

Department of Commerce, Community, and Economic Development

ALCOHOL AND MARIJUANA CONTROL OFFICE 550 West 7th Avenue, Suite 1600 Anchorage, AK 99501 Main: 907.269.0350

MEMORANDUM

TO: Marijuana Control Board DATE: January 23, 2020

FROM: Glen Klinkhart, Interim Director RE: Regulations Project – Umbrella

Categories for Products

The board opened this regulations project at the October 17, 2018, board meeting. The purpose of this project is to address the issue of what variations in the ingredients of a product constitutes a different product that requires a separate board approval. The project proposes the following:

3 AAC 306.520(3)(B), 3 AAC 306.520(3)(C), 3 AAC 306.520(3)(D) are proposed to remove some language that is repetitive and move some language to 3 AAC 306.525.

3 AAC 306.525 is proposed to add some language from 3 AAC 306.520, and add language requiring more detail to be provided for marijuana products to include assigning a product number.

3 AAC 306.990(b)(29) is proposed to further define "marijuana product".

This proposed regulations change was posted for public comment for 45 days, closing on November 15, 2019. Five comments were received and they are attached.

Options for the board:

- Vote to adopt as written
- Amend; if amendment is significant, put out for public comment
- Send back to staff for revisions
- Close the project without action

3 AAC 306.520 is amended to read:

3 AAC 306.520. Application for marijuana product manufacturing facility license.

An applicant for a marijuana product manufacturing facility license, including a marijuana concentrate manufacturing facility license, must file an application on a form the board prescribes, and provide the information required under 3 AAC 306.020 and

- (1) a copy of an active application for a required food safety permit under 18 AAC 31.020 from the Department of Environmental Conservation or a municipality with authority delegated under AS 17.20.072 and 18 AAC 31.945;
- (2) a diagram of the proposed licensed premises required in 3 AAC 306.020(b), identifying the area where
 - (A) in-house testing, if any, will occur; and
 - (B) marijuana and any marijuana product, including marijuana concentrate, will be stored;
- (3) in the applicant's operating plan required under 3 AAC 306.020(c), a description of
 - (A) the equipment and solvents, gases, chemicals, and other compounds used to create concentrates and the processes to be used;
 - (B) the information required for product approval in 3 AAC 306.525

 for each marijuana product the applicant intends to process at this location; [THE PRODUCT DESCRIPTION MUST INCLUDE THE COLOR, SHAPE, TEXTURE, INGREDIENTS AND STANDARD PRODUCTION PROCEDURE TO BE USED AND THE ADDITIONAL INFORMATION REQUIRED FOR PRODUCT APPROVAL IN 3 AAC 306.525;

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(C) THE PACKAGING TO BE USED FOR EACH TYPE OF PRODUCT;

(D) SAMPLE LABELS SHOWING HOW THE LABELING INFORMATION REQUIRED IN 3 AAC 306.570 WILL BE SET OUT;] and (C)[(E)] the applicant's plan for disposal of waste. (Eff. 2/21/2016,

Register 217; am 7/27/2017, Register 223; am ___/___, Register _____)

Authority: AS 17.38.010 AS 17.38.150 AS 17.38.200

AS 17.38.070 AS 17.38.190 AS 17.38.900

AS 17.38.121

3 AAC 306.525 is amended to read:

- **3** AAC 306.525. Approval of concentrates and marijuana products. (a) A marijuana product manufacturing facility, including a marijuana concentrate manufacturing facility, must obtain the board's approval for each product it will manufacture for sale or transfer to another licensed marijuana establishment. The board will not approve a product that is prohibited under 3 AAC 306.510(a)(4).
- (b) An applicant for a marijuana product manufacturing facility license may request the board's approval of its intended products with a new license application by including, in its operating plan
- (1) a photograph, drawing, or graphic representation of the expected appearance of each final product; [and]
- (2) the proposed standard production procedure and detailed manufacturing process for each product:

(3) a product description, including the color, shape, texture, and

ingredients;

- (4) serving sizes proposed for each product;
- (5) the packaging to be used for each product; and
- (6) a sample label for each product showing how the labeling information

required in 3 AAC 306.570 will be set out.

- (c) A licensed marijuana product manufacturing facility may at any time submit a new product approval request to the board on a form the board prescribes along with the fee required under 3 AAC 306.100(c).
- (d) A licensed marijuana product manufacturing facility shall keep its ingredient list and potency limits for any food product containing marijuana on file at the marijuana product manufacturing facility's licensed premises. The ingredient list and potency limits for any product manufactured at the facility must be made available for inspection on request by the director, or an employee or agent of the board.

