a TSCA section 5 or 6 regulation from exporting a chemical substance or mixture, but who is granted an exemption by EPA to export that chemical substance or mixture, shall notify EPA under TSCA section 12(b) of such intent to export or exportation.”

In addition, the risk management provisions under section 5 for new chemicals adopt and adhere to the same *de minimis* levels, which are based on those adopted under OSHA HazCom requirements.<sup>48</sup> The Emergency Planning and Community Right-to-Know Act, section 313 (Toxic Release Inventory (TRI)) regulations also rely on OSHA HazCom for purposes of establishing a chemical’s *de minimis* concentration for reporting as either 1.0% or 0.1% for chemical substances when present in a mixture (40 C.F.R. § 372.38(a)). Internationally the use of *de minimis* concentration levels under the Global Harmonized Standard (GHS) international chemical classification and labeling scheme has served as a basis for incorporation of a *de minimis* concentration level for establishing the general need to evaluate and communicate about chemical hazards.<sup>49</sup> The GHS was adopted by the United Nations Economic and Social Council in July 2003 and is an internationally agreed-upon tool for chemical hazard communication that incorporates a harmonized approach to hazard classification and provisions for standardized labels and safety data sheets. GHS labeling serves as a foundation for national programs to promote safer use, transport, and disposal of chemicals, and to facilitate international trade in chemicals whose hazards have been properly assessed and identified based on internationally agreed-upon criteria. The applicability of GHS is fundamental to understanding the composition and safety of imported products, including articles. A similar presumption should be considered for section 6 during risk management; this is needed to further focus government resources and attention on chemicals in quantities that present an unreasonable risk, to be consistent across a broad range of federal risk evaluation and reporting programs, and to avoid over-regulating these products.<sup>50</sup>

As EPA has noted in the past, chemicals retain toxic properties at low levels. Nevertheless, the *de minimis* concentration thresholds and article exemption recognize that the level of exposure is equally part of assessing risk. The approach remains sound and is relied on throughout the world for taking safety precautions for conditions of use involving hazardous chemicals. Since risk is a function of both hazard and exposure, the low likelihood of exposure when regulated chemicals are present at *de minimis* levels in mixtures and in articles in which they are not designed to be released is far more unlikely to present an unreasonable risk determination. This established regulatory approach should be part of a proposed section 6 risk management rulemaking.

### **III. A Risk Management Rule Must Specify Effective Dates and Provide for Sufficient Notice to Affected Entities.**

Petitioners represent companies that are part of complex, long, and established supply chains. Risk management procedures are needed to explain when and how restrictions would be applied to manufacturers and importers, processors, distributors, and consumers. Rules for managing chemicals that have been in commerce for many years may have direct and indirect effects along the supply chain that should be identified and considered in advance of implementing any given risk management rule. Petitioners envision that a risk management procedural rule would expressly require the agency to

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<sup>47</sup> 40 C.F.R. § 707.60(c).

<sup>48</sup> 40 C.F.R. § 721.72.

<sup>49</sup> Export Notification; Change to Reporting Requirements, Final Rule, 71 Fed. Reg. 66234, 66237 (Nov. 14, 2006).

<sup>50</sup> Although Petitioners do not view it as necessary given the foregoing points, a procedural framework for implementing a consistent *de minimis* approach could be crafted to accommodate the rare instance, if any, where EPA finds unreasonable risk associated with a *de minimis* amount of a chemical.

specify the scope and applicability of the risk management regulations for chemicals found to present unreasonable risks. It would violate the basic tenets of due process and fairness if the subjects of risk management rules did not receive sufficient notice about any restrictions associated with chemicals they manufacture, process, distribute, or use.

