Practical Aspects of Exposure and Risk Assessment for Pesticides

(WHS Photo)

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Outline

- Introduction
  - Pesticides regulated by U.S. EPA and state agencies
  - Law requires pesticide use without undue risk
  - Pesticide use conditions are set by agencies to mitigate risks
- Pesticide exposure and risk assessment
  - Used by agencies to determine if protective measures needed
  - What data are used, data gaps
- Pesticide risk management
  - How potential health concerns are addressed
- Conclusions – Label content drives exposure and risk
  - Need to justify risk management decisions

Introduction

- By law, all pesticides must be registered before use
  - All pesticides used in U.S. registered with U.S. EPA
  - Pesticides sold and used in California registered with the Department of Pesticide Regulation (DPR)
- Before registration both agencies assess how a pesticide will be used
  - Each company wanting to register a pesticide must submit a proposed label with detailed use instructions
  - Company must also submit data
- Risks are re-assessed when needed
  - New data, changes in uses, etc.

Regulation of Pesticides in California

- U.S. EPA and DPR are both obligated to protect human and environmental health
  - Federal law: U.S. EPA must show that allowed pesticide uses do not cause "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits."
  - California law forbids DPR from registering a pesticide if “when properly used” it is “detrimental...to public health and safety”
- DPR is allowed to register only pesticide products that are registered by U.S. EPA
  - DPR can place additional restrictions on use beyond those required by USEPA

Why Additional Restrictions in California?

- Agricultural-intensive state with an extensive ag-urban interface

- Climate
  - Longer growing seasons and mild winters can lead to more pest pressures and more occasions for pesticide use
  - Some pesticides can take longer to dissipate under arid conditions in California

(Photo from Schmidt et al., 2010)

Pesticide Use Conditions for User Safety

More about this later!

- Label sets maximum allowed application rates
  - Rates should be just enough to be effective to control target pests on specific crops
- Precautionary measures on pesticide labels are intended to limit exposure
  - Handler Personal Protective Equipment (PPE)
  - Engineering Controls
- Law requires users to follow label requirements
  - In risk assessment we assume legal uses

Pesticide Exposure and Risk Assessment

- Risk assessment is the process regulators use to assure that pesticides can be used safely (decisions must be defensible)
- Risk includes both toxicity and exposure
  - If there is no exposure, then no risk
  - Low (or practically no) toxicity, low risk
- Risk assessment compares the exposure to the dose where no effects were seen
  - Exposure should be below the no-effects dose, multiplied by one or more safety factors

(WHS Photo)

Purpose of Pesticide Exposure Assessment

- The purpose of the exposure assessment is to estimate exposures resulting from legal uses of a pesticide in California.
  - Uses complying with federal and state laws
- Pesticide uses that fail to comply with label and other legal requirements are handled in the enforcement process
  - Non-legal uses are beyond the scope of the exposure and risk assessment process.

Exposure Assessment Goal

- Realistic, health protective estimates of exposure
  - Protect individuals from injury when pesticide is properly used
  - If not realistic, may waste efforts mitigating exposures when it would be better to focus on more hazardous pesticides, or may even remove pesticides from use when they can be used safely

Exposure Scenarios

- Combination of location and activity that leads to pesticide exposure
- Several types of exposure scenarios
  - Occupational handlers exposed during pesticide applications
  - Occupational reentry (post-application)
  - Residential handlers
  - Residential reentry
  - Airborne exposures of bystanders adjacent to applications and at a distance

(Photo from UFL)

Handler Exposures Assumed to Be...

- Generally independent of crop
  - Crop height can be a factor in exposure in ground and hand-held applications, not so much for aerial
- Dependent upon
  - Formulation
  - Application method
  - Amount of AI handled

(WHS Photo)

Formulation

- Dusty formulations such as wettable powders and dusts are associated with higher exposure
- Granular formulations
  - Generally contain less dust (fines) than wettable powders
  - Handling granules usually results in less exposure than most other formulations

(Photo by T. McCabe, USDA website)

Application Methods

- Higher applicator exposures with airblast than boom sprayers
  - Spraying upward and outward vs. spray directed downward behind applicator

(USDA Photo)

(WHS Photo)

Amount of AI Handled

- Typically handling more AI = more exposure
- We assume the relationship between amount AI handled and exposure is proportional
- Exceptions
  - M/L using closed systems
  - Loading granules from large bags

