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Apr 09 2021
Independent Regulatory Review Commission

DH, MMRegulations

From: Jeff Bittner <jbittner@agri-kind.com>
Sent: Friday, April 2, 2021 5:34 PM
To: DH, MMRegulations
Cc: Jon Cohn; Chad DiFrancesco
Subject: [External] Comments in Response to Proposed Rulemaking under 28 PA Code §§ 1141, 1151, and 1171
Attachments: Proposed Final Regulations Commentary_Agri-Kind.pdf

Mr. John Collins,

I am submitting the attached commentary on behalf of Agri-Kind, LLC. We appreciate the opportunity to relay our suggestions. Please do not hesitate to reach out should you require any clarification.

Sincerely,

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April 1, 2021

Submitted via RA-DHMMregulations@pa.gov

John J. Collins, Director
Office of Medical Marijuana
Department of Health, Room 628
Health and Welfare Building
625 Forster Street, Harrisburg, PA 17120

Re: Comments in Response to Proposed Rulemaking under 28 PA Code §§ 1141, 1151, and 1171

Dear Sir:

On behalf of Agri-Kind LLC, I am submitting comments concerning the recently proposed regulations under 28 PA Code §§ 1141, 1151, and 1171. The sections discussed herein have a direct impact on a Grower/Processor's ability to operate efficiently, which in turn impacts patient care. We appreciate the opportunity to submit commentary, and kindly ask that you consider our suggestions.

Proposed Section 1151a.34(d)(11): This proposed subsection mirrors the current section and requires that Grower/Processors label their products with the purchasing dispensary's name and address. This requirement poses significant challenges operationally, while providing no benefit to patients.

Because many Grower/Processors utilize packaging and labeling machines, the point at which labels are applied occurs before the medication's destination is established. To apply additional labels with the dispensary's name and address after the product is otherwise fully labeled is inefficient. Doing so generally requires manual application on each unit immediately prior to distribution, which increases production time and manual labor costs.

The Department asserts that they have made revisions to other portions of this section to "minimize patient confusion caused by medical marijuana packaging, and also ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary." The importance of these priorities is understood, but requiring a label showing the dispensary name and address on each product does not further these priorities. The patients know where they are purchasing the medication, as they have to be physically present to purchase it. A sticker containing the dispensary information does not provide the patient with information that they do not already have. Further, applying a sticker with the dispensary name and address does not provide any additional information that is not otherwise available in the electronic tracking system (MJ Freeway). The distribution of the medication is traceable based on product identification numbers. There appears to be no benefit for the patients or for law enforcement.

Suggestion: Agri-Kind asks that this proposed subsection be amended so that Grower/Processors are not required to individually label each product with the receiving dispensary's information. If this requirement must persist, Agri-Kind asks that the responsibility of application be shifted to the receiving dispensary. Alternatively, Agri-Kind asks that this requirement be amended to allow for singular application on the exterior shipping container that holds the products rather than on each product individually.

Proposed Section 1151a.34(d)(6): This proposed subsection requires that product labels applied by Grower/Processors include the species of the plant from which the medication is derived. The market currently includes concentrates that are created by extracting and blending active ingredients from several different species. This type of medication is beneficial to the patients that require specific and consistent cannabinoid and terpene content. For this type of medication, the strain is irrelevant and should not be required on the label.

Suggestion: Agri-Kind asks that this proposed section be amended to exclude the species identification requirement for concentrates whenever the concentrate is a blend of multiple strains, formulated to achieve specific cannabinoid and terpene content.

Proposed Section 1151a.34(d)(19): This proposed subsection requires labels to be affixed to the container directly holding medical marijuana and outer packaging. Agri-Kind understands the importance of clear and proper labeling, and the potential benefit of requiring labeling on both the container directly holding the product and any outer packaging. However, in the case of concentrates, the container directly holding medical marijuana is often very small. It is unequivocally impossible to include all necessary elements of the label on such a small container.

Suggestion: Agri-Kind asks that the duplicate labeling process either be removed from the proposal entirely or be amended to exclude concentrate containers that directly hold the medical marijuana.

Proposed Section 1141a.21 – Definition of Medical Marijuana Waste*:* The proposed definition of Medical Marijuana Waste mirrors the current temporary definition. The following items are included within subsection (B) of the definition: "any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots."

The inclusion of roots within this definition creates substantial operational hurdles for Grower/Processors, as roots are difficult to destroy in the ways suggested by the regulations.

