TSCA Reform, Ready for Prime Time?

April 16, 2015

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The TSCA Reform Center is dedicated to tracking legislative and regulatory efforts to reform the Toxic Substances Control Act. The TSCA Reform Center monitors and reports on the important trends that influence policy development at the federal and state level. Check here for the latest information on TSCA, the California Green Chemistry Initiative, and green chemistry initiatives elsewhere.
Keller and Heckman is proud to present a seminar designed by its attorneys and scientists that focuses on relevant TSCA, food-contact substances and FDA regulated products. Regulatory and legal professionals new to the field will learn the basic rules and regulations of these areas. Those with existing knowledge can use this seminar to keep up-to-date on the latest developments.

Dates:
- Tuesday, May 5, 2015: Basic TSCA Seminar
- Wednesday, May 6, 2015: Food-Contact Substances
- Thursday, May 7, 2015: FDA Regulated Products

For additional information, please contact:
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Join Keller and Heckman's attorneys and scientists October 27-28, 2015 in Washington, D.C. for a comprehensive Chemical Control Law Seminar. This two-day seminar is designed for regulatory and legal professionals involved with issues arising under the Toxic Substances Control Act (TSCA) and similar international chemical control laws. Registration will be open soon. A notice will be sent to all attendees of this webinar once registration is open.
Today’s Agenda

- **Part 1** – Review the key provisions and ramifications of S.697  
  *Presented by Thomas Berger and Herb Estreicher*

- **Part 2** – Provide detailed insights regarding specific areas which will impact U.S. and foreign companies, including:
  - **Safety Standard and the Use of Best Science**  
    *Presented by Peter de la Cruz and Martha Marrapese*
  - **State/Federal Preemption**  
    *Presented by Eric Gotting*
  - **Confidential Business Information**  
    *Presented by David Sarvadi*
  - **Fees**  
    *Presented by John Dubeck*

- **Part 3** – Question and Answer Session  
  *Please type your questions into the chat box*
Biographies

Thomas Berger, Partner  
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Tom Berger has extensive experience in representing foreign and domestic companies, large and small, in a broad range of areas, including counseling, advocacy, and rulemaking in environmental law, occupational safety and health law, contracts, EPA enforcement proceedings, and chemical and product liability management.

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Peter de la Cruz has over 25 years of experience advising clients on antitrust, trade association and regulatory matters. His focus is on chemical regulations, compliance strategies for environmental regulations and product stewardship.
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John Dubeck's scientific background (chemical engineering and nuclear propulsion systems) assists him in his largely science-based practice, representing clients and trade associations before the Food and Drug Administration, U.S. Department of Agriculture and the Environmental Protection Agency (toxic substances and pesticides).

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Herbert Estreicher, Ph.D. has a broad practice in international environmental regulatory law. Dr. Estreicher has an interdisciplinary approach combining law and science. He represents leading manufacturers of chemicals, pesticides, insect repellents, food additives, and consumer products before Federal and State regulatory agencies.
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Eric Gotting serves as a partner in the firm's litigation and environmental practice groups specializing in complex civil and appellate matters, with a focus on toxic tort, environmental, and corporate litigation.

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Martha Marrapese facilitates the registration of new technologies in the global economy with a particular emphasis on biotechnology and nanotechnology applications. Ms. Marrapese has an expertise in the Toxic Substances Control Act and its counterparts in Canada, the European Union, and China, and she provides counsel related to the Center for Veterinary Medicine clearances and other associated regulatory needs.
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David Sarvadi practices in the areas of occupational health and safety, toxic substance management, pesticide regulation, employment law, and product safety. Mr. Sarvadi represents clients before a variety of federal and state enforcement agencies in legal proceedings involving OSHA citations, EPA Notice of Violations, TSCA consent orders, CPSC Notices, FIFRA Stop Sale Use and Removal Orders, and EEOC Charges of Discrimination.
Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depends on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors’ alone and not those of the authors’ clients.
INTRODUCTION