(e.g., more bags = more exposure, but amount in bag may not matter)

(WHS Photo)

Data Used in Pesticide Exposure and Risk Assessment

- Data used in assessments come from many sources
  - Pesticide registrants must submit certain data
  - Scientific papers by university and other researchers
- Required studies for registration include several types
  - Chemistry, efficacy (product performance), environmental fate
  - Toxicity studies to indicate hazards to people and animals
- Exposure studies are not necessarily required by law
  - Exposure sometimes estimated with limited information

Toxicity Data

- Required studies include dosing by oral, skin, and inhalation routes
  - Routes by which people can be exposed
  - Multiple laboratory animal species
  - Both short and long-term studies

- Look for most sensitive animals and the lowest dose at which health effects appear
- Uncertainties in moving from animals to people
  - Also high doses in lab to low exposures in field

(Photos from National Cancer Institute)

Exposure Data

- Workers making typical applications
- Dermal (skin) exposure
  - Exposure to skin with either patches or clothing, skin rinses or wipes
- Inhalation exposure
  - Air sampling pump at belt connects to tubing over shoulder

(WHS Photo)

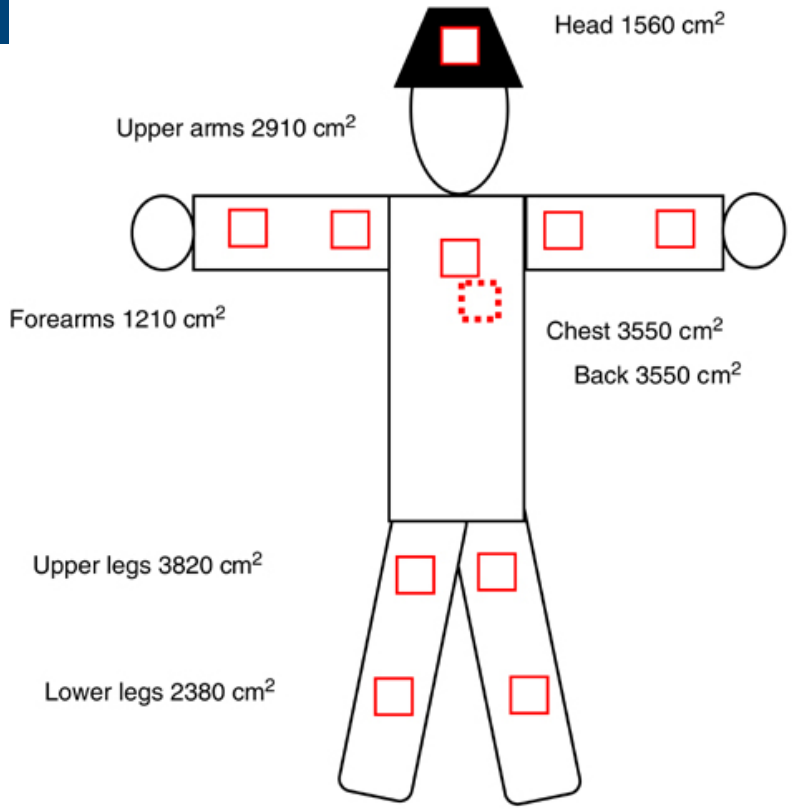
Measuring Dermal (Skin) Exposure

- Patch (common)
  - Patches on shoulder, back, chest, arm, thigh, shin
- Whole-body (preferred)
  - Garments covering body from shoulders to ankles
  - Cut in pieces for analysis

(WHS Photos)

Using Patches to Monitor Skin Exposure

- Older studies (and some newer ones) often measured skin exposure with patches
  - Body region represented by each patch is assumed to have homogeneous exposure



(Image adapted from Figure 1 in Baldi et al., 2006)

(But splashes on the patches can overestimate exposures, and exposures to areas other than patches are missed.)

Dermal Exposure: Head and Hands

- Head
  - Hat, patch or face/neck wipe
- Hands
  - Gloves, rinses or wipes

(AHETF Photo)

(WHS Photos)

Estimating Dermal Exposure

- Pesticide recovered from clothing, wipes, etc.
- Combine with other factors
  - Dermal absorption
  - Body weight
  - Body surface area (if patches were used)
  - Protection factors

(WHS Photo)

Inhalation Exposure Monitoring

- Monitor air in breathing zone
  - Sampler tube attached to pump
  - Chemical captured in tube and analyzed
- Combine with inhalation rate
  - Varies with activity, age, etc.
  - Absorption: How much of the pesticide crosses from the lungs into the bloodstream?

