

## INITIAL STATEMENT OF REASONS

### **SUMMARY OF PROPOSAL**

These proposed regulations serve to implement the California Department of Public Health's (Department) responsibilities under the Medical Cannabis Regulation and Safety Act (Act).

The proposed regulations will:

1. Establish the licensing scheme for manufacturers of medical cannabis products;
2. Set minimum standards for sanitary manufacturing practices; and
3. Establish packaging and labeling standards for manufactured cannabis products.

### **BACKGROUND**

The Department is one of several state agencies with regulatory authority under the Act. Primary responsibilities for administration and enforcement of the Act are divided between:

- **California Department of Food and Agriculture (CDFA)**, which will create, issue, and suspend or revoke licenses for the *cultivation* of medical cannabis;
- **Bureau of Medical Cannabis Regulation (Bureau)** in the Department of Consumer Affairs, which will administer, enforce, create, issue, renew, discipline, suspend, and/or revoke licenses for the transportation, storage unrelated to manufacturing activities, and sale of medical marijuana within the state. The Bureau will issue licenses to *distributors, transporters, testing laboratories, and dispensaries*; and
- **California Department of Public Health**, which will license cannabis *product manufacturers*. The Department is also required to develop standards for the production and labeling of all medical cannabis products.

The Department worked closely with the Bureau and CDFA during the regulation development process to ensure consistency when appropriate.

#### *Legislative History of Cannabis Regulation*

In 1996, voters approved the Compassionate Use Act (CUA), which allows patients and primary caregivers to obtain and use medical marijuana, as recommended by a physician, and prohibits physicians from being punished or denied any right or privilege for making a medical marijuana recommendation to a patient. In 2003, Chapter 875, Statutes of 2003 (Senate Bill (SB) 420) established the Medical Marijuana Program (MMP), which allows patients and primary caregivers to collectively and cooperatively cultivate medical marijuana. It also established a medical marijuana card program for patients to use on a voluntary basis.

Passed in 2015, Assembly Bill (AB) 266 established the Medical Marijuana Regulation and Safety Act (MMRSA) for the licensure and regulation of medical marijuana. The

primary portion of the Act is contained in the California Business and Professions Code, sections 19300-19360. Also passed in 2015, AB 243 and SB 643, in conjunction with AB 266, established the regulatory framework to regulate the cultivation, sale, testing, manufacturing and transportation of medical cannabis in California. In 2016, several provisions of the MMRSA were amended through SB 837, including a renaming of the law to the Act.

Prior to the enactment of the Act, California had no regulatory oversight of medical cannabis at the state level. Some local jurisdictions regulated cannabis cultivation or dispensaries.

In November 2016, voters passed Proposition 64, the Adult Use of Marijuana Act (AUMA). The AUMA legalized the use of marijuana in California for non-medical purposes for adults aged 21 and over. The provisions of the AUMA are similar to those of the Act, but not identical. Additionally, the two laws are contained in different divisions of the Business and Professions Code. Consequently, the Department will be developing separate regulatory packages to implement the two separate laws. This package implements the requirements for medical cannabis oversight as mandated by the Act.

The Act establishes protection of the public as the primary concern of regulatory agencies.<sup>1</sup> The Department considers public health and safety a critical element of protecting the public and developed this proposal to protect public health and safety through the establishment of the following:

- Safety requirements for extraction processes, especially volatile solvent extractions, to minimize potential negative effects;
- Security requirements to protect the physical safety of employees and to minimize the potential for diversion of cannabis or cannabis products;
- Standard operating procedures to protect the integrity of the cannabis product throughout the manufacturing process by preventing contamination; and
- Requirements to ensure uniform distribution of cannabinoids.

### Key Policy Elements of the Proposed Action

#### *The Cole Memo*

Although several states have now legalized the use of cannabis either for medicinal purposes or for adult use, marijuana remains illegal under the federal Controlled Substances Act. The United States Department of Justice (USDOJ) is the federal agency responsible for enforcing the Controlled Substances Act. In 2013, the Office of the Deputy Attorney General, under the signature of James M. Cole, issued a memorandum to federal prosecutors providing guidance regarding the enforcement of the Controlled Substances Act in states that have legalized the use of marijuana. Known colloquially as “the Cole Memo,” the document set forth the main objectives of the USDOJ in terms of enforcing federal marijuana law, including using its limited

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<sup>1</sup> Business and Professions Code section 19303.

resources in an effective way. The memo notes that, although nothing in the memo precludes federal investigations or prosecution if such actions serve federal interests, states that implement and enforce a robust regulatory scheme to control the cultivation, distribution, sale, and possession of marijuana are less likely to pose a threat to federal interests. The federal interests prioritized in the Cole Memo are:

- Preventing distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises;
- Preventing diversion to other states;
- Preventing state-authorized marijuana activity from being used as a cover for other illegal activities;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other public health consequences associated with marijuana use;
- Preventing the growth of marijuana on public lands; and
- Preventing marijuana possession or use on federal property.

The Department considered this list of federal priorities when developing its regulatory package. Although the Cole Memo is nonbinding and can be rescinded in the future, the priorities included within it align with the priorities of the Department and the Act. The Department has determined to use the above-mentioned priorities as a reasonable standard upon which to base the proposed regulations.

#### *Product Safety & Consumer Protection*

The Act specifically defines cannabis products as neither a food nor a drug. Consequently, existing requirements applicable to the manufacturing of food and drug products (US Food and Drug Administration [USFDA] regulations, 21 Code of Federal Regulations [C.F.R.] Part 111 and Part 117) are not applicable to cannabis products. However, because many cannabis products are intended to be consumed, the need to ensure the safety and integrity of the manufacturing process is still present. Using its experience with oversight of food and drug manufacturing, the Department developed these regulations to include substantively similar requirements to ensure sanitary manufacturing practices.

The USFDA regulates the production of food, drugs, and dietary supplements within the United States through good manufacturing practices (GMPs) specified in federal regulation (21 C.F.R. §§117 and 210-211). Food and drug industries outside the United States are similarly required to adhere to the USFDA's GMPs in order to import products into the United States, and numerous other countries also require the use of GMPs during food and drug manufacturing. Practices to protect the safety of final products through sanitary manufacturing procedures are a commonly accepted and used concept. Therefore, given the similarities in the use, manufacturing, and risks associated between food/drugs/dietary supplements and edible cannabis products, it is reasonable that the GMPs necessary to ensure production of safe food and dietary supplements are also necessary to ensure production of safe cannabis products.

Establishing GMPs in this regulation helps the Department to protect the public and to carry out the intent of Business and Professions Code sections 19302.1(f), 19303, and 19347.6. From microbial contamination by employees or the environment, to incorporation of foreign elements such as glass, hair, or insects, to contamination of a product with an unintended allergen, the manufacturing process provides numerous opportunities for hazards to be introduced into a cannabis product. The Department is aware that many consumers of medical cannabis products are immunocompromised and therefore especially vulnerable to many potential contamination hazards. The minimum facility requirements and the standard operating procedures for sanitary manufacturing practices established by this proposal are intended to reduce or eliminate potential contamination.

These proposed regulations also limit the products that are allowed to be infused with cannabis. Certain types of manufactured products are more susceptible to microbial contamination. For example: some products need to be held at certain temperatures or in certain conditions in order to prevent the growth of bacteria, while other products may provide an ideal growing medium for bacteria under normal conditions of handling and storage (such as botulism contamination which can occur in canned products).

#### *Regulated Market and Prevention of Diversion*

In addition to product safety, a key goal of the proposed regulations is to minimize the diversion of cannabis from the regulated market to the underground market. Through the Compassionate Use Act (CUA), California has had a thriving quasi-, underground market for many years. The Act, and subsequently the Adult Use of Marijuana Act, has the policy goal of establishing solid regulatory oversight in a legal marketplace. However, the Department is well aware that the underground market has not been eliminated in California and is still flourishing outside of the state. The Department, therefore, approached the drafting of these regulations with the intent of creating a strong foundation for the protection of public health and safety, without making regulatory compliance so onerous that manufacturers of medical cannabis products would choose to remain in the underground market.

#### *License 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.<sup>2</sup> It further requires that license fees be set on a scaled basis dependent on the size of the business.<sup>3</sup>

The Department 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 costs of program administration, pay the manufacturing industry's share of the track-and-trace database,<sup>4</sup>

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<sup>2</sup> Business and Professions Code section 19350, subdivision (a).

<sup>3</sup> Business and Professions Code section 19350, subdivision (c).

<sup>4</sup> Required by Business and Professions Code section 19350, subdivision (c).

and repay the General Fund loan to the Department for program startup costs.

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 Department estimates that about it will issue approximately 1,000 medical cannabis manufacturing licensees.

Further discussion of the fees to be established by these regulations is included below in the Department's detailed discussion of section 40150.

## **DETAILED DISCUSSION OF EACH REGULATION**

### **Add Subchapter 1: General Provisions and Definitions**

Add Article 1. Definitions to include Section 40100. Section 40100 provides definitions for the terms used throughout the text. The adoption of these definitions is reasonably necessary to provide for uniform interpretation of the text, consistency in the terminology used in the proposed regulations, and to provide clarity to the regulated public in order to effectuate the purposes of the enabling statute.

Throughout this provision, the Department has relied upon definitions based on or substantively similar to those used by the USFDA in their regulation of manufacturing processes for food and drug products. This is reasonably necessary because the intention of this regulation is to ensure protection of the public in accordance with the priority mandated to the Department by statute<sup>5</sup> for activities related to and associated with the manufacturing of medical cannabis. Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates, which may be subsequently used to produce edible cannabis products (Bus. & Prof. Code §19300.5, subd. (ac)). While the Act specifically defines cannabis products as neither a food nor a drug, edible cannabis products are typically made of conventional food products infused with cannabinoids and are intended to be consumed by members of the public. Excepting the cannabis or cannabinoid component, edible cannabis products are made of the same ingredients as food products, are produced using the same manufacturing processes as food products, and are consumed and taken into the body for a physiological purpose, in the same manner as food, drug, and, most similarly, to dietary supplement products. Thus, many of the public health risks associated with unsafe food, drugs, and dietary supplement products also apply to cannabis products.

The USFDA regulates the production of food, drugs, and dietary supplements within the United States through GMPs specified in federal regulation (21 C.F.R. §§117 and 210-211). USFDA practices intended to protect the safety of final products through sanitary manufacturing procedures is a commonly accepted and used concept. Given the similarities in the use, manufacturing, and risks associated between food/drugs/dietary

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<sup>5</sup> Business and Professions Code section 19303.

supplements and edible cannabis products, it is reasonable that the establishment of GMPs, including commonly used definitions, in this regulation will help the Department to protect the public and carry out the intent of Business and Professions Code sections 19302.1(f), 19303, and 19347.6.

Adopt Section 40100. Definitions.

Adopt the term “Act” to mean the Medical Cannabis Regulation and Safety Act. This definition is included in order to provide clarity to the regulated public.

Adopt the term “actual yield” to mean the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular cannabis product. Further provisions of these regulations require manufacturers to provide a statement of the actual yield in the batch production record. This definition is a term under USFDA regulations (21 C.F.R. §111.3) and is necessary in order to provide clarity to the regulated public.

Adopt the term “adequate” to mean that which is necessary to ensure cannabis product safety in keeping with good public health practices. Further provisions of these regulations require manufacturers to implement adequate procedures to ensure sanitary practices. Because cannabis product manufacturing operations may vary widely, it is not feasible for the Department to establish a blanket requirement for each type of facility or operation. Instead, these regulations place responsibility upon the manufacturer to determine which methods are adequate to ensure the production of clean and safe cannabis products. The Department has defined adequate in the same manner as the USFDA in 21 C.F.R. §111.3.

Adopt the term “adulterated” or “adulteration” to mean a product that meets the conditions of section 19347.6 of the Business and Professions Code. This definition is necessary in order to provide clarity to the regulated public.

Adopt the term “allergen” to mean ingredients considered to be allergens further provisions of these regulations require that labels of cannabis products disclose any allergens contained in a cannabis product, and that manufacturing practices be conducted in a manner to protect against allergen cross-contact, this definition is reasonably necessary in order that the regulated public will know what is meant by the term allergen in the context of these regulations. The Department has defined allergen in the same manner as the USFDA.

Adopt the term “allergen cross-contact” to mean the unintentional incorporation of a food allergen into a manufactured cannabis product. This term is used in further regulatory provisions and is reasonably necessary in order to provide clarity to the regulated public.

Adopt the term “applicant” to mean the individual or business entity that is applying for a license to manufacture medical cannabis products and in whose name the license will

be issued. The applicant will be considered the licensee upon issuance of a license. This is a statutory definition <sup>6</sup> and is reasonably necessary to distinguish between the individual and business entity applying for a license to manufacture medical cannabis products.

Adopt the term “batch” to mean a discrete amount of cannabis product produced in one production cycle using the same formulation and standard operating procedures, and that is intended to have uniform character and quality. As further provisions of the regulations specify requirements for each product batch, this definition is reasonably necessary in order to provide clarity to the regulated public.

Adopt the term “Bureau” to mean the Bureau of Medical Cannabis Regulation in the Department of Consumer Affairs. This definition is included in order to provide clarity to the regulated public.

Adopt the term “cannabis product” to include “manufactured cannabis” as defined in section 19300.5(ac) of the Business and Professions Code, and “medical cannabis product” as defined in section 19300.5(af) of the Business and Professions Code. This definition is necessary in order to clarify that the term “cannabis product” as used in this chapter incorporates both definitions.

Adopt the term “cannabis product symbol” to mean the image established by the Department to indicate that a manufactured product contains THC. Further provisions of the regulation require the use of the cannabis product symbol. The definition is included in order to provide clarity to the regulated public. The image is included in these regulations in Section 40412.

Adopt the term “CBD” to mean the compound cannabidiol. This definition is included in order to provide clarity to the regulated public.

Adopt the term “commercial-grade, non-residential door lock” to mean a lock manufactured for commercial use. Further provisions of the regulations contain specific requirements for security procedures including the use of commercial-grade, non-residential door locks. The definition is included in order to provide clarity to the regulated public.

Adopt the term “component” to mean any substance or item intended for use in the manufacture of a cannabis product, including those substances or items that are not intended to appear in the final form of the product. “Component” can include cannabis, cannabis products used as ingredients, other ingredients, and processing aids. Further provisions of the regulations contain specific requirements for components used in the manufacturing process. This definition is modeled after the definition used by the

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<sup>6</sup> Business and Professions Code section 19300.5(x).

USFDA in 21 C.F.R. §111.3 and is included here in order to provide clarity to the regulated public.

Adopt the term “contact surface” to mean any surface that contacts cannabis products and cannabis product components and those surfaces from which drainage, or other transfer, onto the cannabis product or cannabis product components, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging. Further provisions of the regulations contain specific requirements for contact surfaces. The definition is included for the clarity of the regulated public and is modeled after the definitions used by the USFDA in 21 C.F.R. §§111.3 and 117.3.

Adopt the term “Department” to mean the California Department of Public Health. This definition is included in order to provide clarity to the regulated public.

Adopt the term “edible cannabis product” to mean any manufactured cannabis intended to be used, in whole or in part, for human consumption. This is a statutory definition and is included here in order to provide clarity to the regulated public.

Adopt the term “environmental pathogen” to mean a pathogen capable of surviving and persisting within the manufacturing environment such that cannabis products may be contaminated and may result in illness if that cannabis product is consumed or used without first treating it in order to significantly minimize the environmental pathogen. Examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella spp.* but do not include the spores of pathogenic spore forming bacteria. Further provisions of the regulations contain specific requirements on environmental pathogens. The definition is the same definition used by the USFDA in 21 C.F.R. §117.3, and is included in order to provide clarity to the regulated public.

Adopt the term “extraction” to mean the process by which cannabinoids are separated from cannabis plant material through chemical or physical means. This definition is necessary to make specific the provisions of the regulations and to provide clarity to the regulated public.

Adopt the term “finished product” to mean a manufactured cannabis product in its final form that is to be sold at a dispensary. This definition is necessary in order to provide clarity to the regulated public.

Adopt the term “hazard” to mean any biological, chemical, radiological, or physical agent that has the potential to cause illness or injury. Further provisions of the regulations contain specific requirements to minimize hazards associated with the manufacturing process in order to ensure product quality and safety. This definition is included for the clarity of the regulated public, and is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Adopt the term “holding” to mean the storage of cannabis or cannabis products, including activities performed incidental to the storage of a cannabis product. Holding also includes activities performed as a practical necessity for the distribution of that cannabis product. This definition is necessary to make specific the provisions of the regulations and to provide clarity to the regulated public. The definition is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Adopt the term “informational panel” to mean the part of the label on a cannabis product that is not the primary panel and that contains required information. A cannabis product is required to include an informational panel. Further provisions of the regulations contain requirements for the informational panel. The definition is included in order to provide clarity to the regulated public.

Adopt the term “infusion” is defined as a process by which cannabis concentrates or extracts are directly incorporated into a product to produce a cannabis product. The cannabis manufacturing process includes all aspects of the infusion process. This definition is included in order to provide clarity to the regulated public.

Adopt the term “ingredient” to mean any substance that is used in the manufacture of a cannabis product and that is intended to be present in the product’s final form. Further provisions of the regulations contain specific requirements regarding the storage and handling of ingredients. The informational panel is required to include a list of all product ingredients in descending order of predominance by weight or volume. This definition is included in order to provide clarity to the regulated public and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Adopt the term “in-process material” to mean any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a cannabis product. Further provisions of the regulations require manufacturers to include a review of the results of tests and examinations conducted on in-process materials as part of a batch production record. The definition is included in order to provide clarity to the regulated public and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Adopt the term “labeling” to mean any label or other written, printed, or graphic matter upon a medical cannabis product, or upon its container or wrapper, or that accompanies any medical cannabis product. This is a statutory definition (Business and Professions Code section 19300.5(v)); further provisions of the regulations contain specific labeling requirements for medical cannabis products. This definition is included in the regulation text in order to provide clarity to the regulated public.

Adopt the term “limited-access area” to mean an area in which medical cannabis is stored or held and is only accessible to a licensee and authorized personnel. Further

provisions of the regulations contain specific requirements for limited-access areas. This definition is included in order to provide clarity to the regulated public.

Adopt the term “lot” to mean a batch or a specifically identified portion of a batch. This is a statutory definition (Business and Professions Code section 19300.5 (ab)). This definition is included in order to provide clarity to the regulated public.

Adopt the term “lot number” to mean the distinctive group of numbers, letters, or symbols, or any combination thereof that is unique to the lot of cannabis product. Further provisions of the regulations require manufacturers to have a lot number for each manufactured lot. This definition is modeled after the definition used by the USFDA in 21 C.F.R. §111.3 and is included in order to provide clarity to the regulated public.

Adopt the term “manufacturer licensee” or “licensee” to mean the holder of a manufacturer license issued pursuant to the Act and associated with a specific manufacturing premises. This is a statutory definition (Business and Professions Code section 19300.5(x)), and is included in in order to provide clarity to the regulated public.

Adopt the term “manufacture” to define what the term “manufacturer” includes and does not includes so as to avoid confusion among members of the regulated public. Conversations with the other licensing agencies and stakeholders during the pre-regulatory process indicated that there was confusion around what would be considered a manufacturing activity, particularly in terms of the packaging and labeling of products. This provision is necessary to clarify that the Department shall consider any activity in which a cannabis product is processed or handled outside of its packaging to be a manufacturing activity that requires a manufacturing license.

Adopt the term “manufacturing” or “manufacturing operation” to mean all aspects of the extraction and/or infusion processes, including processing, preparing, holding, storing, packaging, or labeling of cannabis products. Manufacturing is further defined to mean any processing, preparing, holding, or storing of components and ingredients. This definition is necessary in order to provide clarity to the regulated public.

Adopt the term “microorganisms” to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including species that are pathogens. The term “undesirable microorganisms” is adopted to mean those microorganisms that are pathogens, that subject manufactured cannabis to decomposition, that indicate that manufactured cannabis is contaminated with filth, and/or that may otherwise cause manufactured cannabis to be adulterated. These definitions are modeled after those used by the USFDA in 21 C.F.R. §117.3, and are reasonably necessary in order to define what constitutes a microorganism so that the Department and the regulated public may minimize opportunities for contamination to cannabis products via microorganisms posing a threat to public health and safety.

Adopt the term “monitor” to mean to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. Further provisions of the regulations contain requirements for monitoring. The definition is included here for the clarity of the regulated public, and is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Adopt the term “nonvolatile solvent” to mean any solvent used in the extraction process that is not a volatile solvent. For purposes of this chapter, a nonvolatile solvent includes carbon dioxide used for extraction. Further provisions of the regulations contain requirements for license type 6 which involves the use of nonvolatile solvents. This definition is included here for clarity of the regulated public.

Adopt the term “package” or “packaging” to mean any container or wrapper that may be used for enclosing or containing any cannabis and/or cannabis products. Further provisions of the regulations contain requirements for packaging of cannabis products. This definition is included here for in order to provide clarity to the regulated public.

Adopt the term “pathogen” to mean a microorganism that can cause illness or injury. As pathogens are capable of surviving and persisting within the manufacturing environment such that cannabis products may be contaminated and may result in illness if that product is consumed or used, this definition is reasonably necessary in order to clarify what constitutes a pathogen so that the regulated public may minimize opportunities for contamination via pathogen(s) posing a threat to public health and safety.

Adopt the term “personnel” to mean any worker engaged in the performance or supervision of operations at a manufacturing facility, and includes full-time and part-time employees, temporary employees, contractors, and volunteers. As applicable to training requirements, “personnel” also includes owner-operators. Further provisions of the regulations contain specific requirements for personnel at a manufacturing facility including training requirements. The definition is included here for the reader’s clarity.

Adopt the term “pest” to mean any undesired insect, rodent, nematode (small worm), fungus, bird, vertebrate, invertebrate, weed, virus, bacteria, or other microorganism that is injurious to health or the environment. Further provisions of the regulations require manufacturers to provide adequate screening or other protection against pests. This definition is included here for the reader’s clarity as to what constitutes a pest.

Adopt the term “premises” to mean as the location specified in the application for a manufacturer’s license that is owned or in the possession of the licensee and within which the licensee is authorized to manufacture medical cannabis in accordance with the provisions of the Act and the regulations. This definition is included in order to provide clarity to the regulated public by making specific what it meant by “premises” in the context of these regulations.

Adopt the term “preventive controls” to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified by a hazard analysis consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Further provisions of the regulations require manufacturers to identify and implement preventive controls to mitigate potential hazards. The definition is included here for the reader’s clarity and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Adopt the term “primary panel” to mean the part of a label most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. Further provisions of the regulations contain labeling requirements for the primary panel. The definition is included here to clarify which portion of the label is the primary panel.

Adopt the term “processing aid” to mean any substance that is added to a cannabis product during manufacture but is removed in some manner from the cannabis product before it is packaged in its finished form. “Processing aid” is included in the definition of component and is necessary to include here for clarity.

Adopt the term “product Identity” or “identity of the product” to mean the generic name of the product type by which it is most commonly known. For edible products, the product identity shall not contain any trademarked identity of a traditional food product. Further provisions of the regulations require manufacturer’s to state the identity of the product on the label. The definition is included here for the clarity of the regulated public.

Adopt the term “qualified person” to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture safe cannabis products as appropriate to the individual's assigned duties. A qualified person may be, but is not required to be, an employee of the licensee. Further provisions of the regulations impose requirements that must be done by a qualified person. The definition is included here to provide clarity to the regulated public and is modeled after the definition used by the USFDA in 21 C.F.R. §§111.3 and 117.3.

Adopt the term “quality” to mean that the cannabis product consistently meets the established specifications for cannabis concentration, composition, and limits on contaminants and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and misbranding. Further provisions of the regulations refer to the quality of the product and to the standards required to ensure the quality of the product. This definition is modeled after the definition used by the USFDA in 21 C.F.R. §111.3 and is included for the clarity of the regulated public.

Adopt the term “quality control” to mean a planned and systematic operation or procedure for ensuring the quality of a cannabis product. Further provisions of the regulations require quality control measures. This definition is modeled after the definition used by the USFDA in 21 C.F.R. §111.3 and is included for the reader’s clarity.

Adopt the term “quality control operation” to mean the planned and systematic procedure for taking all actions necessary to prevent cannabis product from being adulterated or misbranded. Further provisions of the regulations require quality control operations be implemented to ensure that cannabis products are suitable for human consumption or use. The definition is included here for the reader’s clarity.

