American
Fuel & Petrochemical
Manufacturers

1667 K Street, NW
Suite 700
Washington, DC
20006

202.457.0480 office
202.457.0486 fax
afpm.org

May 24, 2018

E. Scott Pruitt
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attention: Docket ID Number EPA-HQ-OPPT-2016-0401
Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: User Fees for the Administration of the Toxic Substances Control Act

Dear Administrator Pruitt:

The American Fuel & Petrochemical Manufacturers (AFPM) respectfully submits the attached comments on the Environmental Protection Agency's (EPA or Agency) *Federal Register* notice titled "User Fees for the Administration of the Toxic Substances Control Act at 83 FR 8212 (February 26, 2018).

AFPM is a national trade association representing companies encompassing virtually all U.S. refining and petrochemical manufacturing capacity. AFPM refining and petrochemical member companies are subject to the Toxic Substances Control Act (TSCA) and will be directly impacted as EPA implements the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), including provisions related to fees collected for administration of TSCA.

AFPM supported EPA's efforts to consult with parties affected by the collection of fees related to TSCA activities. Additionally, AFPM has long supported TSCA modernization and looks forward to working with EPA and other stakeholders throughout the implementation process.

Sincerely,

James Cooper
Senior Petrochemical Advisor

AFPM Comments on User Fees for the Administration of the Toxic Substances Control Act

May 24, 2018

Docket ID No. EPA-HQ-OPPT-2016-0401

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COMMENTS BY TOPIC

The following comments are organized by general topic, then followed by specific responses to EPA requests for comment.

1.0 GENERAL COMMENTS

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (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"), including the maintenance of confidential business information (CBI). The intent is for EPA to have a sustainable source of funds to help offset the additional burdens from the requirements of the LCSA. Congress did not, however, intend for fees to 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*. EPA must adhere to this guidance when developing a TSCA fee structure, including the adoption of specific fees.

2.0 MARKET-BASED APPROACH

2.1 To comply with the Office of Management and Budget's (OMB) *Circular No. A-25 Revised*, EPA must consider the existing market for services related to hazard characterization, exposure assessment and risk evaluation when establishing a fee structure for services under TSCA.

OMB's circular is quite clear in its objective that federal government agencies take a market-based approach when developing fees for the services it renders. 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 understand that the fees paid for government contractors are not necessarily reflective of a competitive market due to the extraneous costs that are often added due to federal contracting requirements and therefore distort actual market conditions.

In Unit III, Part A, Subpart 2 of the proposed rule (see 8217 – 8218), EPA uses its own experience as the primary source for calculating costs. There is no mention of benchmarking or obtaining information from other sources, other than another EPA office that regulates pesticides. 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 risk evaluations in an open market used by public and private customers, and not just the federal government contractors. The benchmarking should be reflective of a chemical company or processor contracting the work.

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

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. While AFPM is not familiar with any formal study or analysis that may have been conducted on service costs for risk evaluations, AFPM members have sufficient anecdotal experience with such services and believe that the estimates provided by EPA are much higher than anything experienced by AFPM member companies.

3.0 POTENTIAL MONOPOLY

3.1 The proposed fee process will unintentionally provide EPA with a monopoly on risk evaluation services.

EPA has estimated the direct and indirect costs incurred when providing its services without acknowledging that other service providers may be in a position to offer similar services. The Agency's proposal assumes that EPA will be conducting all of the work, creating a de facto monopoly that does not acknowledge the possibility for 3rd-parties to conduct risk evaluations for EPA review. The concept of a manufacturer-initiated risk evaluation was born of the notion that a sponsor of a chemical could retain a 3rd-party to conduct a risk evaluation, greatly reducing any potential burden to EPA (since the manufacturer covers 100% of the costs). The results of the evaluation and all supporting documents would then be submitted to EPA. The manufacturer-initiated evaluation process should maximize the throughput of chemicals and still allow EPA to focus its own resources on high-priority chemicals. If the Agency does not include 3rd-parties in the process, it will create a monopolistic atmosphere that does not realize one of the primary goals of the LCSA: increase the number of chemicals evaluated for risk.

4.0 EPA COST ESTIMATES

4.1 EPA should revise its estimates to reflect the actual work done for a chemical.

EPA has estimated the direct and indirect costs incurred when providing its services without benchmarking against other service providers that offer similar services, which, as stated above, is contrary to OMB *Circular No. A-25 Revised*. EPA's estimate of $3,884,000 is well above any cost experienced by AFPM members in other risk evaluation programs.

