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January 17, 2023

Michal Freedhoff, PhD
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, NW, (7410M)
Washington, DC 20004–0001

Attention: EPA–HQ–OPPT–2020–0493–0072; FRL–7911–04–OCSPP

Re: Fees for the Administration of the Toxic Substances Control Act (TSCA)

Dear Assistant Administrator Freedhoff:

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments on the Environmental Protection Agency's ("EPA" or "the Agency") supplemental notice of proposed rulemaking published in the *Federal Register* titled, "Fees for the Administration of the Toxic Substances Control Act (TSCA)" ("the proposed rule").[1]

AFPM is the leading trade association representing the makers of the fuels that keep us moving, the petrochemicals that are the essential building blocks for modern life, and the midstream companies that get our feedstocks and products where they need to go. We make the products that make life better, safer, and more sustainable — we make progress.

AFPM supports EPA's efforts to implement TSCA and generally supports the concept of fees to help offset the costs of implementation. AFPM supported several proposed changes in the original proposed rule; however, petrochemical manufacturers are concerned with the sudden move to dramatically increase risk evaluation and other fees right after proposing to double them in 2021.[2] AFPM is also acutely concerned that the new approaches to risk evaluation being implemented by EPA have caused the Agency's resource challenges and will impede innovation and lead to disruptions in many American manufacturing supply chains.[3]

AFPM strongly urges EPA to retain the current fee structure until the Agency has enough experience and information to fully inform any decision to change those fees. Furthermore, AFPM advises the Agency to return to its tiered, targeted, and risk-based approach to evaluating the safety of chemicals that seems to have been abandoned in favor of tracking every molecule and the "whole chemical approach."[4]

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[1] See 87 *Fed. Reg.* 68647, "Fees for the Administration of the Toxic Substances Control Act (TSCA)", Docket No. EPA–HQ–OPPT–2020–0493; FRL–7911–04–OCSPP, published November 16. 2022, at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0072.

[2] See 86 *Fed. Reg.* 1890, "Fees for the Administration of the Toxic Substances Control Act (TSCA)", Docket No. EPA–HQ–OPPT–2020–0493; FRL–10018–40, published January 11, 2021, at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0493-0001.

[3] EPA decided to reevaluate the first 10 high-priority chemicals and implement a new model to estimate fence line exposures, assume OSHA regulations are not followed and no personal protective equipment is worn, and use something the Agency made up, called a "whole chemical approach." See Page 2 of these comments for further discussion on the whole chemical approach.

[4] EPA has implemented a new approach to risk evaluation, using techniques mentioned in the previous footnote; however, there has been no opportunity for public notice and comment prior to implementation. The Agency has stated it will publish a proposed rule to establish these new methods and procedures, but still uses them as the basis for resource needs in its calculations for fees.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) does not require EPA to reinvent risk evaluations.

EPA alludes in Sec. III(A) of the supplemental proposal that the LCSA requires a different approach to risk evaluations.[5] EPA states that the previous cost estimates for TSCA fees were based on approaches used prior to 2016 when the LCSA was enacted. The Agency asserts the approaches it now uses are different and require more resources to compensate for the extra time spent during each evaluation. There are no provisions in the statute that direct, require, or even suggest EPA use a different approach to risk evaluations than it has been using for decades.

If Congress intended for EPA to use a different approach, it would have made it clear in Sections 5 and 6; instead, Congress just added provisions to Section 6 that direct the Agency to categorize substances as high- and low-priority and to conduct risk evaluations on the high priority substances. Similarly, Congress added provisions to Section 5 that require the Agency to make public an affirmative decision on the safety of new chemicals. Congress did not include any language whatsoever telling EPA *how* to conduct those risk evaluations.

EPA's move from a tiered and targeted risk evaluation to a whole chemical approach introduces unrealistic assumptions of potential exposures and are at the center of its challenges.

EPA paints a misleading picture about risk evaluations under Section 5, when it states that prior to the LCSA the Agency was only "making risk determinations on about 20 percent of the new chemical submittals it received."[6] EPA has conducted a risk evaluation on each and every new chemical substance for which a premanufacture notice ("PMN") has been received. Manufacturers are required to submit information on the entire lifecycle of a substance, including manufacture, use, and disposal, when submitting a PMN. The PMN itself hasn't changed much over the years, nor have the steps of the review process. The only real change is that EPA must now publicly affirm the safety of substances for which it does not find an unreasonable risk. Historically, EPA found that around 20 percent of new chemical substances resulted in a finding of unreasonable risk. That does not mean that EPA only conducted risk evaluations on 20 percent of new chemical substances.