(e) Each product shall

- (1) be assigned a product number by the board;
- (2) contain the product name on the consumer label; the product name may include the marijuana strain name or a flavor name;
- (3) be identified in the marijuana inventory tracking system by the product name.
- (f) Except as follows, any deviation in ingredients or manufacturing process is indicative of a different product. The board may approve variations of secondary

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ingredients s	uch as flavorings or o	ptional additives. (E	ff. 2/21/2016, Register 217; am
//	_, Register)		
Authority:	AS 17.38.010	AS 17.38.150	AS 17.38.200
	AS 17.38.070	AS 17.38.190	AS 17.38.900
	AS 17.38.121		
3 AAC 306.990(b)(29) is amended to read:			
	(29) "marijuana prod	uct" has the meaning g	given in AS 17.38.900; <u>a marijuana</u>
product has a specific name, a specific list of ingredients, and a specific manufacturing			
process;			
(Eff. 2/24/2015, Register 213; am 2/21/2016, Register 217; am 10/11/2017, Register 224; am			
8/11/2018, Register 227; am 10/20/2018, Register 228; am/, Register)			
Authority:	AS 17.38.010	AS 17.38.121	AS 17.38.200
	AS 17.38.040	AS 17.38.150	AS 17.38.900
	AS 17.38.070		

From: Kreative Konfections

To: CED AMCO REGS (CED sponsored)

Subject: Comment on Draft - Umbrella Categories

Date: Wednesday, November 13, 2019 11:28:09 AM

AMCO Board,

As a product manufacturer, I was very concerned about the original discussion on the umbrella categories, as it came across as leading to expensive, paperwork heavy, and meeting-filled regulations. However, in reading the Draft that was put out, I am pleased to see that those concerns have been completely abated. I would therefore like to submit my comment in complete support of the draft regulations on umbrella categories as they are published on the AMCO website today, 11/13/19.

Thank you, Jenny Koenig, CPA, CMA, CVA Co-owner, Licensee Kreative Konfections LLC



Department of Health and Social Services

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November 4, 2019

Erika McConnell, Director Alcoholic Beverage Control Board 550 W 7th Ave, Suite 1600 Anchorage, AK 99501

Dear Ms. McConnell:

On behalf of the Department of Health and Social Services, Office of Substance Misuse and Addiction Prevention, we respectfully submit comments on regulations 3 AAC 306.565(b) regarding packaging of liquid marijuana products. The existing regulations for liquid marijuana products raise concern for Alaskans' health and safety; therefore, we suggest a requirement for all liquid marijuana products to be in a structure that uses a single mechanism to achieve both child-resistance and accurate pouring for each liquid serving in increments consistent with the concentration limits set out in 3 AAC 306.560.

The proposed change to 3 AAC 306.565 (b) is to add a new section:

- (3) for marijuana liquid marijuana products with multiple servings, the packaging must
 - (a) indicate the number and size of individual servings in compliance with 3 AAC 306.560;
 - (b) be in a structure that uses a single mechanism to achieve both child-resistance and accurate pouring measurement of each liquid serving in increments equal to or less than 5 milligrams of active THC per serving; and.
 - (c) the dosing component is within the child-resistant cap or closure of the bottle and is not a separate component.

Given the concern about inadvertent ingestion, particularly by young children, hash marks on the bottle do not qualify as a measuring device.

Public Health Concern: While the current regulations do cover child-resistant packaging for edible marijuana products, limits on their THC content, food-safety requirements and required potency and contamination testing; the regulations for edible liquid marijuana products could be strengthened to make the serving size information comprehensible to the average user. Therefore, we are proposing regulations to ensure that liquid marijuana products are easily separable into single servings containing no more than 5 mg of THC.

Based on these concerns for the health and safety of Alaskans, we recommend the Board consider the proposed changes to regulations 3 AAC 306.565 (b) regarding packaging of liquid marijuana products. Thank you for your time and consideration in supporting the health and safety of all Alaskans.

Sincerely,

Anne Zink, MD, FACEP

Chief Medical Officer



11/15/2019

Via email

Subject: Public comment on Umbrella Categories for Products in the Regulations of the Marijuana Control Board

Dear Members of the Board,

We appreciate the Marijuana Control Board trying to create consistency in the matter of umbrella categories. However, we do not support the current draft as written.

Section 3 AAC 306.525 is regulating the application process for edibles and concentrates by the same criteria and standards. Concentrates and edibles are broadly different - they should be separated from each other to allow specific criteria and standards to effectively regulate them respectively.