In Part D of the Unit II Background (see 8215), EPA mentions the OMB circular and lists items that should be included when assessing direct and indirect costs. AFPM acknowledges the inclusion of direct and indirect costs, as long as those activities are related to carrying out Sections 4, 5 or 6 for a particular chemical. For example, the cost of research is mentioned for inclusion. AFPM firmly believes to be included, that research must be related to a specific activity for a particular chemical and not general research conducted by EPA. The same holds true for supplies, travel and any other costs. If it is not associated with a specific action under Section 4, 5 or 6, it should not be included in the cost estimate.

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 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.

5.0 PROPORTIONALITY

5.1 TSCA fees should reflect the amount of effort EPA puts into a risk evaluation and not adopt a one-size-fits-all approach that assumes all evaluations will require the same amount of work.

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 fee structure that is proportional to the amount of work required for risk evaluations. For example, many products made by AFPM members are used as intermediates. The amount of work to evaluate an intermediate is far less than the amount of work required to evaluate a substance that has multiple uses. Furthermore, industrial uses under controlled environments should not require the same level of effort as consumer or commercial uses, which portend potentially higher exposures. 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."[1] 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 by the Agency.

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 uses:

1 to 2 uses
3 to 5 uses
5 to 10 uses
10 or more uses

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

6.0 INCENTIVES FOR MANUFACTURERS TO PROVIDE RESOURCES

6.1 EPA should incentivize manufacturers to take on a burden that goes beyond the limitations found in TSCA Sec. 6(b)(4)(E).

Under the amended TSCA, the number of manufacturer-initiated risk evaluations can be no more than half of the total number of risk evaluations being conducted by the Agency at any one time. That does not limit EPA, however, in how many manufacturer-initiated evaluations can be conducted during any given period. For example, if a manufacturer provided EPA with a dossier that includes a risk evaluation and report from a competent and qualified 3rd-party, following the manner and criteria established by EPA under TSCA Sec. 6(b)(4)(C)(ii), it should not take the same amount of time as it would if the Agency were conducting an evaluation from scratch. It would not make sense for EPA to discard the completed work already done, especially when that work would likely be conducted by a 3rd-party similar to those that the Agency retains as contractors for work under TSCA. In such circumstances, EPA should quickly evaluate and make a determination on that substance so that manufacturers can initiate another evaluation as soon as possible. Since the full cost is borne by the manufacturer, there should be no significant additional burden on the Agency.

[1] 83 FR 8219 (February 26, 2018), Section III, Part B, Subpart 2.

This premise is supported by Senator Boxer's Colloquy (June 7, 2016), which states:

> *7. PACE OF AND LONG-TERM GOAL FOR EPA SAFETY REVIEWS OF EXISTING CHEMICALS*
> *…These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets procedures established and gains experience, these targets can be exceeded in furtherance of the legislation's goals.*

EPA should find ways to work cooperatively with industry and incentivize engagement, cooperation and contribution of resources and knowledge to meet the human health and environmental protection goals of TSCA. All stakeholders share a similar goal: an efficient and effective TSCA program. It is in everyone's best interest to create a TSCA program that maximizes throughput of evaluations by leveraging industry resources. One of the fundamental objectives for modernizing TSCA was to place a greater onus on industry; therefore, creating a fee structure that, through a lower assessed fee, allows and incentivizes industry to initiate and cover the cost of risk evaluations is by far the best way to meet that objective.

6.2 The proposed fees for manufacture-initiated evaluations are not well-supported.

TSCA Sec. 6(b)(4)(C)(ii) requires EPA to prescribe the process and criteria by which manufacturers are able to request a risk evaluation on a particular substance. There is nothing in the statute that prevents manufacturers from using a 3rd-party to evaluate a chemical and submit to the Agency a full dossier and risk evaluation report; in fact, the intent of Congress was to alleviate the potential burden on EPA, so the Agency could concentrate its resources on high-priority chemicals. It is in the manufacturer's best interest to submit a complete package that does not require the same level of effort by the Agency as when EPA begins a risk evaluation from scratch.