Adopt the term “quality control personnel” is defined as any person, persons, or group, designated by the licensee to be responsible for quality control operations. Further provisions of the regulations specify the tasks required of quality control personnel necessitate that quality control personnel perform specific tasks. This definition is modeled after the definition used by the USFDA in 21 C.F.R. §111.3 and is included for the reader’s clarity.

Adopt the term “raw material” to mean any unprocessed material that is intended to become part of the components of a cannabis product. Further provisions of the regulations specify the storage and handling requirements necessary to minimize the potential growth of microorganisms, allergen cross-contact, contamination of cannabis products, and deterioration of cannabis products. The definition is included here for the reader’s clarity.

Adopt the term “sanitize” to mean to adequately treat cleaned surfaces by a process that is effective in destroying the vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms without adversely affecting the product or the safety of the consumer. Further provisions of the regulations contain sanitation requirements. The Department has defined sanitize in the same manner as the USFDA in 21 C.F.R. §§111.3 and 117.3. The definition is included here for the reader’s clarity.

Adopt the term “sublet” to mean to lease or rent all or part of a leased or rented property. This definition is necessary to make specific provisions of the Act. The definition is included here for the reader’s clarity.

Adopt the term “THC” to mean the compound tetrahydrocannabinol and specifies that the use of the term “THC” in this chapter specifically refers to delta 9-tetrahydrocannabinol. This definition is included here for the reader’s clarity.

Adopt the term “theoretical yield” to mean the quantity that would be produced at any appropriate step of manufacture or packaging of a particular cannabis product, based upon the quantity of components or packaging to be used, in the absence of any loss or

error in the actual production. Further provisions of the regulations require manufacturers to provide a statement of the theoretical yield of a manufactured cannabis product expected at each stage of the manufacturing process. This definition is modeled after the definition used by the USFDA in 21 C.F.R. §111.3 and is included for the reader's clarity.

Adopt the term "track and trace system" to mean the universal identification certificate program for commercial medical cannabis activity authorized by this Chapter. The Act requires the CDFA, in consultation with the Bureau, to establish a track and trace program for reporting the movement of medical cannabis products throughout the distribution chain. Further provisions of the regulations include specific track and trace requirements for manufacturer licensees. This definition is included here for the reader's clarity.

Adopt the term "volatile solvent" to mean any solvent that is or produces a flammable gas or vapor that, when present in the air in sufficient quantities, will create explosive or ignitable mixtures. For the purposes of this chapter, examples of volatile solvents include, but are not limited to: butane, hexane, propane, and ethanol. The Act requires that the Department establish two manufacturer license types based on the type of solvent used; however, as the Act does not define volatile and non-volatile solvent(s), this definition is reasonably necessary in order to make specific the solvent types considered volatile under the Act.

Adopt Section 40102. Owner. Business and Professions Code section 19300.5(b) defines "applicant" to include certain owners. The following section is therefore reasonably necessary in order to make specific which individuals associated with a cannabis manufacturing business are considered "owners." For purposes of licensing under the Act, in the interest of equitable treatment of applicants, the Department is defining owner in the same manner as will be defined under the Adult Use of Marijuana Act (AUMA).

Subsection (a) identifies the owners of a publicly traded company as the CEO or any person with an ownership interest in the company of 5% or more. This provision is necessary to comply with Business and Professions Code section 19300.5(b)(3), and is included here in order to provide clarity to the regulated public.

Subsection (b) specifies that for all other business, an owner is:

Paragraph (1): an individual who has an aggregate ownership interest in the business of 20% or more;

Paragraph (2): the chief executive officer and all members of the board of directors of an entity when that entity has an aggregate ownership interest of 20 percent or more; or

Paragraph (3): any individual that has been delegated discretionary powers to organize, direct, carry on, or control the operations of the business is required to be licensed as an owner. Individuals with discretionary decision making authority,

including authority to hire or fire employees [subparagraph (A)] enter into purchasing contracts [subparagraph (B)] or make policy decisions [subparagraph (C)], can pose a threat to the integrity of the cannabis business, especially in terms of diversion of cannabis. In order to comply with its mandate under Business and Professions Code section 19303 and to uphold the priorities of the Cole Memo, the Department must be able to assess the background of these employees.

Subsection (c) states that individuals with a community property interest (such as a spouse or domestic partner of an owner) are not considered owners if the individual does not participate in the direction, control, or management of the business. This subsection further provides that if an individual is denied a license or has a license revoked, his or her spouse or domestic partner is prohibited from licensure in the same license category for the same time period. This restriction is necessary to close a loophole that could otherwise allow an unqualified applicant to continue to participate in the cannabis business through a license issued in the name of his or her spouse or domestic partner. To this end, the Department is requesting basic identifying information on the owner-applicant's spouse or domestic partner under section 40130.

Subsection (d) states that a bank or financial institution whose interest constitutes a loan is not considered to be an owner. This provision is necessary to clarify that banks or other financial institutions do not need to be licensed.

Subsection (e) further clarifies the individuals who are not considered an owner of the cannabis business.

#### Add Article 2: General Provisions

Adopt Section 40115. License Required to clarify that licenses are required for all manufacturers of cannabis products. This is a statutory requirement. (Bus. & Prof. Code §§19302.1, subd. (f) and 19304, subd. (a).)

Subsection (a) states that every person that manufactures cannabis products must obtain and maintain a license from the Department for each separate premises used for the manufacture of cannabis products. This is a statutory requirement. (Bus. & Prof. Code §19320, subd. (c).)

Subsection (b) states that no person shall manufacturer cannabis products without a valid license from the Department. This provision is necessary in order to meet the requirements of the Act. (Bus. & Prof. Code §19320, subd. (b).)

Adopt Section 40118. Manufacturing License Classifications. The Act establishes two license types for manufacturers – Type 6 for manufacturers using nonvolatile solvents and Type 7 for manufacturers using volatile solvents. (Bus. & Prof. Code §19300.7 subd. (k) and (l).) However, Business and Professions Code section 19302.1(f) allows the Department to create additional license types as needed. This section is necessary

to make specific the Department's licensing authority.

Subsection (a) creates a new license category of "Type P" for manufacturers that only engage in the packaging of cannabis products. Packing operations offer numerous opportunities for contamination of a product if not conducted in accordance with GMPs. In order to mitigate the risk of contamination, it is necessary for packaging operations to be under the oversight of the Department. During the pre-regulatory stakeholder meetings, the Department heard from numerous individuals who expressed an interest in only the packaging or labeling of products. This provision is necessary for the Department to fulfill its mandate under the Act to license and regulate manufacturers. Subsection (a) also clarifies that entities that package and label their own products are not required to hold a Type P license. This provision is necessary in order to prevent confusion to the regulated public. This subsection also establishes that holders of a Type P license are subject to the same additional license restrictions as a Type 6 license. Business and Professions Code section 19328 restricts the types of additional licenses that a licensee may hold. Type 6 and 7 licensees can only hold a cultivation, transporting, or "producing dispensary" license. In keeping with the intent of the Act to restrict the number and types of additional licenses can hold, the Department is imposing the same restrictions on the license types created by this proposal.

Subsection (b) creates a new license category of "Type N" for manufacturers that only infuse cannabinoids into a product formulation to produce a cannabis product. The manufacturing licenses established by the Act only address manufacturers that engage in extractions. Many manufacturers do not conduct extractions, but rather purchase cannabinoid concentrates from other manufacturers and incorporate the concentrate into their own products. Establishing a new license type for infusion-only is reasonably necessary for the Department to appropriately oversee licensing operations.

This subsection also provides that holders of a Type N license are subject to the same additional license restrictions as a Type 6 license. As discussed above, this provision is reasonably necessary to conform this proposal to the intent of the Act.

Subsection (c) implements the statutorily mandated Type 6 license for manufacturers conducting extractions with nonvolatile solvents. This subsection further categorizes manufacturers conducting extractions with mechanical or solvent-less methods as Type 6. This provision is necessary to clarify the license type for which an applicant must apply. Finally, this subsection clarifies that Type 6 licensees can also conduct infusion operations, provided that the information required in Section 40128 is provided to the Department. This provision is reasonably necessary for the Department to fulfill its mandate to issue manufacturing licenses.

Subsection (d) implements the statutorily mandated Type 7 license for

manufacturing conducting extractions with volatile solvents. This subsection clarifies that Type 7 licensees can also conduct mechanical or solvent-less extractions or extractions with nonvolatile solvents. This provision is reasonably necessary for the Department to fulfill its mandate to issue manufacturing licenses.

## **II. Add Subchapter 2: Manufacturing Licenses**

### Add Article 1: Applications for Licensure

Adopt Section 40125. New License Application. This section is adopted to establish the circumstances that will require an application for a new license. This provision, including its subsections, is necessary to implement the licensing scheme mandated for the Department under the Act (Bus. & Prof. Code §§19302.1, subd. (f) and 19320 et. seq.), and to provide clarity to the regulated public. Under the Act, the Department is considered a licensing authority and is charged to create the rules and regulations necessary to effectuate its enabling statute. (Bus. & Prof. Code §19304, subd. (a).)

Subsection (a) requires a new license application when an applicant or premises has not previously been licensed. Licensure of all individuals wishing to engage in commercial cannabis activity, and for each premises in which such activity is to take place, is required by Business and Professions Code section 19320, subdivisions (a)-(c).

Subsection (b) requires a new license application when the prior license has expired and has not been renewed in a timely manner, as further specified in section 40180 of these regulations. The Act requires licenses to be renewed annually. (Bus. & Prof. Code §19321, subd. (a).)

Subsection (c) requires a new license application when the previous license has been revoked by the Department or a local jurisdiction. This provision is reasonably necessary to so that the Department may comply with sections 19320, subdivisions (b), (d), and (e) of the Business and Professions Code.

Subsection (d) requires a new license application when a current licensee holding a Type P (packaging/labeling) license wants to begin conducting infusions or extractions. This provision is reasonably necessary to ensure that the licensee and premises meet the standards required for a Type 6 or 7 (infusions and/or extractions) license.

Subsection (e) requires a new license application when a current licensee holding a Type N (infusion) license wants to begin conducting extractions. This provision is reasonable to ensure that the licensee and premises meet the standards required for a Type 6 or 7 (infusions and/or extractions) license.

Subsection (f) requires a new license application when a current licensee holding a Type 6 license (non-volatile extractions) wants to begin conducting Type 7 (volatile solvents) extractions. This provision is reasonably necessary to ensure that the

licensee and premises meet the standards required for a Type 7 license. This provision is consistent with Business and Professions Code sections 19300.7 and 19341, which establish two different license classifications for manufacturers based on whether the extraction method uses volatile or non-volatile solvents.

Subsection (g) requires a new license application when the license applicant (either an individual or entity) has changed. This provision is reasonably necessary so that the Department may comply with Business and Professions Code sections 19320 (a) and (b) which are intended to ensure that all commercial cannabis activity is conducted by licensees.

Subsection (h) requires a new license application when the licensee intends to relocate any portion of the manufacturing operation to a new location. This provision further clarifies subdivision (a) of this section by requiring a new license application when any portion of existing operations is moved to a new location. This provision is reasonably necessary so that the Department may ensure that the new premises meet the standards required by these regulations.

Adopt Section 40128 Application Requirements. This section is adopted to specify the information and documentation that an applicant for a manufacturing license must submit to the Department. This provision is reasonably necessary in order for the Department to establish the specific rules and regulations needed to provide for the proper licensing of manufacturers in accordance with its enabling statute (Bus. & Prof. Code §19304, subd. (a)), provides clarity to the regulated public, and provides proper oversight of cannabis product manufacturing operations in its role as a licensing authority under the Act.

Subsection (a) requires submission of a complete licensing application form prescribed by the Department, or through online submission as available. A complete application is necessary so that the Department may ensure that applicants are qualified for the type of license sought and so that it may maintain proper oversight of licensing activities in its capacity as a licensing authority. For the purposes of this chapter, a complete licensing application is one which includes the following information:

Paragraph (1) Applicant Information.

Subparagraph (A) identifies the application type (e.g. new license, license renewal, operation change, owner change) that the applicant is applying for. This provision is necessary so that the Department may maintain accurate records and ensure applicants are qualified for the type of license applied for.

Subparagraph (B) identifies the license type sought (Type N, Type P, Type 6, or Type 7). This necessary for the Department's processing of the application.

Subparagraph (C) requires the applicant to provide the legal business name of the manufacturer applicant. The legal business name of the applicant is the

name under which the application will be issued. This information is necessary to ensure that the Department's records are accurate.

Subparagraph (D) requires the applicant to provide the name(s) under which the business will operate (Doing Business As). This information is necessary so that the Department may maintain accurate records in accordance with its role as a licensing authority.

Subparagraph (E) requires that, if the applicant is a sole proprietor, they must provide their social security number and date of birth. Further provisions of these regulations require each owner to submit his or her social security number as required by section 17520 of the Family Code. As a sole proprietor is *not* required to submit the separate owner application required in 40130, it is therefore necessary to include this requirement.

Subparagraph (F) requires the applicant to provide the applicant's mailing address which will serve as the address of record. This information is necessary so that the Department can comply with requirements to send information by mail, such as notices of denial, notices of violations, appeals hearings, and other administrative notices. Additionally, the Business and Professions Code requires each licensing authority provide on the Internet information regarding the status of every license issued. Each licensing authority is required to disclose the licensee's address of record. The address of record can be a post office box number or other alternate address, instead of his or her home address. (Bus. & Prof. Code § 27, subd. (a).)

Subparagraph (G) requires the applicant to provide the name, title, and phone number of the contact person for the applicant, and the applicant's contact e-mail address. This provision is necessary to ensure that the Department can contact the applicant if needed.

Subparagraph (H) requires the applicant to provide the seller's permit number issued by the Board of Equalization, or evidence that the applicant has applied for a seller's permit from the Board of Equalization. This provision is necessary to comply with the statutory requirement that licenses only be issued if the applicant has a seller's permit.

Subparagraph (I) requires the applicant to provide the number, date of issuance and date of expiration of the local jurisdiction's license, permit or other authorization for the manufacture of medical cannabis products. This provision is necessary to comply with the statutory requirement that licenses only be issued if the applicant has first obtained a local license, permit, or other authorization from the local jurisdiction in which he or she proposes to operate (Bus. & Prof. Code §19320(b)). This provision is further necessary so that the Department may verify that the applicant is in compliance with this statutory requirement.

Subparagraph (J) requires the applicant to provide the ownership structure (e.g. limited liability company, joint partnership, S-Corporation) of the applicant as filed with the California Secretary of State. This provision is reasonably necessary to allow the Department to verify that the appropriate owners have submitted owner applications.

Subparagraph (K) requires the applicant provide a list of the owners, as defined in Section 40102 of these regulations. This provision is reasonably necessary so that the Department may verify that the owners have submitted their owner applications.

Subparagraph (L) requires the applicant to identify other medical cannabis licenses the applicant holds or has applied for. This provision is reasonably necessary so that the Department may verify that the applicant is in compliance with the licensing limitations specified in Business and Professions Code section 19328.

Paragraph (2) Manufacturing Premises Information.

Subparagraph (A) requires the applicant to provide the physical address of the manufacturing premises. This provision is reasonably necessary in order to avoid confusion if the physical address of the manufacturing premises is different from the mailing address of the applicant. This provision is further necessary so that the Department can verify that the premises have received the local license, permit, or other authorization(s) required by statute (Bus. & Prof. Code §19320, subd. (a).), and so that the Department will be able to perform inspections of the manufacturing premises and operations in accordance with its role as a licensing authority under the Act.

Subparagraph (B) requires the applicant to provide the name, title, and phone number of the person who manages the operation of the facility. This information is necessary in case the Department needs to contact a person present at the facility in its capacity as a licensing authority or in order to ensure public health and safety.

Subparagraph (C) requires the applicant to provide the name, title, and phone number of an alternate contact person for the facility. This provision is necessary in case the primary contact person cannot be reached.

Subparagraph (D) requires the applicant to provide the number of employees at the manufacturing site. This provision is necessary to implement the statutory requirement that all applicants with 20 or more employees agree to abide by a labor peace agreement. (Bus. & Prof. Code §19322, subd. (a)(6)(A).) Additionally, knowing the number of employees at the site will help the Department to evaluate the security plan established by the applicant. A site with

only a few employees will have different security needs than a site with numerous employees.

Subparagraph (E) requires the applicant to provide the anticipated gross annual revenue from all sales of products manufactured at the manufacturing premises. The annual license fee, as further specified in Section 40150 of these regulations, is based on a manufacturer's gross annual revenue. Applicants that are not currently in operation will not yet have revenue, but should be able to reasonably estimate of the anticipated revenue for the upcoming term of licensure.

Subparagraph (F) requires the applicant to submit a diagram of the manufacturing premises showing the areas in which all commercial cannabis activities will be conducted. The diagram must be specific enough to enable ready determination of the bounds of the property and the proposed premises to be licensed, and show all boundaries, dimensions, entrances and exits, interior partitions, walls, room, windows, and common or shared entryways. The diagram must be to scale and, if the proposed premises consists of only a portion of a property, the diagram shall be labeled indicating which part of the property is the proposed premises and will identify what the remaining property is used for. This provision is necessary so that the Department's inspectors will be able to evaluate the security measures proposed by the applicant and effectively conduct inspections to ensure the premises qualify for licensure.

Paragraph (3) requires disclosure of any of the following specified conditions, including a description of the circumstances. Business and Professions Code section 19323(b) allows, but does not require, the Department to deny a license application if the applicant or owner has been convicted of specified offenses or any offense substantially related to the qualifications, duties, or functions of a manufacturer. Business and Professions Code section 19323(b) requires the Department to conduct a thorough review of the circumstances of the conviction and any evidence of rehabilitation of the applicant or owner. This provision is further necessary in order to provide the applicant a method by which they can describe the circumstances of his or her conviction.

Subparagraph (A) requires the applicant to disclose any criminal conviction substantially related to the qualifications of a manufacturer identified in Business and Professions Code section 19323(b)(4) or in Section 40162 of these regulations. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(4).

Subparagraph (B) requires the applicant to disclose any violation of law that is substantially related to the qualifications of a manufacturer as identified in Section 40162 of these regulations. This provision is reasonably necessary for the Department to implement Business and Professions Code section

19323(b)(4).

Subparagraph (C) requires the applicant to disclose any fines or penalties for cultivation or production of a controlled substance on public or private land. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(6).

Subparagraph (D) requires the applicant to disclose any sanctions by a licensing authority, or a city or county, for unlicensed commercial cannabis activity within the three (3) years preceding the date of the application. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(7).

Subparagraph (E) requires the applicant to disclose revocation of a cannabis license by a licensing authority or a local jurisdiction within the 3 years preceding the date of the application. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(7).

Subparagraph (F) requires the applicant to disclose any conviction of a crime related to fraud or embezzlement. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(4)(D).

Subparagraph (G) requires the applicant to disclose any conviction of a violent felony as specified in section 667.5(c) of the Penal Code. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(4)(B).

Subparagraph (H) requires the applicant to disclose any conviction of a serious felony as specified in subdivision (c) of section 1192.7 of the Penal Code. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(4)(C).

Subparagraph (I) requires the applicant to disclose whether the applicant is on parole or probation for a felony conviction. This provision is necessary to allow the Department to thoroughly review an applicant's qualifications as required by Business and Professions Code section 19323(b)(4).

Subparagraph (J) requires the applicant to disclose whether the applicant has, as a licensed physician, ever made patient recommendations for medical cannabis pursuant to section 11362.7 of the Health and Safety Code. This provision is reasonably necessary for the Department to implement Business and Professions Code section 19323(b)(5).

Subparagraph (K) states that if the applicant is a natural person, instead of a

business entity, the applicant must provide the same information as above. This provision is necessary to clarify that the requirements of this section apply to all applicant types.

Paragraph (4) Licensed Activity

Subparagraph (A) requires the applicant to indicate the type of activity to be conducted (i.e. extraction, infusion, packaging, labeling), including a description of extraction and infusion methods. This provision is reasonably necessary in order for the Department to issue the proper license and to fulfill its mandate under Business and Professions Code section 19322(b)(2).

Subparagraph (B) requires the applicant to indicate the type of products that will be manufactured, packaged, or labeled. This provision is reasonably necessary so that the Department may confirm that the manufacturing operation possesses the correct license for the product(s) produced and procedures used.

Paragraph (5) Attestations. This subsection requires the applicant to attest to the following statements under penalty of perjury, as mandated by Business and Professions Code section 19322(a)(5).

Subparagraph (A) requires the applicant to attest that the applicant is not licensed as a retailer of alcoholic beverages pursuant to Business and Professions Code, Division 9 (commencing with Section 23000). This provision is necessary to comply with the statutory requirement.

Subparagraph (B) requires the applicant to attest that, if the applicant has 20 or more employees, that the applicant will enter into and abide by a labor peace agreement, as required by Business and Professions Code section 19322(a)(6). This provision is necessary to comply with the statutory requirement.

Subparagraph (C) requires the applicant to attest that the applicant is in compliance with the licensing limitations specified in Business and Professions Code section 19328. This provision is necessary to comply with the statutory requirement.

Subparagraph (D) requires that the applicant to attest that the applicant understands that the requirements of operation specified in Subchapter 3 must be met. This provision is intended to ensure that the applicant is aware of the operating requirements that need to be adhered to and is necessary to comply with the statutory requirement.

Paragraph (6) requires the applicant to sign, under penalty of perjury, that the information provided is complete, true, and accurate, as required by Business and Professions Code section 19322(a)(5).

Subsection (b) requires the applicant to submit the following documentation with the

application.

Paragraph (1) requires the applicant to submit a description of inventory control procedures that is sufficient to demonstrate how the applicant will comply with the requirements of Section 40282 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under Business and Professions Code section 19322(b)(4), and to comply with the intent of the Cole Memo. One of the priorities outlined in the Cole Memo is preventing diversion. This provision furthers the intent of preventing diversion through inventory control.

Paragraph (2) requires the applicant to submit a description of quality control procedures sufficient to demonstrate how the applicant will comply with the requirements of Sections 40232-40268 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under Business and Professions Code section 19322(b)(5).

Paragraph (3) requires the applicant to submit a description of the transportation process to be used by the applicant. This provision is reasonably necessary in order for the Department to fulfill its mandate under Business and Professions Code section 19322(b)(5).

Paragraph (4) requires the applicant to submit a description of security procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40200 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under Business and Professions Code section 19322(b)(6) and to comply with the Cole Memo. One of the priorities outlined in the Cole Memo is preventing diversion. This provision furthers the intent of preventing diversion by mitigating opportunities for theft.

Paragraph (5) allows the applicant to submit the processes and procedures used by the applicant in lieu of a description of said methods. This provision is reasonably necessary in order for the Department to fulfill its mandate under Business and Professions Code section 19322(b) while allowing the applicant some flexibility in fulfilling the application requirements for licensure.

Paragraph (6) requires the applicant to submit a written statement signed by the owner of the property, or the owner's agent, identifying the physical location of the property and acknowledging and consenting to the manufacture of medical cannabis products thereon. The name, address, and contact phone number for the owner or owner's agent is also required so that the Department may verify the information provided. Business and Professions Code section 19322(a)(3) requires the applicant provide this documentation. This provision is reasonably necessary in order to comply with the statutory requirement.

Paragraph (7) requires the applicant to provide documentation issued by the local

jurisdiction certifying that the applicant will be in compliance with all local ordinances and regulations by the time the Department issues a license. Business and Professions Code section 19322(a)(2) requires the applicant to provide this documentation. This provision is reasonably necessary in order to comply with the statutory requirement.

Paragraph (8) requires the applicant to provide proof of having obtained a surety bond in the amount of \$5000 to cover the cost of destruction of medical cannabis product necessitated by a violation of the Act or the regulations adopted thereunder. Business and Professions Code section 19322(a)(11) requires the applicant provide proof of bond to cover the costs of destruction of medical cannabis products if necessitated by a violation of licensing requirements. This provision is reasonably necessary in order to comply with the statutory requirement.

Subsection (c) requires the applicant to submit a non-refundable application processing fee with the application package. Business and Professions Code section 19322(a)(10) requires the applicant to pay all applicable fees required for licensure by the licensing authority. This provision is reasonably necessary in order for the Department to comply with the statutory requirement and so that it may collect the fees necessary to provide for the processing of applications for licensure.

