Handler and Worker Exposure Assessment

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Outline

- Labels and Use Information
- Worker Protection Standard (WPS)
- Criteria for Occupational Exposure
- Incidents
- Toxicity
- Exposure Data
- The Assessment (Back to the Labels and WPS)

Start With The Label

Labels and Use Information

- Continue to be the main source of information.
  - Legal document (all regulatory decisions are delineated here).
  - Can provide many details regarding the application (e.g., crops, rates, pests).
  - Pre-harvest Intervals (PHI), Restricted Entry Intervals (REI).
  - Applicator Clothing Requirements.

Labels and Use Information

- What labels don’t tell you about applications.
  - Who applies (professional v.s. private grower)?
  - What are the major crops and where are they grown?
  - When and where are the applications made (all season or brief windows)?
  - How many acres does someone treat in a day and how often?
  - Why is it applied (what are pest pressures)?

Labels and Use Information

- We need detailed use information to identify the activities of concern.
  - Phosmet controls codling moth on apples and is used throughout the period when workers are thinning fruit in the PNW (about 6 weeks).
- Why? Because frequency and duration are critical when identifying toxicity endpoints of concern. Exposure durations longer than 30 days trigger the comparison of exposures to intermediate term endpoints which are often much lower than short term endpoints.

Labels and Use Information

- Other sources of information.
  - LUIS reports have summarized label information.
  - Quantitative Usage Analysis (QUA).
    - Summarizes use information from USDA's National Agricultural Statistics Service and proprietary marketing research (e.g., Doane and Maritz).
  - Registrants, Cal-EPA and the internet.

Worker Protection Standard (WPS)

- Implemented in 1992 and established *interim* handler and early –entry personal protective equipment (PPE) and restricted entry intervals (REI).
  - Leveled the playing field for chemicals with similar acute toxicities.
  - Provided for wash water to be available in the field.
  - Got rid of “sprays have dried and dusts have settled.”

WPS

- Interim PPE and REI's are based on acute toxicity
  - Acute Dermal Toxicity
  - Acute Inhalation Toxicity
  - Primary Eye Irritation
  - Primary Dermal Irritation
- Handlers (mixer/loaders, applicators, flaggers)
  - Acute toxicity of end-use-products
- Workers (field reentry)
  - Acute toxicity of the active ingredient

WPS

- The interim PPE and REI requirements are to be re-evaluated in the risk assessment process.
- Why?
  - Because the risk assessment is based on the toxicity of, and exposure to the active ingredient.
  - Which means comparing occupational exposure to the appropriate toxicity studies from the entire database of toxicity studies for a given AI.

Criteria For Occupational Exposure

- Conditional not generic
- Exposure and toxicity criteria must be met
- Toxicity concerns often identified prior to risk assessment
- Data are expensive, rely on surrogate data
- Use few studies to address many uses

Toxicity Criteria

- Acute Dermal and Inhalation Toxicity (I and II)
- Cholinesterase Inhibition
- Acute Delayed Neurotoxicity
- Developmental Toxicity
- Cancer

Toxicity Studies Used

- Short Term Exposure (1-30 days)
  - Cholinesterase
  - Acute Delayed Neurotoxicity
  - Developmental
- Intermediate Term Exposure (30-90 days)
  - 90 day Neurotoxicity
  - 90 and 21 day Dermal Toxicity Studies
  - 90 day Inhalation Toxicity

Incident Data

- Sources
  - 6a2, California other states, NPTN
- Limitations
  - Tank mixes (which one responsible?)
  - Symptoms such as irritation caused by soil, crops, pollen
  - Adverse effects we regulate on cannot be noted by individuals
  - Under-reported (language, fear, cost)

Exposure Data

- Guidelines (875 Group A and B)
- Dermal: dosimetry data to derive applicator and reentry exposure values
  - Group A - Applicator (unit exposure)
  - Group B – Reentry (transfer coefficient)
- Inhalation: personal air monitors
  - Group A and B
- Dislodgeable Foliar Residue (DFR)
  - Group B

Handler Exposure Data

- Unit Exposure (mg/lb ai handled)

$$\frac{\text{mg expo during an activity (e.g., airblast)}}{\text{amount ai handled}}$$

