

ORIGINAL PAPER

Toxicology

Impact of cannabis-infused edibles on public safety and regulation

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Abstract

Popularity of cannabis-infused products has bloomed since legalization for recreational use of marijuana started. Consumption of cannabis edibles has steadily increased, as restrictions on recreational cannabis smoking have become tighter. This phenomenon enhanced the possibility of these products crossing the state line. The most psychoactive component of cannabis, $\Delta 9$ -tetrahydrocannabinol (THC) is infused in "edibles" and linked to physiological and psychological effects. Consumers unfamiliar with these edibles may mistake them for non-THC containing products, causing unintended use or overconsumption. In addition, these cannabis-infused edibles are posing significant health risks. The FDA has recognized the potential dangers and recommended that cannabis remain as a Schedule I substance and illegal at the federal level. However, states maintain control of determining the legality of cannabis related products, and creating guidelines distinguishing cannabis edibles from the non-cannabis containing products. Recently, the State of Maine offers a blueprint for edible regulation that should be implemented in all states that are considering or have legalized marijuana.

KEYWORDS

$\Delta 9$ -tetrahydrocannabinol, cannabis, edibles, legalization, marijuana, regulation, THC

Highlights

- Cannabis-infused edibles show increased prevalence with more states legalizing recreational cannabis use.
- Increased overconsumption of cannabis-infused products is a public health issue.
- Forensic laboratories are struggling to develop validated methodologies for the analysis of edibles.
- Recreational marijuana legislation regarding marijuana-infused edibles should be modeled after Maine's cannabis laws.

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1 | INTRODUCTION

Cannabis sativa is a psychotropic dioecious herb that contains Δ^9 -tetrahydrocannabinol (THC), a famous psychoactive compound [1-3]. THC was identified in the 1960s [2]. It interacts with the cannabinoid receptors (mainly CB1 and CB2) and affects pleasure, memory, thinking, movement, coordination, and sensory and time perception [3]. In the United States, marijuana, which contains THC concentration greater than 0.3% of the *Cannabis sativa*'s dry weight, is still classified as a Schedule I substance under the Controlled Substances Act [4]. Cannabis is typically smoked as a joint but can also be orally ingested through infused food and beverages.

In contrast to smoking, the THC in cannabis-infused edibles does not show immediate effects after ingestion [5, 6]. The delay is due to gastrointestinal absorption and digestion before the drug reaches the bloodstream. The delay can deceive consumers and lead to inadvertent overconsumption. Biotransformation of THC involves first-pass metabolism. During the process, THC is oxidized to its active metabolite, 11-hydroxy-THC (11-OH-THC), which is further converted to inactive 11-nor- Δ^9 -carboxy-THC (THCCOOH). Both THC and THCCOOH can undergo extensive conjugation to form the respective glucuronides with THCCOOH-glucuronide being the predominant metabolite in human urine.

2 | ADVERSE EFFECTS OF CANNABIS-INFUSED EDIBLES

The legalization of marijuana recreational use starting in Colorado a decade ago catalyzed the rapid expansion of cannabis edibles industry [7]. To date, edibles are the second most common form of cannabis consumption [8]. Skyrocketed popularity of the edibles is in part due to convenience of consumption, a calmer more relaxing "high," and less harmful toxins and health risks associated with smoking [9]. Moreover, emerging new infusion technologies have created a wide variety of novel cannabis-infused edibles

including baked goods, candies, gummies, seasonings, oils, chocolates, mints, beverages, and many other forms [10]. The edibles generally contain 10 mg THC per serving and 100mg per package. As the consumption of cannabis edibles increases, addressing public safety and health concerns associated with the edibles are becoming more important, because they are posing a significant risk to consumers, especially those who are unaware of the actual potency these edibles possess.

