

ACA — 2020 MEMBER WEBINAR SERIES

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Overview



Tracy Heinzman, Hume Ross — Wiley

Introduction



Tracy Heinzman, Partner
Environment & Product Reg. Practice Chair

Twenty eight years of experience in environmental law with a focus on FIFRA. Nationally recognized for her strategic representation of businesses that manufacture and market chemicals, pesticides, biocides, and other highly regulated products.



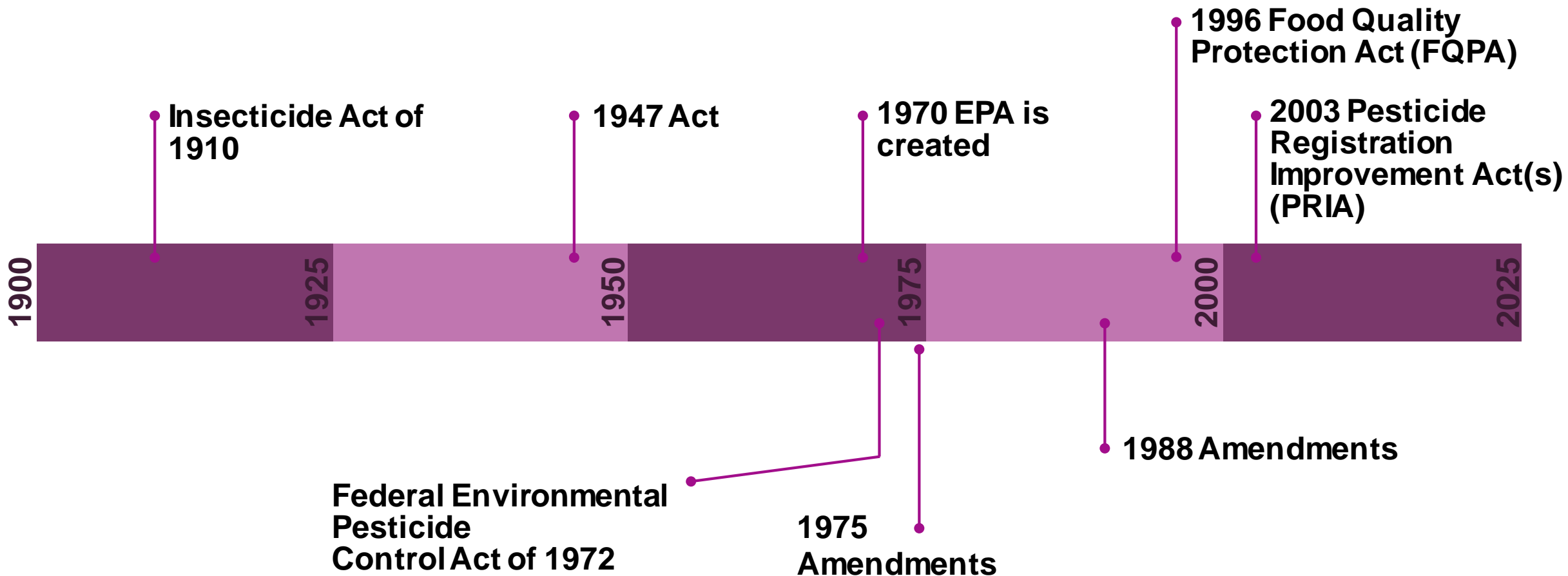
Hume Ross, Associate

Advises clients regarding federal and state regulatory compliance and in related litigation and administrative proceedings. A former practicing civil engineer, his practice focuses on the chemical, construction, and consumer product industries.

