Via Docket Submission

March 25, 2021

Michal Freedhoff
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460

Re: Proposed Amendments to Fees for the Administration of the Toxic Substances Control Act (TSCA) at 40 C.F.R. § 700.45; Docket Number EPA–HQ–OPPT–2020–0493.

Dear Acting Assistant Administrator Freedhoff:

The Ad Hoc Downstream Users Coalition (Coalition) would like to take this opportunity provided by the Environmental Protection Agency (EPA) to comment on the proposed amendments to the TSCA Fee Rule at 40 C.F.R. § 700.45.[1]

Our Coalition advocated for the 2016 Lautenberg Amendments to TSCA, and we support the implementation of a robust federal approach for risk evaluations and risk management of existing chemicals. We favor reviews of all known and reasonably foreseeable conditions of use of the chemicals evaluated under TSCA section 6 to foster federal preemption. These shared interests have brought us together as a group that includes, in alphabetical order, the Alliance for Automotive Innovation (Auto Innovators), the American Coatings Association (ACA), American Forest & Paper Association (AF&PA), the Motor & Equipment Manufacturers Association (MEMA), the Plastics Industry Association (PLASTICS), the Toy Association, and the U.S. Tire Manufacturers Association (USTMA). Each association is a not-for-profit organization serving as a collective voice for their respective members.

The Coalition's trade association members represent diverse industries and over one thousand downstream companies.[2] Our members also represent product and component

[1] Fees for the Administration of the Toxic Substances Control Act; Proposed Rule, Environmental Protection Agency, 86 Fed. Reg. 1890 (Jan. 11, 2021). Original rule issued 83 Fed. Reg. at 52694 (October 17, 2018); https://www.govinfo.gov/content/pkg/FR-2018-10-17/pdf/2018-22252.pdf.

[2] Formed in 2020, the Alliance for Automotive Innovation (Auto Innovators) is the singular, authoritative and respected voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, the Alliance for Automotive Innovation represents the manufacturers producing nearly 99 percent of cars and light trucks sold in the U.S. The organization, a combination of the Association of Global Automakers and the Alliance of Automobile Manufacturers, is directly involved in regulatory and policy matters impacting the light-duty vehicle market across the

country. Members include motor vehicle manufacturers, original equipment suppliers, technology and other automotive-related companies and trade associations. The Alliance for Automotive Innovation is headquartered in Washington, DC, with offices in Detroit, MI and Sacramento, CA. For more information, visit our website http://www.autosinnovate.org.

ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

The American Forest & Paper Association (AF&PA) serves to advance a sustainable U.S. pulp, paper, packaging, tissue 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 Planet 2020. The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly $300 billion in products annually and employs approximately 950,000 men and women. The industry meets a payroll of approximately $55 billion annually and is among the top 10 manufacturing sector employers in 45 states.

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 900,000 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); MERA – The Association for Sustainable Manufacturing; and, Original Equipment Suppliers Association (OESA).

The Plastics Industry Association (PLASTICS) is the only organization that supports the entire plastics supply chain, representing over one million workers in the $432 billion U.S. industry. Since 1937, PLASTICS has been working to make its members and the industry more globally competitive while advancing recycling and sustainability.

The Toy Association is the North America-based trade association for the toy sector; our membership includes more than 950 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US$90 billion annually, and our members account for more than half this amount, and approximately 90% of North American toy sales by dollar volume. Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to

manufacturers and companies involved in upstream portions of the product supply chain. As such, the Coalition is uniquely situated to offer comments to EPA on the effectiveness and workability of TSCA's proposed fee requirements. In recognition of other trade associations outside this group that also represent companies in the supply chain and downstream users, these comments represent only the views of the aforementioned trade associations.

A. Executive Summary.

We would like to thank EPA for recognizing the immediate obstacles presented by the 2018 TSCA Fee Rule when it was applied for the first time last year for the next 20 risk evaluations.[3] The EPA's March 2020 "No Action Assurance" letter provided vital reporting relief for importers of articles containing high priority chemicals, and those that manufacture or import high priority chemicals as impurities or byproducts.[4] In these and earlier comments on the TSCA Fees Rule,[5] we are asking EPA to make these and other exemptions permanent. The proposed exemptions improve EPA's administration of this rule because they:

- **Ensure a more workable fee structure.** As EPA has acknowledged, "[t]he decision to provide no exemptions for these entities in the TSCA Fees Rule has resulted in an overly broad universe of entities subject to self-identification requirements for these EPA-

safeguard the health and safety of their citizens with protective standards for children. The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

USTMA is the national trade association for tire manufacturers that produce tires in the U.S. Our 13 member companies operate 58 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 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.

[3] TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016, provides EPA with authority to establish fees to defray a portion of the costs associated with administering TSCA sections 4, 5, and 6, as well as managing information claimed as confidential business information (CBI) for chemical substances under TSCA section 14. EPA is required to collect fees to defray approximately 25% of the costs to carry out these activities. Section 26(b)(4)(A) states that EPA must "prescribe lower fees for small business concerns . . ." TSCA section 26(b)(4)(F) also requires EPA to review and -- if necessary -- adjust the fees every three years, after consultation with parties potentially subject to fees, to ensure that funds are sufficient to defray part of the cost of administering TSCA.