Subsection (d) requires manufacturers submitting operating procedures and protocols to the Department to clearly identify information considered a trade secret or confidential by identifying the document as “confidential” when it is submitted to the Department. This provision is reasonably necessary in order for the Department to protect confidential information that may be communicated during the licensing process.

Adopt Section 40130 Owner Applications. Each owner of a manufacturing operation is subject to the same requirements as an applicant<sup>7</sup> as described in section 40128 of these regulations (above). This section is adopted to specify the information and documentation that each owner must submit to the Department as part of the application process. This provision is reasonably necessary so that the Department may provide for the proper licensing of manufacturers in accordance with its enabling statute (Bus. & Prof. Code §19304, subd. (a)), and so that it may provide clarity to the regulated public.

Subsection (a) requires each owner to complete an owner information form as provided by the Department or through online submission as available. This provision is necessary in order for the Department to comply with Business and Professions code section 19320(a).

Paragraphs (1)-(10) require each owner submit the same information and attest to the same statements as the licensee. The owner is also required to sign the form as

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<sup>7</sup> “Applicant” as defined in Business and Professions Code section 1300.5, subdivision (b) includes any person having an ownership interest in the manufacturing premises.

provided by the Department under penalty of perjury, that the information provided is complete, true, and accurate.

Subsection (b) requires specified information on the owner's spouse or domestic partner, including name [paragraph 1], date of birth [paragraph 2], social security number or tax payer identification number [paragraph 3], mailing address [paragraph 4], whether the spouse has financial interest in any other licensed entity. These sections are required in order to ensure that a spouse of a denied or revoked license holder does not apply for licensure as provided in Section 40102(c).

Subsection (c) to sign, under penalty of perjury, that the information provided is complete, true, and accurate, as required by Business and Professions Code section 19322(a)(5).

Adopt Section 40132. Waiver of Sovereign Immunity. This section will specify the rules required in order for sovereign entities, such as federally recognized tribes, to apply for and receive a license to manufacture medical cannabis. The following provisions are reasonably necessary for the Department to fulfill its mandate to only issue licenses to qualified entities.

Subsection (a) requires the licensing application to include a waiver of sovereign immunity and agreement to all of the following: (1) to provide documentation that the applicant has the lawful authority to enter into the waiver; (2) to conduct all commercial in full compliance with state laws and regulations; (3) to allow access by the licensing authorities; (4) to provide any records; (5) to meet all of the requirements for licensure under state law to conduct commercial activities only with other licensees; (6) to abide by all applicable state laws; and (7) to be subject to the jurisdiction of the California courts.

Subsection (b) requires the applicant or licensee to notify the Department of any changes that may affect compliance with this section.

Subsection (c) states that any failure to comply with the requirements of this section shall be a basis for denial or discipline of a license.

Adopt Section 40135. Incomplete Applications. This section will implement and make specific the rules and regulations adopted by the Department in order to properly license manufacturers in accordance with the Act. (Bus. & Prof. Code §§19302.1, subd.(f) and 19304, subd.(a).)

Subsection (a) specifies that an incomplete application will not be processed. This provision is reasonably necessary so that the Department may comply with section 19320(b) of the Business and Professions Code (mandating that licensing authorities only issue licenses to qualified applicants), and in order to provide clarity to the regulated public.

Subsection (b) provides that applications that remain incomplete 180 days after the Department has provided notice to the affected applicant(s) will be deemed abandoned. This provision is necessary in order to provide clarity to the regulated public and to provide applicants with a reasonable amount of time in which to review the application requirements, correct any deficiencies in their application, and provide the Department with any additional documents necessary in order to complete the application.

Adopt Section 40137. Application Withdrawal.

Subsection (a) provides that an applicant may withdraw an application for licensure at any time prior to the issuance or denial of a license by submitting a written request to the Department. This provision is necessary to make specific elements of the Department's licensing scheme.

Subsection (b) clarifies that an applicant can reapply for a license at any time following withdrawal. Because cannabis manufacturing is a newly regulated industry and the regulations are new and complex, the Department believes it is reasonable to allow an applicant an opportunity to withdraw its application, if the applicant determines appropriate, and to reapply at any time. For example, an applicant that self-identifies deficiencies in its application or operations can withdraw the application, correct any deficiencies and then reapply prior to any formal application denial by the Department.

Add Article 2. Operations in Existence as of January 1, 2018.

Adopt Section 40140. Applicants Operating Prior to January 1, 2018. Business and Professions Code section 19321(b) establishes that a business in operation as of January 1, 2018, can continue to operate until the Department approves or denies its license, to the extent that certain conditions are met. Section 40140 is necessary in order to make specific those required conditions.

Paragraph (1) requires the application for licensure to be submitted by July 2, 2018. The Act authorizes the licensing authorities to determine the date by which an application needs to be submitted in order for the applicant to continue operations. The Department, in conjunction with the Bureau and the CDFA, has set the deadline at 6 months. This provision is reasonably necessary to provide businesses in current operation a sufficient amount of time in which to compile the required elements of their application.

Paragraph (2) requires the applicant to be operating pursuant to a local license, permit, or other authorization. This provision is a statutory requirement. (Bus. & Prof. Code §19320, subd.(b).)

Paragraph (3) requires the applicant to continue operating in accordance with all state and local requirements. This is a statutory requirement. (Bus. & Prof. Code §19321, subd.(b)(2).)

Paragraph (4) requires the applicant to submit documentation of operation prior to January 1, 2018. Subparagraphs (A) – (E) provide examples of the types of documentation the Department will accept as documentation. Subparagraph (F) allows the applicant to submit any other business record that demonstrates the applicant's dates of operation. This paragraph and its subparagraphs are necessary in order to provide clarity to the applicant.

Adopt Section 40141. Priority Review of Applications. Business and Professions Code section 19321(b) requires the Department to give priority review of applications to applicants that can demonstrate they were in operation before January 1, 2016, and have been in "good standing" with the local jurisdiction. This section is necessary to make specific the Department's mandate under the Act.

Subsection (a) specifies that, other than described in subsection (b), below, applications will be reviewed in the order they are received and determined to be complete. This provision is necessary in order to provide clarity to applicants.

Subsection (b) restates the statutory requirement to give priority review to certain applicants. This provision is necessary to provide clarity to applicants.

Subsection (c) states that the applicant is obligated to provide evidence of operations prior to January 1, 2016, and to attest under penalty of perjury that the business is in good standing with the local jurisdiction. This provision is necessary to provide clarity to applicants on how to demonstrate that they were in operation at the required time.

Subsection (d) specifies how to demonstrate "good standing" with the local jurisdiction. This subsection establishes that the applicant must provide a document issued or signed by the local jurisdiction with the name and address of the manufacturing premises, the name and contact information of the person signing the document on behalf of the jurisdiction, and a statement that the business is operating in good standing. During the pre-regulatory stakeholder meetings, the Department heard from local jurisdiction representatives that a clear and specific method to verify the applicant's good standing. This subsection is intended to provide the specificity requested, without being overly burdensome on the local jurisdiction. This provision is necessary in order for the Department to fulfill its mandate to give priority review.

### Add Article 3. Fees.

Adopt Section 40150. Fees. As previously mentioned, the Department is mandated to charge a fee to cover its costs and to scale the fee based on the size of the business. (Bus. & Prof. Code §19350, subd.(c).)

Subsection (a) establishes a nonrefundable application fee of \$1,000. This provision is reasonably necessary so that the Department may cover its costs in accordance

with the Act.

As a new program with a newly regulated industry, the Department has no historical data on which to base its estimated workload assessments. Using information from various licensing programs within the Department, the Department has estimated the cost of processing and reviewing each application for licensure. Application reviews will be conducted by a licensing unit that has both administrative and scientific staff. Staff will review the application for completeness and will process and review all submitted documents.

The Department estimates that it will take an average of 27 hours to fully process and review an application package, with the majority of the work performed by an Associate Governmental Program Analyst and an Environmental Scientist. Multiplying the annual classification salary by the number of hours needed per classification, the total annual salary cost for licensing manufacturers is estimated to be \$1,019,113. Dividing this number by the 1,000 licenses anticipated to be issued under the proposed regulations results in a per license application cost of \$1,019, which has been rounded down to \$1,000.

Application fees will be nonrefundable. This is necessary because the Department's cost for processing and reviewing the application remains regardless of the outcome of the application.

Subsection (b) establishes the annual license fee previously discussed in section 40128(a)(2)(E), above. The fee is based on the gross annual revenue of the licensed premises and is tiered accordingly. The tiers were determined by the research conducted by HIIMR as part of the SRIA. The fees are as follows:

Paragraph (1): For a licensed premises with an annual gross revenue of up to \$100,000 (Tier I), the fee shall be \$2,000.

Paragraph (2): For a licensed premises with an annual gross revenue of \$100,001 to \$500,000 (Tier II), the fee shall be \$7,500.

Paragraph (3): For a licensed premises with an annual gross revenue of \$500,001 to \$2,000,000 (Tier III), the fee shall be \$15,000.

Paragraph (4): For a licensed premises with an annual gross revenue of \$2,000,001 to \$5,000,000 (Tier IV), the fee shall be \$35,000.

Paragraph (5): For a licensed premises with an annual gross revenue of over \$5,000,000 (Tier V), the fee shall be \$50,000. These license fees were determined by accounting for the cost of administering the manufactured cannabis safety program. These costs include, but are not limited to: operational staff, Department administrative staff, IT system for licensing, the Track and Trace Fees required by section 19350(c) of the Business and Professions Code, and reimbursement of the

General Fund Loan by Fiscal Year 2020-21 (required by Bus. & Prof. Code §19351, subd.(b)(1)). Total estimated annual expenditures for the first four years peak at \$16 million. Upon completing the repayment of the loan, and only maintaining the operational cost of the program, the anticipated cost of the program is \$6 million annually.

The Department used the estimated market share of each tier to estimate the number of businesses that would be included in each tier. The fees were then set at an amount sufficient to fund the Department's costs as described above.

Add Article 4: Approval or Denial of Application for Licensure

Adopt Section 40155. New License Approval. This section requires the Department to notify the applicant upon approval of the license, and specifies that the applicant has 30 calendar days to pay the license fee. Upon receipt of the fee, the Department will issue the license with an effective date of the day the license fee was received. This provision is reasonably necessary to implement the fee structure specified in Business and Professions Code section 19350 which establishes an application fee in addition to a license fee.

Adopt Section 40159. Denial of License. Adopt this section to clarify and set forth grounds for denial of a manufacturing license for the purposed of the Act. This provision is necessary in order for the Department to comply section 19323 of the Business and Professions Code (governing the denial of licenses to applicants that fail to comply with state rules and regulations).

Subsection (a)(1) specifies that an application may be denied when the applicant or associated applicant has committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself or another, or to substantially injure another. This is a statutory requirement under section 19323(b)(2) of the Business and Professions Code, which authorizes the Department to deny a license for the reasons specified in Business and Professions Code section 480. The reasons for denial listed in section 480 of Business and Professions Code are duplicated here in order to provide clarity to the regulated public.

Subsection (a)(2) specifies that an application may be denied when the applicant or associated applicant made a material misrepresentation in their application for licensure. This provision is reasonably necessary so that the Department may comply with the denial criteria in Business and Professions Code section 480 and is included here for the clarity of the regulated public.

Subsection (a)(3) specifies that an application may be denied when the applicant or associated applicant has been convicted of a crime or has committed a violation of law substantially related to the qualifications, functions or duties of a manufacturer as identified in Section 40162 of these regulations. Business and Professions Code section 19323(b)(4) identifies offenses that are substantially related to the

qualifications for licensure for all applicants under the Act, and which may serve as grounds for license denial. The Department has identified additional acts, as specified in Section 40162 of these regulations, which are specifically related to the qualifications of a manufacturer and which the Department believes are appropriate reasons for denial of a manufacturing license. This provision is reasonably necessary so that the Department may establish and enforce the criteria for the denial of licensing applications in accordance with the intent of its governing statute.

Subsection (a)(4) specifies that an application may be denied when the applicant has been denied a license, permit, or other authorization to engage in commercial cannabis activity by a state or local licensing authority. This provision is reasonably necessary to comply with Business and Professions Code section 19320, which requires a licensee to possess both a state and local authorization in order to engage in commercial cannabis activity.

Subsection (a)(5) specifies that an application may be denied when the applicant has denied the Department access to the manufacturing premises. Business and Professions Code section 19327 specifies that a licensee who refuses an inspection of the premises has committed a violation of the Act. Violations of the Act are grounds for disciplinary actions, license revocation, or license denial. (Bus. & Prof. Code §§ 19311 and 19312.) This provision is necessary to clarify and make specific that the Department's authority under the Act.

Subsection (b) specifies that an application shall be denied if the applicant or an associated applicant holds additional licenses in violation of Business and Professions Code section 19328. This is a statutory requirement (and is included here for the clarity of the regulated public.

Subsection (c) is adopted to clarify the meaning of the word "conviction." This definition is in accordance with the definition of conviction contained in Business and Professions Code section 480(a)(1) and is necessary in order to clarify what constitutes a conviction under the Act.

#### Adopt Section 40162: Substantially Related Acts.

Subsection (a) is adopted in order to clarify and set forth the criteria the Department shall use in order to determine the denial of a manufacturing license based upon "substantially related acts." Business and Professions Code section 19323 authorizes the Department to deny a license if the applicant has been convicted of an offense "substantially related to the qualifications, function, or duties of the business or profession for which the application is made." For purposes this section, a crime or act shall be considered substantially related to the qualifications, functions, or duties of a manufacturer if, to a substantial degree, it evidences present or potential unfitness of a licensee to perform the functions authorized by the license in a manner consistent with the public health, safety, or welfare. This provision is reasonably necessary in order for the Department to carry out its mandate under

section 19320(b) and section 19303 of the Business and Professions Code.

Paragraphs (1) – (5) identify the specific felony convictions for which a person may be denied a license. These convictions correspond to Business and Professions Code section 19323 and additionally reflect the convictions under the AUMA for which an individual may be denied a license.

Paragraphs (6) – (8) of this section define the specific California food safety laws whose violation may result in a denial of licensure. Because the Department will license the manufacturers of products intended for human consumption, the Department has further determined that it is reasonably necessary for the Department to include consideration of an applicant's violation of other relevant food safety laws when determining whether to deny a license application on the grounds of a substantially related act. This provision is reasonably necessary so that the Department may effectuate the intent of its governing statute. (Bus. & Prof. Code §19323, subd.(a),)

Subsection (b) states that a prior conviction for possession, sale, manufacture, transportation, or cultivation of a controlled substance is not substantially related, provided that the sentence for the conviction has been completed. This provision is part of the AUMA; the Department has determined it is reasonable to apply the same standard to manufacturers of medical cannabis products.

Adopt Section 40165. Criteria for Evidence of Rehabilitation. Business and Professions Code section 19323(b), paragraph (4) requires that the Department consider evidence of the applicant's rehabilitation prior to a license denial due to an applicant's prior conviction of a substantially related offense. This section makes specific the information that the Department will accept in order to conduct the statutory-required evaluation of evidence of rehabilitation.

Adopt Section 40167. Appeal of License Denial.

Subsection (a) specifies the notification requirements the Department must issue upon denial of an application for license as a manufacturer. This is a statutory requirement under section 19324 of the Business and Professions Code, which requires licensing authorities to notify an applicant of a denial in writing. This provision is necessary in order to comply with statutory requirements and to provide clarity to the regulated public.

Subsection (b) sets forth the process by which the applicant may appeal the denial of the application, specifies the content of the petition to appeal the denial, and requires an applicant who elects to petition the Department to file the written petition within 30 days of the date of denial. This section specifies that the applicant waives the right to a hearing on the denial if the petition is not filed within 30 days, and specifies that a petition is considered filed in a timely manner if it is postmarked within the 30-day period. This provision is necessary to implement and make specific Business and Professions Code section 19324 and to provide clarity to the regulated

public.

Subsection (c) provides that the Department shall schedule a hearing date upon timely receipt of the petition. This provision further specifies that the hearing will be conducted in accordance with the formal hearing provisions of the Administrative Procedure Act. This provision is a statutory requirement under Business and Professions Code section 19324 and is reasonably necessary in order to provide clarity to the regulated public.

Adopt Section 40169. Denial of Application – Reapplication. Adopt this section to specify that an applicant that has been denied licensure based on an act or offense substantially related to the qualifications for licensure as a manufacturer may not reapply until one year has elapsed from the effective date of denial. This provision is reasonably necessary in order for the Department to fulfill its statutory requirement to ensure that only qualified persons hold manufacturing licenses. (Bus. & Prof. Code §19320(b).)

#### Add Article 5: Licensing

Adopt Section 40175. License Constraints. The following provisions are reasonably necessary in order for the Department to fulfill its statutory requirement to ensure that only qualified persons hold manufacturing licenses and to protect public health and safety. (Bus. & Prof. Code §19320, subd.(b) and 19303.)

Subsection (a) is added to specify that a manufacturer licensee cannot hold a testing license or a distributor license as specified by the Act. (Bus. & Prof. Code §19328).

Subsection (b) is added to specify that no product other than a cannabis product may be manufactured on the premises of a licensee. This provision is reasonably necessary to protect public health and safety in accordance with section 19303 of Business and Professions code, and to ensure that non-cannabis products subject to regulation under other state and/or federal requirements are not manufactured at a premises licensed to manufacture cannabis products.

Subsection (c) specifies that a licensee may not sublet any portion of the licensed premises. This provision is reasonably necessary for the Department to carry out its mandate to license the individuals and premises involved in cannabis manufacturing.

Adopt Section 40178. Material Change Request. This section requires the licensee to submit to the Department any changes to the application information through a “Material Change Request.” The use of a Material Change Request, rather than a full new application, will ease the administrative burden on the licensee and the Department, but still provide the information the Department needs to enforce the Act.

Subsection (a) requires a licensee to immediately notify the Department of any change in the information contained in the application for licensure filed with the

Department. This provision is necessary in order to clarify that licensees must keep its application information current with the Department and is reasonably necessary to enable the Department to monitor changes to a licensee's operations that may have an impact on compliance with the Act.

Subsection (b) specifies those circumstances under which the Department would consider a "material change" to the license information and for which a material change request must be submitted to the Department. This provision is reasonably necessary to provide clarity to the regulated public.

Paragraph (1) requires a licensee to report a change in an owner to the Department via a material change request and requires the new owner to complete an owner form, and to submit his or her fingerprints to the Department of Justice (DOJ). Submission of a material change request and owner form is reasonably necessary to ensure that new owners are qualified for licensure in accordance with the Act. Submission of fingerprints to DOJ is a statutory requirement under section 19322(a)(A) of the Business and Professions Code. This subparagraph further specifies that the Department may deny a change of owner if the proposed owner meets the qualifications for denial as previously described. This provision reasonably is necessary in order to provide clarity to the regulated public.

Paragraph (2) requires a licensee to seek authorization for additional extraction methods, infusion processes, or the manufacture of additional products by submitting a material change request to the Department. This paragraph also requires approval of the request by the Department prior to the conducting the new operations by the licensee. This approach is reasonably necessary to ensure that all new manufacturing processes and products comply with the requirements under the Act.

Subsection (c) specifies the circumstances in which a material change request *cannot* be submitted to the Department and which, instead, would require a new license application to be submitted by the licensee. This provision is reasonably necessary in order to provide clarity to the regulated public.

Paragraph (1) requires a new application to be submitted when there is a change in the license applicant. This provision is reasonably necessary to establish that the applicant meets the requirements for licensure under the Act prior to commencing operations.

Paragraph (2) requires licensees to submit a new application in the event of a relocation of the licensed premises. This provision is reasonably necessary to implement the statutory requirement that each premises be separately licensed.<sup>8</sup> This provision is further necessary to ensure that the new premises meets the manufacturing standards required under the Act.

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<sup>8</sup> Business and Professions Code section 19320, subdivision (c).

Adopt Section 40180. License Renewal. The purpose of this section is to establish the annual license renewal process in order to make specific the Department's obligation under Business and Professions Code section 19350(a) to establish a licensing scheme with an annual renewal fee.

Subsection (a) establishes that a licensee must submit a renewal application to the Department at least 30 calendar days prior to the expiration date of the licensee's existing license. This provision is necessary to ensure that the Department has sufficient time to review and process the renewal application prior to the expiration of the current license. This subsection also establishes that the Department will not accept renewal applications more than 60 days in advance of the expiration date. This restriction is necessary to ensure that the renewal application contains up-to-date and accurate information about the licensee and premises.

Subsection (b) establishes that a licensee may continue operations until the Department takes action on the renewal application, if the application has been submitted in a timely manner (prior to the expiration of the current license). The Act prohibits any person from engaging in commercial cannabis activity without a valid license. However, the time needed by the Department to process and review renewal applications is yet unknown and may vary according to the scale of the operation and whether any significant proposed operational changes are included in the application. Allowing continued operations during review of a renewal application mirrors the provision in Business and Professions Code section 19321(b).<sup>9</sup> This provision is necessary to carry out the Department's mandate to license manufacturers of cannabis products.

Subsection (c) provides that a late fee of \$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 reasonably necessary to provide deterrence from untimely submission of renewal applications, which impedes the Department's processing of applications.

Subsection (d) provides that a licensed manufacturer that fails to submit a renewal application within 30 days after the expiration of their license is no longer eligible to renew the existing license and must instead apply for a new license. Commercial cannabis activity can only occur between holders of a valid license. It is reasonable to establish a date by which an expired license is no longer valid and therefore not eligible for renewal. Between the time the licensee is eligible to submit the renewal application and the time provided after the expiration date, the licensee will have 90 days to submit a renewal application, a sufficient amount of time to provide the information the Department is requesting (see subsection (e) below).

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<sup>9</sup> Under this section of the Business and Professions Code, any business in operation as of January 1, 2018, may continue to operate until the licensing authority takes action on the business' application for licensure. This provision was included in the statute to prevent cessation of all commercial medical cannabis activity between the effective date of the regulations developed by the licensing authorities and the date licenses have actually begun to be issued.

Subsections (e), (f), and (g) specify the procedure by which a licensee must apply for a renewal application. Licensees and owners must submit any updates to the information provided in the previous application and sign the form under penalty of perjury. These subsections further specify that any applicant or owner that has previously submitted fingerprint images to the DOJ does not need to submit images again. This provision is necessary to clarify the process of applying for a renewal.

### **III. Add Subchapter 3: Requirements of Operation**

#### Add Article 1: Safety and Security

Adopt Section 40200. Security Plan. This section establishes the requirements that each licensee must include in a security plan for their manufacturing facility. The Act requires applicants for licensure to submit security protocols as required by the licensing authority<sup>10</sup> and requires the Department to establish minimum security requirements for the storage of medical cannabis products at the manufacturing site.<sup>11</sup> The Cole memo further establishes the priority of the prevention of diversion of cannabis products. Adequate security measures are a necessary component of preventing diversion.

Subsection (a) requires the security plan to include a description of the security measures taken to prevent access to the manufacturing premises by unauthorized personnel and to protect the physical safety of employees. This provision is reasonable necessary because the presence of cannabis or cannabis products at a manufacturing premises creates a risk of theft. Additionally, the cannabis industry is heavily cash-based, which creates further risk of theft. In order to protect the physical safety of employees and the integrity of the manufacturing process, it is necessary that manufacturers establish security procedures. In order to meet its responsibility under the Act (which requires the establishment of security protocols) and to accomplish the goals of the Cole Memo, it is reasonably necessary for the Department to require the following elements to be included in the security plan: Paragraph (1): physical barriers to secure perimeter access and all points of entry. Physical barriers can include fencing, locks, or other means of preventing entry.

Paragraph (2): security alarm system capable of alerting personnel to security breaches.

Paragraph (3): an identification and sign-in procedure for authorized personnel, suppliers, or visitors. This will help keep track of who is located onsite and if the person is authorized to be there.

Paragraph (4): maintaining the premises so that visibility and monitoring of the premises is possible. This requirement will ensure that there are fewer places for unauthorized persons to hide.

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<sup>10</sup> Business and Professions Code section 19322, subdivision (b)(6).

<sup>11</sup> Business and Professions Code section 19344, subdivision (c).

Paragraph (5): procedures for investigation of suspicious activities. This is intended to ensure that the licensee follows up on suspicious activities in a systematic manner.

Subsection (b) requires the security plan to include a description of the security measures taken to prevent against theft or diversion of cannabis and cannabis products. Similar to subsection (a), above, this provision is reasonably necessary so that the Department may comply with its responsibility to establish security protocols under the Act and to accomplish the goals of the Cole Memo. Methods to meet this requirement must include:

Paragraph (1): establishing an inventory system. An inventory control system is necessary so that the licensee may ensure accurate accounting of the location and quantity of the operation's cannabis or cannabis products.

