



BEYOND PESTICIDES

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July 14, 2015

Mitchell Yergert
Director
Division of Plant Industry
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, CO 80021

Dear Mr. Yergert,

On behalf of Beyond Pesticides, we are writing to oppose the Colorado Department of Agriculture's recently published list of pesticides that may be used to produce marijuana and alert the state of Colorado to Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) violations associated with the list. It is our position that, given the federal law and existing regulations, the state of Colorado does not have the authority to (i) register a pesticide use not federally registered, generally exempt from federal registration, or specifically determined by the U.S. Environmental Protection Agency (EPA), based on findings, to comply with exceptions to FIFRA registration; and (ii) approve or set tolerances for any pesticides that have not been approved specifically for use on cannabis by the EPA. Additionally, the EPA does not have the authority to grant the state of Colorado a local use exemption under section 24(c) of FIFRA. Given these restrictions on Colorado and the EPA under the existing framework for regulating pesticide use, it becomes clear that the only pesticides available for use on cannabis in the state of Colorado are those that are those of a character unnecessary for regulation under section 25(b) of FIFRA.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

As you are aware, pesticide use in the U.S. is governed by FIFRA, which was established with the goal of preventing "unreasonable adverse effects" from pesticide use. FIFRA provides a comprehensive scheme for pesticide labeling and generally makes it unlawful for any U.S. manufacturer to sell an unregistered pesticide, stating that "no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter."¹ Registration is a defined process culminating with the EPA Administrator's approval of the product's label and determination that other FIFRA requirements have been satisfied.² The manufacturer must file information, including the proposed label, the purpose of the pesticide and "any directions for its use," and, if requested, test descriptions and results.³ The EPA

¹ FIFRA § 3(a), 7 U.S.C. §136a(a)

² See § 136a(c)(5)(B)

³ See § 7 U.S.C.A. § 136a(c)(1)(C)-(F); 40 C.F.R. § 156.10 (2003)

reviews the filing and the label, and determines whether the label information is adequate to protect the public from misleading claims or “unreasonable adverse” effects.⁴

Section 3 of FIFRA requires federal registration of all pesticides produced or sold in the U.S. and establishes minimum standards for allowable uses. Under this system, state and local governments may adopt more stringent standards than those set by EPA under FIFRA, but states must meet the minimum standards established under FIFRA, as they serve as a floor for regulatory standards. The only regulatory exception for pesticides under FIFRA are those that fall under the aforementioned section 25(b) and are pesticides that EPA has determined to be of a character unnecessary for regulation. Falling under 25(b) means that a pesticide is exempt from having to undergo traditional review and registration with EPA, though there are still guidelines established for their use that must be adhered to.

Currently, EPA is barred from registering pesticides for use on cannabis or setting (or exempting from) tolerance limits for pesticide residues on cannabis crops, given the plant’s federal classification as a Schedule I narcotic.⁵ Given these constraints, EPA is unable to register or set tolerances for pesticides that do not fall under the 25(b) exceptions for non-toxic materials. Under FIFRA, any determination on a use pattern cannot be made by a state unless the federal government has approved it, and since the EPA cannot approve use patterns on cannabis, we see no legal avenue for establishing and regulating use of nonexempt pesticide for cannabis cultivation.

Tolerance Setting

Before a pesticide can be used on a food crop, EPA sets a tolerance, or maximum residue limit for the specific pesticide, which is the amount of pesticide residue allowed to remain in or on each treated food commodity.⁶ The power of EPA to set such tolerances comes from section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).⁷ If residue levels are found to be above the approved tolerance levels, enforcement actions can be triggered and the commodity will be subject to seizure.⁸

In setting tolerances, EPA must make a finding that the tolerance is "safe." A tolerance is defined as “safe” if there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue."⁹ To make the safety finding, EPA considers, among other things:

- (i) The toxicity of the pesticide and its breakdown products.
- (ii) How much of the pesticide is applied and how often.

⁴ *E.I Du Pont de Nemours and Co. v. Aquamar S.A.*, 881 So.2d 1 at 3. March 31, 2004. Citing 7 U.S.C.A. § 136a(c)(5).