- Introduction of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S.697) has certainly sparked renewed and earnest discussion about TSCA Reform
- As reported in the press, the bill has been endorsed by key trade associations and environmental groups as worthy of passage, with the tenor of those remarks suggesting that the Act represents a reasonable step forward
- Today’s webinar, however, is not focused on political speculation, but an assessment of the statutory language
- We are basing our comments on the proposed statutory language, and our experience with the existing statutory language of TSCA
- We seek to answer a basic question: How would it work, and what are the key issues if enacted in its current form?
- Our analysis does not answer the question of whether the bill is good or bad, because that judgment depends on your individual perspective and interests.
Key Provisions and Ramifications of S.697

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TSCA is an OLD Statute

- TSCA (1976) – Main Title Never Amended
- OSH Act (1970) – Also Never Amended
- Food & Drug Act (1938) – Last Major Amendment (2011)
- CPSA (1972) – Last Major Amendment (2008)
- CAA (1963) – Last Major Amendment 1990
- CERCLA (1980) – Last Major Amendment 1986
- CWA (1972) – Last Major Amendment 1987
- FIFRA (1910) – Last Amended 2007
- RCRA (1976) – Last Major Amendment 1984
- SDWA (1974) – Last Major Amendment 1996
Dealing with the Legacy of the Past

- Grandfathering of Existing Chemicals on National Chemical Inventories
- Canada – DSL Categorization (2006+)
- EU REACH (2007+)
- Australia – Existing Chemical Program (ECP)(2007+)
- Japan, Korea, Taiwan
- Where Does the U.S. Stand?
How Would S. 697 Deal With the Legacy of the Past?

- Identifies chemicals in commerce (manufactured or imported during the past 10 years)
- Prioritize into high priority and low priority
- Call-in data to fill gaps
- Assess high priority chemicals without overwhelming Agency or societal resources
- Regulate chemicals that do not meet the safety standard (S/S)
Safety Standard and Science Based Decision-making

- New safety standard of “no unreasonable risk of harm to health or the environment from exposure to a chemical substance under the conditions of use,” including no unreasonable risk to sensitive populations.
- Costs and benefits not to factor into safety assessments or safety determinations.
- EPA to develop any necessary policies, procedures and guidance no later than two years after enactment. These are to be reviewed and updated every five years to reflect emerging science.
- Policies, procedures and guidance are to address testing, safety assessments and determinations, use of science in decision-making, as well as policies aimed at reducing animal testing.
- Establishes a new Scientific Advisory Committee on Chemicals to provide EPA independent scientific advice.
Risk-based Prioritization Screening Process

- Requires EPA to establish a risk-based prioritization screening process, by rule, within one year of enactment.
- EPA to designate active substances as high or low priority for safety assessment and determination.
- Must establish an interim list of at least 10 high and 10 low priority substances within 180 days of enactment, drawing on the existing TSCA Work Plan Chemicals list.
- Within 3 years of enactment, EPA is to have designated at least 20 high priority and 20 low priority chemicals.
- No later than 5 years after enactment, a total of 25 high priority and 25 low priority substances are to have been designated.
- As the safety assessment and determination process is completed for each high priority substance, it must be replaced by a new high priority chemical.
Prioritization screening process

- Lack of information is a sufficient basis to designate a substance as a high priority.
- States to have input in the prioritization process and may seek judicial review of EPA decisions to designate a substance as a low priority.
- EPA decisions to designate a substance as a low priority must be based on information sufficient to establish that the substance is likely to meet the safety standard.
- Prioritization screening decisions are subject to public notice and comment.
- Prioritization screening decisions may be postponed where development of additional information is needed, which EPA may request or require.
- The prioritization screening process is subject to review and modification every 5 years.
- Manufacturers may request that EPA designate a substance as an “additional priority” for safety evaluation, subject to the payment of 100% of the costs. No more than 15 percent of the total number of chemicals in the safety evaluation process can be designated under this approach.
Filling Data Gaps

