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VICE PRESIDENT
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August 24, 2016

Ms. Barbara Cunningham
Deputy Director
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
Via email to www.regulations.gov docket # EPA-HQ-OPPT-2016-0401

Re: ACC Comments to Inform EPA's Rulemaking on Fees for the Administration of the Toxic Substances Control Act

Dear Ms. Cunningham:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide input to the Office of Pollution Prevention and Toxics (OPPT) to inform the Agency's development of a rule to establish a fee system for the administration of the Toxic Substances Control Act (TSCA), as required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA, Public Law No. 114-182). ACC and its members have a significant interest in a TSCA fee system that supports the efficient and effective implementation of LCSA.

The attached comments are intended as general recommendations for establishing a fee system that generates sufficient revenue for the TSCA program, while meeting the objective of a simple, transparent system with the least overall burden on the regulated community. ACC appreciates the Agency's several efforts to consult with industry on the fee program, including the consultation meeting held on August 11, 2016 and an anticipated future consultation. ACC is committed to providing EPA constructive input into this process, and looks forward to working with the Agency as a draft rulemaking is developed.

If you have any questions on ACC's recommendations, please feel free to contact me at 202 249 6400, or at mike_walls@americanchemistry.com.

Sincerely,

Attachment

cc: Pam Myrick

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. The products and processes employed by chemistry companies are significantly regulated under the Toxic Substances Control Act; many of the industry's interactions with EPA under TSCA will likely be subject to the TSCA fee program.

Comments of the American Chemistry Council
Fees for the Administration of the Toxic Substances Control Act
Docket No. EPA-HQ-OPPT-2016-0401

Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to provide these brief comments to the Environmental Protection Agency (EPA), highlighting considerations and recommendations relating to establishing fees for the administration of the Toxic Substances Control Act (TSCA). ACC and its member companies strongly supported the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA, Public Law No. 114-182), including the amendments to TSCA section 26 that expand EPA's TSCA fee authority.

ACC and its members recognize that LCSA imposes on EPA an obligation to screen all chemicals in commerce, evaluate the risks of high priority substances, and regulate certain conditions of use where necessary. The Act also requires EPA to review all claims to protect chemical identity from public disclosure and a significant representative portion of all other confidentiality claims. These are Agency activities typically funded by appropriations, but because the level of activity is expected to increase under LCSA, Congress provided EPA authority to impose fees as a means of defraying some of the Administrative costs associated with implementing the Act. The anticipated burden on the regulated community of those fees is expected to be offset by efficient and effective EPA decisions.

ACC believes that the TSCA fee system should reflect the key principles included in Attachment 1 to these comments. EPA should consider the following elements in proposing a rule on the TSCA fee program:

- In order to meet the LCSA requirement that fees be "sufficient and not more than reasonably necessary" to defray up to 25% of the costs of administering the program, EPA must be clear about its current and anticipated costs, and realistic in its expectations for fee revenue. EPA must assure that fees are not set at a level that would adversely impact innovation and competitive standing.
- Although LCSA confers authority for EPA to assess fees for certain activities under TSCA sections 4, 5, and 6, not all of that authority must be exercised. As under TSCA prior to LCSA, EPA should not assess fees for the submission of data under section 4.
- Fees for submissions and Agency actions under sections 5 and 6 should reflect the level of effort required of EPA.
- EPA should establish a single fee per substance for risk evaluations under section 6, and afford consortia the flexibility to make their own decisions on how those fees should be allocated among different market participants. Fees for risk evaluations should reflect the amount of effort the Agency anticipates or experiences (e.g., a substance may have many uses that require complete evaluations, compared to another substance that has a single use).

A. EPA Must be Clear about Current and Anticipated TSCA Costs to be Defrayed by Fees, and Realistic in its Expectation about the Amounts Fees will Generate

Section 26(b)(1) provides EPA discretionary authority to assess fees related to the submission of information under TSCA sections 4 or 5, or on manufacturers or processors of substances subject to risk evaluation under section 6(b). The authority imposes several important limitations on EPA's ability to assess fees, however:

- The aggregate total of TSCA fees cannot exceed $25 million, or up to 25% of the costs of administering the relevant sections of TSCA, whichever is lower. Section 26(b)(4)(B).
- Lower fees for small businesses must be established, in consultation with the Small Business Administration. Section 26(b)(4)(A).
- Fees must be "sufficient and not more than reasonably necessary" to defray the costs of administering sections 4, 5, 6 and 14. Section 26(b).
- EPA may not charge a fee for the submission of claims for protection against disclosure under section 14.
- Importantly, the section distinguishes between the fee "attachment" points (sections 4, 5 and a portion of section 6) and the purposes for which fee revenue may be used (to defray the cost of activities under sections 4, 5, 6 and 14). For example, EPA cannot charge a fee for the submission of confidential business information (CBI) claims, but can include the costs associated with reviewing such claims in section 5 and 6 fees.
- Section 26(b)(5) limits the ability to impose fees if appropriations fall below the Fiscal Year 2014 level (approximately $56 million).