[4] EPA No Action Assurance Regarding Self-Identification Requirement for Certain "Manufacturers" Subject to the TSCA Fees Rule (March 24, 2020) (No Action Assurance).

[5] EPA Docket No. EPA-HQ-OPPT-2016-0401-0068 (May 24, 2018); EPA Docket No. EPA-HQ-OPPT-2019-0677-0001-0090 (June 8, 2020).

initiated risk evaluations."[6] The proposed exemptions make the fee program workable by allowing EPA to collect TSCA section 6 fees from a smaller universe of companies;

- **Recognize that the administrative burden to collect fees from all companies is greater than the value of the fee allocation that would be derived**. We agree with EPA's determination that chemical manufacturers should continue to bear primary responsibility for these fees, even as they pass some of these costs to their customers, including importers, processors and chemical users, as allowed by law.[7] This result is consistent with chemical monitoring rules here and abroad that do not require companies to routinely monitor all chemicals in imported articles or substances imported as impurities and byproducts; and

- **Do not compromise EPA's ability to cover the cost of risk evaluations or to fully evaluate these conditions of use.** The proposed exemptions do not change the amount of the fee EPA collects or its ability to evaluate all conditions of use in a risk evaluation.

In addition to our strong support for the exemptions EPA is proposing, we have additional comments for improving this rule as follows:

- **The proposed rule does not fully eliminate the need for companies that could be subject to section 6 fees to test imported mixtures.** We support EPA's proposal to exempt chemicals manufactured or imported under 2,500 pounds annually from section 6 fees, but we do not think these companies should lose exempt status once it is granted. This proposed exemption does not address the need to test imported mixtures whose compositions are not fully known by the importer. A concentration-based exemption for imports of mixtures still is needed to avoid disproportionate impacts on this group of companies. In prior comments, our Coalition has supported a concentration exemption of 0.1%. While 0.1% is an internationally adopted threshold for regulation, EPA could also choose a different threshold depending on the chemical and the use;

- **The process for claiming these proposed exemptions must be simplified, and EPA should allow new market entrants and re-entrants.** We believe EPA's proposed mechanism to remove companies from the preliminary list of manufacturers if they are eligible for one of the proposed exemptions is overly cumbersome. Many such companies are listed in error, through no fault of their own. EPA should require nothing more than a brief notice that does not involve having to register or use the Central Data Exchange (CDX). A submission in the public docket could suffice. In addition, EPA should not require any company that is <u>not</u> on the preliminary list to "*self-identify*" to claim an exemption allowed by the rule. No notice to EPA is required to claim similar exemptions

[6] Request for No Action Assurance Regarding Self-Identification Requirements for Certain "Manufacturers" Subject to the TSCA Fees Rule (March 18, 2020) (EPA No Action Assurance Request), page 3.

[7] 86 Fed. Reg. at 1901.

elsewhere under TSCA. Moreover, while EPA is conducting a risk evaluation, a process is needed to allow a company to start non-exempt production of the chemical under review and pay its share of the section 6 fee;

- **The proposed fee for chemicals manufactured solely for export fails to consider potential impacts on complex supply chains.** Our Coalition supports the request by the Plastics Industry Association (PLASTICS) to add an exemption from TSCA section 6 fees for processors that source a high priority chemical domestically, export it solely for incorporation into a mixture, and then reimport the high priority chemical as part of a mixture for final processing. Similarly, imports for export only should be exempt from TSCA section 6 fees. EPA should exempt these other activities in fairness to processors who purchase high priority substances. Paying twice as a downstream customer and as a re-importer is a significant concern for many companies that export and reimport chemicals. The proposed exemptions for this rule operate so that processors like these are not directly responsible for TSCA fees associated with risk evaluations;

- **We suggest that any changes EPA makes to section 6 fees be applied to section 4**. EPA has issued test orders to fill data gaps for the 20 high priority chemicals. In limited instances, those test orders have included chemical processors. We believe that processors should not have to pay the same amount as a major producer(s) or pay again when these costs are passed through the supply chain. The same exemptions and market-share payment approach are needed for section 4 test rules and orders; and

- **EPA should modify subsection (d) of the fee rule.** Section 26(b)(4)(F) of TSCA gives EPA discretion to adjust fees up or down and take inflation into account "as necessary". However, the 2018 rule requires an upward inflation adjustment every three years. TSCA fees are already significant. We believe increases should not be automatic and that EPA should consult with stakeholders prior to increasing TSCA fees.

In the remainder of these public comments, we offer further support and explanation for these and other recommendations.

B. The Proposed Section 6 Fee Exemptions Ensure a Workable Fee Structure.

We support EPA's proposed exemptions from TSCA section 6 fees for companies that import articles containing a chemical substance, manufacture a chemical substance as a byproduct, impurity, as a non-isolated intermediate as defined in § 704.3, in quantities under 2,500 pounds, and for a chemical substance used solely for research and development (R&D). Our members rely on these exemptions in other parts of TSCA. For example, articles are exempt from section 8(a) Chemical Data Reporting (CDR) and from section 13 import certification,[8] and chemicals in imported articles are exempt from PMN reporting under section 5(a) of TSCA.[9]

[8] 40 C.F.R. § 711.10(b) and 19 C.F.R. §§ 12.120(a) and 12.121(b).