- Authorizes EPA to obtain new information on chemical substances at all stages of the safety evaluation process.
- EPA can mandate new testing by rule, order, or consent agreement.
- EPA must strive to minimize the use of animals in testing.
- Data sharing for fair and equitable reimbursement to avoid duplicative testing.
- In order to avoid unnecessary testing, the data set may be tailored to specific chemicals or category of chemicals.
Safety Assessment and Determinations (Section 6)

- EPA to conduct a safety assessment and safety determination for all high priority substances under strict deadlines.
- Within 6 months of designation as a high priority, EPA must define the scope of the assessment and determination, including the conditions of use that will be evaluated.
- Safety assessments and determinations must be completed within 3 years of designation as a high priority.
- If EPA finds a chemical does not meet the safety standard, risk management measures must be imposed within 2 years subject to extension for an aggregate period not to exceed 2 years upon showing of cause.
- If the safety standard cannot be met through risk management measures, EPA is authorized to ban or phase out the substance, subject to public notice and comment. Cost and technical feasibility are to be considered only in the choice of the risk management measure but least burdensome regulatory requirement of existing TSCA Section 6 is eliminated.
The “Heart” of TSCA

- Section 5 – PMNs and SNURs
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
Section 5 – PMNs and SNURs

- 5(a) – PMNs and SNUNs
- 5(b) – Submission of test data
- 5(c) – Extension of notice period
- 5(d) – PMN contents, FR notices
- 5(e) – Regulation
- 5(f) – Unreasonable risks
- 5(g) – Reasons for not taking action
- 5(h) – Exemptions
- 5(i) – Commercial purposes
Section 5(d)

- Within 90 days of receipt of §5 notice, EPA must conduct initial review and make §5(d)(3) determination
  - Can extend review period (RP) for “good cause” but no more than 90 additional days (except §5(d)(5))

- §5(d)(3) – before end of RP, EPA must determine that
  - (A) Substance or SNU is not likely to meet S/S
    - Must take §5(d)(4) action
  - (B) Substance or SNU is likely to meet S/S
    - RP must end, no restrictions, NOC upon commencement
  - (C) Additional information required (§5(d)(5))
Section 5(d)(3)(A) – “Not Likely”

- If §5(d)(3)(A) determination made then §5(d)(4) requires that
  • Before end of RP, by consent agreement or order “as appropriate,” EPA must restrict or prohibit substance/SNU such that substance/SNU likely to meet S/S
  • Within 90 days after order/agreement, initiate SNUR rulemaking or publish statement indicating reasons for not promulgating SNUR
  • Subsection (A) restrictions can include labeling, recordkeeping, monitoring/testing, PV restrictions, etc.
  • Prior to adopting restrictions to address workplace exposures, EPA must “consult with” OSHA
Section 5(d)(3)(C) – Insufficient Information

- If 5(d)(3)(C) determination made then EPA:
  - Must provide opportunity for submitter to provide additional information
  - May extend RP by agreement for reasonable time
  - May issue §4 test rule, agreement, or order to require development of information
    – “Pioneer” issue?
  - Must make §5(d)(3)(A) or (B) determination “promptly” upon receipt of information that supports the determination
Section 5(h) - Exemptions

- Conforming amendments made
- 5(h)(4) exemptions (e.g., “polymer” and “low volume” exemptions) need not be promulgated in accordance with §§6(c)(2) and (3)
  - NPRM, hearings, etc.
Section 8 – Recordkeeping and Reporting

- 8(a) – PAIR/Chemical Data Reporting (CDR)
- 8(b) – TSCA Inventory
- 8(c) – Allegations of significant adverse reactions
- 8(d) – Unpublished health and safety studies
- 8(e) – Substantial risk reporting
Section 8(a)

- Within two years of enactment, EPA must promulgate rules to allow EPA to carry out (“new”) §§ 4 and 6
  - May modify earlier promulgated rules
  - May establish different requirements for processors
  - Must take measures to minimize small business impacts
  - Must develop guidance relating to rules
Section 8(b)(3) - Nomenclature

