

Addendum

This document is added to the rulemaking record for DPH-17-010E. It supplements the Department's Finding of Emergency for Cannabis Manufacturing Licensing and further describes the necessity for certain provisions of the proposed emergency text.

I. Necessity for Specific Regulatory Sections

§40133. Limited Waiver of Sovereign Immunity

This section is intended to specify the rules required in order for sovereign entities, such as federally recognized tribes, to apply for and receive a license to manufacture cannabis. This is necessary to ensure that tribes or other qualifying sovereign entities can participate in the regulated cannabis cultivation in the same way as the general public. The Department is statutorily mandated to issue licenses only to qualified applicants and must be able to conduct reviews of all applications. Requiring sovereign entities to waive certain aspects of immunity will allow the Department to fulfill its mandate. Furthermore, the Department is tasked with ensuring the protection of public health through oversight of manufacturing operations. Without a waiver of immunity, the Department will be unable to properly oversee manufacturing operations located on sovereign lands, leaving those located on sovereign land unable to participate in the legal cannabis market. In order for sovereign entities to participate in the cannabis market, the Department is using its general rulemaking authority provided under Business and Professions Code section 26013 to require a limited waiver of immunity. The section is included based on inquiries from tribes within California expressing interest in participating in the cannabis marketplace.

The protection of the public is paramount for all licensing agencies pursuant to Business and Professions Code section 26011.5. Therefore, the regulation of activities related to manufactured cannabis products on sovereign lands is necessary to protect that paramount interest. Only a unified system of regulation protects the interests of the public purchasing cannabis products on tribal lands.

Proposed Section 40133 will provide for fair and efficient regulation in the cannabis industry, while allowing tribal governments the opportunity to participate in the legal regulated industry. The requirement that a new waiver accompany each license and renewal application will ensure that a valid waiver will be in place for the entire period of the license or renewal. The requirement for the applicant to demonstrate the waivers signatory has the authority to enter into such an agreement is necessary to ensure the waiver is valid and binds the applicant or licensee to the terms and conditions listed therein. This subsection is necessary to ensure the waiver is a valid executed contract entered into by the tribal government and the Department.

Proposed subsections (a)(2) –(a)(6) require the tribal sovereignty waiver to include language that clearly states all tribal entity applicants shall conduct all cannabis business activity in full compliance with all state laws and regulations, that the Department has access to all licensed areas, access to all records pertaining to commercial cannabis activity, and that all licensees may only sell product to other licensees and customers meeting the legal requirements to purchase cannabis goods. These subsections are necessary to ensure the Department has the ability to fully enforce all statutes and regulations related to the licensing of cannabis business activity and that all cannabis licensees are regulated with the same standards and expectations. Without this specific language it may be unclear which regulations would be applicable to a tribal government creating business and enforcement uncertainty.

Proposed subsection (7) clarifies the applicable body of substantive and procedural laws and which legal forum will be used to resolve disputes. Without this language in the waiver it is unclear which court or administrative tribunal is the appropriate forum for redress of claims, which could lead to confusion and delay. This language is necessary to clarify this complex intersection of state, federal, and sovereign immunity law and avoid conflict of legal jurisdiction and choice of forum for dispute resolution. It also clarifies the applicable law, legal claims and rights afforded the parties. This provision is necessary to ensure that all matters related to the license issued by the Department related to commercial cannabis activity in California will be governed by California law and litigated in California.

Proposed subsection (b) specifies that the Department will not approve an application for a state license if approval would violate the provisions of any local ordinance or regulation, which is a restatement of the law, under Business and Professions Code section 26055, subdivision (d), and is included to provide clarity.

Proposed subsection (c) requires the licensee to notify the Department when any material changes have been made to their business entity, their premises, or any other information supplied in their application. Without requiring a licensee to update the Department of material alterations of facts there is no assurance the changes are permitted within the statutory and regulatory framework. Without an affirmative duty placed on a licensee to notify the Department, a noncompliant change may go a significant amount of time before discovery. Placing an affirmative duty to notify ensures the Department is kept consistently aware of the shape, condition and legality of the licensee and licensed premises. This requirement is applicable to other licensees as well, therefore it is included here for clarity.

