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PRODUCTS REGULATION

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Key Federal Chemical Use Laws

- Toxic Substances Control Act (TSCA)
  - Regulation of industrial chemicals

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Regulation of pesticides (agricultural chemicals, biocides)

- Both laws rely upon risk-benefit analysis
Many Chemical-Specific Laws

- **Chemical Byproducts Laws**
  - **Clean Air Act (CAA)**
    - Criteria and hazardous emissions from manufacturing facilities
    - Greenhouse gas stationary source requirements
    - Regulation of fuels and fuel additives
    - Restrictions on ozone depleting substances
  - **Clean Water Act (CWA)**
  - **Safe Drinking Water Act (SDWA)**
Many Chemical-Specific Laws (cont’d)

- Chemical Waste and Disposal Laws
  - Resource Conservation and Recovery Act (RCRA)
  - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- Workplace Laws
  - Occupational Safety and Health Administration (OSHA)
    - Workplace Exposure and Hazard Communication Standards
Many Chemical-Specific Laws (cont’d)

- Chemical Transportation Laws
  - Hazardous Materials Transportation Act (HMTA)

- Other Laws Affecting Chemicals
  - Consumer Product Safety Improvement Act (CPSIA)
  - Federal Hazardous Substances Act (FHSA)
  - Hazardous Substances in Household Products

- Department of Homeland Security
    - Chemical Facility Anti-Terrorism Standards (CFATS)
TSCA
TSCA Definitions -- Chemical Substance, Mixture

- TSCA regulates “chemical substances”
  - Some key exclusions: mixtures, pesticides, food additives, drugs, cosmetics, or devices
  - Dual-use chemicals

- A mixture is any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction
  - Each component of a mixture is considered a chemical substance
  - Mixtures are still subject to certain TSCA requirements
Persons subject to TSCA include:

- Manufacturers and Importers -- TSCA imposes most of its requirements on manufacturers. “Manufacture” is defined in TSCA as meaning “to produce or manufacture in the United States or import into the customs territory of the United States.” This broad definition, therefore, includes importers of chemical substances.

- Processors -- Several TSCA provisions, including TSCA Sections 4, 5, 6, 8, and 12(b), can apply to processors of chemical substances.
TSCA Definition -- TSCA Inventory

- Initial TSCA Inventory (1979)
  - Companies informed the U.S. Environmental Protection Agency (EPA) what chemicals were produced at that time
  - These substances referred to as “grandfathered chemicals”

- Current TSCA Inventory
  - Grandfathered chemicals on initial TSCA Inventory PLUS
  - Any new chemical developed and marketed after 1979
    - Subject to EPA New Chemical Review -- Section 5
TSCA Section 5 authorizes EPA to review activities associated with the manufacture, processing, use, and disposal of any new chemical substance before it enters the marketplace -- premanufacture notice (PMN) reporting.

TSCA Section 5 also authorizes EPA to regulate existing chemical substances with significant new use rules (SNUR), which are similar to PMNs.

Section 5 does not require specific testing or minimum data to be submitted.
Section 5 -- Process

Following review of PMN, EPA could

- Determine more data are needed
  - Company can decide to withdraw PMN or develop data and have PMN re-reviewed

- Allow the PMN but impose certain restrictions
- Allow the PMN without any restrictions
- Not allow the PMN

If the PMN is allowed, company submits a Notice of Commencement (NOC)

- At this point, the substance is added to the Inventory; and
- Is no longer considered a “new” chemical
TSCA Inventory

- TSCA Inventory -- A list of all chemical substances that can be manufactured or imported in the U.S. for commercial purposes
  - About 85,000 to 90,000 substances listed
  - Not a reflection of chemicals currently in commerce

- TSCA Inventory status determines whether a substance is “new” or “existing”:
  - New Chemical Substance -- Any chemical substance *not* included on the TSCA Inventory
  - Existing Chemical Substance -- Any chemical substance included on the TSCA Inventory
TSCA -- Information Collection on Existing Chemicals

TSCA Inventory

8(a) Preliminary Assessment Information Rule (PAIR): EPA can collect production, use, and exposure information via rulemaking.

8(a) Inventory Update Rule (IUR): Companies report production, use, and exposure information on substances over threshold every five years.

8(c) Allocations: Companies must retain allegations of adverse effects and submit them to EPA upon request.