The reason risk evaluations under Section 6 for the first ten substances took as long as they did was because even after they were all complete, EPA made the decision to reopen each one. EPA reopened these risk evaluations to incorporate fence line exposures, which are typically orders of magnitude below direct exposures. In addition, these evaluations were reopened to implement a new consideration called the "whole chemical approach," something largely made up by the Agency that allows it to declare a chemical has an unreasonable risk on the whole, even if individual uses pose no such risk. Congress did not authorize this type of approach when it enacted the LCSA.

EPA's current approach to risk evaluation under both Section 5 and Section 6 tries to consider every conceivable situation under which a substance is used and account for every molecule of a chemical in commerce rather than its traditional, tiered and targeted approach that uses sentinel exposures to allow the Agency to focus on exposures that could lead to the highest doses of a particular substance. The default values on its exposure models, such as large amounts of residue left in containers and transfer hoses, all residuals being washed down the drain, and zero treatment efficiency at water treatment facilities, make

[5] The Lautenberg Chemical Safety Act was signed into law on June 22, 2016, and amended and updated TSCA.
[6] See 87 *Fed. Reg.* 68650, "Fees for the Administration of the Toxic Substances Control Act (TSCA)."

its exposure models unrealistic. These grossly exaggerated exposure scenarios lead to constant findings of unreasonable risk for both new and existing substances.

To make matters worse, EPA now assumes that workers (including those in the most tightly regulated manufacturing facilities) do not wear any protective gear and just leave spilled material on their skin for the day. Unlike before, when the Agency would meet with industry experts to determine realistic use scenarios and practices, EPA now refuses to change its assumptions unless it receives an abundance of measured data, leading to delays and enormous costs. This holds true for both toxicity and exposure information.

The TSCA statute calls for tiered and targeted approaches, using toxicity information to inform the level of detail for exposure analysis and vice versa. The statute specifically mentions the use of sentinel exposures, which means that Congress never intended for EPA to account for every molecule.[7] AFPM strongly urges EPA to abandon its new approach to regulatory risk evaluation and resume its traditional tiered, targeted, and risk-based approach that the Agency has used for decades.

TSCA Fees should follow the fee-for-service model employed by other federal agencies and adhere to OMB "Circular No. A-25 Revised."

The LCSA authorizes EPA to collect fees for services rendered under Sections 4 ("Industry Testing Requirements"), 5 ("Manufacturing and Processing Notices"), and 6 ("Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures").[8] In the statute, Congress provides EPA with a sustainable source of funds to help offset the additional burdens from the Agency review requirements added by the LCSA; however, fees should not be used as a source of general funds for the Office of Pollution Prevention and Toxics ("OPPT"). The Office of Management and Budget (OMB) provides clear direction to federal agencies with respect to charging fees, which is found in Circular No. A-25 Revised.[9] EPA must continue to adhere to this guidance when updating the TSCA fee structure. EPA's proposal contradicts this guidance.

OMB's circular is clear in its objective that federal government agencies take a market-based approach when developing fees for the services rendered. In Section 6(a)(2)(b), the circular directs agencies to base fees on market prices, including fees for services. Section 6(d)(2) of the circular defines market price to mean a price that is "based on competition in open markets."

In Section 6(d)(2)(a)(ii), the circular guides agencies to look at prevailing prices in competitive markets when a "substantial competitive demand" exists. Historically, the demand for risk evaluation services has surpassed EPA's ability to provide such services in the New Chemicals Program such that EPA has hired contractors to assist with the work. It is important that EPA understands that the fees paid for government contractors are not necessarily reflective of a competitive market due to the added costs associated with federal contracting requirements.

EPA continues to only use its own experience as the primary source for calculating costs. There is no mention of benchmarking or obtaining information from sources outside the Agency. EPA's proposal, therefore, does not conform to the requirements in OMB Circular No. A-25 Revised, which specify that the market price be "based on competition in open markets." To conform to the OMB guidance, the fees established by EPA should be in line with the costs charged by independent organizations that conduct

[7] *See* TSCA Sec. 6(b)(F)(ii)

[8] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act for an explanation and access to The Frank R. Lautenberg Chemical Safety for the 21st Century Act.