Proposed subsection (d) clearly states the consequences for statutory or regulatory non-compliance. This subsection is necessary to clarify non-compliance of any of these terms and conditions could lead to denial or discipline of a licensee. This subsection

also clarifies that all licensees, tribal governments and non-tribal governments, are governed by the same standards and disciplinary guidelines.

§40126. Temporary Licenses

This regulatory action establishes a system for temporary licenses. Temporary license authority is provided to the Department in Business and Professions Code section 26050.1, along with the basic requirements. Due to the time constraints created by SB 94 (which became law on June 27, 2017), the Department would be unable to meet its statutory mandate to issue licenses beginning January 1, 2018 if it needed to both promulgate complete regulations and review license applications before January 1, 2018. A temporary license process is thus necessary because it allows the Department to issue licenses on an accelerated schedule, minimizing disruption in the medicinal cannabis market and allowing the adult-use cannabis market to begin as intended by California voters.

§ 40182. Disaster Relief

This section allows the Department to waive certain regulatory licensing requirements during a disaster and is necessary to ensure that licensees who have been impacted by a disaster are not deemed to have surrendered, abandoned, or quit their licenses, due to the impacts of the disaster, if their intent is to continue as a licensee. Additionally, as the Act places public safety as the top priority for licensing authorities (Business and Professions Code section 26011.5), the provisions allowing a licensee to move product to a location different than the original location approved by the Department is critical to public safety to ensure that cannabis and cannabis products are secured and unable to be accessed by the general public. The Department has determined that 24 hours is sufficient time for the licensee to immediately secure cannabis or cannabis products while providing prompt notice of the change in location to the Department. Further, the Department has determined that 10 business days is the appropriate time to allow a licensee to provide the Department with a request for relief as it allows the licensee time to address the immediate effects of the disaster on the licensee's business while not allowing too much time to elapse before the Department can evaluate the proposed plan.

Proposed Section 40182 is necessary, in part to ensure that, pursuant to Business and Professions Code section 26013, subdivision (c), compliance with the regulations is not so onerous that the operation under a cannabis license is not worthy of being carried out in practice by a reasonably prudent businessperson. The Department has determined that in certain circumstances a licensee may be relieved from regulatory provisions. Additionally, Government Code section 8571 provides that during a state of emergency the Governor may suspend any regulatory statute, or statute prescribing the procedure for conduct of state business, or orders, rules, or regulations of any state

agency, where the Governor determines and declares that strict compliance with any statute, order, rule, or regulation would in any way prevent, hinder, or delay the mitigation of the effects of the emergency. This section would allow licensees that have been impacted by a disaster to be relieved from rules, orders and regulations that would otherwise delay mitigation of the effects of the disaster and the ability to keep cannabis and cannabis products secured to prevent diversion in the illegal market and prevent minors from accessing cannabis or cannabis products. This section is also necessary to ensure that licensees are provided an opportunity to exercise the privileges of their license, when otherwise prohibited from doing so by forces and circumstances beyond their control, that have made compliance with the regulations so onerous that the operation under their license is not worthy of being carried out in practice.

Subchapter 3, Article 1. Safety and Security

The Act places public safety as the top priority for the licensing authorities (Business and Professions Code, § 26011.5) and specifically requires applicants to submit a description of the applicant's security protocols (Business and Professions Code, § 26051.5(b)). The requirements of Section 40200 and Section 40205 are necessary to ensure this safety in the cannabis industry and are based upon similar requirements for other highly-regulated, cash-heavy industries, primarily alcohol manufacturing and distribution and gambling establishments.

Subchapter 3, Article 3. Good Manufacturing Practices

The Act requires the Department to develop sanitation standards for the manufacture of cannabis products that are similar to the standards for preparation, storage, handling, and sale of food products. Article 3 incorporates the requirements of the United States Food and Drug Administration (USFDA) for food, drug, and dietary supplement manufacturing specified in the Code of Federal Regulations (21 C.F.R. §§111, 117, and 210-211). The Act places public safety as the top priority for the licensing authorities (Business and Professions Code, § 26011.5) and requires edible products to be manufactured under standards that are similar to standards for preparation of food (Business and Professions Code, §26130(c)(5)).