8(d) Health and Safety Studies: EPA can collect information on ongoing or existing studies via rulemaking.

8(e) Risk: Companies must immediately report substantial risk information to EPA.
If available information is not sufficient or raises concerns, Section 4 gives EPA authority to require manufacturers to conduct testing on specified chemicals.
TSCA Section 4 -- Overview

- Section 4 allows EPA to require testing on the health and environmental effects of such substances.
- Manufacturers and importers are primarily responsible for testing; processors are subject to testing requirements only in certain circumstances.
- About 200 chemicals tested through Section 4 or enforceable consent agreements through Section 4.
TSCA -- Risk Management on Existing Chemicals

Section 4 gives EPA authority to require manufacturers to conduct testing on specified chemicals.

If concerns continue after testing and information collection:
Section 6 gives EPA authority to address unreasonable risk through restrictions, warning labels, recordkeeping, product bans.
Specific list of risk management options identified in Section 6
  - Includes labeling, recordkeeping, use restrictions, bans

Only five substances have been restricted under Section 6
  - Thousands of substances with restrictions in place from Section 5 review

Asbestos court decision often flagged as indication that Section 6 does not work
TSCA -- Criticisms of Current TSCA System

- No requirement for data generation on new chemicals under Section 5
- No minimum data set required for existing chemicals
- Too few chemicals tested under Section 4
- Too few chemicals regulated under Section 6
- Too easy to claim confidential business information (CBI)

OVERALL CRITIQUE: How many of the 85,000 to 90,000 chemicals on the Inventory have been assessed for safety?
Responding to Criticisms -- Legislative Proposals

- Senate Bill: *Safe Chemicals Act of 2010 (SCA)*
  - Senator Lautenberg

  - Representatives Rush and Waxman

- House Bill: Expected as soon as July 22, with a hearing possibly scheduled for July 29
Definitions Relating to “Chemical Substance” (CS)

- While TSCA definition of CS is largely maintained, important changes are found in both bills.
- “CS” explicitly includes any CS in an article.
- “Mixture” explicitly includes any mixture contained in or formed into an article.
- “New chemical” CS for which the manufacturer or processor has not submitted a Section 8(a)(2) declaration.
Other Definitions

- “Adverse effect”: Very broadly defined
- “Aggregate exposure”: Very broad meaning
  - In addition to “TSCA exposures,” includes exposure to food, food additives, drugs, etc., and to any mixtures of these materials, and
  - All environmental sources include background
- “Cumulative exposure”: Sum of aggregate exposure to chemicals “known or suspected to contribute appreciably to risk of same or similar adverse effect”; and mixtures containing such substances
- “Vulnerable population”: Population subject to disproportionate exposure to, or to potential for a disproportionate adverse effect from exposure to, a CS or mixture; includes workers and “members of any other appropriate population identified by EPA”
Recent Regulatory Developments

- **Nano Developments**
  - Section 4 -- EPA is preparing a proposed test rule under which chemical manufacturers would be required to develop data to determine the health effects of certain multi-wall carbon nanotubes (CNT) and nanosized clays and alumina.
  - Section 5 -- EPA is preparing a proposed TSCA categorical SNUR for nanoscale substances.
  - Section 8(a) -- EPA is preparing a proposed rule establishing reporting requirements for “certain nanoscale materials.” The rule is likely to include “existing chemical nanoscale materials.”
Recent Regulatory Developments (cont’d)

- TSCA Section 5(a)(4) Chemicals of Concern List
- Chemical Action Plans to Date
  - Bisphenol A (BPA)
  - Phthalamates
  - Perfluorinated chemicals (PFC)
  - Penta, octa, and decabromodiphenyl ethers (PBDE) in products
  - Short-chain chlorinated paraffins
Recent Regulatory Developments (cont’d)

- Chemical Action Plans Being Developed
  - Benzidine dyes
  - Diisocyanates
  - Hexabromocyclododecane (HBCD)
  - Nonylphenol and nonylphenol ethoxylates (NP/NPE)
  - Siloxanes

- Proposed IUR Reporting Amendments
FIFRA
FIFRA

Who Implements the Program?