Paragraph (2): limit access of personnel within the premises to only those areas necessary to complete job duties, and to only those time periods scheduled for completion of such duties. This provision is necessary to ensure that no personnel have unknown access to cannabis or cannabis products, reducing the opportunity for theft.

Paragraph (3): supervising tasks with high potential for diversion in order to reduce the potential for theft.

Paragraph (4): providing designated areas in which personnel may store and access personal items, particularly purses, bags, or other receptacles that may be used in the theft of cannabis and cannabis products.

Subsection (c) requires the plan to include the methods to electronically secure, back up, and control access to all electronic records. Electronic records can provide information that can be used to gain access to the premises or identify vulnerabilities in the security system. This provision is reasonable necessary to protect the safety of personnel and the facility.

Adopt Section 40205. Video Surveillance. This section sets forth the minimum requirements for video surveillance system placement, technical requirements and record retention regulations that the Department considers reasonably necessary in order to provide security for the storage of cannabis products on a manufacturing premises in order to protect against instances of diversion. This is a statutory provision. (Bus. & Prof. Code §19334, subd.(c).)

Subsection (a) requires licensed premises to have a complete digital video surveillance system with a minimum camera resolution of 1280 x 1024 pixels, capable of recording in any lighting conditions. This requirement is reasonably necessary to ensure that the surveillance system's cameras produce clear images

regardless of the time of day or lighting conditions that might otherwise inhibit camera function. This provision is reasonably necessary to allow for the clear and certain identification of any person and activities in all areas required in this section in order to protect against the diversion of cannabis products. Business and Professions Code section 19334(c) requires the Department to establish minimum security requirements for the storage of medical cannabis products at the manufacturing site. The lowest resolution in the megapixel range in the security surveillance market is around 1.3 megapixels, which provides 1280 x 1024 pixel resolution (or 1.3 million pixels).

Subsection (b) requires that the surveillance system be capable of being accessed remotely by the licensee. In order to most effectively track activities on the premises, it is necessary that licensees be able to monitor activities on the premises remotely.

Subsection (c) requires that all video surveillance cameras be installed in a manner that prevents them from being intentionally obstructed, tampered with or disabled, to the extent reasonably possible. This provision is reasonably necessary to ensure that camera placement is done in way to maximize the video surveillance system's purpose.

Subsection (d)(1) through (d)(6) requires video surveillance of specific areas on the premises where medical cannabis or medical cannabis products are weighed, packed, stored, quarantined, loaded, and unloaded for transportation, prepared, or moved within the premises. These requirements are reasonably necessary to monitor activities where there might be an opportunity for diversion.

Subsection (e) requires the surveillance system be capable of continuous 24 hour recording at a minimum of 20 frames per second. The standard capture rate for video is 30 frames per second. This provision is reasonably necessary to ensure that the video surveillance system is able to capture a video stream of high enough quality to be effective.

Subsection (f) requires that all recording and monitoring equipment be stored in a secure room or area of the premises so that access is controlled. This provision is reasonably necessary to ensure that recording and monitoring equipment is not tampered with.

Subsection (g) requires that all surveillance recordings be kept for a minimum of 30 days on the licensee's recording device. This provision is reasonably necessary to allow for review by the Department and/or the licensee.

Subsection (h) provides the licensee notice that all video surveillance recordings are subject to inspection by the Department and that copies of any video surveillance recording be provided to the Department upon request. This provision is reasonably

necessary to protect against instances of diversions, and to allow the Department to inspect any video surveillance recordings for enforcement purposes.

Subsection (i) requires that video recording equipment to include date and time generators which display the current date and time of recorded events. This provision is reasonably necessary to verify the time and date that the recorded event took place in the case of an investigation.

### Add Article 2: Extractions

Adopt Section 40220. Permissible Extractions to describe the types of extraction methods permissible in California. This provision is reasonably necessary to provide clarity to the regulated public, establish the rules and regulations necessary for the Department to administer the Act, and to make specific any details involved in extraction methods that the regulated public must comply with and/or that pose a threat to public health and safety. Protecting public health and safety is a statutory requirement. (Bus. & Prof. Code §19303.)

Subsection (a) - Based on information collected during the pre-regulatory meetings, the Department has established the following general categories of extraction types: mechanical/solvent-less extractions, chemical extractions with nonvolatile solvents, chemical extractions with volatile solvents, and chemical extraction using supercritical CO<sub>2</sub>. These categories represent the existing methods of extraction to the best of the Department's knowledge.

Paragraph (1) allows mechanical or solvent-less extraction methods such as screens or presses. Mechanical extractions pose little safety risk to personnel, so there is no need at this time to impose additional requirements on mechanical extraction methods. This provision is reasonably necessary in order to make explicit that mechanical extraction methods are permissible in California.

Paragraph (2) allows chemical extractions using a nonvolatile solvent. This subsection also establishes the requirement that non-hydrocarbon-based solvents be food-grade. Nonhydrocarbon-based solvents primarily include various types of fats and oils, such as butter or olive oil. Because some solvent residue may remain in a cannabis product after the extraction process is complete, requiring the use of food-grade solvents is necessary in order to ensure that the product is safe to consume. This provision is intended to clarify the requirements of a nonvolatile solvent and is necessary to implement the Department's mandate to set standards for manufacturing activities.

Paragraph (3) allows CO<sub>2</sub> extractions and Paragraph (4) allows for the use of volatile solvent extractions. Both types of extractions are required to be conducted in a professional closed loop system designed to recover the solvent used. This provision is reasonably necessary to protect public health and safety. If a closed loop system is not used, volatile solvent vapors can collect in the air, posing a serious risk of fire or explosion if a spark is applied. Similarly, CO<sub>2</sub> can also build in

the air, posing a risk of asphyxiation to personnel. Without the use of a closed system, the residual solvent represents a safety risk for the facility operators and a potential health risk for consumers. Specific requirements of the closed loop system are included in Section 40226 of these regulations (below).

Subsection (b) allows an applicant or licensee to request approval from the Department to use other extraction methods, provided that the applicant or licensee submits a detailed description of the extraction methods, including any documentation that validates the method and any safety precautions to be used to mitigate any risk to public or worker safety or health. Although the methods allowed in subsection (a) represent the existing methods of extraction to the best of the Department's knowledge, additional extraction methods are likely to be developed. This subsection will allow an applicant or licensee to use other methods, provided that they can establish the safety of the method and is reasonably necessary to provide for public health and safety should additional extraction methods be developed.

Adopt Section 40222. Volatile Solvent Extractions to specify the requirements for manufacturers using volatile solvents for extractions.

Subsection (a) requires that hydrocarbon-based solvents be of at least 99% purity. Otherwise, the solvent may contain impurities that could be harmful for human consumption. This provision is necessary to protect the health of consumers.

Subsection (b) requires volatile solvent extractions to be conducted in a closed loop extraction system that meets the requirements specified in Section 40225. A volatile solvent can form a significant concentration of vapor. If that vapor is flammable, a fire or explosion can result. A closed loop extraction system reduces the risk of fire or explosion by recapturing the solvent so that the vapor does not build up. The requirements of a closed loop system are further described below. This provision is reasonably necessary to protect the safety of facility personnel and/or any members of the public in the vicinity of the manufacturing operation.

Adopt Section 40225. Closed-Loop Extraction System Requirements to establish specific requirements for closed-loop systems for volatile solvent and CO2 extractions. This provision is necessary because volatile solvents and CO2 pose a public safety risk. Volatile solvents can build up vapor, leading to a risk of fire or explosion. CO2 can also build up, posing a risk of asphyxiation to personnel and bystanders. Closed loop systems are designed to mitigate these risks. The following provisions are necessary in order to ensure that closed-loop systems comply with established safety standards in order to protect the public in accordance with the Act.

Subsection (a) requires the system to be commercially manufactured and bear a permanently affixed and visible serial number. This provision is necessary to ensure that the system has been commercially manufactured and built to accepted industry

codes intended to protect operator safety.

This subsection further requires a licensed engineer to certify that the system was commercially manufactured, is safe for its intended use, and is built to codes of recognized and generally accepted good engineering practices as specified by the American Society of Mechanical Engineers, American National Standards Institute, Underwriter's Laboratory, or the American Society for Testing and Materials. These organizations are widely accepted as preeminent experts on engineering practices. This provision is necessary because the Department does not have the required engineering expertise to know if a system is built to all applicable standards for safe operation. The Department must therefore rely on the expertise of licensed professional engineers capable of evaluating the system to ensure public safety. This provision is necessary to protect personnel safety.

Subsection (b) requires that the closed-loop system, any other equipment used, the extraction operation, and the facility are approved for use by the local fire code official and meet any required fire, safety, and building code requirements.

Paragraphs (1) – (4) of this subsection specify the standards and codes to be considered – the National Fire Protection Association, International Building Code, International Fire Code, or other applicable fire, safety, and building codes. This provision is necessary because the Department does not have the required expertise to know if a system is built to all applicable standards for safe operation. The Department must therefore rely on the expertise of fire officials capable of evaluating the system to ensure public safety. The local fire code official has the knowledge and training to properly assess the safety of the system in its entirety. This provision is necessary to protect personnel safety.

Add Article 3. Good Manufacturing Practices. This provision requires the establishment of GMPs in order to ensure the protection of the public in accordance with the priority mandated to the Department by statute for activities related to and associated with the manufacturing of medical cannabis.<sup>12</sup> Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates which may be subsequently used to produce edible cannabis products (Bus. & Prof. Code §19300.5(ac)). While the Act specifically defines cannabis products as neither a food nor a drug, edible cannabis products are typically made of conventional food products infused with cannabinoids and are intended to be consumed. Excepting the cannabis or cannabinoid component, edible cannabis products are made of the same ingredients as food products, are produced using the same manufacturing processes as food products, and are consumed and taken into the body for a physiological purpose, in the same manner as 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 apply to cannabis products.

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<sup>12</sup> Business and Professions Code section 19303.

The USFDA regulates the production of food, drugs, and dietary supplements within the United States through GMPs specified in the Code of Federal Regulations (21 C.F.R. §§117 and 210-211). Food and drug industries outside the United States are similarly required to adhere to the USFDA's GMPs in order to import products into the United States. Numerous other countries require the use of GMPs during food and drug manufacturing, and practices intended to protect the safety of the final product through sanitary manufacturing procedures are a commonly accepted standard in food, drug, and dietary supplement manufacturing.

Dietary supplement industries in the United States also have GMPs (21 C.F.R. 111). Dietary supplements are most similar to cannabis products in that the intended physiological effect of such products is not related to nutrition such as food, and not for treating a medical condition, like a drug. Additionally, dietary supplements lack the safety data and physiological evidence available for food and drugs, making such supplements similar to cannabis products for the purposes of regulation. Given the similarities in the use, manufacturing, and risks associated between food/dietary supplements and edible cannabis products, it is reasonable that the GMPs necessary to ensure production of safe food and dietary supplements are also necessary to ensure production of safe cannabis products. Establishing such GMPs in this regulation is therefore necessary in order to establish a reasonable regulatory standard, to protect the public, and to carry out the intent of Business and Professions Code sections 19302.1(f), 19303, and 19347.6.

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 came up 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, so that most of the product batch may be sold and used, rather than destroyed in testing. Instead of relying only on testing or evidence of harm to public health to identify adulterated products, the GMPs established in this provision are 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 has a significant impact on increasing product safety and protecting public health from the harms of using or consuming adulterated products.

The following hazards/contaminants intended to be controlled or prevented through established food and dietary supplement GMPs include:

- Microbial contaminants. Microbial contaminants include bacteria such as *Listeria*, which is among the leading cause of death in foodborne illness; viruses such as Hepatitis A, the cause of liver disease; and fungi such as *Aspergillus flavus* and *A. parasiticus*, which can be found on common agricultural commodities such as corn and is the source of aflatoxin, which can cause cancer. Microbes are of special concern due to their ability to persist and multiply under a range of conditions and on minimal nutrient resources. A 1999 study of foodborne illnesses in the United States, utilized by the World Health Organization (WHO) to compile their estimates of the global burden of foodborne diseases, concluded that “foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year . . . [and] three [microbial] pathogens [alone], Salmonella, Listeria, and Toxoplasma, are responsible for 1,500 of [those] deaths . . . .”<sup>13</sup> The Bad Bug Book, a handbook compiled by the USFDA, reviews the current information known about the major agents that cause foodborne illness, and list 27 pathogenic bacteria, each with the potential to cause illness and/or death.<sup>14</sup> This provision is reasonably necessary to ensure that the presence and quantity of microbes in manufactured products are controlled so as to safeguard public health.
- Chemical contaminants. Chemical contaminants include pesticides, arsenic, and acrylamide. These chemicals have the potential to cause short term illness, such as the nausea and vomiting induced by many pesticides, to long term illness such as cancer that are associated with the consumption of arsenic and acrylamide. Often times these chemicals fulfill a reasonable purpose at a manufacturing facility; however, in order to avoid contamination of products manufactured in the facility, it is necessary that their use and storage be controlled.

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<sup>13</sup> Mead et al., *Food Related Illness and Death in the United States* (Sept.-Oct. 1999) 5 Journal of Emerging Infectious Diseases, pages 607-625

<sup>14</sup> USFDA, *Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins* (2012).

- Physical contaminants. Physical contaminants include hard or sharp objects that have the potential to cause traumatic injury to consumers. Such injuries include the laceration and/or perforation of the tissues of the mouth, throat, and intestine. The USFDA Health Hazard Evaluation Board evaluated approximately 190 cases of food adulterated with hard or sharp foreign objects between 1972 and 1997. As a result of this evaluation, the USFDA established Compliance Policy Guidance Sec. 555.425: Foods, Adulteration Involving Hard or Sharp Foreign Objects. While some physical contaminants may be visible to the consumer, many, such as transparent broken glass, may be difficult to detect. Therefore, it is necessary that additional measures be taken in situations where physical contaminants are present, in order to protect against the adulteration of manufactured products intended for human consumption.
- Allergens. Allergens are an increasing problem in food safety in the United States. Evidence from the USFDA 2014 Reportable Food Registry, which tracks when there is a reasonable probability that an article of human food or animal food/feed (including pet food) will cause serious adverse health consequences or death, indicate that unlabeled allergens are the leading cause of recalls and of reportable FDA regulated foods. As cannabis products may also be used for medical purposes by consumers with compromised health who are therefore particularly vulnerable to an allergic reactions, allergens are of special concern to the Department. The Department therefore finds that this provision is reasonably necessary in order to protect the public in accordance with Business and Professions Code section 19303.
- Other substances. Any other substance or material that has the potential to carry or harbor the above items, such as bodily fluids, dust, and pests. This provision is reasonably necessary in order to prevent contamination of cannabis products and to protect the public in accordance with Business and Professions Code section 19303. The specific hazards of the above-mentioned substances are outlined below. Bodily fluids, such as saliva and nasal discharge have the potential to carry infectious particles for various infectious diseases. Therefore, measures must be taken to prevent contaminating cannabis products meant for public consumption.

According to the WHO, dust may contain microbial hazards such as fungal spores, chemical hazards such as pesticides, physical hazards such as asbestos, and allergen hazards.<sup>15</sup> The introduction of dust into manufactured products may contaminate cannabis products and negatively impact public health. Therefore, reasonable measures must be taken to protect cannabis products from dust-related contaminants.

Pests include rodents and insects. The Center for Disease Control (CDC) currently maintains a webpage that discusses diseases directly transmitted by

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<sup>15</sup> World Health Organization , Hazard prevention and control in the work environment: Airborne dust (August 1999).

rodents (<https://www.cdc.gov/rodents/diseases/direct.html>). Insects may also play a major role in the spread of disease. In regards to foodborne pathogens, insects such as house flies carry pathogens such as *Salmonella* and *Listeria*,<sup>16</sup> while cockroaches carry pathogens responsible for a plethora of human diseases including those that cause dysentery, food poisoning, and typhoid fever.<sup>17</sup> Additionally, insects have a role as indicators of unsanitary conditions, for example, ants and weevils.<sup>18</sup> Manufactured products that are infested or have come in contact with pests are considered adulterated and, due to potential disease transmission, are not safe for use or consumption by the public.

In addition to ensuring that the presence and quantity of microbes in manufactured products are controlled so as to safeguard public health, 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 reasonably 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.<sup>19</sup>

This article and its sections are necessary to protect public health and safety by establishing good manufacturing practice requirements for producing safe and clean cannabis products.

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<sup>16</sup> Pava-Ripoll et al., *Detection of Foodborne Bacterial Pathogens from Individual Filth Flies* (Feb. 13, 2015) *Journal of Visualized Experiments* .

<sup>17</sup> World Health Organization, *Cockroaches: Their biology, distribution and control* (1999).

<sup>18</sup> United States Food and Drug Administration, *Compliance Policy Guidance: Filth from Insects, Rodents, and other Pests in Foods* (Last updated: Nov. 14, 2002).

<sup>19</sup> 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

The USFDA GMPs for food and dietary supplements are already used by the Department for ensuring food and dietary supplement safety in California. The USFDA GMP has a long record of establishing requirements and guidelines that are effective in protecting public health. For example, the North America region which includes the United States and Canada, reported the lowest total median rates of foodborne Disability Adjusted Life Years (sum of: number of years lost due to death + number of years lived with disability) of all global regions in 2010, according to the WHO (estimates of the global burden of foodborne diseases: foodborne disease burden epidemiology reference group 2007-2015. Page 78). This suggests that the USFDA has effective measures in place to prevent and control foodborne diseases. The USFDA GMPs for food and dietary supplements address common areas where each of the hazards discussed here can be prevented in order to protect product safety and the health of the public. Provisions in this regulation taken from the USFDA GMPs for food and dietary supplements are cited in the body of the text. To ensure compliance with all GMP requirements, written SOPs must be developed and implemented for all the following GMP sections. This is necessary to provide a means for verification of compliance, ensure inclusion of GMPs-based SOP information in the training program, and provides documentation for corrective and inspection purposes. This article and the following sections are necessary to protect public health and safety by establishing good manufacturing practice requirements for producing safe and clean cannabis products.

Adopt Section 40232. Requirements for Personnel. This section is adopted to require that the manufacturing licensee establish and implement written hygiene standards for all personnel at a licensed premise in order to address the issues of disease control and cleanliness described in subsections (a) and (b), below. As personnel are involved at all levels of cannabis and cannabis product manufacturing, their personal hygiene practices have the potential to affect product safety and quality and to impact public health. In order to protect the public and ensure compliance with sections 19302.1(f), 19322(b)(5), and 19347.6(a)(1) of the Business and Professions Code, the Department must establish personnel hygiene standards to address potential harm to product safety and/or to members of the public. These provisions are based upon USFDA GMPs included in 21 C.F.R. §§117.130, 111.8 and 111.10. These same requirements are used by the Department's Food and Drug Branch to ensure personnel hygiene for all food and dietary supplement manufacturers in California. The following hygienic requirements for personnel are necessary in order to prevent contamination of cannabis products by personnel. Contamination may result in adulterated cannabis products that pose harm to public health through severe injury and illness in consumers.

Subsection (a) Disease control. This subsection requires that personnel suffering from illness or an infected wound be excluded from any operations which may result in contamination of cannabis products, product-surfaces, or product packaging due to contact with such personnel. This is a standard practice under the USFDA (21 C.F.R. §§117.10(a) and 111.10(a)) and is necessary in order to protect against product contamination of cannabis products as a result of ill or infected personnel.

This subsection further provides that personnel with infected wounds may continue to work provided their wound is properly covered with an impermeable bandage. This requirement is necessary in order to prevent personnel capable of transmitting diseases from coming in contact with and contaminating cannabis products via an improperly covered wound.

Subsection (b) Cleanliness. This subsection requires the establishment of policies and procedures for personnel working in direct contact with cannabis products, and specifies the hygienic practices such personnel must adopt in order to protect against product contamination and allergen cross-contact in accordance with established USFDA GMPs. (21 C.F.R. §§117.10(b) and 111.10(b).) This provision, further detailed in the paragraphs (1)-(9), below, is necessary in order to make specific the practices for maintaining personnel cleanliness required by this regulatory proposal. The following paragraphs provide guidance and examples on the common methods of maintaining personnel cleanliness:

Paragraph (1): Requires personnel to wear appropriate outer garments in a manner that protects against allergen cross-contact and against the contamination of cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials. As clothing can easily be a source of contamination, this provision is reasonably necessary in order to control the potential transfer of contaminants in the facility via the clothing worn by personnel. Proper outer garments include garments made of materials that can be easily cleaned, and that do not attract filth, contaminants, or allergens. Such garments may also include appropriate shoe covers in order to prevent transfer of materials on shoes and/or soles as personnel move about the facility. The wearing of appropriate outer garments is based on USFDA regulations 21 C.F.R. §§117.10(b)(1) and 111.10(b)(1).

Paragraph (2): Requires personnel to maintain adequate personal cleanliness. If personnel do not maintain personal cleanliness, they may pose a source of contamination and/or make a contamination event more difficult to recognize. For example, a person wearing outer garments suitable for the operation he or she is engaged in (e.g. a lab coat), must also maintain the lab coat in a clean and sanitary condition. This requirement is necessary in order to prevent personnel from becoming a source of contamination to cannabis products and is based on USFDA regulations 21 C.F.R. §§117.10(b)(2) and 111.10(b)(2).

Paragraph (3): Requires personnel to wash their hands thoroughly before starting work, after each absence from the work station, and at any time when the hands may have become soiled or contaminated. Maintaining clean hands decreases the risk of contaminating products during the handling of manufacturing materials and/or equipment and is based on USFDA regulations 21 C.F.R. §§117.10(b)(3) and 111.10(b)(3).

Paragraph (4): Requires that personnel remove all unsecured jewelry or other objects that might fall into products, equipment, or containers during manufacturing. This is an accepted GMP under USFDA regulations. (21 C.F.R. §§117.10(b)(4) and 111.10(b)(4).) Unsecured jewelry and similar objects may pose a source of contamination and/or act as foreign object causing harm to the consumer if intentionally or accidentally incorporated into a cannabis product. This provision is reasonably necessary in order to prevent jewelry and other objects worn by the personnel from being a source of contaminants and/or hazards in the cannabis product, and to specify that such jewelry and/or objects are only allowed to be worn in conjunction with an intact and sanitary covering adequate to protect the jewelry and/or object from coming in contact with cannabis products.

Paragraph (5): Requires personnel to maintain any gloves worn in the handling of cannabis products in an intact, clean, and sanitary condition. This is a GMP under USFDA regulations. (21 C.F.R. §§117.10(b)(5) and 111.10(b)(5).) Gloves are used during manufacturing to ensure the clean and sanitary handling of products and product materials during production. If gloves are not intact, clean and sanitary, they no longer fulfill their function of protecting products from contamination. This requirement is therefore necessary to ensure that the use of gloves by personnel is effective in preventing adulteration of cannabis products during handling.

Paragraph (6): Requires personnel to wear hair nets, headbands, beard covers, or other appropriate hair restraints. This is a GMP under USFDA regulations (21 C.F.R. §§117.10(b)(6) and 111.10(b)(6)) and is reasonably necessary to ensure that the use of hair restraints is effective in preventing adulteration of cannabis products with hair from personnel. Hair is considered a physical contamination if incorporated into a product and contamination of cannabis products with unclean hair may also introduce microorganisms that negatively affect the safety of the cannabis product. If personnel have hair that is likely to fall into the product, effective use of hair restraints is necessary in order to prevent contamination of the product with hair.

Paragraph (7): Requires personnel to store their clothing or other personal belongings in areas other than where cannabis products are exposed or where equipment or utensils are washed. As personnel clothing and personal belongings, such as raincoats and wallets, may not be maintained in an adequately clean and sanitary condition, these items should be kept in an area of the facility where it does not pose a risk of contaminating cannabis products or cannabis product contact surfaces, including equipment and utensils. This requirement is based on similar GMPs established by the USFDA for the protection of food-related product safety (21 C.F.R. §§117.10(b)(7) and 111.10(b)(7)), and is necessary to prevent adulteration of cannabis products with personal belongings from personnel.

