AmericanCoatings
ASSOCIATION℠

January 17, 2023

Marc Edmonds,
Existing Chemicals Risk Management Division,
Office of Pollution Prevention and Toxics, Environmental Protection Agency,
1200 Pennsylvania Ave. NW,
Washington, DC 20460-0001

Submitted via eRulemaking Portal: www.regulations.gov

Re: Fees for the Administration of the Toxic Substances Control Act
Dockets No.EPA-HQ-OPPT-2020-0493

Dear Mr. Edmonds,

The American Coatings Association ("ACA")[1] appreciates the opportunity to comment on the proposed changes to fees to administer the *Toxic Substances Control Act* as required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"). We are committed to working with EPA to help ensure accurate risk evaluations under TSCA.

The Association's membership represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paints, coatings, sealants and adhesives and their raw materials, whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluations for several of the high priority chemicals and directly affected by EPA's new chemical review process. Our membership is concerned about EPA's proposed fee amounts, justifications for those amounts and process for identifying responsible parties and collecting fees. ACA is eager to assist EPA in developing

[1] 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.

an effective system for chemical risk evaluations with successful implementation of the *Lautenberg Act's* mandates.

ACA appreciates EPA's willingness to interact with stakeholders during the process of revising TSCA fees. ACA understands that implementation of the *Lautenberg Act* presents several challenges, and we commend EPA on its careful analysis and responding to stakeholder concerns in its proposed rule. We are optimistic that through continued involvement with the public and stakeholder community, EPA will successfully implement a stronger, federal chemicals management program for years to come.

EPA's proposal to amend TSCA fees demonstrate EPA's acute understanding of compliance challenges caused by its current fee rule. ACA supports several elements of the proposal as measures necessary to accommodate companies that manufacture or import small volumes of high priority chemicals. ACA members report import in amounts as small as 0.5 kg-2kg per year. Without EPA's proposed changes, small volume manufacturers are subject to disproportionately high risk evaluation fees, compounded by relatively high fees to join a consortium.

ACA is also a member of *Ad Hoc Downstream Users Coalition* (hereinafter "the Coalition").[2] With the Coalition, ACA has a developed a separate comment, detailing some of the points noted below. ACA notes its support of the Coalition's comments and incorporates them as a supplement to ACA's comment below.

ACA and its members respectfully submit the following:

I. Volume-based exemptions should be based on percent concentration in mixture aligned with SDS disclosures.

ACA appreciates EPA's willingness to propose an exemption from TSCA fees for manufacture and import of high priority chemicals below an amount of 2,500 pounds per year, for five years prior to compilation of the list of responsible manufacturers and five years after. An exemption for small amounts is necessary to relieve administrative burdens on EPA and industry. ACA suggests that an additional exemption is necessary, exempting chemicals in mixtures below OSHA's thresholds for disclosure on a Safety Data Sheet.

[2] The Coalition is comprised of trade associations that represent a broad cross-section of U.S. industry, representing well over a thousand companies that manufacture, process or use chemical substances subject to TSCA. Members of the Coalition commenting on this supplemental notice include the Alliance for Automotive Innovation ("Auto Innovators"), the American Coatings Association ("ACA"), American Forest & Paper Association ("AF&PA"), the Motor and Equipment Manufacturers Association ("MEMA"), the Plastics Industry Association ("PLASTICS"), the Toy Association, and the U.S. Tire Manufacturers Association ("USTMA").

The proposed exemption threshold of 2,500 pounds, although providing industry some relief, still presents industry with significant compliance challenges. With a threshold of 2,500 pounds, downstream formulators must identify amounts imported that are not disclosed on a Safety Data Sheet. This information is necessary for a formulator to evaluate and certify whether it is importing amounts that meet the proposed exemption threshold. Evaluation and certification may require additional testing, identification of additional information or certification from suppliers.

Downstream formulators often face significant barriers when trying to obtain information about small amounts from upstream actors. Because of complexities in the supply chain, suppliers often do not know this information or simply do not want to disclose information about trace amounts, even when known. EPA rationalized its proposal to exempt by-products, impurities and non-isolated intermediates as a way of avoiding this kind of burden on industry, for a relatively minor fee amount. EPA should similarly exempt amounts below OSHA's SDS disclosure thresholds to avoid the undue burden on industry of identifying chemicals imported in amounts at or below 2,500 pounds.

