

ELI 2026 Summer School Session 5: Toxic Chemical Regulation

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Federal Chemicals Regulation

- FIFRA
 - Federal Insecticide, Fungicide, and Rodenticide Act
- FFDCA
 - Federal Food, Drug, and Cosmetic Act
- TSCA
 - Toxics Substances Control Act
- FHSA
 - Federal Hazardous Substances Act
- OSHA
 - Occupational Safety and Health Act

Federal Chemicals Regulation

- FIFRA

- <https://www.agriculture.senate.gov/imo/media/doc/Federal%20Insecticide,%20Fungicide,%20And%20Rodenticide%20Act.pdf>

- TSCA

- <https://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim>



Brief History of FIFRA

- Insecticide Act of 1910
 - Focused on prohibiting the sale of fraudulently labeled “economic poisons”.
No standards for pesticides or registration requirements – this was a marketing – not regulatory -- statute.
- 1947 Act
 - Two main features – Established labeling requirements and mandated USDA “registration” of pesticides sold in interstate commerce.
- 1970 – EPA is created. Responsibility to register pesticides transferred from USDA to EPA, and EPA given responsibility for establishment of pesticide tolerances under FFDCA.
- 1972 – FEPCA: Established the foundation of the current comprehensive **regulatory** structure.

Brief History of FIFRA

- Insecticide Act of 1910 and 1947 Act
 - (See <https://libraryguides.law.pace.edu/c.php?g=892839&p=6420334> for a brief overview of the early history of FIFRA.)
- 1970 – History of EPA
 - <https://www.epa.gov/history>
- 1972 – FEPCA
 - <https://www.presidency.ucsb.edu/documents/statement-signing-the-federal-environmental-pesticide-control-act-1972>

Brief History of FIFRA (cont.)

- Federal Environmental Pesticide Control Act of 1972
- 1975 Amendments
- 1988 Amendments
- 1996 Food Quality Protection Act (FQPA)
 - Significant changes to both FIFRA and FFDCA
 - Single health-based standard for all pesticide residues in foods
 - Heightened focus on potential effects to infants and children
 - Registration review process established

Brief History of FIFRA (cont.)

Pesticide Registration Improvement Act of 2003
(Re-authorized and amended in 2007, 2012, 2019, 2022 (and 2026?))

- Established fee for service system in exchange for defined decision timelines
- Unique legislative approach in that provisions are “negotiated” with industry, then presented to Congress as a standalone package
- Fees and decision timelines based on specified regulatory categories
- Each amendment has adjusted fees and timelines and added new categories

See 7 U.S.C. § 136w-8

Scope of FIFRA Jurisdiction

- Regulates “pesticides”
- Pesticides are generally subject to registration requirement (pre-market approval) with limited exceptions
- Extent of FIFRA jurisdiction set by key definitions (including):
 - “Pesticide”
 - “Pest”
 - “Plant Regulator”

Scope of FIFRA – Key Definitions

- “Pesticide”
 - Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any “pest;”
also
 - Any substance or mixture intended for use as a plant regulator, defoliant, or desiccant.

Scope of FIFRA – Key Definitions (cont.)

- “Pest”
 - Any insect, rodent, nematode, fungus, weed; or
 - Any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) that EPA declares to a pest.

Scope of FIFRA – Key Definitions (cont.)

- “Plant Regulator”
 - Any substance that affects the rate of plant growth or plant physiology.

What Is A Pesticide?

- “Pesticide” not defined in terms of inherent characteristics of a particular substance, but, rather, in terms of an intended effect, i.e.:

‘intended to destroy, prevent, repel, or mitigate’ any pest; or

‘intended for use as a plant regulator, desiccant, or defoliant’.

■ How do you know?

What is a Pesticide? (cont.)

Types of Pesticides:

■ Chemicals (“conventionals”)..... **RD**

■ **Biopesticides**

■ Biochemicals

■ Microbes

■ Genetically engineered crops

■ Genetically engineered insects

BPPD

■ **Antimicrobials** **AD**

Devices

- “Any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest.”
- Use physical or mechanical means to trap, destroy, repel or mitigate = Device



FIFRA Registration

FIFRA Section 3 (7 U.S.C. 136a)

- Requirement of Registration
 - No person in any State may distribute or sell to any person any pesticide that is not registered under FIFRA.

(<https://www.epa.gov/enforcement/stop-sale-use-or-removal-order-issued-ebay-inc>)

(<https://www.epa.gov/enforcement/stop-sale-use-or-removal-orders-issued-amazoncom-services-llc>)

FIFRA Section 3

- Standard for Registration – FIFRA 3(c)(5)(C) and(D)
 - The pesticide will perform its intended function **without *unreasonable* adverse effects on the environment;**
 - When used in accordance with widespread and commonly recognized practice the pesticide **will not cause *unreasonable* adverse effects on the environment.**

“Unreasonable Adverse Effects”

- (1) any unreasonable risk to man or the environment, *taking into account the economic, social, and environmental costs and benefits of the use of any pesticide;*
- (2) a **human dietary risk** from residues that result from use of a pesticide in or on any food that is inconsistent with the FFDCA food safety standard (“**reasonable certainty of no harm**”).

