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#### To: Local Boards of Health and DPH-licensed or Inspected Facilities

From: Massachusetts Department of Public Health and the Massachusetts Department of Agricultural Resources

Date: May 29, 2024

RE: Hemp Derived CBD and THC Not Allowed in Food and Beverages Manufactured or Sold in Massachusetts pursuant to 105 CMR 500.00: *Good Manufacturing Practices for Food* and 105 CMR 590.00: *Minimum Sanitation Standards for Food Establishments* 

In order to address questions regarding the recent influx of products manufactured or sold in Massachusetts containing cannabidiol (CDB) and/or delta-8-tetrahydrocannibinol<sup>1</sup> and/or delta-9-tetrahydrocannabinol (THC), the Massachusetts Department of Public Health (DPH) and the Massachusetts Department of Agricultural Resources (MDAR) issue the following Frequently Asked Questions to make clear that addition of CBD and/or THC to food manufactured or sold in Massachusetts is illegal. This does not apply to edible marijuana products licensed and sold under the jurisdiction of the Cannabis Control Commission.

#### The Cannabis Control Commission and Marijuana Products

In Massachusetts, marijuana and edible marijuana products are regulated by the Cannabis Control Commission (CCC). This notice does not apply to marijuana products manufactured under the jurisdiction of the Cannabis Control Commission pursuant to G.L. c. 94G. Instead, this notice applies to food and beverages regulated by MDPH under its regulations 105 CMR 500.00 and 105 CMR 590.00.

#### The Federal Farm Bill and Hemp-derived CBD and THC

In 2018, the federal Agricultural Improvement Act of 2018 (Farm Bill) removed hemp (as defined by the Farm Bill) from the federal Controlled Substances Act and deemed it an agricultural commodity that could be lawfully produced in the United States. The Farm Bill, however, did not remove the existing federal prohibition of adding CBD or THC to food or beverages.<sup>2</sup> This prohibition still exists regardless of whether the CBD or THC is hemp derived as further discussed below.

#### Food and Beverages Regulated by MDPH and Hemp Products Regulated by MDAR

This notice applies to food and beverages regulated by MDPH under its regulations 105 CMR 500.00 and 105 CMR 590.00, which include bottled water and non-alcoholic carbonated beverages As explained

<sup>&</sup>lt;sup>1</sup> The MDAR Hemp Program does not allow hemp-derived delta-8 THC products to be processed or sold in Massachusetts. <u>https://www.mass.gov/guides/hemp-in-massachusetts-faqs</u>

<sup>&</sup>lt;sup>2</sup> The Farm Bill did not change the law regarding certain food ingredients derived from hemp (such as CBD and THC) and expressly provided that it did not make any changes to the authority of the U.S. Food and Drug Administration (FDA).

further below, retail and wholesale manufacturers, distributors and sellers of food, water, alcohol, and dietary supplements, are reminded that CBD and/or THC may not be added to food manufactured or sold in Massachusetts in accordance with MDPH regulations 105 CMR 500.00 and 105 CMR 590.00. These prohibitions apply whether such hemp products are processed or manufactured outside of the Commonwealth or by a licensee of the Massachusetts Department of Agricultural Resources (MDAR) operating under its Hemp Program pursuant to M.G.L. c. 128, Sections 116 through 123 and the regulation promulgated at 330 CMR 32.00.

MDPH regulation 105 CMR 500.00 requires that all food must be from approved sources that comply with federal, state, and local law and must not contain any prohibited ingredients. The FDA has concluded that, under 21 U.S.C. § 331(ll), federal law prohibits the addition of CBD and delta-9 THC (THC) to food products because CBD and THC are active ingredients in FDA-approved drugs. Since CBD and THC are not approved ingredients under 21 U.S.C. § 331(ll), they may not be added to manufactured foods, which also includes, but is not limited to, bottled water and non-alcoholic carbonated beverages. For more information about manufactured foods, please contact the Food Protection Program at fpp.dph@mass.gov.