⁵ Controlled Substances Act, 21 U.S.C. 13

⁶ See EPA Pesticides: Topical & Chemical Fact Sheets. Setting Tolerances for Pesticide Residues in Food. <http://www.epa.gov/opp00001/factsheets/stprf.htm>.

⁷ See: EPA Summary of the Federal Food, Drug and Cosmetic Act. <http://www2.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>.

⁸ *Id.*

⁹ *Id.*

- (iii) How much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed or prepared.
- (iv) Aggregate exposure to the pesticide in foods and from other sources of exposure.
- (v) Any special risks posed to infants and children.¹⁰

It is important to note that some pesticides are exempt from this process. EPA may grant exemptions in cases where the exemption is found to be safe and the pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances. To make this exemption determination, EPA must review toxicity and exposure data, the same as for tolerance setting. In addition, there must be a practical method for detecting and measuring levels of the pesticide residues so regulatory officials can ensure that any residues are at or below the level found to be safe.

Several noteworthy agencies are involved in this process and their roles are mentioned below:

- (i) The Office of Pesticide Programs (OPP) regulates the use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply. OPP implements key parts of the FFDCA.
- (ii) The federal Food and Drug Administration (FDA) tests food produced in the United States and food imported from other countries for compliance with these residue limits.
- (iii) State enforcement agencies also check foods produced in this country.
- (iv) In addition, the U.S. Department of Agriculture tests meat and milk.
- (v) USDA and FDA have programs designed to develop statistically valid information on pesticide residues in foods. They provide this information to EPA to use in its risk assessment for pesticides.

State of Colorado

Use of pesticides in Colorado is regulated by the Pesticide Applicators' Act, which prohibits the use of a pesticide "*inconsistent with labeling directions or requirements, unless otherwise provided for by law, or in an unsafe, negligent, or fraudulent matter.*"¹¹ Additionally, it is a violation of the state law for commercial pesticide applicators and those persons making applications for hire, to use products not registered with the Colorado Department of Agriculture (CDA) or EPA, or exempt from registration by EPA.¹²

Recently, CDA issued a memo that outlined the Criteria for Pesticides Used in the Production of Marijuana in Colorado (Memo).¹³ Through faulty analysis of existing law, this document outlines the pesticides that could be potentially used for cannabis cultivation in the

¹⁰ See EPA Pesticides: Topical & Chemical Fact Sheets. Setting Tolerances for Pesticide Residues in Food. <http://www.epa.gov/opp00001/factsheets/stprf.htm>.

¹¹ C.R.S. 35-10-117(l)(i).

¹² C.R.S.A §35-9-120.

¹³ Criteria for Pesticides Used in the Production of Marijuana in Colorado. Colorado Department of Agriculture. March 25, 2015.

state. CDA, claiming guidance from EPA, developed a list of allowed pesticides¹⁴ based on broadly written labels it felt could be construed to include marijuana, despite a failure to name cannabis explicitly as a registered use on the labels of any of the products. In our view, this is an overreach of state authority and allowing the use of these pesticides places Colorado in direct violation of FIFRA.

According to the Memo, the state's reasoning in developing a list based on broad/generalized uses of pesticides is as follows. First, CDA outlines the test it uses to establish whether a pesticide may be used in cultivating marijuana. The test is threefold, and states that in order for a pesticide to be available for use on marijuana, the label must:

- (i) Allow for use on unspecified crops and/or plants.
- (ii) Allow for use at the intended site of application.
- (iii) Not prohibit, by directions, use on crops or plants intended for human consumption.

CDA does not believe that current federal or state laws require that pesticides used on marijuana must be food tolerance exempt, even though it fully admits that consumption through edibles is one of the main ways marijuana is consumed. In the Memo, CDA reveals that "CDA and EPA in our initial discussion felt that since marijuana was being processed and consumed in different forms of edible foods, then pesticide tolerances should apply." However, CDA then goes on to make the determination that a tolerance does not need to be set for pesticides used on marijuana because it is not a food, even though it recognizes that "marijuana is consumed several ways including most commonly through smoking [and] through marijuana extracts that are used to produce edibles[.]"

