Pest Management Regulatory Agency

Environmental Risk Assessment

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Overview

- The PMRA
- Role of EAD
- Exposure assessment
- Toxicology assessment
- Risk characterization
- Risk mitigation
- Conclusion

Mandate of PMRA

- Protecting the health and environment of Canadians and supporting Canadian competitiveness by regulating pest control products (pesticides) and their use in an effective and transparent manner.

Environmental Assessment Directorate (EAD)

- Assess scientific data on the ecotoxicology and environmental fate and behaviour of pesticides;
- Conduct environmental risk assessments
- Recommend mitigation measures;
- Document scientific literature
- Participate in scientific committees within PMRA, HC and other departments and institutions (USEPA, OECD, NAFTA, etc.)
- Other projects: Improvement of risk assessment methods, buffer zones, water modeling, Tech teams, etc.

Objectives of environmental risk assessment

- Evaluate the likelihood that adverse ecological effects may occur (or are occurring) following exposure to pesticides and/or their transformation products
- Determine if changes in the use pattern (or proposed use pattern) are required to better protect the environment

Risk assessment framework
Environmental exposure assessment

- Evaluate the potential exposure (direct and indirect) to plants, insects and other animals of pesticide residues in water, food, soil and air;
- Includes information on the quantity of pesticides to which an organism can be exposed and the frequency and duration of exposure;
- Based on data on the fate and behaviour in the environment, modelling and monitoring in the field;
- Information on the active ingredient and the end-use product(s)
- For new chemicals and older already registered products

Data that may be required to assess exposure

- Physical-chemical properties
  - Solubility, vapour pressure, $K_{ow}$, $pK_a$, UV absorption.
  - Transformation (abiotic and biotic)
    - Hydrolysis, phototransformation, biotransformation (soil and water) aerobic/anaerobic.
  - Mobility
    - Leaching, volatilization.
  - Field Dissipation (DIR2006-01)
    - Fate and mobility at sites representative of pesticide use in various regions in Canada.
  - Bioaccumulation

Ref:
1. Guidelines for Determining Environmental Chemistry and Fate of Pesticides (T-1-255).
2. Harmonization of environmental chemistry and fate data requirements for chemical pesticides under NAFTA (DIR2003-03).

Exposure Assessment

Abiotic Transformation

- Phototransformation
  - Soil
  - Water
  - Air

- Hydrolysis
  - The pH can significantly influence the rate of hydrolysis (half-life)

Exposure Assessment

Biotransformation (20-30°C)

- Soil
  - Aerobic
  - Anaerobic (flooded)
- Aquatic systems
  - Aerobic water/sediments
  - Anaerobic water/sediment

- Provides information on the identity, formation and persistence of transformation products

Exposure Assessment

Mobility

- Adsorption/desorption
- Leaching in soil column
- Volatilization
Exposure Assessment

Adsorption/desorption

- The tendency of a pesticide to be adsorbed on soil particles can be expressed as the soil water-organic carbon coefficient ($K_{oc}$)
  - $K_{oc} = K_d / \% OC$
  - $K_d =$ distribution coefficient between soil and water
  - $\% OC = \%$ organic carbon

A high $K_{oc}$ = strong affinity to soil particle; A low $K_{oc}$ = highly mobile in the soil

Exposure Assessment

Terrestrial field Dissipation Studies

- Shows the fate and mobility of pesticides and their transformation products on sites representative of areas where the proposed product is to be used in Canada.

Exposure Assessment

Terrestrial field Dissipation Studies

- Applicants MUST consider the ecological regions of Canada
- Crosswalk with EU countries

Exposure Assessment

Dissipation (aquatic environment)

- Water solubility > 30 ppm
- $K_d < 5$ and most often < 1 or 2 mL/g
- $K_{oc} < 300$ to 500 mL/g
- Henry’s Law Constant $< 10^{-2}$ atm·m$^3$/mole
- Negatively charged (either completely or partially) at environmentally relevant pH
- Hydrolysis half-life $> 25$ weeks
- Photolysis half-life $> 1$ week
- Soil half-life $> 2$ to 3 weeks

Leaching

Characteristics of a chemical that has the potential to leach into the soil, Cohen et al. 1984

- Water solubility $> 30$ ppm
- $K_d < 5$ and most often $< 1$ or 2 mL/g
- $K_{oc} < 300$ to 500 mL/g
- Hydrolysis half-life $> 25$ weeks
- Photolysis half-life $> 1$ week
- Soil half-life $> 2$ to 3 weeks

Leaching

Calculated GUS score classification system (Gustafson, 1989)

$$GUS = \log\left(\frac{1}{t_{1/2}_{soil}}\right) \times \left(4 - \log_{10}(K_{oc})\right)$$

