



**Comments on**  
**Rule on Fees for the Administration of TSCA**  
**EPA–HQ–OPPT–2016–0401**  
**Submitted August 24, 2016**

Environmental Defense Fund (EDF) appreciates the opportunity to provide these comments to EPA as input into its development of the rule authorized under section 26(b)(1) governing the collection of fees to be paid by companies to help defray the costs of EPA’s implementation of sections 4, 5, 6, and 14 of TSCA. These comments are provided in part in response to comments made by various industry representatives participating in EPA’s August 11, 2016 public meeting on this rule.<sup>1</sup>

As a general principle, EDF believes EPA should assess fees in direct proportion to the level of effort the Agency will expend in the particular activity in question. We oppose the concept espoused by some in industry that EPA should entirely exempt from fees certain EPA reviews or other activities that clearly will require resources to conduct and that fall under areas of the law that are squarely within its fee authority. In addition, *all* of the costs to EPA associated with such reviews and other activities need to be included in the baseline budget on the basis of which the overall level of fees is to be determined.

These comments address the following issues:

- [1. The fees required of a manufacturer making a request for a risk evaluation must be sufficient to cover the full or 50% portion of EPA costs for the \*full\* risk evaluation it conducts.](#)
- [2. EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, should always establish the scope of the risk evaluation.](#)
- [3. EPA should not initiate industry-requested risk evaluations until it has received the applicable fees mandated to defray its costs.](#)
- [4. Companies should not be allowed to pay a higher fee in order to expedite EPA’s review of its new or existing chemical.](#)
- [5. EPA should impose fees on companies to help defray its costs of requiring testing and managing information received in response to testing requirements under section 4.](#)
- [6. EPA should impose fees on companies to help defray its costs of reviewing and processing exemption notices required to be submitted under section 5.](#)

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<sup>1</sup> See US EPA. “Meetings and Webinars on the Amended Toxic Substances Control Act.” Updated 15 August 2016. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control>.

Provisions of the new law relevant to these comments include the following:

- Section 6(b)(4)(E)(ii): All industry requests for risk evaluations are subject to the payment of fees.
- Section 26(b)(4)(D): These fees are as follows:
  - a fee that is sufficient to defray EPA’s full costs to conduct a risk evaluation requested by a manufacturer, except that
  - if the chemical for which the request is made is listed on the 2014 update to EPA’s work plan, the fee shall be sufficient to defray 50 percent of EPA’s costs to conduct the risk evaluation.
- Section 6(b)(4)(E)(ii): EPA “shall not expedite or otherwise provide special treatment” to industry-requested risk evaluations.
- Section 26(b)(1): EPA can require fees to be paid by any person:
  - required to submit information under section 4;
  - required to submit a notice or other information under section 5; or
  - who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b).
- Section 26(b)(1): Fees can be used to defray EPA’s costs of:
  - administering sections 4, 5, and 6, and
  - collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances.

Our specific comments follow.

**1. The fees required of a manufacturer making a request for a risk evaluation must be sufficient to cover the full or 50% portion of EPA costs for the full risk evaluation it conducts.**

Some industry representatives have raised the possibility that the fees EPA imposes to cover the full or 50% portion of costs EPA incurs in conducting industry-requested risk evaluations should only apply to EPA’s costs for the portion of the scope of the risk evaluation corresponding to the requestor’s portion of the manufacture of the chemical in question.

There simply is no basis for such an approach in the law. Section 26(b)(4)(D) provides no such allowance, and rather requires that, “[i]n setting fees under this section, the Administrator shall ... establish the fee at a level sufficient to defray the full costs [or 50 percent of the costs] to the Administrator of conducting the risk evaluation.” This requirement applies regardless of whether or not the requesting manufacturer manufactures the chemical for only a subset of the conditions of use included in the scope of the risk evaluation.

In its fee rule or its risk evaluation rule (or both), EPA should affirm this requirement that fees collected for industry-requested risk evaluations be sufficient to cover all or a 50 percent portion of its costs to

conduct the risk evaluation, the scope of which is to be established by EPA, not the requesting manufacturer (see next comment).

**2. EPA, not the manufacturer requesting a risk evaluation of one of its chemicals, should always establish the scope of the risk evaluation.**

The new law's allowance for companies to request and pay for risk evaluations was intended to expand the number of chemicals being reviewed and provide companies with some ability to have a risk evaluation done on a chemical sooner than would otherwise be the case through the normal prioritization process. It was never intended, nor does the law allow, for the conduct of risk evaluations undertaken in response to industry requests to deviate in any manner from those EPA initiates on its own.

Yet some industry representatives are suggesting that EPA can and should conduct risk evaluations only on conditions of use requested by manufacturers. This is clearly not allowed by the law.