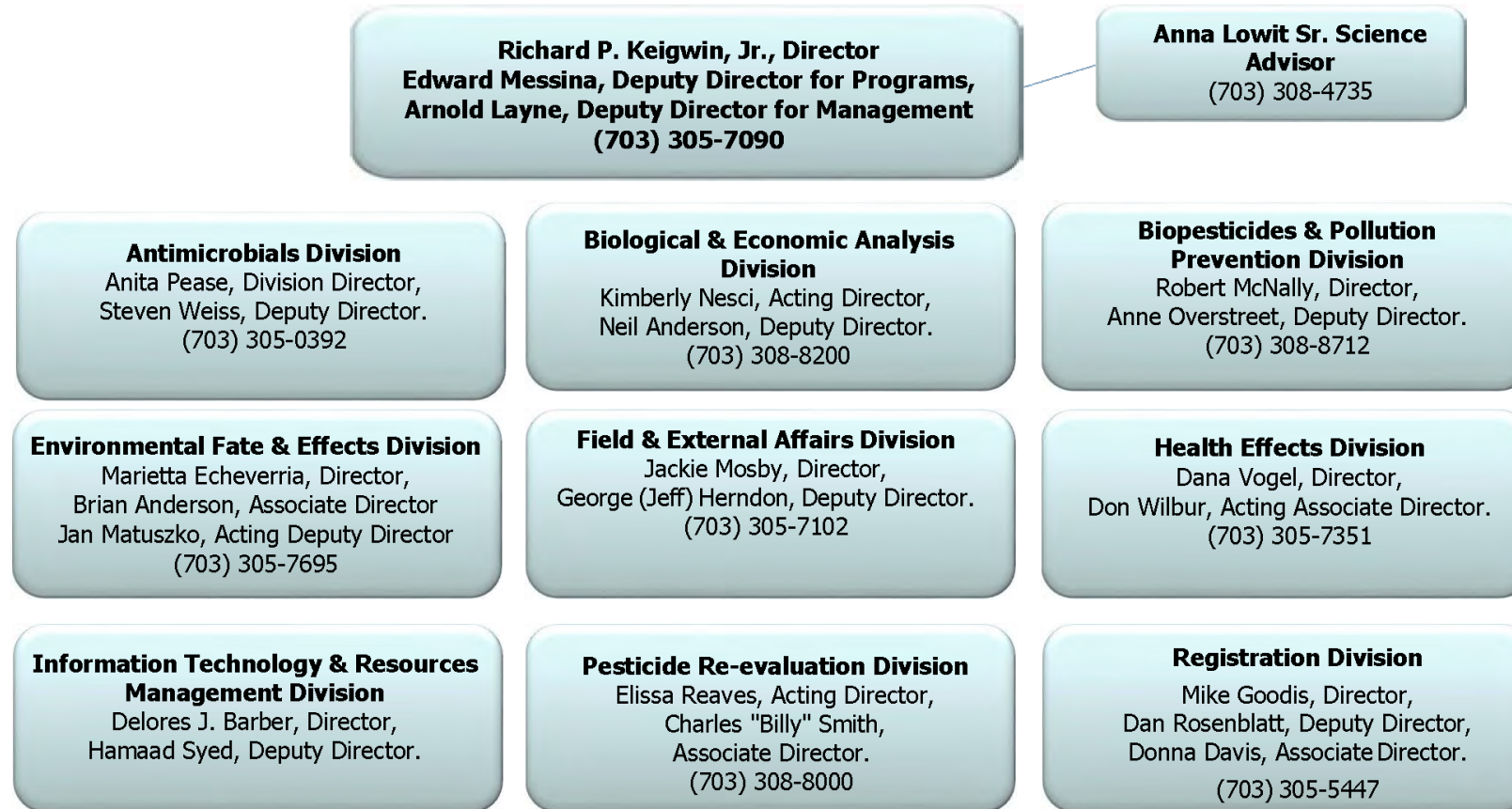
Topics for Today

- **Top-Level review of the regulation of pesticides under FIFRA in the U.S.**
 - What products fall under FIFRA?
 - Overview of FIFRA requirements for pesticides
 - The “Treated Articles” exemption
 - Marketing and advertising considerations
 - State regulation of pesticides

Important Milestones — FIFRA Timeline



U.S. EPA — Office of Pesticide Programs Organizational Chart



Scope of FIFRA Jurisdiction

- **Regulates “pesticides” and “devices”**
- **Pesticides are subject to registration (pre-market approval) with limited exceptions**
- **FIFRA jurisdiction set by a few key definitions:**
 - **“Pesticide”**
 - **“Pest”**

Scope of FIFRA – Key Definitions

- “Pesticide”
 - Any substance or mixture intended for preventing, destroying, repelling or mitigating any “pest” AND
 - Any substance or mixture intended for use as a plant regulator, defoliant, or desiccant
- “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) which the EPA declares to be a pest



3 Avenues to Regulation under FIFRA: How a coating becomes a pesticide

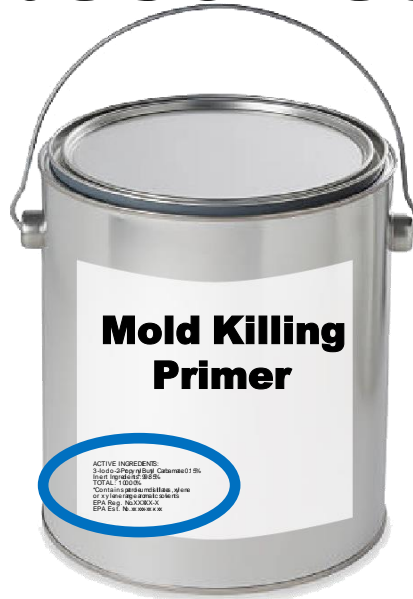
Contains active ingredient (with no other commercially valuable use)

Or

Claims of pesticidal purpose part of sale or distribution

Or

Person selling has constructive knowledge of use as pesticide



ACTIVE INGREDIENTS:

3-Iodo-2-Propynyl Butyl Carbamate: 0.15%

Inert Ingredients*: 99.85%

TOTAL: 100.00%

*Contains petroleum distillates, xylene or xylene range aromatic solvents

EPA Reg. No. XXXXX-X

EPA Est. No. xxxxx-xx-xxx

ACTIVE INGREDIENT:

Chlorothalonil..... 0.48%

OTHER 99.52%

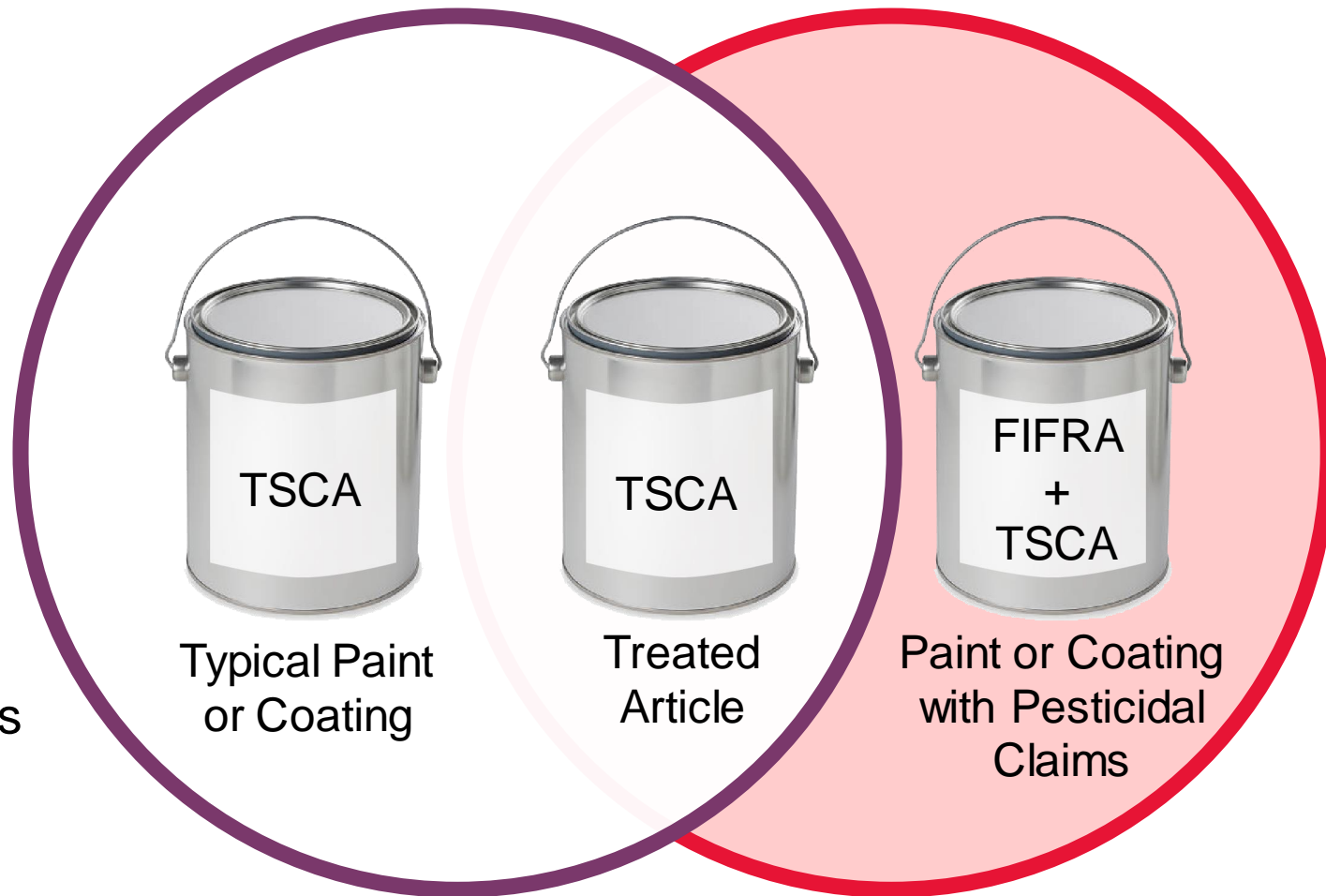
TOTAL 100.00%

EPA Reg. No. XXXXX-XX

EPA Est. No. xxxxx-AB-CD



TSCA, FIFRA, or Both?



TSCA – components must be on TSCA inventory or exempt

FIFRA – Required to register product and production facilities, submit data in support of any claims, get label pre-approved, and more...