- GUS: Groundwater Ubiquity Score
- $t_{1/2}_{soil}$ = time required for the chemical to decline by 50% under field conditions;
- $K_{oc} =$ soil water-organic carbon coefficient

<table>
<thead>
<tr>
<th>GUS</th>
<th>Leaching potential</th>
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<tbody>
<tr>
<td>&gt; 2.8</td>
<td>Leacher</td>
</tr>
<tr>
<td>&gt; 1.8 and &lt; 2.8</td>
<td>Borderline leacher</td>
</tr>
<tr>
<td>&lt; 1.8</td>
<td>Non leacher</td>
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Leaching
Assessment of the potential for leaching

We consider:
- The Cohen et al. 1984 criteria;
- The GUS scores;
- Field dissipation studies and modelling;
- Studies conducted with lysimeters;
- Other field studies
  - e.g.: Prospective groundwater studies
- And, for re-evaluations, ground water monitoring data.

Environmental Hazards Assessment

- Describes the types of effects that a pesticide may elicit on organisms and how these effects may vary according to the exposure;
- Based on internationally accepted guidelines and surrogate species;
- Determine ecotoxicological endpoints and dose-response (e.g.: LD₅₀, NOEC, EC₂₅)
- Identifies the most sensitive organisms and helps predict the potential adverse effects to non-target organisms

Toxicity Tests

- Short term (acute)
  - e.g.: LC₅₀, LD₅₀, LR₅₀
  - LD₅₀ = dose at which 50% of the population dies
- Long term (chronic)
  - e.g.: NOEC, LOEC, NOEL, LOEL
  - NOEL = No effect level
  - Species Sensitivity Distribution (SSD) when data is available
  - E.g.: HD₃
  - Lab vs. Field

Non-Target Organisms: Terrestrial Invertebrates

Honey bee *(Apis mellifera)*

Earth worms *(Eisenia sp)*

Non-Target Organisms: Terrestrial Invertebrates

Beneficial Predators and parasites

- The Crab spider, predator of aphids *Misumena vatia*
- The Ladybird beetle, predator of aphids and scale insects *Harmonia axyridis*
- Wasps: *Tricogramma* (parasitic wasp)
Non-Target Organisms:
Terrestrial vertebrates

- Birds
  - Bobwhite quail (*Colinus virginianus*)
  - Mallard duck (*Anas platyrhynchos*)
  - Zebra finch (*Taeniopygia guttata*)

Non-Target Organisms:
Mammals

- Mammalian toxicity studies are assessed by the Health Evaluation Directorate for human safety
- The typical endpoints used by EAD to assess the risk to wild mammals are the acute oral toxicity and 2-generation Reproduction.
- Studies conducted with rats and/or mice

Non-Target Organisms:
Terrestrial Vascular plants

- Seedling emergence
- Vegetative vigour

Non-Target Organisms:
Freshwater

- Invertebrates
  - Crustaceans: Daphnia (Water flea)
    - (Acute toxicity and reproduction)
  - Fish
    - Warm water (Blue-gill sunfish)
    - Cold water (Rainbow trout)
      - (Acute toxicity, Early life stage (ELS) and full life cycle)
  - Amphibian
    - Often, fish study is used as a surrogate

Non-Target Organisms:
Freshwater plants (Algae and vascular plants)

- Green alga (*Selenastrum capricornutum*)
- Cyanobacteria (*Anabaena* sp.)
- Duckweed (*Lemna gibba*)

Non-Target Organisms:
Estuarine / marine

- Crustaceans: Acute toxicity and Chronic
- Mollusc embryo Larvae or shell deposition
- Fish
  - Acute toxicity
  - Salinity challenge test
- Algae (1 species)
  - Marine diatom

- Sheephead minnow
  - *Cypripedium variegatum*
Risk assessment framework

- Problem formulation
- Exposure assessment
- Hazards assessment
- Risk characterization
- Risk mitigation options

Risk Characterization

- Compare the exposure (Estimated Environmental Concentration – EEC) in the environment, according to the existing or proposed use pattern to the level at which adverse effects are observed in laboratory or field studies.
- If the EEC exceeds the level at which adverse effects are likely to occur (Level of concern – LOC), mitigative measures can be proposed to reduce the expected risk.