Incinerators are incapable of destroying the growing media in which the roots reside and removing the roots from the growing media for incineration requires substantial manual labor.

It is our understanding that roots do not contain a level of cannabinoids that are useable. Further, if the Department is concerned with the roots being revived and utilized for illegal purposes, there are efficient and effective methods to prevent this from happening. For example, roots can easily be rendered completely incapable of future growth through the application of Department-certified organic chemicals. Recognizing the challenges of root disposal and the unlikely possibility of roots being utilized for improper purposes, other states have specifically excluded roots from the definition of medical marijuana waste. See, for example, the statutes in both Maine (§ 9.2.1 - Marijuana Waste Exceptions) and Oklahoma (§ 63-428.1 Definitions).

> **Suggestion**: Agri-Kind asks that roots be excluded from the definition of medical marijuana waste. Alternatively, Agri-Kind asks that reasonable alternative destruction methods be permitted.

Proposed Section 1171a.29(d): The proposed subsection (d) mirrors the current regulatory provisions. This proposed subsection provides the minimum elements for which a laboratory must test. The current regulatory provisions are supplemented with additional guidance (*see* Guidance for Quality Testing and Sampling by Approved Laboratories, issued 1/16/2018 and Updated 8/10/2018). This guidance provides clarity about which elements must be tested during harvest testing and process testing.

Harvest testing under the proposed regulations includes the following elements: moisture content & water activity, microbiology, mycotoxins, heavy metals, pesticides, potency, and terpenes. Potency and terpene testing during harvest testing is unnecessary, as the results of those tests are not determinative of a passing or failing result. In Agri-Kind's opinion, the elements relevant to harvest testing are moisture content & water activity, microbiology, mycotoxins, heavy metals (if grown in soil), and pesticides.

Requiring that non-essential elements be included in harvest testing creates a significant financial burden on Grower/Processors because each element tested carries a separate price. For the 2020 calendar year alone, Agri-Kind has found that testing expenses were approximately 22% of Net Profit. The cost associated with these tests is significant, yet some of the results have no value.

> **Suggestion**: First, Agri-Kind asks that the final regulations be amended to incorporate the Guidance document, either directly or by reference. Second, Agri-Kind asks that harvest testing requirements be limited to items that are necessary to establish a passing result. To this end, cannabinoid and terpene potency should be removed from the elements required during harvest testing.

Proposed Section 1171a.29(c) – Relating to the use of multiple laboratories: This proposed subsection amends the current subsection (c) by providing that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates unnecessary logistical issues for Grower/Processors who would have to coordinate with two separate laboratories. In instances where testing prices are influenced by volume, the volume will be spread, limiting a Grower/Processor's ability to utilize such cost savings. Further, this requirement could double the number of visitors coming into a Grower/Processor's facility for testing purposes, which is contrary to the Department's stance on visitor access. Additionally, the laboratories are approved by the Department, and their approved operating procedures should be sufficient to ensure accurate results. If a lab is not meeting Department standards, that should be addressed individually with the lab, not through administrative rulemaking.

> **Suggestions**: Agri-Kind asks that this proposed subsection be eliminated in its entirety, allowing the same laboratory to complete both harvest testing and process testing at the discretion of the Grower/Processor.

Proposed Section 1171a.29(c) – Relating to the harvest testing of all harvest batches generally: Currently, every harvest batch must be tested prior to using the harvest batch to produce a medical marijuana product. This means that even if the same strain, with the same genetics, growing methodology, and environmental controls, is harvested multiple times, harvest testing must none-the-less happen after each harvest. Agri-Kind asks that the Department reconsider the necessity of having each harvest batch tested when passing results have already been received for the same strain within the same year.

The current harvest testing approach is inefficient and provides no benefit to patients. Other jurisdictions, acknowledging that genetics and growing conditions do not generally change once established, require only one harvest test per strain on an annual basis. Additionally, finished product testing guarantees that products are safe prior to entering the market. Harvest testing every harvest batch provides little to no value to the patients, and in most cases also provides no value to Grower/Processors who already have their strain profiles and growing methodologies established.

> **Suggestions**: Agri-Kind asks that harvest testing be required once per strain to establish the initial suitability of that strain. Thereafter, the strain should be tested annually as needed.

We sincerely appreciate the public commentary period established in this rulemaking procedure, and hope that our comments and suggestions are informative. Should you have any questions regarding these suggestions, please do not hesitate to reach out to me directly.

Sincerely,

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