United States Environmental Protection Agency

Toxic Substances Control Act (TSCA)

Fee Requirements and Processes for EPA-Initiated Risk Evaluations

April 16, 2020

Overview

- Background on:
  - TSCA Fees Rule
  - EPA-Initiated Risk Evaluations and
  - Risk Evaluation Fees
- Recent Announcement and “No Action Assurance”
- Entities Subject to TSCA Fee Requirements
- Identification of Fee Payers
- Reporting in CDX
- Payment through Consortia
- Fee Payment Calculation and Invoicing
- Next Steps

BACKGROUND: TSCA FEES RULE

- 2016 amendments to TSCA provided EPA with expanded authority to collect fees to help defray a portion of the costs associated with overall TSCA implementation efforts – including the costs of EPA-initiated risk evaluations
- TSCA required EPA to establish the new fee structure by rule - finalized October 2018.
- TSCA fees for:
  - Test rules and orders under TSCA section 4
  - New chemical notices and exemption applications under TSCA section 5
  - Manufacturer-requested risk evaluations under TSCA section 6, and
  - EPA-initiated risk evaluations under TSCA section 6

BACKGROUND: EPA-INITIATED RISK EVALUATIONS

- In December 2019, EPA finalized high-priority designations for 20 chemicals, initiating the risk evaluation process for each of those chemicals
- TSCA risk evaluations involve development of:
  - a scoping document that identifies the hazards, exposures and conditions of use that EPA expects to consider,
  - an assessment of those hazards and exposures,
  - a characterization of any risks and
  - a risk determinations, which may or may not lead to additional risk management actions
- TSCA risk evaluations to be completed within 3 years with a possible 6-month extension

Risk Evaluation Fee

- Total fee amount per EPA-initiated risk evaluation is $1.35 million
- Responsible payers identified through the current process share the total fee amount, generally on a per capita basis
- “Small business concerns” receive 80% discount
- Option for fee payers to pay individually or to form/join consortia of multiple payers

Recent Rulemaking Announcement

- EPA released Preliminary Lists of manufacturers of each of the 20 high-priority substances undergoing risk evaluation in January 2021
- Following that release, stakeholders raised concerns regarding practical challenges of complying with the self-identification requirements associated with the TSCA Fees Rule
- In response, on March 25, 2020, EPA announced its plan to consider proposing exemptions for certain manufacturers subject to EPA-initiated risk evaluations that:
  - Import the chemical substance in an article;
  - Produce the chemical substance as a byproduct; or
  - Produce or import the chemical substance as an impurity.
- EPA expects to begin this rulemaking process in the very near term with the goal of finalizing a rule by October 1, 2021

"No Action Assurance"

- As a bridge to the final revised rule, EPA issued a "No Action Assurance" for these same three categories of manufacturers subject to TSCA fee requirements for the 20 ongoing EPA-initiated risk evaluations:
  - Import the chemical substance in an article;
  - Produce the chemical substance as a byproduct; or
  - Produce or import the chemical substance as an impurity.
- EPA will not pursue enforcement action against entities in the three categories of manufacture for failure to self-identify under 40 CFR 700.45(b)(5)
- A copy of the "No Action Assurance" and the associated request can be found on EPA's website: https://www.epa.gov/tsca-fees/information-plan-reduce-tsca-fees-burden-and-no-action-assurance

Implications of Announcement and NAA

- The recent rulemaking announcement and "No Action Assurance" effectively changed the Agency's expectations for reporting during the current period that closes on May 27, 2020
- Reporting implications for manufacturers in those three categories are discussed later in this presentation
- CDX system has been modified to accommodate these changes
- New FAQs on EPA's website also address the common scenarios: https://www.epa.gov/tsca-fees/frequent-questions-about-tsca-fees-epa-initiated-risk-evaluations

Entities Subject to TSCA Fee Requirements

Requirements apply to:

- Manufacturers of the high-priority chemical under TSCA (i.e., those who manufacture, produce or import the high-priority chemical)

Requirements do NOT apply to:

- Processors and downstream users who do not otherwise manufacture/import the chemical
- Domestic manufacturers of products that might incorporate the high-priority chemical into a product, but who do not actually produce or import the high-priority chemical itself

Entities Subject to TSCA Fee Requirements

Exemptions

- There are no exemptions in the current rule for specific groups of manufacturers or importers, or for specific types of manufacturing activities
- However, EPA recently announced intention to propose exemptions via rulemaking for three categories of manufacturers:
  - Import of the chemical substance in an article;
  - Produce of the chemical substance as a byproduct; or
  - Produce or import the chemical substance as an impurity.