In addition, cannabis-infused edibles are currently similar in appearance in packaging to non-THC containing products (Figure 1). Consumers are unlikely able to distinguish them. This has become of more alarming concern towards children and older populations. According to the National Poison Data System (NPDS), the American Association of Poison Control Centers reported that roughly 4000 cases of children under 9 were hospitalized for accidental cannabis exposure from 2017-2019 [11]. On a boarder scale, one case study conducted in Michigan reported that of the 155 cases reported to emergency departments related to cannabis ingestion, 39 patients showed psychiatric symptoms (agitation, hallucination, paranoia), 32 suffered from cardiovascular disorders (tachycardia, hypertension, palpitations), and 21 exhibited neurological issues (amnesia, seizure, syncope, unresponsive) [12]. Other patients reported various gastrointestinal symptoms, respiratory abnormalities, and visual alterations. The same study highlighted children who were exposed through ingestion of the edibles also experienced hallucinations, syncope, seizure, tachycardia, or hypoventilation. Adults over 65 may face increased cognitive impairment, risk of falls, and heart arrhythmia in addition to other drug interactions with prescription drugs [12]. Moreover, hyperemesis syndrome is a growing medical issue where severe cyclical nausea, vomiting, and abdominal pain may be triggered by long-term cannabis use [13]. Though a novel study, Baylor Scott and White Medical Center in Texas discovered that hospital admission costs roughly \$4000 on average when related to imaging, lab, medication, and procedure costs associated with "cannabis hyperemesis syndrome" [13]. With easier accessibility to cannabis-infused edibles, both the likelihood of hospital visits and



FIGURE 1 Comparison of edible product packaging with commercial product packaging [41]

the resulting financial burden on patients and hospitals related to cannabis overconsumption increases.

3 | CANNABIS-INFUSED EDIBLES AND DRIVING UNDER THE INFLUENCE

Driving while under the influence (DUI) of cannabis is another public safety issue. The percentage of fatalities in the US involving cannabis moved up from 9.0% in 2000 to 21.5% in 2018. Fatalities involving cannabis and alcohol impairment while driving jumped from 4.8% in 2000 to 10.3% in 2018 [14]. In Colorado alone, traffic deaths caused by cannabis intoxicated drivers have increased by 135% since 2013 [15]. Colorado DUI citations involving cannabis has increased roughly 8% since cannabis legalization. The prevalence of drivers under the influence of alcohol and cannabis use combined doubled in the same time frame [7]. This is also creating challenges for law enforcement trying to establish an analytical threshold of intoxication, similar to the blood alcohol content (BAC). Several states have per se laws that determine an individual's impairment level with a specific THC and/or its metabolite(s) blood concentration over a certain threshold since traditional sobriety tests lack sensitivity to detect THC influences [16]. Although utilizing per se limit is an interesting attempt to provide a quantifiable and simplified standard to law enforcement and legal communities, the reality is far more complicated. Currently there is no uniform per se limits or even standardized analytes in the United States [17]. For example, in Illinois, Montana, Nevada, Ohio, Pennsylvania, Washington, and West Virginia, THC in whole blood is targeted and the per se limits are in the range of 1–5 ng/ml. In Colorado, a permissible inference law has been adopted and a driver can be considered under THC influence if the THC concentration in blood is more than 5 ng/ml at the time of offense. It is noteworthy that in Nevada, Ohio, and Pennsylvania, per se limits also cover THC major metabolites (11-OH-THC and THCCOOH) blood concentrations. Unlike BAC, blood THC concentration is poorly correlated to impairment level and peak THC concentrations in blood (C_{max}) were often less than common per se limits even with notable signs of impairment [18]. In addition, THC C_{max} and T_{max} (the Time to reach C_{max} after ingestion of THC containing substances) in blood vary drastically depending upon the route of administration. For example, averaged C_{max} in blood after Cannabis oral ingestion is much lower than that from inhalation, in part due to remarkably reduced THC bioavailability (6–18%) caused by drug degradation in stomach and first-pass metabolism in the liver. Averaged T_{max} in blood was reported less than 10 min after inhalation, while it was delayed to 1–2 h with cannabis-infused edibles [19]. The delay often created a false impression to the drug user that consumption of the edibles is safer and healthier. One particular danger associated with cannabis-infused edibles is that THC effects often long persist even after the THC concentration in blood drops to below the analysis limit of detection. This unique phenomenon makes the edibles induced impairment more challenging to predict and detect [19]. As a result, new biomarkers for marijuana exposure that can indicate impairment are

required, but development of practical technologies is unfortunately lacking.