Types of Registration

- Unconditional Registration – FIFRA 3(c)(5)
 - Grant of license; property right
- Conditional Registration – FIFRA 3(c)(7)
 - Limited grant of license
 - Time limited
 - May be granted on condition of renunciation of procedural rights

Unconditional Registration

- FIFRA 3(c)(5) (7 U.S.C. 136a(c)(5))
 - All required data received and reviewed
 - No additional data are necessary
 - EPA has sufficient basis to make “no unreasonable adverse effects” finding
 - FFDCA Tolerances in place

Section 3(c)(2)(B)(i) [7 U.S.C. 136a(c)(2)(B)(i)]

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

Section 3(c)(2)(B)(iv) [7 U.S.C. 136a(c)(2)(B)(iv)]

(iv) If the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional is required.

Pesticide Labels and Labeling



The Pesticide Label

- The fulcrum on which regulation of pesticides turns
- “The Label is the Law”
- An EPA-registered pesticide label is a legal instrument that is enforceable under Federal law.

Labeling (cont.)

- “Labeling” – the container/packaging label itself, PLUS
 - All other written, printed or graphic matter accompanying the pesticide when it is sold or distributed
 - Written material referenced on the label (or material accompanying the label)
 - Websites – (url or website referenced on label = labeling)
- The label and labeling must be approved by EPA prior to sale or distribution of a registered pesticide.
- It is a violation of FIFRA to distribute a product without an EPA-approved label

Labeling – Misbranding

- Violation of FIFRA to sell or distribute “misbranded” product
- Misbranded – specifically defined in FIFRA
 - “Labeling bears any statement, graphic representation or design that is false or misleading in any particular.”
 - FIFRA 2(q); 40 CFR 156.10(5)(a)
- Whether the label statement is “true” may not be material as to whether it is “misleading”

(<https://www.epa.gov/enforcement/monsanto-company-fifra-settlement>)

Labeling – Misbranding (cont.)

- Examples of Misbranding:
 - **Labeling is inconsistent with approved label**
 - Required information is omitted from the label
 - Text is too small; misplaced text
- EPA has deemed certain statements to be *per se* misleading:
 - “Safe”
 - “harmless”
 - “nontoxic to humans and pets”

Illustrative EPA Enforcement Actions

<https://www.epa.gov/enforcement/stop-sale-use-or-removal-order-issued-ebay-inc>



[https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf/Filing-s-and-Attachments/391DC5BDCED98D3F85258C37006D4D4E/\\$File/Twin%20Med,%20LLC%20\(FIFRA-09-2025-0033\)%20-%20Filed%20Complaint.pdf](https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf/Filing-s-and-Attachments/391DC5BDCED98D3F85258C37006D4D4E/$File/Twin%20Med,%20LLC%20(FIFRA-09-2025-0033)%20-%20Filed%20Complaint.pdf)





State Regulation of Pesticides

State Regulation of Pesticides

- Pursuant to FIFRA Section 24(a), States may regulate the sale or use of Federally registered pesticides:
 - States may not allow any sales or uses prohibited under Federal law
 - A State may impose additional requirements for use of a pesticide within that State.
 - data requirements
 - licensing requirements
- Pursuant to FIFRA Section 24(c), States may allow the use of registered pesticides to meet “special local needs”

State Regulation of Pesticides

Pursuant to FIFRA Section 24(b) – “Uniformity”:

A State “shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required” by EPA.

Monsanto Co. v. Durnell

- Supreme Court, October Term, 2025
 - 25 June 2026
- John Durnell successfully sued Monsanto Co. in MO state court alleging that use of a Monsanto pesticide product that is subject to EPA's FIFRA jurisdiction caused his cancer and that Monsanto failed to include an appropriate cancer warning on the product label.
- On appeal, the MO Court of Appeals confirmed the verdict.

Monsanto Co. v. Durnell

The Supreme Court held that the FIFRA Section 24(b) “Uniformity” provision expressly preempts state “failure to warn” claims that would require language different from, or in addition to, the language specifically required and approved by EPA on the registered pesticide label.

Monsanto Co. v. Durnell

The primary bases for the decision are:

- EPA (along with numerous regulatory agencies worldwide) has concluded that the pesticide product at issue is not likely to cause cancer in humans.
- In EPA's view, including a cancer warning on the pesticide label would be false and misleading.
- The registrant is legally required to utilize a label on its registered product that does not contain a cancer warning, until such time as EPA approves or requires the addition of a cancer warning to that approved label.

Monsanto Co. v. Durnell

Therefore,

“The question, then, is whether the Missouri failure-to-warn claim – which would require a cancer warning on the Roundup label – would impose a labeling requirement that is “in addition to or different from” federal labeling requirements imposed “under” FIFRA. The answer is yes.”

For any questions or to discuss,
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