

Environmental Law Institute: Summer School 2008

CHEMICAL REGULATION

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B E R G E S O N & C A M P B E L L , P . C .

Many Chemical-Specific Laws

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- Chemical Use and Assessment Laws
 - Toxic Substances Control Act (TSCA)
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Emergency Planning and Community Right-to-Know Act (EPCRA)
 - Federal Food, Drug, and Cosmetic Act (FFDCA)



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Many Chemical-Specific Laws (cont'd)

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- Chemical Byproducts Laws
 - Clean Air Act (CAA)
 - Clean Water Act (CWA)
 - Safe Drinking Water Act (SDWA)
- Chemical Waste and Disposal Laws
 - Resource Conservation and Recovery Act (RCRA)
 - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)



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Many Chemical-Specific Laws (cont'd)

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- Chemical Transportation Laws
 - Hazardous Materials Transportation Act (HMTA)
- Other Laws Affecting Chemicals
 - Consumer Product Safety Act (CPSA)
 - Federal Hazardous Substances Act (FHSA)



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Key Federal Chemical Use Laws

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- TSCA
 - Regulation of industrial chemicals
- FIFRA
 - Regulation of pesticides (agricultural chemicals)



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TSCA -- Scope

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- TSCA regulates “chemical substances” and “mixtures”
- TSCA defines the term “chemical substance” as “any organic or inorganic substance of a particular molecular identity, including --
 - (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
 - (ii) any element or uncombined radical”



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TSCA's Major Provisions for Chemical Data Collection/Control

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- Section 4 -- Chemical Testing
- Section 5 -- New Chemical Review and Significant New Use Rules (SNUR)
- Section 6 -- Chemical Regulation
- Section 8 -- Industry Reporting of Chemical Data
- Section 9 -- TSCA's Relationship to Other Laws
- Section 14 -- Disclosure of Chemical Data



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TSCA -- Exclusions

- Excluded from TSCA are:
 - Chemicals already covered by FIFRA
 - Tobacco or any tobacco product
 - Any source material, special nuclear material, or byproduct material covered under the Atomic Energy Act
 - Firearms and ammunition
 - Anything defined under FFDCA Section 201 (food, food additives, drugs, cosmetics, devices)



Testing of Chemical Substances and Mixtures

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- The U.S. Environmental Protection Agency (EPA) may require testing under TSCA Section 4 if a material or mixture:
 - Presents an unreasonable risk to health or the environment in the manufacture, transit, storage, use, or disposal
 - Has insufficient data or experience with a material or mixture to assess risk



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Premanufacture Notices (PMN)

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- No one may manufacture or import a substance that is not on the TSCA Inventory (called a “new chemical substance”) unless there is an exemption or EPA approves a PMN
- No one may manufacture or import a new chemical substance for which a PMN has been submitted until EPA’s 90-day review period has expired
- No one may use an existing chemical substance (one that is listed on the TSCA Inventory) for a use that is subject to a SNUR unless a significant new use notice (SNUN) is approved by EPA
 - SNUNs are similar to PMNs



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Reporting and Recordkeeping

- TSCA Section 8 imposes reporting and recordkeeping requirements. Main features include:
 - TSCA Section 8(a) -- Preliminary Assessment Information Rule (PAIR) and Inventory Update Rule (IUR);
 - TSCA Section 8(c) -- Significant Adverse Reactions;
 - TSCA Section 8(d) -- Health and Safety Studies; and
 - TSCA Section 8(e) -- Substantial Risk Information



Recent Developments

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- Perfluorooctanoic acid (PFOA) Enforceable Consent Agreement (ECA) process
- TSCA Section 8(e) EPA enforcement actions against DuPont
- 2010/15 PFOA Stewardship Program
- Nanoscale Materials Stewardship Program (NMSP)/TSCA Inventory Guidance



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PFOA ECA Process

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- EPA announced the process on April 16, 2003, and held the first Plenary meeting on June 6, 2003
 - Process was preceded by EPA's Preliminary Risk Assessment of PFOA
- On October 25, 2004, EPA signed a Memorandum of Understanding (MoU) with 3M/Dyneon
- On November 3, 2005, EPA signed an MoU with DuPont