- Must retain “Class” 2 and SDA nomenclature
- Must “treat all components of categories that are considered to be statutory mixtures” as being included on the Inventory
  - Portland cement, frits, ceramics, *etc.*
- If existing guidance permits multiple nomenclature conventions, EPA must maintain them and develop new guidance on equivalency
- For substances on the Inventory “multiple times” must develop guidance recognizing multiple listings as single substance
Section 8(b)(4)-(5) – Active/Inactive Substances

- TSCA §8(b)(1) Inventory = retained(!)
- Within one year of enactment, EPA must require within 180 days reporting by manufacturers, importers, and processors of Inventory-listed substances
  - M, I, or P within 10 years prior to enactment
    - Most recent CDR substances = interim list
    - Can claim as CBI, but EPA must establish by rule a plan to review CBI claims
  - Reported substances become “Active”
    - Others are “inactive,” must notify before non-exempt manufacture, import, or processing
      - Then designated as “active”
Section 8 – Other

- 8(a) – PAIR/CDR
- 8(c) – Allegations of significant adverse reactions
- 8(d) – Unpublished health and safety studies
- 8(e) – Substantial risk reporting

Largely or completely unchanged…
Section 12(a) Export-Only Exemption

- Exemption retained, but cannot be used for substance that EPA determines
  - “is not likely” to meet S/S under §5
  - does not meet the S/S under §6
- For mixtures/articles containing such substances, EPA can make exemption inapplicable or establish threshold concentrations
- EPA can require §4 testing for such substances to ascertain whether S/S met within U.S.
Section 12(b) Export Notification

- Must notify EPA if export or intend to export substance/mixture
  - for which EPA has determined not likely to meet §5 S/S and §5 restriction/prohibition proposed/established
  - for which EPA has determined does not meet §6 S/S and §6 restriction/prohibition proposed/established
  - for which U.S. required by treaty to provide notification
  - subject to restriction/prohibition under rule, order, or consent agreement “in effect” under Act
  - for which submission of information required under §4

- Must promulgate rules to: (a) specify exemptions as appropriate; and (b) indicate whether or to what extent, rules apply to articles
Section 13(a) – Prohibited Imports

- Sec. of Homeland Security must refuse entry of any substance, mixture, or article containing a substance or mixture if:
  - substance or mixture is 6(d) banned
  - substance not on Inventory and not exempt
  - substance, mixture, or article offered for entry in violation of
    - TSCA rule, consent agreement, or order, or
    - order issued in civil action under §7 or Title IV
Section 13(b) – Import Certification

- Must certify to DHS that
  - “after reasonable inquiry and to the best of my knowledge and belief” of the person, the substance/mixture is
    - in compliance with §§ 5 and 6
    - on the Inventory or exempt

- EPA may by rule require 13(b) certification for §5 or §6 rule substances in “articles”
  - Must identify, with reasonable specificity, types/components of articles subject to requirement
    - Must consider utility, risk, impact on commerce, specification of concentration, etc.
Section 13(c) – Notice

- Must notify DHS if imported substance / mixture is
  - High priority substance
  - One for which U.S. is required to provide export-notification by treaty
  - Subject of a §6 safety assessment and determination and has been found to not meet the S/S
Safety Standard and the Use of Best Science

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Safety Standard

Safety Standard “means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of harm to—

“(A) the general population; or
“(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.”
Potentially Exposed or Susceptible Population

Means “one or more groups (A) of individuals within the general population who may be—

(i) differentially exposed to chemical substances under the conditions of use; or

(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.
“SAFETY ASSESSMENT — The term ‘safety assessment’ means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.”

“SAFETY DETERMINATION — The term ‘safety determination’ means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.”
Use of Science

- Requires EPA to “establish policies, procedures, and guidance on the use of science in making decisions . . . .”

- “A goal of the policies and procedures . . . to make the basis of decisions clear to the public.”