The Department is requiring the establishment of Good Manufacturing Practices (GMPs) because such standards are necessary to ensure the protection of the public in accordance with the safety priority mandated to the Department by statute for activities related to and associated with the manufacturing of cannabis. Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates, which may be subsequently used to produce edible cannabis products. While the Act specifically defines cannabis products as neither a food nor a drug, edible cannabis products are typically made with conventional food products infused with cannabinoids that are intended to be consumed by members of the public. Except for the cannabis or

cannabinoid component, edible cannabis products are made of the same ingredients as other regulated food products, are produced using the same manufacturing processes as regulated food products, and are consumed and taken into the body for a physiological purpose, in the same manner as regulated food, drug, and (most similarly) dietary supplement products. Thus, many of the public health risks associated with unsafe food, drugs, and dietary supplement products also exist with cannabis products.

GMPs for food and dietary supplements are general minimum standards and practices necessary to produce safe and clean food and dietary supplements products. These are *minimum* standards and practices because they are intended to apply to all food and dietary supplement manufacturing activities. These are *general* standards and practices because they are intended to allow individual variation by manufacturers to implement the requirements in a manner that best suit their needs. The establishment of general and minimal requirements stems from issues that arose during development of GMPs by the USFDA; that specific and comprehensive regulations might be especially burdensome for small companies without necessarily improving product safety, and that specific conditions to ensure sanitary conditions can be different for each manufacturer. As a result, the use of general terms such as “adequate”, “sufficient,” and “suitable” are used in the GMPs to allow manufacturers flexibility to comply with these requirements in an effective manner. (Dunkelberger, Edward. 1995. The statutory basis for the FDA's food safety assurance programs: From GMP, to emergency permit control, to HACCP. Food and Drug Law Journal 50. 357-383.).

The standards and practices established by the GMPs set forth in this regulatory provision are further necessary because often consumers cannot detect through smell, touch, or sight that a manufactured product is contaminated and unsafe to use. Additionally, testing alone is not sufficient to ensure product safety. While a product may pass all required tests, that product may still contain microbial, chemical, physical or allergen contaminants if manufactured or packaged under unsanitary or disorderly conditions. This is because only a representative sample of each product is tested. Instead of relying only on testing or evidence of harm to public health to identify adulterated products, the GMPs established in this provision are necessary and intended to ensure that product safety and quality is built into the manufacturing process at every step. The GMPs allow identification of products that may be adulterated based on the standards and practices established and implemented by a manufacturer for that product, before it is released for public sale or use. Identification of adulterated products before release to the public also has a significant impact on increasing product safety and protecting public health from the harms of using or consuming adulterated products.

The GMPs in this regulatory proposal also provide general minimum standards and practices to guide the development of specific Standard Operating Procedures (SOPs) by manufacturers. The establishment of SOPs at manufacturing facilities is necessary to ensure the safety and cleanliness of all products manufactured. Under the proposed regulations, the Department requires manufacturers to develop SOPs in accordance with GMPs, but has not prescribed specific or uniform SOPs for manufacturers because, like the USFDA, the Department has found that specific, comprehensive regulations might be burdensome for smaller manufacturing operations without necessarily improving their product safety, and because specific requirements for ensuring sanitary conditions may vary for each manufacturer. Under the proposed regulations, manufacturers must, instead, identify their specific SOPs on a case-by-case basis (see section 40256 of these regulations on Hazard Analysis). This is necessary to provide a means for verification of regulatory compliance without unduly burdening manufacturers, to ensure inclusion of GMP-based SOP information in manufacturer training programs, and to provide documentation for corrective and inspection purposes. Rather than prescribing specific measures, the use of general terms such as “adequate,” “sufficient,” and “suitable” (used in USFDA GMPs) are used in the Department’s GMPs in order to allow manufacturers the flexibility to develop their SOPs in the manner most applicable to their given operation.¹

Subchapter 3, Article 4. Production and Process Controls

As previously mentioned, the Act requires the Department to develop sanitation standards for the manufacture of cannabis products that are similar to the standards for preparation, storage, handling, and sale of regulated food products. Article 4 incorporates requirements of the United States Food and Drug Administration (USFDA) for food, drug, and dietary supplement manufacturing specified in the Code of Federal Regulations (21 C.F.R. §§111, 117, and 210-211).

