

## Pesticide Registration and Labeling – Part II

### Presentation 2

## Different Types of Registration

- New Chemical or New Active Ingredient
- New Use
- Identical/Substantially Similar to Registered Pesticides
  - Distributor Registration
  - Me too registration
- Conditional Registration
  - Require studies, but allow use until studies are complete (example MON 863);
  - Carry out monitoring programs (example acetochlor)

## Registration Processes

- New Registration (7 USC 136a)
- Reregistration (7 USC 136a-1)
- Experimental Use Permits (7 USC 136c)
- State Registrations and Emergency Use of Pesticides
- Pesticide Producing Establishments (7 USC 136e)

## New Registration Lots of Data Required

- A pesticide that contains a new chemical or active ingredient.
- New manufacturing-use product; registered active ingredient.

## New Registration Steps

- Meet with EPA to determine data requirements.
- For field studies of more than 10 acres or 4 hectares require and experimental use permit from EPA.
- Complete studies according to Good Laboratory Practices requirements
- Submit all studies and forms to EPA

## New Use Data Required

- New use a registered active ingredient.
  - Add use to Federal label
- Seek state registration if the State agency, based upon **satisfactory supporting information**, has determined that an appropriate federally registered pesticide product is not sufficiently available.

### Pesticide Registration Improvement Act Fees

- Fees for the review of application of pesticides vary depending on if the product contains a new chemical or adds a new use
- Fee table for the Pesticide Registration and Improvement Act 2012
- Table provides information on new and current conventional pesticides, biopesticides and antimicrobials.

### Fees for Different Pesticide Classes

- New active ingredient for a food use:
  - Conventional Pesticide: \$569,221
  - Biopesticide: \$46,305
- New manufacturing-use product; registered active ingredient: \$256,883
- New use for a registered chemical or active ingredient
  - Food Use: \$60,000 Non-Food: \$25,000

### Identical or Similar Products (Me Too) Registrations

“Identical/Substantially Similar” pesticide registration application refers to a request to register a new pesticide product that is identical in its uses and formulation or substantially similar in its uses and formulation to one or more products that are currently registered and marketed in the United States or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. Fee cost \$1,500 - \$11,000

### Other Types of Federal Registration

- Conditional Registration
  - Registration is issued and data specified by EPA must be submitted to continue registration.
  - Acetochlor a substitute for atrazine was registered with the condition that atrazine use be reduced.
- Distributor Registration
  - Registration of a product already registered but relabeled with the name and address of the seller or distributor; not the manufacturer.

### State Registrations

- There are 50 States in the United States. This compares to 23 Provinces in China.
- States may register pesticides to meet local pest problems if necessary and comply with Federal guidelines.
- The manufacturing use product and the technical grade active ingredient must be registered with the EPA.

### Data Evaluations

- As part of the pesticide registration process, data is evaluated to determine hazards.
- Some pesticides may be restricted.
- Only qualified pesticide applicators may purchase or use restricted pesticides.
- Pesticide products may be classified for restricted use if any of the following levels are met.

### Restricted Classification Points Slide 1

For residential or institutional pesticides

- The pesticide, as diluted for use, has an acute oral LD50 of 1.5 g/kg or less.
- The pesticide, as formulated, has an acute dermal LD50 of 2000 mg/kg or less.
- The pesticide, as formulated, has an acute inhalation LC50 of 0.5 mg/liter or less, based upon a 4-hour exposure period

### Restricted Classification Points Slide 2

- The pesticide, as formulated, is corrosive to the eye (causes irreversible destruction of ocular tissue) or results in corneal involvement or irritation persisting for more than 7 days.
- The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe irritation (severe erythema or edema) at 72 hours

### Restricted Classification Points Slide 3

- When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic, chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues.