In this regard, the effective date of a particular risk management rule has significant implications for manufacturers and downstream users of the regulated chemical. Therefore, Petitioners request that EPA's risk management procedural rule codify the effective date provisions of section 6(d), in addition to specifying how it will handle certain circumstances. The procedural requirements enumerated in section 6(d)(1) require the Administrator to include the following in any risk management rule:

- (A) specify the date on which it shall take effect, which date shall be as soon as practicable;
- (B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);
- (C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);
- (D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and
- (E) provide for a reasonable transition period.<sup>51</sup>

Given the potential for commercial disruption, EPA should be mindful that reasonable phase-outs and sell-through allowance should be generally provided to allow the affected stakeholders the ability to reduce their current stocks and transition to alternative chemicals. For long-standing, existing commercial activities, the agency should consider measures that will minimize unduly disruptive impacts on the economy. EPA should also codify the agency's statutory authority to establish different compliance dates for different affected persons.<sup>52</sup> To increase transparency and certainty, EPA should also identify the factors it will consider when applying different compliance dates.

The risk management framework rule should require EPA, where applicable, to (1) specify which entity or entities should be responsible for any market withdrawals, with preference given to manufacturers, and include the factors that EPA would consider when determining such responsibility, (2) provide an exemption to commercial entities that have already sold the chemical or articles that incorporate the chemical to a downstream entity or consumer, and (3) specify the acceptable methods of disposal. For example, a prohibition on distribution should not force companies to recall finished products and articles that are already in the supply chain if no unreasonable risk is identified from the (temporary) exhaustion of existing stocks in question. For example, the Consumer Product Safety Commission (CPSC) instructs companies to recall products that (1) are defective in a manner that could create a substantial risk of injury to consumers, (2) create an unreasonable risk of serious injury or death, or (3) result in choking incidents involving children (regardless of age) that, as a result of the incident, results in serious injury, a cease in breathing for any length of time, or treatment by a medical professional.<sup>53</sup> Similarly, the Food and Drug Administration (FDA) is authorized to recall food when there

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<sup>51</sup> *Id.* at §§ 2605(d)(1)(A)-(E).

<sup>52</sup> *Id.* at § 2605(d)(2).

<sup>53</sup> <https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance/Duty-to-Report-to-the-CPSC-Your-Rights-and-Responsibilities/>.

is a reasonable probability that the food is adulterated or misbranded and use of or exposure will cause serious adverse health consequences or death to humans or animals.

Product withdrawals under a section 6(b) rule should be held to the same high standard. TSCA provides the agency with a range of alternatives so as to avoid unnecessary disruption to critical supply chains, and the agency must incorporate a number of considerations in the selection of the appropriate risk management tool. These considerations include the authority to take into account costs and other non-risk factors at the risk management phase. Otherwise, the continuous implementation of immediate bans on distribution for already finished goods as EPA manages 20 or more risk management outcomes in a given period of time over the coming years may cause numerous, unintended market disruptions, and require complex supply chain interventions that either do not currently exist or are unable to effectively, reliably function within the proposed timeframes EPA has put forward in certain proposals (*e.g.*, 60 days).<sup>54</sup> EPA's framework rule should mandate that EPA address whether it will allow entities the ability to sell-through a particular date or the ability to export the chemical after a domestic ban or restriction. EPA should also provide the criteria for when destruction of existing stocks will be required.

Finally, Section 6(d) also allows the Administrator to declare a proposed rule under section 6(a) to be effective – *i.e.*, compliance with the proposed requirements to be mandatory – immediately upon publication in the Federal Register of the proposed rule through the compliance dates applicable to such requirements in a final rule.<sup>55</sup> EPA's risk management procedural rule should establish factors for when EPA will invoke this unique statutory authority, especially since the public may not have notice of any mandatory requirement prior to the release of a proposed section 6(a) rule.

#### **IV. The Risk Management Procedural Rule Should Codify the Critical or Essential Use Exemption and Establish Procedures for Routine Consideration of These Exemptions.**

Because TSCA risk management rules could have significant disruption to the national economy, national security, and critical infrastructure, Congress included a new provision in the Lautenberg Act to give EPA the authority to grant exemptions for uses that the Administrator finds to be critical or essential.<sup>56</sup> Section 6(d)(3) provides criteria for granting these exemptions. EPA is required to “analyze the need for the exemption” and make its analysis public. EPA can consider these exemptions as part of a risk management rule or in a separate rulemaking. When establishing exemptions for critical or essential uses of a regulated chemical, EPA must set time limits on these exemptions, and the exemptions can be extended, modified, or completely eliminated by rule. As part of the exemption process, EPA must consider conditions, such as reasonable recordkeeping, monitoring, and reporting requirements, necessary to protect health and the environment while achieving the purposes of the exemption.

