Cannabis Regulation
Laboratory Issues-
Activities of some SLA’s to date

• State hemp regulation- <0.3% THC
• State certification of applicators using pesticides
• Laboratory method development- Unique Matrix
• Authority to provide access to approved (legal) pesticide products
• National Workgroup to obtain multi-state input for human & environmental risk assessment resources (toxicology, env. fate, worker exposure…)
• National agriculture workgroup “proposed model bill”
EPA Special Local Needs “State Registration” for pesticide products

- EPA letter of intent of Colorado
- Provides a path forward
- Outlines conditions required
- States to perform risk assessments
- Requires support from the pesticide product registrants

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Mr. Mitchell Yangert, Director
Division of Plant Industry
Colorado Department of Agriculture
365 Interstate Parkway
Bronnfield, Colorado 80121

Subject: Special Local Needs Registration for pesticide use for legal marijuana production in Colorado

Dear Mr. Yangert:

Thank you for your inquiry regarding the utilization of Special Local Need (SLN) registrations of pesticides under FIFRA section 24(a) for use on cannabis. As you are aware, EPA’s regulations, 40 CTR 182.155(a)(4), state that any SLN registration must be in accord with the purposes of FIFRA, which mandates the registration of a pesticide only on a finding that it will not lead to “unreasonable adverse effects on the environment.” In order to facilitate this finding, EPA strongly encourages a State to pursue SLN authorizations only where a federal registration of the pesticide is approved for use(s) similar to the manner in which the SLN pesticide would be used. EPA expects that a showing of such similarity would provide the best support for making the necessary determinations. Given our understanding of how cannabis is cultivated and the intended way cannabis plant materials may be consumed by humans, we anticipate that a federal registered pesticide would be regarded as having similar use patterns if the federally registered pesticide is approved for use:

1. on food (in order to have a complete toxicology database to evaluate the potential toxicity of acute, short-term, intermediate, and chronic exposure)
2. on tobacco (in order to have a poisonology study to determine the breakdown products formed when the treated plant material is burned)
3. by the same (or an) application method (in order to assess the exposure of workers who mix, load, and apply the pesticides)
4. on crops with agronomic characteristics similar to cannabis (in order to adequately protect workers removing areas following application of the pesticide) and
5. in the same kind of structure (e.g., greenhouse/hothouse) or on the same kind of site (e.g., outdoor fields/sites) as the proposed SLN use (in order to ensure that workers handling the pesticide are adequately protected when applying the pesticide – for example, ensuring that the adequate personal protective equipment is required – and that the environmental fate and effects of the SLN use are adequately understood and that any appropriate measures are in place to protect non-target organisms and water resources).

In addition, EPA encourages the State to consider pesticides for which the agency’s aggregate and cumulative risk assessment indicates that some modest additional exposure would not approach a risk of concern, i.e., that there is “suse in the human health risk cap.”

The intent of the list is to assist growers in distinguishing those pesticide products whose labels do not legally prohibit use on cannabis from those that clearly do not allow use. The list is not an endorsement or recommendation to use these products in the production of cannabis in Oregon.

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Criteria for Pesticides Used for the Production of Marijuana in Washington

September 2015

Washington State Department of Agriculture
Pesticide Management Division
State FIFRA Issues Research and Evaluation Group- SFIREG

• Workgroup – Created December 2015
  • NV has been developing two 24(c) applications.
  • CropLife America expressed concerns from registrants, and suggested that they be included in a workgroup as well. They also want hemp to be included in the conversation.
  • Risk cup considerations are a significant issue. If the risk cup is already close to full, the product will not be pursued.
  • Colorado agricultural statistics for the 2015 season show $800 M for alfalfa, $700 M for cannabis, and $600 M for corn.

• Meeting in March with State Lead Agency's and EPA
Why do we need legal pesticides and certified applicators?

If there is not a legal solution growers will use whatever works.

