OVERVIEW OF EPA PESTICIDE REGISTRATION

presented to:

Maryland Pesticide Reporting and Information Workgroup
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Office of Pesticide Programs

Topics

Regulatory Framework

Data Requirements

Registration Process

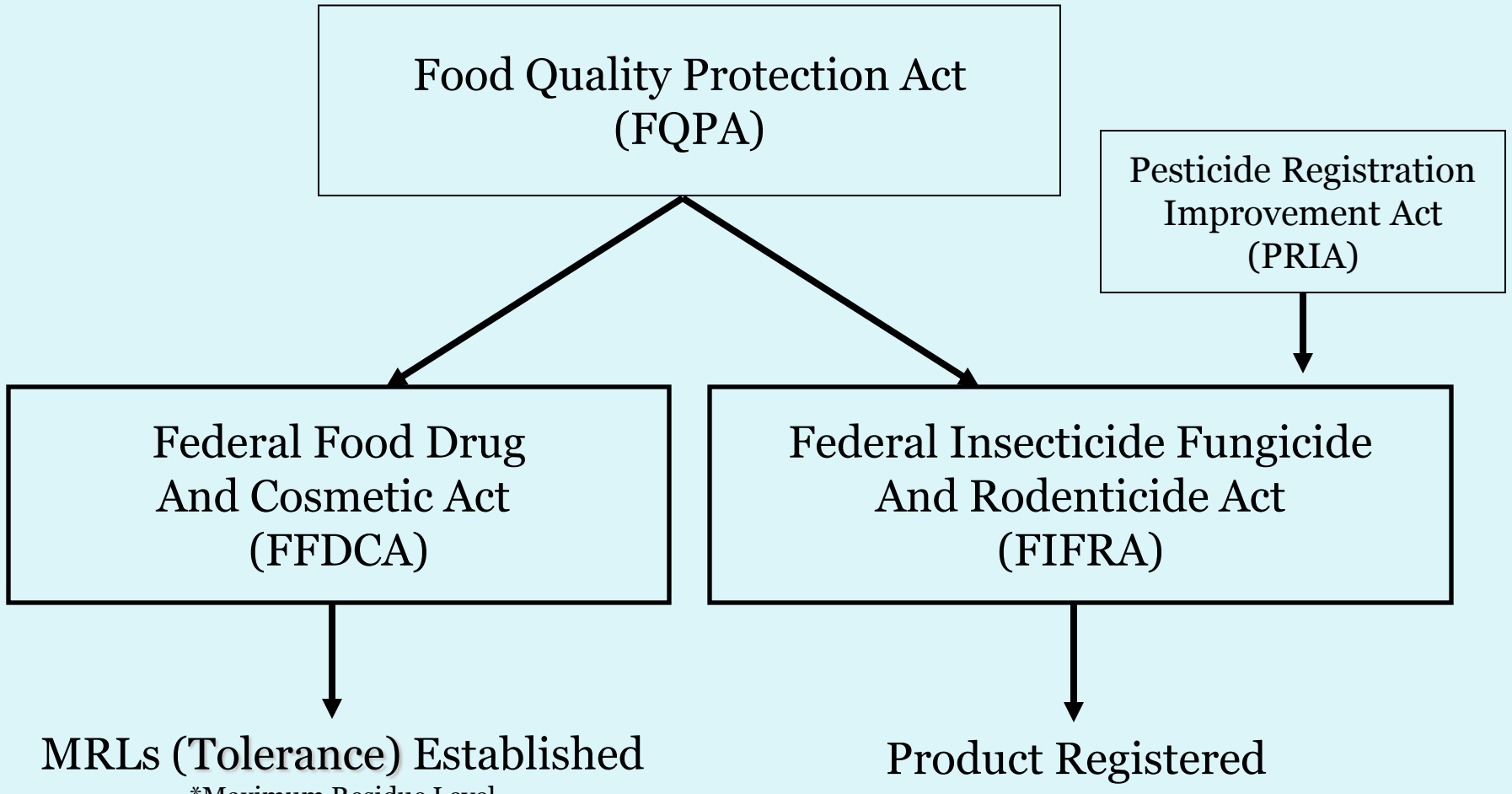
Usage Data

Regulatory Framework

Pesticide Registration Program

- EPA's Office of Pesticide Programs (**OPP**) mission:
  - Protect public health and the environment by ensuring pesticides and alternatives are safe and available for a healthy America.
- OPP must approved all pesticide products before they can be sold and used in the US.
- By law, EPA must act on all pesticide registration applications that it receives.