FIFRA Regulates Entire Spectrum of Manufacture and Distribution of Pesticides



...and creates numerous requirements:

- Registration for each product
 - Submittal/citation of data (for registration and later “reevaluation”)
- Registration of “establishments” that produce product
- Pre-approval of label
 - And strict requirements not to deviate from approved label in advertising, distribution and sale
- Notices of Arrival – for importing pesticides
- Recordkeeping and reporting
 - Adverse effects reporting

Standard for Registration

- **FIFRA 3(c)**
 - Product will not cause “unreasonable adverse effects” on human health and the environment
 - Benefit/risk standard
 - Product works as claimed
 - Labeling and other information submitted with application comply with FIFRA
- **EPA’s decision that pesticide meets standard is evidenced by giving applicant “Notice of Registration”**

Product “Registration”

- **“Registration” is:**
 - Specific to a particular product/formulation
 - Each pesticide product must be registered; can have several slightly different formulations for one product (within certain limits of variation – 40 CFR 152.43)
 - Encompasses all aspects of the particular product:
 - Raw materials to make it
 - Manufacturing/Formulation process
 - Composition/Chemical Formula
 - Labeling/Packaging

Types of Registrations

- **Technical – Manufacturing Concentrate**
 - The pesticide itself – most intensive data requirements
- **Formulated products**
 - Incorporate registered technical grade product into an end-use product
 - Still have to submit some data, but not as extensive as technical
- **New products**
 - Incorporate active ingredients and/or use patterns not currently registered or ever registered before
- **“Me-Too” products**
 - Products “identical or substantially similar to existing/registered products”



Substantially Similar

Identical Products	Substantially Similar	NOT Substantially Similar
<ul style="list-style-type: none"> • Same Actives • Same Intentionally Added Inerts (or impurities) • Same % of active /inerts/impurities • Same uses (patterns/directions for use) 	<ul style="list-style-type: none"> • Same Actives • Different Inerts (or impurities) • Different % of active /inerts/impurities • Same or similar uses • Differences NOT of toxicological significance 	<ul style="list-style-type: none"> • Significantly different formulation or uses • Inerts not currently in any other registered pesticide • Significant difference in % of A.I. • Significant difference in dosage rates • Different directions for use



Data Requirements – Key Considerations

- **Heart of pesticide registration application is data that applicant must submit or cite to support the proposed product**
- **Breadth of data requirements depends on type of product and type of registration**
 - Most extensive data requirements are for new “active ingredients” and technicals – “generic” safety data on the chemical itself, not a product-specific formulation
 - Product-specific formulations with registered technical require less data

Data Requirements – Types of Data

- **Product-specific data:**
 - Product Chemistry – Confidential Statement of Formula (“CSF”), physical and chemical characteristics, formulation process
 - Acute Toxicity – short term mammalian studies
- **AI data:**
 - Complicated Mammalian Toxicity
 - Environmental Fate
 - Non-Target organisms
 - Residue Chemistry
 - Efficacy – Maybe

Data Requirements – Formulator's Exemption

- **If AI is registered in concentrated form, formulator may use the formulator's exemption and reduce data requirements**
 - No need to cite or provide AI data; just product-specific data
 - Must meet criteria of FE to take advantage
- **If AI is already contained in other registered products, and those products are identical or substantially similar to product sought to be registered, then may be able to cite data submitted by others**

Additional Data Requirements – Data Call-Ins

- **FIFRA 3(c)(2)(B) – EPA can require new data for existing pesticide products – issues “Data Call In”**
- **Usually part of reregistration or registration review process**
- **EPA issues DCI notice to each registrant**
 - Can be product-specific or AI-based
 - Registrants of same AI usually form consortium to jointly develop and/or share costs of data for DCI