Sections 6(b)(4)(C) and (F) make clear that both EPA-initiated and industry-requested risk evaluations are to conform to the same requirements, including that they both be conducted "in accordance with the rule" EPA is to promulgate to govern its conduct of risk evaluations. Nor does the provision of the law establishing requirements for the scope of risk evaluations [section 6(b)(4)(D)] make any distinction between the scopes of EPA-initiated and industry-requested risk evaluations.

In its risk evaluation rule (and in its fee rule as necessary), EPA should affirm that EPA has sole responsibility and authority to establish the scopes of all risk evaluations it undertakes.

**3. EPA should not initiate industry-requested risk evaluations until it has received the applicable fees mandated to defray its costs.**

Congress intended that EPA conduct risk evaluations requested by industry only subject to the payment of fees sufficient to defray all or 50 percent of EPA's costs to conduct such risk evaluations. The fee provision is a clear acknowledgment by Congress that additional resources would be needed in order for EPA to conduct industry-requested risk evaluations. Coupled with the concern that EPA's conduct of such risk evaluations not interfere with risk evaluations EPA initiates on its own – a concern reflected in multiple provisions in the law that limit or condition industry-requested risk evaluations [see sections 6(b)(4)(C) and (E)] – it only makes sense that EPA not initiate such risk evaluations until it receives the requisite fees as they are best estimated by EPA at that time.<sup>2</sup>

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<sup>2</sup> To the extent that fees are individually assigned to specific risk evaluations based on their expected resource needs, any adjustments to reflect higher or lower actual resources expended could be made at the conclusion of the risk evaluation.

To ensure it is developing and sustaining the capacity (including sufficient personnel, contractors, etc.) required to conduct such risk evaluations, EPA will need to be able to budget and plan prospectively – which in turn requires, or would at least be aided substantially, by having received the fees prior to initiating the requested risk evaluations.

EPA's risk evaluation and fee rules should require receipt of applicable fees prior to initiating such risk evaluations.

**4. Companies should not be allowed to pay a higher fee in order to expedite EPA's review of its new or existing chemical.**

Some industry representatives have suggested that a company should be able to pay a higher fee in exchange for a speedier review by EPA of its chemical. EDF strongly opposes this concept. First, for industry-requested risk evaluations, the law expressly forbids such expedited or other special treatment [see section 6(b)(4)(E)(ii)]. Second, it suggests that EPA's mission is somehow to provide a service to a company in exchange for the fee, rather than protect human health and the environment. Third, the suggestion raises clear equity concerns with respect to small businesses, because companies with more resources could "buy their way to the front of the line."

EPA's fee rule should not allow companies to gain a speedier review by EPA of its chemical or other special treatment through payment of a higher fee.

**5. EPA should impose fees on companies to help defray its costs of requiring testing and managing information received in response to testing requirements under section 4.**

Some in industry have argued that EPA should not assess fees on companies subject to testing requirements under section 4, because those companies are already responsible for paying the costs of the testing itself. EDF opposes this proposal.

First, EPA has real costs arising from implementing section 4 requirements, including costs of developing rules or orders, negotiating consent agreements, and collecting, managing, and providing access to information received pursuant to required testing.

Second, Congress made clear in TSCA that companies should bear the burden of developing information needed to assess the safety of their chemicals. Section 2(b)(1) of TSCA states:

It is the policy of the United States that ... adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that *the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures ...* . [emphasis added]

The fact that companies are being held to that responsibility – which was only rarely the case under the old law due to onerous burdens that EPA had to meet to require testing – should in no way “exempt” them from the clear intent of the provisions of section 26(b) that companies pay to defray a portion of EPA’s costs of implementing TSCA, specifically including its costs of administering section 4.

EPA’s fee rule should include fee requirements for companies subject to testing requirements under section 4. In addition, all of the associated costs to EPA – including costs of developing rules or orders, negotiating consent agreements, and collecting, managing, and providing access to information received pursuant to required testing – need to be included in the baseline budget on the basis of which the overall level of fees is to be determined.

**6. EPA should impose fees on companies to help defray its costs of reviewing and processing exemption notices required to be submitted under section 5.**

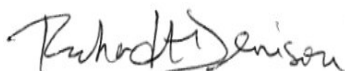
Some in industry have argued that EPA should not assess fees on companies submitting exemption notices for new chemicals under section 5. EDF disagrees: Real costs are expended by the Agency to review and process those applications. While those costs may be lower than for many PMN reviews, that fact should be reflected in a lower fee— not no fee at all.

The law is clear on this point: EPA is to collect fees to help defray its costs of administering section 5, not only specific parts of section 5. And fees are to be paid by “any person required to submit a notice or other information to be reviewed by the Administrator under section 5.” [section 26(b)(1)]

EPA’s fee rule should include fee requirements for companies submitting required exemption notices under section 5. In addition, all of the associated costs to EPA for reviewing and managing such notices need to be included in the baseline budget on the basis of which the overall level of fees is to be determined.

EDF appreciates the opportunity to provide these comments to the Agency as it develops this important rule.

Sincerely,



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