

Regulating the Safety of Cannabis-Infused Foods:
Alternatives to Prohibition

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Executive Summary

Proposed regulations released by California's Manufactured Cannabis Safety Branch in April 2017 included a blanket prohibition on potentially hazardous foods (PHFs), including refrigerated products, low-acid canned foods, juices, perishable baked goods, meats, dairy, and seafood. As the MCSB prepares to release emergency regulations in November 2017, this paper seeks to inform an alternative solution that effectively regulates, rather than bans, cannabis-infused PHFs. A review of regulatory systems in Oregon and Colorado finds precedent for the effective regulation of cannabis PHF products, and a review of California's existing regulatory structures for conventional foods finds that California already possesses the key resources necessary to effectively regulate cannabis food safety. This paper suggests that MCSB should emulate Oregon's approach by applying California's existing food safety framework to the regulation of cannabis PHFs.

Introduction

In April 2017, the Manufactured Cannabis Safety Branch released proposed regulations governing the manufacturing of cannabis products under the Medical Cannabis Regulation and Safety Act. These proposed regulations included a prohibition on the production of food items classified as potentially hazardous foods (PHFs), including refrigerated products, low-acid canned foods, juices, perishable baked goods, meats, dairy, and seafood.

In its response to public comment, MCSB has communicated its understanding of the drawbacks of a blanket prohibition on PHFs, including the elimination of many currently-existing businesses; narrowing of consumer choice; pushing patients towards processed foods with little nutritional value; and incentivizing the continued operation of the black market. At the same time, MSCB communicated its concern that edible cannabis products must be manufactured in a way that ensures safety for consumers.

Under new requirements in the MAUCRSA, developing rules to regulate PHFs is a particularly urgent task. Business and Professions Code 26001(t) states that edible cannabis products are technically neither a food nor a drug. However, Business and Professions Code 26130(c)(5) – a new statute included in the MAUCRSA, but not in the MCRSA – states that edible cannabis products must be regulated in a manner *similar to* foods. Specifically, the statute reads:

“edible cannabis products shall be... manufactured and sold under sanitation standards established by the State Department of Public Health, in consultation with the bureau, *that are similar to the standards for preparation, storage, handling, and sale of food products.*”

As a result, DPH and MCSB are arguably under statutory obligation to implement food safety regulations for cannabis that are analogous to the standards for conventional food products.

Towards that end, the goal of this paper is to help inform a regulatory system governing PHFs by contextualizing the issue within the existing regulation of cannabis edible production in Oregon, Colorado, and Washington, as well as existing California food safety regulations.

In examining each of these existing systems, this paper concludes that there is substantial precedent for the regulation of cannabis food safety, and that the state of California already possesses the necessary structures to regulate cannabis PHFs even without federal assistance.

With that conclusion in mind, this paper proposes a number of options for amending MCSB regulations to enable the production of cannabis-infused PHFs.

Food Safety Regulation in Cannabis-Legal States

1. Oregon

Oregon allows cannabis-infused PHFs and regulates their safety in similar manner to the regulation of conventional food products. The Oregon Department of Agriculture's program for food safety – analogous to California Food and Drug Branch's Food Safety Division – issues licenses for retail establishments, bakeries, food processing and warehousing, home food production, meat, eggs, shellfish, dairy, non-alcoholic beverages, and frozen food storage.¹ Upon applying for a state cannabis producing license, the Oregon Department of Agriculture determines if further licensing specific to food production is required, and if so, reaches out to the applicant to initiate that process.²

Cannabis food businesses in Oregon are inspected on the same minimum requirements as other food establishments, including verification of compliant dishwashing and handwashing facilities, restrooms, floors, ventilation, and garbage disposal.

Some special rules apply to Oregon cannabis businesses that are not applicable to non-cannabis food manufacturers. Under Rule 845-025-3250, edibles cannot be prepared at home and cannot be prepared in the same establishment as non-cannabis foods.