Paragraph (8): Requires personnel to confine the eating food, chewing of gum, drinking of beverages, or tobacco use to areas of the manufacturing facility separate from those where cannabis products may be exposed or where equipment or

utensils are washed. These activities may increase the chances of introducing contaminants into cannabis products or onto contact surfaces via the transfer of saliva and/or food, drink, or tobacco-related components. These components may increase the spoilage of cannabis products with which they come into contact or act as a physical hazard or allergen in the finished product. This requirement is a GMP under USFDA regulations (21 C.F.R. §§117.10(b)(8) and 111.10(b)(8)), and is necessary to prevent personnel from contaminating cannabis products, equipment, and utensils with saliva, food, chewing gum, beverages or tobacco products.

Paragraph (9): Requires personnel to take any other necessary precautions to protect against allergen cross-contact and against contamination with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin). This is a GMP under USFDA regulations. (21 C.F.R. §§117.10(b)(9) and 111.10(b)(9).) Microorganisms and other foreign substances may pose an allergen risk to consumers if incorporated into a cannabis product. Thus depending on the situation, the licensee has the responsibility to ensure that any personnel with the potential to introduce any such substances into cannabis products take measures to prevent such contamination. This requirement is necessary to ensure that the licensee undertake whatever precautions are necessary, specific to each personnel and his/her duties, to prevent adulteration of cannabis products.

Adopt Section 40234. Grounds. This section is adopted to require the manufacturing licensee to establish and implement written procedures to ensure that the grounds of the premises controlled by the licensee are kept in a condition that prevents the contamination of components and cannabis products. This provision further specifies the minimum standards that shall be adopted for adequate maintenance of the grounds immediately surrounding the manufacturing facility or plant. The proximity to the manufacturing facility and the necessity of accessing this area by personnel on a routine basis means that the presence of contaminants and pests on the nearby grounds presents a source of hazards that may enter, or be transferred into the manufacturing facility and result in adulteration of cannabis products. Therefore, the condition of the grounds immediately surrounding the manufacturing facility or plant has the potential to affect product safety and quality and impact public health. In order to protect the public and ensure compliance with sections 19302.1(f) and 19347.6(a)(1) of the Act, the Department must establish maintenance standards for the grounds immediately surrounding the manufacturing facility to address potential harm to product safety, quality, and/or to members of the public. As this regulation includes oversight of edible cannabis products, the following requirements are based on GMPs established by USFDA regulations which represent accepted standards for ground maintenance for manufacturing of food and dietary supplements (21 C.F.R. §§117.20(a) and 111.15(a)). These same requirements are used by the Department's Food and Drug Branch to ensure maintenance of manufacturing grounds for all food and dietary supplement manufacturers in California. These requirements are necessary to ensure that the grounds immediately surrounding the manufacturing facility are not a source of pests

and hazards that may be brought into the manufacturing facility and contaminate cannabis products. Contamination results in adulterated cannabis products that may harm public health by causing severe injury and illness in consumers.

Subsection (a) requires the licensee to properly store equipment, remove litter and waste, and cut weeds or grass that may attract, harbor, or breed pests within the immediate vicinity of the cannabis manufacturing facility. Making the grounds immediately surrounding the facility unattractive for pests reduces the amount of pests that may enter the facility due to proximity. This provision is based on USFDA regulations 21 C.F.R. §§117.20(a)(1) and 111.15(a)(1), and is reasonably necessary to control the amount of pests near the manufacturing facility that may result in the contamination of cannabis products and the rendering of such products unsafe for public health.

Subsection (b) requires the licensee to maintain roads, yards, and parking lots so that these areas do not constitute sources of contamination. This provision is reasonably necessary to reduce the amount of contaminants that may proliferate in the above-named areas and that could then be introduced into the facility, contaminating the cannabis products within. This provision is also necessary to reduce incidents of personnel coming in contact with contaminants such as dust, dirt, chemicals, or pests before entering the facility. For example, a concrete road covered with dirt and dust that is adjacent to a manufacturing facility may be a source of dirt and dust contaminants entering the facility, either by personnel carrying dirt and dust into the facility on their clothing, or by wind blowing dirt and dust into the facility when doors are opened to allow the passage of personnel. The maintenance of roads, yards, and parking lots in order to minimize contamination of products is a GMP under USFDA regulations (21 C.F.R. §§117.20(a)(2) and 111.15(a)(2)).

Subsection (c) requires the licensee to drain areas that may contribute to contamination by seepage, foot-borne filth, or that may provide breeding grounds for pests. This is a GMP under USFDA regulations. (21 C.F.R. §§117.20(a)(3) and 111.15(a)(3).) Seepage can infiltrate cracks or unsealed part of the facility, and contaminate the facility with unclean moisture. This can encourage the growth of mold, which can contaminate cannabis products and render them unsafe for the public. Liquid accumulation on facility grounds also increases the risk of personnel tracking filth such as mud and accompanying insects or microorganisms into the facility, further introducing filth that might contaminate cannabis products. Additionally, unsanitary conditions permit the proliferation of pests near the facility, as many insects (such as mosquitos) and microorganisms require moisture or a body of water in order to complete their life cycles. Liquid accumulation on facility grounds may also increase the transfer of potentially hazardous materials into the facility and allow for the proliferation of pests that may enter the facility and contaminate cannabis products. This subsection is reasonably necessary to prevent the tracking of unsanitary material into the facility, reduce the amount of pests near

the facility, and protect the public by mitigating incidents of cannabis product contamination.

Subsection (d) requires the licensee to operate waste treatment and disposal systems in such a way as to prevent sources of contamination in areas where cannabis may be exposed to such a system's waste or waste by-products. Waste and disposal systems are intended for unclean materials. If such materials are not contained or controlled by a waste or disposal system, they may contaminate anything they it came in contact with, including roads and personnel accessing the facility. Once facility grounds or personnel are contaminated with material from a waste or disposal system, the potential of transferring contamination to products greatly increases. Improperly maintained waste treatment and disposal systems may also provide an ideal environment for pest proliferation. As discussed in the above subsections of this provision, the proliferation of pests near the facility poses a threat of contamination to cannabis products. Therefore, this subsection is necessary to prevent facility waste and disposal systems from posing a threat of contamination to cannabis products. Proper maintenance of waste treatment and disposal systems is a commonly accepted GMP under USFDA regulations (21 C.F.R. §§117.20(a)(4) and 111.15(a)(4)) and is necessary to ensure the manufacture of safe and clean cannabis products un-contaminated by waste, waste disposal materials, and/or pests.

Subsection (e) requires that, if the cannabis manufacturing plant grounds are bordered by grounds outside the licensee's control which are not maintained in the manner described in subsections (a) through (d) of this section, inspection, extermination, and other reasonable care shall be exercised within the cannabis manufacturing plant in order to eliminate any pests, dirt, and/or filth that pose a source of cannabis product contamination. This requirement is based GMPs under USFDA regulations (21 C.F.R. §§117.20(a)(5) 111.15(a)(5)), and is necessary to ensure that, if nearby grounds are beyond the control of the licensee and cannot be maintained as required, the licensee is aware of their responsibility to take measures ensuring pests, dirt, and filth that might be present in the bordering grounds be prevented from entering the facility. For reasons discussed in subsections (a)-(d), above, this provision is reasonably necessary in order to protect against the contamination of cannabis products.

Adopt Section 40236. Facility Construction and Design. This section is adopted to establish minimum requirements of construction and design for cannabis manufacturing facilities in order to facilitate cleaning, maintenance, and manufacturing operations that protect public health and safety. The construction and design of a manufacturing facility physically affects the activities that take place within the facility and has the potential to affect product safety and quality and to impact public health. In order to protect the public and ensure compliance with Business and Professions Code sections 19302.1(f), 19347.6(a)(1) and 19347.6(a)(6) of the Act, the Department must establish facility construction and design standards to address potential harm to product safety, quality

and/or members of the public. As this regulation includes oversight of edible cannabis products, the following requirements are based on GMPs established by the USFDA regulations which represent accepted standards for facility design and construction for the manufacturing of safe food and dietary supplements (21 C.F.R. §§117.20(b) and 111.20). These same requirements are used by the Department's Food and Drug Branch to ensure facility construction and design is suitable for the intended purposes for all food and dietary supplement manufacturers in California. For example, a manufacturer that intends to wash equipment must have be able to direct runoff to a drain, and a floor constructed of materials capable of withstanding the cleaning agents used. If standing water and crevices in the floor cannot be easily cleaned, this may create conditions that encourage the growth of microorganisms, which may, in turn, be introduced into the cannabis product during processing and render that product contaminated and unsafe for public health. The following subsections clarify the minimum requirements of facility construction and design needed to make the facility suitable for manufacturing safe products. These requirements are necessary to ensure products manufactured at a facility are not contaminated as a result of improper facility construction or design. Contamination may result in adulterated cannabis products that harm public health by causing severe injury and/or illness in consumers.

Subsection (a) requires that the licensee ensures that the facility provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe cannabis products. (21 C.F.R. §§117.20(b)(1) and 111.20(b)). This provision is necessary to ensure that facilities provide adequate space to allow for physical separation of operations during which allergen cross-contact or contamination is likely to occur. Adequate space is also required to prevent mix up of raw ingredients, in-process materials, finished products, and other materials. This provision also necessary to ensure that the space and placement of equipment be such that personnel performing cleaning activities can easily access the area around fixed equipment in order to effectively clean any spills or prevent buildup of dust. Adequate space is necessary to ensure that products manufactured at the facility are not contaminated with contaminants, unintended materials (such as raw materials in the finished product), or allergens due to inadequate space within the facility.

Subsection (b) requires the facility to have in place adequate precautions to reduce allergen cross-contact and contamination of cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials with microorganisms, chemicals, filth, and other extraneous material (21 C.F.R. §§117.20(b)(2) and 111.20(c)). These precautions allows for proper cleaning during routine maintenance and for the sanitization of areas when a contamination event has occurred. This provision is intended to control the presence and amount of contaminants that may contaminate cannabis products during manufacture. For example, ensuring that windows that open to the outside can be sealed to prevent pests, dust, or other contaminants from entering the facility and contaminating in-process material. Another example would be having doors without holes or gaps

separating rooms that house different activities to prevent drift of materials or dust from one activity, such as washing raw materials, from contaminating the activity in the other room, such as packaging finished products. This is necessary to prevent the production of contaminated cannabis products due to inadequate facility precautions.

Subsection (c) requires the construction and design of the facility to permit the taking of adequate precautions to protect product ingredients in stalled outdoor bulk vessels by any effective means (21 C.F.R. §117.20(b)(3)). Manufacturers of cannabis products may store bulk quantities of major ingredients, such as flour, in outdoor bulk vessels. These vessels are part of the facility, and must be constructed and designed to prevent exposure to contaminants and to prevent pests from accessing or proliferating in the material stored in the vessels. To achieve this, this provision provides commonly used precautions that are effective in preventing pest infestations of ingredients installed in outdoor bulk vessels, including protective coverings, maintaining nearby areas, and checking the vessels and material on a regular basis for infestation. This is necessary to ensure product safety by preventing the production of contaminated cannabis products due to use of adulterated ingredients stored in outdoor bulk vessels.

Subsection (d) requires that the floors, walls, and ceilings of a facility be constructed so that they may be cleaned and kept in good repair. This is a commonly accepted GMP under USFDA regulations (21 C.F.R. §§117.20(b)(4) and 111.20(d)(1)(i)), and is reasonably necessary in order to ensure that a facility's floors, walls, and ceilings do not promote unsanitary conditions or foster the growth of microorganisms that may contaminate cannabis products. Maintaining clean surfaces minimizes the presence and amount of contaminants in facilities and reduces the potential for cannabis products to become contaminated by filth or microorganisms sheltered or proliferating on the floor, walls, and ceilings of a facility. As discussed in section 40234, subsections (a)-(d) above, reducing instances of cannabis product contamination via microorganisms, chemicals, filth, and other extraneous material is necessary in order to protect public health.

Subsection (e) requires that a facility's fixtures, ducts, and pipes be maintained and situated in such a way as to prevent contamination of cannabis products, product contact-surfaces, or product packaging materials through drips or condensation that may be contaminated with filth from unsanitary surfaces. This provision is reasonably necessary because moisture from a facility's fixtures, ducts, or pipes may condense and drip onto cannabis products and may carry microorganisms or filth from fixture or duct surfaces that pose a threat to public health. As discussed in section 40234, subsections (a)-(d) above, reducing instances of cannabis product contamination via microorganisms, chemicals, filth, and other extraneous material is necessary in order to protect public health. Protecting the public is, furthermore, one of the primary requirements of the Department under the Act. (Bus. & Prof. Code. §19303.) This provision is based upon a commonly accepted GMP under USFDA

regulations (21 C.F.R. §§117.20(b)(4) and 111.20(d)(1)(ii)), intended to protect the public from consuming harmful food-related products.

Subsection (f) requires that a facility's aisles and working spaces are unobstructed and of a width that will allow employees to perform their duties without contaminating work surfaces or product via clothing or skin contact. Additionally, materials or equipment shall not obstruct areas or walkways in the facility for which regular access is required. This provision is a commonly accepted GMP under USFDA regulations (21 C.F.R. §§117.20(b)(4) and 111.20(d)(1)(v)) and is reasonably necessary to prevent the inadvertent transfer of harmful materials or contaminants to cannabis products by personnel moving within the facility of the cannabis product. As discussed in section 40234, subsections (a)-(d) above, reducing instances of cannabis product contamination is necessary in order to protect public health.

Subsection (g) requires that adequate lighting be available in specified areas of the manufacturing facility where components or cannabis products are examined, manufactured, processed, packed, or held, and in all areas where equipment or utensils are cleaned. Adequate lighting in a facility is an accepted GMP under USFDA regulations, (21 C.F.R. §§117.20(b)(5) and 111.20(e)) and is reasonably necessary in order to allow visual confirmation of proper cleaning, safety operations, and hazard identification a manufacturing facility. Such GMPs are necessary in order to protect public health.

Subsection (h) requires that shatter-resistant light bulbs, fixtures, skylights, and/or other shatter-resistant glass fixtures be used in all areas of a facility where glass-breakage could cause cannabis products to become contaminated with glass. This provision is necessary to ensure that glass materials will not be unintentionally introduced into cannabis products due to breakage. As lighting fixtures are likely to be in close physical proximity to processing steps to aid observation, glass breakage has the potential to introduce hard-to-detect glass material into the finished cannabis product. Therefore, measures must be taken to prevent this potential hazard. This provision is reasonably necessary to protect public safety by preventing the production of an adulterated cannabis product contaminated with broken glass.

Subsection (i) requires that ventilation or other control equipment be used as necessary within a facility to avoid allergen cross-contact or other contamination. This provision is a GMP under USFDA regulations (21 C.F.R. §§117.20(b)(6) and 111.20(d)(2)) and is reasonably necessary in order to ensure that the operation of any ventilation or equipment in the facility that manipulates air movement does not contaminate cannabis products by blowing allergens or contaminants into materials or onto areas where such contaminants might be incorporated into the product. The location and operation of fans and other air-blowing equipment must be managed to prevent the dispersion of unintended materials, and the path of the airflow must be configured so as to minimize disbursement of harmful, unsanitary or allergenic materials towards a cannabis product-contact surface or material.

Subsection (j) requires that screening or other protection be used at facilities as necessary to prevent the intrusion of pests. This provision is a GMP under USFDA regulations (21 C.F.R. §§117.20(b)(7) and 111.20(h)) and is reasonably necessary because, even if the grounds surrounding a facility do not pose a source of pests, the ability of pests to move and travel means that all facilities must have measures in place to prevent pest entry. The entry of pests (e.g. insects, rodents, birds) into a facility increases the risk of contaminating facility spaces, equipment, utensils, personnel, contact surfaces, materials, and cannabis or cannabis products with filth and pathogens. This requirement is necessary to ensure that the licensee undertakes whatever measures are necessary to prevent pests from entering the facility to protect cannabis products in the facility from contamination by pests.

Adopt Section 40238. Sanitary Operations. This section is adopted to require that licensees establish and implement written standards for sanitary operations for all activities that take place within the manufacturing facility, including activities that are incidental to manufacturing, such as the storage of pesticides used in the facility to prevent pests from contaminating cannabis products.

Because manufacturing operations have the potential to generate waste and contaminants, sanitary standards for the operation of the facility are necessary in order to protect product safety and public health. In order to comply with Business and Professions Code sections 19302.1(f), 19347.6(a)(1), 19347.6(a)(3) and 19347.6(a)(6), the Department must establish sanitary standards for facilities to address potential harm to product safety, quality and/or to members of the public. As this regulation includes oversight of edible cannabis products, the following requirements are based on GMPs under United States Food and Drug Administration (USFDA) regulations for the sanitary manufacturing of food and dietary supplements (21 C.F.R. §§111.15, 111.27, and 117.135). These same requirements are used by the Department's Food and Drug Branch to ensure the establishment and implementation of sanitary operations in the facilities of all food and dietary supplement manufacturers in California.

The following requirements are necessary to ensure that cannabis product manufacturing facilities are continuously maintained in a clean and sanitary condition in order to prevent the contamination of cannabis products that may pose harm to public health and safety. Protecting public health and safety is a primary requirement of the Act. (Bus. & Prof. Code § 19303.)

Subsection (a) requires the licensee to establish and implement written procedures in order to ensure that buildings, fixtures, and other physical aspects of the premises are routinely maintained in a clean and sanitary condition and are kept in repair adequate to prevent cannabis products from becoming adulterated. This provision is a GMP under USFDA regulations (21 C.F.R. §§111.15(b) and 117.35(a)) and is reasonably necessary to protect product safety by preventing or minimizing contaminants that may occur as a result of disrepair or unsanitary maintenance of

the manufacturing facility. For example, if the floor in the facility has a large crack in which filth may accumulate, this crack must be regularly cleaned or repaired to avoid creating an environment where microorganisms may proliferate and pose a source of microbial contamination. This provision is necessary to protect product safety by preventing or minimizing contaminants that may occur as a result of disrepair or unsanitary maintenance of the manufacturing facility.

Subsection (b) requires the licensee to establish and implement written procedures in order to ensure that the cleaning and sanitizing of utensils and equipment on the premises is conducted in a manner that protects against allergen cross-contact or contamination of cannabis products, product components, cannabis product-contact surfaces, or cannabis product-packaging materials. This provision establishes that licensees are responsible for ensuring that proper measures are taken during cleaning and sanitizing activities so that contamination does not occur. Specifically, this provision requires that the cleaning and sanitizing activities themselves do not constitute a source or method of contamination. For example, care should be taken to prevent splashing while soaping and rinsing a piece of equipment, in order to ensure that newly cleaned utensils that are ready for use in processing cannabis products are not contaminated by the soap/water mixture. Proper measures may also include covering or storing cleaned utensils in an enclosed environment in order to prevent subsequent contamination by dust or accidental contact. This provision is based on GMPs under USFDA regulations (21 C.F.R. §117.35(a)) and is necessary in order to protect cannabis products from contamination due to cleaning and sanitizing activities, or by use of soiled equipment and utensils that were believed to be clean and sanitary.

Subsection (c) requires the licensee to establish and implement written procedures for cleaning compounds and sanitizing agents, and clarifies the criteria for any toxic materials that may be used or stored in the facility.

Many cleaning compounds and sanitizing agents used at manufacturing facilities may be toxic. For example, ammonia, while considered a common household cleaner, is also a corrosive substance that can cause permanent blindness, lung disease, or death if used in high concentrations. In order to protect public health and limit the exposure of persons and products to potentially harmful compounds and/or agents this provision requires the licensee to limit the toxic compounds at their manufacturing facility to only those that are essential to specific operations and safe to use. Under this provision, cleaning compounds and sanitizing agents must also be safe to use in order to mitigate danger to facility personnel and/or to any members of the public in the immediate and/or surrounding area. Cleaning compounds and sanitizing agents that are un-safe for their intended use may degrade or damage the utensil, equipment, or surface they are applied to. (For example, ammonia can damage metal materials made with copper or zinc and pose a source of physical hazard due to corroded metal.) Cleaning compounds and sanitizing agents must be validated to successfully achieve the goal of cleaning or

sanitizing the item in question. If the use of a cleaning compound or sanitizing agent does not achieve its purpose, any contaminated contact surfaces will remain contaminated after cleaning and sanitizing, and may pose a risk of product contamination. This provision is therefore necessary to prevent contamination of cannabis products by nonessential toxic materials, use of ineffective or spoiled cleaning compounds and sanitizing agents, or by the inappropriate use of cleaning compounds and sanitizing agents in the manufacturing facility. Limiting the types of toxic materials that can be used or stored in manufacturing facilities decreases the potential that the use or storage of such materials will result in adulterated cannabis products.

Additionally, this provision specifies that cleaning compounds and sanitizing agents must be free from undesirable microorganisms. This provision is reasonably necessary in order to prevent such compounds and agents from acting as a source of microorganism contamination. (For example: if such materials have been stored for a long period of time, active ingredients preventing microbial growth may either have degraded or settled into a specific portion of the compound or agent, leaving the other portions susceptible to contamination. Such a cleaning compound or sanitizing agent would be ineffective in its intended purpose and act as a source of contamination.)

The provisions in this subsection, including those in paragraphs (1)-(3), below, are based on commonly accepted GMPs under USFDA regulations (21 C.F.R. §§111.15(c)(1) and (2), 111.27(d)(6), and 117.35(b)(1)) and are reasonably necessary in order to protect public health. Accordingly, the following paragraphs limit the toxic materials used or stored in a cannabis manufacturing facility to: Paragraph (1): Those required to maintain clean and sanitary conditions. For example: a 10% bleach solution will effectively kill most microorganisms, but is safe for humans to use with proper protective equipment. The negligible risk to human health posed by this and similar compounds is outweighed by the benefits such compounds provide in producing clean and sanitary products and manufacturing conditions. This provision is based on GMPs as described above and is reasonably necessary so that the Department may protect public health and safety.

Paragraph (2): Those necessary for plant and equipment maintenance and operation. For example: some equipment cannot operate properly without the use of specific materials that may be toxic. This includes the use of lubricants to control wear and tear, paint to prevent corrosion, hydraulic fluid for hydraulic equipment, and fuels such as butane and propane. These materials may be considered toxic if incorporated into cannabis products, but their safe and proper use is necessary in order to keep equipment running. Thus, the benefit of using such materials outweighs the risk to human health by product contamination. This provision is based on GMPs as describe above and is reasonably necessary so that the Department may protect public health and safety.

Paragraph (3): Those necessary for use in the plant's operations. As described in paragraph (2), above, some materials that may be toxic may also be required and/or necessary for plant operations. For example, cannabinoid extraction uses a variety of solvents some of which, like hexane, are toxic. With proper use of equipment and handling procedures, the potential for injury and illness may be prevented, and the benefit of using of such material is deemed to outweigh the risk to human health. This provision is based on GMPs under USFDA regulations (21 C.F.R. §§111.15(c)(2)(iv) and 117.35(b)(1)(iv)) and is reasonably necessary facility so that the Department may protect public health and safety.

Subsection (d) requires the licensee to implement and establish written procedures in order to ensure that all toxic cleaning compounds, sanitizing agents, and pesticide chemicals are identified, held, and stored in a manner that protects against contamination of product components, cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials. This provision is based on GMPs under USFDA regulations (21 C.F.R. §§111.15(c)(3) and 117.35(b)(2)) and is reasonably necessary in order to prevent harm to public health in case of the accidental use of these materials for unintended purposes. The above-mentioned materials have the potential to cause severe harm to personnel, consumers, and other members of the public, and would be a contaminant if incorporated into a cannabis product. The precautions described in this subsection are necessary in order to lower the risk of accidental/unintended use which would result in adulterated cannabis products and public health concerns.

Subsection (e) requires the licensee to implement and establish written procedures for the measures that must be taken in order to exclude pests from all areas of a cannabis manufacturing plant. This requirement is unique from the pest requirements described in the "Grounds" and "Facility Construction and Design" sections of this regulation (above), in that, under this provision, the facility is required to maintain a pest-free status. This means that, even if a facility is designed with screens to prevent pest entry, any pest found in the facility is a violation of this provision. As the situation for each facility may vary, this provision requires the licensee to determine the appropriate measures for pest exclusion in order to protect against the contamination of cannabis products. This provision further stipulates that pesticides used in the eradication of pests are only permitted in the facility under precautions and restrictions intended to protect against the contamination of cannabis products. This requirement is based on GMPs under USFDA regulations (21 C.F.R. §§111.15(d) and 117.35(c)) and is reasonably necessary in order to protect public health and safety by eliminating the presence of pests in manufacturing facilities and protecting against the contamination of cannabis products via pest and/or pesticide-related activities which may result in an adulterated cannabis products and subsequent public health concerns.