To support its reasoning, CDA made the following determinations:

- (i) Marijuana is currently defined as a Schedule I drug, not a food crop.
- (ii) USDA and FDA do not consider marijuana a food crop.
- (iii) USDA cannot enforce tolerances unless the food is intended for interstate commerce.
- (iv) Since marijuana cannot legally cross state boundaries, even if it were a food crop the USDA could not enforce a tolerance.
- (v) CDA does not have the authority to establish the tolerances themselves.

Although we believe that the known consumption of marijuana in edible products should be enough to render it a "food" under EPA and CDA standards, failure to label it as such has no bearing on the illegality of pesticide use in marijuana cultivation. In fact, the refusal of CDA to classify marijuana as a food and rely on its federal status as a Schedule I drug only strengthens our position that CDA cannot allow the use of any pesticides on marijuana that do not fall within the 25(b) minimum risk pesticide exemption because they cannot be regulated by the EPA as FIFRA requires.

To reiterate, in order to achieve compliance with existing FIFRA requirements, CDA should allow marijuana producers only the use of pesticides that are of a character not

¹⁴ See: Pesticides for use in marijuana production. <https://www.colorado.gov/pacific/agplants/pesticide-use-marijuana-production>.

requiring regulation, as provided by section 25(b) of FIFRA. CDA should adopt this rule as prevailing agency policy both because the active ingredients of these pesticides have been determined to pose minimal threat to human health and the environment, and because under the federal registration scheme established by FIFRA, these are the only pesticides available for use on marijuana.

FIFRA Exceptions

Under FIFRA, there are two exceptions to the rules that require a pesticide only be used in accordance with its approved, registered, and labeled uses, the Emergency Use and the Special Local Need exemptions. A clear federal determination is required to permit either of these exceptions, which would allow on a crop an unregistered use of a registered pesticide or an unregistered pesticide making progress toward registration. Based on the intent of the exceptions and examples of their use in the past, there is no conceivable scenario in which Colorado would satisfy either exemption available under FIFRA.

FIFRA Section 18 Emergency Use

Section 18 of FIFRA¹⁵ authorizes EPA to allow an unregistered use of a pesticide for a limited time if it determines that an emergency condition exists. The regulations governing §18 of FIFRA define the term “Emergency Condition” as an urgent, non-routine situation that requires the use of a pesticide(s).¹⁶ According to EPA’s guidance,¹⁷ in order to determine whether a request qualifies for an emergency exemption, EPA performs a multi-disciplinary evaluation of the request that assesses the following criteria:

- a. The validity of the emergency claim and economic loss.
- b. Human dietary risk assessment.
- c. Occupational risk assessment.
- d. Ecological and environmental risk assessment.
- e. Assessment of the progress toward registration for the use for specific or public health exemption requests.

Additionally, if the exemption program involves the treatment of agricultural goods, which marijuana may or may not be under various reasoning, EPA will establish formal tolerances (maximum allowable residue levels) to cover any pesticide residues in food that may result. These tolerances established for emergency exemption uses are time-limited, corresponding to the time that treated commodities might be found in channels of trade.

It is clear from the language of the regulation that an emergency exemption is not intended to be a long-term solution, but instead an acute, short term response to an immediate and unforeseen problem. The existing categories of emergency exemptions under §18 are specific, quarantine, public health, and crisis, none of which would conceivably include the

¹⁵ 7 U.S.C 136p Exemption of Federal and State Agencies.

¹⁶ Code of Federal Regulations, Title 40, §166.3.

¹⁷ See: Pesticide Emergency Exemptions. Evaluating Emergency Exemption Requests. <http://www2.epa.gov/pesticide-registration/pesticide-emergency-exemptions>.

long-term, continued use of pesticides to grow cannabis. Furthermore, even if the EPA were to grant such a use, EPA would be required to perform a human health risk assessment for the use under the Food Quality Protection Act (FQPA) based on the pesticide's risk profile for currently registered uses, an action EPA is once again unable to perform because of marijuana's classification as a Schedule I drug, and the FQPA's status as a federal statute governing review.

FIFRA Section 24(c) Special Local Need Exemption

In a recent letter to CDA,¹⁸ EPA indicates that there may be a way for CDA to achieve Special Local Need (SLN) registrations of pesticides under FIFRA section 24(c) for use on cannabis. Once again, this is a place where EPA is clearly barred, under the language of FIFRA and its own guidance documents, from approving pesticides for such use. Therefore, we urge CDA to abandon any attempts to register pesticides for cannabis use under a SLN exemption.