FIFRA – Data Citation and Compensation

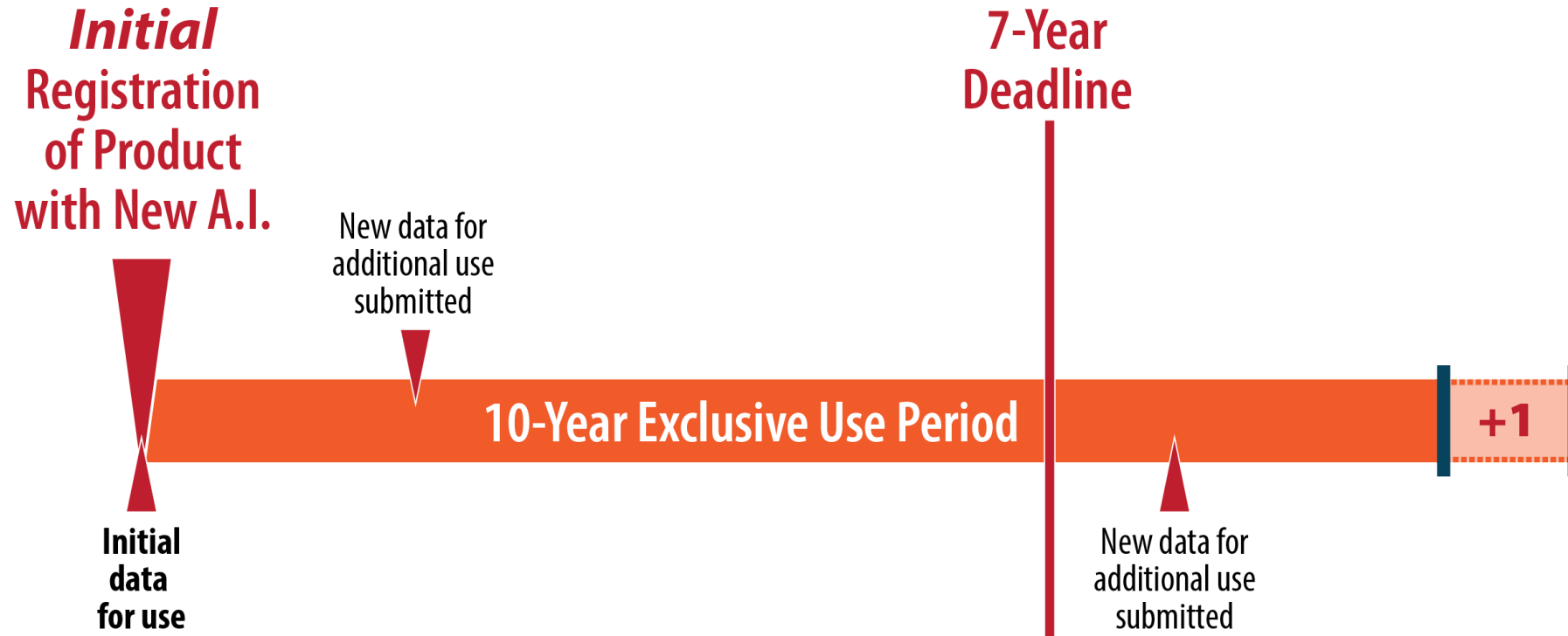
- **To promote competition, FIFRA allows subsequent applicants to cite health and safety data submitted by initial applicant**
- **Four critical concepts for data citation:**
 - “Offer to Pay”
 - 15-Year Period – Citation with “Offer to Pay” Compensation
 - 10-Year Period of Exclusive Use – No Citation Without Authorization from Data Owner
 - Compensation determined via private commercial arbitration or via settlement
 - You can obtain a registration by making the “Offer to Pay”
 - You do not need to have paid any compensation due to obtain a registration and enter the market



EPA 15-Year Period



EPA 10-Year *Exclusive Use Period*



Potential additional 1-Year for every 3 minor uses added to original registration submitted before 7-Year Deadline



Labeling

- The fulcrum of FIFRA regulation
- “The Label is the Law”
- Specified components:

<p>PRECAUTIONARY STATEMENTS</p> <p>Hazards to Humans & Domestic Animals</p> <p>Danger...Do not get in eyes, on skin, or on clothing.</p> <p>ENVIRONMENTAL HAZARDS</p> <p>PHYSICAL & CHEMICAL HAZARDS</p> <p>Manufactured by: Registrant's Name & Address</p> <p>EPA Reg. No.</p> <p>EPA Est. No.</p>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>RESTRICTED USE PESTICIDE Due to: XY For Retail Sale & Use Only by Certified Applicators</p> </div> <p style="text-align: center;">Product Name <i>Marketing Statements</i></p> <p>ACTIVE INGREDIENT(S): Common chemical name90.0%</p> <p>OTHER INGREDIENTS:10.0%</p> <p style="text-align: right;">TOTAL: 100.0%</p> <p style="text-align: center;">KEEP OUT OF REACH OF CHILDREN</p> <p style="text-align: center;">SIGNAL WORD</p> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">FIRST AID</p> <p>If in eyes: Hold eye open and rinse slowly and gently with...</p> <p>If on skin or clothing: Take off contaminated clothing...</p> <p>If inhaled: Move person to fresh air....</p> <p>If swallowed: Call poison control center or doctor immediately...</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">HOT LINE NUMBER: Contact 1-800-xxx-xxxx for emergency medical treatment...</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">NOTE TO PHYSICIAN</p> </div> <p style="text-align: center;">See back panel for additional precautionary statements.</p> <p style="text-align: center;">Net Contents/Net Weight:</p>	<p>DIRECTIONS FOR USE Restricted Use Pesticide</p> <p>It is violation of Federal law to use this product in a manner inconsistent with its labeling.</p> <p>General Information & Restrictions:</p> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">AGRICULTURAL USE REQUIREMENTS <i>Language and specific to the Worker Protection Standard.</i></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">STORAGE & DISPOSAL Pesticide Storage: Pesticide Disposal: Container Disposal:</p> </div> <p style="text-align: center;">WARRANTY STATEMENT</p>
---	--	--



Import Procedures

- **Prior to arrival of pesticide shipment, the importer must prepare and submit a “Notice of Arrival” (EPA Form 3540-1)**
- **Form is submitted to appropriate EPA Regional Office**
- **EPA completes the NOA by adding directions for U.S. Customs clearance**
 - Detain for inspection
 - Release
 - Refuse entry
- **EPA returns copy of completed NOA to importer**



Adverse Effects Reporting

- **Section 6(a)(2):**
 - “[i]f at any time after registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.”
- **EPA Regulations:**
 - 40 C.F.R. Part 159



Post Fire
Smoke
Encapsulant

Treated Article Exemption

“Designed with an EPA-registered chemical package, this product resists microbial growth, locks down offensive particles, and removes odors caused by fugitive emissions from fire deposits below the detectable limit.”