Represents exposure to the skin

Handler Exposure Data Use of Unit Exposure (UE)

$$\text{Dose} = \frac{\left[\textit{unit exposure}\right] \times \left[\text{application rate}\right] \times \left[\frac{\text{acres}}{\text{day}}\right] \times \left[\%\text{dermal absorption}\right]}{\text{Body Weight}}$$

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Dose (mg/kg/day)}}$$

We have different unit exposure values for each job
Unit exposure = mg ai on skin per lb ai applied or mixed
Monitors are very sensitive (1 mg = 0.000002 pounds)

Handler Exposure Data (UE)

- Unit Exposures are believed to be generic because exposure is a function of formulation (mixing/loading) and application equipment (airblast v.s. groundboom)
- Basis for Pesticide Handlers Exposure Database (PHED)
- PHED Surrogate Table (Version 1.1, August 98)

Handler Risks: Application Rate

$$\text{Dose} = \frac{\left[\text{unit exposure}\right] \times \left[\textit{application rate}\right] \times \left[\frac{\text{acres}}{\text{day}}\right] \times \left[\%\text{dermal absorption}\right]}{\text{Body Weight}}$$

Handler Risks: Acres Per Day

$$\text{Dose} = \frac{\left[\text{unit exposure}\right] \times \left[\text{application rate}\right] \times \left[\frac{\textit{acres}}{\textit{day}}\right] \times \left[\%\text{dermal absorption}\right]}{\text{Body Weight}}$$

Reentry Exposure & Residue Data

$$\text{Dose} = \frac{\text{DFR} \times \text{TC} \times \text{Hours per day} \times \text{Der. Abs.}}{\text{Body Weight}}$$

- Transfer Coefficients = measure of contact with treated plants for specific jobs (e.g., thinning)
- Dislodgeable Foliar Residue = what can rub off on your skin, varies with time and application rate

Reentry Exposure Data

- Transfer Coefficient (cm^2/hr)

  mg expo/hr during an activity (thin apples)

  Dislodgeable Foliar Residues (mg/cm^2)

  Represents exposure to the skin

Reentry Exposure Data (Transfer Coefficient)

- Transfer Coefficients are believed to be generic because exposure is a function of crop and activity
  - Harvesting sweet corn v.s. hoeing weeds in lettuce
- Timing of applications with respect to reentry activities is key
- Policy 003.1 Surrogate Transfer Coefficients

Reentry Exposure: Transfer Coefficient (TC)

$$\text{Dose} = \frac{\left[\text{TC}\right] \times \left[\textit{DFR}\right] \times \left[\frac{\text{hours}}{\text{day}}\right] \times \left[\frac{\%\text{dermal}}{\text{absorption}}\right]}{\text{Body Weight}}$$

Reentry Exposure: Dislodgeable Foliar Residue (DFR)

$$\text{Dose} = \frac{\left[\text{TC}\right] \times \left[\textit{DFR}\right] \times \left[\frac{\text{hours}}{\text{day}}\right] \times \left[\%\text{dermal absorption}\right]}{\text{Body Weight}}$$

Reentry Data: DFR Sampling…

Triplicate samples, typically 40 – 5 cm^2 punches

0, 1, 2, 3, 4, 5, 7, 10, 14, 21 & 28 days after application

Reentry Data: DFR Sampling

- 5 cm^2 (area of one side of leaf) x 40 punches = 200 cm^2
  - Leaves have two sides 400 cm^2
- Dislodge in a water/surfactant mixture
- Extract residue from mixture in lab (mg/400 cm^2)
- and adjust to mg/cm^2

Reentry Data: DFR Sampling

- Remember, some older studies did not assume two sided leaves (has big impact on TCs and use in risk assessments)
- Single sided DRFs result in 2x higher DFR values and 2x lower TCs.

The Assessment

- Handlers
  - Reregistration evaluates WPS *interim* PPE
    - Based on analysis of all uses, PPE can be increased, decreased or stay the same based on NOELs specific to the Active Ingredient
    - Additional PPE may be needed based on the toxicity of the end-use product
  - Registration actions may be limited to evaluation of the end-use product.

The Assessment

- Reentry
  - The WPS *interim* REI can be increased, decreased or stay the same
  - Generally not lower than 12 hours (4 hours possible)
  - Eye and skin irritation are special cases