Under the authority of §24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs. A SLN is "an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available."¹⁹ EPA then has 90 days to review the registration and make a determination.²⁰ A registration will not be approved if it: (a) has been previously denied, disapproved, suspended or canceled by EPA because of health or environmental concerns, or voluntarily canceled subsequent to a notice of intent to cancel, (b) would cause an imminent hazard (i.e., should be suspended), or (c) may result in food residues not covered by tolerances.

In its letter to CDA, EPA encourages states to pursue SLN authorizations only where a federally registered pesticide is approved for use(s) similar to the manner in which the SLN would be used. Moreover, despite the previously discussed refusal of CDA to label marijuana as a food product, EPA says that "given our understanding of how cannabis is cultivated and the intended way cannabis plant materials may be consumed by humans," it anticipates that a federally registered pesticide would have to meet the following similar use patterns to be approved:

- (i) On food (in order to have a complete toxicity database to evaluate the potential toxicity of acute, short-term, intermediate, and chronic exposure);
- (ii) On tobacco (in order to have a pyrolysis study to determine the breakdown products formed when the treated plant material is burned);
- (iii) By the same type(s) of application methods (in order to assess the exposure of workers who mix, load and apply the pesticides);
- (iv) On crops with agronomic characteristics similar to cannabis (in order to adequately protect workers reentering areas following application of pesticide) and;

¹⁸ See: EPA letter to CDA SLN's for Marijuana. May 19, 2015. <https://www.colorado.gov/pacific/agplants/pesticide-use-marijuana-production>.

¹⁹ 40 CFR 162.151.

²⁰ 40 CFR 162.154(c).

- (v) In the same kind of structure (e.g., greenhouses/shadehouses) or on the same kind of site (e.g., outdoor dryland site) as the proposed SLN use (in order to ensure that workers handling the pesticide are adequately protected when applying the pesticide).

The fact that EPA has identified use on food as a likely prerequisite to attain a SLN exemption simultaneously creates an impermeable barrier to CDA. Because section 24(c) explicitly outlines that any exemption used on food must be in compliance with tolerance levels set by EPA (an authority given to it by the Federal Food Drug and Cosmetic Act), and EPA has consistently refused to set tolerance levels for pesticides used on cannabis because of marijuana's status as a Schedule I drug, there would be no way for CDA to be in compliance with the requirements necessary for a SLN exemption if the pesticide being used is in any way approved for use on foods. Even in the non-food scenario that Colorado suggests as plausible, a federal involvement or determination cannot be fulfilled. In this case, even if CDA fulfilled the application requirements under 40 CFR 162.153, EPA would be unable to review those materials because of cannabis' federal status.

It is important to note that in addition to the aforementioned use patterns, Colorado would also have to show that use of the pesticides meets the no "unreasonable adverse effects on the environment" test through the use of the human and ecological risk assessment methodologies used by the Office of Pesticide Programs (OPP).

CDA has taken this response from EPA and passed on the information to stakeholders within the state, outlining the necessary criteria and the process by which it could potentially achieve a SLN exemption.²¹ However, despite the fact that EPA has put the onus for receiving a SLN exemption on the state, the required review by EPA of any SLN application relating to use of a pesticide on cannabis is barred under current law due to the status of cannabis as a Schedule I drug under federal law. Additionally, EPA's continuous and explicit refusal to register pesticides for marijuana use would certainly constitute a "previous denial" of use under FIFRA, an act that cannot be present in order to get a SLN exemption approved.

Pesticides Allowed for Cannabis Cultivation

25(b) of FIFRA

Given the challenges demonstrated by attempting to reconcile the illegal federal status of marijuana with its legal status in Colorado and other states, and the obstacles it creates for thoroughly testing and registering pesticides for use on the crop, the only synthetic pesticides allowed in cannabis cultivation are those that have been deemed of a nature not requiring regulation by EPA under §25(b) of FIFRA.

Section 25(b) of FIFRA states that:

The Administrator may exempt from the requirements of this Act by regulation any pesticide which the Administrator determines either

²¹ See: CDA letter to Marijuana stakeholders- SLN's for Marijuana. June 2, 2015.
<https://www.colorado.gov/pacific/agplants/pesticide-use-marijuana-production>.