Federal Pesticide Laws



Office of Pesticide Programs
Organizational Chart

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William Jordan, Deputy Director
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Oscar Morales, Director
Michael Hardy, Deputy Director
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Jay Ellenberger, Deputy Director
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Jennifer McLain, Deputy Director
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Dan Rosenblatt, Deputy Director
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Robert McNally, Director
John Leahy– Associate Director
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Pesticide Re-evaluation Division
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Michael Goodis, Associate Director
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Dana Vogel, Deputy Director
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Environmental Fate & Effects Division
Donald Brady, Director
Jim Cowles, Associate Director
Anita Pease, Associate Director
(703) 305-7695

Current as of September 2013

Scope of U.S. Registrations

- **1,200** active ingredients
- **16,000** products
  - **1,000** Restricted Use Products (RUP)
- **16,000** tolerances (MRLs)

Data Requirements

Data Requirements

- 40 CFR 158
- Data requirements depend on the proposed use(s):
  - Requirements vary by type of chemical: antimicrobial, biopesticide, and conventional
  - Requirements depend on use (food involves more data than non-food)
- Hundreds of studies may be required to register a pesticide, including:
  - Product Chemistry
  - Toxicology and Health Effects
  - Applicator and Post-Application Exposure
  - Residue Chemistry
  - Environmental Fate
  - Ecotoxicity
  - Efficacy

Product Chemistry

- Identity and composition
  - All ingredients: active pesticide, inerts, impurities
- Manufacturing process
  - Identify the potential for impurities
- Physical and chemical properties
  - Determine physical and chemical hazards on label
- Analytical methods
  - Used for enforcement analyses

“Other” (inert) Ingredients

- All inerts must be approved by the Agency.
- EPA regulates the entire product formulation. All ingredients, including inerts, must meet the standard for registration.
- Inert ingredients in pesticide products used on food and feed crops, agricultural commodities, or livestock must have a tolerance or tolerance exemption.

Health Effects

- Toxicology
- Residues
- Exposure

Environmental Effects

- Ecological Toxicity
- Environmental fate
- Non-target exposure

Efficacy
Data must be Submitted For Certain Pests

Pesticide Registration Notice 2002-1

Proposed Labeling

- Uses on label determine the data which is required.

- Label directions for use define some parameters in risk assessment

Registration Process

Types of Registration Applications

Type	PRIA Application Fee	Review Timeframe
New active ingredient	$200-600 K	14-24 months
New use	$20-400 K	6-21 months
New product	$2-12 K	4-12 months
Label amendments (data based)	$4-12 K	4-9 months
Label amendments (text)	$0	3 months