MDPH regulation 105 CMR 590.00 incorporates the FDA's Food Code, which requires that food be obtained from sources that comply with federal, state, and local laws and must not contain any prohibited ingredients. As noted above, the FDA has concluded that 21 U.S.C. § 331(ll)prohibits the addition of CBD or THC to food products because CBD and THC are active ingredients in FDA-approved drugs. Since CBD and THC are not approved ingredients under 21 U.S.C. § 331(ll), they may not be added to foods distributed at retail.

For any questions related to 105 CMR 500.00 or 105 CMR 590.00, please contact the Food Protection Program at DPH 617-983-6754 or <u>fpp.dph@mass.gov</u>.

For questions related to MDAR's Hemp Program, please email mahemp@mass.gov.

Cc: Massachusetts Cannabis Control Commission Alcoholic Beverages Control Commission

### CBD and THC in Food Manufactured or Sold in Massachusetts

Below are the Massachusetts Department of Public Health's (MDPH) answers to some frequently asked questions about whether it is allowable in Massachusetts to add cannabidiol (CBD) or delta-9-tetrahydrocannabinol (THC) to food or to cosmetics. The below FAQs do not apply to marijuana products regulated by the Massachusetts Cannabis Control Commission

In 2018, the federal Agricultural Improvement Act of 2018 (Farm Bill) removed hemp, (as defined by the Farm Bill) from the federal Controlled Substances Act and deemed it an agricultural commodity that could be lawfully produced in the United States. The Farm Bill, however, did not remove the existing prohibition under the Federal Food, Drug and Cosmetic Act of adding CBD or THC to food or beverages. This prohibition still exists regardless of whether the CBD or THC is hemp derived as further discussed, below.

It is not legal to manufacture or sell food with CBD and/or THC in Massachusetts. These FAQs concern MDPH's regulations 105 CMR 500.00 and 105 CMR 590.00. They do not apply to marijuana products regulated by the Massachusetts Cannabis Control Commission.

### **Frequently Asked Questions**

### If I have a Massachusetts license or permit under 105 CMR 500 (Regulations for Good Manufacturing Practices for Food) to manufacture food, is it legal to add hempderived CBD or THC to food?

No. The Massachusetts Department of Public Health (DPH) regulates food manufacturing in the Commonwealth (see <u>105 CMR 500</u>). These regulations require that all food must be from approved sources that comply with federal, state, and local laws and must not contain any prohibited ingredients. The <u>FDA has concluded</u> that the Federal Food, Drug and Cosmetic Act prohibits the addition of hemp-derived CBD and THC to food products because CBD and THC are active ingredients in FDA-approved drugs. Since CBD and THC are not approved ingredients under the Food, Drug and Cosmetic Act, they may not be added to manufactured foods. For more information about manufactured foods, please contact the Food Protection Program at <u>fpp.dph@mass.gov</u>.

#### If I have a Massachusetts permit under 105 CMR 590 (Regulations for Minimum Sanitation Standards for Food Establishments) as a Food Establishment, is it legal to add hemp-derived CBD or THC to food I distribute at retail?

No. DPH sets minimum sanitary standards for food establishments in the Commonwealth. These regulations are enforced by local boards of health in partnership with the state (see <u>105 CMR 590</u>). The regulations incorporate the FDA's Food Code, which requires that food be obtained from sources that comply with federal, state, and local laws and must not contain any prohibited ingredients. As noted above, the <u>FDA has</u>

**concluded** that federal law prohibits the addition of CBD or THC to food products because CBD and THC are active ingredients in FDA-approved drugs. Since CBD and THC are not approved ingredients under federal law, they may not be added to foods distributed at retail. For more information about food sold in retail, please contact your local board of health.

### I manufacture a carbonated non-alcoholic beverage that includes hemp-derived CBD and/or THC as an ingredient. May I sell this product in Massachusetts?

