PESTICIDE REGISTRATION

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MASSACHUSETTS DEPARTMENT OF AGRICULTURAL RESOURCES

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AUTHORITY, RULES, REGULATIONS

- Federal Insecticide Fungicide Rodenticide Act ("FIFRA")
- Federal Food, Drug and Cosmetic Act ("FFDCA")
- Endangered Species Act ("ESA")
- Massachusetts Pesticide Control Act
- 333 CMR State Regulations

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DEFINITION OF A PESTICIDE

333CMR Section 2.03

"a substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant"

What is actually means:

Anything that claims to kill something…

Insecticides, Fungicides, Herbicides, Rodenticides, Antimicrobials

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FEDERAL PROCESS

APPLICATION

- The identity and quantity of all chemicals in the product.
- Data on potential risks to human health and the environment, including about the potential for pesticide residues on food (if applicable).
- Proof that the product manufacturing process is reliable.
- Labeling, including directions for use, contents, and appropriate warnings.
- Evidence of meeting all legal and financial obligations.

FEDERAL PROCESS CONFIDENTIALITY BUSINESS INFORMATION

- **FIFRA, Section 10 establishes to what extent information submitted to the Agency under FIFRA may fall under Confidential Business Information ("CBI").**
  - manufacturing or quality control processes (FIFRA 10(d)(1)(A));
  - information that discloses methods for testing and measuring the quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(B)); and
  - **information that discloses the identity or percentage quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(C)).**

- **Safety and efficacy data does not fall under CBI.**

- **EPA does obtain and review this information but cannot disclose to the public if it falls under CBI**

FEDERAL PROCESS ASSESMENT

- **Human Health (including sensitive groups such as children and immune-suppressed individuals)**
  - Toxicity studies: full spectrum of potential health effects; from eye and skin irritation to cancer and birth defects
  - Aggregate risks–through food, water, and residential uses
  - Cumulative risks–from different pesticides with the same effects
  - Occupational risks to those applying the product during their work
  - A safety factor of at least 100x but up to 1000x is used (per the FQPA)

- **Environmental Risks**
  - Wildlife and Plant Toxicity
  - Environmental Fate and Exposure (Soil, Water, Air)
  - Ecological Risks:
    - Aquatic: fish, invertebrates, plants
    - Terrestrial: mammals, birds, insects (incl. honeybees), plants
  - Endangered and threatened species
  - Potential for endocrine-disruption effects

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FEDERAL PROCESS ASSESSMENT

- **Implement Risk Assessment and Peer Review**
  - Review all the scientific data on the pesticide product and develop risk assessments that look at the potential effects of the product or ingredient on human health and the environment.
  - The human health and environmental risk assessment evaluation process undergoes a peer review by scientific experts.
  - Opportunities for the public to comment on registration actions

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FEDERAL PROCESS

- **Based on the review process, EPA will decide the following:**
  - Register the product
  - Classification of the product (General Use or Restricted Use)
  - Final label language

- **EPA conducts registration reviews on active ingredients at least every 15 years. If a new use pattern is requested than EPA conducts risk assessments as needed.**

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FEDERAL PROCESS, LABELING REQUIREMENTS

1. **Restricted Use Statement (if necessary)**
2. **Product name**
3. **Ingredient Statement (active ingredient and %)**
4. **Signal Word (refers to the toxicity of the product)**
5. **First aid**
6. **EPA Registration Number and Establishment Number**
7. **Hazards and Precautionary Statements**
8. **Hazards to Humans and Domestic Animals**
9. **Environmental Hazards**
10. **Worker Protection (if necessary)**
11. **Directions for Use**
12. **Storage and Disposal**
13. **Statement: *"IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING"***

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LABELING

- **It is important to note that the label reflects the data and potential risks that were presented during the registration process. The label mitigates potential risks associated with the use of the product.**

  - *"Apply when wind speed is less than 10mph or drift may cause damage or death to nontarget area vegetation. DO NOT apply when conditions favor drift from target area."*

  - *"This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow to drift to blooming crops if bees are visiting the treatment area."*