At this time, there is no publicly available information that can be used to determine the Agency's historical costs for administering sections 4, 5, 6 and 14.[1] The Agency clearly has experience reviewing submissions under sections 4 and 5, but there is no clear benchmark of EPA's costs to administer those programs. EPA also has experience in prioritizing and evaluating substances under the Work Plan Chemical program, but it is not clear what those costs are, or if they are relevant to the LCSA section 6(b) risk evaluation program. It is also not clear what costs EPA anticipates it will incur in administering sections 4, 5, 6 and 14 as amended by LCSA.

ACC notes that in July, 1986, when EPA first considered establishing fees under sections 4 and 5 of TSCA, the Agency made available for public comment a paper entitled "Options for PMN Fees."[2] The options paper discussed fee options and provided preliminary estimates of the economic impact of a fee. ACC has not been successful in obtaining a copy of the 1986 Options Paper. We believe EPA should consider developing a similar options paper as a basis for articulating its proposed TSCA fee structure under LCSA. The 1986 Options Paper would be a useful addition to the public docket.

In our comments at the August 11, 2016 stakeholder discussion on TSCA fees, ACC noted that additional information on EPA's current and anticipated costs are key to

[1] We note that such information would also appear to be necessary to meet the audit requirements established under LCSA section 26(b)(3)(D)(ii).
[2] 51 Fed.Reg. 25250 (July 11, 1986).

understanding what fees might be assessed. ACC appreciates EPA's commitment at that discussion to providing information that stakeholders could use to better understand TSCA costs.

Nevertheless, there are a few benchmarks for the fee program already available. In a statement made at the March 18, 2015 hearing of the Senate Environment and Public Works Committee, Senator Tom Udall indicated that, on the basis of information provided by EPA, the cost of "evaluating and regulating from the start to the finish is at least $2.5 million"[3] per chemical. Assistant Administrator Jim Jones confirmed that estimate in response to a question posed at the April 14, 2015 hearing of the House Subcommittee on Environment and the Economy, in which he attributed 60 percent of those costs to the regulatory phase,[4] for which fees cannot be assessed under LCSA. At this point, it seems fair to estimate that a risk evaluation would, on average, cost approximately $1 million (40% of $2.5 million).

EPA statistics indicate that over the last three years, the Agency reviewed a rolling average of approximately 625 PMNs a year. Assuming all of those PMNs are assessed the current fee of $2,500, EPA would expect to raise approximately $1.5 million in PMN fee revenue. Because PMNs filed by qualified small businesses are assessed a fee of $100, EPA may not realize the full $1.5 in fee revenue. Generally, PMN fees currently account for revenue in the range of $1 to $1.5 million a year.

According to EPA, appropriations for the TSCA program have averaged slightly more than $56 million over the last three fiscal years.[5] Assuming this is an accurate representation of the Agency's current costs for the Administration of TSCA, and for the administration of sections 4, 5, 6 and 14 in particular, EPA should expect the fee program to raise approximately $14 million in the aggregate under LCSA (to meet the 25% threshold).

These three basic assumptions about the cost of section 5 PMN review activities, the costs attributable to risk evaluations under section 6(b), and the total cost to administer the TSCA program provide a minimal benchmark to evaluate proposed fees. ACC hopes that EPA's proposed rule will provide a detailed review of the total current costs to administer sections 4, 5, 6 and 14, EPA's estimate of the anticipated costs of administering those sections under LCSA, and a range of options for fees under sections 4, 5, and 6. This information will allow stakeholders a better opportunity to evaluate the proposed fee program, including an understanding of EPA's expectations for the aggregate amount of fees to be raised.

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[3] Statement of Senator Tom Udall, March 18, 2015, contained in the unofficial transcript of the hearing record, page 23, available at http://www.epw.senate.gov/public/_cache/files/6072fb1c-06a0-48b5-9dd4-2d894a81e9c0/spw031815.pdf.

[4] House Subcommittee on Environment and the Economy, Hearing on H.R. __, TSCA Modernization Act of 2015, Serial No. 114-30, at 34, available at https://www.gpo.gov/fdsys/pkg/CHRG-114hhrg95937/pdf/CHRG-114hhrg95937.pdf.