Types of Data for Handler Estimates

- Chemical-specific data (pesticide being assessed)
  - Study conducted with the pesticide being assessed
    - Only used if it meets quality criteria, etc.
- Surrogate data with chemical:
  - Having similar properties
    - Such as volatility or water solubility
- Generic data
  - Data from multiple studies pooled
    - All studies used must meet criteria

(Photo by T. Bowman, VTPP website)

The Pesticide Handlers Exposure Database (PHED)

- Computerized database containing:
  - Monitoring data on inhalation and dermal exposures
  - Data from handlers performing mixing, loading, application, and flagging tasks
  - Primarily in support of agricultural pesticide applications
- Major source of handler exposure data used by DPR
  - Combines data from many studies
- PHED was developed in the early 1990s
  - By the U.S. EPA, Health Canada, and the American Crop Protection Association

Caveats in Using PHED

- Data from multiple studies
  - Different methods, reporting limits, etc.
- Limited data in many scenarios
  - Several scenarios are based on just one or two studies
- Studies are older (conducted in 1977 – 1994)
  - Not always conducted according to current standards
  - May not reflect current handler practices
- Some studies only did partial monitoring
  - For some scenarios, exposure of parts of the body based on one or a few observations

Updating Handler Exposure Data

- The Agricultural Exposure Task Force (AHETF) has been conducting studies in recent years
  - Exposure of activities not covered by PHED, or covered with poor quality data
- AHETF created a new database for these studies
  - Agricultural Handlers Exposure Database (AHED)

(Opening screen of AHED)

Open-Pour Mixer-Loader of Liquids

- More exposure data available for this scenario than any other
  - Many studies in different locations using a variety of pesticides and PPE
  - Large “generic” data set
  - Workers monitored for as little as 10 minutes, some longer
  - We assume an 8-hour workday in the exposure assessment for this and other occupational scenarios

(USDA Photo)

Exposure Data Gaps

- Relatively few studies
- Enough exposure data to cover application methods in general but not all specific equipment
- Often lack information about how much pesticide is absorbed into body

Exposure Durations in Assessment

- **Short-term: Considered for all pesticides**
  - Upper-bound estimate: want realistic worst case
  - **1 Hour:** If health impacts occur rapidly
  - **8 Hours:** Occupational scenarios
  - **24 Hours:** Residential scenarios

- **Seasonal**, **Annual** and **Lifetime: Considered for pesticides with repeated use and long-term health effects**
  - Want typical exposures – evidence suggests that over longer intervals, individuals would not consistently have high-end exposures

Basic Exposure Calculation for Handlers

- Exposure = [(exposure rate) x (absorption) x (acres treated/day) x (application rate)]/(body weight)
  - **Exposure rate** (µg/lb AI handled) comes from chemical-specific, surrogate, or generic data
  - **Absorption (%)** for dermal and inhalation exposure routes comes from study data or defaults
  - **Acres treated/day** comes from default, how much is typically treated in a workday
  - **Application rate** comes from product labels

(WHS Photo)

Hand-Held Greenhouse Sprayer

- High exposure
  - Higher than aerial, airblast, or groundboom
- Higher exposure if applicator walks forward into spray
  - Higher still for overhead spray
- Depending on product, required PPE may include full coverage of head and body with chemical-resistant suit and gloves, plus full-face respirator
  - “Chemical resistance” not always tested

(WHS Photo)

Protection Factors Sometimes Used to Estimate Handler Exposure

- Used to estimate amount reaching skin or respiratory tract, if exposure monitoring study did not include required PPE
  - Exposure = (uncorrected estimate) x (1 - protection factor)
  - Uncertainty for some protection factors because level of protection may differ for specific chemicals and because data are lacking
- Most commonly used protection factors:
  - Dust mask/respirator: 90% (Cal/OSHA, 2007)
  - Gloves: 90% (Aprea *et al*., 1994)