The only factors EPA appears to consider in its cost estimate for manufacturer-initiated evaluations are the amount of existing information and likelihood that the risks associated with that chemical will be low. There is no mention, or even an assumption, that the actual work would be done by a 3rd-party and that EPA would receive a full dossier and risk evaluation report (the most likely scenario). EPA should at a minimum use a tiered system for fees associated with manufacturer-initiated risk evaluations. AFPM suggests the following categories:

- Complete dossier (includes hazard characterization and exposure assessment), along with a risk evaluation and report from a credible 3rd-party provider
- Complete dossier, along with a risk evaluation and report from the manufacturer
- Complete dossier, but no risk evaluation
- Complete hazard characterization, but no exposure assessment

6.3 EPA should enhance incentives for participation in the Sustainable Futures Program.

AFPM supports the Sustainable Futures Program and views it as a valuable approach that allows greater use of industry time and resources in the New Chemicals Program. The Program entails training in EPA methods and models used in the risk evaluation process for new chemicals. Upon successful completion, companies use those approaches and submit the results along with the Premanufacture Notice (PMN).

AFPM believes incentives for participation in the Sustainable Futures Program should go beyond Test Market Exemptions (TMEs) and apply to PMNs as well. A reduced fee for graduates of the program would provide appropriate incentives and maximize participation and the use of EPA methods and tools.

7.0 COST ACCOUNTING

7.1 EPA must track and detail costs for each chemical that is subject to action under Sections 4, 5 or 6.

To comply with the accounting and auditing provisions found in TSCA Sec. 26(b)(3)(D), in addition to OMB *Circular No. A-25 Revised*, specifically Section 8.g.[2] EPA must track and detail costs for all of its work under Sections 4, 5 and 6. In the proposed rule and supporting documents, the Agency has provided estimates based on its previous experience; however, that is not the same as actually tracking costs while performing tasks associated with test rules and risk evaluations. Tracking costs for each chemical will make the fee process much more transparent and lead to more precise estimates that the Agency is required to submit to Congress in its reports. It will also help EPA when it reviews and adjusts the fees every three years, which is required by statute [see Sec. 26(b)(4)(F)]. Furthermore, TSCA Sec. 26(b)(4)(D)(iii) limits EPA to "apply feed collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses." This provision makes tracking and detailing costs imperative.

8.0 TIMING OF FEE ASSESSMENTS

8.1 EPA should assess and collect fees at different points of the review process.

It is rare in the private sector that a customer is expected to pay all costs for services at the beginning of the process. That should also be the case with fees associated with government services, which is supported by OMB *Circular No. A-25 Revised*, especially if the fees apply to services that have specific deadlines. Collecting a portion of the fee upfront will help establish necessary funding for EPA to carry out its work. Collecting the full amount, however, would not provide any incentive for the Agency to complete its work on time. Additionally, it would leave manufacturers little recourse if the Agency failed to complete its review in a timely manner. EPA should consider a series of payments at strategic points during the risk evaluation processes under Sections 5 and 6. In addition, a phased fee system should be tied to specific milestones and scientific standards, which will allow manufacturers to pause the risk evaluation process before all funds are spent.

9.0 FEES ASSOCIATED WITH TEST RULES

9.1 EPA should not collect fees for information submitted under Section 4, then additionally collect fees for evaluation of that same information under Section 5 or 6.

AFPM anticipates that EPA will issue test rules, consent agreements and orders under Section 4 to require new testing on chemicals. Those Section 4 actions must have a purpose related to risk evaluation; therefore, the time to collect those fees should be consistent with collection of fees associated with risk evaluations. To charge two separate fees will be akin to double-charging for evaluation of the same information. For example, if EPA conducts a risk evaluation under Section 5 for a new chemical and requires a company to develop new test data, that data will be reviewed as part of the review of the PMN.

[2] Section 8.g. outlines the maintenance of readily accessible records that cover services or activities, extent of benefits, exceptions to the policy of the circular, information used to establish charges, collections from each user and records of the information used to establish the fees.

Charging a fee for both the submittal of the test results and review under Section 5 is double-charging for the same data. The same holds true for test rules that involve high priority chemicals that will undergo risk evaluation under Section 6.

10.0 HANDLING OF CONSORTIA

10.1 EPA should extend the period for which fees must be paid to allow consortia time to form and reach agreement on cost-sharing.

It is likely that in many cases for actions under TSCA Sections 4 and 6, more than one company will be affected. The group of companies will probably decide to form a consortium and share work and subsequent costs. The proposed 60-day period for payment may be inadequate due to the complexities of identifying all market players and developing an equitable assessment for each company's share of costs. AFPM urges EPA to adopt a 90-day period for payment.

In the event that a consortium cannot reach an agreement on cost-sharing, EPA has stated that it will assess fees to each member. In these cases, the Agency should adopt a systematic approach where the apportionment of fees is based on market share or a similar method that results in an equitable apportionment.

11.0 REFUNDS OF FEES

11.1 EPA should expand the discussion of refunds to include situations where the Agency fails to meet the appropriate deadlines for review of PMN substances.

