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Policy Statement on Food Safety Related to Consumable Cannabis Products

Adopted: July 2023 Policy Sunset: July 2028

NEHA supports the implementation of regulations related to consumable cannabis products that contain sufficient authority to prevent illness and encourage the inclusion of the following policies and actions:

- Consumable cannabis products (edibles) should be safe for human consumption and processed to comply with all regulatory requirements for quality, safety, potency, dosage, storage, distribution, packaging, and labeling.
- All ingredients for food items should be from approved sources and compliant with relevant food and cannabis laws of the regulatory authority.
 - Raw agricultural commodities should be cultivated in accordance with good agricultural collection practices, including the inspection of fields or areas where crops are grown.
 - Extracts, concentrates, isolates, edibles, etc. should be processed and manufactured in accordance with good manufacturing practices, including the inspection of extraction and manufacturing facilities.
 - Edibles sold at retail should be received, stored, and sold in compliance with relevant laws of the regulatory authority.
- In accordance with a state's determined potency limits for cannabinoids (e.g., tetrahydrocannabinol [THC], cannabidiol [CBD], etc.) edibles should be clearly labeled, and individually packaged with concentrations clearly listed on the label per serving and as a total.
- Active ingredients in edibles should be tested by accredited laboratories to effectively label and quantify products with the range of cannabinoids that are present (e.g., THC, CBD, cannabigerol [CBG], etc.).

- Regulatory authorities should exercise enforcement oversight of pertinent regulations including the ability for a compulsory recall and to cease production of items that are improperly labeled, adulterated, prepared in an unsafe facility or in an unsafe manner, or otherwise pose harm to human health or are outside of required product specifications.
- Regulatory authorities should prohibit the production and sale of edibles that appeal to children in terms of product shape, packaging, advertising, etc.
- Jurisdictions intending to develop new cannabis regulatory programs should consider basing the health and safety portions of the regulations on federal requirements such as good manufacturing practices, good agricultural and collection practices, and federal models such as the Food and Drug Administration (FDA) *Food Code*.
- Collaborative approaches between all regulatory authorities, including identification of the roles and responsibilities of each authority, should be established to determine how they will efficiently and effectively communicate to address and resolve issues.
- Regulatory authorities should consider regulating artificially-derived THC products from hemp, such as delta-8 THC, delta-10 THC, THC-O, and hexahydrocannabinol (HHC), in the same manner as cannabis-derived THC products.

Analysis

Due to increasing legalization of cannabis for medical and adult use (sometimes referred to as retail or recreational use), the consumption of edibles has become popular in many communities. Edibles are defined as a consumable food or beverage to which cannabis or its derivatives has been added. Edibles can include cannabinoids extracted from cannabis plants (*Cannabis sativa* L.) and cannabinoids extracted from hemp (*Cannabis sativa* L. with <0.3% concentration of THC.)

Many states have enacted laws that permit the inclusion of cannabis and its derivatives in food products. Edibles raise questions as to how cannabis should be grown, harvested, and then further processed, including labeling, packaging, and distribution to protect public health. Regulations for edibles are imperative considering that one in six people in the U.S. get sick from contaminated foods or beverages and 3,000 die each year (Centers for Disease Control and Prevention, 2018; Scallan et al., 2011).

NEHA advocates for national, state, local, tribal, and territorial policies, regulations, research, and resources that will enhance the ability of environmental health professionals to ensure the production of safe food and protect the public's health. NEHA neither endorses nor repudiates the use of cannabis.

Background

Cannabis Overview: Regulations



Cannabis is the most widely used, federally illegal drug in the U.S., with more than 52 million people reporting using cannabis at least once in 2021. (Substance Abuse and Mental Health Services Administration, 2022).

California was the first state to legalize medical cannabis use in 1996, while Colorado and Washington were the first states to legalize adult-use recreational cannabis in 2012 (Barrus et al., 2016).

According to the National Conference of State Legislatures (Hartman, 2022):

- 37 states, 3 territories, and Washington, DC, allow medical-use cannabis
- 21 states, 2 territories, and Washington, DC, regulate cannabis for adult use (nonmedical)
- 37 states, Washington, DC, Guam, Puerto Rico, and the U.S. Virgin Islands regulate medical-use cannabis for qualified individuals
- Idaho, Kansas, Nebraska, and South Carolina have no public access programs for cannabis.

While numerous U.S. states and territories have allowed for the production and sale of cannabis products, including cannabis edibles, cannabis remains a Schedule I substance under the Controlled Substances Act, which makes distribution a federal offense (Hartman, 2022). Countering the Controlled Substances Act, the U.S. Department of Justice (2013) stated that while cannabis is a federally illegal substance, states are expected to create "strong, state-based enforcement efforts." Furthermore, due to federalism, states are within their right to challenge legalization laws. Despite these changes, many regulatory food programs consider cannabis-derived products unapproved food ingredients unless there are specific state and local laws that allow for their incorporation into food. Varying legalization across the country has created a patchwork of regulations.