Petitioners respectfully submit that EPA should anticipate and provide the ability to routinely consider the need for these exemptions when issuing risk management rules. It is already apparent from the risk evaluation scopes and problem formulations that the chemicals EPA is evaluating under section 6 may be used in technologies and industries where there are no technically and economically feasible safer alternatives available.

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<sup>54</sup> Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 84 Fed. Reg. at 36759.

<sup>55</sup> 15 U.S.C. § 2605(d)(3).

<sup>56</sup> 15 U.S.C. § 2605(g).

Accordingly, EPA's risk management procedural rule should codify the statutory exemption for critical or essential uses and establish a formal exemption process to ensure transparency, certainty, and reasonable agency action. Specifically, the framework rule should set forth formal procedures for (1) the agency to engage affected stakeholders, as part of a chemical risk management rule or in a separate rulemaking, in a transparent process prior to deciding whether to grant an exemption, (2) affected stakeholders to petition EPA for an exemption, and (3) issuing proposed exemption decisions.

TSCA instructs that EPA may grant an exemption as part of a risk management rule or as a separate rule for a specific condition of use of a chemical if the agency finds the following:

- (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
- (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
- (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment or public safety.<sup>57</sup>

In the risk management procedural rule, EPA should codify the standard dictionary definitions for certain key terms found in the operative provisions: "critical,"<sup>58</sup> "essential,"<sup>59</sup> "significantly,"<sup>60</sup> "reasonably,"<sup>61</sup> and "substantial."<sup>62</sup>

The framework rule should also discuss the factors the agency will consider when determining whether to invoke this authority. This explanation will inform affected stakeholders of the type of information that EPA needs when deciding whether to issue an exemption. EPA's procedural rule should also provide illustrative examples of when the agency would likely decide to grant or refuse to issue an exemption under this provision.

As noted above, Section 6(g) also requires the Administrator to "analyze the need for the exemption" and to "make public the analysis and a statement describing how the analysis was taken into account."<sup>63</sup> To increase transparency, the risk management procedural rule should require the Administrator to perform and publish this analysis any time an affected stakeholder formally requests EPA to grant an exemption for an upcoming or previously issued risk management regulation.

When granting an exemption, TSCA compels EPA to establish a reasonable time limit of that exemption on a case-by-case basis.<sup>64</sup> Through a rulemaking, EPA may extend, modify, or eliminate an exemption based on reasonably available information and after adequate public justification.<sup>65</sup>

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<sup>57</sup> *Id.* at §§ 2605(g)(1)(A)-(C).

<sup>58</sup> Indispensable or vital. <https://www.merriam-webster.com/dictionary/critical>.

<sup>59</sup> Of the utmost importance: basic, indispensable, or necessary. <https://www.merriam-webster.com/dictionary/essential>.

<sup>60</sup> In a significant manner, to a significant degree. <https://www.merriam-webster.com/dictionary/significantly>. *Cf.* <https://www.merriam-webster.com/dictionary/significant> (having or likely to have influence or effect, of a noticeably or measurably large amount).

<sup>61</sup> Moderate or fair, inexpensive. <https://www.merriam-webster.com/dictionary/reasonably>.

<sup>62</sup> Considerable in quantity, significantly great. <https://www.merriam-webster.com/dictionary/substantial>

<sup>63</sup> *Id.* at § 2605(g)(2).

<sup>64</sup> *Id.* at § 2605(g)(3).

<sup>65</sup> *Id.*

Moreover, the emphasis on reasonableness in this provision should be displayed in a risk management procedural rule by requiring EPA to explain its basis for the time period of the exemption when issuing a proposed exemption. This requirement would assist the public and affected stakeholders in understanding the agency's rationale, which would facilitate the submission of helpful information regarding the reasonableness of the proposed time limit in response to the proposed exemption decision.