[9] Substances imported as part of an article are exempt from PMN reporting per 40 C.F.R. § 720.22(b)(1).

Articles containing a high-priority substance may be imported into the U.S., exported and re-imported again – perhaps multiple times – and by different entities. A single article like an automobile or a piece of complex manufacturing equipment can have hundreds, or thousands, of individual components shipped from multiple suppliers across the globe, in various stages of assembly. As a result, companies that import plastic parts, automotive parts and equipment, tires, sheets of plywood and finished wood products, toys, and a wide variety of coated products all rely on the article exemption of TSCA for the movement of these goods. Articles also are exempt from the Occupational Safety and Health Administration (OSHA) hazard communication standard.[10] We thank EPA for improving the rule so it will not disrupt the complex, existing supply chains associated with imported articles.

Likewise, impurities, byproducts, and non-isolated intermediates are exempt from PMN reporting under section 5(a)[11] and quantities of regulated chemicals under 2,500 pounds are exempt from reporting under CDR.[12] The proposed TSCA section 6 fee exemption categories carry across other regulatory programs administered by EPA, so as to be exempt from reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA), for example.[13] We thank EPA for recognizing the need for consistency across its regulatory programs.

Companies monitor ingredients based on existing legal requirements. TSCA and EPCRA are examples of laws that exempt businesses from monitoring and reporting ingredients in articles, impurities and byproducts, and in quantities of < 2,500 pounds in the case of the CDR. As a result, many downstream companies in supply chains do not currently have systems for tracking their quantities. These companies need the exemptions that EPA is proposing for collecting TSCA section 6 fees.

Without the proposed exemptions, the administration of fees under TSCA would be cost prohibitive, time-consuming and unduly burdensome for companies and the agency. EPA's proposed exemptions are a more workable approach for collecting fees, but there are still equity

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[10] 29 C.F.R. § 1910.1200(b)(6)(v).

[11] 40 C.F.R. § 720.30(h)(1), (3), and (8).

[12] The CDR reporting threshold is 2,500 pounds (1,134 kilograms) for any person who manufactured a chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 5(a)(2), 5(b)(4) or 6; an order issued under TSCA sections 5(e) or 5(f); or relief that has been granted under a civil action under TSCA sections 5 or 7. 40 C.F.R. §§ 711.8(b) and 711.15.

[13] Under EPCRA § 313, when an article is processed or otherwise used without a change in shape or design, and results in the release of 0.5 pounds or less of the chemical in a reporting year from all like articles, the article is exempt from threshold determinations and release and other waste management reporting. https://www.epa.gov/sites/production/files/documents/1999chem.pdf. Also, EPCRA recognizes low concentration limits consistent with the OSHA Hazard Communication Standard. 40 C.F.R. § 372.38(a). The level is 1.0 percent except if the listed toxic chemical is an OSHA-defined carcinogen. The level for OSHA-defined carcinogens is 0.1 percent. EPCRA Section 313 Questions and Answers, Revised 1998 Version, Question No. 315, https://www.epa.gov/sites/production/files/2015-05/documents/qas_1998.pdf. There is no exemption for non-isolated intermediates under EPCRA Section 313. EPCRA Section 313 Questions and Answers, Revised 1998 Version, Question No. 114.

and implementation issues with the current Fee Rule that EPA needs to address. While the 2,500-pound exemption is a reasonable exempt level, EPA should not propose to collect fees on these small amounts even in the situation where there is no major manufacturer or importer. We also urge EPA to consider providing a low concentration threshold exemption for mixtures to avoid the unintended consequences of requiring costly testing for negligible amounts of chemicals. There should be a simpler way for exempt companies that appear on EPA's preliminary list to the agency know they need to be removed from the list. Moreover, exempt companies that do not appear on the preliminary list should not have notify EPA at all in order to claim their exemption. In addition to the workability concerns these requirements raise, EPA has not accounted for this level of opportunity cost in this rulemaking.[14]

1. Support for < 2,500 Pound Exemption.

Our Coalition supports EPA's proposal to exempt high priority chemicals manufactured or imported under 2,500 pounds annually from TSCA section 6 fees.[15] Particularly if fees are not allocated on the basis of market share, a low volume threshold is necessary to avoid the most disproportionate allocation of fee costs to small volume producers. Even with market share allocation, the under 2,500-pound threshold will greatly simplify the administrative challenge of identifying potentially reportable manufacture or imports by limiting the scope of inquiry. Again, we think this proposed exemption is a good one that EPA should make part of the final rule.

