

# Conventional Pesticide Registration Process



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## Office of Pesticide Programs (OPP)

The Office of Pesticide Programs' mission is to protect public health and the environment by ensuring pesticides are safe and available for a healthy America.

## What We Do

- ▶ Licensing program – OPP regulates products
- ▶ By design, pesticides are intended to kill something, so OPP must balance between controlling pests and protecting human health and the environment
- ▶ When registering pesticides, OPP takes into account the risks associated with the use and compares it to the benefits (i.e., do the benefits outweigh the risks?)
- ▶ Each registered pesticide is reviewed at least every 15 years to ensure that it can carry out its intended function(s) without creating unreasonable adverse effects to human health and the environment.
- ▶ Strong authority to collect scientific data
  - ▶ Many countries look to our science and decision making to support decision making in their countries

# Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

- ▶ 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 and the environment
- ▶ Risk-benefit balancing statute
- ▶ Governs registration of pesticides, registration review, worker protection, mitigation of ecological risks

# Federal Food Drug and Cosmetic Act (FFDCA)

- ▶ EPA may establish a tolerance (maximum residue level) if there is a reasonable certainty that no harm will result from residues of the pesticide in food or feed
- ▶ Health-based safety standard
- ▶ Tolerances apply to both domestic and imported foods

# Food Quality Protection Act of 1996 (FQPA)

- ▶ Required more sophisticated science
  - ▶ Aggregate exposure
  - ▶ Cumulative risk
- ▶ Additional safety factor for protection of children
- ▶ Emphasizes open public process

## Pesticide Registration Improvement Act (PRIA)

- ▶ PRIA was first passed on March 23, 2004, and has been reauthorized three times
  - ▶ Fee-for-Service Act
  - ▶ Created time frames for completion of registration actions
- ▶ We are working under PRIA 4, which was enacted March 8, 2019, through 2023
  - ▶ <https://www.govinfo.gov/content/pkg/PLAW-116publ8/pdf/PLAW-116publ8.pdf>
- ▶ Planning is underway for the next proposed reauthorization of PRIA

## Examples of PRIA 4 Fee Categories for Conventional Chemical Pesticides

- ▶ New Active Ingredients
  - ▶ R010: New Active Ingredient; Food Use
  - ▶ Timeframe: 24 months
  - ▶ Cost: \$790,737
- ▶ New Uses
  - ▶ R170: Additional Food Use
  - ▶ Timeframe: 15 months
  - ▶ Cost: \$83,317
- ▶ Amendments to Registration
  - ▶ R340; Amendment Requiring Data Review (within RD)
  - ▶ Timeframe: 4 months
  - ▶ Cost: \$5,238

## 40 CFR Parts 150 to 189

- ▶ Part 156 – Labeling Requirements for Pesticides and Devices
- ▶ Part 158 – Data Requirements for Pesticides
- ▶ Part 180 – Tolerances and Exemptions For Pesticide Chemical Residues in Food

# Endangered Species Act (ESA)

- ▶ Aims to conserve threatened and endangered plants and animals and the habitats in which they are found
- ▶ Requires federal agencies, in consultation with the U.S. Fish and Wildlife Service and/or the NOAA Fisheries Service, to ensure that actions they authorize, fund, or carry out are not likely to
  - ▶ **jeopardize** the continued existence of any listed species, or
  - ▶ result in the **destruction** or **adverse modification** of designated critical habitat of such species

# ESA Protection Policy

## for Pesticide New Active Ingredients

- ▶ On January 11<sup>th</sup>, 2022, EPA announced meaningful action to address its obligations under the Endangered Species Act (ESA)
- ▶ Prior to registration, EPA will evaluate potential effects on federally threatened or endangered (listed) species and their designated critical habitats when registering new conventional active ingredients (AIs)

# ESA Protection Policy

## for Pesticide New Active Ingredients

- ▶ Previously, EPA was not consistently assessing potential effects of conventional pesticides on listed species during new AI registration
  - ▶ Resource-intensive litigation against EPA for registering new AIs
- ▶ The new policy will improve the legal defensibility of new AIs, which often have lower human health and ecological risks than older pesticides

# Registration Division

RD is responsible for:

- ▶ Registering conventional pesticide products
- ▶ Establishing pesticide tolerances
- ▶ Evaluating inert ingredients
- ▶ Reviewing special local needs (SLNs) applications
- ▶ Issuing emergency exemptions
- ▶ Conducting scientific reviews of product chemistry, acute toxicology, and efficacy data