Treated Articles

- **Treated articles are exempt from regulation under FIFRA by 40 C.F.R. 152.25(a)**
 - “An article or substance treated with, or containing, a pesticide to protect the article or substance itself
 - (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infection)
 - [is not regulated under FIFRA]
 - if the pesticide is registered for such use.”

Treated Articles Exemption – Requirement 1

- **“to protect the article or substance itself”**
 - The pesticide must be acting to preserve the article
 - No “Public Health Claims”
 - Anything suggesting control of infectious diseases
 - Claims that the article acts as a sterilant, disinfectant, virucide, or sanitizer
 - Claim of “antibacterial” or “germicidal” activity
 - Claim to control “spread” of allergens, bacteria, etc.
 - Unspecific claims that public health will be improved
 - EPA determinations of what protects “the article or substance itself”
 - Wood preservatives ✓
 - Biocidal marine antifouling paints ✗
 - Treated clothing ✗

Treated Articles Exemption – Requirement 1

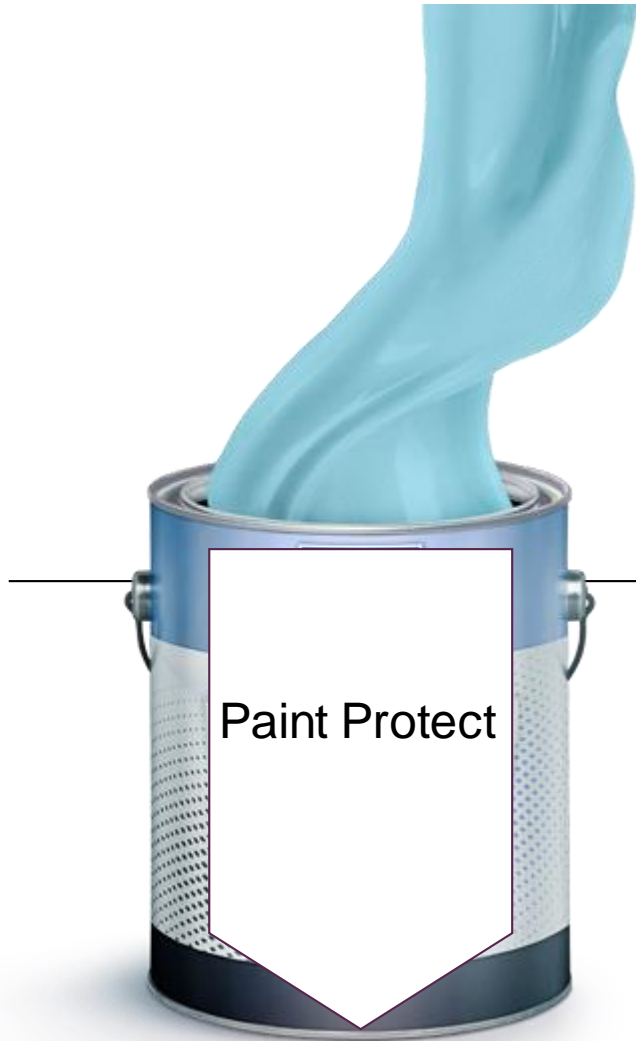
- **What can you say?**

- Article inhibits growth of mold or mildew on surface of coating
- Article itself resistant to foulage/spoiling
- Article inhibits offensive odors in/on itself
- “Antimicrobial,” “fungistatic,” “mildew-resistant,” and “preservative” OK only if clearly qualified as not serving a public health purpose
 - “Antimicrobial properties built in to protect product”
 - “Provides mildew-resistant dried paint coating”
- Very detailed review of claims is needed:
 - Antibacterial ✗
 - Kills Mold ✗
 - Mildew-resistant ✓

Treated Articles Exemption – Requirement 2

- **“if the pesticide is registered for such use”**
 - The registration for the pesticide you use has to say it is approved for use in the type of article you want to use it in
 - EPA used to allow broad categories (“hard surfaces” “coatings”) – no more
 - Now required to be very specific:
 - “animal carriers” “turf flooring” “hand weights”
 - Ex: Technical registration for a widely used antimicrobial additive – entire page of label about specific coatings/sealant chemistries and application that are approved
 - Or possibly the technical grade registrant will have a label that says:
 - “Formulators using this product are responsible for obtaining EPA registration of their formulated products”
(Chlorothalonil)
 - Formulators can rely on most recent approved label – but keep an eye on registration review process