[5] Environmental Protection Agency, Justification of Appropriation Estimates for the Committee on Appropriations for Fiscal Year 2016, at 485 (Feb. 2015), available at https://www.epa.gov/sites/production/files/2015-02/documents/epa_fy_2016_congressional_justification.pdf.

B. The TSCA Fee Program Should be Fair, Equitable, Simple and Efficient

ACC believes that the overriding objectives in an expanded TSCA fee program should be fairness, simplicity, and efficiency.

ACC recognizes that there are fundamental differences between manufacturers and processors. Historically, processors have not had significant TSCA responsibilities, but under LCSA processors may have obligations under section 4, 5, and 6 (including, in some cases, an obligation to pay fees associated with the evaluation of certain conditions of use). The differences should be recognized in the fee system to ensure fundamental fairness to manufacturers and processors in the chemical value chain.

ACC believes that EPA should help ensure fairness by considering the potential impact on innovation and competitive standing in determining fees. There is a significant risk that section 5 PMN fees could be set at a level that provides a disincentive to bringing new chemistries forward for EPA review.[6]

TSCA fees should also be set at levels that consider the possible competitive and economic impact of the fee. In part, the regulatory framework created by TSCA in 1976 – a framework that promotes active industry engagement with EPA – helped establish the United States as the preferred geography to bring new chemicals to market. EPA's TSCA fee policies should seek not only to ensure appropriate supplemental resources to implement the LCSA reforms, they should also seek to protect the U.S. industry's significant global competitive advantage. Executive Order 12866 provides important guidance to the Agency in expanding the TSCA fee program.[7]

LCSA mandates consideration of small business needs in a broader TSCA fee program. Section 26(b)(4). In general, ACC believes EPA's approach to small business issues is workable, although the current PMN fee of $100 for qualified small businesses should be updated appropriately. A specific consultation with small business interests may be in order as the Agency develops its thinking on fees to be paid by small businesses.

The Congressionally-mandated fee programs under the Pesticide Registration Improvement Act (PRIA),[8] the Prescription Drug User Fee Act (PDUFA),[9] and the Medical Device User Fee and Modernization Act (MDUFMA),[10] provide important lessons for a broader TSCA fee program. Notably, these fee programs are too complicated to serve as models for a TSCA fee program and pose an expectation of raising significantly more revenue than is allowed in the TSCA fee program. Moreover, the regulatory objectives under these programs are intended to register or license products to individual manufacturers – a far different regulatory

[6] We note that according to the U.S. Department of Commerce's Bureau of Labor Statistics, the inflation-adjusted current buying power of $2,500 in 1988 dollars (the year PMN fees were first payable) is $5,085.52. *See* 53 Fed.Reg. 31252 (Aug. 17, 1988). *See also* http://www.bls.gov/data/inflation_calculator.htm.
[7] Executive Order 12866, Sept. 30, 1993. In particular, paragraphs 3, 5, 6, and 11 of Section 1 of E.O. No. 12866 apply to EPA's consideration of the TSCA fee program.
[8] Public Law No. 108-199 (Jan. 23, 2004).
[9] Public Law No. 102-571 (Oct. 29, 1992).
[10] Public Law No. 107-250, (Oct. 26, 2002).

outcome than TSCA. In our view, a simple, easy to understand TSCA fee schedule that attaches to as few specific activities as possible should be reflected in the proposed rule.

TSCA fees should be paid in the most efficient way possible. In general, TSCA fees should be paid up-front, concurrent with the submission of the applicable notice, information, or request, as the case may be. The notable exception to up-front payment should be fees with respect to a section 6(b) risk evaluation. EPA should also make section 6(b) risk evaluation fees payable in stages, beginning with the definition of the scope of the evaluation (which will likely determine which manufacturers and processors may have fee obligations). Interim payments may be warranted depending on the length and complexity of the risk evaluation. Section 6(b) fees should not be fully paid until EPA completes the risk evaluation. This approach will ensure that the Agency has an incentive to complete the risk evaluation within the deadlines established by LCSA.

C. Specific Comments on Fees under TSCA Sections 4, 5, and 6.

1. EPA Should Not Exercise Its Authority to Charge Fees for Section 4 Submissions

Section 26(b)(1) provides clear discretionary authority for EPA to assess fees, continuing the approach adopted in TSCA as it was first enacted in 1976. EPA has consistently declined to exercise its authority to assess fees for the submission of section 4 information.[11] In ACC's view, EPA should continue this policy and not establish fees for section 4 data and information submissions. Indeed, the LCSA reform provides no basis for reversing this long-standing policy.