TSCA allows EPA to include certain conditions, such as reasonable recordkeeping, monitoring, and reporting requirements, when granting an exemption.<sup>66</sup> Notably, the Administrator is required to determine that these conditions are necessary to protect health and the environment while achieving the purposes of the exemption.<sup>67</sup> The risk management procedural rule should incorporate this requirement for any proposed rule that grants an exemption with conditions. EPA will need to know whether its proposed conditions defeat the purpose of the exemption by effectively removing the chemical from that particular condition of use.

**V. To Conserve Limited Resources and Ensure Consistent Federal Regulations, a Risk Management Procedural Rule Should Establish a Process by Which the Agency Delegates to Other Federal Agencies and Other Laws It Administers – Wherever Possible and Appropriate.**

When enacting TSCA, Congress expressly stated that “[i]t is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner.”<sup>68</sup> The Administrator has an obligation to implement the pertinent environmental laws under the agency's purview in a manner that effectively and efficiently uses the agency's limited resources. Congress recognized this duty when enacting section 9 in the original version of TSCA and later including additional text in the Lautenberg Act.<sup>69</sup> Specifically, the Administrator is authorized to delegate risk management actions to other federal agencies and statutes, where appropriate.

If the Administrator finds that a chemical presents an unreasonable risk and determines that risk can be “prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator,” TSCA permits EPA to submit to a relevant federal agency the opportunity to regulate a specific condition of use for a particular chemical.<sup>70</sup> Section 9(a) already includes a detailed process by which the Administrator may delegate risk management actions to another federal agency. Petitioners request that a risk management framework rule adopt these same process requirements.

The procedural rule, however, should go further and codify the statute's affirmative directive that EPA ensure its regulations are not duplicative of another agency's jurisdiction or regulations. To wit, TSCA requires the Administrator to consult and coordinate with the heads of other federal departments or agencies “for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes.”<sup>71</sup> This authority is consistent with the directive in Executive Order 12866: “Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal

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<sup>66</sup> *Id.* at § 2605(g)(4).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at § 2601(c).

<sup>69</sup> *Id.* at § 2608.

<sup>70</sup> *Id.* at § 2608(a).

<sup>71</sup> *Id.* at § 2608(d).

agencies.”<sup>72</sup> Accordingly, a risk management procedural rule should require EPA to determine whether another federal agency could prevent or reduce the identified unreasonable risk and, if so, initiate the process outlined in section 9(a).

In addition to conserving EPA’s limited resources, this determination and delegation would help avoid potentially duplicative and contradictory regulations between EPA and other federal agencies. For example, if choosing to delegate risk management actions to OSHA for unreasonable risks to workers, EPA could support a singular, consistent approach to workplace safety. Similarly, EPA could delegate consumer product labeling requirements to the CPSC – given the CPSC’s experience and expertise in this area and to ensure consistency with the Federal Hazardous Substances Act and Consumer Product Safety Improvement Act.

TSCA section 9(b) also contains an affirmative directive to the Administrator to “coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator.”<sup>73</sup> The statute further requires that “[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk.”<sup>74</sup> This mandate to defer to other laws would not apply if the Administrator determines that it is in the public interest to protect against the unreasonable risk through regulations implemented under TSCA.<sup>75</sup>

To help EPA conserve and efficiently use its limited resources, Petitioners request that the risk management procedural rule require the Administrator to make an affirmative determination in each risk management rule whether actions taken under other federal laws administered by the Administrator could eliminate or reduce to a sufficient extent the identified risk. This requirement would be consistent with EPA’s approach to refining the scope of its risk evaluations and carving out pathways that are adequately assessed and managed under other environmental statutes. It would be logical to require EPA to continue this approach of deferring and delegating to other EPA programs by incorporating such procedures as necessary for this purpose into the agency’s risk management decisions.