[9] See https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.

risk evaluations in an open market used by public and private customers, and not just federal government contractors.

EPA should not use a one-size-fits-all approach to assessing risk evaluation fees.

EPA has proposed set fees for risk evaluations that appear to assume all evaluations will require a similar amount of work. AFPM does not agree with this assumption and strongly urges the Agency to adopt a tiered fee structure that is proportional to the amount of work required for risk evaluations. For example, many chemicals made by AFPM members are used as intermediates. The amount of work required to evaluate an intermediate is far less than the work needed to support a substance that has multiple conditions of use. Furthermore, industrial uses under controlled environments or already regulated by OSHA should not require the same level of effort as consumer end uses. Similarly, substances with data-rich dossiers will be easier to evaluate than those that require modeling, structure-activity analysis, and other techniques. Even the Agency acknowledges that "there are significant differences in the level of effort necessary to complete…evaluations."[10] At a minimum, EPA should generally categorize the number of uses and develop a fee structure that acknowledges the difference in effort that will be undertaken.

EPA should create ranges that capture the number of uses that will require quantitative estimates of exposure and assess fees accordingly. For example, the Agency could set fees according to the following number of conditions of use:

1 to 10 conditions of use
10 to 20 conditions of use
20 to 50 conditions of use
50 or more conditions of use

Using appropriate ranges would allow EPA to develop a more equitable fee structure proportional to the amount of work required to evaluate a chemical.

The proposed fees are not in line with the costs experienced by AFPM members under similar evaluation programs.

AFPM already had concerns with the near doubling of costs for EPA-initiated risk evaluations proposed originally in 2021. EPA has limited experience in conducting risk evaluations under Section 6 and did not seek input from risk evaluation experts outside the Agency to help estimate costs. EPA has not made public any type of benchmarking for similar services outside government agencies. AFPM members have direct experience in a variety of testing and evaluation programs, such as the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Programme, Canadian Chemicals Management Program, and under the European Union's REACH regulations. AFPM members have sufficient experience with such services and believe that even the original estimates provided by EPA in 2018, let alone the doubling of fees, are much higher than the fees previously charged to AFPM member companies for the same type of services under those other programs. The supplemental proposal of nearly 5 times the fee for risk evaluations is totally unrealistic.

Congress did not intend for EPA to create a general operating fund for OPPT; rather, its intent was to provide a source of revenue to help offset the costs of specific activities under Sections 4, 5, and 6. Congress makes clear in TSCA Sec. 6(b)(1) that fees should be "sufficient and not more than reasonably

[10] See EPA–HQ–OPPT–2016–0401, "User Fees for the Administration of the Toxic Substances Control Act" (83 Fed. Reg. 8212).

necessary to defray the cost related to such chemical," which means that all activities should be directly tied to a particular chemical when assessing fees.

EPA should not collect fees for test rules, orders, or consent agreements under TSCA Section 4 because the cost of review and analysis of data is captured under the fees associated with TSCA Section 5 and Section 6 risk evaluations.

AFPM has opposed EPA's collection of fees for submissions under TSCA Section 4 test rules as a matter of principle since EPA began seeking comments on how to implement the fee provisions in the LCSA.[11] The costs of testing, data analysis, and report preparation are already borne by industry so there is no service being provided by EPA under Section 4. Any subsequent review and analysis are conducted during the risk evaluations under TSCA Section 5 and Section 6. Collecting fees for the submission of data results in double-charging for the review and analysis of the same data.

Conclusion

EPA has had a long history of tiered and targeted risk evaluations under Section 5, whereby hazard information informed the areas and extent to which exposure information would be considered, and exposure informed the types of hazard information that would need to be collected. This tried-and-true approach has allowed the Agency to efficiently and effectively use its resources to determine the risk of thousands of substances each year. With these tiered, targeted, and risk-based approaches, EPA has been able to foster innovation and facilitate a robust manufacturing supply chain. Now it appears that the Agency will settle for nothing less than perfect information.

AFPM strongly urges EPA to retain the current fee structure until the Agency has enough experience and information to fully inform any decision to change those fees. Furthermore, AFPM advises the Agency to return to its tiered, targeted, and risk-based approach to evaluating the safety of chemicals.

Sincerely,

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[11] See AFPM comments submitted on August 24, 2016, and May 27, 2020, to docket number EPA-HQ-OPPT-2016-0401, entitled "User Fees for the Administration of the Toxic Substances Control Act."