Pesticide Use in Cannabis: 
What’s Holding Registrants Back?

Ashlea Frank
Compliance Services International
Lakewood, WA

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Pesticide Registration Process

FIFRA and CFR Section 40 outline basic framework for registration, rules of conduct, implementation mechanisms and decision-making guidelines.

Distribution, sale, and use of pesticides in US regulated by EPA-OPP under FIFRA
Pesticide Registration Process (cont.)

Registrant conducts research and submits data and application for registration to EPA

Registrant must show that use of the pesticide “will not generally cause unreasonable adverse effects on the environment”

FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."
Pesticide Registration Process (cont.)

EPA grants registration or license only after registrant meets scientific and regulatory requirement

Applicators are required by law to adhere to the label
Meeting Scientific Data Requirements

Over 140 different scientific tests required

Product Chemistry

<table>
<thead>
<tr>
<th>Physical/Chemical Test</th>
<th>OPPTS Guideline</th>
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<tr>
<td>Color and Odor</td>
<td>830.6302 &amp; 6304</td>
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<td>Physical State</td>
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<td>Oxidation/Reduction</td>
<td>830.6314</td>
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<td>Flammability</td>
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<td>Dissociation Constant</td>
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<td>Vapor Pressure</td>
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<td>Partition Coefficient</td>
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<td>Water Solubility</td>
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<td>UV-Visible Spectrum</td>
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<td>Stability to Heat &amp; Metal ions</td>
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Product Performance

Hazard to Humans and Domestic animals

Acute, Subchronic, chronic toxicity

Applicator and Post-application Exposure

Spray Drift

Residue Chemistry

Hazard to Non-targets

Ecotoxicology Studies for U.S. Pesticide Registration

- Adult LC, Tread
- Adult LC, Sprout
- Adult LC, Marine Fish
- Adult LC, Marine Shrimp
- Oyster Worm Growth
- Fish Emergence
- Life Stage
- Intermediate Life Cycle
- Risk Fall (ConCen)
- Microorganisms
- Reproductive (Mammals)
- Field Monitoring

- Monsanto Herbs (Herb 1)
- Non-target Tests (Herb 2)
- Field Testing (Test 3)
- Acute Residues
- Residue Blending
- Soil Drying - Evaluations

http://www2.ca.uky.edu/newsreleases/2000/Apr/pestrain.htm


Acute, Subchronic, chronic toxicity

http://pubs.usgs.gov/fs/2006/3119/

Product Development and Registration Cost and Time

Estimate to develop and register a new crop protection product expected to be > $250M; process can take up to 10 years

Registration Service Fee (PRIA 3) - $246,253 (conventional, new use, first food use)

Pesticide Registration for Use in Cannabis: Roadblocks and Other Issues

Photo of a rock slide on Highway 2 taken on Monday between Orondo and Waterville. The photo was taken by a Washington State Department of Transportation maintenance supervisor who sent it to a crew in Olympia that was coming over to assess the stability and safety of the slope before any work could start to remove the rock.
1 - No Regulatory Framework

#1 - Currently no regulatory framework since cannabis use is not legal at federal level

Special Local Needs labeling process not yet attempted mainly due to issues discussed here
2 – Risk Assessment Methods

Risk assessment methods have not been developed

Tolerances not established and registrants are not willing to help determine these because in the end, the product would still be in violation of federal law.

Additionally, any tolerance issues would begin to consume the total allowable residues for the product’s use.
3 – Complicated Potential Risk Profile

Multiple routes of exposure = lots of testing
  – Inhalation via smoking or vaporizing
  – Ingestion
  – Oral Absorption
    • Under tongue
    • On tongue
    • Mucosa tissues
  – Topical

Method for testing standard exposure is not established

http://www.crescolabs.com/consumption-methods/
3 – Complicated Potential Risk Profile (2)

Could rely on a surrogate for testing (i.e., tobacco, other herbs, etc.)

No established tolerance for pesticide residues on tobacco leaf and there are no surrogates that would cover all routes of exposure

Nicotiana tabacum field
https://www.cals.ncsu.edu/course/pp728/Phytophthora/Pnicotianae.htm
4 - Enforceability

Method for enforcing adherence to pesticide label for use in cannabis is not established; registrants do not want products used without a clear enforcement process.

Bottles of chemicals that the department said was found at a medical caregiver cooperative marijuana grow house. A Denver City Council decision could close down warehouses like this one due to safety concerns. (Denver Fire Department/ via City & County of Denver Communications Office)
5 – Legal Ramifications

• With such a high-value crop, registrants are aware of potential lawsuits
  – Crop insurance and loss claims
  – Abusing pesticide products

Walnut leaves after exposure to pesticide
Image by Terry Shafer
6 - Cost

Cost of product registration would be very high

Similar to issues minor crop growers face, registrants are hesitant about current market (high barrier to new registrations of any kind on low-acreage crop/use)
7 – Public Perception

Pesticide registrants are very concerned with public image and perception.

Discrepancies between state legalities and how that would be handled in federal registration process could bring even more hesitancy to pesticide companies.

In our current cultural environment, the negative public perception of cannabis is enough to make registrants leery of taking the risk.
The Future

What will it take to get registrants on-board?

• Federal regulatory process
• Established risk assessment methods
• Market needs
• Shift in cultural environment
Thank You!
Questions?

Ashlea Frank
Compliance Services International
Lakewood, WA

afrank@complianceservices.com