Office of Chemical Safety and Pollution Prevention

Program Overview

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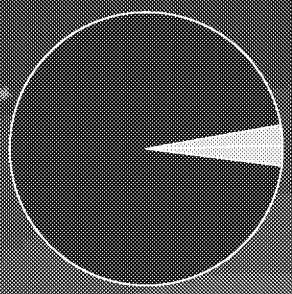
Office of Chemical Safety and Pollution Prevention (OCSPP)

Office of Pollution, Prevention, and Toxics (OPPT)

~84,000 Chemicals

- Toxic Substances Control Act (TSCA)
- Emergency Planning and Community Right-to-Know Act (EPCRA)
- Pollution Prevention Act (PPA)

Office of Science Coordination and Policy (OSCP)



Office of Pesticide Programs (OPP)

Pesticides

~1200 Chemicals (Active Ingredients)

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Federal Food, Drug and Cosmetic Act (FFDCA)
- Food Quality Protection Act (FQPA)

Office of Pollution Prevention and Toxics

- **Recent Amendments to TSCA**
  - "The Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed into law on June 22, 2016 and effective immediately, bringing significant changes and new responsibilities for EPA:
    - Framework rules – finalized by June 2017, currently out for public comment
    - First 10 chemicals for risk evaluation – scope documents by June 2017
    - New chemicals – new affirmative safety determination within 90 day review period
    - Confidential business information (CBI) – new substantiation requirements
    - Industry fees rule – new authority to collect fees to defray implementation costs
    - Persistent, bioaccumulative and toxic (PBT) chemicals – expedited risk management
- **Annual Workload**
  - About 1,000 new chemical submissions are received annually
  - Currently evaluating risks of 10 existing chemicals (plus 5 PBT chemicals)
  - Numerous other responsibilities including regulatory development and implementation, CBI claim review, TRI and pollution prevention programs, etc.

Office of Pollution Prevention and Toxics

- **New Chemicals - Review and Management**
  - Any person who plans to manufacture or import a new chemical must provide EPA with advance notice, also called a premanufacture notice (PMN)
  - Before a new chemical can proceed to market, EPA must make an affirmative determination on the chemical's safety – 90 day review period
  - Where warranted, EPA can impose restrictions or additional requirements
  - Objective is to ensure that the new chemical goes into commerce in a manner that protects health and the environment
  - Once EPA completes this process, the new chemical is added to the TSCA Inventory and becomes an "existing" chemical

PMN includes information such as chemical identity, estimated production volume, proposed uses, human exposure, disposal methods and estimates, and test data concerning human or environmental effects.

If EPA can allow the chemical to proceed to market unrestricted, require development of additional information, impose conditions on the manufacture, or ban the production of the chemical altogether

Office of Pollution Prevention and Toxics

- **Existing Chemicals - Review and Management**
  - About 62,000 chemicals were grandfathered in 1976 when TSCA was originally enacted without any safety review.
  - TSCA now requires EPA to prioritize and evaluate existing chemicals, and take regulatory action to manage identified unreasonable risks
  - For each risk evaluation completed, EPA must initiate another; increase ongoing number of evaluations to 20 existing chemicals by December 2019
- **Toxics Release Inventory (TRI)**
  - EPA annually collects and manages information from industry about chemical releases to air, water and land, providing a resource for informed decision-making by companies, government agencies, NGOs, and the public

Office of Pesticide Programs

- **What is a Pesticide?**
  - In the US, a pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest
  - EPA separates pesticides into three general categories: conventional chemical pesticides, antimicrobial pesticides, biopesticides.
- **Scope of US Pesticide Registrations**
  - Over 1,200 active ingredients; over 16,800 pesticide products; over 16,300 tolerances (maximum allowable pesticide residue on food)
- **Annual Workload**
  - About 2,000 applications/year received
  - Majority of applications are for new uses and label amendments
  - In 2016, EPA approved 22 new active ingredients and 213 new uses

Office of Pesticide Programs

Registration Process

- Applicant develops a pesticide, generates data and submits an application to the EPA
- EPA reviews submitted data to assess risk
- EPA makes its decision based on all available information
  - Typical application for a new active ingredient would include over a hundred studies

Office of Pesticide Programs

Registration Review

- Statutorily required to review every registered pesticide at least every 15 years to ensure the pesticides continue to meet the requirement of "no unreasonable adverse effects" on human health and the environment and that human dietary risks meet the "reasonable certainty of no harm" standard
- EPA must complete registration review by October 1, 2022

Pesticide Hot Topics

- Specific Pesticides
  - Chlorpyrifos
  - Glyphosate
  - Atrazine
- Worker Protection Standard Implementation
- Endangered Species Act

Office of Science Coordination and Policy (OSCP)

Science Coordination

- Assure science integrity, quality assurance and peer review of our scientific evaluations

Endocrine Disruptor Screening Program

- Mandated in bipartisan 1996 amendments to Food and Drinking Water laws
- Coordination across EPA programs – pesticides, water, toxics, R&D
- Challenges with implementation – thousands of chemicals & animal tests slow and expensive
- "Pivot" from traditional toxicological approaches → high throughput/ computational toxicological approaches