

**Challenges and Practices Associated with the Implementation and Enforcement
of Cannabis-Infused Food Product Regulations**

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Abstract

While cannabis has been decriminalized in eleven states and the District of Columbia, ten states currently allow the sale of recreational cannabis edibles outside of a medical marijuana program. Federally cannabis is considered a controlled substance and, without an established federal program and comprehensive guidance on best practices and policies, states have developed unique regulations, policies, and procedures to regulate edibles in their jurisdictions. Key personnel from five states with edibles regulatory programs that had been in place for at least two years were identified and interviewed on the challenges and practices associated with regulating edibles. Information gathered from key informant interviews was analyzed to identify challenges and practices. Interagency communication and coordination as well as training and education for both the industry and regulatory communities are highlighted as important aspects to effective edibles programs. Requiring laboratories that test cannabis edibles to be certified or accredited is an important factor for ensuring consistency in validation and verification. Additionally, the creation of a national framework to help guide states in developing edibles regulations is paramount for a consistently regulated edibles food supply. As cannabis legalization sweeps the country, states should consider the importance of coordination, communication, education, and training when developing cannabis edibles regulations.

Key words: Cannabis, cannabis-infused edibles, CBD, edibles, marijuana, THC

Challenges and Trends Associated with the Implementation and Enforcement of Cannabis-Infused Food Product Regulations

Background

In 2012, Oregon and Washington became the first two states to decriminalize adult-use recreational cannabis. Today, eleven states, the District of Columbia, and several U.S. territories allow adult use of marijuana (National Conference of State Legislatures, 2019). Of those eleven states and the District of Columbia, ten allow the sale of recreational cannabis-infused food products, commonly known as edibles.

Federally, cannabis remains a Schedule I controlled substance. Therefore, there is no federal regulatory program to provide guidance or a comprehensive regulatory framework for edibles. The National Environmental Health Association (NEHA) (2018) identifies multiple key food safety concerns with the production and sale of edibles that should be considered when developing a recreational edibles program: storage, collection and testing, laboratory accreditation, tracking, transportation and distribution, serving size and homogeneity, labeling and packaging, education and training, food safety plans, waste disposal, and regulatory oversight.

In response to the rapid legalization of cannabis across the United States and in the absence of federal guidelines and recommendations, states with legalized recreational edibles programs worked quickly to define their own regulatory requirements. These regulations were often created based on a limited amount of tested and proven data. A trial-and-error approach was often used, particularly for early adopters of legalized sale (Calonge, 2019).

As additional states adopt laws that allow the sale of edibles, regulatory agencies are faced with developing and enforcing regulations to ensure the safety of these food products. Agencies may be able to learn from the experience of earlier adopters in terms of the challenges faced for foods that include tetrahydrocannabinol (THC), the psychoactive component of cannabis (Grayson, 2015). The aim of this study is to identify challenges and reveal varying practices to provide a summary of strategies and recommendations for states developing and implementing edibles regulations. A relatively controversial, yet rapidly growing industry, edibles demand immediate and consistent regulatory attention as the United States adjusts to this new line of food production.

Problem Statement

Multiple states have allowed the sale of cannabis-infused food products for several years. However, challenges associated with regulation of those products are relatively unknown.

Research Questions

- What are the most frequent food safety violations amongst states that have enforced edibles regulations for at least two years?
- What unique food safety challenges have been identified in the implementation and enforcement of edibles regulations?
- Are there training requirements for edibles processors and what do they entail?

Methodology

The target population included U.S. states and territories that have had recreational cannabis edibles regulations in place for at least two years. Six states were

identified for the scope of this project: Alaska, California, Colorado, Oregon, Nevada, and Washington. Data was collected from five of the six states. The Association of Food and Drug Officials (AFDO) Directory of State and Local Health Officials as well as resources and committee members from the AFDO Cannabis Committee were used and contacted to identify key personnel from each state. Additionally, an internet search revealed state-specific information that was used to identify the appropriate agencies to contact and gather additional information on each state's edibles program(s).

Key informant interviews were conducted with ten representatives from five states representing various agencies involved in the regulation of edibles. The interviews occurred over the phone and were recorded and transcribed for accuracy. The key informants were interviewed between October 2019 and February 2020. Each interview was conducted with one to three participants, not including the interviewer. The phone interview responses were organized using Microsoft Excel, and analyzed for similarities and differences in both quantitative and qualitative information.

Results

Multiple agencies in each state were identified as having some degree of jurisdiction over the enforcement of edibles regulations. Four out of five states in this study had at least two agencies responsible for the regulation of cannabis edibles: one with jurisdiction over the legalities, security, and tax requirements, and another with jurisdiction over the food safety requirements, with varying degrees of overlap. Among the food safety agencies studied, all five of the states use their respective versions of the Food and Drug Administration's Model Food Code, the Good Manufacturing Practices (GMP) Regulations, or have regulations which include all or parts of these federal documents.

Two states consider edibles to be neither a food nor a drug and have created a separate edibles definition. The remaining three states consider edibles to be food products and consider cannabis and its byproducts to be an approved additive, requiring the substance to come from an approved source. States varied in the degree to which they restrict food products that can be sold as part of their recreational program. One state had no restrictions on types of foods that could be processed, while two allowed only non-temperature control for safety (TCS) foods. Two states allowed products on a case by case basis, with restrictions on meat products and some dairy products. One state had unique allowances for cannabis-infused juices produced under juice Hazard Analysis Critical Control Points (HACCP) and infused butter, two products that had previously been approved amongst the medical cannabis industry. However, limited numbers of process authorities working with cannabis stunted some states' abilities to validate specialized processes for edibles.