We have two recommendations that we believe would make this exemption more practical. First, due to potentially disproportionate impacts, we do not think EPA should impose fees on these small quantity producers in the event that no major manufacturer or importer is found. EPA proposal to double the amount of the TSCA section 6 risk evaluation fee from $1,350,000 to $2,560,000, which would make this "contingency plan" even more inequitable for companies that manufacture or import such small quantities of a chemical. As proposed, fees could be levied for quantities as low as under 1 pound. Small businesses would be adversely impacted, even at the reduced percentage of fees for which they would be responsible. Because this situation will rarely if ever happen, it does not warrant being addressed as part of this rule.[16]

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[14] Economic Analysis of the Proposed Rule for Fees for the Administration of the Toxic Substances Control Act, EPA-HQ-OPPT-2020-0493; RIN2070-AK46; (January 2020), Section 4.1, p. 4-1; Section 4.1.4, p. 4-4.

[15] This exemption will be used by our members when the high priority chemical is knowingly imported under this amount. For example, if importers receive a safety data sheet (SDS) that reports the identity and percent composition of a high priority chemical, they will be able to calculate whether imported quantities are at or under this amount. Although not universally practiced, a foreign supplier of an imported service chemical like a lubricating oil may discloses the presence of small amounts of a high priority chemical on the SDS. The SDS alerts the importer to the presence of the high priority chemical who then can document whether it is being imported under 2,500 pounds per year.

[16] We think that if EPA were to require these companies to pay a fee, it should be no more than a nominal amount, e.g., $1,000. In general, we urge EPA to reserve flexibility in the rule to work out

Second, our Coalition supports having a low concentration exemption for mixtures subject to the Fees rule. Low concentration exemptions have been universally adopted by international regulatory bodies, many of the states, as well as by private governance mechanisms, to provide business certainty under existing reporting and declaration requirements. Our basis for requesting this additional exemption is that to rely on the under 2,500-pound exemption, a company has to already know whether a high priority chemical is present in a mixture and the precise amount. In many cases, this information is simply not made available by the supply chain. So that companies do not need to test imported mixtures – or self-identify to avoid potential noncompliance – we urge EPA to implement a concentration exemption for imported mixtures.

In prior comments, our Coalition has supported a 0.1% concentration exemption based on OSHA Hazard Communication principles. Under the OSHA Hazard Communication Standard, if test data are not available for the mixture itself, and there is insufficient information to apply OSHA bridging principles, employers are instructed to estimate hazards based on the application of cut-off values/concentration limits for the ingredients.[17] Typically the cut-off values/concentration limits are 0.1% or 1%, depending on the seriousness of the hazard.[18] Chemicals (including but not limited to byproducts and impurities) below these levels are not traceable by the importer without testing or initiating formal requests through supply chains.

The European Union's (EU's) Registration, Evaluation, and Authorization of Chemicals (REACH) regulation has both a quantity threshold of one metric ton per year (for registering a chemical substance) and a < 0.1% concentration exemption for monitoring and reporting substances of very high concern (SVHCs) for articles. The 0.1% limit has proven effective in allowing the EU to focus on chemical manufacturing and use scenarios where the concentration of the chemical is significant enough to pose a potential for risk. The International Material Data System (IMDS) used by the automotive industry also has a 0.1% concentration tracking requirement.[19] A low concentration exemption for imported mixtures avoids having to change established practices or depart from globally recognized chemical management systems.

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equitable solutions in exceptional cases. It is difficult to prescribe solutions in a rule for every possible contingency, and inflexible rules can lead to inequitable outcomes.

[17] 29 C.F.R. § 1910.1200, Appendix A - Health Hazard Criteria (Mandatory), section A.0.4 Considerations for the Classification of Mixtures, subsections A.0.4.1(c) and A.0.4.2.

[18] 29 C.F.R. § 1910.1200, Appendix A, subsection A.0.4.3. By way of one example, these concentration levels are used in Table A.4.5, Cut-Off Values/Concentration Limits of Ingredients of a Mixture Classified as Either Respiratory Sensitizers or Skin Sensitizers That Would Trigger Classification of the Mixture.

[19] IMDS has been adopted as the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern are present in finished materials and components. The automotive industry has made significant investments in this data system in order to track compliance with global regulations impacting their products. The threshold for reporting for this

In issuing its March 2020 No Action Assurance and this Proposed Rule, EPA has recognized that if companies were required to identify all of the 20 high priority chemicals in the categories proposed for exemption, these companies would need to undertake significant and expensive data collection and/or product testing efforts that they are not currently required to perform to find out if these chemicals are present at low concentrations in products.[20] Without a concentration exemption, this remains a significant concern, especially for the paint and coatings industry, which has complex supply chains for many of the chemical mixtures they import.

2. Three Policy Reasons Why a More Workable Fee Administration Structure is Needed.

As explained above, the proposed exemptions as well as a low concentration exemption for imported mixtures are consistent with provisions in other parts of TSCA and other federal and international requirements. The Coalition would like to highlight three policy reasons for why finalizing these exemptions makes sense.

a. Without these exemptions, downstream companies and products not previously subject to TSCA reporting will have to put new testing and monitoring systems in place.