This section is necessary to establish production and process control measures that cover all stages of manufacturing (such as processing, packaging, labeling, and holding) a cannabis product. This provision is necessary to ensure product safety, quality, and that the product conforms to all specifications. This Article is distinct from Article 3 (Good Manufacturing Practices (GMPs)) in that GMPs are general and minimum requirements for producing a clean and safe product, while this article specifically clarifies the safety and quality-related requirements that manufacturers must meet at each step of their specific manufacturing activities. As described in Article 3, given the similarities between food/dietary supplements and manufactured cannabis products in their use, manufacturing, and associated risks, it is reasonable to assume

¹ Dunkelberger, *The Statutory Basis for the FDA’s Food Safety Assurance Programs: From GMP, to Emergency Permit Control, to HACCP* (1995) 50 Food & Drug L.J. 357.

that the production and process controls established in regulation by the USFDA (21 C.F.R. §117 (C) and 111 (H),(I),(O)) to ensure production of safe food and dietary supplements is also necessary to ensure production of safe quality cannabis products. GMPs and production and process controls are complementary concepts and are intended to work in conjunction with one another to capture all safety and quality issues that may occur at a manufacturing facility.

Each manufacturer has processes and materials that are specific to the product being made, therefore, the potential or reasonably foreseeable hazard that applies to each process and material is unique and must be evaluated by the manufacturer, who has access to necessary information about its own product. The “control measures” mentioned in this article refer to activities that are undertaken to ensure that products are kept in a safe and unadulterated state throughout all steps of manufacturing; the absence of control measures increase the risk of producing an unsafe food that may cause illness or death in consumers. Control measures are therefore necessary to prevent the occurrence of contamination events and the manufacture and release of a product that is injurious or fatal. The requirements detailed in these regulations are also necessary and intended to provide oversight of processes and materials that are unsafe (ideally before products are released to the public) and mirror the purpose of the USFDA Food Safety and Modernization Act, namely: to *prevent* (food) safety problems from arising as early as possible during production, rather than simply reacting to such problems after they are discovered post-production. As discussed in Article 3, above, oversight of food or, in this case, food product-related safety activities is particularly necessary and important because consumers often cannot detect that products are unsafe, and testing alone is inadequate to identify all products that may be adulterated. According to the Centers for Disease Control, 1 in 6 Americans become sick from contaminated food and beverages, and 3,000 die each year from such adulterated products (<https://www.cdc.gov/foodsafety/cdc-and-food-safety.html>).

From the ingredients, to processing, to the packaging of a manufactured product, if safety and quality measures are built into each step of the manufacturing process, the chances of introducing a hazard or allowing a hazard to develop is prevented, ensuring that the finished product available to the public is safe. These regulations are therefore necessary to ensure, to the extent possible, that such safety occurs at each of these steps in the production process.

Subchapter 3, Article 5. Special Processing Requirements

Section 40270 establishes the processing requirements for juice-related cannabis products. The USFDA, in 21 CFR §120, requires additional hazard analyses and control plans, known as the juice hazard analysis and critical control points (HAACP), to be developed for manufacturers of juice products. This regulation is therefore necessary to establish similar requirements for manufacturers of cannabis-infused juice. The critical element of a juice HAACP is a 5-log reduction of pathogens. Numerous types of microorganisms can be found on fresh fruits and vegetables, including yeasts, molds, *Pseudomonas*, *Erwinia*, *Salmonella* spp., *Shigella* spp, *Y. enterocolitica*, *E. coli* O157:H7, *L. monocytogenes*, *C. botulinum*, and *B. cereus*. Fruits and vegetables, including juices that are not subjected to a type of processing that can destroy the microorganisms (such as pasteurization), can pose a significant threat to human health, especially for immunocompromised individuals.

Section 40272 is necessary to require manufacturers of dried-meat products (i.e., beef jerky) to manufacture those products in accordance with United States Department of Agriculture requirements for jerky production. Those requirements are incorporated by reference into the Department's regulations. USDA requirements provide the manner in which jerky products can be safely manufactured in order to be shelf-stable and prevent microbial contamination.