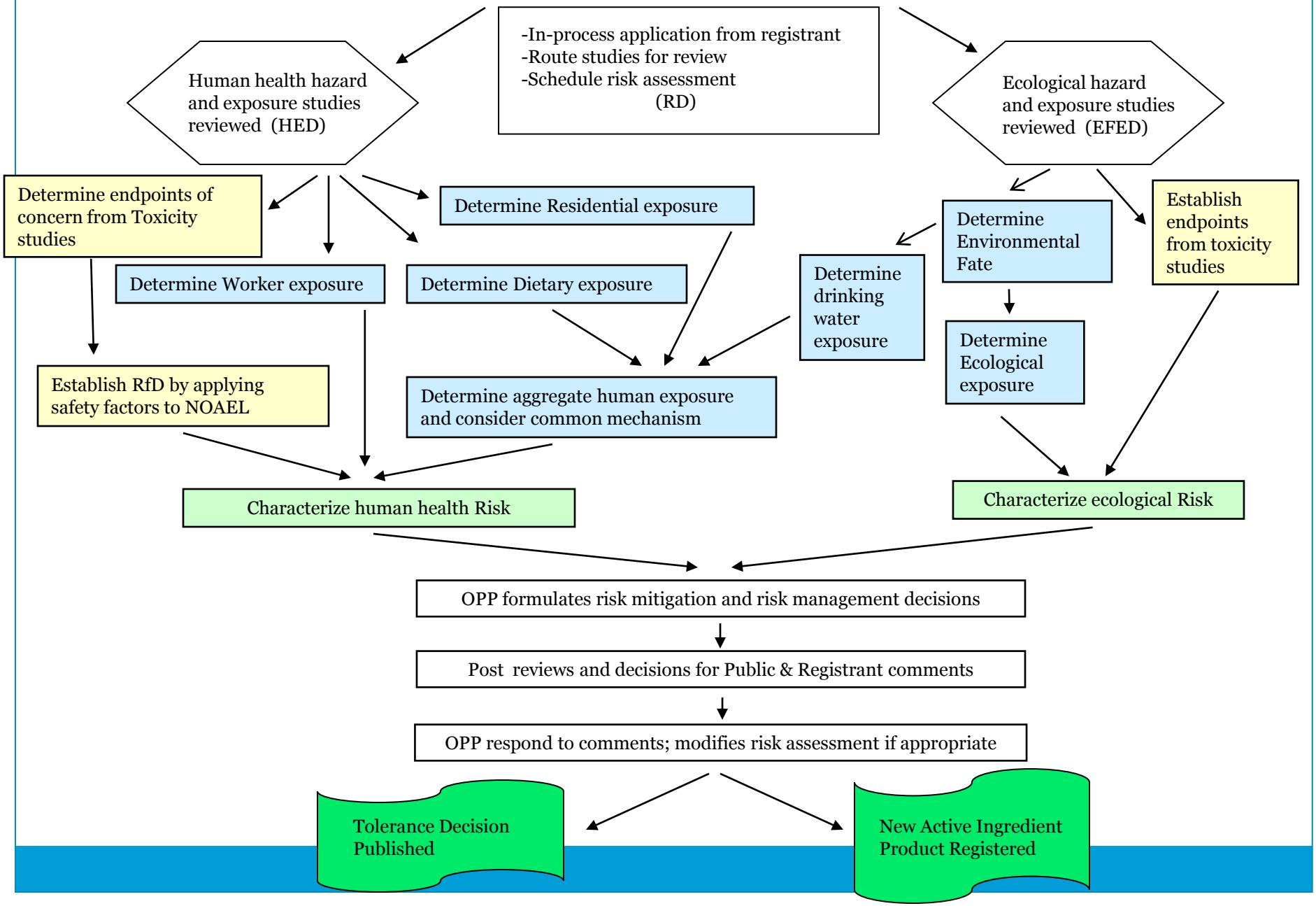
OPP Registration Process:
Risk Assessment & Risk Management

1. Registrant develops a pesticide, conducts studies, and submits a registration application.

2. OPP risk assessors review studies and assess risk.

3. OPP risk managers make registration decision based on the risk analyses, benefits, and any adverse incident information.

OPP Registration Process (new a.i.)



Transparency and Public Process

- Transparency and public participation are critical.

- OPP began implementing public participation process in October, 2009 for the following types of applications:
  - new active ingredients;
  - first food use;
  - first outdoor use;
  - first residential use; and
  - other actions of significant interest.

Transparency and Public Process

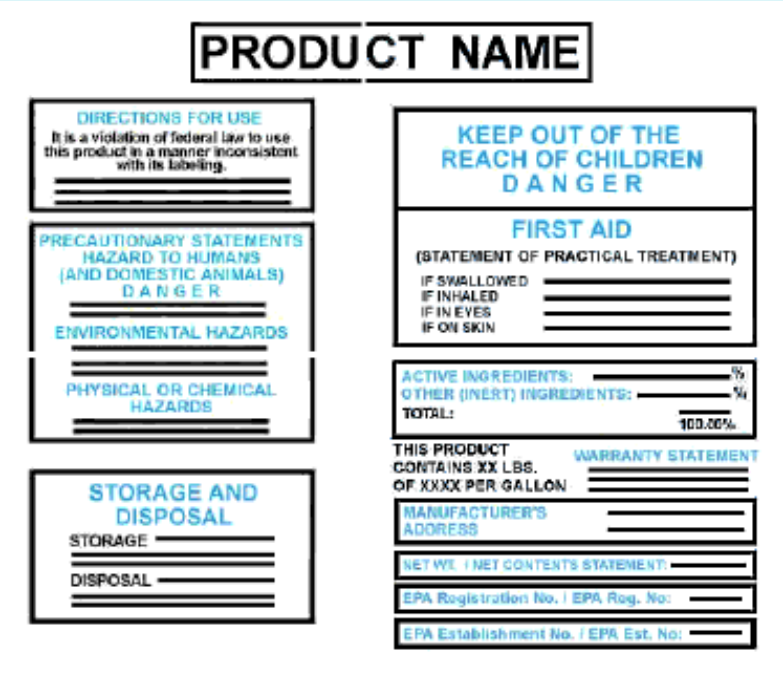
- OPP reviews, proposed labels, and proposed OPP decision are posted in a Docket (available via www.regulations.gov).
- The general public and the registrants may submit comments during a defined time period.
- OPP reviews and writes a response to comments (which itself is then posted in the Docket).
- Risk assessments and regulatory decision may be revised based on comments.