Subsection (f) requires the licensee to implement and establish written procedures to ensure that all cannabis product-contact surfaces (including utensil and equipment

surfaces) are cleaned as frequently as necessary to protect against allergen cross-contact and contamination of cannabis products. Some contact surfaces may require more frequent cleanings because their design more easily traps contaminants, while others may require fewer cleanings because they are used less frequently. This provision is based upon GMPs under USFDA regulations (21 C.F.R. §§111.27(d) and 117.35(d)), and is reasonably necessary in order to clarify that a licensee must maintain the sanitary condition of all contact surfaces in order to prevent harm to public health and safety as a result of contamination due to insufficient cleaning.

Subsection (g) requires the licensee to implement and establish written procedures to ensure that cannabis product-contact surfaces used for manufacturing/processing, packing, or holding low-moisture cannabis products remain clean, dry, and sanitary before use. Contact surfaces must be free of contaminants in order to prevent contamination of products during contact. Contact surfaces must also be dry, as wet contact surfaces can introduce moisture into products and alter their moisture content. Surfaces that remain wet after wet-cleaning may support the growth/presence of microorganisms. Therefore, when surfaces are wet-cleaned, they must be sanitized and thoroughly dried before subsequent use. Such surfaces must also be sanitized and dried in order to reduce the presence and growth of undesirable microorganisms. This requirement is based upon GMPs under USFDA regulations (21 C.F.R. §§111.27(d)(2) and 117.35(d)(1)), and is reasonably necessary in order to ensure the safety of low-moisture cannabis products and to prevent such cannabis products from becoming adulterated by proliferation of microorganisms which may pose a threat to public health.

Subsection (h) requires the licensee to implement and establish written procedures to ensure that all contact surfaces used in wet processing be cleaned and sanitized prior to use and after any interruption in manufacturing activities. As wet environments favor microorganism growth, special measures are required to prevent microorganism proliferation during wet processing. The requirement to clean and sanitize contact surfaces before use is intended to eliminate contaminants that may have accumulated on surfaces during storage or inactivity. An interruption is another event that may introduce contamination and which requires cleaning and sanitation before proceeding. During continuous production operation, contact surfaces may become contaminated or soiled, for example, by dust or accumulation of ingredient remnants. This should be cleaned to prevent introduction of contaminants into products as well as to minimize areas that might support the growth of microorganisms. The potential for microbial growth during wet-processing necessitates special attention to maintaining all contact surfaces in a clean and sanitary condition throughout the entire process. This requirement is based upon GMPs under USFDA regulations (21 C.F.R. §§111.27(d)(3) and 117.35(d)(2)), and is reasonably necessary to ensure the safety of wet-processed cannabis products for public use or consumption.

Subsection (i) requires the licensee to implement and establish written procedures to ensure that single-use articles (such as plastic silverware and disposable coffee cups or paper towels etc.) to be handled and stored in a sanitary manner. Single-service articles are often present in bulk quantities in manufacturing facilities, and are disposed of rather than cleaned after use/contamination. If not stored properly, these articles may pose a source of contamination to cannabis products, either via the article itself or because the article has been soiled in storage and then subsequently employed in production processes. Such articles must be handled correctly. For example: when grabbing a paper towel with soiled hands, care should be taken to ensure the remaining paper towels are not soiled. The disposal of such articles typically occurs when the article used is soiled or contaminated. Therefore, such articles may act as a repository of contaminants or a favorable environment for the growth of microorganisms. The disposal of such articles must therefore be conducted in such a way as to prevent the accumulation or exposure of such articles to cannabis products, contact surfaces, or packing materials. This requirement is based upon GMPs under USFDA regulations (21 C.F.R. §§111.27(d)(5) and 117.35(d)(3)), and is reasonably necessary in order to protect public health by ensuring that single-use articles do not become sources of contamination for cannabis products.

Subsection (j) requires the licensee to implement and establish written procedures to ensure that that surfaces that do not come in direct contact with cannabis or cannabis products be cleaned in a manner and as frequently as necessary to prevent contamination. Personnel engaged in processes that come in direct contact with cannabis products or contact surfaces may need to come in contact with other equipment or surfaces as part of their everyday duties. Decreasing the overall contaminants on all contact surfaces decreases the amount of contaminants that may adulterate manufactured products. This requirement is based upon GMPs under USFDA regulations (21 C.F.R. §§117.35(e) and 111.27(d)(4)), and is reasonably necessary in order to ensure that all surfaces in a manufacturing facility, including those that do not come in direct contact with cannabis products, are not a point of possible contamination for cannabis products.

Subsection (k) requires the licensee to implement and establish written procedures to ensure that portable equipment is maintained in such a manner as to prevent contamination. As proper cleaning and sanitation of portable equipment can easily be overlooked, this requirement requires portable equipment to be considered in the policies and procedures of a manufacturing operation in order to decrease incidences of contamination. This requirement is based upon GMPs under USFDA regulations (21 C.F.R. §§117.35(f) and 111.27(d)(7)), and is reasonably necessary in order to ensure that portable does not present a possible source of contamination to cannabis products.

Adopt Section 40240. Sanitary Facility and Controls. This section is adopted to require adequate sanitary accommodations within the manufacturing facility. This section is

distinct from the previous sections related to sanitary procedures in manufacturing facilities in that the requirements here involve the functional accommodations that must be made available in order to ensure sanitary conditions at facilities. These functional accommodation requirements relate to the effective cleaning and sanitation of the facility and its equipment, utensils, and personnel. Effective cleaning and sanitation of the facility, equipment, utensils, and personnel have the potential to improve product quality and safety, and thereby decrease potential negative impacts to public health. In order to protect the public and ensure compliance with Business and Professions Code sections 19302.1(f), 19322(b), 19347.6(a)(1), and 19347.6(a)(6), the Department must establish sanitary facility and control requirements to address potential harm to product quality and/or to members of the public.

As this provision includes oversight of edible cannabis products, the following requirements are based on United States Department of Food and Drug Administration regulations (USFDA) for sanitary facility and controls at manufacturing operations involving food and dietary supplements (21 C.F.R. §§117.37 and 111). These same requirements are used by the Department's Food and Drug Branch to ensure sanitary facility and controls for all food manufacturers in California. The following requirements are necessary to ensure that cannabis products produced in a manufacturing facility are not adulterated as a result of inadequate sanitary accommodations within a facility. Adulterated cannabis products may harm the public by causing severe injury and illness in consumers.

Subsection (a) Water supply. This subsection requires the water supply for licensed premises to be adequate for the operations intended and derived from an adequate source. This requirement is necessary to minimize risk of contamination of cannabis products, contact surfaces, and packaging materials by unsanitary water. This subsection further requires that running water must be available at a suitable temperature and pressure for cleaning of equipment, utensils, and employee sanitary facilities.

Subsection (b) Plumbing. This section establishes specific standards for plumbing on the licensed premises:

Paragraph (1): Requires that water must be adequately supplied throughout the premises.

Paragraph (2): Requires the premises' plumbing system be sufficient to properly convey sewage and liquid disposable waste from the facility. This requirement is reasonably necessary to prevent the accumulation of contaminants such as sewage or other liquid disposal waste on the premises, which may lead to contamination.

Paragraph (3): Requires that the premises' plumbing system must avoid constituting a source of contamination. This requirement could include the prevention of leaks or other plumbing related malfunctions that may lead to contamination. Improperly installed or maintained plumbing may increase the risk of contamination by the

transfer of contaminants via displaced water, or by the transfer of water carrying sewage or liquid disposable waste onto products, water supplies, equipment, or utensils. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Paragraph (4). Requires that the premises plumbing system provide adequate drainage in areas where floors are subject to flooding-type cleaning or where normal operations discharge or release water or other liquid onto the floor. This requirement is intended to ensure that areas where floors are flooded with water or liquid waste are equipped with adequate drainage to properly convey and remove water or liquid waste. Proper drainage prevents the accumulation of water or liquid waste that may create a hazardous situation for personnel and/or equipment, and/or act as a source of contamination of other areas of the facility. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Paragraph (5): Requires that the premises' plumbing system shall have no backflow or cross-connection between water pipes and waste pipes. This requirement is necessary in order to prevent contact between clean influent water with effluent water intended for disposal. Backflows and cross-connections between influent and effluent plumbing systems have the potential to contaminate water systems and any product manufactured using that water. This provision is necessary to adulteration in accordance with section 19347.6 of the Act.

Subsection (c) Sewage disposal. This subsection requires that sewage produced in and on the premises be disposed of via an adequate sewerage system or other appropriate means. This requirement is necessary to ensure that sewage does not accumulate in or on the licensed premises causing contamination. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (d) Toilet facilities. This subsection requires that employees have access to an adequate number of clean and readily available toilet facilities. Such provisions have been shown to minimize the need for personnel to access parts of manufacturing facilities where they do not have duties, and thus to decrease risks of contamination via contact between employees, toilet facilities, and product manufacturing surfaces and materials, including packaging materials. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (e) Hand washing facilities. This subsection requires the provision of hand-washing facilities on the licensed premises. These facilities must be of adequate number and be able to furnish running water of up to at least 100° F (30° C). This requirement is necessary in order to ensure that hand-washing facilities outside of toilet facilities are adequate, convenient, and provide running water at suitable temperatures. The availability and easy access of such facilities minimize personnel movement throughout the manufacturing plant when washing activities are required. This decreases the opportunity for personnel hands to be a source of contamination. Additionally, running water at a temperature of 100° F aids the

function of soaps and detergents to effectively solubilize and remove certain materials, such as oils on the hands of personnel that may trap soil and microorganisms. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (f) Rubbish disposal. This subsection requires that rubbish disposal on a licensed premises be handled in a manner to prevent contamination cannabis products, contact-surfaces, packaging materials, water supplies, and ground surfaces. Rubbish must be conveyed in appropriate containers that are designated for such purpose, and which control the exposure of potential contaminants to the surrounding environment. Odors from improperly stored rubbish may attract and encourage the multiplication of pests, thus increasing risk of contamination throughout the licensed premises, and seepage or rot from improperly stored or disposed of rubbish has the potential to compromise water supplies and ground surfaces. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Adopt Section 40242. Equipment and Utensils. This section is adopted to establish requirements for the design and maintenance of all cannabis manufacturing equipment and utensils so as to ensure proper cleaning and the prevention of contamination. As this regulation includes oversight of edible cannabis products, the following requirements are in accordance with GMPs established by USFDA regulations regarding facility equipment and utensils used in the production food and dietary supplements (21 C.F.R. §117.40). This provision is necessary to ensure that all equipment and utensils that come in direct contact with cannabis product during manufacturing are clean and safe to prevent adulteration of cannabis products in accordance with section 19347.6 of the Act.

Subsection (a) requires that all equipment and utensils used in manufacturing cannabis products to be adequately cleanable and be adequately maintained to protect against allergen cross-contact and contamination. Material in equipment and utensils must be able to withstand appropriate cleaning without degradation or incorporation of materials with which it comes in contact. Workmanship must allow cleaning, such as proper access to allow scrubbing or removal of materials adhered to the equipment or utensil. Equipment and utensils that degrade during cleaning or workmanship that inhibits cleaning may trap contaminants and allergens and may be a source of contamination. This provision is necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (b) requires that equipment and utensils used in cannabis product manufacturing be designed, constructed, and used in such a way as to avoid contamination via lubricants, fuel, metal fragments, contaminated water, or any other physical contaminants. This provision is necessary to ensure that any lubricants, fuels, water, or other materials used for equipment and utensil maintenance or operation are not introduced into the cannabis product, and that equipment and utensils are constructed appropriately in order to avoid the contamination of

cannabis products due to parts-breakage. This provision is intended to reduce any contamination to cannabis products due to the introduction of equipment or utensil parts (such as screws or metal fragments) that may occur during operation, and is reasonably necessary to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (c) requires equipment be installed so as to facilitate proper cleaning and maintenance of the equipment and of adjacent spaces. This requirement is intended to ensure that personnel will have the ability to physically access the equipment and parts of the equipment that need maintenance or cleaning. This provision is necessary in order to prevent incidents of contamination due to improperly cleaned or maintained equipment and to prevent adulteration in accordance with section 19347.6 of the Act.

Subsection (d) requires that product-contact surfaces be corrosion-resistant. Because corroded surface material may be transferred into and contaminate cannabis products, such surfaces pose a risk of contamination that may affect product-quality and consumer/public health.

Subsection (e) requires that product-contact surfaces be made of nontoxic materials, be designed to withstand their intended use and, if applicable, any cleaning compounds, sanitizing agents, and cleaning procedures used in their maintenance. This provision is intended to prevent any transfer of toxic material into/onto the cannabis product by maintaining the nontoxic nature of the product-surface.

Subsection (f) requires product-contact surfaces to be maintained to protect cannabis products from allergen cross-contact and from being contaminated by any source, including prohibited additives. Contact surfaces must be maintained in good working order to prevent damages that may result in the trapping or collection of contaminants or allergens. Additionally, contact surfaces may not be used for unintended purposes/prohibited activities such as trash or rubbish storage, or for placing or otherwise storing prohibited additives. Allergens and prohibited additives on contact surfaces present a clear threat of contamination to the finished product and, thus to public health and safety.

Subsection (g) requires that seams on product-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. Seams on contact surfaces that are not smoothly bonded or regularly maintained may trap and accumulate materials that may contaminate cannabis products during processing. The accumulated materials may become an environment that favors the harboring and multiplying of microorganism.

Subsection (h) requires equipment in areas where cannabis products are manufactured and that does not come into contact with cannabis products be so

constructed as to be kept in a clean and sanitary condition. Though such equipment may not come into direct contact with cannabis products, it may still be a source of other contaminants or other unintended materials that may find their way onto cannabis products through cross contamination. Personnel handling cannabis products in an area may come in contact with surrounding equipment that, if not kept in sanitary condition, may introduce contaminants into cannabis products via handling and/or cross contamination.

Subsection (i) requires that holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, be of a design and construction that enables them to be maintained in a clean and sanitary condition. Though they may not come into direct contact with cannabis products, the above systems must be kept in sanitary condition in order to prevent potential contamination.

Subsection (j) requires freezers and cold storage compartments used to store and hold cannabis products, ingredients, or components capable of supporting growth of microorganisms be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so as to show the correct temperature within the compartment. Freezers and cold storage are only effective in minimizing the growth of microorganisms when the non-permissive temperatures are maintained. Devices to continually verify and monitor the temperature in storage are necessary to ensure that proper temperatures are achieved.

Subsection (k) requires instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in cannabis products, ingredients, or components to maintain accurate readings and be kept in good working order and in a quantity sufficient for their designated use. This provision is reasonably necessary so that facilities may prevent contamination of cannabis products due to instrument malfunctions.

Subsection (l) requires compressed air or other gases mechanically introduced into cannabis products or used to clean cannabis product-contact surfaces or equipment be treated in such a way that cannabis products are not contaminated with prohibited additives. Compressed air and other gases must be used in a controlled and deliberate manner in order to minimize the inclusion of unintended materials into cannabis products or ingredients, or onto contact surfaces. For example, if compressed air is used to blow powder off of a cannabis contact surfaces, the air supply must include a contaminant filter system that removes any unsanitary liquid (known to build up in air compressor holding tanks) from the air prior to use. Precautions such as the installation of inline filters to avoid contamination of contact surfaces with unsanitary water are necessary so that cannabis products will not be contaminated due to airborne hazards.

Add Article 4. Production and Process Controls. This section is adopted in order 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 reasonably 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 that the production and process controls established in regulation by the USFDA (21 C.F.R. §§117 (C) and 111 (H), (I), and (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. 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 essential to prevent the occurrence of contamination events and the manufacture and release of a product that is injurious or fatal. The requirements detailed in the following sections are 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 rather than simply reacting to such problems after they occur. As discussed in Article 3, above, oversight of food or, in this case, food product-related safety activities is particularly important because consumers often cannot detect that products are unsafe, and testing is inadequate to identify all products that may be adulterated. According to the Center for Disease Control, 1 in 6 Americans get sick from contaminated food and beverages and 3,000 die each year (<https://www.cdc.gov/foodsafety/cdc-and-food-safety.html>).

From the ingredients, to processing, to the packing of a manufactured products, 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.

Adopt Section 40250. General Provisions. This section is adopted to establish the general provisions required of all cannabis manufacturing activities. This section

specifically addresses the activities that take place as part of the SOPs at a facility that are carried out by facility personnel. As this regulation applies to the manufacturing of cannabis products, which includes edible cannabis products, the following requirements are based upon USFDA regulations regarding processes and controls for food and drugs (21 C.F.R. §117.80).

Subsection (a) requires that appropriate quality control operations be employed to ensure that cannabis products are suitable for human consumption and/or use and that cannabis product-packaging materials are safe and suitable. This provision requires the licensee to have quality control operations in place to ensure that products are of a quality that is appropriate for its use as a cannabis product. Due to the great variety of products that might be manufactured by a licensee, the licensee must develop their own quality control operations to ensure product quality as appropriate. The same principle applies to cannabis product-packaging materials because it will be in direct contact with cannabis products.

Subsection (b) requires that the overall sanitation of the premises be under the supervision of one or more competent individuals assigned responsibility for the function. This provision is reasonably necessary to ensure that competent individuals are responsible for ensuring that the sanitation of the premises meet the sanitation standards required by this regulatory proposal (see §40264, Batch Production Record below) . In the event of a sanitation activity or sanitation violation, this provision also permits ready contact with the responsible individual.

Subsection (c) requires that adequate precautions be taken to ensure that manufacturing procedures do not contribute to contamination or allergen cross-contact. This requires the licensee to ensure that all personnel engage in precautions to avoid behaviors, activities, or habits that might lead to contamination events. This provision is reasonably necessary in order to protect public health and safety in accordance with the Act. The use of the term adequate in this provision is due to the myriad precautions that might be relevant, depending on the particular production procedure or activities performed at a given facility.

Subsection (d) requires that testing be used as needed to identify sanitation failures or possible allergen cross-contact and cannabis product contamination. This provision is necessary in order to ensure that the licensee employ testing to resolve issues with processes that have a high potential for contamination. Some parts of the routine manufacturing process may inherently have increased risk of cross-contamination or introduction of contaminants, and/or atypical events may occur during a process. In either instance, testing may be the only way to identify and ensure correction of the problem.

Subsection (e) requires that any cannabis product that has become contaminated to the extent that it is adulterated shall be rejected. This clarifies that the licensee has

the responsibility to reject adulterated product(s), and to protect public health by ensuring that adulterated products are not made available to the public.

Adopt Section 40252. Quality of Raw Materials and Ingredients. This section is adopted to require that licensees establish written policies and procedures to ensure the quality of raw materials and ingredients used in the manufacture of cannabis products. As this regulation applies to the manufacturing of cannabis products, which includes edible cannabis products, the following requirements are based on GMPs as used in USFDA regulations for raw materials and other ingredients. (21 C.F.R. §117.80(b).)

Subsection (a) requires the licensee to establish procedures for the inspection of raw materials and other ingredients in order to ensure they are suitable for manufacturing. This provision is necessary in order to protect consumers from the consumption of harmful ingredients or materials.

Subsection (b) requires that raw materials and other ingredients be free of visible dirt or other contaminants, and that they must be washed or cleaned as necessary to remove such contaminants. Dirt may harbor biological and chemical hazards, and must be removed. Other contaminants may include physical hazards such as rocks or fabric that must be removed in order to protect consumers.

Subsection (c) requires that raw materials and other ingredients be free of microorganisms that may cause the cannabis product to be harmful to human health, or be pasteurized or otherwise treated so that the raw material or ingredient does not contain levels of microorganisms that would result in the cannabis product being contaminated. Depending on a given ingredient or material, microorganisms may be present and may require various processes in order to mitigate impact to a consumer.

Subsection (d) requires that raw materials and other ingredients be within the generally accepted limits set by USFDA for aflatoxins, other natural toxins, pest contamination, undesirable microorganisms, or extraneous materials. The raw materials and ingredients used for cannabis manufacturing include those that are typically used for food, and a number of these materials are susceptible to contamination. Some of these compounds and materials may not be entirely preventable in the raw material or ingredient. In the absence of data to support a “safe” level of these compounds and materials in cannabis products, the Department proposes that raw materials and ingredients used for producing medical cannabis should at minimum fall within the limits established by USFDA for these compounds and materials in food ingredients.

Subsection (e) requires the licensee to establish procedures to ensure that all raw materials and other ingredients are stored, held, and handled in a manner that protects against allergen cross-contact, contamination, and growth of

microorganisms. This subsection is reasonably necessary in order to protect against the spread of contagious endangering public health and safety.

Subsection (f) requires frozen materials and ingredients to be kept frozen and to be thawed in a manner that prevents adulteration. This is necessary to prevent the growth of undesirable organisms in order to protect public health.

Subsection (g) requires raw materials and other ingredients that are or are known to contain food allergens be identified and held in a manner that prevents allergen cross-contact with other materials used in cannabis product manufacturing. Food allergens may pose life-threatening reactions to consumers with food allergies. Identifying and holding food allergens separate from other ingredients aids in the prevention of accidental cross-contact which may endanger public health and safety.

Adopt Section 40254. Manufacturing Operations. This section is adopted to require that licensees adopt written manufacturing procedures in order to ensure that manufacturing processes undertaken at the facility are capable of producing a safe and clean product. As this regulation applies to the manufacturing of cannabis products, which includes edible cannabis products, the following requirements are based on GMPs as used in USFDA regulations for raw materials and other ingredients (21 C.F.R. §117.80(c).)

Subsection (a) requires a licensee to conduct all cannabis products manufacturing in a manner that minimizes the potential for the growth of microorganisms, allergen-cross contact, contamination of cannabis products, and deterioration of cannabis products. This requirement provides guidance on what conditions and controls are necessary for the production of a safe and clean product that meets product specifications.

Subsection (b) requires cannabis products that can support the rapid growth of undesirable microorganisms be held at temperatures that prevent the cannabis product from becoming contaminated. This requirement clarifies that such products must be held at temperatures that prevent the growth of undesirable microorganisms throughout all manufacturing processes, not just during storage. This specification is important because the cell division for microorganisms can occur every 20-30 minutes, leading to the doubling of the microorganism population during a 30 minute process under permissive conditions.

Subsection (c) requires the licensee take appropriate measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH or controlling moisture levels in order to destroy or prevent the growth of undesirable microorganisms and prevent adulteration of the cannabis product. This provision provides examples of common measures employed to destroy or prevent the growth of undesirable microorganisms and prevent product adulteration. This provision is reasonably necessary because some of the materials and ingredients used in cannabis product production may have low levels of microorganisms that may

continue to grow in the material or ingredient, or may have enzymes that change the nature of the material or ingredient if not deactivated by one of the methods referenced in this requirement.

Subsection (d) requires that work-in-process cannabis products be protected from contamination or allergen cross-contact by raw materials, other ingredients, rejected components, or waste products. This requirement is necessary in order to clarify that cannabis products must be protected from contamination or allergen cross-contact during processing. Processing may involve various activities, or movement, and such activities and movement may introduce opportunities for contamination or allergen cross-contact.

Subsection (e) requires that effective measures be taken to protect finished products from allergen cross-contact or contamination. Safe manufacturing practices become meaningless if finished cannabis products are allowed to become contaminated.

Subsection (f) requires that equipment, containers, and utensils to constructed, handled, and maintained in a manner that protects against cross-contact and contamination. Equipment, containers, and utensils can provide a source of contamination.

Subsection (g) requires that adequate measures be taken to protect against inclusion of metal or other extraneous materials. Metal and other similar substances can be harmful to the consumer. This provision is necessary to protect public health.

Subsection (h) requires that adulterated materials or products be disposed in a manner that protects against contamination of other products or materials.

Subsection (i) requires that process steps such as washing, peeling, cutting, and so on be conducted in a manner that protects against contamination or cross-contact.

Subsection (j) requires that heat blanching for producing cannabis products be conducted by heating the cannabis product to the required temperature, holding that temperature for the required amount of time, then either rapidly cooling the cannabis product or passing it to subsequent manufacturing without delay. In the event that blanching activities are undertaken, this requirement clarifies the process for successfully accomplishing the purpose of blanching (e.g. inactivating enzymes, or effecting other physical or biochemical changes in the food). Additionally, this requirement is necessary in order to clarify that, subsequent to completion of blanching activities, the product must be further processed without delay to prevent it being held in a condition that may be favorable for microbial growth. Sanitary requirements for blanchers are included in this provision order to provide clarity to the regulated public.

