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TO: DHSS BEHS and LPHA Inspection Staff

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SUBJECT: Tetrahydrocannabinol (THC) in Food Products

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The Department of Health and Senior Services' (DHSS) retail food program recently received several inquiries regarding the addition of varieties of tetrahydrocannabinol (THC) into food products. This technical bulletin is intended to share DHSS' current thinking on this subject. Technical Bulletins do not create or confer any rights for or on any person and do not operate to bind DHSS, Local Public Health Agencies, or the public. Alternative approaches may be possible if the approach satisfies the requirements of the applicable statutes and regulations.

According to the U.S. Drug Enforcement Agency, marijuana is a mind-altering (psychoactive) drug, produced by the *Cannabis sativa* plant. Marijuana contains over 480 constituents and THC-9 (delta-9-tetrahydrocannabinol) is believed to be the main ingredient that produces the psychoactive effect.¹ Yet another constituent of marijuana is Delta-8-THC or THC-8 (delta-8-tetrahydrocannabinol). THC-8 is less potent and not as well-known but appears to be gaining recognition. Some individuals believe that THC-8 was exempted from the Controlled Substances Act in the 2018 federal farm bill. This idea is explained in a recent *Rolling Stone* article: <https://www.rollingstone.com/culture/culture-features/delta-8-thc-legal-weed-explained-1113859/>.

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The U.S. Food and Drug Administration's stance on cannabis and cannabis-derived products is posted online at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. FDA's stance is summarized in the response reproduced below from Question 2 of their Q and A section:

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

In Question 10, FDA goes on to state that that it is not legal under federal law to add THC to a food product.

The ongoing conflicts with federal and state regulations as well as enthusiasm from cannabis advocates has created a difficult and confusing regulatory environment. However, the following Missouri laws and rules do not support the addition of THC into food:

- 19 CSR 20-1.025 3-101.11 *Food shall be safe, unadulterated, and, as specified under 3-601.12, honestly presented.* Food additives must typically be recognized by U.S. FDA as safe and preapproved to be included in food. This is not the case with THC.
- 19 CSR 20-1.025 3-201.11(A) *Food shall be obtained from inspected and approved sources that comply with law.* There are no inspected or approved sources of THC compounds in Missouri, except those licensed through the DHSS Section for Medical Marijuana Regulation (Missouri legalized medical marijuana through an initiative petition in November 2018).
- 19 CSR 20-1.025 3.202.12 *Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 relating to food additives...* THC is not an FDA-approved food additive.
- 196.010 RSMo defines *food*, *drug*, and *new drug* separately. They are consistently addressed separately throughout Chapter 196 RSMo. This is consistent with the federal FD&C Act, as state law is based on early versions of the federal law. In other words, an article is usually regarded as a *food* or a *drug*, but not both.

Food products with THC-9 are regulated as drug products under state medical marijuana laws. There are no permissive state laws for adding other forms of THC including THC-8 to foods. Food companies that wish to add THC ingredients to their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS approval processes. Those wanting to pursue approval as a food ingredient should be referred to FDA and its website for more information about these approval processes.

¹ <https://www.dea.gov/taxonomy/term/336>