In the May 2018 problem formulation documents for the initial ten risk evaluations, EPA recognized that “certain programs under other federal environmental laws adequately assess and effectively manage the risks” for certain conditions of use.<sup>76</sup> This delegation allows EPA to use “resources efficiently under the TSCA program” and to “avoid duplicating efforts taken pursuant to other Agency programs.”<sup>77</sup> As the agency recognized, “[t]he provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.”<sup>78</sup> For example, EPA should rely on the Clean Air Act and the Clean Water Act – rather than TSCA – to sufficiently address risks to air and water, respectively.

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<sup>72</sup> Executive Order 12866 (Sept. 30, 1993), at <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>.

<sup>73</sup> 15 U.S.C. § 2608(b)(1).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> See, e.g., Problem Formulation of the Risk Evaluation for 1-Bromopropane, p. 13, at [https://www.epa.gov/sites/production/files/2018-06/documents/1bp\\_problem\\_formulation\\_05-31-18.pdf](https://www.epa.gov/sites/production/files/2018-06/documents/1bp_problem_formulation_05-31-18.pdf).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

By requiring an affirmative determination by rule on whether EPA can delegate to other federal agencies or federal statutory programs, the risk management framework rule will ensure that EPA satisfies its statutory mandate to implement TSCA in a reasonable and prudent manner, while ensuring consistency and efficiency throughout the federal government.

**VI. A Risk Management Framework Should Include a Process to Petition the Agency to Amend or Repeal a Section 6(a) Rule.**

Another important element of a risk management procedural rule is a process to guide change. Once EPA has issued a final risk management rule under section 6(a), there needs to be a process by which affected stakeholders and the general public can petition EPA to amend or repeal that rule if warranted by changed circumstances. Even though section 21 generally provides such authority to petition the agency, EPA needs to establish a process specifically tailored for existing risk management rules – as opposed to the historical use of section 21 petitions asking the agency to issue new section 6(a) rules.<sup>79</sup>

One can envision section 750 as the existing chemical counterpart to EPA's Significant New Use Rule (SNUR) modification provisions at 40 C.F.R. § 721.185. EPA's SNUR rules specify the criteria EPA employs for modifying or revoking significant new use notification requirements for a chemical substance. Such action may be taken most typically in the case of new information provided through testing the chemical. The rules allow any affected person to request modification or revocation of significant new use notification requirements for a chemical substance using the procedures described in § 721.160 or § 721.170, by submitting a request that is accompanied by information sufficient to support the request. Part 721 has both a procedural aspect to it as well as a library of substantive, carefully tailored control measures specific to each new chemical being regulated. It is a successful example of how a more detailed risk management rule effectively operates to carry out the basic instructions provided in the statute. Existing chemicals are equally deserving of their own risk management framework rule. A section 6 risk management procedural rule should identify the type of information and/or data that EPA will generally need to amend or repeal an existing section 6(a) risk management rule, the menu of available risk management measures, and the procedures to modify these rules where warranted. Given the relatively short timeframe for EPA to decide whether to grant or deny a section 21 petition, it is vital that affected stakeholders and the general public know what information and/or data must be submitted with the petition.

**Conclusion**

For the foregoing reasons, Petitioners respectfully request that the Administrator grant this section 21 petition for a risk management procedural rule. We advocated on behalf of our members for TSCA reform and applauded the passage of the Lautenberg Act in 2016. Almost four years later, we remain vested in ensuring its success. To that end, we think a procedural risk management framework rulemaking is consistent with the need for a strong federal chemical control regulatory program. Without it, the TSCA framework for existing chemicals is incomplete. We welcome the opportunity to meet with you and discuss the details of this petition, in addition to supporting the work that would be

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<sup>79</sup> 15 U.S.C. § 2620.

necessary to issue this requested rule. Thank you for your consideration of this petition and requested rule.

Sincerely,

The American Coatings Association  
The National Association of Home Builders  
The National Association of Manufacturers  
The Toy Association  
The U.S. Chamber of Commerce

CC: The Hon. Alexandra Dapolito Dunn  
Assistant Administrator  
Office of Chemical Safety and Pollution Prevention

Mr. David Fischer  
Deputy Assistant Administrator  
Office of Chemical Safety and Pollution Prevention

Ms. Yvette T. Collazo  
Director  
Office of Pollution Prevention and Toxics