We thank EPA for acknowledging that many companies brought into TSCA's fee administration process by the original 2018 rule are not typically required to report under existing TSCA rules and regulations.[21] EPA has long recognized the need to carefully balance the burdens of TSCA reporting.[22] Without the proposed exemptions, the administrative support necessary to comply with self-identifying for TSCA fees will be far greater for these companies, like the members of MEMA, with typical product inventories upward of 80,000 SKUs. In addition, the exemptions provide business certainty to the toy industry, which has been facing questions regarding whether TSCA "*self-identification*" is required for components in imported articles that

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system is 0.1% by weight. The IMDS now has over 15 years of data compiled relying on a level of 0.1%. The presence of any chemical below this threshold is not required to be reported in IMDS.

20 EPA No Action Assurance Request, p. 2.

21 *Id.*

22 When TSCA was first implemented and EPA was compiling the TSCA Inventory, the agency recognized that "[a]s was discussed in the preamble to these proposed regulations (42 FR 39185) comments from Industry and Trade Associations argued that it would be extremely burdensome for importers to identify the chemical substances contained in the articles they import. According to estimates from the American Importers Association, the total direct cost would range from $187 million to about $437 million . . . [a]ccordingly, . . . to require an importer of the article to identify its constituent chemical substances would impose a proportionately greater burden." 42 Fed. Reg. 53804, 53805 (October 3, 1977); 42 Fed. Reg. 39182, 39185 (August 2, 1977). Similarly, when EPA finalized rules for PMN reporting, it stated: "[b]ecause it would be enormously difficult for an importer to determine the identity and Inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles." 48 Fed. Reg 21722, 21726 (May 13, 1983). As a result, these companies have little or no experience with filing reports under TSCA.

are not accessible to consumers. It is not clear why testing inaccessible components and an EPA filing are needed to claim an exemption.

b. The proposed exemptions decrease EPA's administrative burden while still allowing the agency to collect the total fee amount required by law.

EPA's authority to establish a payment schedule that can be reasonably administered is grounded in section 25(b)(1) of TSCA, which states --

> The Administrator may, by rule, require the payment from any person . . . who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 2605(b) of this title. . . [i]n setting a fee under this paragraph, the Administrator shall take into account . . . the cost to the Administrator of carrying out the activities described in this paragraph.

Based on the language above, EPA has the authority to choose who pays these fees and administer the Fee Rule in a more efficient matter.[23] All of the proposed exemptions represent reasonable choices because they focus fee payments on a smaller group of manufacturers, which makes the fee program easier to administer.

The proposed exemptions keep the initial payment of fee obligations under TSCA where it has always been – on the chemical manufacturers upstream in the supply chain. As EPA explains in the proposed rule, "[g]enerally limiting fee obligations to manufacturers is the simplest and most straightforward way to assess fees for conducting risk evaluations under TSCA section 6." Moreover, "EPA expects that manufacturers required to pay fees will have a better sense of the universe of processors and will pass some of the costs on to them."[24] We thank EPA for recognizing that downstream companies do not escape these fees – they pay for them.[25] The proposed exemptions simply help direct EPA's resources toward conducting risk evaluations and away from spending more time than is reasonably necessary to collect these fees.

c. EPA retains full authority to conduct a risk evaluation for the exempted categories.

Our Coalition supports a robust federal program of chemical regulation, together with a consistent set of rules across the country as TSCA risk management rules go into effect. Our members understand that securing TSCA preemption calls for a use to be reviewed in an EPA risk evaluation. We support the inclusion of articles, impurities, byproducts, non-isolated intermediates, R&D chemicals, and low concentrations of high priority chemicals in mixtures in

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[23] The term "any" that describes who may be required to pay TSCA's fees is understood to mean "one or some indiscriminately of whatever kind." https://www.merriam-webster.com/dictionary/any.

[24] 86 Fed. Reg. at 1901.

[25] In addition, duplicative payments are avoided. Without the proposed exemptions, downstream companies could have to pay EPA directly and pay a second time when these fees, like other business costs, are passed through the supply chain in a lawful manner, in whole or in part.

EPA risk evaluations for this reason.[26] EPA's selection of fee payers under TSCA section 26 bears no relation to and does not alter the conditions of use that must be evaluated under TSCA section 6(b). Allocation of those costs to certain parts of industry not others does not prejudice in any way EPA's ability to collect all fees necessary to support programming. We are satisfied that the proposed exemptions do not change 1) the need for EPA to explain decisions on whether to include these conditions of use in the risk evaluation; 2) how EPA will conduct these evaluations; or 3) the agency's obligation to establish a robust public record for its risk determinations. Section 19 of TSCA sets forth the applicable standard of judicial review. Courts will evaluate everything EPA has considered, and the public has submitted into the administrative record for both the underlying risk evaluation and the subsequent risk management rulemaking. The proposed exemptions do not change the level of funding EPA receives for this important work, and EPA's obligation to establish a robust record for its decisions remains intact.