- Decisions to be “based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science”
Use of Science

- Use of best available science to include the manner in which EPA deals with assumptions, variability, uncertainty, and validation of the data.
- Based on the “weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information”
- “If appropriate,” consider NAS report on “assessing the hazards, exposures, and risks of chemical substances”
Use of Science

- New EPA materials “shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies”

- Review the adequacy of policies, procedures and guidance every five years
Summary

- No unreasonable risk of harm to health or the environment from exposure to a chemical substance under conditions of use including susceptible or differentially exposed populations
- using a weight of evidence assessment that employs the best available science
- without taking costs into consideration
Federal Preemption

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Preemption 101

- Based on Supremacy Clause
- Various forms of preemption
  - Express
  - Field
  - Conflict
    - Obstacle
    - Impossibility
- TSCA Preemption (Section 18)
  - Limited express preemption
  - Enumerated exceptions
  - State waiver provision
Existing State Laws (Section 18)

- Narrow preemption for prohibitions or restrictions
  - Preserves state actions taken before January 1, 2015
  - No preemption of low priority chemicals
  - Preemption of high priority chemicals
- Broader preemption for . . .
  - Test rules
  - Notification requirements for significant new uses
- Conflict preemption
New State Laws (Section 18)

- Broader preemption for prohibitions and restrictions
  - High priority chemicals at time of safety assessment
  - No preemption of low priority chemicals
- Preemption for . . .
  - Test rules
  - Notification requirements for significant new uses
- Conflict preemption
Exceptions and State Waivers (Section 18)

- **Exceptions**
  - Adopted pursuant to federal law
  - Reporting, monitoring, or information collection requirements
  - Air, water, and hazardous waste management laws

- **State Waivers**
  - Compelling conditions or interests
  - Will not unduly burden interstate commerce
  - Compliance will not cause a violation of federal law
  - Science-based issues
Additional Provisions (Section 4A)

- “Additional Priority” Reviews
  - Manufacturer or processor requests safety review
  - Impact on preemption somewhat limited

- State notification to EPA
  - State laws proposed or enacted after Udall/Vitter adopted
  - Chemicals that have not been designated high priority
  - EPA must make a prioritization decision
  - Highlights patchwork regulation and burdens on interstate commerce
Confidential Business Information

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Current CBI Protection

- **TSCA §14 (a)** no disclosure by EPA of information obtained under TSCA if exempt under FOIA section 552(b)(4)
  - **trade secrets** – e.g., commercially valuable plan, formula, process, or device;
  - commercial or financial information obtained from a person and privileged or confidential
Current CBI Protection

- **Carveouts (i.e., no protection)...**
  - If necessary to protect against an unreasonable risk of injury to health or the environment;
  - § 14(b): subsection (a) does not prohibit the disclosure of:
    (A) any health and safety study which is submitted under this chapter with respect to:
      (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
      (ii) any chemical substance or mixture subject to testing is under TSCA § 4 or notification under TSCA § 5
    (B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in (i) or (ii) above.

  “Nothing in this paragraph authorizes the release of any information that discloses—
  (i) a process used in the manufacturing or processing of a chemical substance or mixture; or
  (ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture”
Proposed Changes to CBI Protection Under S697

- 10 year protection period
  - Unlimited extensions available
  - Burden on information owner
  - Renew substantiation
  - Agency will notify company of looming expiration
  - Administrator can approve or deny request

- Review at any time:
  - EPA requires additional information (section 6(c)(1)(C))
  - For any inactive chemical substance identified under section 8(b)(5)
  - If Administrator determines disclosure of CBI would assist him in conduct safety assessment/determination under section 6(b), 6(c) or rules promulgated under 6(d);
  - No disclosure
    - Protection claim is withdrawn
    - EPA determines information does not meet comply with subsection (d)

- Denial
  - fails to meet the requirements set forth in the statute (subsection (d))
CBI Problems in S697

• Assumptions
  – Information becomes less important as it ages
  – 10-year protection period is sufficient

• Increased administrative costs to both EPA and industry
  – Information owners will find continuous substantiation of CBI is required
  – Unlikely that EPA will have the staff to review all claims
S.697 Proposed Fees

