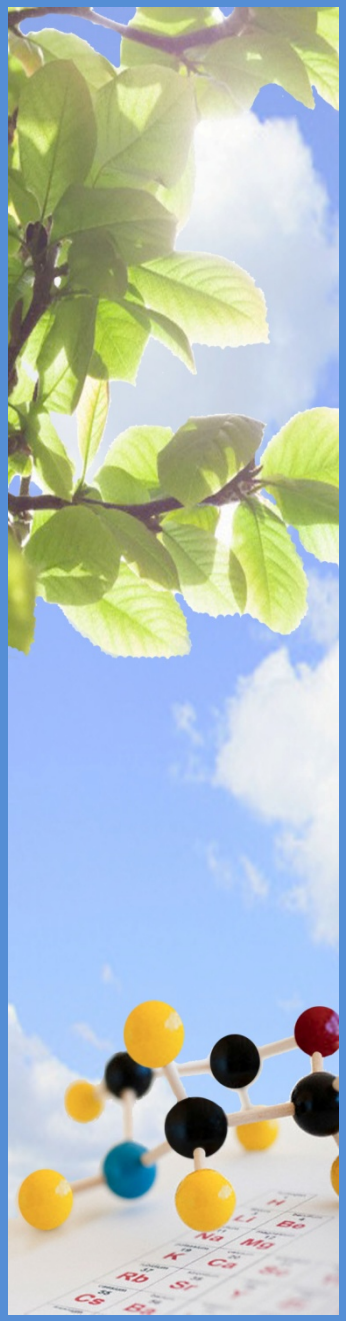


United States Environmental Protection Agency

Consultation to Obtain Input on the New TSCA Provision to Collect Fees

August 11 – 12, 2016

The New Law

- The "Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed by the President and went into effect on June 22, 2016
- Amends and updates the Toxic Substances Control Act of 1976
- Passed by large bipartisan margins in the U.S. House and Senate
- Received broad stakeholder support

Funding Source

- Provides new funding source of up to 25% of costs to carry out Sections 4, 5, 6 and 14 or $25 million (whichever is lower) in annual user fees, supplemented by Congressional appropriations
  - *Old TSCA, 1976 – Cap on individual user fees at $2,500, and limited fee collection authority*
- Section 26(b)(4)(E) of TSCA requires EPA to consult:
  - with "parties potentially subject to the fees or their representatives"
  - "prior to the establishment or amendment of any fees"

Consultation Meeting

- Purpose:
  - To consult with manufacturers and processors potentially subject to the fees, or their representatives
  - To inform the development of a proposed rule on the establishment of fees under TSCA
    - Proposed rule: December 2016
    - Final Rule: June 2017

Comments provided orally at this meeting, as well as comments submitted to docket EPA-HQ-2016-0401 will be considered

- Written comments should be submitted by August 24, 2016

Desired Outcomes

- Industry understanding of the types of activities associated with TSCA Sections with authorized cost defrayment
- EPA understanding of industry considerations
- Industry dialogue on approaches for fee responsibilities
- Clear expectation of procedural rule timeframe

AGENDA

- **Thursday, August 11**
  - Introduction
  - Review of Statute Authorities
  - Review of Activities Associated with Sections 4, 5, 6 and 14
  - Questions for Industry to Consider
  - Open the floor for Industry comments
- **Friday, August 12**
  - Opening
  - Review of Consultation Input, Day 1
  - Industry Comments/Proposals
  - Next Steps & Close of Meeting

REVIEW OF STATUTE AUTHORITIES

FEES - GENERAL

- In setting fees, EPA shall--
  - prescribe lower fees for small business concerns
  - set the fees at levels such that the fees will, in aggregate, provide a sustainable source of funds

Fees - Collection

- EPA has authority to collect fees from manufacturers and processors who:
  - Are required to submit test data (§4);
  - Submit notification of or information related to intent to manufacture a new chemical or new use of a chemical (§5);
  - Manufacture or process a chemical substance that is subject to a risk evaluation (§6); or
  - Request EPA to conduct risk evaluation on an existing chemical (§6)

Fees - Use

- Fees are to annually defray the lower of--
  - 25 % of the costs of carrying out sections 4, 5, 6 and 14 (CBI) responsibilities for chemical substances under this title; or
  - $ 25,000,000

Fees - Manufacturer-Requested Assessment

- Allows for manufacturers to request that EPA evaluate specific chemicals, and pay costs as follows:
  - For chemicals on the TSCA Workplan, manufacturers pay 50% of costs of risk evaluation;
  - For all other chemicals, manufacturers pay 100% of costs of risk evaluation

Fees

- Fees must be set via rulemaking

- Goal – publish proposed rule by mid-December 2016 and final rule by mid-June 2017

Sections 4, 5, 6 and 14

REVIEW OF ACTIVITIES

Section 4: Testing of Chemical Substances & Mixtures

- Provides authority by rule, order, or consent agreement to require testing and the development of new information

SECTION 4 - ACTIVITIES

- Activities include but are not limited to:
  - Order/Rule Development
  - Test Plan Review
  - Data Analysis
  - Data Management
  - Transparency
  - Confidential Business Information

Section 5: Manufacturing & Processing Notices (New Chemicals)

- Section 5 of TSCA requires notice be provided to EPA before initiating manufacture (this includes import) of:
  - a new chemical substance or
  - a significant new use of a chemical substance
- Amended TSCA requires affirmative determinations for all notices EPA reviews
- Risk Management action as needed

SECTION 5 – NOTICES & INFORMATION

Examples of notices or other information:

- Pre-Manufacture Notices (PMNs)
- Exemption Notices:
  - Low Volume Exemptions (LVEs)
  - Test Marketing Exemption Applications (TMEAs)
  - Low Release/Low Exposure Exemption (LoREX)
- Biotechnological related submissions, such as:
  - Microbial Commercial Activity Notice (MCAN)
  - TSCA Experimental Release Application (TERA)
- Exemption Modifications
- Test/Exposure Data (follow-up)
- Notices of Commencement (NOCs)
- Significant New Use Notifications (SNUNs)

SECTION 5 – RISK MANAGEMENT ACTIONS

Examples of Risk Management Actions:

- Determination of Not Likely to Present Unreasonable Risk
- Section 5(e) Consent Orders
  - Significant New Use Rules (SNURs) following Section 5(e), Consent Orders
- SNURs following PMN Review
- Voluntary testing actions
- PMNs withdrawn in face of action
- Action to grant or deny Exemption

Section 5 – Activities

- Activities include but are not limited to:
  - Notice Review/Data Analysis
  - Affirmative Determination
  - Development/Refinement of Analytical Tools
  - Order/Rule Development/Risk Reduction
  - Data Management
  - Transparency
  - Confidential Business Information

Section 6: Prioritization, Risk Evaluation & Regulation

- Risk Evaluations:
  - Within 3.5 years, EPA must have 20 risk evaluations ongoing at all times
  - Manufacturer requested, capped at 25% - 50% of ongoing reviews (e.g., if EPA is evaluating 20 high priority chemicals, an additional 5-10 industry petitioned evaluations could proceed in parallel)
- Risk Management:
  - For unreasonable risk determination, propose regulation NLT 1 year and issue final NLT 2 years after final risk evaluation published

SECTION 6 – ACTIVITIES

- Activities include but are not limited to:
  - Prioritization – high & low
  - Risk Evaluation – Data gathering, Data analysis, Unreasonable Risk
  - Rule Development/Risk Management – Data gathering, Data analysis
  - Data Management
  - Transparency
  - Confidential Business Information
  - Development/Refinement of Analytical Tools
  - Peer Review, as appropriate

Section 14: Confidential Information

- Statutory requirements include but are not limited to:
  - In 90 days review all CBI claims for chemical identity and make a determination
  - In 90 days review a representative 25% for most other CBI claims
  - 10 year claim period unless reasserted
  - After Inventory Active list set, review chemical identity claims within 5 years

Section 14 – Activities

- Activities include but are not limited to:
  - CBI docket
  - Data Management specifically for receiving and managing CBI data
  - Tracking and notification for reassertion of claims
  - Claims Reviews
  - Transparency, as appropriate
  - Disclosure to authorized persons, including States
  - Clearance and Security

Sections 4, 5, 6 and 14 – Indirect Costs

- Indirect Costs may include but not limited to:
  - Agency infrastructure
  - Office of Inspector General – support fees audit function
  - Office of General Counsel

WHAT IS EPA CONSIDERING IN REGARDS TO FEE COLLECTION?

CONSIDERATIONS

- EPA has discretion to establish fees based on different factors
  - After consultation with parties potentially subject to fees
- Fee structure should not be complicated
- Fee structure must take into account factors such as:
  - the costs to EPA of carrying out activities
  - lower fees for small businesses
- Fee structure should defray, as appropriate, 25% of costs for administering Sections 4, 5, 6 and 14

WE WANT TO HEAR FROM YOU

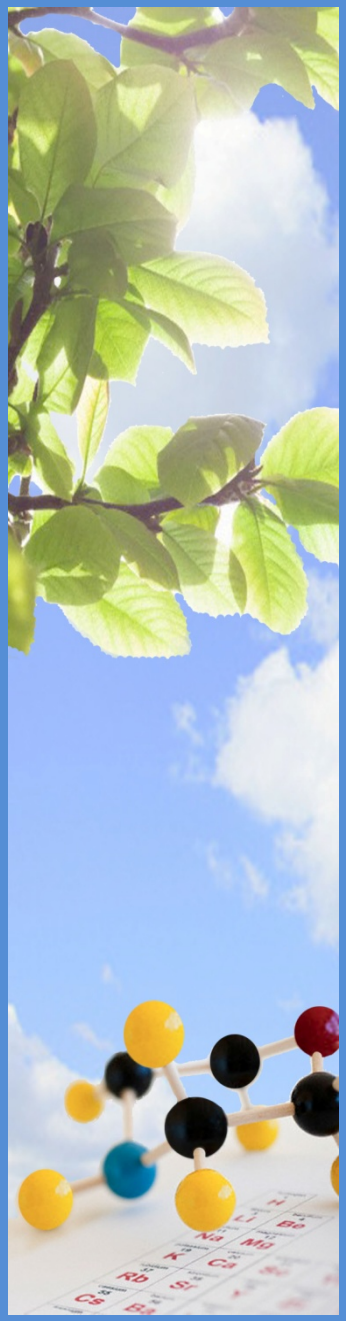
QUESTIONS

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

- Does industry have thoughts on the types of factors (types of submissions, numbers of submissions, level of difficulty, etc.) that EPA should consider when structuring the fees?

QUESTIONS

- Has industry considered how to distribute payment amongst multiple manufacturers and/or processors?
- Does industry have thoughts on how to identify the whole universe of manufacturers, including importers, and processors affected?
- Does industry have thoughts on how to arrive at an appropriate balance between manufacturers and processors?



United States Environmental Protection Agency

Meeting to Obtain Input on the New TSCA Provision to Collect Fees

EPA will consider comments submitted to docket

EPA-HQ-OPPT-2016-0401

Submit comments at www.regulations.gov by August 24, 2016.