§40290. Waste Management

There are two concerns associated with the disposal of cannabis or cannabis waste. First, the Department wants to ensure that cannabis or cannabis products that are contaminated or adulterated in some way will not further contaminate other products or areas of the manufacturing operation. Second, cannabis or cannabis waste that is recognizable as such can provide opportunities for diversion to the illicit market. The requirements established in these regulations are necessary to ensure that cannabis waste is properly handled and not diverted.

The protection of the public is paramount for all licensing agencies pursuant to Business and Professions Code section 26011.5. The disposal of cannabis waste must be regulated more than the other manufacturing business in California to prevent the above noted concerns regarding this waste and against possible diversion. The Department received comments during the public comment period for the proposed and now withdrawn medical cannabis regulations, regarding waste disposal requirements in the state. The licensing authorities worked with Cal Recycle on the development of this language.

§40300. Prohibited Products

This section is necessary to prohibit the manufacture of cannabis products that pose a higher than usual risk to public health. Specifically:

(a) Alcoholic beverages - The concurrent consumption of alcohol and cannabis has been shown to result in increased peak concentration of cannabinoids in the blood and plasma of human subjects.² This concurrent consumption has the potential of altering the effect of the intended dosage of medical cannabis products as well as increasing the level of physiological and psychological impairment of medical cannabis users, in addition to the well-documented adverse health effects from the use of alcohol alone. This restriction is therefore necessary to protect the health of the consumer.

(b) Any product containing any non-cannabinoid additive that would increase potency, toxicity, or addictive potential. There is currently very limited scientific data available on the full health effects of cannabis use at various doses and frequency. It is not possible, therefore, to know with any certainty the universe of potentially dangerous or damaging physiological and/or psychological effects that may occur with concurrent use of cannabis and other physiologically and/or psychologically active substances. The concern with introduction of these particular additives into cannabis products includes the inherent effects of these additives, which in combination with cannabis, may produce additive, unpredictable, and possibly harmful effects to a cannabis consumer's psychological and/or physical well-being.

This subsection further specifies that prohibited additives include nicotine and caffeine. The recommendation that caffeine not be allowed as an additive comes from the FDA determination that caffeine (a stimulant) in certain alcoholic (a depressant) beverages is an "unsafe food additive" due to the unpredictable negative effects of the two substances.

(c) Any perishable cannabis product that must be held at or below 41 degrees Fahrenheit – any perishable product not held at or below 41 degrees can support the growth of infectious or toxigenic microorganisms. Perishable products improperly held can present a serious threat to public health.

(d) A low-acid product meeting specified criteria - The pathogen *Clostridium botulinum*, which causes botulism, is a common microorganism in the environment. When held in anaerobic conditions, such as those created by vacuum packing or canning, the microorganism can proliferate, creating a potent neurotoxin. The spores are heat-resistant and can survive in foods that are incorrectly or minimally processed. Almost any type of food that is not very acidic

² Meier, A review of the additive health risk of cannabis and tobacco co-use (Sept. 1, 2016). 166 Drug Alcohol Depend. pages 6-12.

(pH above 4.6) can support the growth of the microorganism.³ Botulism has a high mortality rate and is especially concerning for immunocompromised individuals. It is therefore necessary to prohibit the manufacture of canned or low-acid, vacuum packed products because of the potential public health threat.

(e) Juice, unless the juice is shelf-stable or processed in a manner to reduce pathogens - Numerous types of microorganisms can be found on fresh fruits and vegetables, including yeasts, molds, *Pseudomonas*, *Erwinia*, *Salmonella* spp., *Shigella* spp, *Y. enterocolitica*, *E. coli* O157:H7, *L. monocytogenes*, *C. botulinum*, and *B. cereus*. Fruits and vegetables, including juices, that are not subjected to a type of processing that can destroy the microorganisms (such as pasteurization), can pose a significant threat to human health, especially for immunocompromised individuals.

(f) Dairy products – Business and Professions Code section 26001(t) prohibits infused dairy products.

(g) Meat, other than dried meat products - Meat offers a rich environment for microbial growth. In order to be processed safely, very careful handling and processing is required. In addition to HACCP controls, meat must be handled in accordance with specific guidelines issued by the United States Department of Agriculture. Due to the high potential for contamination and corresponding risk to public health, meat products are considered potentially hazardous.