4 | ANALYTICAL CHALLENGES IN TESTING FACILITIES

The proliferation of cannabis-infused edibles has a profound impact on both private cannabis testing facilities and public crime laboratories. One study published by Jikomes and Zoorob (2018) revealed that there was no standardized laboratory testing methodology in the legal cannabis industry in the State of Washington [20]. The authors discovered systematic differences in cannabinoid concentrations measured by various state-certified laboratories regulating these products. Difficulties in cannabinoid detection and confirmation in various matrices also challenge public laboratories. For example, the Texas Department of Safety crime laboratories attempted to develop a standardized analytical methods using a Drug Enforcement Administration (DEA) analytical scheme to differentiate hemp from marijuana by quantifying the THC concentration [21]. Although the method initially proved successful in plant materials, it later turned out to be not reliable for cannabis-infused edibles [21]. Many law enforcement agencies and public forensic laboratories are facing the similar issues and require more resources to develop and validate analytical methods and standards in order to provide better infrastructure for assessing laboratory quality.

5 | FDA REVIEW

The concerns associated with cannabis-infused edibles are important when these products get involved in interstate commerce. Under the Comprehensive Drug Abuse Prevention and Control Act, the Food and Drug Administration (FDA) currently still classifies marijuana as a Schedule I substance, due to its high potential for abuse [22]. In 2016 the FDA recommended that the drug be kept in the category of Schedule I substances, after an extensive review of published data on cannabis caused effects. Therefore, marijuana remains illegal at the federal level up to date [23]. Under Section 331 (II) of the Food Drug and Cosmetic Act, it is prohibited to introduce or deliver for introduction into interstate commerce “any food to which has been added a substance, which is an active ingredient in a drug product that has been approved under section 355 of the act, any drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public unless falling into one of four exceptions [24].” FDA-approved drug administration studies confirming substances as new drugs are used solely for diagnosis, mitigation, treatment, or prevention of disease, and intended to affect the structure or any function of the body. Drugs with accessible clinical reports, providing evidence for strict medical uses, are not to be included in food products easily accessible in interstate commerce [25]. Exceptions can be made if the drug is initially marketed as a food before it

gets approved as a drug or before substantial clinical investigations are conducted. However, there is no such evidence for THC [26]. Furthermore, it is prohibited to introduce any food product into interstate commerce where any THC is added due to the Federal Food Drug and Cosmetic Act of 1938.

The FDA also uncovered issues with cannabis products with misleading health claims. In February 2016, FDA warning letters were sent out to businesses that produced marketed products containing unapproved drugs [27]. These products claimed to be used for the diagnosis, treatment, or prevention of diseases that the FDA did not find compatible with their scientific findings. The FDA has not collected sufficient research data to conclude that certain cannabinoids are safe when infused with food. A study conducted at University of Pennsylvania found inconsistency in the labeling of cannabis-infused products in unregulated products and discovered that these products contain higher levels of THC than advertised [27]. Conclusions like these are alarming when consumption of cannabis-infused edibles continues to increase. The FDA is continuing to provide oversight for cannabis research and drug development in order to educate consumers of the potential negative health and safety outcomes of ingesting these edibles.