# Registration Process

- ▶ Registrant submits and EPA reviews data on new pesticide products
- ▶ Data requirements depend on proposed use
  - ▶ More data required to register new food use pesticide than one with no food uses
  - ▶ Antimicrobials, biopesticides, and conventional pesticides each have different data requirements

# Application Package Screen

- ▶ Complete application package must be submitted
- ▶ When data packages are submitted to RD, the science divisions will screen early to determine if there are major data deficiencies
  - ▶ The 45/90-day screen is not intended to be a full review of the data, but rather a cursory review for package completeness
  - ▶ 90-day screen for actions > 6 months
- ▶ Request labels be revised to clarify any uncertainties before the reviews begin
- ▶ If science divisions identify any “showstoppers,” the division will provide a memo outlining the data deficiencies

## Data requirements

- ▶ Up to 150 different studies may be required to register a pesticide, including
  - ▶ Physical and chemical properties
  - ▶ Toxicology
  - ▶ Residue chemistry
  - ▶ Environmental fate
  - ▶ Ecotoxicity
  - ▶ Efficacy

# Technical Review

## ▶ **Health Effects Division (HED)**

- ▶ Typical outputs: Occupational and Residential Exposure Assessment; Dietary Exposure Assessment; Residue Chemistry Assessment; and Human Health Aggregate Risk Assessment

## ▶ **Environmental Fate and Effects Division (EFED)**

- ▶ Typical outputs: Drinking Water Assessment and Ecological Risk Assessment

## ▶ **Biological and Economic Analysis Division (BEAD)**

- ▶ Possible outputs: Alternatives or Benefits Assessment; Percent Crop Treated Analysis

## ▶ **Registration Division (RD)**

- ▶ Possible outputs: Label review per 40 CFR Part 156; Reviews of product-specific chemistry and acute toxicology data; Efficacy evaluation for a public health pest

# Public Participation

- ▶ **Notice of Filing:** “proposed rule” for requests to establish or modify tolerances
  - ▶ 30-day comment period
- ▶ **Notice of Receipt:** announce the receipt of applications to register new uses for products containing currently registered active ingredients
  - ▶ 30-day comment period
- ▶ **Additional public process** for some actions: new active ingredient, first food use, or new use of significant public interest

# Final Regulatory Decision

- ▶ Review the risk assessments and determines whether the action will be approved
- ▶ Discuss with the applicant if modifications to the product or labeling must be made to mitigate risk
- ▶ Ensure product labeling is in compliance with 40 CFR Part 156
- ▶ If a tolerance action is required, finalize before issuing a decision

# The Pesticide Label

- ▶ The label is the law:
  - ▶ “It is a violation of Federal law to use this product in a manner inconsistent with its labeling.”
- ▶ The label is the primary tool of the Office of Pesticide Programs to minimize pesticide exposures to mitigate risk concerns
- ▶ The label is how the EPA communicates with end users

# Label Components

- ▶ Ingredient Statement
  - ▶ Percent by weight
  - ▶ Active Ingredient(s)
  - ▶ Inert Ingredient(s)
- ▶ Precautionary Statements
  - ▶ Based off acute toxicity data
    - ▶ Signal Word
    - ▶ Hazards to Humans and Domestic Animals
    - ▶ First Aid
- ▶ Physical or Chemical Hazards
  - ▶ Based off product chemistry data

Active Ingredients  
Bifenthrin.....0.1%  
Other Ingredients.....99.9%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION** See back panel booklet  
for additional precautionary statements

**NET WT 10 lb (4.53kg)**

# Label Components

- ▶ Environmental Hazards
- ▶ Directions for Use
  - ▶ Application instructions
  - ▶ Restrictions
  - ▶ Advisory language
  - ▶ Storage and Disposal



## Label Changes are Common

- ▶ Registrant requests (this is the number 1 reason for label changes):
  - ▶ New sites, pests, claims, etc.
  - ▶ New names, clarify directions for use, etc.
  - ▶ Removal of sites, pests, uses
- ▶ State driven changes:
  - ▶ Use Restrictions in specific states
  - ▶ Regulatory or statutory changes
- ▶ OPP driven changes:
  - ▶ New rules or policies
  - ▶ PR Notices
  - ▶ Reregistration Eligibility Decisions (REDs)/Registration Review

# What do you do if you have a labeling question?

- ▶ Consult the Labeling Q&A Website
  - ▶ <https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers>
- ▶ Consult the Label Review Manual
  - ▶ <https://www.epa.gov/pesticide-registration/label-review-manual>
- ▶ Contact the appropriate Product Manager (for product specific questions) or Pesticide Product Registration Ombudsman
- ▶ Contact the Labeling Consistency Committee (LCC) for generic labeling questions

Thank you!