Entities Subject to TSCA Fee Requirements

Statutory Exclusions

- Certain chemical manufacture/import activities excluded from TSCA jurisdiction and therefore not subject to TSCA Fees Rule requirements
  - TSCA Section 3 - Chemicals manufactured for use solely as a food, food additive, drug, cosmetic, tobacco product, pesticide, and special nuclear materials are not "chemical substances" under TSCA.
  - TSCA Section 12 – Chemicals manufactured solely for the purpose of export from the United States consistent with TSCA section 12(a), unless EPA has found the chemical presents an unreasonable risk

Identification of Fee Payers

Process to Identify Fee Payers

- To assign fees for EPA-initiated Risk Evaluations, EPA must undergo a process to identify manufacturers of the high-priority chemical. The process includes:
  - Publication of a preliminary list;
  - A requirement for all manufacturers to self-identify;
  - Period of public comment and opportunity for correction; and
  - Publication of a final list.
- This process for the 20 EPA-Initiated Risk Evaluations is already underway

Identification of Fee Payers

The Preliminary Lists

- In January, EPA published preliminary lists of manufacturers/importers associated with each of those chemicals and opened a 60-day period for self-identification and public comment
- Comment/Reporting period extended to May 27, 2020
- EPA used publicly-available reporting data from EPA's Chemical Data Reporting (CDR) rule and the Toxics Release Inventory (TRI) to develop the lists
- EPA anticipates that these Preliminary Lists may be underinclusive or contain errors, and expects to use information received during the comment/reporting period to develop comprehensive and accurate Final Lists of responsible fee payers

Identification of Fee Payers

Self-Identification and Other Certifications

- The TSCA Fees Rule at 40 CFR 700.45(b) requires all manufacturers of a high-priority chemical to self-identify – irrespective of whether or not they were identified on a preliminary list.
- Purpose of this reporting is to inform EPA's development of the Final Lists of responsible fee payers
- All responses must be reported in EPA's Central Data Exchange (CDX) system.
  - Self-Identify as a Manufacturer
  - Certify as to "No Manufacture" or "Cessation" to avoid fee obligation
  - Certify as "Small Business Concern" to reduce fee obligation

Identification of Fee Payers

Response Options*

- **Self-Identification - 40 CFR 700.45(b)(5):** I represent a company that is a manufacturer or importer of the chemical substance subject to this Risk Evaluation Activity. I understand the fee obligation for this activity.
  - The company was included on the Preliminary List.
  - The company was not included on the Preliminary List.
- **Certification of No Manufacture - 40 CFR 700.45(b)(5)(iii):** I represent a company that was or was not included on the Preliminary List. I certify that the company EITHER has not manufactured or imported the chemical substance subject to the Risk Evaluation Activity at any point in the five-year period preceding publication of the Preliminary List, OR falls into one or more of the following categories: (1) imports the chemical in an article, (2) produces the chemical as a byproduct, or (3) produces or imports the chemical as an impurity.
  ***Based on this certification, the company should not be included on the final list of responsible fee payers subject to fee obligations for this activity.
- **Certification of Cessation - 40 CFR 700.45(b)(5)(ii):** I represent a company that was a manufacturer or importer of the chemical substance subject to this Risk Evaluation Activity, and either was or was not included on the Preliminary List. I certify that the company has ceased manufacturing/importing the chemical substance prior to initiation of the prioritization process for the chemical substance (March 21, 2019) and further certify that the company will not manufacture or import the chemical substance again for at least five years from the date of this certification. The company is not subject to fee obligations for this activity.