Subsection (k) requires that manufacturing processes that utilize any sort of preparations that are held and used repeatedly (such as batters, breadings, sauces, gravies, dressing, and dipping solutions) be maintained in a manner that protects against allergen cross-contact and minimizes the potential for growth of undesirable organisms. This requirement is necessary in order to clarify that such preparations must be maintained in a manner that protects against contamination. Preparations that are used repeatedly have a higher potential for contamination compared to materials that are only used once.

Subsection (l) requires that filling, assembling, packaging, and other related operations be performed in a manner that protects against allergen cross-contact, contamination, or growth of undesirable organisms. This provision is necessary to protect public health by preventing contamination of products.

Subsection (m) requires that cannabis products that require moisture control in order to prevent the growth of undesirable microorganisms be processed and maintained at a safe moisture level. This requirement is reasonably necessary in order to prevent the opportunity for microorganisms to grow and multiply during processing steps. The generation time for certain microorganisms may be as short as 30 minutes. If a product's process takes 30 minutes and the environment is not controlled to prevent microorganism growth, the microbe population can effectively double, posing a threat to product safety and public health.

Subsection (n) requires that potable water be used for ice that contacts cannabis products. This provision is necessary to ensure that licensees only use ice that is safe for human consumption in the manufacturing process.

Adopt Section 40256. Hazard Analysis. This section is adopted to establish the requirement that licensees perform a hazard analysis for their specific manufacturing operation(s), and is intended to clarify the specific requirements of such an analysis. As this regulation includes oversight of edible cannabis products, the following requirements are based on GMPs used in USFDA regulations for the hazard assessment of food and dietary supplements. (21 C.F.R. §§ 117.130 and 117.135).

Subsection (a). For the purpose of their hazard assessment, this subsection requires the licensee to consider the potential forms of contamination found in paragraphs (1)-(3) (including paragraph 3 and all its subsections), below. These contaminants are commonly found in food and may result in injury or illness to consumers. Paragraph (1): Biological hazards, including microbiological hazards. These hazards may be inherent in the ingredients comprising a product and can be introduced during handling and processing. They include a number of microbiological hazards known to cause major food-borne illnesses, such as *Salmonella* and *Clostridium botulinum*.

Paragraph (2): Chemical hazards, including radiological hazards, pesticide(s) contamination, solvent or other residue, natural toxins, decomposition, unapproved additives, or food allergens. As cannabis crops are often heavily manipulated and/or grown in artificial settings requiring the heavy application of pesticides and/or fertilizers, the resulting products may present chemical or radiological hazards affecting consumer health. Such hazards may be compounded by the extraction process, which may concentrate various chemical compounds on the product and result in injury or illness if consumed. Additionally, the use of various solvents for extraction of cannabinoids from cannabis makes solvents a likely chemical contaminant for extract products. Natural toxins may thrive on product ingredients, and decomposition of product components may affect the chemical makeup of a product resulting in destabilization and harm if consumed. Unapproved additives and food allergens must, likewise, be considered in a hazard assessment due to the detrimental affect they may have on sensitive individuals such as patients who use cannabis products to treat medical symptoms.

Paragraph (3): Physical hazards, such as stone, glass, metal fragments, hair, or insects. The USFDA has identified the above materials and organisms as common physical hazards found in food products. Stones may be incorporated into products due to failed oversight in the harvest of agricultural material used as ingredients and may cause damage to teeth if consumed. Glass may be introduced during handling of input materials or equipment or light-fixture breakage during the manufacturing process and may result in laceration of the mouth, throat, and intestine if consumed. Metal fragments, including screws, if similarly introduced into the product may pose a choking hazard, as may sharp metal objects such as metal fragments. Additionally, hair and insects may be incorporated into food products due to unsanitary conditions during handling or processing, and may become vectors for disease.

Subsection (b) requires the evaluation of the identified hazards to include an assessment of the severity of any illness or injury that may occur. This responsibility is identical to the responsibility placed on manufacturers under USFDA authority.

Subsection (c) requires the consideration of hazards at specific locations or during specific situations where contamination may occur. These location and situational hazards include, but are not limited to, the hazards or situations listed in paragraphs (1)-(10), below.

Paragraph (1): The sanitation conditions of the manufacturing premises;

Paragraph (2): The product formulation process. The process of formulating the product could provide opportunities for contamination.

Paragraph (3): The design, function, and condition of the manufacturing facility and its equipment.

Paragraph (4): Ingredients or components. Ingredients derived from field crops may contain soil or insects that must be removed before further processing. Ingredients containing food allergens should be assessed so as to avoid inclusion in “allergen-free” products or operations.

Paragraph (5): Transportation practices. Transportation practices may affect ingredients or products requiring refrigeration or other special care in order to maintain ingredient or product freshness and/or integrity, and to prevent contamination via spoilage.

Paragraph (6): Product manufacturing procedures. Products may change form or appearance during the manufacturing process such that contaminants may be harder to detect.

Paragraph (7): Packaging and labeling activities. Packaging may introduce contaminants into finished products through contact with unsanitary packing materials or through improper packaging techniques. Mold, for example may proliferate in an enclosed package and result in an unsafe product. Packaging may also obscure the contents of the package such that contamination may not be detected until a consumer opens it. Improper labeling activities resulting in puncturing or insufficient closure or sealing of a product package may compromise the integrity of the package and expose the product to contamination.

Paragraph (8): Storage of components or finished product. Improper storage of a finished product or a product component—such as storing a component or finished product in unsanitary conditions, or improper storage practices that result in a tearing of component or product packaging, may compromise product quality or integrity and result in exposure to contaminants.

Paragraph (9): The intended or reasonably foreseeable use of the finished product. The manner in which the product will be used can impact the evaluation of hazards.

Paragraph (10): any other relevant factors. The manufacturer is best positioned to know where the vulnerabilities may be in the manufacturing process.

Adopt Section 40258. Preventive Controls. This section requires a licensee to establish preventive controls for any hazard identified in the hazard analysis. A preventive control for an identified hazard is any procedure or practice that will significantly minimize or prevent the hazard from occurring. This provision is necessary in order to ensure that licensees take action to correct identified hazards and prevent adulteration of cannabis products.

Subsection (a) requires preventive controls to identify “critical control points” –(i.e. any points, steps, and/or procedures where a control can be applied to correct or prevent identified hazards). The specific control will vary according to the nature of

the hazard. For example, a licensee that uses perishable ingredients in a product would identify that the perishable ingredient, if improperly stored, could be contaminated with bacteria that could lead to illness of the consumer, and would develop procedures to ensure that the ingredients remain at proper temperature.

Subsection (b) requires the control plan to establish critical limits for each critical control point. As commonly required in food manufacturing, the licensee must establish the parameters that can be used to assess if the hazard is being controlled. For example, if an ingredient needs to be kept at a certain pH level to prevent bacterial growth, the licensee would establish values for the highest and lowest pH value the ingredient may possess in order to still be considered unadulterated and safe for use. The USFDA provides guidance on how to determine critical limits.

Subsection (c) requires the control plan to establish the monitoring procedures by which the licensee will ensure the ingredient stays within the established critical limits. Using the example above, the licensee may use a pH meter to monitor whether the pH level is within established limits.

Subsection (d) requires the control plan to establish corrective actions to be taken when monitoring indicates deviation from the critical levels established pursuant to subsection (b). In the event of a control failure, manufacturing personnel must be able take appropriate and timely action to prevent failures further down the line. For example, upon detecting mold in ingredients, the personnel must know what other ingredients can be used instead and how to handle or dispose of the contaminated ingredients.

Subsection (e) requires the control plan to include record keeping procedures to document the hazard analysis and each element of the control plan, the person responsible for each step, and the corrective actions that were taken upon finding of a deviation. These records allow a licensee to trace the history of an ingredient or finished product in the event of a problem, and helps to identify trends that could lead to a problem in the future if not corrected. This also serves as documentation that a licensee has complied with the requirements of this section.

Subsection (f) requires the control plan to include verification procedures to ensure that the hazard analysis and the preventive control plan are working correctly to prevent adulteration. This includes reviewing records and testing the product to ensure that the controls applied are effective.

Adopt Section 40260. Equipment and Machinery Qualification. This section is adopted to establish the requirement that the equipment and machinery used in the manufacturing process are appropriate for their intended use. As the inappropriate use of equipment poses a health risk not only to personnel within a licensed premises, but to members of the public (via unsafe products), and to individuals occupying the

immediate area (via potential accidents such as fires), this provision is reasonably necessary in order to protect the public.

Subsection (a) requires the licensee to establish and implement procedures to ensure that each piece of equipment and machinery is suitable for its intended use prior to operation.

Paragraph (1) requires licensees to establish and implement procedures to verify that all equipment and machinery has design specifications, operating procedures, and performance characteristics appropriate for their intended use. This provision is intended to prevent the use of modified or inappropriate equipment that may pose a threat to worker safety.

Paragraph (2) requires licensees to establish and implement procedures to verify that all equipment and machinery have been built and installed in compliance with design specifications including, but not limited to, specifications that equipment and machinery have been built as designed with proper materials, capacity, and functions for their intended use, and that all equipment and machinery is properly connected and calibrated. Closed loop systems (as discussed in section 40225, above), for example must be built and installed according to design specifications. If such a system is not made with proper materials or calibrated properly, the solvent used may degrade and escape during processing, resulting in increased risk of explosion or fire.

Paragraph (3) requires the manufacturer establish and implement procedures to verify that all equipment and machinery perform in accordance with quality requirements in all anticipated operating ranges using the licensee's standard operating procedures. This requirement is to ensure that the equipment and machinery perform as expected under the licensee's anticipated use. This requirement is to verify that the actual performance of the equipment and machinery is appropriate for the actual operating ranges utilized by the licensee. This is necessary because equipment and machinery may be unable to perform as expected due to defect or maintenance issues, despite the intended specifications being correct, leading to contamination of cannabis products.

Paragraph (4) requires the manufacturer establish and implement procedures to establish a schedule for routine re-verification of all equipment and machinery. This requirement is necessary in order to keep all equipment and machinery in good repair and thus minimizes hazards from malfunction or failure that may result in harm to personnel, the public, individuals in the immediate vicinity, or product quality. This provision is necessary so that the Department can prevent adulteration in accordance with Business and Professions Code section 19347.6 of the Act.

Subsection (b) requires the licensee to maintain verification records for all equipment and machinery. This provision is reasonably necessary so that licensees can prove their compliance with the requirements of subsection (a) above. Because

equipment/machinery malfunction and/or failure may result in harm, licensees must keep records so that they may preemptively identify and minimize potential sources of malfunction and/or failure. This requirement establishes the minimum requirements for the verification records as follows:

Paragraph (1) requires that documentation of successful verification of each piece of equipment and machinery be dated and signed by the person conducting the verification. Each piece of equipment and machinery must be identified in the records to be effective in identifying which piece of equipment or machinery requires corrective action. The date and signature on the verification allows tracking of records to identify trends, identification of personnel to follow-up with in the event of a failure, and provides proof of verification activities.

Paragraph (2) requires documentation of successful re-verifications of each piece of equipment and machinery upon any modification to the equipment or machinery, intended use, or SOP. As such modifications are likely to affect the performance of the equipment and machinery, this provision is intended to ensure that the equipment and machinery is still capable of performing according to the requirements of this section after any modification.

Paragraph (3) requires the manufacturer maintain a log detailing the verification and re-verification of all equipment and machinery in operation on the licensed premises. This requirement will help the licensee keep track of the performance of all equipment and machinery in operation on the licensed premises. This requirement also ensures the record is available to the licensee to review, personnel to update or review, and inspectors during inspections.

Adopt Section 40262. Master Manufacturing Protocol. This section requires that the licensee establish a written “master manufacturing protocol.” As further detailed in subsections (a) and (b) of this section, the master manufacturing protocol is similar to a recipe, except that, in addition to the ingredients and process, the master manufacturing protocol specifies the controls and processes necessary to protect the quality of a product. The master protocol is critical to ensuring consistency during manufacturing processes, and must be adequately detailed to minimize any deviation that may result in a product that fails to meet the quality standards.

Subsection (a) requires each licensee to establish a master manufacturing protocol for *each unique formulation of product manufactured and for each batch size produced*. Each unique formulation of cannabis product will have its own “recipe” and required manufacturing steps. Consequently, a master protocol is required for each type of product. A master protocol is also required for each batch size produced. As each batch size may use differing amounts of raw materials and ingredients, this requirement ensures the uniformity of each product. Uniformity of product, specifically uniformity of cannabinoid distribution, is critical to protecting public health through prevention of unintentional overdose. This section also establishes that the master manufacturing protocol must:

Paragraph (1) any controls identified in the hazard analysis described in section 40256 of these regulations. As discussed in section 40256 implementing measures to address anticipated hazards is necessary to protect cannabis products from contamination.

Paragraph (2) any controls needed to ensure that each batch is manufactured according to specifications. Conformance with specifications cannabinoid content is critical to protecting public health through prevention of unintentional overdose.

Subsection (b) establishes the elements that the master manufacturing protocol must include. This provision is necessary in order to provide clarity to the regulated public, and to ensure that a complete protocol is developed for each unique formulation of product manufactured and each batch size produced. Accordingly, the master manufacturing protocol must include the following elements:

Paragraph (1): the name and batch size of the cannabis product to be manufactured.

Paragraph (2): a complete list of components to be used.

Paragraph (3): the weight or measure of each component.

Paragraph (4): the identity and measurement of each ingredient that will be declared on the product label. (This requirement is further necessary in order to ensure that the product label is properly prepared and accurately reflects the product ingredients. Accurate labeling helps protect consumers.)

Paragraph (5): a statement of the theoretical yield of a product expected at each step of the manufacturing process and the expected yield of the finished product. (As the manufacturing process may provide opportunities for diversion of cannabis or cannabis product, a listing of the theoretical or expected yield at each step and in the final product is necessary in order to provide a mechanism by which licensees may better determine if diversion has occurred.)

Paragraph (6): a description of packaging and a representative label, or a cross reference to where the actual label is located. (This requirement is intended to provide another means of identifying the product and ensuring proper labeling.)

Paragraph (7): written instructions for all of the following:

Subparagraph (A): each step where controls are necessary to ensure quality of the product. This provision ensures that personnel involved in the manufacturing process know the appropriate steps or precautions needed to ensure a safe and sanitary manufacturing process and, ultimately, to produce safe products for public consumption.

Subparagraph (B): procedures for sampling and a cross-reference to sampling and testing procedures. The Act allows licensees to perform in-house quality

assurance testing. If such testing is done as a part of the regular manufacturing process, the master manufacturing protocol should reflect that.

Subparagraph (C): specific actions necessary to verify controls are maintained. This provision, including the provisions described in subdivisions A-B and their corresponding paragraphs, below, is necessary to ensure that cannabis products are properly manufactured and are of a quality suitable for public consumption.

Subparagraph (D): Such specific actions must include verifying the weight or measure of any component used in the formulation of a cannabis product and the verification of any additional components added. As some components unintended for inclusion in the final product may be used as processing aides during manufacturing, this requirement is intended to ensure that such components are tracked so as to avoid their inclusion in unsafe levels in the final product. Certain component levels may result in a harmful final product if too much or too little is introduced during the manufacturing process and/or the component itself is harmful at certain levels. Unsafe component levels may pose a threat to public health and safety.

Subparagraph (E): For manual operations, such specific actions must include the procedures described in clauses (i)-(iv) (below). This provision is reasonably necessary in order to provide clarity to the regulated public by specifying the need for additional verification when manual operations are carried out by personnel, and to provide oversight of potential human-error in manual operations which may threaten public health and safety.

Clause (i): One person weighing or measuring a component and another person verifying the weight or measure. Weighing and/or measuring activities have the potential for human error as devices may be misread. Such errors have the potential to affect product quality and, ultimately, pose a health and/or safety risk to consumers. Second-person verification has been known to minimize such errors. The mechanism can be verified through statistics, for example: if a person has an error rate of  $\frac{1}{4}$ , and a second person has an error rate also of  $\frac{1}{4}$ , then the chances of both persons committing error is  $\frac{1}{4} \times \frac{1}{4}$ , or  $\frac{1}{16}$ . This reduces the chance of error from 25% to 6.25%.

Clause (ii): One person adding the component and another person verifying the addition. As the adding of inaccurate, unsafe, or otherwise inappropriate components or component levels to a given product may result in harm to public health and safety, this section mandates that second-person verification must be performed at any manufacturing step where components are added to a product.

Subparagraph (F): Special notations and precautions to be followed. This provision requires any special instructions and precautions used during the manufacturing process to be documented in the master manufacturing protocol. Special precautions may include certain equipment needs or additional preparation that is atypical of other manufacturing processes and/or procedures

used by a unique operation. This provision is intended to ensure that all products processed have a master manufacturing protocol so as to ensure product consistency. As discussed above, product consistency helps to promote health and safety for personnel, consumers, and members of the public.

Subparagraph (G): Corrective action plans for use when a specification is not met. This provision requires that corrective action plans must be documented in the master manufacturing protocol. As stated above Section 40528, corrective action plans reduce risks to public health and safety by reducing response time between the identification of a hazard and the action needed to address it.

Adopt Section 40264. Batch Production Record. This section establishes requirements for the licensee to prepare a written batch production record and clarifies the specific information that must be included in each such record. A batch production record is a record of each batch of cannabis product(s) produced. Further requirements for batch records are described below. As this regulation includes oversight of the manufacturing practices for edible cannabis products, the following requirements are based on the GMPs used in USFDA regulations for batch production. (21 C.F.R. §§111.255 and 111.260.) The following provisions, including their coinciding paragraphs and subparagraphs are reasonably necessary to protect public health and safety from the risk of contamination so that the Department may carry out its mandate under the Act. (Bus. & Prof. Code §19303)

Subsection (a) requires the licensee to prepare a written batch production record each time a batch of cannabis product is manufactured. This provision is necessary so that licensees will be able provide the Department with accurate information about a given batch in case of a batch and/or product recall, and so that licensees may identify defects or failures in batches or batch-production (for example: improper component levels) that pose a threat to public health and safety.

Subsection (b) requires that the batch production record must document the following details:

Paragraph (1): the batch number of the finished batch of cannabis product and the unique identifier(s) of all cannabis or cannabis products used in the batch. This will allow the licensee to associate cannabis or cannabis products back to the batch from which they originated.

Paragraph (2): the lot number assigned for each of the following:

Subparagraph (A): each lot of finished product. In case of adulteration and recall, the licensee or the Department must be able to track the location and disposition of the lot numbers associated with the batch.

Subparagraph (B): each lot that is transferred to another manufacturer for further processing. Again, in case of adulteration or recall, the licensee or the

Department needs to be able to track the disposition of the lot numbers associated with the batch.

Paragraph (3): the identity of equipment and processing lines used in production of the batch. A processing line is a set of sequential manufacturing operations whereby materials are put through a process to produce a finished product. Keeping track of equipment and processing lines used in the production of a specific batch makes it easier for licensees to identify causes of a failed batch due to equipment or process failure or malfunction. Identification of specific equipment also enables faster maintenance or troubleshooting to prevent further batch failures. Batches that fail due to breakdown of equipment or process lines may pose a threat to public health and safety.

Paragraph (4): the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained. This serves two purposes, first, to ensure that the maintenance, cleaning and sanitizing required for batch production takes place and is documented. Secondly, that the maintenance, cleaning and sanitizing that took place is recorded in the event a batch fails due to inadequate maintenance, cleaning, or sanitation.

Paragraph (5): the identification number assigned to each component (or, when applicable, to a product received from a supplier for packaging or labeling as a cannabis product), packaging, and label used. In the event of a batch failure due to an adulterated component, identification numbers permit the licensee to identify the component and any other batches in which it may have been included. This information is necessary to recall products that might pose a risk to public health.

Paragraph (6): the identity and weight or measure of each component used in a batch. Providing this information on the batch production record ensures that the personnel engaged in weighing and measuring activities have two opportunities to verify the identity and measure of each component: once on their manufacturing master protocol document and once on the batch production record. As stated above, this sort of second-person verification may help reduce threats to public health and safety by minimizing human error.

Paragraph (7): a statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing. During processing, some material may be lost due to unavoidable incomplete recovery. This should be accounted for to produce a final product that meets the intended yield. Statement of theoretical and actual yield can indicate if diversion of cannabis or cannabis product has occurred during the manufacturing process.

Paragraph (8): the results obtained during any monitoring operation. Documentation of factual and empirical information on the performance of the production process

allows for the identification of trends that might be help better regulate the growing cannabis industry and further protects public health and safety.

Paragraph (9): the results of any testing or examination performed during the batch production, or a cross-reference to such results. This must be included in the batch records in order for the relevant information to be readily available during review of a batch.

Paragraph (10): documentation of the date and time the manufacturing steps for each batch took place:

Subparagraph (A): the date on which each step of the master manufacturing protocol was performed. Such documentation enables the licensee and/or Department to cross-check the quality of a particular batch with other timelines, for example: the maintenance or cleaning schedule of other facility operations. In the event a batch does not meet quality standards, this record allows investigation to identify other operating procedures that might need adjustment to ensure product quality and this protect the public health. If any processes have specific timeframes for completion, documentation of the date allows responsible personnel to verify that such timeline requirements were met.

Subparagraph (B): the initials of the persons performing each step as specified in clauses (i)-(iv), below. In the event of product failure, such documentation allows identification of the personnel responsible for a given step and ensures corrective action can be taken to prevent further errors.

Clause (i) requires the initials of the person responsible for *weighing or measuring* each component used in the batch be recorded.

Clause (ii) requires the initials of the person responsible for *adding the component* to the batch also be recorded.

Clause (iii) requires the initials of the person responsible for adding the component to the batch.

Clause (iv) requires the initials of the person responsible for verifying the addition of components to the batch.

Paragraph (11): Documentation, at the time of performance of specified elements of the packaging and labeling operations. This provision is reasonably necessary to provide clarity to the regulated public by making specific the packaging and labeling activities that must be documented for each batch. The elements to be documented are:

Subparagraph (A): the actual or representative label, or a cross-reference to the location of the label specified in the master manufacturing protocol. This information is necessary to maintain an accurate record of the manufacturing

activity. Recording of the actual packages and labels used can be useful in identifying misbranded (i.e. mislabeled) products.

Subparagraph (B): the quantity of labels and packaging issued and used, and a reconciliation of any discrepancies between the issuance and use of such labels. Discrepancies between the anticipated number of labels needed (issuance) and the actual number used may indicate improper packaging (i.e. overfill or underfill), which may mean that the package of cannabis product contains an amount of cannabinoids that differs from the label claim. Additionally, the use of fewer packages than expected may also indicate that diversion has occurred somewhere in the manufacturing process.

Subparagraph (C): the results of any tests or examinations conducted on packaged and labeled cannabis products. Including this information in the batch record ensures that all relevant information for a batch is easily accessible.

Paragraph (12): documentation that quality control personnel conducted the tasks specified in subparagraphs (A) – (E) (below). These requirements provide a checklist for quality control personnel in order to record fulfillment of their duty to verify the products that result from a batch meet quality standards. This information must also be included in the production records for ease of access and so that in the event of a recall or related issue, the activities undertaken by quality control personnel are available for review and adjustment as necessary. The tasks quality personnel must document are:

Subparagraph (A): that quality control personnel *reviewed the batch production record*. This review is necessary in order to ensure that all the information recorded fulfills the requirements set forth in the master manufacturing protocol, and to address any deviation that might have occurred before the release of the finished product.

Subparagraph (B): that quality control personnel *monitored operations as required*. This requirement is necessary to provide additional verification that all monitoring operations performed by quality control personnel were successful.

Subparagraph (C): that quality control personnel *reviewed the results of any tests and examinations*. The review of test or examination results is necessary so that quality control personnel to make informed and knowledgeable decisions on whether a product meets the quality standards and is ready to be released. While the personnel involved in the processing steps may have documented the results, it is the job of the quality control personnel to evaluate the all the information in the batch production records to make competent decisions.

Subparagraph (D): that quality control personnel *approved and released or rejected the batch for distribution*. This approval provides verification that the

quality control personnel has completed review of all relevant information regarding the batch and has made an appropriate determination.

Subparagraph (E): that quality control personnel *approved and released, or rejected, the packaged and labeled cannabis product, including any repackaged or relabeled cannabis product*. As above, this is verification provides needed verification that quality control personnel have successfully completed their duties.