Data generated under section 4 will be developed at the expense of the manufacturer or processers subject to a section 4 test rule, order or consent agreement. Assessing a fee for the submission of that data or information would effectively charge the manufacturer or processor a second time for EPA's review of that material, particularly when the review of the information will be in the context of a section 5 or 6 action. Moreover, the number of likely section 4 rules, orders or consent agreements cannot be accurately estimated at this time. As a result, the amount of revenue likely to be raised by section 4 fees is uncertain, and it is certainly not apparent that the amount would be significant in terms of EPA's anticipated aggregate fee total. One possible alternative would be a fee to defray the costs of developing a section 4 test rule (as opposed to an order or consent agreement), although we recognize that there may be instances where a rulemaking is the most efficient mechanism to require the generation of information.

We recommend that EPA's proposed fee rule avoid establishing a section 4 fee.

[11] In the July, 1986 Federal Register notice announcing the availability of the Options Paper, EPA specifically indicated that Agency was "not considering the possibility of requiring fees in connection with data submitted to EPA under TSCA section 4." *See* 51 Fed.Reg. 25250 (July 11, 1986). That approach has apparently never changed in the 30 years since the paper was developed.

2. Section 5 Fees Should be Modified Appropriately

ACC believes that the Section 5 fee program has operated well. Several modifications are warranted as EPA considers the program.

Clearly the current $2,500 fee for Pre-Manufacturing Notices (PMNs) must be amended. In this respect it will be important for EPA to identify a target for the aggregate amount of TSCA fees, as well as a target for the contribution made by section 5 and 6 fees, respectively. A target amount will assist industry and EPA in assessing recommended fee levels for specific section 5 and 6 activities.

EPA should also consider modifying its approach to fees for Significant New Use Notices (SNUNs). Under 40 C.F.R. §700.45(b)(2)(iii), EPA requires SNUN submitters to pay the same $2,500 fee assessed for PMNs. ACC believes that SNUNs warrant a lower fee, because EPA has already conducted a hazard assessment for that substance in the context of the original PMN. A SNUN fee should be tailored to reflect EPA's activities in reviewing the proposed new use, particularly any relevant exposure considerations.

Similarly, EPA should consider modifying its fee policy for exemption applications and exemptions notices under 40 CFR §700.45(b)(2)(iv) and (v). The fee rate imposes a disincentive to claim the benefits of the PMN exemptions. EPA should consider charging no fees, or reduced fees, for PMN exemption notices. This is especially the case for the exemption applications or notices that are the subject of little to no EPA review. For example, polymer exemption notices face little to no EPA review and should not be subject to fees.

ACC also believes the section 5 fee schedule should provide credit for specific reviews conducted by submitters prior to submission of a PMN or SNUN. Specifically, EPA should consider affording credit for evaluations under the Sustainable Futures program.[12] In light of the fact that Sustainable Futures evaluations qualify for expedited PMN review, the fee schedule applicable to related PMNs should be adjusted accordingly.

3. Fees for Section 6(b) Activities Should Track LCSA

Section 26(b) authorizes EPA to assess a fee on any person who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b). Section 6(b) contains both a prioritization step (section 6(b)(1)) and a risk evaluation step (section 6(b)(4)) for substances designated as high priorities for review. In addition, EPA is directed to identify 10 substances for initial risk evaluations within 180 days of enactment of LCSA. Section 6(b)(2). ACC believes that EPA should consider assessing fees (at an appropriate level) for both the prioritization step and the risk evaluation step.

Prioritization is an appropriate activity to assess a fee, as EPA will be reviewing the available data and information to determine whether a substance is a low or high priority for evaluation. Such a fee should be established at a lower level than fees for section 6(b) risk evaluations, as the level of Agency effort will be less than that applied in risk evaluations,

[12] *See* https://www.epa.gov/sustainable-futures.

particularly as EPA applies emerging computational methods in the prioritization process. In the short term, EPA will likely incur higher costs in screening chemical substances under the conditions of use to identify high and low priorities, so a fee (again at an appropriate level) may be warranted.

An estimate of the cost of the 6(b) risk evaluation should be published along with the scope for risk evaluation, as these fees may vary considerably for individual risk evaluations. As suggested earlier, fees for section 6(b) risk evaluations should be assessed at specific stages of the evaluation process. Although some risk evaluations will be inherently more complex than others, EPA should establish a single fee for risk evaluations. A single fee could nevertheless reflect relative complexity in a risk evaluation through an "assessment factor" applied in calculating the fee.