Marketing and Advertising

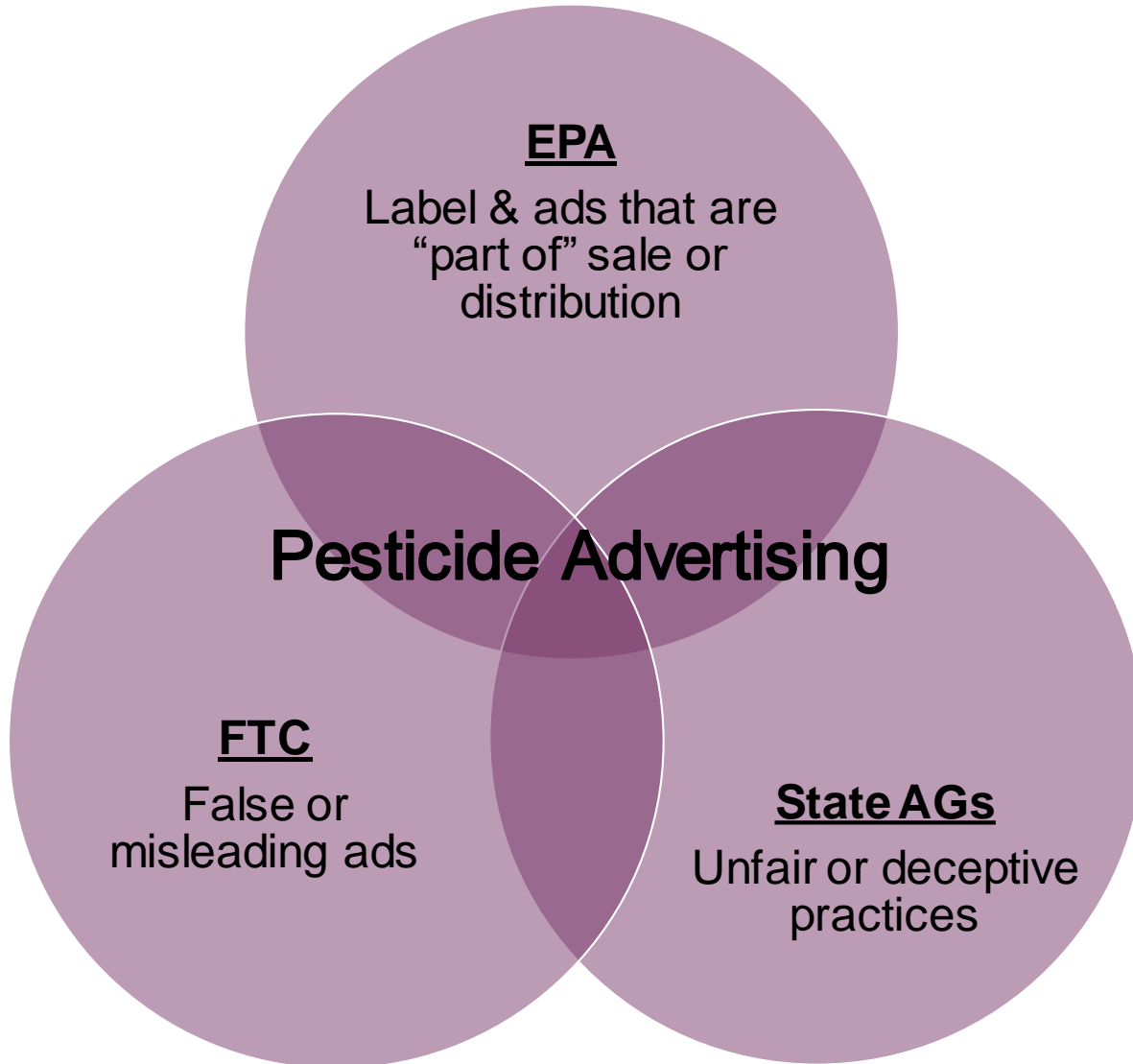


OPTIONAL LABEL CLAIMS

[One or more of the following claims may appear on front panel and / or elsewhere on label:]