(h) Seafood - Seafood is more perishable than other high-protein products due to the high level of soluble nitrogen compounds in the tissue. Because of the potential public health threat, seafood-related cannabis products of any kind are prohibited.

(i) Any product manufactured by applying cannabinoids to commercially available candy or snack food – this provision is intended to reduce potential confusion to the public, both adults and children. A product that may appear to be a non-infused, commercially-available food could be unintentionally consumed. Business and Professions Code section 26130(b)(5) prohibits edible products that the Department determines could be easily confused with non-cannabis candy and food.

(j) Products attractive to children – Business and Professions Code section 26130(b)(5) prohibits edible products from being attractive to children.

³ USFDA, Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).

(k) Products easily confused with commercially available food - Business and Professions Code section 26130(b)(5) prohibits edible products that could be easily confused with non-cannabis candy and food. This provision is intended to reduce potential confusion for consumers and reduce the possibility of unintentional consumption.

(l) Products in the shape of humans, animals, insects, or fruit – this restriction is based on a similar restriction in Oregon. It is intended to reduce a product's appeal to children. Many products geared toward children, such as gummy candies and fruit snacks, are in these shapes.

§ 40305. Requirements for Edible Products; and § 40306, Requirements for Other Cannabis Products

These two sections are necessary to provide limits on the amount of THC that a cannabis product may contain. The Act limits the THC for edible products to 10 mg per serving. Of primary concern with edible cannabis products is: 1) the potential, because of their resemblance to other food products, for accidental ingestion by children; and 2) over consumption by novice consumers unaware of the delay in effect of ingestion. Other delivery options with higher THC concentrations, that are less attractive to minors, are available to consumers desiring the effects of that higher THC concentration. Limiting the THC concentration for an edible cannabis product is therefore necessary to protect children and reduces the risk of accidental overdose and injury while balancing consumer needs.

The Department conducted a survey of neighboring states with legalized cannabis (Washington, Oregon, Nevada, and Colorado) to ascertain the rationale behind setting THC concentration limits. A common theme across all states in the survey was concern to limit or prevent attractiveness to minors, accidental ingestion by children, and overconsumption by novice consumers. For the adult-use market, Oregon limits THC content to 5 mg per serving and 50 mg per package. Washington, Nevada, and Colorado limit THC content to 10 mg per serving and 100 mg per package. Oregon, Washington, and Colorado also limit edibles in the medicinal market to 100 mg THC per package.

Subchapter 6, Article 2. Track and Trace

The protection of the public is paramount for all licensing agencies pursuant to Business and Professions Code section 26011.5. Further, the status of federal law makes the protection of the illegal diversion of California manufactured products of primary importance. Business and Professions Codes sections 26067 – 26069.9 are therefore necessary to set forth the track and trace requirements. The California Department of Food and Agriculture has selected the vendor that will implement the

California Track and Trace System. The track and trace system must be able to be consistent and functional throughout the entire chain of the cannabis supply to avoid diversion (sending legally grown or manufactured cannabis to the illegal market) or inversion (bringing illegally grown or manufactured cannabis into the legal market for sale) of cannabis.

Subchapter 7. Transitional Period

Because of the long-standing existence of the medical cannabis marketplace, there are numerous existing businesses with cannabis product inventory on-hand. Subchapter 7 is necessary so that these businesses can transition into the regulated marketplace. Without a transition period to address current inventory, products may be diverted into the illicit market.

The current inventory of medical cannabis businesses will be addressed by the allowed use of temporary stickers/labels, or exit packaging--but all new manufactured products on or after January 1, 2018, will be required to comply with all statutory and regulatory labelling and packaging requirements.

II. Necessity for General Regulatory Concepts

A. Fees

The Act mandates that each licensing agency charge a licensure and a renewal fee calculated to cover the agency's costs for administering the law. It further requires that license fees be set on a scaled basis dependent on the size of the business.

These regulations are necessary to enable the Department to cover its cost associated with implementing the Act and therefore is proposing two separate fees: (1) an application fee to be submitted with a new license application to cover the Department's costs for reviewing and processing the application; and (2) an annual license fee to cover the Department's costs of program administration, and the manufacturing industry's share of the track-and-trace system.