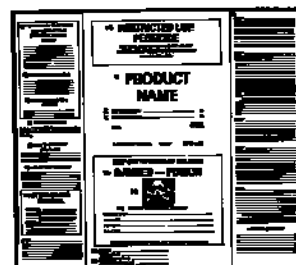
### Example of Chemical Burns to Skin



### Ways to Prevent Injury

- Labeling
- Packaging
- Control of Distribution

### Example of Label with Required Text



### Required Statements

- Name and address of registrant or distributor;
- EPA Registration Number;
- Active Ingredient and its percentage;
- Signal word or hazard classification;
- Precautionary statements, hazards to humans and domestic animals, first aid and environmental hazards.

### Label - Directions for Use 1

Provide legal framework for how a pesticide may be applied and how it must not be applied.

- Have a statement that it is a violation of Federal law to use the product in a manner inconsistent with its labeling;
- Labels list sites (crops) where a pesticide may be applied;
- How much pesticide may be applied (rate of application);

### Label – Directions for Use 2

- Restrictions such as weather, time of day, season of year;
- How often or frequently the pesticide may be applied;
- How long to wait before people may enter the area treated with the pesticide (re-entry interval or REI);
- How long to wait before crops treated may be harvested (pre-harvest interval or PHI);
- How to store and dispose the pesticide.

### EPA Website for All Pesticide Labels

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch1>

### Packaging Requirements

- Packaging requirements for pesticides are found in 40 CFR Part 157
- Criterion for Child Resistant Packaging are:
  - Product intended for home or residential use;
  - Has low oral, dermal (skin), or inhalation toxicity;
  - Has a history of accidents that child resistant packaging could prevent.
  - For more details see Reference 2.

### Child Resistant Packaging



### Emergency Exemptions

- The leader of a State or Federal Department may seek emergency use of a pesticide.
- The department must first contact EPA to inform them about the emergency.
- There is an emergency if no registered pesticide is sufficiently available to control the pest problem.

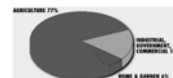
### Minimum Risk Pesticides

- EPA has determined that some products making claims for pest control do not require regulation.
- These are called minimum risk pesticides and are exempt from National regulation.
- Most are natural products and oils.
- List is at 40 CFR 152.25(f)
- States may require registration.

### Reregistration

- EPA is required to review registration of pesticides after 15 years.
- Registration eligibility document issued is and registrants must submit additional data to support registration (if required) to continue with the registration.
- A link to EPA Pesticides Chemical Search page is Key Reference 7.

### Pesticide Use by Market



### Pesticide Production Locations



### Pesticide Producing Establishments

- Pesticides producing establishments are also required to register with EPA.
- Annual production of pesticides must be reported to EPA.
- Production reports are confidential.
- Rules covering the registration of establishments and reporting requirements are in Key Reference 2 (40 CFR 167)

### Summary

- Pesticides must be registered with EPA before they can be distributed in the United States.
- How the pesticide will be used determines data requirements.
- Labels instruct pesticide applicators how a product is to be used.
- These labels become law and must be followed.

### Summary

- Pesticide manufacturing plants must be registered with EPA.
- Annual production reports are required.

### References, Acknowledgements and Web Addresses

- Pesticide Registration Improvement Act Link to Fee Table – This table shows lower fees for safer products. The fee for registering Biopesticides is about one-tenth (1/10) the cost of conventional pesticides.
- <http://www.epa.gov/pesticides/fees/tool/category-table.html>
- Link to registration programs for State governments.
- <http://www.epa.gov/opprd001/registrationmanual/chapter17.html>
- Classification of Pesticides for Restricted use
- Link to EPA List of Restricted use pesticides.
- <http://www.epa.gov/opprd001/rup/rupreport.pdf>
- Link to ISO website and Child Resistant Packaging Credit
- [http://www.iso.org/iso/home/news\\_index/news\\_archive/news.htm?refid=Ref861](http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref861)
- Key Reference 7
- <http://iaspub.epa.gov/apex/pesticides/?p=chemicalsearch:1>
- Chart on Pesticide Markets
- <http://www.brighthub.com/environment/science-environmental/articles/33448.aspx>