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PFOA ECA Process (cont'd)

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- On July 8, 2005, EPA published two final ECAs
 - Incineration testing of four formulated composites of fluoropolymer chemicals and two formulated composites of fluorotelomer-based polymer chemicals
- PFOA ECA process concluded in November 2006



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DuPont Enforcement Actions

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- On July 8, 2004, and December 6, 2004, EPA issued complaints against DuPont alleging violations of TSCA and RCRA
- EPA alleged that the TSCA violations resulted from DuPont's failure to report to EPA under TSCA Section 8(e) information regarding "substantial risk of injury to health or the environment" from PFOA



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DuPont Enforcement Actions (cont'd)

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- On December 14, 2005, EPA forwarded to EPA's Environmental Appeals Board a settlement to resolve DuPont's alleged liability. The settlement was for the largest civil administrative penalty EPA has ever obtained under any federal statute -- \$10.25 million in penalties plus \$6.25 million in expenditures for Supplemental Environmental Projects. DuPont reportedly had set aside \$15 million in connection with EPA's complaints



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2010/15 PFOA Stewardship Program

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- Initiated by EPA on January 25, 2006
- Eight fluoropolymer and telomer manufacturers invited to participate, and all eight agreed
- Two key commitments
 - Achieve, no later than 2010, a 95% reduction in:
 - facility emissions of PFOA and related chemicals
 - product content levels of PFOA and related chemicals
 - Work towards the elimination of PFOA from emissions and products by no later than 2015



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NMSP/TSCA Inventory Guidance

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- On January 28, 2008, EPA launched the NMSP
- Goal of the program is to “help provide a firmer scientific foundation for regulatory decisions by encouraging submission and development of information including risk management practices for nanoscale materials”
- Basic and In-Depth Programs
- Simultaneous with the NMSP’s launch, EPA published its “TSCA Inventory Status of Nanoscale Substances -- General Approach (January 23, 2008)”
 - EPA elaborates in the paper, for the first time, on how it construes the term “molecular identity”



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FIFRA

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- What Is the Purpose?
 - To protect public health and the environment against the misuse of pesticides
- What Is the Scope?
 - All pesticide manufacturers must submit data regarding the safety and efficacy of their pesticides
- Who Implements the Program?
 - EPA
 - Where a state has a federally-approved pesticide program, the state is the primary enforcement authority



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FIFRA (cont'd)

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- Examples:
 - DDT
 - Aldrin/Dieldrin
 - 2,4,5-T/Silvex
 - Methyl Bromide



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FIFRA -- What Is a Pesticide?

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- 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



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FIFRA -- Provisions

- What Are the Major Provisions?
 - **Registration Requirements (Section 3):** Based on the data submitted by the manufacturer on its registration application, EPA decides whether the pesticide poses unreasonable adverse effects to the environment. EPA takes into account the economic, social, and environmental costs and benefits of the pesticide's use
 - **Suspension or Cancellation of Pesticides (Section 6):** EPA may suspend, cancel, or restrict the use of a pesticide that poses unreasonable adverse effects or imminent hazards to the environment



FIFRA -- Provisions (cont'd)