In Unit III (Detailed Discussion), Section H of the proposed rule (see 8225), EPA discusses circumstances under which PMN fees, or a portion of the fee, would be refunded. What is not mentioned, but is an essential component, is the refund when EPA misses the 90-day PMN review period. Sec. 5(a)(4) of TSCA contains the provisions and requirements for such refunds, but these are not discussed in the proposal. The Agency should develop a transparent process by which it will implement the statutory requirement of PMN fee refunds in cases where EPA misses the statutory deadline.

12.0 SPECIFIC RESPONSES TO EPA COMMENT REQUESTS

12.1 EPA seeks comment on the process by which fees will be readjusted every three years.

Generally, AFPM supports the process by which EPA will adjust fees every three years. Adjustments should include a transparent analysis of detailed costs associated with the actual work that the Agency has conducted over the previous three years when proposing to adjust fees. This will avoid unnecessary delays in establishing the adjustments. Please see Section 8.0 of these comments for details.

12.2 EPA seeks comment on identification of responsible parties for TSCA fees.

If EPA desires to publish a preliminary list of companies likely to be affected by a proposed action, it should only use information submitted under the most current Chemical Data Reporting (CDR) rule. The Toxic Release Inventory (TRI) identifies both manufacturers and users, which would be difficult to distinguish, so it would be of limited value for identification of just manufacturers. In addition, the list should be appropriately characterized as a listing of potentially affected parties and not a definitive list for compliance purposes. The Agency must recognize that the information in the CDR may not be reflective of a company's current manufacturing practices. Companies should then be allowed to check against that list and in cases where a company is not on the list but should be, that company should be afforded the

opportunity to self-identify before the list is finalized. Likewise, if a company is placed on the initial list but no longer makes or imports that chemical, it should be afforded an opportunity to be removed from the list.

In addition to identifying potentially affect parties, EPA should also recognize that because of potential costs or regulatory action, a company may wish to exit that particular market. Those companies that exit the market should not be expected to share in the costs of a risk evaluation or any other action under TSCA. In light of these plausible situations, EPA should outline a process to assess fees on companies that enter the market after a risk evaluation or regulatory action has taken place. The process should include a limitation on the period of time in which a company is required to pay a fee, to avoid excessive record-keeping and other requirements. The process should be subject to notice and comment, even if not part of the final fees rule.

12.3 EPA seeks comment on its definition of small businesses.

The definition of a small business should be aligned with the definition used by the Small Business Administration (SBA), which is based on the number of employees. Sales figures are not used by SBA because those figures are not necessarily reflective of a company's size. Basing the definition on sales will dramatically limit the number of small businesses that should qualify.

12.4 EPA seeks comment on whether to assess fees for risk management actions under Sec. 6(a).

AFPM agrees that the Agency should not charge a unique fee for risk management actions. At that point, the work conducted by EPA is no longer considered a service that "enables the beneficiary to obtain more immediate or substantial gains or values."[3]

12.5 EPA seeks comment on the proposed discontinuation of reduced fees for intermediates submitted as part of the PMN for a final product.

EPA should not discontinue the reduced fee for intermediate PMNs that are submitted as part of a PMN for a final product. Furthermore, EPA should not be charging the same amount for any PMN for an intermediate. The Agency claims that it takes the same amount of effort to evaluate an intermediate as it does for a final product. AFPM disputes this claim. The only use of an intermediate is to make another chemical. This conversion to another chemical takes place in a closed process, even in cases where the intermediate may be isolated, stored or even shipped to another location. AFPM cannot identify a situation where the risk evaluation for a substance that is used in a closed industrial system, and completely transformed into a totally different substance, would require the same level of effort as a substance that is distributed into commerce for one or more end uses that are outside of a controlled industrial site. EPA should continue to encourage packaged submissions of chemicals that include intermediates.

12.6 EPA seeks comment on alternative fee proposals.

EPA should disregard the alternative proposals and concentrate on one proposal that incorporates the suggestions in these comments.

[3] OMB *Circular No. A-25 Revised*, Section 6.a.1.

13.0 CONCLUSION

AFPM appreciates the opportunity to submit these comments. AFPM expects the Agency to create a more flexible fee structure that is reflective of the services provided under Sections 4, 5 and 6, and accounts for the actual work performed by EPA. EPA should leverage industry resources and maximize participation in the process for industry-initiated risk evaluations, as well as the Sustainable Futures Program. AFPM will continue to work constructively with the Agency to develop a fee structure and process that is efficient, effective and reaches the goals of TSCA modernization.