- (1) to be adequately regulated by another Federal agency, or*
- (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.*

Beyond Pesticides agrees with New Hampshire's approach that these are the only pesticides that are allowed for use in the production of marijuana because they are exempt from registration by the EPA. These pesticides are not required to undergo the federal registration process because their ingredients, both active and inert, are "demonstrably safe for [their] intended use."²² Adhering exclusively to the 25(b) list of pesticides both offers growers options for managing pests and provides protections to consumers, absent studies necessary to establish tolerance levels that are safe for humans based on the use of the crop.

This is the approach that has been adopted by New Hampshire, which requires cannabis "safe growing methods that are consistent with U.S. Department of Agriculture organic requirements at 7 CFR Part 205 shall be used."²³

According to New Hampshire law, a pesticide product may be applied to cannabis if:

- (1) It is approved for organic²⁴ cultivation in accordance with the requirements of the national organic program, 7 CFR Part 205; and
- (2) The active ingredients contained in the pesticide product are exempt from federal registration under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).²⁵

CDA has acknowledged that people can be exposed to cannabis in several ways, whether it be through ingestion, inhalation, or dermal absorption. CDA notes in its Memo that marijuana extracts are used to produce edibles that people eat, which equates to dietary exposure. Users also experience nondietary exposure through inhalation and dermal exposure, which is of concern for marijuana grow-house workers, though CDA acknowledges that smoking marijuana is the most common exposure pattern.²⁶ Finally, it can be applied to, and absorbed through the skin in salves, lotions, and creams containing marijuana extracts, adding an additional dermal level of exposure.

EPA has not evaluated any of these exposure routes (all of which are acknowledged by CDA) because of the classification of marijuana as a Schedule I drug. Without this analysis, it is impossible for EPA to determine health and environmental effects of the pesticide, and toxicological impact must be subject to a scientific or regulatory review before pesticides

²² EPA About Pesticides. http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/min-risk-pesticides.html

²³ New Hampshire Therapeutic Cannabis Program. He-C 402.14(e)(1).
http://www.gencourt.state.nh.us/rules/state_agencies/he-c400.html.

²⁴ Note that this must be "organic" as defined by local certifying agencies because the EPA cannot regulate organic standards of cannabis at the federal level due to marijuana's classification as a Schedule I drug.

²⁵ New Hampshire Therapeutic Cannabis Program. He-C 402.14(e)(2).
http://www.gencourt.state.nh.us/rules/state_agencies/he-c400.htm.

²⁶ See CDA Memo.

regulated under FIFRA can be used on cannabis, and therefore CDA must comply with federal law and prohibit the use of any pesticides that would require EPA review under FIFRA.

Recommendation

In summary, it is clear that the use of registered pesticides on marijuana, either allowed by CDA or used by marijuana growers in Colorado, is not legally permitted under FIFRA. Because of marijuana's current status as a Schedule I drug under federal regulation, no pesticides have been reviewed and approved for use on cannabis by EPA, making their general use illegal. Given this analysis, the current list of allowed pesticides published by CDA is in violation of FIFRA standards and should be revoked immediately. Additionally, CDA and marijuana growers in Colorado do not qualify for either the Emergency Use and Special Local Need exemptions under FIFRA. Any application for exemption would be barred from review by EPA due to marijuana's status as an illegal drug, resulting in a failure to meet the review standards for human and environmental safety required by FIFRA and FFDCA.

As a result of these violations, and in order to limit liability, avoid lawsuits, and protect the health and safety of marijuana consumers in Colorado, CDA should only allow the use of List 25(b) Federally Exempt Minimum Risk Pesticides on cannabis grown within the state. These pesticides are exempt from regulation under FIFRA because they have been determined to be of a character not requiring regulation, and provide numerous options to growers while still maintaining a threshold of safety to marijuana users in Colorado.

We appreciate your immediate attention and response to this legal matter and trust that it will be resolved in a timely fashion.

Sincerely,

A handwritten signature in black ink that reads "Annie D'Amato". The signature is written in a cursive, slightly slanted style.

Annie D'Amato, J.D.
Policy and Legal Associate