



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

Non-Target Organism & Ecological Effects Data Requirements for Biochemical Pesticides

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Approach to Biochemical Pesticide Ecological Risk Assessment

- Under FQPA, pesticidal effects on wildlife and environment are considered equally important with human health effects
- Reduced data requirements due to:
 - non-toxic mode of action
 - generally low use rates
 - no to low persistence in environment
 - active ingredient(s) may be indistinguishable from substance(s) already present in environment



Non-Toxic Mode of Action

- **Non-toxic biochemicals can be lethal to target pests!!!!**
 - suffocation
 - desiccation
 - growth regulation (insects)
- **Potential lethality to non-targets**



Components of the Risk Assessment (I)

- **Chemistry of the active ingredient**
 - mode of action
 - potential mutagen/carcinogen
 - persistence
 - environmental fate
- **Product Formulation**
 - liquid
 - granular
 - powder/dust



Components of the Risk Assessment (II)

- **Application Method/Rate/Timing**
 - foliar, soil, fog
 - amount per application per unit area
 - applications per growing season/calendar year
- **Use Site(s)**
 - terrestrial, aquatic
 - agricultural, natural area, urban/homeowner
 - target pest(s)



Components of the Risk Assessment (III)

- Requirement for Other Data/Information on a Case-by-Case Basis
- Chemistry/Toxicity of Other (Inert) Ingredients in product Formulation



The Risk Assessment (I)

- **Risk Assessment Components Used To:**
 - assess exposure to non-targets and fate in environment
 - assess adverse effects/toxicity to non-targets



The Risk Assessment (II)

Biochemical Pesticide Data Requirements

- 40 CFR 158.690 (d) Non-Target Organism, Fate, and Expression
- Tiers I, II, and III



The Risk Assessment (III)

- **Tier I (Acute Effects on Non-Targets) Study Guidelines**
 - Avian Acute Oral
 - Avian Dietary
 - Freshwater Fish LC50
 - Freshwater Invertebrate LC50
 - Non-Target Plant Studies
 - Non-Target Insect Studies



The Risk Assessment (IV)

- **Tier I (Acute Effects on Non-Targets) Study Guidelines**

- Subdivision M Series 154-6 to 154-11

- OPPTS Series 850

www.epa.gov/docs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/



The Risk Assessment (V)

Guideline Studies vs. Waiver Requests

- **Guideline Studies – Unambiguous**
- **Waiver Requests**
 - accompanied by quantitative data
 - scientifically credible rationale
 - no data needed if rationale demonstrates a lack of exposure to non-target(s)



The Risk Assessment (VI)

- **If One or More Tier I Studies Demonstrate Severe Adverse Effects/Toxicity, Higher Tier Studies Will Be Triggered**



The Risk Assessment (VII)

- **Tier II Studies – Environmental Fate**
 - Volatility
 - Leaching
 - Adsorption/desorption
 - Octanol/Water Partition Coefficient.
 - UV absorption
 - Hydrolysis
 - Aerobic soil/aquatic metabolism
 - Soil/aquatic photolysis



The Risk Assessment (VIII)

- **Tier III Studies – Long-term and/or More Detailed Non-Target Studies**
 - Terrestrial wildlife Testing
 - Aquatic Animal Testing
 - Non-Target Plant Studies
 - Non-Target Insect Studies



The Risk Assessment (IX)

40 CFR 158.690(d) Non-Target Organism, Fate,
and Expression Data Requirements*

***Read the Footnotes!!!**



Risk Managment

Risk Assessment Completed

- **Product Label**
 - Environmental Precautionary Statements
 - Use Restrictions (rate, timing, location)

OR

- **Recommend Denial of Registration**



QUESTIONS?