Risk Characterization:

- Screening level or refined assessment?
  - Screening level risk assessment (triage)
    - Pesticides and/or specific uses that do not pose a risk to non-target organisms;
    - Groups of organisms that are not expected to be at risk;
    - Pesticides and groups of organisms where there may be a potential for concern and for which further characterization of the risk is required
      - Based on conservative scenarios and simple methods.
  - Further risk characterization
    - Objective: Refine the risk characterization with more detailed exposure scenarios.
    - Refinement steps to further characterize and understand the risks

Expected Environmental Concentrations (EEC) – Terrestrial species

- Screening assessment
  - Soil: g ai/kg soil (Earthworms)
  - Application rate: g ai/ha (honey bees, beneficial arthropods, plants)
  - Food source: g ai/kg food (birds and small mammals)
    - Consumption of contaminated food items estimated according to the Hoerger and Kenaga (1972) and Fletcher et al. (1994)

Risk Characterization – Screening assessment for terrestrial species

- Integrates exposure and effects to determine risk using a Risk Quotient (RQ) for the most sensitive group of organisms.
- RQ = [EEC / Toxicity Endpoint]
  - RQ ≥ 1 environmental concerns may exist
  - RQ < 1 indicates margin of safety

Aquatic Risk Characterization – Screening assessment

- Water: g ai/L
  - 15 cm deep: forest and/or seasonal water body
  - 80 cm deep: permanent water body
  - Conservative hypotheses: Maximum yearly application rate, shortest application interval, adjusting for transformation for multiple applications, direct application
  - RQ ≥ 1 environmental concerns may exist
  - RQ < 1 indicates margin of safety
Aquatic Risk Characterization
Refined risk assessment

- Spray drift
  - If RQ ≤ 1 – Default 1 m buffer zones are required
  - If RQ > 1 – Appropriate buffer zones are determined
    - Aerial spray – AgDISP v.8.15 (2005)
    - Ground boom application (Wolf et Caldwell, 2001)
    - Ground Airblast application – (Ganzelmeier et coll., 1995)

- Run-off
  - EEC obtained by the models PRZM-EXAMS
    - If RQ < 1 – potential risk due to run-off has been identified
    - May characterize further – risk mitigation measures may be required

- NOAEC/NOAEL – NOEC/NOEL
  - The highest concentration/dose where NO effects are observed
  - No observed effects vs No observed adverse effects
    - Adverse: some effects may be observed but are not deemed deleterious
    - Used for human health assessment, not in EAD
  - C is for concentration; L is for Level (aka: dose)
    - For aquatic or soil dwelling organisms
    - In birds risk assessment, concentrations must be converted to dose (or level)
    - Mammal studies are almost always in doses

- NOEC/NOEL
  - Converting concentration to dose for birds - Example
    - Knowing that: 1 ppm a.i. = 1 mg a.i./kg diet = 0.0001 g a.i./kg diet
      - NOEL = NOEC x FIR/BW

    - Bobwhite quail
      - NOEC = 1000 ppm of a.i. diet = 1 g a.i./kg diet
      - Average BW = 214.5 g or 0.2145 kg
      - Average FIR = 19.14 g/bird/d
      - NOEL = 1 g a.i./kg diet x (19.14 g/bird/d ÷ 0.2145 kg bw) = 89.24 g a.i./kg bw/d

    - Mallard duck
      - NOEC = 60 ppm a.i. diet = 0.06 g a.i./kg diet
      - Average BW = 214.5 g or 0.2145 kg
      - Average FIR = 19.14 g/bird/d
      - NOEL = 0.06 g a.i./kg diet x (146.1 g/bird/d ÷ 1.04725 kg bw) = 8.37 g a.i./kg bw/d

Aquatic Risk Characterization – Other options for risk refinement

- Further characterize input to the modelling to more realistic scenarios.
- SPN2004-01, Estimating the Water Component of a Dietary Exposure Assessment
- Other ecotoxicity endpoints;
- Monitoring data and incident reports;
- Probabilistic risk assessment (uses distribution of effects ad exposure concentrations)

Risk assessment framework

- Problem formulation
- Exposure assessment
- Hazards assessment
- Risk characterization
- Risk mitigation options

NOAEC/NOAEL – NOEC/NOEL

- The dose will vary depending BW and FIR
  - Information on BW and FIR are usually found in the study, but not always
  - FIR can be estimated using the following equations (Nagy, 1987):
    - Birds: FIR = 0.648(BW in g)0.651
    - Mammals (Rarely needed): FIR = 0.398(BW in g)0.850
  - If avian BW not available, use of default average BW for species tested from (Dunning, 1993)

Risk mitigation measures – examples

- Reduce the number of applications per season;
- Establish buffer zones to reduce adverse effects caused by spray drift to sensitive habitats;
- Only allow ground applications (no aerial applications);
- Limit application for consecutive years;
- Use lower application rate (Supported by VSAD);
- Modify application timing (time of day or season);
- Use only some types of product formulations;
- Require immediate soil incorporation;
- Limit certain uses or active ingredient (ai);
- Adding hazard statements on the label

Buffer Zones

- Distance between the point of direct application and the closest downwind edge of a sensitive terrestrial and/or aquatic habitat
  - Calculated by spray drift models
  - Risk based (i.e., $\uparrow$ RQ $\rightarrow$ $\uparrow$ buffer zone)
  - Pesticide specific

Habitats to be protected