Unlike proposed California regulations, Oregon's Rule 845-025-3255 allows multiple edibles manufacturers to share commercial kitchen space, so long as the space is scheduled such that only one operator is present in the space at a given time.

2. Colorado

Colorado does not place any special restrictions on PHFs, and products such as infused beef jerky and ice cream are available at Colorado dispensaries.³ Rule 604 of the Marijuana Enforcement Division's adult use cannabis regulations outlines the steps required to ensure food safety in edibles production. Owners and licensees are required to obtain a ServSafe Food Handling Certificate and complete a food safety course that covers the causes of foodborne illness, personal hygiene and food handling practices, approved sources of food, potentially hazardous foods and food temperatures, sanitization and chemical use, and emergency procedures.

¹ *About Food Safety Licenses*. Oregon Department of Agriculture, <http://www.oregon.gov/ODA/programs/FoodSafety/FSLicensing/Pages/AboutLicenses.aspx>

² *Cannabis and Food Safety*. Oregon Department of Agriculture, <http://www.oregon.gov/ODA/shared/Documents/Publications/FoodSafety/CannabisFoodSafety.pdf>

³ Auslander, Jason. *Pot-infused jerky made in Aspen getting high marks in industry*. The Aspen Times, 30 April 2017, <http://www.aspentimes.com/news/high-mountain/>

Licenses are also required to detail their standard operating procedures and manufacturing processes and abide by sanitation requirements. Licenses are inspected and may be audited on suspicion of a violation.

In addition, city and county health inspectors may impose their own requirements. Denver, for instance, has required that edibles manufacturers be inspected twice yearly.⁴

3. *Washington*

Washington is the only state with legal adult use cannabis that prohibits cannabis-infused PHFs.⁵ The Washington State Department of Agriculture, which is responsible for food safety for conventional foods, is also delegated responsibility for the regulation of edible cannabis products.⁶ The WSDA enforces requirements related to fixtures, equipment, sinks, and water supply, and requires an inspection prior to beginning operation. Like Oregon, Washington does not permit conventional and cannabis-infused foods to be manufactured in the same facility.

Conventional Food Safety Regulation in California

The structure of food safety regulation in California is similar to that in Oregon. The Food and Drug Branch (FDB) of the California Department of Public Health currently permits and regulates uses related to food manufacturing and storage.⁷ The baseline health permit required for most food processors is the Processed Food Registration (PFR) certificate. Applicants for a PFR certificate are inspected by FDB prior to granting a certificate, and again at least once annually. Inspections verify compliance with regulations regarding business and product information, production and process controls, sanitation, and product labeling.

Depending on the type of food manufacturing business, additional FDB permits may be required:

- Juice and seafood manufacturers are required to implement HACCP plans as detailed under Title 21 of the Code of Federal Regulations.
- Producers of low-acid canned products are required to obtain a special FDB cannery license.
- Cold storage facilities are required to obtain a special FDB license to ensure proper refrigeration protocols.

⁴ Wyatt, Kristen. *Marijuana Edibles Need to Pass Food Safety Tests for Credibility*. Food Manufacturing, 23 June 2014, www.foodmanufacturing.com/news/2014/06/marijuana-edibles-need-pass-food-safety-tests-credibility.

⁵ *Scope of Marijuana-Infused Edibles*. Washington State Department of Agriculture, https://agr.wa.gov/FP/Pubs/docs/FSCS/MIE_Allowable_Products6-25-15.pdf

⁶ *Marijuana-Infused Edibles Inspections*. Washington State Department of Agriculture, https://agr.wa.gov/FoodAnimal/Marijuana_Infused_Edibles.aspx

⁷ *Food Safety Program*. California Department of Public Health, Food and Drug Branch, www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram.aspx.