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Self-Funding Government Approvals

- Modern push began with PDUFA – Prescription Drug User Fee Amendments
  - Pushed by industry as a solution to inadequate funding
  - Objective was to reduce review times
  - FDA shares the applicants objective to accelerate time to market of safe and effective therapies (paradigm shift caused by slowness in initially dealing with treatments for HIV patients -- “Dallas Buyers Club”)
  - Specific Performance Goals for Reviewing Applications
  - Periodic Renewal of Legislation is Required
  - Pressure to “Christmas Tree” Renewal Bills has to be resisted
  - 100% of review costs are covered
  - Viewed by Big Pharma as very successful
  - Some fees are collected per facility and per product, but the largest fees are for application review and are paid by the submitter
Self-Funding Government Approvals

- Envy at success of PDUFA resulted in:
  - GDUFA - Generic Drug User Fee Amendments of 2012
  - The key difference from PDUFA is that fees are set to assure specific percentages of program costs come from specific various industry segments
    - Applicants/Manufacturing facilities/Active Ingredient Suppliers
  - As with PDUFA, FDA and industry interests are aligned in providing inexpensive generics
Self-Funding Government Approvals

- PRIA – Pesticide Registration Improvement Act (and its extensions)
- Expanding plethora of fee categories and deadlines
  - Creates a burden on staff to ensure applicants request extensions so deadlines are not missed
  - Despite a lack of common interest, staff accountability for managing deadlines is finally yielding benefits in review times as well
Self-Funding Government Approvals

- **TSCA (1976)**
  - Fees for PMNs set at a max of $2,500
  - Defrays cost; not intended to fund program
  - Limited adjustments to per chemical cost for consolidations, synthetic sequence and small business
  - Fees for Section 4 never implemented
  - While many PMNs drop from review early, extensions are normally required for applications that raise issues
Self-Funding Government Approvals

- **S.697 - The Frank R. Lautenberg Chemical Safety for the 21st Century Act**
- **Sec 23 Administration**
  - Amends TSCA section 26.
    - Funds 25% of cost (not to exceed $18 Million) of:
      - Controlling access to confidential information
      - Review of Notices
      - Prioritization decisions
      - Section 6(d) safety assessments and related rulemaking
    - Funds 100% of costs for additional priority substances under section 4A(c).
S.697 Additional Fee Factors

Fees should take into account:

- Small Business status
- Appropriate balance in assessment between manufacturers and processors after consultations that will not be subject to the Federal Advisory Committee Act
- Adjust fees as needed every 3 years
- Adjust or waive fees on account of differing circumstances.
  - Unclear if this is only by rule or ad hoc
S.697 Activities Subject to Fees

- Fees to be established by rule within 1 year
- Fees for specific events:
  - Notifications under section 5
  - Identifying a substance as active
  - Activating an inactive substance
  - Reporting information under section 8
- Fees for manufacturing or processing a chemical substance subject to a safety determination pursuant to section 6.
  - A tax on handling section 6 regulated substances?
S.697 TSCA Implementation Fund

- No fees can be collected if appropriations for OPPT are less than FY2015
- Fee Authority expires in 10 years
- Periodic auditing to review, *inter alia*,
  - compliance with the deadlines in section 6

Note that although fees are collected for PMN submissions, there is no auditing of compliance with deadlines under section 5. Also, there is no specific fee related to having claimed information as confidential.
S.697 Final Thoughts on Fees

- PMN submitters will face higher fees, but it seems likely that the added funds will need to be spent regulating existing chemicals.
- For new chemicals, the fee paradigm compares favorably to PDUFA, GDUFA and PRIA, i.e., pay for an approval.
- For existing chemicals, the industry is paying to be restricted; a very different paradigm.
- Fee allocation between manufacturers and processors is likely to be contentious.
Question and Answer Session

Thank you for submitting your questions through the chat feature of the webinar software. We will answer as many questions as time permits.
Thank you

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