6 | ATTITUDES AND LAWS TOWARDS RECREATIONAL MARIJUANA

Although there have been noteworthy health concerns related to cannabis-infused edibles, attitudes towards cannabis have altered over the last a few decades. A study conducted by Pew Research Center showed that U.S. public opinion supporting the legalization of marijuana has kept growing from 1969–2019 [28]. Today, over two-thirds of Americans believe that marijuana should be legal [28]. At the same time, 59% of Americans surveyed believed that cannabis should be legal for medical and recreational use, while 32% of individuals believe cannabis should be for medical purposes only [28]. In a separate Marijuana Research Report by the National Institute on Drug Abuse (NIDA) showed an increase in cannabis use among adolescents, specifically middle and high schoolers. The report stated that 7.1% of 8th graders, 17.3% of 10th graders, and 30.5% of 12th graders surveyed used marijuana in 2021 [29]. With perceptions of cannabis use being more favorable, the use of cannabis-infused edibles is becoming more acceptable in modern culture.

As of June 18, 2022, 19 U.S. states established various requirements for recreational marijuana use from consumption to cultivation of cannabis (containing >0.3% THC by dry weight) for personal use [29]. Marijuana use is allowed for adults of 21 years old or older and must be done in private [30]. Except for Washington, cultivation of cannabis plant in residential areas is permitted with no more than 2 plants in Vermont but as many as 12 in Massachusetts, Michigan, and Nevada. In general, public possession of cannabis should not exceed 1 ounce per person [31]. However, not all states specify the requirement on cannabinoids concentrations, specifically, the concentration of THC. States generally regulated cannabis-infused

edibles to contain no more than 10 mg of THC per serving up to 10 servings per package (Table 1). In addition, states incorporate restrictions on product packaging so the products do no appeal to individuals under 21 years of age [31]. Table 1 shows regulation on cannabis-infused edibles in the states where recreational use is legal. The table contains pertinent variables from a survey conducted by the Network for Public Health Law addressing public health challenges associated with the edibles [31]. Full regulations on protecting children refers to producers creating child-detering packaging designs, child-resistant packing, and product designs that do not appeal to minors.

7 | A POSSIBLE APPROACH FOR REGULATION ON THE EDIBLES

In the opinion of the authors, the State of Maine has introduced a series of regulatory legislation regarding marijuana-infused edibles on the market. Edible marijuana products are prohibited to contain more than 10 mg THC per serving or more than 100mg THC per package. It is illegal to manufacture the products in the form of a human, animal, or fruit that would appeal to persons under the age of 21. Additives that are toxic, harmful, or designed to make the product more addictive are prohibited [32]. In addition, there are restrictions applied to the product packaging. Each package must contain a universal warning symbol stamped or described on each serving. Products are not allowed to be packaged or labeled in a way that causes confusion with a trademarked non-THC containing product. All cannabis-infused edibles must include ingredients, possible allergens, recommended use-by and/or expiration dates, a nutritional fact panel, and the license number of the cultivation facility, products manufacturer, and store, along with the batch number on the packaging. That same packaging must also include health and safety warning labels, as developed by regulators, which include THC potency and cannabinoid profile information, information on any gases, solvents, and chemicals used in extraction, and instructions on usage for safety purposes [33]. The packaging for these products must be opaque, child-resistant and tamper-evident, and have an integral measurement component [33]. These safety measures can prevent accidental consumption of THC-infused edibles.

The State of Maine also requires producers to submit their cannabis products to testing by law to ensure the purity of the product and correct labeling before being placed on the market [34]. The analytical testing of these products covers the product's THC potency, homogeneity, cannabinoid profiles, as well as residual harmful chemicals and microbes, especially solvents, pesticides, fungicides, toxins, and mold and mildew to address the safety of the product. The State of Maine requires all laboratories conducting analysis on cannabis-infused edibles must receive the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17,025: 2017 accreditation, and must implement a quality assurance program with proficiency testing conducted on all analysts before the CDC

TABLE 1 Requirements for recreational cannabis edibles in legal cannabis states [38–40]