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LABELING

- **Labels also have informative language and suggestions for the applicators to follow to reduce risk.**
  - *"This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having a high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of [insert active ingredient] from runoff water and sediment."*
  - *"Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."*

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25B MINIMUM RISK PESTICIDES

- **EPA exempts products from the registration process if they contain specific ingredients as outlined in FIFRA 152.25**
- **Examples of these ingredients:**
  - Rosemary Oil
  - Garlic Oil
  - Thyme Oil
  - Calcium Carbonate
  - Beeswax
- **Other Conditions that the product must adhere to:**
  - Active ingredient and inert ingredients listed on label
  - No false claims
  - No public health claims
  - Company Information

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25B MINIMUM RISK PESTICIDES

- EPA does not review products that claim to be a 25B product
- Public health claims cannot be made because EPA does not review the products (ie: no efficacy data)
- Massachusetts does not currently register these products
- Industry has indicated that efficacy of these product varies
- Enforcement staff has found some companies adding traditional pesticides into tank mixes to enhance the efficacy.

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STATE PROCESS

- **PESTICIDE SUBCOMMITTEE**
  - Established by the Massachusetts Pesticide Control Act
  - Five members:
    - Massachusetts Department of Agricultural Resources
    - Massachusetts Department of Conservation and Recreation
    - Massachusetts Department of Public Health
    - Director of Division of Food and Drug
    - Commercial Applicator

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STATE PROCESS

- **The process can be split into two different processes:**

  1. "Routine" Registration: New product but contains an active ingredient that is products already registered in the state.

  2**. New Active Ingredient:** New product that contains an active ingredient that is not in any products registered in the state.

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Routine Registration

- **Applications are sent to MDAR**
- **An administrative review is conducted**
  - Fees, labels, forms, etc.
- **A technical review is conducted**
  - Review label
  - Determine if active ingredient is new in Massachusetts
  - Determine if active ingredient is on the groundwater protection list and if so, review the use pattern to assess if reclassification is needed
  - Determine if product needs reclassification due to previous decisions made by the Subcommittee
  - Determine if a there is a new use pattern for active ingredients and assess whether additional review is needed

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New Active Ingredient Registration

- **Obtain and review EPA registration documents, including human health and ecological risk assessments**
  - Screen for use patterns that are relevant to MA
  - Consider risks that are relevant to MA, if any.
  - Evaluate if an additional restrictions may be needed in MA

- **Evaluation for Ground Water Protection**
  - Assess leaching and toxicological properties
  - Compare with regulatory criteria for potential ground water pollutant (333 CMR 12.00)

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STATE PROCESS

- **Information is presented to the Subcommittee to determine if:**
  - Product should be registered
  - Product should be reclassified (groundwater contaminate, previous policy determined by Subcommittee, other reasons)

****Confidential Business Information is not submitted as part of the registration process. If it was, certain information would not be able to be disclosed to the public. This could cause some complications as the Subcommittee is a public entity and subject to the open meeting law.**

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PRODUCT SELECTION FOR AERIAL ADULTICIDE APPLICATIONS

- **Conducted by the State Reclamation and Mosquito Control Board ("SRB") when there is a public health hazard as determined by DPH.**
- **Several state agencies reviewed a list of products that were labeled for aerial use:**
  - MDAR
  - DEP
  - DFW
  - DCR
  - DFM

- **MDAR provided information on each active ingredient to the group for review. Information included:**
  - Efficacy Data
  - Ecotoxicity Data
  - Ecological Risk for Aquatic Invertebrates and Fish
  - Environmental Fate

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PFAS

- In 2020, Anvil 10+10 was found to contain PFAS residues
- Working with DEP and EPA, the PFAS residues were linked to fluorinated containers
- MDAR and DEP collected samples of liquid pesticides used by the MCDs to test for PFAS
  - Most samples came back clean
  - If a product showed measurable levels of PFAS, use of the product was ceased and alternative products were used
- A total of 153 samples were collected costing approximately $109,892.73
- PFAS compounds are not allowed as ingredients in pesticides, and it is considered a contaminant
- EPA continues to work on this issue relative to fluorinated containers
- EPA recently developed a standard method to test for PFAS in oily substances

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