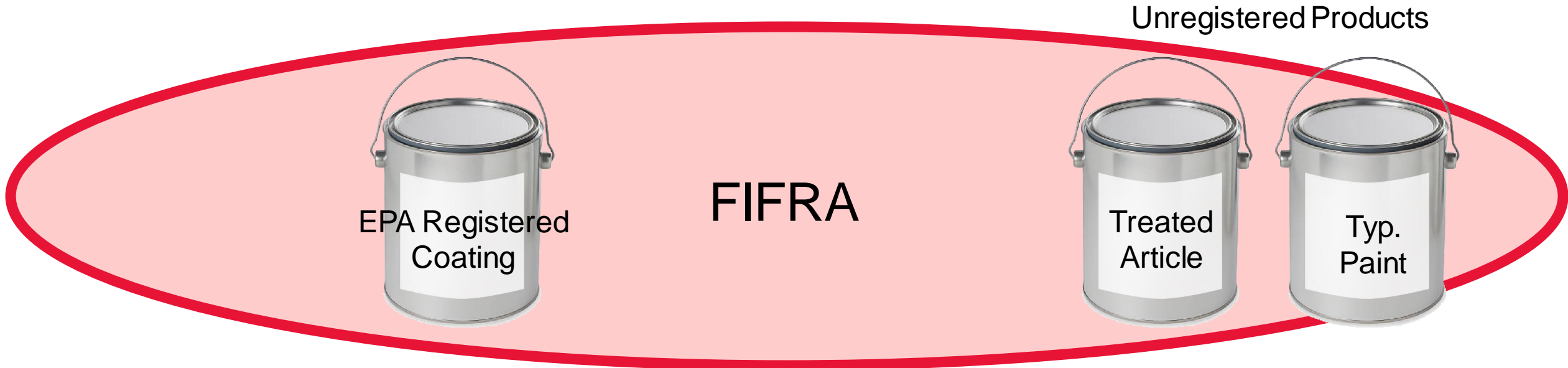
- By killing [pathogenic] [disease causing] [harmful] bacteria, _____ offers customers an additional new [tool] [way] [measure] to help [combat] [control] [prevent the spread of] bacteria [such as Staph and MRSA] on painted surfaces.
- By killing [pathogenic] [disease causing] [harmful] bacteria on painted surfaces, _____ helps support customer's [infection] control [teams] [efforts] [practices]
- By killing [pathogenic] [disease causing] [harmful] bacteria [on painted surfaces], _____ helps support customers' environmental [infection] control [teams] [efforts] [practices]
- Interior Latex EG-SHEL
- Introducing the first EPA-registered paint that continuously kills 99.9% of MRSA, *Enterobacter aerogenes*, *Staphylococcus aureus*, and Vancomycin resistant Enterococci (VRE) [within] [after] 2 hours of exposure.

Intersection Between Enforcement Agencies



- **EPA** is primary enforcer for claims made in pesticide marketing and advertising
- **FTC or State Attorneys General** can fill in gaps; overlapping control of advertising claims but typically don't enforce if EPA has FIFRA authority

EPA Enforcement Avenues



EPA will review **Label and Labeling**
Any deviation from approved label is “**Misbranding**” under FIFRA

EPA will also look at **Advertising Materials**
A claim that **substantially differs** from approved claims is a violation of FIFRA

Any pesticidal claim not within exemption made in/on **Label/Labeling OR Advertising** will cause EPA to allege sale of an **unregistered pesticide**



Advertising Enforcement — “Labeling”

Labeling is not only what is on the label

- Written, printed, or graphic matter on pesticide
- Packaging
- Material accompanying the pesticide at any time (invoices, bills of lading, brochures, shelf tags, etc.)
- Material referenced on the label (incl. product or company websites)

Why It's Important

- EPA's most clean-cut authority relates to claims on labeling
- But any claim made “as part of distribution or sale” can be evaluated



What is “Advertising”?

EPA’s Definition –

“A notice in any advertising medium to which pesticide users or the general public have access that recommends or suggests the purchase or a use of a pesticide”

- **Company websites are:**
 - Part of labeling if referenced on label
 - Information about products on websites cannot “substantially differ” from approved labels even if the website is not referenced on the label
- **Most claims on company or product-specific websites subject to EPA enforcement**
- **Narrow exception: some “passive” websites with very general information and no e-commerce functionality (if also not part of labeling)**



Advertising — Practical Points

- Review all advertising, marketing, and promotional material before use to ensure it has been approved
 - Includes trade show displays/materials
 - Includes social media
- Include Regulatory and Legal personnel early in the process of designing marketing materials
- Include Marketing during finalization of label with EPA if possible
 - Optional marketing claims on labels becoming more common

Note on Federal/State Authority Overlap

- FIFRA gives the federal government extensive authority to regulate pesticide use and distribution
- FIFRA also carves out a role for the states in setting standards for pesticides
- Generally, the states may regulate use or sale of pesticides more strictly than the federal government
- States may not regulate labeling or packaging of pesticides differently than the federal government

State Programs

- **States are not required to have regulatory programs, but virtually all do**
- **Key aspects of programs:**
 - Product registration
 - Applicator certification
 - Pesticide dealer licensing
 - Use restrictions
- **CA and NY have most extensive programs**

State Registration

- Federally registered pesticide products must be registered in each State. Cannot register in a State unless first registered under FIFRA
- The National Pesticide Information Center provides the telephone numbers and addresses for the primary pesticide regulatory agency in each state and U.S. territory:

<http://npic.orst.edu/reg/regstate.html>

Questions?



Tracy Heinzman
T: 202.719.7106
M: 703.231.5447
theinzman@wiley.law



Hume M. Ross
T: 202.719.7296
M: 202.552.9631
hross@wiley.law