C. No "*Self-Identification*" for Exempt Companies, Simplifying "*Certification*", and Support for an Opt-In Provision.

The proposed rule sets forth a process by which companies must claim a proposed exemption from TSCA section 6 fees. After careful review, we think this process can and must be simplified. Specifically, § 700.45(b) sets forth the following notice requirements for companies:

- Publication of "preliminary list". First, companies will have to monitor for whether they are on a preliminary list that EPA creates and publishes. This "*preliminary list of manufacturers and importers subject to section 6 fees*" is issued with the final designation of the chemical substance as a high priority for risk evaluation.[27]

- Companies on the preliminary list that want to claim a proposed exemption. Next, companies on the "*preliminary list*" must register on CDX and submit an electronic "*certification of meeting exemption*". This "*certification*" is not optional.[28] A provision to remove these companies from the preliminary list has our support, but EPA should require nothing more than a brief notice that does not involve having to register or use CDX.

- Companies not on the preliminary list. Companies that do *not* appear on the "*preliminary list*" face a confusing array of options that stem from EPA's desire to require "*self-identification*" notice to claim some exemptions, but not others.

    - As proposed, the rule allows a company not on the "*preliminary list"* to rely on three of the proposed exemptions -- imported articles containing the chemical substance,

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[26] The following sections of the law are specifically unaffected by the outcome of this rule: 15 U.S.C. §§ 2605(a)(3) and (a)(6)(A), §2605(c)(E).

[27] 40 C.F.R. § 700.45(b)(1) and (3)(i).

[28] 40 C.F.R. § 700.45(b)(5)(iv).

production as a byproduct, and production as an impurity – without self-identifying or certifying its entitlement to the exemption (self-identifying is not required at all, and as drafted, self-certification is optional).[29] These companies must keep records to demonstrate they comply. We support how these provisions operate so that these companies never have to notify EPA up front to rely on these exemptions. We think this courtesy should be extended to all the (a)(3)(i) through (vi) categories in the same way that these exemptions are administered under other parts of TSCA.

- *"Self-identification"* is required for companies that are not on the "preliminary list" to rely on the exemptions for manufacturing a high priority chemical as a non-isolated intermediate, in small quantities solely for R&D, or in quantities under 2,500 pounds annually. Per proposed § 700.45(b)(5)(iv), a company is removed from the final list of manufacturers only if it files the "*certification of meeting exemption*".[30] Companies not on the preliminary list should be treated the same regardless of exemption on which they rely – no notice to EPA should be required. In other parts of TSCA these exemptions are self-executing, and they should remain so here. We do not support requiring these (or any) companies to "self-identify" or "certify" as a condition for qualifying for an allowable exclusion from section 6 fee process.

- **Certifications for exemption are legally binding for five years.** The proposed provisions in § 700.45(b)(5) require that companies will have had to rely on the exemption they are claiming for five years prior to making a "*certification*" to EPA. In addition, companies have to "*certify*" there will be no change in this status for five years afterward. As explained below, we support shortening these terms to three years.

1. Comments on the Proposed "*Self-Identification*" Requirements.

Our Coalition strongly supports a process for removing companies that qualify for the proposed exemptions, or those listed in error, from EPA's "*preliminary list*". We urge EPA to make this a very simple process for these companies. Although EPA needs a record to document the reason for removing companies from this list, filing a "*certification of meeting exemption*" should not be required to meet this need when less burdensome alternatives effectively

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[29] Proposed § 700.45(b)(5) provision clearly excludes companies in these categories from having to "s*elf-identify"* in stating that: *"*All manufacturers *other than those listed in paragraph (a)(3)(i) through (iii)* of this section . . . must submit notice to EPA (emphasis added). Since these companies never self-identify, it makes little sense to refer to them in the certification step. For this reason, we think there may be an error in the cross-references in proposed § 700.45(b)(5)(iv). We think that proposed subsection (iv) is supposed to express a mandatory requirement to file a "certification for meeting exemption" for categories (a)(3)(iv) through (vi), rather than make this particular submission optional for all six proposed categories.

[30] Only "[i]f EPA receives such a certification statement from a manufacturer, the manufacturer will not be included in the final list of manufacturers. . . and will not be obligated to pay the fee under this section."

accomplish the same result. These companies should be able to file simple paper notices or submit a comment to the docket on regulations.gov.

Moreover, the different treatment EPA is proposing for the (a)(3)(i) through (vi) categories is not warranted. The introductory paragraph of proposed subsection (b)(5) should be modified to change the "(iii)" to "(vi)" to read: "All manufacturers *other than those listed in paragraph (a)(3)(i) through (vi) of this section* who have manufactured or imported the chemical substance in the previous five years must submit notice to EPA, irrespective of whether they are included in the preliminary list specified in paragraph (b)(3) of this section" (emphasis added).

Although our Coalition appreciates having assurance in the language of the rule that filing a "*certification of meeting exemption*" operates to remove a company from the "*final list of manufacturers*" obligated to pay the section 6 fee, we do not think EPA should require any of the companies that qualify for the (a)(i) through (vi) categories to submit this filing as a condition for using them. Many of companies we are talking about are unfamiliar with having to report for TSCA at all and these exemptions operate elsewhere under TSCA in a self-executing manner.