ACA requests that that this exemption is in addition to the 2,500 pound threshold, instead of replacing the threshold. Although ACA suggests an additional exemption with the current proposed volume-based exemption, ACA recognizes the importance of having some form of a volume-based exemption. Currently, manufacturers and importers of small amounts are subject to disproportionate fee amounts, at the same scale as large-scale companies. Often the fees for joining consortia are considerably high also.

ACA further recognizes that a volume-based exemption would not inequitably penalize chemical manufacturers who are subject to TSCA fees, effectively paying for evaluation of all conditions of use, including uses associated with small amounts exempted from fee payment. As downstream users, ACA members will pay for TSCA risk evaluations through costs passed down by raw materials manufacturers. Proposed exemptions would prevent double payment for small amounts under the current fee structure where a downstream formulator must pay a risk evaluation fee when importing to supplement its domestic supply and pay increased costs from domestic suppliers passing down a risk evaluation fee.

II. ACA requests an exemption for re-imported substances to avoid double payment of fees

ACA members commonly ship formulated mixtures to Canada, Mexico or other countries for further processing followed by re-import into the United States. Under the current

proposal, ACA members risk double payment of the risk evaluation fee for high priority chemicals. Members would pay a risk evaluation fee first when importing a raw material or as pass-through costs when purchasing domestically. A company would then pay a second time when re-importing after foreign processing. To promote consistency in how the fee rule is applied upon re-import, ACA requests EPA explicitly exempting re-import as triggering payment of risk evaluation fees.

Absent such an exemption, a volume-based exemption would provide relief for small amounts re-imported in this manner, noting a volume-based exemption alone leaves a significant regulatory gap resulting in double fee payment for amounts above the low volume threshold. Here also, its important to note that under the currently proposed volume-based exemption for less than 2,500 pounds, companies re-importing may need to perform additional testing where a foreign processor uses trace-level additives not disclosed on an SDS. An additional exemption based on OSHA SDS disclosure thresholds would provide consistency.

III. ACA supports EPA's proposed exemptions for by-products, impurities and non-isolated intermediates

ACA supports the proposed exemptions for by-products, impurities and non-isolated intermediates, noting that the administrative costs associated with fee collection does not justify the small amounts of fees that would be collected. Notably, these fee exemptions would not affect scope or quality of risk evaluations, as EPA would collect complete fee amounts from manufacturers of larger volumes and exempted amounts for fee payment can be in scope for risk evaluation. ACA also commends EPA's decision to allow these exemptions be self-executing, without requiring qualifying companies to self-identify. Exemptions in TSCA are typically self-executing, whereas self-identification would require companies to track and test for small amounts to qualify for exemptions.

EPA has previously recognized it has commonly exempted by-products, impurities and non-isolated intermediates from other requirements that apply to "manufacture" of chemicals, including exemptions for impurities and by-products from PMN requirements (40 CFR 720.30), by-products from CDR reporting and by-products and non-isolated intermediates from SNUR requirements. Finalizing these exemptions would maintain compliance uniformity while avoiding supply chain disruptions potentially brought by compliance with a complex regulatory program and the need to identify non-exempted amounts. Without the exemption, manufacturers would have to undertake additional measures to track and identify chemicals, potentially having to test for trace amounts with minimal addition to TSCA fee payment.

IV. ACA recommends a self-executing exemption for small quantities.

As noted above, self-executing exemptions alleviate unnecessary tracking and testing across complex supply chains to document qualification for an exemption. ACA requests EPA extend self-execution to the exemption for small quantities by redacting its proposed submission of import volumes to qualify for the small quantity exemption. EPA reasons that it must track all small quantity manufacturers for possible fee payment in the event that no larger scale manufacturers exist. As a regulatory alternative, ACA suggests EPA issue a federal register notice requiring manufacturers of small quantities to self-identify, in the rare occurrence that no larger scale manufacturers of a chemical exist.

EPA has not adequately justified or considered the reporting costs on manufacturers of small quantities, in relation to the rare event that no larger scale manufacturers exist. EPA's economic analysis focuses on the following factors for industry costs: 1) rule familiarization; 2) reduced fee eligibility determination; 3) CDX registration; 4) notification of participation in a consortium; and 5) fee payment and recordkeeping. EPA has not adequately accounted for any testing or tracking needed to identify qualifying small amounts, online self-identification and certification of exempt status.

V. EPA's listing procedures for manufacturers and importers do not provide procedures to initiate manufacture or import after the list is finalized.