When approving new product applications for concentrates, the board should consider a single MJ-16 form to approve an extraction process (i.e. equipment, solvents, and the related operating plan). Any concentrates that are created from that approved extraction process should be considered approved regardless of color, consistency, texture of the concentrate that is produced. This will significantly reduce the proliferation of new product applications and thus will drastically reduce the burden on staff and licensees.

Licensees submitting new product applications for edibles should be permitted to include a list of optional ingredients (e.g., flavoring) that may be added in accordance with their standard operating procedures. The addition of optional ingredients may be expected to alter the flavor of the product, but should not substantially change the size or shape of the product. The specific ingredients used in the product batch should be listed on the label to reflect what was added to create the product, including any potential allergens. We feel that this reflects the latest guidance from the Marijuana Control Board during recent meetings. Allowing optional ingredients in a single product application would reduce the number new product applications need to be assessed and processed by AMCO and MCB. It would also help reduce bureaucratic burden for licensees.

We look forward to AMCO staff, the MCB, and industry crafting this project together to make a more efficient and effective regulation.

Sincerely,

Barret Goodale, Cultivation Manager, GOOD LLC (Lic. # 10165, 10166, 12325) Trevor Haynes, General Manager, GOOD LLC (Lic. # 10165, 10166, 12325)



CED AMCO REGS (CED sponsored) Proposed Regulations change comments Wednesday, October 30, 2019 2:25:04 PM Subject Date:



Here are the public comments for the Proposed Regulation changes from Midnight Greenery CEO and Director of AKCannaED Tina Smith.

OWNERSHIP OF MARIJUANA TESTING FACILITIES (3 AAC 306.015)

I am NOT in support of ANY outside marijuana related business types at this time.

APPLICATION AND RENEWAL DATES (3 AAC.306.025, 3 AAC 306.035) I am in general support of these regulation changes.

INFANTS ON PREMISES (3 AAC 306.710)

I am in complete favor of these regulation changes

OVERLAPPING PREMISES (3 AAC 306.405, 3 AAC 306.705 3 AAC 306.710, 3 AAC 306.990)

I am in general favor of these regulation changes

TESTING OVERSIGHT (3AAC 306.100, 3 AAC 306.620, 3 AAC 306.635, 3 AAC 306.640)

I am in general favor of these proposed regulation changes

UMBRELLA CATEGORIES (3 AAC 306.520, 3 AAC 306.525, 3 AAC 306.990)
EXCEPT for specifically 306.525 (e)(1) I am in general favor of these proposed regulations.

306.525(e)(1) can be problematic for individual business book keeping and product labeling inside business records as well as waiting for the board to give them those numbers before being able to produce and distribute product to the retail establishments. I would suggest allowing the businesses themselves to assign the product numbers they choose, while being required to share those numbers along with the rest of their plan for each product being created...

Thank you for your time and consideration regarding smart business practices and regulations for our ever growing industry. Sent from my iPad



November 15, 2019 Via email

Subject: Public Comment on 3 AAC 306, dealing with umbrella categories for products

Dear Honorable Marijuana Control Board Members:

Thank you for the opportunity to comment on the proposed regulations.

The proposed regulation should <u>not be adopted as written</u>. While the AMIA believes the intent of the project to be sound, the current draft doesn't seem to achieve much other than to move same or similar language from one section to another. This does little to establish the legality of umbrella categories. Therefore, we urge this project to be sent to a working group or an appropriate committee.

We have provided many comments recently to this board, and a reccurring theme is the hope that regulators utilize expertise through working groups and committees. In this way, regulations will be promulgated with more thought and efficiency. Communicating with experts not only saves the state money in Reimbursable Services Agreements to the Department of Law, but also saves the industry time and money. Attempting to comprehend and implement changes to regulations that often have no bearing in logic only distracts these businesses from generating commerce.

An appropriate committee or working group on the subject of umbrella categories should include at least one industry member familiar with drafting and reviewing regulations and at least one industry member familiar with product manufacturing. We assure you that these individuals exist. Crafting common sense rules and regulations is a complex challenge.

The responsibilities of the MCB are daunting and its work will be criticized. While the AMIA cannot prevent loud opposition, we can continue to offer our collective knowledge and willingness to show up at the table.

Thank you for your continued commitment to our state, our communities, and this industry.

Respectfully,

Alaska Marijuana Industry Association Board of Directors

The Alaska Marijuana Industry Association is Alaska's only statewide cannabis industry trade group. Our mission is to promote and advocate for a vibrant and reasonably regulated Alaska-based marijuana industry. The AMIA serves to strengthen and enhance a network of connected, independent, informed, regionally and community directed Alaska marijuana organizations.