Meat and dairy products are regulated by the California Department of Food and Agriculture rather than FDB. Facilities that process meat derived from state or federally-inspected slaughterhouses are exempt from USDA inspection and instead fall under the authority of the CDFA's Meat, Poultry, and Egg Safety Branch. Specifically, meat processing establishments which "prepare meat and poultry products by curing, smoking for preservation, drying, or rendering for retail sales only" must submit an application to the CDFA, comply with state-level requirements, and be inspected by a MPES inspector.⁸ A similar process exists for dairy, which requires CDFA inspection and permitting for a variety of milk and dairy manufacturing operations.⁹

In addition to these requirements, the California Retail Food code requires that at least one operator at a business working with PHFs possesses a Food Safety Manager's Certification, and requires that all employees obtain a food handler card. Existing requirements for retail food outlets are often applicable to cannabis manufacturing business under the MAUCRSA, since dispensaries are required to receive products in final packaged form and do not engage in food preparation.

Perishable foods are also required to be labeled as "Perishable Keep Refrigerated" under requirements in the California Health and Safety Code.

Conclusion: A Path Forward for Cannabis Food Safety in California

As the above review indicates, CDFA and FDB already possess the resources and structures to regulate each category of prohibited PHFs on a state level, without federal government involvement. Regulations that cover PHFs could be implemented in a manner analogous to Oregon simply by requiring that cannabis edibles producers obtain the appropriate food safety license in addition to their cannabis license. If a cannabis business cannot meet the initial standards necessary to obtain a food safety license, MCSB would have the option to withhold a cannabis operating permit until the necessary changes are made. Fees for regulation could scale depending on the enforcement resources required for a particular food product, as is currently the case for non-cannabis PHFs.

Requiring food safety licensing would guarantee strict oversight when combined with the already-proposed MCSB requirements, which often exceed oversight of food safety in other cannabis-legal states as well as safety requirements for conventional foods. Proposed MCSB regulations already contain detailed requirements for employee personal hygiene, facility

⁸ *Procedures for Obtaining State Meat or Poultry Inspection*. California Department of Food and Agriculture, <https://www.cdfa.ca.gov/ahfss/mpes/pdfs/ProcedureStateMeatPoultryInspect.pdf>

⁹ *Licenses, Permits, Dairy Exemption Numbers, Registrations*. California Department of Food and Agriculture, https://www.cdfa.ca.gov/ahfss/AHFSS_Licensing.html

design, sanitation, equipment and utensils, control of ingredient quality, written SOPs, hazard analyses, written manufacturing protocols, employee training, and waste disposal. Additional contingency plans are required for complaints, recordkeeping, and recalls. All personnel – even those not involved in food handling – are required to be trained on food safety, and all food handling employees are required to complete a food handler course accredited by the American National Standards Institute. The terms of local and state cannabis permits also hold cannabis food manufacturers to additional scrutiny as compared to convention food operations, including DPH inspections under Section 40500 of the proposed regulations, and any requirements under a local cannabis permit.

This review, which stems from a regulatory and legal perspective, likely doesn't cover every challenge MCSB faces in the regulation of cannabis food safety. It does suggest, however, that a regulatory precedent and institutional framework are already in place to resolve the bulk of the potential food safety issues identified in MCSB's ISOR. If these existing frameworks are not in themselves sufficient to address every challenge, manufacturers of edible cannabis products are happy to work in collaboration with MCSB and public health advocates to find solutions. In this sense regulating cannabis food safety is not materially different from regulating mobile food trucks, cottage food producers, or small organic farms, all of which may create challenges distinct from industrial-scale food producers and fixed retail location, but which nevertheless deserve regulation rather than blanket prohibition.

Working towards these solutions is crucial given that MCSB is not setting initial rules for a new marketplace, but rather deciding on regulations that will determine the winners and losers in a California cannabis market that has existed for over twenty years. Getting these regulations right is crucial for patients, existing businesses, and the success of California's new regulated marketplace.