Based on information provided by the Humboldt Institute for Interdisciplinary Marijuana Research (HIIMR), an economic team based at California State University, Humboldt, and contracted by the Department to conduct research and economic analyses for this regulatory package, the analysis conducted estimates that CDPH will issue about 3,000 licenses.

Using information from various licensing programs within the Department, the Department created a fee model that would cover the administrative, licensing and scientific requirements of the program.

Application Fees

Application reviews will be conducted by a licensing unit that has both administrative and scientific staff. Staff will review the application for completeness and mandated regulatory requirements to ensure that public health safety requirements are met. Application fees will be nonrefundable. These application fees are necessary because the Department's cost for processing and reviewing the application is a tangible cost regardless of the outcome of the application. The number of FTEs (Full-Time Equivalent employees) was determined by calculating the number of hours it would take to complete a task (processing hours) multiplied by the number of licenses (3,000) divided by 1,800 (the hours equivalent of one FTE annually). To arrive at the \$1,000 application fee, the total cost was derived by multiplying the annual classification salary by the FTEs needed to complete the task annually, divided by 1,800.

Annual Fees

The annual license fee is also necessary and determined by accounting for the cost of administering the manufactured cannabis safety program based on the mandates of the Act. These costs to administer the manufactured cannabis safety program are solely provided by license fees and include, but are not limited to: program staff, Department administrative staff, IT system for licensing, the Track and Trace licensing system fees, and Track and Trace Unique Identifier tags. The Act requires that all license fees be set on a scaled basis by the licensing authority, dependent on the size of the business. Size in this model references the total annual revenue. The tiers are based on revenue as a result of industry feedback from focus groups that were conducted in 2016 throughout the State.

The license tiers were developed by the Humboldt Institute for Interdisciplinary Marijuana Research (HIIMR), an economic team based at California State University, Humboldt, and contracted by the Department to conduct research and develop the economic impact analyses for this regulatory package. The tiers are based on estimated market share from a survey of manufacturers.

Change in licensed operations

At any time after issuance of a license and prior to submission of an application to renew the license, a licensee may request to change the manufacturing operations conducted at the licensed premises. To request approval for additional manufacturing operations, the licensee must submit the same documentation as that required for an initial application. The same team of analysts and scientist that conduct the review for an initial annual license application; will conduct the review for the change in licensed information thus the fee of \$1,000 is the same as an application fee. This regulation is necessary to cover the additional costs imposed by these changed operations applications.

Late fee

\$500 will be applied to a renewal application that is not submitted by the expiration date of the current license. The imposition of a late fee is necessary to provide deterrence from untimely submission of renewal applications, which impedes the Department's processing of applications.

B. Timelines

- § 40129(b) – a local jurisdiction has 10 calendar days to respond to a request to confirm the validity of a local authorization for a temporary license. Temporary licenses are necessary in order for the Department to meet its statutory deadline to begin issuing licenses as of January 1, 2018. A longer delay (beyond 10 calendar days) in the response by a local jurisdiction to the Department will impede that mandate. Due to the potential volume of applications and the time of year in which the requests will be made, the Department wanted to allow a reasonable amount of time for local jurisdictions to respond without also causing an undue delay in the processing of applications.
- § 40135(b) – applications that remain incomplete 180 days after the request for information is sent to the applicant shall be deemed abandoned. Six months is a reasonable amount of time to allow applicants to collect any needed information and respond to the Department. This regulation is necessary to ensure that the Department's time is spent on processing active applications.
- §40155(b) – the applicant shall pay the applicable license fee within 30 calendar days of notification of application approval. Many cannabis businesses primarily use cash. This regulation is necessary because a business may need some time to collect the required amount of cash and transport it to a cash collection location.
- § 40167(c) – an applicant must request an appeal hearing within 30 days or the right to appeal is waived. This is a statutory requirement.
- § 40169(a) – a licensee shall notify the Department of any criminal conviction within 48 hours of the conviction. This requirement was developed in conjunction with the Bureau of Cannabis Control and is a standard timeframe imposed upon other licensees of the Department of Consumer Affairs and is necessary to ensure that individuals with criminal convictions are brought to the attention of the licensing authorities.
- § 40177(d) – licensees shall notify the Department within 10 days of the cessation of any licensed activity. The Department needs to ensure that its records are kept up-to-date. Licensees can notify the Department by any means, including email, phone call, or letter; 10 days is a reasonable amount of time in which to require notification.