- High residues in concentrates
- Undisclosed pesticide active ingredient in products
- Word of mouth

News release: Pesticide product Guardian™ ordered removed from sale

Pesticide product Guardian™ ordered removed from sale, growers asked to stop its usage

- February 5, 2016... The Oregon Department of Agriculture has ordered stoppage of sale and the removal of the pesticide product Guardian, which is labeled for use on ornamental, food, and feed crops for mite control but also used by cannabis growers. In addition, ODA is asking growers who may have purchased the pesticide product to refrain from using it. ODA’s actions come following an investigation of the product that found the presence of the pesticide active ingredient abamectin, which is not listed on the product label.
Pot products made with unapproved pesticides recalled by Denver companies

Scope of recall covers dozens of products from several retailers, all grown by TruCannabi
Denver
By David Migoya
The Denver Post

Colorado’s largest pot grower sued by two consumers over pesticide use

Colorado marijuana business LivWell has been sued by two cannabis consumers over selling pot grown with an unallowed pesticide that allegedly turns into cyanide when smoked

Check Your Stash: Are you consuming pesticide-peppered pot? Full recall list

DENVER AND THE WEST
Denver releases 28,000 marijuana products it had recalled for pesticides
The release comes despite Gov. John Hickenlooper’s executive order mandating all contaminated cannabis be destroyed
By Ricardo Baca and David Migoya
The Denver Post

Hickenlooper issues executive order to declare tainted pot a threat to public

Any marijuana grown with unapproved pesticides would be removed from commerce and destroyed
By David Migoya and Ricardo Baca
The Denver Post

Advanced Medical Alternatives yanks pot concentrates in state’s 11th recall

Denver marijuana shop Advanced Medical Alternatives is recalling some pot concentrates with extremely high levels of pesticides banned for use on cannabis plants in Colorado
Cannabis Laboratory Issues

- Cannabinoid concentration validation
  - THC
  - THCA
  - CBD
  - CBDA
  - CBN

- Pesticide Residue Analysis
- Pesticide Formulation Analysis
- Adulterated products
  - Powdery Mildew
  - Pathogens (e-coli, salmonella)

- Establish testing protocols and reporting requirements
## Laboratory Needs

### Have

- Condemnation authority over raw agricultural commodities (flowers) – when deemed adulterated.
- Pesticide use & applicator certification regulatory authority
- Consumer protection (recalls), environmental and human health program experience
- In-depth knowledge of pesticide registration process

### Need

- Condemnation authority over all cannabis products. (oils, dabs, waxes and shatters)-when deemed adulterated.
- Authority for laboratory standards
- Human resources
  - Laboratory
  - Field
  - Program
Extraction Equipment

- Super Critical Fluid Extraction
- Solvents
  - Rotovap
- Butane -BHO

Dabs, Waxes, Shatters, Oils
Possible Matrix

Cannabis Oil
www.CureYourOwnCancer.org

HELPS WITH
- Killing cancer
- Diabetes
- Crohn's Disease
- Gout
- Glaucoma
- Opioid Dependence
- Treating Alcohol Abuse
- Epilepsy
- Psoriasis
- Anorexia
- Asthma
- Adrenal Disease
- Inflammatory Bowel Disease
- Fibromyalgia
- Rheumatoid Arthritis
- Migraines
- Dry Eye Syndrome
- Dementia
- Multiple Sclerosis
- Many more...

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(Cannabinoids)
Helps to relieve symptoms of inflamma-
tion, fibromyalgia, cancer, muscle spasm,
PTSD, ADHD and neurodegenerative disease.

- 10mg CBD
- 6mg THC
- 0.5mg CBD

MEDICAL | RECREATIONAL
<table>
<thead>
<tr>
<th>Commercial laboratories certification</th>
<th>State (Auditing &amp; Consumer Protection)</th>
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<tbody>
<tr>
<td>Ensure 3rd party laboratories are compliant</td>
<td>Ensure product meets Vermont standards</td>
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<tr>
<td>- Establish QA/QC standards</td>
<td>- Assess product content (cannabinoid content)</td>
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<tr>
<td>- Establish performance testing program</td>
<td>- Pesticide residues</td>
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<tr>
<td>- Establish auditing programs</td>
<td>- Inorganics</td>
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<tr>
<td>- Establish reporting requirements</td>
<td>- Pathogens</td>
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<td></td>
<td>- Drift</td>
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