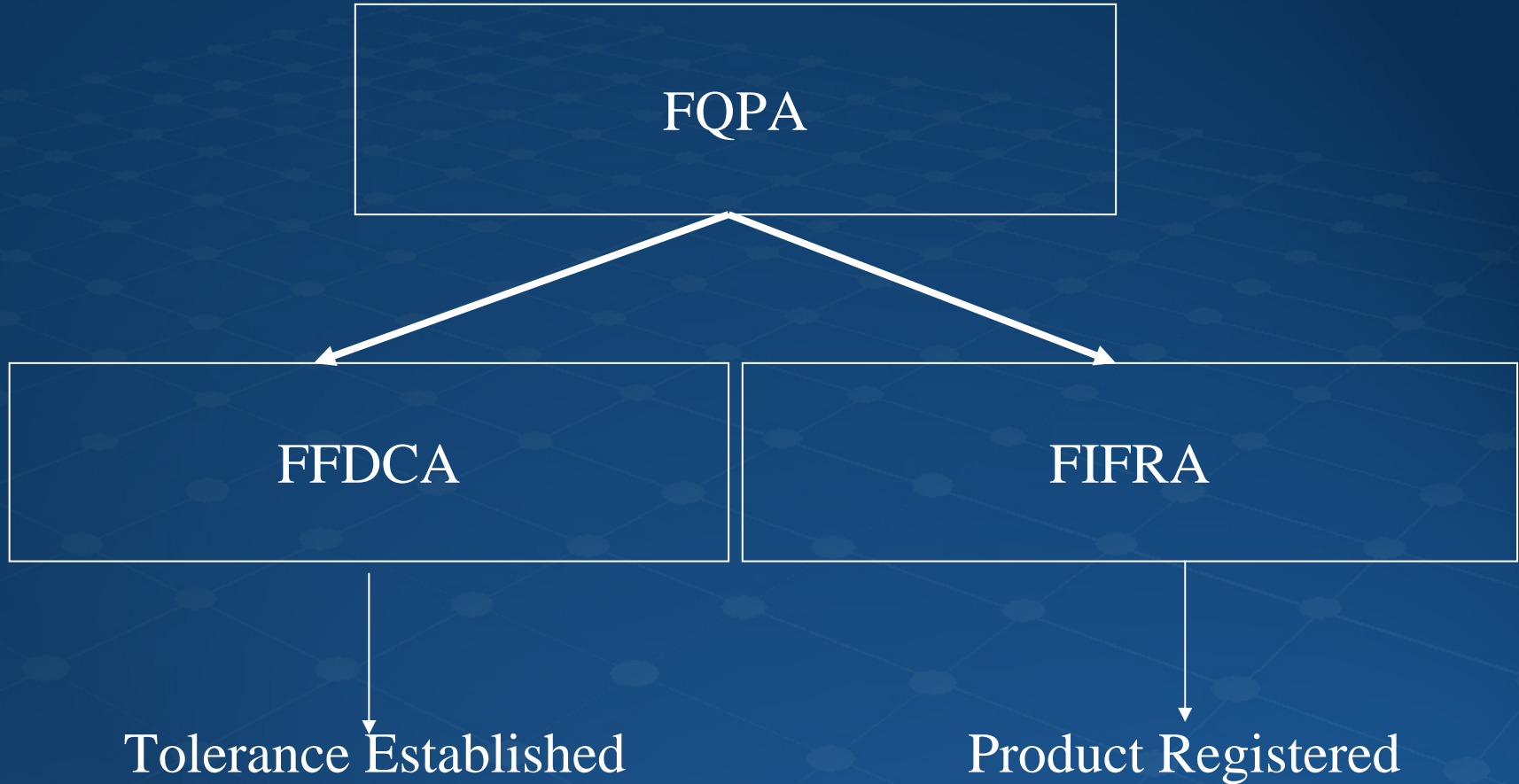
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- What Are the Major Provisions? (cont'd)
 - **Labeling Requirements (Section 2):** All registered pesticides must be properly labeled for lawful sale. The label must specify the pesticide's active ingredients, how to use the pesticide on particular crops, and limitations on how or when it may be used



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Applicable Statutes



FFDCA

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- Sets a general standard for tolerances -- a reasonable certainty that no harm will result from aggregate exposure. Aggregate exposure includes food, water, and occupational exposure
- Establishes special provisions for infants and children. In particular, EPA must add a safety factor of up to ten-fold if there is uncertainty in data relative to children
- Requires EPA to take into account cumulative effects for chemicals with common mechanisms of toxicity



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FIFRA -- Risk Assessment

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- Risk based on hazard and exposure
- Registration requires seven to ten years; \$100 to \$200 million per product
- Pesticide registration requires at least 120 safety evaluations:
 - Chronic
 - Acute
 - Environmental Fate



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FIFRA -- Recent Developments

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- Pesticide Registration Improvement Act of 2003 -- “fee for service” legislation
- Human studies
- FQPA deadlines: August 3, 2006, and October 3, 2008



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