Basic Calculation for Fieldworker Exposure

- Emphasis on dermal exposure to residues contacted as worker brushes against foliage
- Exposure = $\frac{[DFR \times TC \times ED \times DA)]}{BW}$
  - DFR: Dislodgeable foliar residue
  - TC: Transfer coefficient (cm^2/hour)
  - ED: Exposure duration (hours)
  - DA: Dermal absorption (%)
  - BW: Body weight (kg)

(WHS Photo)

Pesticide Risk Management

- Address potential health concerns identified in risk assessment
  - Decrease application rate
  - Change formulation or packaging for handlers
  - Additional engineering control or PPE for handlers
  - Extend REI for reentry

(WHS Photo)

Decrease Handler Exposure Using…

- Engineering measures or protective clothing/PPE

(Photo from TAMU)

(WHS Photo)

Engineering Control: Types Available

Closed Systems

Enclosed Cabs

Water Soluble Bag

Engineering Control: Enclosed Cabs

Enclosed cabs protect the worker by surrounding them with a protective barrier.

Only vehicles which meet the American Society of Agricultural Engineers Standard S-525 are considered to be eligible for designation as an “enclosed cab” as per regulatory definitions (Title 3, Section 6000 of the California Code of Regulations).

Engineering Control: Closed System

Closed systems must be able to remove the pesticide from its original container and transfer it, via mixing and storage systems, into an application device with little to no exposure to the mix/load crew.

Water-soluble bags are considered, **when used properly**, to be equivalent to a closed system.

PPE: CA Regulatory Requirements for Handlers

Title 8 CCR Section 5192

and

Title 3 CCR Section 6738

Employer shall select and require the use of appropriate PPE.

(i.e., Employers shall ensure proper PPE is used, in accordance with the label. They may also require more protective PPE.)

PPE for Handlers Respiratory Protection

- Particulates
  - Solid or liquid material suspended in air and are referred to as dust, mists, fogs, or smokes. These are the most common physical states for pesticide applications.
- Gasses and Vapors

  - Materials that are in solution in air, including true gasses (chlorine, methyl bromide, sulfuryl fluoride), and vaporized materials (DDVP, 1,3-D, chloropicrin). These can be simple asphyxiants (inert atmospheres), irritants (ammonia) or systemic poisons (hydrogen cyanide, methyl bromide).

PPE to Protect Handler's Eyes DPR Regulation, 3 CCR 6738(b)

Eye protection shall be provided and worn when required. There are exceptions.

Protective eyewear includes:

1. **Goggles**
2. **Face-shield**
3. **Full-face respirator**
4. **Safety glasses with temple/brow protection**
5. **Visors (for aircraft pilots ONLY)**

Not exactly what we had in mind.

PPE to Protect Handler's Skin DPR Regulation, 3 CCR 6736 & 6738

- Regulations specify that the employer shall provide coveralls for each employee who handles any pesticide with the signal word "DANGER" or "WARNING" on the label. There are exceptions.
- Regulations also specify glove materials if the label does not
  - Absorbent materials are prohibited, unless pesticide label specifically allows.

Handler PPE Exceptions DPR Regulation, 3 CCR 6738(i)

Exceptions to Required PPE:

Closed Systems/Mechanical transfer

Water soluble packets

Enclosed cabs

No gloves required for pilots during flight

Changes in Pesticide Use, Required PPE, etc., Require Justification

- Regulatory decisions must be defensible
  - May cost money to implement, or limit ability to use a product
- DPR can also cancel uses and products
  - If DPR determines that its use results in unacceptable risks that cannot be mitigated by other means

(Photo from UFL)

Ways to Implement Changes

- DPR can issue regulations
  - Lengthy legal process, requires outside consultation and public comment
- DPR also has option to recommend permit conditions for some pesticides
  - Restricted Materials: require permits from County Agricultural Commissioner before Use
- DPR can work with registrants and U.S. EPA to change product labels

U.S. EPA Must Approve All Pesticide Product Labels

- DPR does not have the authority to change product label content
  - Only U.S. EPA can require changes to labels
  - DPR can refuse to register a product if the label leads to a potential health concern
- U.S. EPA has issued guidance for label statements
  - Use their risk assessment
  - Based on toxicity studies

Conclusions

- DPR has an obligation to assure that all legal pesticide uses are protective of people and the environment.
- Exposure estimates are driven by label instructions and available data.
  - Sometimes data are very limited or non-existent.
- Data, assumptions, and extrapolations must be justifiable.