Cannabis Edibles Industry

The number of full-time equivalent jobs supported by legal cannabis has more than tripled from 2017, reaching 428,059 jobs in 2022 (Barcott & Whitney, 2022). In addition, \$24.6 billion in cannabis products was sold in 2021 (Barcott & Whitney, 2022).

With the legalization of medical- and adult-use cannabis, the inclusion of cannabis in food and beverages has increased. In particular, the use of edible cannabis products has been highlighted as an issue of concern, principally in states where cannabis has been legalized (MacCoun & Mello, 2015; Monte et al., 2015). Edibles have become the choice product for many users as they offer a discrete way to intake cannabis via ingestion as opposed to inhalation (Gourdet et al., 2017). In 2022, edibles made up 12.1% of total cannabis sales, up from 10.7% in 2021. Gummies dominate sales, accounting for 73.9% of total sales, followed by caramels and chocolates at 9.5%, and 9.4%, respectively (Headset, 2022).

Labeling

Current state requirements for labeling of licensed cannabis products are inconsistent and might contribute to consumer confusion. There are a wide number of considerations for labeling

requirements, including but not limited to manufacturer identification, cannabinoid content, serving sizes and dosage, lot numbers or batch identification, net weight, allergens, expiration dates, storage instructions, cannabis concentration, warnings, and poison control contact information. Requirements vary per jurisdiction (Soroosh et al., 2021). There are only two labeling requirements shared by all state programs: delta-9-THC content and manufacturer contact information (Kruger et al., 2022).

Labeling for dosage is particularly important because inhalation and ingestion of active ingredients (e.g., cannabinoids) present different effects over different time periods that many users might not fully understand. In short, inhalation exhibits effects within minutes, whereas the effects of edibles begin within 30 min to ≥ 1 hr after ingestion, with a peak effect within 3–4 hr. Depending on weight, metabolism, sex, and the content of the most recent meal, effects can be felt at different rates and could lead users to ingest higher than recommended doses (Page et al., 2020).

Dosing and Serving Size and Importance of Homogeneity

Documented procedures and formulations should be followed to ensure the homogeneity of cannabinoids in edibles. Package sizes and servings contained within vary across states. For example, while 10 mg of THC is recommended per serving in Colorado, packages generally contain around 100 mg of THC (Monte et al., 2015). The homogeneity of the product is essential to ensure the dosage of cannabinoids is consistent in each serving. Products labeled as containing 100 mg of THC have been shown to contain anywhere from 0–146 mg of THC (Monte et al., 2015). Vandrey et al. (2015) found that 83% of labels for edibles differed from actual product content by >10%. Additionally, the study found that only 17% of the products were labeled correctly.

Processing and Storing

Food processed for human consumption should meet requirements to ensure safety. Cannabis processors should adhere to robust operating systems that include approved suppliers, safe food processing procedures, and adequate food safety plans to mitigate food safety risks. Incoming materials should be from an approved source and should meet food safety standards. Processes and controls should be in place to ensure edibles are produced in a safe manner.

In addition, storage conditions of edibles could potentially affect the chemical makeup and safety of the food product (Gourdet et al., 2017). To mitigate food safety risks, it is important that edible processors and retailers adhere to food safety practices and requirements such as good manufacturing practices and good retail practices. These practices help ensure a safe, consistent edible product for the end user.

Underage Access and Appeal

Regulations around packaging and marketing should serve to protect highly susceptible populations such as children. Many states have enacted policies to prohibit the sale of edibles that resemble candies that might be appealing to children. All states require packaging of cannabis products to be child-resistant.

The incidence of pediatric exposures to edible cannabis products continues to grow with the expansion of cannabis markets across the country. An analysis of the National Poison Data System revealed the number of exposures to edible cannabis products in children <6 years went from 207 reported cases in 2017 to 2,054 cases in 2021—an increase of 1,375% (Tweet et al., 2023). States that legalized cannabis saw a 30.3% increase in calls per year to poison control centers, whereas states undergoing the transition to legalize cannabis saw an 11.5% increase in calls and states without legalized cannabis showed a 1.5% increase in calls (Barrus et al., 2016).

Testing Cannabis Edibles

Laboratory testing is an important part of ensuring a safe edible product. Accurate testing for cannabinoid content and contaminants by ISO 17025 accredited laboratories is critical to verify that products are safe to consume and to ensure that product labels accurately reflect the contents. There does, however, exist the potential for manipulation of results. Jurisdictional oversight of sample collection reduces the likelihood of laboratory shopping, sample manipulation (e.g., testing a sample that will knowingly pass but labeling it as a sample that may not pass), or altering a sample by microwaving, dehydrating, or spraying samples with an acidic agent. To minimize opportunities for the manipulation or alteration of test samples by business operators, regulators might consider requiring that either regulators or laboratory personnel conduct the sampling activities.