A further process improvement, in our view, is to remove the option to self-identify altogether for all companies that are not on EPA's "*preliminary list*" that qualify for the (a)(3)(i) through (vi) categories. These categories for exclusion are rationale for all the same reasons, and they should be handled in the same manner. Requiring companies to keep records that demonstrate that they qualify adequately serves to document their compliance and is in keeping with other parts of TSCA.

Our Coalition recognizes and appreciates the effort EPA makes to prepare "*preliminary list*", then engage with stakeholders to identify missing parties, correct errors, and provide opportunities for manufacturers to be removed.[31] However, we think many companies are appearing on the "*preliminary list*" in error due to EPA's use of the Toxic Release Inventory (TRI) database.[32] Unlike CDR, TRI is not just a manufacturer reporting obligation. We think these lists may be more reliable in the future if EPA relied only on the self-reported manufacturing information in TRI.

2. Comments on the Proposed "*Certification*" Requirement and Request for an "Opt-In" Provision.

As proposed, after submitting a "*certification of meeting exemption*" a company cannot re-enter the market for a non-exempt purpose for five years under any circumstances. The company also needs to have relied on the exemption it is claiming for five years leading up to their "*certification*". We respectfully ask EPA to consider a less severe approach.

We want to make sure that EPA has sufficiently considered *why* it may not be possible for companies that otherwise qualify as exempt to certify their actions for either of these five-year periods. There may be several reasons for this. First, the time that a company is given to file a

[31] 86 Fed. Reg. at 1900.

[32] The statute and regulations do not tell EPA how to identify manufacturers and importers of chemicals under evaluation, so EPA can choose not to rely on TRI data when compiling these lists.

"*certification of meeting exemption*" may be insufficient to make a reasoned business decision with effects five years into the future. Second, filing a "*certification of meeting exemption*" for past commercial activities also can be difficult – the ability to look back a full five years may not be possible if sufficient records are not available. These records may no longer be available when businesses are sold or transferred, which happens with some frequency. Third, Rule 902 of the Federal Rules of Evidence[33] stipulates that domestic, signed and certified public documents are self-authenticating in evidentiary proceedings. Certification carries significant weight, so the inability to be able to confidently see five years into the future or five years in the past may prevent many companies from relying on the proposed exemptions. Fourth, for publicly held companies, forward looking statements may have other impacts on their business. To address these concerns, we ask EPA to make the following adjustments to this rule:

- Shorten the term of the "*certification*". Again, we disagree that "certification" should be required at all for companies to rely on the (a)(3)(i) through (vi) categories. However, this provision be retained in some fashion, we urge EPA to shortening the "*certification*" term to three years back and three years forward, which is the same period as the risk evaluation. EPA should not hold exempt companies to longer terms.

- Give companies an "opt in" that requires them to pay their portion of the section 6 fee. EPA should reconsider and adopt the alternative regulatory approach the agency has initially rejected, to allow new or exempt manufacturers to notify EPA that they will begin to manufacture or import the chemical for a non-exempt commercial purpose.[34] If follow-on companies pay the same TSCA fee amount and incur the same or greater administrative costs as their competitors, those who have already remitted these fees are not adversely affected. This process should apply to new market entrants as well as exempt companies who require a change in status. The rule currently allows companies to start making a high priority chemical after the list of fee payers is finalized without having to pay for the risk evaluation. EPA should close this gap.[35]

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[33] 2012 US Code, Title 28 - Judiciary and Judicial Procedure, Appendix (rules 1 - 1103). FEDERAL RULES OF EVIDENCE (rules 101 - 1103), ARTICLE IX. AUTHENTICATION AND IDENTIFICATION (rules 901 - 903), Rule 902 - Evidence That Is Self-Authenticating.

[34] 86 Fed. Reg. at 1901.

[35] We recognize there are a variety of ways to accomplish this within the fee rule. However, one concept we considered for the record was publishing the final list of fee payers and issuing an expedited SNUR at the same time to make the manufacture of a high priority chemical a new use for companies not on the list. EPA could determine projected quantities and assess section 6 fees when a company submits a Significant New Use Notification (SNUN). The SNUR procedure already exists to provide companies with a level playing field, and it is not overly burdensome to administer. The SNUR could describe the new use as "manufacture that is not compliant with 40 C.F.R. § 700.45(a)(3) as of X date". Paragraph (g) referenced therein is the remittance procedure. EPA is already proposing to amend (g)(3)(iv)(A) to extend and change the date section 6 fees are due. This language could be further modified to prescribe a timeframe to collect fees from new market entrants. EPA could add language to (g)(3)(iv) that references the final list

Again, we think these changes would improve the program. Market entrants and re-entrants may be a rare occurrence, but we think that EPA still needs a mechanism for dealing with them.

D. Proposed Export Only Fee Considerations.

EPA is proposing that a manufacturer who exports a high priority chemical exclusively should pay a proportionate share of the fee for an EPA-initiated risk evaluation when the same chemical is manufactured for domestic use by others. Based on the broad TSCA definition of the term "manufacturer" and the nature of our complex supply chains, we are concerned that this requirement has undetermined impacts.