- EPA
  - Office of Pesticide Programs (OPP)
    - Antimicrobials Division (AD)
    - Biological and Economic Analysis Division (BEAD)
    - Biopesticides and Pollution Prevention Division (BPPD)
    - Environmental Fate and Effects Division (EFED)
    - Field and External Affairs Division (FEAD)
    - Health Effects Division (HED)
    - Information Technology and Resources Management Division (ITRMD)
FIFRA (cont’d)

- Pesticide Re-Evaluation Division (PRD)
- Registration Division (RD)

➢ Where a state has a federally-approved pesticide program, the state is the primary enforcement authority

- Several states have developed mature pesticide laws -- California, New York, Florida
FIFRA -- What Is a Pesticide?

- Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pests.
- A substance is considered to be intended for a pesticidal purpose requiring registration if the person who distributes or sells the substance claims, states, or implies that the substance can or should be used as a pesticide.
Core Statutory Authority

- FIFRA, 7 U.S.C. §§ 136 et seq.
Regulatory Scope

- **Active Ingredients**
  - Ingredients that prevent, destroy, repel, or mitigate pests
  - Plant regulators, defoliants, desiccants, and nitrogen stabilizers

- **Inert Ingredients**
  - “Other ingredients” in pesticide formulations

- **Pesticide Types**
  - Conventional pesticides
  - Minimum-risk pesticides
  - Biopesticides
  - Antimicrobials
  - Treated articles
Core Programs

- Register new actives, products, uses
- Establish pesticide residue limits for food and feed
- Reregister/review older actives/products/uses
- Other narrowly-tailored permits/exemptions
- Establish worker protection requirements
- Consultation on endangered species issues
FIFRA -- Regulatory Framework

- Premarket Approval
- Risk-Based Safety Standard
  - No unreasonable risk (non-food uses)
  - Reasonable certainty of no harm (food uses)
- Risk = Hazard x Exposure
- Burden on registrant to meet safety standard
EPA reviews registrant-submitted data against applicable standard

Data requirements codified at 40 C.F.R. Part 158, Part 161

- Battery of testing requirements
- EPA has authority to require additional data
- EPA discretion to waive data requirement

Data development can cost millions and take years before an application can be submitted to EPA
FIFRA -- Regulatory Framework (cont’d)

- Protections for trade secrets and CBI
- EPA has adopted a narrow interpretation of protected information; enhanced transparency
- Compensation provisions for third-party use of proprietary data
Mandatory Label Requirements

- Ingredients
- Approved claims
- Use directions
- Warning statements
- Registrant information

Use inconsistent with label prohibited

Labeling covers all written materials (and then some)
FIFRA -- Regulatory Framework (cont’d)

■ New Actives/Products/Uses
  - Review timeframes established by statute (Pesticide Registration Improvement Act (PRIA))
  - 3 months to 24 months review standard, but can be longer

■ Existing Actives/Products/Uses
  - Review older pesticides against current health standards
  - That review typically yields label amendments, use restrictions, or other legal redress (cancellation)
Promote “Safer” or “Reduced-Risk” Pesticides Alternatives
- Reduced fees
- Expedited reviews
- Dedicated resources

Various Programs to Register Reduced-Risk Pesticides
- Minimum-risk pesticides
- Reduced-risk conventional pesticides
- Biopesticides
FIFRA -- Regulatory Framework (cont’d)

- Restrict Future Sale of Products
- Stop-Sale Orders
- Civil Penalties
- Criminal Penalties
FIFRA -- Recent Developments

- Increased Transparency/Reduced Confidentiality
  - Starting in FY10, EPA risk assessments and proposed decisions for new pesticide active ingredients and certain new uses are published in a public docket for review and comment.
  - EPA is soliciting comments on mandatory disclosure of inert (other) ingredients.

- Nanoscale Ingredients
  - OPP regards nanoscale active and inert ingredients as new.
  - Under imminently-expected new interpretation of FIFRA Section 6(a)(2), presence of nanoscale material in formulation would be reportable.
FIFRA -- Recent Developments (cont’d)

- Misbranding: *Reckitt Benckiser* appellate decision

- EPA Regions will be proposing draft National Pollutant Discharge Elimination System (NPDES) General Permits to cover previously exempt pesticide applications to/over/near U.S. waters

- EPA recently settled a lawsuit concerning its human subjects testing rule to add further protections for pregnant women and children and follow National Academy of Sciences (NAS) scientific and ethical standards
Thank You

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