No. The bottling and sale of water and non-alcoholic carbonated beverages is regulated by Massachusetts law, including the Regulations for Good Manufacturing Practices for Food discussed above (see G.L. c. 94 §10A; 105 CMR 500.090 et seq). As with other food, since CBD and THC are not approved ingredients under the Federal Food, Drug and Cosmetic Act, they may not be added to bottled water and carbonated non-alcoholic beverages.

Other resources regarding bottled water are available here: <a href="https://www.mass.gov/lists/bottled-water-resources">https://www.mass.gov/lists/bottled-water-resources</a>.

### I hold an alcoholic beverage retail license. May I sell a carbonated non-alcoholic beverage that includes hemp-derived CBD and/or THC as an ingredient?

No. The bottling and sale of water and non-alcoholic carbonated beverages is regulated by Massachusetts law, including the Regulations for Good Manufacturing Practices for Food discussed above (see G.L. c. 94 §10A; 105 CMR 500.090 et seq). As with other food, because CBD and THC are not approved ingredients under the Federal Food, Drug and Cosmetic Act, they may not be added to bottled water and carbonated non-alcoholic beverages. Only retail establishments licensed and regulated by the Cannabis Control Commission may sell beverages that include THC as an ingredient.

### I manufacture a product that contains "full-spectrum," "broad-spectrum," or "whole plant" hemp extracts. Can these extracts be added to food or beverages in Massachusetts?

No. Because "full-spectrum," "broad-spectrum" and "whole plant" hemp extracts are made from parts of the hemp plant that include hemp flower, they contain CBD, THC, and other cannabinoids. Whether the product label indicates the presence or concentration of these cannabinoids, they contain CBD and/or THC and may not be added to food.

# If I am licensed or permitted as a food manufacturer or retailer in Massachusetts, is it legal to add hulled hemp seeds, hemp seed protein, and/or hemp seed oil to food I manufacture and/or sell at retail?

Yes. The **FDA has completed** its evaluation of generally recognized as safe (GRAS) notices for hulled hemp seeds, hemp seed protein and hemp seed oil. These products can be legally added to human food, provided they comply with all other requirements.

# I have a license issued by the Massachusetts Department of Agricultural Resources (MDAR) to process hemp. Is it legal for me to add CBD or THC to manufactured or retail food?

No. The <u>MDAR Hemp Program</u> does not provide an exception to the Food, Drug and Cosmetic Act's prohibition against adding CBD or THC into food products.

### May I market my hemp products (e.g., hulled hemp seeds, hemp seed protein and hemp seed oil) by making therapeutic claims without FDA approval?

No. The <u>FDA has reiterated</u> that cannabis products (hemp-derived or otherwise) that are marketed with claims of therapeutic benefit or any other disease claim must be approved by the FDA.

### Is it legal to process or sell hemp-derived delta-8 THC products in Massachusetts?

No. The <u>MDAR Hemp Program</u> has <u>stated</u> that because delta-8 THC is not naturally occurring in hemp (except for possible trace amounts), to produce delta-8 THC in commercial quantities it must be derived from hemp synthetically. While the Farm Bill did remove hemp from the Controlled Substances Act, it did not impact the control status of synthetically derived cannabinoids, thus delta-8 THC remains a controlled substance, regardless of the source. As a result, the MDAR Hemp Program does not allow hemp-derived delta-8 THC products to be processed or sold in Massachusetts.

## May I sell cosmetic products containing hemp, CBD, or THC at retail in Massachusetts?

The FDA has advised that under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way.

For more information on cannabis and cannabis-derived ingredients in cosmetics, please visit the FDA's <u>Frequently Asked Questions</u>.

## What can I do if I had an adverse reaction to a cosmetic product labeled as containing CBD or THC?

You can report a cosmetic related complaint <u>directly to the FDA</u>. FDA tracks these through their <u>Adverse Events Reporting System (FAERS)</u>.

### Where can I find additional information on medical and adult use marijuana, or hemp in Massachusetts?

For more information regarding medical and adult use marijuana, please contact the <u>Cannabis Control Commission</u>.

For more information regarding hemp-derived products, please contact the <u>Massachusetts Department of Agricultural Resources (MDAR)</u>.