Identification of Fee Payers

Certifications to Avoid Fee Obligations

"No Manufacture"

- Allows mistakenly identified companies to correct errors on the Preliminary List and avoid fee obligations
- No manufacture within 5 years preceding publication of the Preliminary List
- Recently modified to accommodate response from manufacturers in the 3 categories impacted by the announcement/NAA who were identified on a preliminary list or who had already self-identified

"Cessation"

- Allows avoidance of fee obligations for manufacturers who have ceased manufacturing prior to the cutoff date in the rule (i.e., the date prior to initiation of the prioritization process for the high-priority chemical undergoing risk evaluation) and will not manufacture 5 years into the future from the date of the certification

Identification of Fee Payers

Reporting & Recent Announcement/NAA

- For those in the three categories of manufacturers affected by the recent announcement and "No Action Assurance," reporting action depends on the circumstances:
  - If not on a preliminary list and not yet self-identified in CDX
    - No action expected
  - If on a preliminary list, but have not yet self-identified in CDX
    - Respond with "No Manufacture" which now includes new language on the three categories
  - If already self-identified in CDX
    - Amend response to "No Manufacture" which now includes new language on the three categories
- Entities not identified on the Final Lists will not be responsible for paying a portion of the Risk Evaluation fee.

Identification of Fee Payers

Certification to Reduce Fee Obligation

- Those who are able to certify as a "small business concern" in CDX will receive an approximate 80% reduction in the fee obligation
- Defined in TSCA Fees Rule at 40 CFR 700.43, and modeled on SBA's small business standards
- To qualify, the number of employees (including employees of all parent companies and subsidiaries within the corporate chain) must not exceed the size threshold for the applicable industry
- Does not require submission of supporting documentation
- Additional information available on TSCA Fees Website here: https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses

Identification of Fee Payers

The Final Lists

- After considering responses from the manufacturers and importers in CDX and any other public input, EPA will develop the Final Lists of responsible fee payers.
- Entities identified on a Final List will be responsible for paying a portion of the Risk Evaluation fee for that chemical.
- EPA will publish those lists no later than concurrent with publication of the final risk evaluation scoping documents, or by ~June 2020.

REPORTING IN CDX

- Link to CDX: https://cdx.epa.gov/
  - Also available on TSCA Fees website – www.epa.gov/tsca-fees
- Resources within CDX
  - How to register a new account in CDX
  - Helpful FAQs
  - CDX Helpdesk
  - General CDX User Guide
- Resources on TSCA Fees Website
  - Step-by-step instructions for completing self-identification and other certifications
  - Step-by-step instructions for amending initial response
  - "Risk Evaluation Rule" CDX User Guide
  - "Frequent Questions"

PAYMENT THROUGH CONSORTIA

- Companies may pay individually or through a consortium of fee payers.
- Formation of a consortium is not a requirement, but it is something that EPA welcomes as it could create efficiencies for both the Agency and consortia members
- Allows consortia members to determine an equitable allocation of fee responsibility amongst membership
- Rule requires that EPA be notified of formation of a consortium (and the names of its members) within 60 days of publication of the final scope of risk evaluation, or by ~August 2020.

Payment Calculation

- For manufacturers that are not part of a consortium, the total fee for EPA-Initiated Risk Evaluations is shared amongst identified manufacturers on a per capita basis, with discounts for small businesses
  - Formula for allocating the fee amongst payers is specified by rule
  - Does not consider factors like production volume or market share
- Individual amounts each entity is responsible for will vary depending on the total number of fee payers identified, and the number of small v. non-small businesses
- Example:
  - 100 manufacturers identified on final list
    - Base fee of $13,500 for each ($1.35m total fee amount/100)
  - 10 of 100 manufacturers are “small business concerns”
    - Adjusted fee of $2,700 each (80% discount off the base fee)
  - 90 of 100 manufacturers are not “small business concerns”
    - Adjusted fee of $14,700 each (per capita share of remainder of total fee - $1,323,000)

INVOICING

- EPA expects to begin sending invoices – through CDX - shortly after the close of opportunity to form a consortium in ~August 2020
  - Because fee amounts are dependent on the number and membership of consortia – this is the earliest possible date EPA can begin invoicing
- Payment due 120 days from the publication date of the final scope of the risk evaluation, or by ~October 2020
- Payments are made within the CDX system

Next Steps

- Timeframe for Self-Identification and Certifications
  - Closes May 27, 2020
- Rule Updates/Amendments
  - EPA expects to initiate that process in very near future
- Publication of Final Lists
  - No later than concurrent than publication of final risk evaluation scoping documents, or ~ June 2020

Additional information:

https://www.epa.gov/tsca-fees