State	Edible dosage restrictions	Must include warning label	Full restrictions to protect children	Producers fall under existing food safety regulations	Prohibitions on what products can be infused with Marijuana
Alaska	5 mg/serving 50 mg/Package	Yes	Yes	Yes	No
Arizona	None	No	No	No	Yes
California	10 mg/serving 100mg/package	No	Restrictions on Packaging and Design	No	Yes
Colorado	10 mg/serving 100mg/package	Yes	Yes	No	No
District of Columbia	None	Yes	Yes	No	Yes
Illinois	10 mg/serving 100mg/package	Yes	Restrictions on Packaging and Design	Yes	No
Maine	10 mg/serving 100mg/package	Yes	Yes	Yes	No
Massachusetts	5 mg/serving 100mg/package	Yes	Yes	Yes	No
Michigan	Laws Rescinded	Laws Rescinded	Laws Rescinded	Laws Rescinded	Laws Rescinded
Montana	None	Yes	Restrictions on Packaging and Design	No	No
Nevada	10 mg/serving 100mg/package	Yes	Yes	No	Yes
New Jersey	None	No	No	No	No
New Mexico	None	Yes	Yes	No	Yes
New York	None	Yes	Yes	Yes	No
Oregon	None	Yes	Yes	Yes	Yes
Rhode Island	None	Yes	Yes	Yes	Yes
Vermont	None	Yes	Restrictions on Packaging and Design	No	No
Virginia	5 mg/serving 50mg/package	Yes	Restrictions on Packaging and Design	Yes	No
Washington	10 mg/serving 100mg/package	Yes	Yes	Yes	Yes

issues a provisional certificate [34]. Once laboratories acquire the certification, they can implement either validated or nonstandard methods. The validated testing method must follow guidelines from the *FDA Bacterial Analytical Manual*, the *Association of Official Analytical Chemists (AOAC) International's Official Methods of Analysis for Contaminant Testing*, or *methods of analysis for contaminant testing published in the United States Pharmacopeia and the National Formulary* to perform analysis [35]. Nonstandard test methods for each matrix must follow either the *FDA Guidelines for the Validation for the Detection of Microbial Pathogens in Food and Feeds*, or the *FDA's Guidelines for Validation of Chemical Methods for the FDA FVM Program* [35]. Once an appropriate method is established, the facility must provide a certificate of analysis to the requestor and the CDC for every batch tested. Analysts must be trained and certified by the laboratory per the laboratory's SOPs prior to forming the duties [35].

In addition, Maine has created a 15-member Marijuana Advisory Commission composed of legislators, public health experts, representatives of the industry, members of the community and members of the state's major industries (Financial services, Agriculture, Conservation and Forestry, Labor, and Public Safety and Health and Human Services) to study marijuana laws and report annually to the legislature on its findings and recommendations [36]. The commission reviews adult-use and medical use of cannabis laws, especially in regards to criminal and civil offenses. The commission is also tasked with addressing cannabis regarding public health and safety, workplace drug testing and safety, motor vehicle safety, impact on landlords and tenants, personal use information, and the state financial implications. The group solicits comments from the public and submits recommended changes to the legislature. This is performed to safeguard public health and safety, to preserve voters' intent on cannabis legalization, and to standardize, coordinate, or integrate the adult-use and medical cannabis laws [37].

8 | CONCLUSION

As public support for federal legalization of marijuana continues to grow, it is necessary to ensure the welfare of the consumer. Although the FDA currently expresses concerns on safety of cannabis use, the federal government has empowered states to create their own legislation on this matter. Each state now has the responsibility to ensure marijuana-infused edibles do not jeopardize the safety of its residents. Regulatory controls that address safety concerns with drugs are important in modern culture. We believe that the State of Maine can be utilized as a model for other states to emulate in ensuring public health and safety.

DISCLAIMER

The opinions or assertions herein are those of the authors and do not necessarily reflect the views of the United States Army, Defense Health Agency, or Department of Defense.

CONFLICT OF INTEREST

None.

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