Result – EPA accepted Labeling

- Label defines where and how to use the product including limitations to use.

- EPA approves the “master label” which defines all uses for product label. This may be subset into several labels for state registration.

The Label is the Law



- EPA Registration Number
- Establishment Number
- Directions for Use
- Signal Word
- First Aid
- Ingredients Statement
- Precautionary Statements
- Hazards Statements
- Environmental Hazards
- Physical or Chemical Hazards
- Storage and Disposal
- Warranty Statement
- Net Contents

Labeling requirements are product-specific, and are informed by the data.

Label Review Manual: http://www.epa.gov/oppfead1/labeling/lrm

Usage Data

When is usage data used

- Screening Level Risk Assessment
  - Conservative
  - Based on proposed label (max rate, max # apps/year, etc)
  - 100% crop treated

- Refined Risk Assessment
  - Based on usage data
  - Percent Crop Treated
  - Typical use rates
  - Typical application rate
  - Typical # applications/year, et al

Usage data examined by

- **Biological & Economic Analysis Div (BEAD)**
- Environmental Fate & Effects Div (EFED)
- Health Effects Div (HED)

Screening Level Usage Analysis (SLUA)

- Inputs to dietary exposure assessment
- National agricultural usage data by a.i.
  - crops treated
  - pounds applied
  - percent crop treated (PCT) (avg and max)
- Published in Final Rules & EPA Dockets

- **Recipients:** RD, HED, SRRD, EFED, BEAD

Projected Percent Crop Treated (PPCT)

- Inputs to dietary exposure assessments
- Forecast of the % of a crop that will be treated (new a.i. or new use)
- Methodology (market leader approach) developed in BEAD
  - Based on the Market Leader Analysis conducted in 2006
- Published in Final Rules

- **Recipients:** RD, HED

State-level Usage Reports

- Inputs to Drinking Water Risk Assessment
  - Average application rate
  - Typical number of applications
  - Application timing
  - Total acres treated
  - Maximum application rate per acre

- **Recipients:** EFED, BEAD

Production Data (CBI)

- Reports contains:
  - How much of a chemical is produced by a.i. or product (registration number)

- **Recipients:** RD**,** SRRD, HED, BPPD, AD,

Data Sources: Proprietary

- GfK Kynetec AgroTrak (Doane)
- SIGMA *(Strategic Information for Global Markets in Agrochemicals)*
- Kline & Company (non-ag) studies
- Section 7 Tracking System (SSTS) Production Data

Data Sources: Public

- USDA NASS
- California DPR
- NPUD *(National Pesticide Use Database), CropLife Foundation*

Challenges

- Rising cost of primary usage data sources
- Outdated data
- Lack of regional or national usage data
- Common limitations (esp. non-ag)
  - Only one proprietary source
  - Lack of periodic updates
  - Data for several a.i's grouped together
  - No information on treatments of commodities

Incident Data

- Adverse non-target effect due to pesticides
- 80,000 incidents reported / year tracked in database (IDS)
- Majority reported by registrant under FIFRA 6(a)(2); others reported by public or enforcement
- Data examined:
  - Post-registration reviews (Registration Review)
  - Emerging hot topics (pet collars)
- Patterns of unintended problems or intentional misuse may result in changes to registration.

Additional Information - Data Requirements

- Data requirements are listed in 40 CFR Part 158.

  http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=b554cfeeee1568ccd5319444fccdf025&rgn=div5&view=text&node=40:25.0.1.1.9&idno=40

Additional Information – Registration Process

- Pesticide Registration Kit & Forms.
  http://www.epa.gov/pesticides/registrationkit/
- Pesticide Registration Manual (Blue Book).
  http://www.epa.gov/pesticides/bluebook/
- PRIA (fee schedule, fee determination, waivers, refunds).
  http://www.epa.gov/pesticides/fees/
- Data Requirements Checklist.
  http://www.epa.gov/pesticides/fees/data_require_check.htm
- Examples of Completed Registration Forms.
  http://www.epa.gov/pesticides/bluebook/appendix-d.html

Additional Information - Labeling

- Label Review Manual. http://www.epa.gov/oppfead1/labeling/lrm/
- Pesticide Product Labels Webpage. http://www.epa.gov/pesticides/regulating/labels/product-labels.htm
- Pesticide Registration Notices. http://www.epa.gov/PR_Notices/index.htm

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Thank you!

Questions?