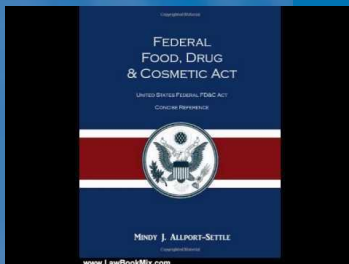


EPA Role in Biotech Pesticide Oversight
American Association of Pest Control Officials

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Pesticide Regulation

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Food Quality Protection Act (FQPA)
- Pesticide Registration Improvement Act (PRIA)
- Other Statutes:
 - *Endangered Species Act*
 - *Migratory Bird Treaty Act*
 - *Clean Water Act*



Registration of Pesticides

FIFRA Standard - EPA may register a pesticide if, when used in accordance with widespread and commonly recognized practice, it generally will **not cause unreasonable adverse effects on human health or the environment.**

FFDCA Standard - EPA may establish a tolerance or tolerance exemption if there is a **reasonable certainty that no harm** will result from residues of the pesticide in food or feed.

U.S. Pesticide Laws

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Registration of pesticides, re-evaluation of older pesticides
 - Field testing/experimental use of pesticides

U.S. Pesticide Laws (cont.)

- Federal Food, Drug, and Cosmetic Act (FFDCA)
 - Establish tolerances (maximum residue limits) for pesticides on food and feed.
 - Tolerances apply to both domestic and imported foods.

Microbial Pesticides

- Include microorganisms used as pesticides, e.g. bacteria, fungi, viruses, bacteriophages; both naturally occurring and genetically engineered.
- Pesticidal modes of action can include competition or inhibition, toxicity, use of pest as growth substrate.

Genetically Modified Microbial Pesticides

- Small Scale Testing Notification Requirement
- Is an Experimental Use Permit needed for testing under 10 acres?
- 40 CFR Part 172.45 – Pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.

PIPs Are Pesticides

- Regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA)
- EPA registers, establishes tolerances or exemptions (MRLs), issues experimental use permits, Section 24c's, etc. for PIPs

What is a PIP?

- A Plant Incorporated Protectant (PIP) is a **pesticidal substance**, intended to be produced and used **in a living plant** or in the produce thereof, **and the genetic material necessary for production** of such pesticidal substance. Includes inerts contained in the plant or its produce. (40 CFR 152.3)

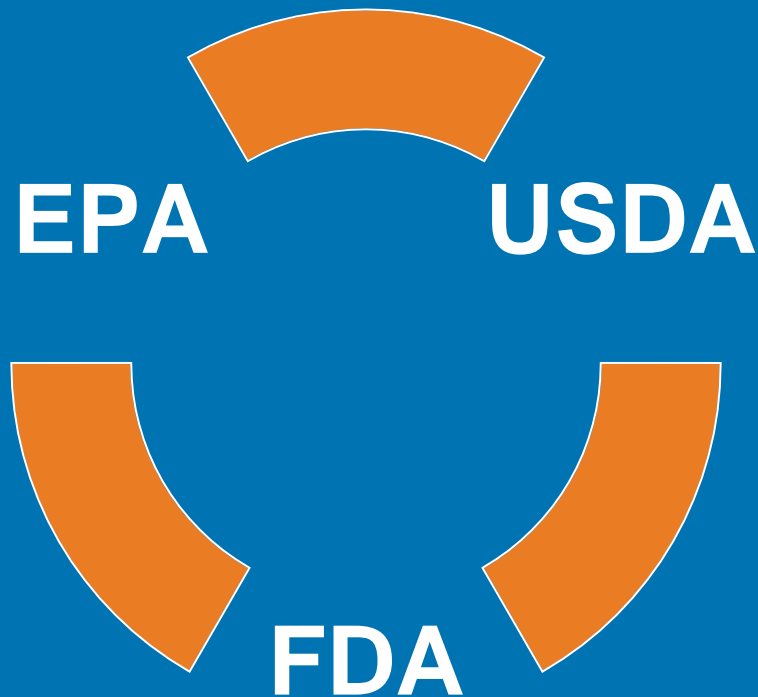
When an Experimental Use Permit is Required for PIPs

- Testing on a cumulative total of over 10 acres requires an experimental use permit for pests that occur in different geographical situations, over 10 acres per pest
- A tolerance may be needed without an EUP

Field Testing Containment of PIP and PIP Pollen

- Out-crossing of PIP pollen must be prevented regardless of test plot size **if no tolerance exemption**
 - Destroy crop before pollination occurs
 - Bagging and detasseling corn
- Without a tolerance (or exemption), harvested crop must not enter commerce

U.S. Federal Oversight of GE Crops with Pesticidal Traits



U.S. Federal Oversight of GE Crops with Pesticidal Traits

- EPA works closely with USDA and FDA to implement the Coordinated Framework

Transparency

- Biopesticide Regulatory Action Documents (BRADS) that include risk and benefit assessments are published on our website for PIP products as well as records of Scientific Advisory Panel meetings on these products
- Notices in the Federal Register (registration applications/decisions, tolerance/exemption petitions/final rules, EUPs, etc.)

For More Information

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■ Visit Us on the Web

- www.epa.gov/pesticides/biopesticides
- www.epa.gov/opp00001/biopesticides/contacts_bppd.htm