Justification

There have been several cannabis-associated outbreaks, recalls, and adverse events reported by or to officials in states that have legalized cannabis. Jurisdictions seeking to create regulations that protect public health should be aware of these events and other incidents.

Over 100 adverse event reports related to children and the consumption of look-alike edible products were reported to FDA (2022a) from January 2021 through April 24, 2022.

Food safety concerns over edibles have also caused an increase in product recalls due to unapproved pesticides and other public health concerns, such as the grade of oils used and different ingredients allowed by various states. These recalls include:

- Although no adverse reactions were reported in Ohio due to the recall of edibles infused with THC that were produced from August through October 2020, heavy metals were found in abundance. The amount of cadmium in the edibles exceeded state thresholds, which can pose significant health risks if the product is consumed (Borchardt, 2020).
- Non-food-grade flavoring oils used in the production of cannabis edibles in Denver prompted a recall of cannabis products in August 2017 (Shaw & Stuck, 2018).
- An edible product with no records to indicate the product could be stored at room temperature safely was recalled in 2012 over concerns of botulism (Shaw & Stuck, 2018).
- In February 2017, a dispensary in Coconino County, Arizona, voluntarily recalled edibles for not meeting processing and packaging requirements (Gaither et al., 2018; Suerth, 2017).

- Edible products were recalled in 2014 after it was discovered the cannabis extract had been made inside a washing machine that was in poor condition (Shaw & Stuck, 2018).
- From September 2015–November 2017, the Colorado Department of Revenue and Denver Department of Public Health and Environment issued recalls on edibles, as well as other cannabis products, due to the use of unapproved pesticides such as myclobutanil, abamectin, and other pesticides (Baca & Migoya, 2016; Markus, 2015; Migoya, 2017).
- In March 2017, the Oregon Liquor Control Commission issued a recall after edibles were found to have pesticide residue levels greater than the state-approved limit (Mortenson, 2018).

Intoxicating Hemp Products

In addition to the recommendations above for cannabis edible products, public health concerns currently exist for hemp-derived THC edible products. As a result of the wording of the term "hemp" in the Agricultural Improvement Act of 2018 (known as the 2018 Farm Bill), hemp was removed from the Controlled Substances Act, which federally legalized hemp and hemp products. The definition of hemp in the 2018 Farm Bill includes all "derivatives," "extracts," and "isomers" of hemp and limits only delta-9 THC as needing to be >0.3% in hemp and hemp products instead of limiting the total THC. Unknown to Congress, CBD (a non-intoxicating cannabinoid) extracted from hemp can be chemically converted to intoxicating THC compounds such as delta-8 THC, delta-10 THC, THC-O, and HHC. Because these artificially derived THC compounds originate from hemp and because the definition of hemp in the 2018 Farm Bill includes all derivatives and isomers and limits the 0.3% THC threshold to only delta-9 THC, the intoxicating hemp product industry has found loopholes to operate within.

Many states do not regulate the production of hemp edible products as part of their wholesale food manufacturing programs. After hemp and hemp products were federally legalized, states may have been holding off on creating state regulations for hemp edible manufacturing in hope of a model or guide from FDA. FDA (2023) issued a statement that indicated a new regulatory pathway for CBD products as there is no existing regulatory path for hemp products. Some states, such as Virginia, are regulating intoxicating hemp products the same as cannabis products but for the most part, the intoxicating hemp product market is unregulated.

Due to the market being mostly unregulated, intoxicating hemp products lack requirements or standards for labeling, testing, dosing, processing, age restrictions, packaging, and child appeal. The products are sold on the internet, in convenience stores, in smoke shops, and elsewhere. Although FDA does not regulate these products, it does collect data on adverse health events associated with ingestion. FDA (2022b) released a consumer alert in 2021 about the serious health risks of delta-8 THC products. In addition to the FDA consumer alert, the Centers for Disease Control and Prevention (2021) released a health advisory to alert public health departments, healthcare professionals, first responders, poison control centers, laboratories, and the public to the increased availability of delta-8 THC products and the potential for adverse health events. In 2022, a 4-year-old boy in Virginia died from delta-8 THC toxicity after consuming high levels of delta-8 THC in gummy products (Fine, 2022).

To protect public health and safety from potential adverse health effects of intoxicating hemp products, it is recommended that states develop similar regulations as have been developed for cannabis-derived products, which provide requirements for labeling, dosing, processing, underage access and appeal, and testing. Alternatively, if states have legalized medical- or adult-use cannabis and have regulations for such, intoxicating hemp products could be regulated the same as cannabis products.

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