EPA's fee proposal leaves manufacturers without an option to initiate or resume manufacture of a high priority chemical for a five-year period after EPA finalizes its list of manufacturers. ACA members would appreciate flexibility to initiate manufacture or import during that time. Flexibility would allow companies to adjust to changes in the market or products, as required. Moreover, selection of a chemical as a "high priority" chemical is not an indicator of risk. Initiating manufacture or import in the five-year period after initiating a risk evaluation cannot be assumed as a cause of undue risk.

ACA suggests that EPA allow a company to initiate manufacture or import after issuance of a final list of manufacturers with payment of a fee. ACA suggests a fee in the same amount as required in EPA's volume-based fee schedule for the high priority chemical at issue, based on the company's estimated annual manufacture and/or import volumes. ACA further suggests that companies certify actual amounts manufactured and imported while being required to pay the difference where the actual amount requires a higher fee then the initially estimated amount.

VI. ACA requests changes to proposed regulatory language to clarify fee payment obligations of processors.

In the Supplemental Notice of Proposed Rulemaking, EPA explains that processors could be subject fees for section 4 test orders or enforceable consent agreements (ECAs) "in the event that there are no manufacturers receiving a test order or ECA . . . "[3] This limitation is not reflected in the proposed regulatory language. As proposed, processors could be subject to Section 4 test order or ECA fees anytime a processor is required to submit information, including instances where a manufacturer is also required to submit data elements in a test order or ECA.[4]

ACA requests that EPA explicitly provide processors will not be subject to Section 4 fees, unless a manufacturer is not paying the fee. In the alternative, ACA requests Section 4 fees are proportionate to the requested data elements to avoid inequitably high fee payments by processors possessing relatively less and possibly more specialized information than manufacturers. Majority of data about downstream uses will be held by the upstream chemical manufacturer, who in most cases, instructs downstream users about chemical uses and safety. ACA recognizes that processors play an important role in filling in any data gaps. ACA also recognizes that processors will have specialized information, whereas the manufacturer will be submitting the bulk of requested information. The proposed rule must be modified to avoid inequities in processor fee payment.

VII. EPA proposed method of volume-based fee allocation could result in extreme inequity in fee payment.

ACA generally supports volume-based fee allocations and commends EPA's efforts for a related proposal while preserving confidentiality. ACA notes that EPA's proposed method could result in extreme inequities in fee amounts for manufacturers on the cusp of the 80% / 20% divide for higher level of fee payment. Manufacturers near the divide could have minimal differences in manufacture volumes, yet one company could be allocated in the

[3] 87 Fed. Reg. at 68660.

[4] As proposed Section 700.45(a)(2) requires:
"(2) Manufacturers and processors of chemical substances and mixtures required to submit information for these chemical substances and mixtures under a TSCA section 4(a) test order or enforceable consent agreement, or manufacturers of chemical substances and mixtures required to submit information for these chemical substance and mixtures under a TSCA section 4(a) test rule, shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section. and mixtures required to submit information for these chemical substance and mixtures under a TSCA section 4(a) test rule, shall remit for each such test rule, order, or enforceable consent agreement the applicable fee identified in paragraph (c) of this section in accordance with the procedures in paragraphs (f) and (g) of this section."

top 20% by volume while another could be in the lower 80%, with a large disparity in fee amounts. ACA prefers EPA's prior proposal allocating fees based directly on manufacture volumes, provided this approach could be implemented with CBI protections.

VIII. Program Cost Estimates Should be Further Refined

ACA is concerned that EPA's cost estimates have not adequately accounted for transitional program inefficiencies or the impact of extreme increases in fees on the chemical industry. ACA recommends further refinement of EPA's estimates. EPA posits that based on experience, it currently estimates program costs of $181.9 million per year – more than double its 2021 estimate of $87.5 million. Charging the statutorily defined 25% to industry, EPA estimates that about $45 million can be recovered from industry in fees. This results in significant increases in fees directly charged to manufacturers, including a:

- PMN fee of $45,000 increased from $19,020.
- LVE fee of $13,200 increased from $5,590.
- EPA-initiated risk evaluation fee of $5,081,000 collectively, increased from $2,560,000.
- Test order fee $25,000, increased from $11,650.

EPA's estimates are based on general descriptions of payroll versus nonpayroll costs, but EPA has not accounted for revisions to risk evaluations and related policy shifts during this initial implementation period. Further the extreme increase in PMN fees, coupled with continued delays and inconsistency in PMN review procedure will certainly result in fewer PMNs being filed than estimated, with even fewer new chemicals being brought to market. EPA has not accounted for these effects in its cost estimates.