- § 40178 – licensees shall notify the Department within 10 days of the addition or deletion of an owner. The Department is statutorily mandated to approve the owners of a licensed cannabis manufacturing business. Ten days is a reasonable amount of time to allow for a licensee to provide notice of a change in ownership.
- § 40180 – a renewal application shall be submitted at least 30 days in advance of the license expiration, but not more than 60 days in advance. The Department needs time to complete its review of the renewal application. A 30-day window should be sufficient to review the application. The Department also needs the most up-to-date information on the licensee and manufacturing operation, thus the restriction on submitting the application too far in advance.

C. Miscellaneous

- § 40129(a)(10) – proof of having obtained a surety bond in the amount of \$5,000. Business and Professions Code 26051.5(a)(10) requires applicants to provide proof of a bond to cover the costs of destruction of cannabis or cannabis products if necessitated by a violation of licensing requirements. Discussions with other states indicated that cannabis businesses had difficulty obtaining surety bonds, and that if the requirement was set any higher than \$5,000, businesses would not be able to comply.
- § 26130(c)(5) – requires the Department to consult with the Bureau of Cannabis Control in development of sanitation standards for edible products. The Department met extensively with both the Bureau of Cannabis Control and the California Department of Food and Agriculture in the development of these regulations.

Incorporation by Reference:

The incorporation by reference of requirements published by the United States Food and Drug Administration, the United States Department of Agriculture, and the United States Consumer Product Safety Commission in Sections 40252, 40270, 40272, 40306, and 40415 is appropriate as publishing these documents in the California Code of Regulations would be cumbersome, impractical, and unnecessary. The documents consist of numerous pages of text. The documents are easily available to the public, will be made available on the Department's website, and will be provided to anyone upon request to the Department.

The incorporation by reference in Section 40126 of Form CDPH-9041 (Rev. 10/17) is appropriate for ease of use to the regulated industry. The form is designed so that individuals can complete it electronically, then mail or email it to the Department. It is unnecessary to duplicate the information in the text of the regulation itself, as adopting the form by reference will provide clarity and ease of use.

The following documents are incorporated by reference in the proposed regulation text:

1. Form CDPH-9041 (Rev. 10/17)
2. United States Food and Drug Administration (USFDA), Defect Levels Handbook: The Food Defect Action Levels, revised February 2005.

<https://www.fda.gov/RegulatoryInformation/Guidances/ucm056174.htm#CHPTA>

3. USFDA, 21 Code of Federal Regulations, Part 120, subpart B, revised January 2001

<https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/Juice/JuiceHACCPRegulations.pdf>

4. United States Department of Agriculture (USDA), FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments: 2014 Compliance Guideline

<https://www.fsis.usda.gov/wps/wcm/connect/5fd4a01d-a381-4134-8b91-99617e56a90a/Compliance-Guideline-Jerky-2014.pdf?MOD=AJPERES>

5. USFDA, 21 Code of Federal Regulations, Part 700, subpart B, revised March 2016.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=700&showFR=1&subpartNode=21:7.0.1.2.10.2>

6. United States Consumer Product Safety Commission, Title 16 Code of Federal Regulations, section 1700.1(b)(4)

<https://www.gpo.gov/fdsys/pkg/CFR-2005-title16-vol2/pdf/CFR-2005-title16-vol2-sec1700-1.pdf>

Non-Duplication

These proposed regulations include many of the statutory provisions imposed by the Act. Such provisions are duplicated in these proposed regulations in order to provide clarity and ease of understanding to the reader, and to provide a single location in which members of the public and the regulated industry can find applicable requirements.

These proposed regulations should not be considered duplicative of federal law, even in instances where federal law has been incorporated by reference. Due to the nature of cannabis products, specifically that they are considered by statute neither a food nor a drug, existing federal rules are not applicable to cannabis products. Specific inclusion of the federal rules in the Department's regulations is necessary for the Department to hold cannabis product manufacturers responsible for the same health and safety precautions as manufacturers of food and drug products.