Four out of five states indicated the majority of violations frequently observed during edibles inspections were not specific to cannabis processors, but rather food processors in general. The remaining state identified one frequent violation specific to cannabis: cleaning and sanitizing of THC extraction equipment. Unapproved source was recognized by one state as a frequently cited violation during edibles inspections. That state further explained that unlicensed operators were a pervasive problem. Two states mentioned frequent facility construction violations, specifically not having the appropriate food safety equipment such as warewashing sinks. Three states provided examples of improperly labeled edibles, one of which indicated allergen labeling was a frequently cited violation. Conversely, one state indicated labeling of edibles was not a frequently cited

violation, due to an extensive plan review process prior to edibles items reaching the market. Lack of recordkeeping pertaining to tracking and sale was identified by one state as the most frequently cited violation during edibles inspections.

A variety of unique challenges were identified by the states in this study. Two states expressed concern over the lack of federal oversight, indicating difficulties with products illegally introduced into interstate commerce coupled with ineffective interstate recall capabilities. An additional state's response was mixed, indicating that a federal framework would have been beneficial in the initial regulation development stage, however, development of that framework post-regulation adoption in the varying states may threaten to complicate regulations even further.

Inspector training and understanding of the risks and equipment associated with edibles was identified by one state as a significant issue. Unique challenges with understanding the equipment used by edibles processors and how it is cleaned and sanitized was identified by one state. Three states indicated that inconsistency in laboratory testing and lack of certification programs for cannabis edibles-specific testing created challenges in the enforcement of state regulations. One state explained that for edibles products that do not have THC markings on the physical food, it is impossible to tell the difference between a THC-containing food and a traditional food in absence of the packaging, posing a risk to the public. Four states revealed that having multiple agencies which have a hand in the regulation of edibles can complicate communication both internal to the government and external to industry members.

Finally, two states indicated that edibles processors often do not have a food safety background, thus education and training was a challenge. Four out of five states required

a certified food protection manager, or equivalent, at the edibles establishment, or that the person(s) in charge demonstrate adequate food safety knowledge. Additional training is required by all five states, specifically to tracking, labeling for safety, and legal requirements. One state required edibles operators and their staff to attend a specific state-provided training focused on the licensure, tracking, safety, and security requirements imposed on edibles operators in addition to the food safety training.

Conclusions

Food safety violations identified in this study essentially mirrored those that may be found in a traditional food processing operation with several violations that would be unique to edibles. Unique equipment for THC extraction poses a challenge for ensuring appropriate cleaning and sanitizing measures. This requirement was met by the industry in one state by using laboratory-grade chemicals to clean and sanitize extraction equipment. State laws require strict adherence to tracking from seed to sale, thus recordkeeping unique to edibles processors may be a pervasive violation in states with similar requirements.

Regardless of the degree to which states limit the types of food products permitted to be infused with THC, the cannabis market in this study was found to be generally self-limiting. In one example, a state with minimal food restrictions explained that when cannabis edibles were first legalized, a plethora of different types of foods and processes were marketed. However, the industry adjusted based on customer demand, which generally included items such as lozenges, cookies, or baked goods. This limited selection of items is reportedly less expensive for the consumer to purchase than those

items which require extensive processing, yet the consumer still experiences the psychoactive effects of THC.

Product labeling can be a challenge in the regulation of edibles. In some cases, product labels may be determined to be non-compliant only after the processor had already invested in mass label printing and sometimes after products were already on market. Strict plan review requirements or requiring photos of final product packing may reduce the number of recalls and/or product labeling violations.

The allowance of specialized food processing may require additional oversight such as HACCP plan development or Process Authority involvement. A significant gap in the availability of Process Authorities willing to work with edibles was repeatedly emphasized during data collection and may pose a barrier to entry for new and innovative edibles.

Lack of certified or accredited laboratories that could consistently test edibles was identified as a pervasive issue. States with a laboratory accreditation program specifically for cannabis products believe the program helps to ensure consistency and confidence in edibles testing. States that lacked certified or accredited laboratories have experienced inconsistencies when testing and expressed the desire to have more consistent testing programs.

Providing inspectors with a greater understanding of what to expect during an edibles inspection may help ease the fears of the inspectors and prepare them to work in the edibles processing environment. Involving a member of the cannabis industry may be beneficial in educating the regulatory workforce as this was done with great success in one state studied.

States would benefit from availability of a regulatory framework to use in development of their edibles programs. While development of such a framework might pose challenges for those states already regulating edibles, it may ease the burden on those states that are in the process of developing such programs. The legalization of edibles at the federal level may allow for more studies to occur which could provide more evidence-based information that can be used to develop comprehensive edibles regulations.

Food safety training is a vital requirement for edibles operators, as many cannabis producers were reportedly not familiar with food safety regulations prior to legalization and regulatory enforcement.

Recommendations

Future adopters of edibles regulations may take the following recommendations into consideration when developing their programs:

- Require food safety-specific training for all food handlers of cannabis edibles operations
- Require laboratory testing of edibles from accredited/certified laboratories
- Provide training on cannabis extraction, unique cannabis processing equipment, safety protocols and any identified risks of edibles processing to inspectors
- Develop policies and procedures for effective interagency communication and collaboration

Finally, associations such as the NEHA and AFDO should consider collaborating to work with regulators, industry members, and stakeholders on developing comprehensive guidelines, best practices, or a model regulatory framework that can be referenced or

adopted by states and/or U.S. territories which are developing or implementing their own cannabis edibles regulations.

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