Problematic issues with PMN review and risk evaluation procedures are largely systemic. It is unlikely that increased program budgets will resolve these systemic issues. ACA requests that EPA refine cost estimates to detail cost allocations to clearly identify program improvements. Transparency here is paramount to justifying extreme increase in costs. ACA members are concerned that they will pay high fee amounts while EPA continues to perpetuate its current systemic flaws in chemical evaluation.

For example, EPA's risk evaluation of PV-29 relies on extrapolating exposure data for actual shift times to assume exposure over a full 8-hour time frame assuming exposure at the limit of quantitation during that time. EPA also identifies a hazard for PV-29 not identified by OSHA or under international GHS criteria, due to the presence of a residual anhydride

compound.[5] This varies significantly from current understanding of PV-29 particles. PV-29 particles are currently considered nuisance dust. EPA also assumes exposure at the nanoscale. This is a physical impossibility at the levels assumed, due agglomeration that naturally occurs.

EPA's assumptions are not typical under standard methods of industrial hygiene exposure analysis. As a result, EPA's risk evaluation provides an estimation of risk that varies broadly from the existing understanding of PV-29 as a nuisance dust in the workplace. If EPA has information that legitimately provides an enhanced understanding of risk for any high priority chemical, the risk evaluation must be rigorously conducted to demonstrate risk and not based on unjustified assumptions. Any variations from typical data interpretation, hazard and exposure conditions must be carefully analyzed for accuracy. Additional program operating costs will not improve risk evaluations, if EPA does not recognize flaws in its risk evaluation methods and implements a transparent strategy to improve them.

Similar inconsistencies exist in review of new chemicals. ACA supports reforms to PMN regulations suggested in a Section 21 petition filed by a coalition of chemical manufacturers on November 11, 2022. ACA notes that the following reforms in particular are useful to ACA members:

- Limiting extensions to PMN review periods: EPA should implement a standard definition of "good cause" for extension of PMN review and reimburse the PMN submitter 50% of the notice fee if an extension does not fall within the "good cause" requirements. EPA should be able to reset the review period when a submitter substantially amends a PMN. EPA should allow the submitter to extend an exemption period for more than 90 days upon only for "good cause."
- Timely notification: Require EPA to notify the PMN submitter of errors in the notice or that the PMN is incomplete within 15 days of receipt.
- Major Amendment Transparency: Develop a consistently applied definition of "major amendments" and provide the PMN submitter with options regarding PMN review due to a "major amendment."

IX. Conclusion

ACA appreciates this opportunity to provide comment on EPA Supplemental Notice of Proposed Rulemaking. As described above, ACA suggests:

[5] At p. 65 of EPA's Final Risk Evaluation for PV-29 (Jan. 2021), EPA explains, "The REACH SDS for C.I. Pigment Violet 29 indicates the presence of an anhydride residual compound which would have concerns for dermal and respiratory sensitization (3,4,9,10-perylenetetracarboxylic dianhydride)."

- Volume-based exemptions should be based on percent concentration in mixture aligned with SDS disclosures, in addition to the 2,500 pounds per year threshold.
- Implement an additional exemption for re-imported chemicals.
- Finalize EPA's proposed exemptions for by-products, impurities and non-isolated intermediates
- Implement a general, *self-executing* exemption for small quantities, while EPA use a federal register notice requiring small-scale manufacturers self-identify when necessary to inform fee requirements.
- Develop a procedure for market entry after finalizing the list of responsible parties for fee payment by allowing payment of a proportionate fee.
- Refine regulatory language related to Section 4 test order fee payment by processors so processors are required to pay only when manufacturers are not identified or so the processor fee is proportionate to data submission.
- Refine EPA's approach to volume-based fee allocation.
- Refine program cost estimates to consider initial implementation costs and impact of higher fees on the chemical industry, while clearly identifying program improvements to justify escalated fees.
- Implement significant changes to PMN review and risk evaluation procedures to enhance accuracy, transparency and timeliness.

ACA appreciates the opportunity to provide comment about these issues. Please feel free to contact me if I can provide any additional information.

Sincerely,

Riaz Zaman
Sr. Counsel, Government Affairs
American Coatings Association
901 New York Ave.
Washington, DC 22101
Telephone: 202-719-3715
e-mail: rzaman@paint.org