ACC recognizes that the scope of a risk evaluation will determine what manufacturers or processors may be subject to section 6(b) fees. ACC believes that EPA has considerable discretion to determine the scope of a risk evaluation, and that LCSA does not mandate that EPA necessarily review all conditions of use of a high priority substance. EPA is likely to identify specific conditions of use that prompt a designation of a substance as a high priority, and those conditions of use (and perhaps others) will be the subject of the risk evaluation. Only those manufacturers and processors with an interest in the substance should be subject to the section 6(b) fee.[13] ACC recognizes this approach will require a consideration of mechanisms to address potential "free-rider" problems, and to address those evaluations where some but not all conditions of use are under review.

Similarly, manufacturers who request risk evaluations of a chemical substance under section 6(b)(4)(C)(ii) should only be assessed a fee with respect to the specific conditions of use identified in the request. EPA should of course retain the discretion to expand a particular risk evaluation beyond the conditions of use identified by a manufacturer or processor, but in such cases the requester should not bear the burden of any associated additional costs.

As in section 5, consortia of manufacturers and/or processors should have the opportunity to pay relevant section 6 fees. Consortia should have the flexibility to allocate fees among participants as they negotiate; EPA should not dictate the fees payable by any individual consortia member. EPA should consider establishing a mechanism by which late market entrants or free-riders can be held accountable for their fair share of fees, perhaps by establishing reimbursement rules similar to those in 40 CFR Part 791 (applicable to section 4 test costs).

D. ACC Responses to EPA Questions

EPA posed five questions to stakeholders at the August 11, 2016 public session on TSCA fees.

1. To be able to defray 25% of the costs of administering sections 4, 5, and 6, and CBI, does industry have considerations of weight amongst the three areas of fee collection?

[13] EPA is required under section 8(b)(4) to "reset" the TSCA Inventory to categorize the inventory listings into substances in "active" commerce, and those in "inactive" commerce. This process should be useful as a means of identifying relevant manufacturers and processors.

EPA should not assess fees for the submission of information under section 4. The Agency should first estimate the total amount of fees expected to be raised, and then make an appropriate allocation of the fee "burden" to activities under sections 5 and 6.

2. Does industry have thoughts on the types of factors (types of submissions, number of submissions, level of difficulty, etc.) that EPA should consider when structuring the fees?
   In general, EPA's relative level of effort in reviewing a section 5 notice, and in conducting a section 6 risk evaluation, should be the major factor in structuring fees. The relative level of complexity expected in a given section 6 risk evaluation should be considered, and EPA should establish some mechanism (e.g., a "risk evaluation factor") that would modify the fee to reflect that complexity. As noted earlier, EPA should consider lower fees for SNUNs (as hazard will already have been evaluated in the context of a PMN), and should provide credit for certain prior review actions (e.g., Sustainable Futures).

3. Has industry considered how to distribute payment amongst multiple manufacturers and/or processors?
   Affected manufacturers and processors should have the freedom and flexibility to allocate responsibility for fee payment among themselves. EPA should retain the ability to settle disputes regarding fee payments, however, similar to the reimbursement provisions applicable under section 4.

4. Does industry have thoughts on how to identify the whole universe of manufacturers, including importers, and processors affected?
   ACC believes that the inventory "reset" mandated in section 8 is an appropriate mechanism to identify the universe of manufacturers (including importers) and processors potentially affected by the TSCA fee rule. An appropriate amendment to the Chemical Data Reporting (CDR) rule could ensure that the list of manufacturers and processors is kept up to date.

5. Does industry have thoughts on how to arrive at an appropriate balance between manufacturers and processors?
   The interests of manufacturers and processors in TSCA, and in the TSCA fee rule, will vary according to the context. A manufacturer or group of manufacturers will likely have fee responsibilities under sections 5 and 6. Processors of a given chemical substance may have responsibility for fees at a level proportionate to their relative interest in the substance, but at a level lower than manufacturers. For example, processor fees under section 6 could be established at a level proportionate to the share a respective condition of use compared to the total number of uses for that substance as whole. Section 6 evaluations of conditions of use <u>not</u> supported by the manufacturers should require processors to pay the same fee that manufactures would pay for the same evaluation (i.e. same fee for the same service, regardless of entity requesting the service).

E. <u>Conclusion</u>

ACC very much appreciates EPA's continuing efforts to engage stakeholders in the development of an appropriate TSCA fee program. We look forward to working with the Agency as concepts and approaches to the fee program are considered in advance of a proposed rule later this year.