Our Coalition supports the request by the Plastics Industry Association (PLASTICS) to add an exemption from section 6 fees for processors that source a high priority chemical domestically, export it solely for incorporation into a mixture, and then reimport the high priority chemical as part of a mixture for final processing. Processors are not directly responsible for TSCA fees associated with risk evaluations. EPA should maintain this approach in all fairness to processors who purchase high priority substances domestically from a manufacturer that is already subject to these fees. Paying twice as a downstream customer and as a re-importer is a significant concern for many our members who ship chemicals back and forth from the U.S. to other countries.

In addition, some of our members may import chemicals for export only. The potential hazard and exposure potential for these activities is low, similar to the processing activities that EPA is proposing to exempt in this rule. We urge EPA to ensure that any fee requirement for manufacturers of export only chemicals is narrowly tailored so as to exclude imports for export only.

E. Comments on EPA's Proposals to Add, Assess or Increase Other TSCA Fees.

Now that so many more aspects of TSCA compliance have added fee requirements, our members ask that EPA allow companies to consolidate fee payments where this makes sense. For example, EPA should allow a company to try to reduce the number of fee events or combine them if fees for separate activities are due at the same time.

To provide stakeholders with greater certainty on when TSCA fees may come due, EPA should issue a public schedule for the prioritization of existing chemicals. EPA does not publicly disclose what chemicals will undergo prioritization and decisions are announced with no advance notice. As a result, companies cannot make plans to support or to exit the market for a high priority chemical until after these announcements. The lack of notice is of increasing concern as the cost of the risk evaluations TSCA continues to mount. Our members who participate in the section 6 fee assessment process would like the opportunity to plan and

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of manufacturers subject to the fee and provide that when a manufacturer is added to the list, the applicable fee would need to be paid at a prescribed time.

budget for these regulatory impacts that issuing a schedule would provide. Where possible, companies also want to receive information early in the process on the test data EPA anticipates needing, so these needs can be incorporated into business planning cycles. Our Coalition continues to find strong merit in having EPA publish a schedule of chemicals with this information. Advance notice to industry of prioritization candidates before the cutoff date allows companies to voluntarily exit certain manufacturing activities in a considered and orderly way. Without notice, this is not possible and "certifying out" is only possible for companies that had already ceased manufacturing or importing activities. Advance notice may be given by moving the cut of date to later in the process, such as when candidates are formally proposed for high priority risk evaluation.

In addition to the opportunity to establish meaningful exemptions that we think strengthen the fee program, we are pleased that EPA has reviewed the cost of risk evaluations based on the experience it has gained in conducting them. We think the proposed fee increase will allow for more comprehensive chemical risk evaluations, which we support. Also, on behalf of our members that will participate directly in the section 6 fee assessment process, we thank EPA for proposing additional time to pay these fees. We support the extended times proposed, up to 180 days in certain cases. The proposed timeframes are consistent with the deliberate pace of the multi-year risk evaluation process.

In the final rule, we respectfully ask EPA to clarify that the increase in section 6 fees will not commence before June 22, 2022. Section 26 of TSCA allows EPA to review and adjust fees on a three-year cycle.[36] As a result, adjustments in fee amounts will not take effect until next year. Also, given the anticipated and sizable increase in the section 6 fee, our Coalition asks EPA to reconsider subsection (d) of the fee rule, which automatically adjusts fees every three years according to the inflation rate. It would be more consistent with the language of the statute for EPA to have the flexibility to decide whether any adjustment is warranted and engage with stakeholders in reaching these decisions.

With respect to assessing section 6 fees, our Coalition supports EPA's market-share proposal, which we have urged the agency to consider in our prior comments. EPA's original decision to use equal cost sharing for section 6 fees turned out to be a disincentive for companies to voluntarily enter into their own market share arrangements. The lack of exemptions for administering section 6 fees resulted in an unanticipated expansion of the number of affected companies. We are concerned that the same issues will be encountered for section 4 testing. EPA is using its section 4 authority to obtain data to inform the risk evaluations, so it makes sense to use the same method to allocate costs and recognize the same

[36] Section 26(b)(4)(F) of TSCA states that EPA may: "beginning with the fiscal year that is 3 years after June 22, 2016, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient . . ." We interpret this language to mean that fees can remain at the same level until such time EPA decides they need adjustment. For example, EPA did not adjust TSCA fees in the first three-year cycle in 2019.

exemptions. While EPA has maintained that section 4 fees are too low to justify this approach, it is the precedent that EPA's policy establishes that matters. Companies may seek to extend an equal share payment requirement to the cost of the testing itself. Finally, we ask EPA to reconsider the proposed fee for companies each time they resubmit data EPA is requiring, at least until EPA completes its re-evaluation of the agency's review process for selecting and accepting studies for use in these risk evaluations.

F. Conclusion.

These comments are intended to help the fee collection process become more efficient, fair and routine for EPA and the regulated community. Our Coalition thanks EPA for proposing exemptions that will help achieve these goals. We think these exemptions, along with our proposed low concentration exemption, and simplification of the procedure for claiming them, will better mesh the implementation of TSCA's fees on industry with current business operations and how these exemptions operate in other parts of TSCA. Thank you for the opportunity to provide our collective perspective.