Paragraph (13) - documentation at the time of performance of any required material review and disposition decision. This provision is necessary to ensure that any disposition decision was based on review of all of the required material. This documentation must take place at the time of performance in order to ensure accuracy and minimize errors.

Subsection (c) establishes the required content of the batch production record. Specifically:

Paragraph (1): the record must contain the actual values and observations obtained during the monitoring of manufacturing operations. This provision is necessary to ensure an accurate picture of manufacturing operations/the production of finished products.

Paragraph (2): the record must be accurate, indelible, and legible. Recording errors could lead to release of a batch that failed testing. The record must also be indelible, so that the record serves the purpose of retaining information over time. Lastly the record must be legible, as poor legibility may cause a failed batch to be approved or a satisfactory batch to be needlessly disposed of. If a failed batch is approved due to illegibility of the record, this poses a public health risk. Furthermore, Department inspectors must be able to read the record during an inspection, particularly in cases of suspected or actual product adulteration.

Paragraph (3): the record must be created concurrently with the activity documented. In order for the record to be as accurate as possible, activities must be documented at the time they are conducted.

Paragraph (4): the record must be as detailed as necessary to provide the history of work performed on the batch. This will ensure that the full manufacturing history of the product can be ascertained if the licensee or Department needs to track the source of a contamination. Required details include:

Subparagraph (A): any information that identifies the plant or facility that produced the product. As a licensee may hold licenses at more than one facility and produce similar products at the different facilities, this provision is reasonably necessary for clarity. .. As the batch record includes information that is specific to the facility and equipment, etc., it is important to clearly identify the plant or facility in the event of product failure.

Subparagraph (B): the date and time of the activity that is being documented in the record. The provision of this information is necessary to allow identification of the point at which equipment may have ceased performing correctly, or what component was utilized, if other errors occurs in the record.

Subparagraph (C): the signature or initials of the person performing the activity. This provision is necessary to ensure that, in the event that the Department or licensee has further questions concerning the performance of an activity, the person responsible for that activity may be identified for follow up.

Subparagraph (D): the identity of the product and the lot number. This provision is reasonably necessary so that the products resulting from each batch may be tracked once released from the manufacturing facility. Tracking is critical for recall purposes, as well as for enabling the licensee to investigate their manufacturing processes for any failures that might be responsible for a product recall.

Adopt Section 40266. Product Complaints. This section is adopted to make specific the licensee's responsibilities related to product complaints. Product complaints are one method by which a licensee may be alerted to possible contamination or other product quality issues. A systematic approach to accepting and responding to product complaints is necessary to protect the public.

Subsection (a) requires that a qualified individual must review and investigate all product complaints. This provision is reasonably necessary to ensure that quality control personnel have appropriate knowledge and experience, and that licensees are able adequately assess and investigate product complaints.

Subsection (b) requires quality control personnel to review and approve decisions regarding product complaints. This requirement is necessary to make specific the role of the quality control personnel in the product complaint process.

Subsection (c) requires that product complaint reviews and investigations performed by quality control personnel take into account all relevant batches and records associated with the product featured in the complaint. This requirement makes specific the responsibilities of the quality control personnel. A review of all records and relevant batches is necessary to properly evaluate if any manufacturing processes contributed to a failure in the product's quality.

Subsection (d) requires quality control personnel to maintain records regarding product complaints and any subsequent investigation. This provision is necessary in order for the Department to ensure that any potential public health threats have been adequately addressed. Paragraphs (1) – (4) of this provision (below) establish the records to be maintained and are necessary to ensure that accurate records are

maintained by the licensee and are available for review by the Department for regulatory and/or inspection purposes. The specific records to be maintained in order to facilitate the review of product complaints are:

Paragraph (1): the name and description of the cannabis product involved.

Paragraph (2): the batch, lot, or control number of the cannabis product involved, if available.

Paragraph (3): the date the complaint was received and the name, address, or telephone number of the complainant, if available.

Paragraph (4): the nature of the complaint including, if known, how the product was used.

Paragraph (5): the reply to the complainant, if any.

Paragraph (6): findings of the investigation and any follow-up action taken when an investigation is performed.

Subsection (e) defines “product complaint” and is reasonably necessary in order to provide clarity to the regulated public.

Adopt Section. 40268 Recalls. This section requires each licensee to establish written recall procedures. In the event of product contamination, public health protection necessitates a recall of the contaminated product(s) in order to mitigate the threat to public health. Advance preparation of recall procedures is, likewise, necessary to protect public health. This section requires each licensee to establish and implement written recall procedures in the event that cannabis products are found to be misbranded or adulterated, and establishes that such procedures must include the following:

Subsection (a): the factors necessitating the recall.

Subsection (b): the personnel responsible for implementing a recall.

Subsection (c): notification protocols. Licensees must have mechanisms in place to contact the necessary persons in the event of a recall so that the product does not remain in the stream of commerce. The notification protocols must include the following:

Paragraph (1): a mechanism to contact all customers that have, or could have, obtained the recalled product. In the case of a manufacturer initiated recall, it is necessary that a manufacturer contact all customers (including other manufacturers or distributors) in a timely manner. Such communication may include outreach via media, if necessary and appropriate.

Paragraph (2): a mechanism to contact any licensees that supplied or received the recalled product.

Paragraph (3): instructions for the return or destruction of any recalled product by the general public or other licensee. Notification of a recall must provide holders of the product with information on how to return or dispose of the product.

Subsection (d): procedures for the collection and destruction of any recalled product. This provision is necessary to ensure that licensees have procedures in place in advance to address collection and destruction of recalled product. Without established procedures, products collected during a recall may not be properly handled or destroyed, posing a further threat to public health.

Paragraph (1) requires that recalled products that are intended to be destroyed be quarantined for a minimum of 72 hours, and that the Department must be notified of such quarantine. This notification and holding time is necessary so that the Department has sufficient time to inspect products and take samples if such activities are warranted.

Paragraph (2) requires that, following the quarantine period, the licensee shall render the recalled product unusable and unrecognizable as specified in section 40290 (Disposal of Cannabis and Cannabis Products) (below), and on video surveillance as specified in section 40205(e) (Video Surveillance) (below). These requirements are necessary to ensure that recalled product is not diverted.

Paragraph (3) requires that the licensee notify the Department if the licensee initiates a cannabis product recall. This provision is necessary to allow the Department the ability to oversee that all relevant products are removed from the channels of trade and destroyed in an appropriate manner.

Paragraph (4) restricts the licensee from disposing of the recalled product in an unsecured waste receptacle that is not in possession and/or control of the licensee. This provision is reasonable to prevent diversion of recalled cannabis products.

Subsection (e) requires the licensee to enter destruction events into the track-and-trace database. This provision is reasonably necessary to prevent diversion of recalled cannabis products.

Subsection (f) requires the licensee to notify the Department within 24 hours of initiating a recall.

#### Add Article 7. Record Keeping.

Adopt Section 40270. Record Keeping Requirements. This section is adopted in order to establish the minimum requirements for record keeping by a licensee. Business and Professions Code section 19327 requires licensees to keep accurate records of commercial cannabis activity. This section makes specific the records that are required

to be kept by the licensee and is reasonably necessary to provide clarity to the regulated public.

Subsection (a) establishes the specific documents that the licensee must make available at all times to the Department and to any enforcement agency upon request.

Paragraph (1): the state license issued by the Department. This provision allows the Department to identify whether or not the manufacturer is currently licensed for commercial cannabis activities and is necessary so that the Department may carry out its mandate under the Act. (Bus. & Prof. Code §19302.1, subd.(f).)

Paragraph (2): any other license issued by a state cannabis licensing agency. This provision is necessary so that the Department may identify whether the manufacturer holds other licenses that are not permitted with a manufacturer license.

Paragraph (3): the license, permit, or other approval issued by the local jurisdiction. This provision is necessary so that local authorities identify whether or not the manufacturer is maintaining the local authorization required by statute. (Bus. & Prof. Code §19320, subd.(b).)

Paragraph (4): the premises diagram. This is necessary so that Department inspectors can verify that the diagram on hand, the diagram provided to the Department, and the actual operations are in alignment.

Paragraph (5): standard operating procedures as defined in section 40275 (Standard Operating Procedures). This provision is necessary so that employees and Department inspectors may review the standard operating procedures at any time.

Paragraph (6): Shipping manifests. This provision is necessary so that Department inspection staff can review and verify that inventory controls are effective in accordance with the track and trace database required by statute. (Bus. & Prof. Code §19355 et. seq.)

Paragraph (7): Employee records, including evidence of employee qualifications and training procedures and logs. This is necessary so that the Department can identify if the licensee is in compliance with the employee training requirements specified in section 40280 (Training Program).

Paragraph (8): Any other record or documentation required to be kept pursuant to this Division. This will allow the Department to require records or documentation be kept that may be critical to further the intent of the Act and these regulations.

Subsection (b) establishes the record retention schedule for the records outlined in subsection (a). This will identify the length of time that records must be kept. The Act

requires the licensee to keep accurate records of commercial cannabis activity for a minimum of seven years.<sup>20</sup> These regulations identify that records outlined in subsection (a) shall be maintained in a manner immediately accessible on the premises to the Department and any enforcement agencies for a period of two years with the exception of outdated standard operating procedures, which should not be accessible to onsite employees to avoid confusion between document versions. After two years, the licensee may maintain the records in an alternate manner as long as the records can be made available within 48 hours following a request by the Department or enforcement agency. This will allow the licensee some flexibility in the manner of record retention while making records accessible for review by the Department and any enforcement agencies at the same time.

Subsection (c) requires that all documentation be maintained in English. This will make document review accessible by the Department and any enforcement agency without delay, which is critical especially if there is a potential public health concern.

Adopt Section 40272. Track-and-Trace Requirements for Manufacturers. Business and Professions Code section 19335 requires the use of a track-and-trace program to track the movement of cannabis items through the distribution chain. This section makes specific the provisions of the Act by establishing the requirements for manufacturers to enter information for specific events into the track-and-trace database:

Subsection (a) requires licensees to enter the following events into the track-and-trace database:

Paragraph (1): Receipt of cannabis material. This requirement is part of the implementation of the track-and-trace requirements required by Business and Professions Code section 19335 to track the movement of cannabis.

Paragraph (2): The transfer to or receipt from another licensed manufacturer of cannabis products for further manufacturing. This requirement is part of the implementation of the track-and-trace requirements required by Business and Professions Code section 19335 to track the movement of cannabis.

Paragraph (3): Transfer of cannabis products to a distributor. This requirement is part of the implementation of the track-and-trace requirements required by Business and Professions Code section 19335 to track the movement of cannabis.

Subsection (b) requires the licensees to enter the following information for each event mentioned in subsection (a). This subsection is necessary to make specific the licensee's responsibilities under the Act.

Paragraph (1): the licensed entity from which the cannabis material or product is received, including that entity's license number, and the licensed entity to which the cannabis product is transferred, including that entity's license number. This

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<sup>20</sup> Business and Professions Code section 19327, subdivision (b).

requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to ensure that cannabis material or products are transferred between licensees only.

Paragraph (2): the name and license number of the transporter of the cannabis material or cannabis product. This requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to ensure that cannabis material is transported by licensed transporters only.

Paragraph (3): the type of cannabis material or cannabis product received or transferred. This requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to ensure that the cannabis material or cannabis product received or transferred can be identified.

Paragraph (4): the weight or volume of the cannabis or cannabis product received or transferred. This requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to fulfill the Department's obligation under the Act and the Cole memo to ensure that the amount of cannabis or cannabis received or transferred is accounted for and that there has been no theft or loss of product.

Paragraph (5): the date of receipt or transfer. This requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to ensure that the date of receipt or transfer can be verified.

Paragraph (6): the unique identifier assigned to the cannabis material or cannabis product. This requirement is part of the implementation of the track-and-trace requirements specified in Business and Professions Code section 19335. This provision is necessary to fulfill the Department's obligation under the Act and the Cole memo to ensure that all cannabis material or cannabis products are accounted for from cultivation to dispensary.

Paragraph (7): any other information required by the other licensing authorities. This provision is necessary so that licensees are aware that they are obligated to abide by other requirements established in law even if those requirements are not specified in the Department's regulations.

Adopt Article 6. Other Responsibilities. This article will incorporate other responsibilities of a licensee. This article is necessary to clarify and make specific the licensee's responsibilities under the Act so that they will be able to comply with the proposed regulations.

Adopt Section 40275. Standard Operating Procedures. This section will establish the written policies and procedures that must be maintained as part of a licensee's standard operating procedures. This provision is necessary to clarify and make specific what the Department considers to be the minimum standard operating procedures for manufacturers under this regulatory proposal in order to provide clarity to the regulated public and to protect the public in accordance with the Act. (Bus. & Prof. Code §19303.)

Adopt Section 40280. Training Program. This section is necessary to clarify the responsibility of the licensee to implement a training program in order to ensure that all personnel are qualified for their job duties. Competent and qualified personnel are less likely to endanger public safety, personnel safety, or product safety and quality.

Subsection (a) establishes the minimum requirements of the training program that a licensee must implement. The following paragraphs are necessary in order to make specific the requirements all manufacturer training programs must include in order to protect public health and safety.

Paragraph (1): establishes a deadline of 30 days from the start of the employment date for personnel to receive training on the elements specified in subparagraphs (A)-(F) below. This provision is reasonably necessary to ensure that personnel will receive, in a timely manner, the information they need to safely perform their duties. The required training elements are as follows:

Subparagraph (A) - identification and communication of health and safety hazards. This provision is reasonably necessary to protect the safety of the facility personnel and members of the public in the area where the licensed premises is located.

Subparagraph (B) – identification of hazards presented by all solvents used at the facility. This provision is necessary as some solvents used for cannabis manufacturing poses health and/or fire risks. Requiring personnel to be trained on the hazards posed by solvent will protect the safety of the facility personnel as well as the safety of the public in the area the licensed premises is located.

Subparagraph (C) – emergency procedures. In order to protect the safety of facility personnel, it is necessary that all personnel be trained in appropriate emergency procedures. Such training will protect facility personnel, as well as the nearby public and/or any emergency crews that might be affected due to an emergency at the licensed premises.

Subparagraph (D) – security procedures. This subparagraph is necessary to ensure the participation of all facility personnel in maintaining the security of the licensed premises in order to prevent instances of harm occasioned by improper handling of volatile or otherwise dangerous chemicals during the manufacturing process. This provision is reasonably necessary to protect the safety of the personnel and members of the public within the vicinity of the licensed premises,

as well as to ensure the safety and quality of products with the potential to impact consumer safety and/or public health.

Subparagraph (E) – recordkeeping requirements. This requirement is part of the implementation of the records requirement specified in Business and Professions Code section 19327. The communication of record-keeping requirements to all personnel and the participation of all personnel is necessary in order to provide the Department with current and accurate records of all relevant activities.

Subparagraph (F) – training requirements. This provision requires the licensee to inform their personnel of all training program requirements, and allows the licensee to include additional training requirements as appropriate. This provision is necessary to clarify the licensee's responsibilities regarding the training of personnel so that the licensee may comply with the requirements of this section.

Paragraph (2): Establishes the specific training requirements that personnel must undertake prior to independently operating any aspect of the manufacturing process. These requirements are necessary to ensure personnel are qualified for their specific tasks. Unqualified or improperly trained personnel may pose a safety hazard to themselves, their supervisors, their fellow personnel, and/or to members of the public within the vicinity of the licensee's premises. It is therefore necessary that personnel demonstrate an understanding of the procedures in which they are involved in order to protect public health and safety. Protecting public health and safety is a stated intention of the Act. The specific training elements of the training that must be provided to personnel are:

Subparagraph (A) – an overview of the manufacturing process and its standard operating procedures. This requirement is necessary to ensure that personnel are familiar with all relevant details regarding their specific duties.

Subparagraph (B) – quality control procedures. This requirement is necessary to ensure that personnel are familiar with procedures affecting the quality and safety of the cannabis product(s).

Subparagraph (C) – hazard analysis and control procedures. This requirement is necessary to ensure that personnel engaged in a process involving an identified hazard(s) are aware of the control procedures used to protect the safety and/or quality of the cannabis product(s).

Subparagraph (D) – the proper and safe usage of equipment or machinery. This requirement is necessary to ensure the personnel are knowledgeable as to the safe and proper use of facility equipment and machinery. Proper usage may help to reduce accidents and hazards affecting persons within the facility or within the vicinity of the licensed premises.

Subparagraph (E) – safe work practices, including appropriate use of any safety equipment. This requirement is necessary to ensure that personnel are aware of the practices intended to protect their safety and the safety of all persons in and around the licensed premises.

Subparagraph (F) – cleaning and maintenance requirements. This requirement is necessary to ensure that personnel are knowledgeable of procedures for cleaning and maintaining manufacturing areas, equipment and utensils, to minimize contamination of cannabis products. Contaminated products pose a health risk to personnel and/or members of the public.

Subparagraph (G) – emergency operations, including shutdown procedures. This requirement is necessary to ensure that, in the event of an emergency, personnel know what actions to take to minimize or prevent hazardous situations. As some of the processes employed in cannabis manufacturing may create or exacerbate hazardous situations, personnel knowledge of the emergency shutdown procedures is necessary in order to increase the likelihood that personnel will respond quickly to address such situations in the event of an emergency.

Subparagraph (H) – any additional information reasonably related to a person’s job duties. This requirement is necessary to ensure that personnel are aware of all information related to their job duties so that those duties will be performed in such a way as to protect personnel, public, and product safety.

Paragraph (3) requires a licensee that produces edible cannabis products to ensure that all personnel who prepare, handle, or package edible products successfully complete a food handler course accredited by the American National Standards Institute (ANSI). ANSI is a non-profit organization that develops widely accepted standards in a variety of industries, as well as performing accreditations to assess the competence of organizations’ conformance to standards. ANSI does not directly provide training courses, but rather accredits third-party providers of training. The requirement for edible product manufacturers is modeled after the Department’s Cottage Food Program, which requires cottage food manufacturers to complete ANSI-accredited food handler courses. Food handler courses cover the basic information on handling edible products to keep them safe for consumers, including personal hygiene, cross-contamination, temperature controls, and other elements of proper food safety. This requirement is reasonably necessary to ensure that licensees and personnel have the basic knowledge required for product safety. Food handler training can be done through online courses and costs roughly \$10-15 per course. These proposed regulations require that all personnel take the training within 90 days from the start of employment, or for those manufacturers in operation at the time of licensure, within 90 days of the effective date of the license. The 90-day timeline is intended to ensure that manufacturing operations have the

knowledge necessary to protect public safety without imposing an undue burden on the regulated industry.

Paragraph (4) requires the licensee to ensure all personnel receive annual refresher training and that the information included in such trainings be updated as needed to ensure relevance and applicability. This provision is necessary in order to ensure that personnel remain informed of the most relevant safety and/or procedural information relating to their duties so that they will be better able to protect public health and safety.

Subsection (b) requires the licensee to maintain a written training record. This requirement is necessary so that the Department's inspectors can verify the licensee's compliance with the requirements of this subsection specified in paragraphs (1)-(6) below. As untrained personnel may pose a safety hazard to themselves, their supervisors, their fellow personnel, and/or to members of the public within the vicinity of the licensed premises, it is necessary to establish reasonable controls, such as verification of personnel participation in training requirements, in order to protect public safety. The training record must include, at a minimum:

Paragraph (1): an annual written attestation by the licensee that all personnel have received and understood the information and training provided. This provision is necessary in order to ensure that licensees comply with the requirements of this section.

Paragraph (2): a list of all personnel at the manufacturing premises, including, at minimum, the name and job duties of each. This provision is necessary so that the Department may protect public health and safety by ensuring compliance with the training standards specified in section 40280 et. seq. of this regulatory proposal.

Paragraph (3): a list of all training topics and dates of training completion for all personnel. This provision is reasonably necessary for the Department to verify the licensee's compliance with the established training requirements.

Paragraph (4): a list of all training topics and dates of refresher training completion for all personnel. This provision is reasonably necessary for the Department to verify the licensee's compliance with the established training requirements

Paragraph (5): the signature of the individual personnel and the licensee verifying receipt and understanding of each training or refresher training completed by the personnel. This provision is necessary so that the Department can verify licensee and personnel compliance with training requirements.

Paragraph (6): official documentation such as certificates or permits attesting to the successful completion of required training by an employee or licensee. provision is

necessary so that the Department can verify licensee and personnel compliance with training requirements.

Subsection (c) clarifies that a licensee is allowed to designate specific personnel to implement the required training and training verification activities described in section 40280 et. seq. provided such personnel have met the training requirements described in subsection 40280, subsection (b), et. seq. above. This provision is necessary to provide clarity to the licensee.

Adopt Section 40282. Inventory Control – Cannabis and Cannabis Products. This section establishes the requirement that the licensee must implement and maintain a written inventory control process for cannabis and cannabis products in order to prevent diversion (as defined in § 40100 (Definitions), above). This section is reasonably necessary to protect the public from acts of diversion which may result in harm to public health and safety

Subsection (a) requires that a licensee implement and establish a written inventory control plan that accounts for the location and disposition of all cannabis and cannabis products at the licensed premises. The inventory control plan enables the licensees to keep track of the physical location of cannabis and cannabis product. While the track-and-trace requirements will log cannabis and cannabis product in and out of the facility, the inventory control plan will document where in the facility any cannabis or cannabis product is located. Keeping strict control over the location of cannabis will reduce potential for diversion. This provision is reasonably necessary to reduce the potential for diversion of cannabis or cannabis products which may cause harm to public health and safety.

Subsection (b) requires a licensee to reconcile all inventories of cannabis and cannabis products in inventory with the records in the track-and-trace database at the close of business each day. This provision is reasonably necessary to ensure that all cannabis and cannabis products are accounted for on a regular basis so as to prevent opportunities for diversion. This subsection further requires reconciliation to be performed by one person and independently verified by a second person. Such reconciliation is necessary in order to reduce the potential for to diversion.

Subsection (c) requires the licensee to conduct an audit if a discrepancy is found between the inventory and the track-and-trace database. This provision is reasonably necessary to ensure that the source of the discrepancy is identified and that appropriate measures taken to rectify.

Subsection (d) requires the licensee to notify the Department within 24 hours if the audit required by Section 40282, subsection (c) reveals a discrepancy of more than five percent between the track-and-trace data-base and the documented inventory. This provision is reasonably necessary to ensure that the Department has in place a

means of ensuring licensee accountability and to help prevent instances of diversion at manufacturing facilities which may ultimately impact public health and safety.

Subsection (e) requires the manufacturer to immediately report theft or diversion to the Department. This will allow the Department to take appropriate oversight actions as necessary.

Adopt Section 40290. Disposal of Cannabis Waste. This section establishes requirements for the disposal of cannabis and cannabis products, including the requirement that cannabis waste be rendered unusable and unrecognizable before disposal, and makes specific the steps necessary to accomplish this requirement. This section further establishes the requirement that licensees are responsible for ensuring that cannabis waste is rendered unusable and unrecognizable before disposal. Finally, this section establishes the requirement that licensees keep a written record of all activity related to the disposal of cannabis waste.

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. Secondly, cannabis or cannabis waste that is recognizable as such can provide opportunities for diversion which may also result in contamination of other cannabis products and/or pose a threat to public health. In order to protect public health and safety and comply with the intention of the Act (Bus. & Prof. Code §19303), it is necessary for the Department to establish requirements for the proper disposal of cannabis waste.

Subsection (a) clarifies that cannabis waste that is not hazardous is considered solid waste in accordance with Public Resources Code section 40191, that cannabis waste must be made unusable and unrecognizable prior to disposal, and that a licensee cannot sell cannabis waste.

Subsection (b) requires a licensee to manage cannabis waste that is a hazardous material in accordance with all applicable federal, state, and local statutes, regulations. Compliance with applicable federal, state, and local laws for the disposal of chemical, dangerous, or hazardous waste protects public health and safety by mitigating contact between the public and any harmful substances and is reasonably necessary so that the Department may carry out its mandate under the Act (Bus. & Prof. Code §19303).

Subsection (c) prohibits a licensee from disposal of cannabis waste in an unsecured waste receptacle not in possession and control of the licensee. This requirement is reasonable necessary to ensure that cannabis waste is not tampered with or diverted.

Subsection (d) requires licensees to hold in quarantine any medical cannabis products that are to be rendered into cannabis waste for a minimum of 72 hours. This provision also provides that the quarantined waste is subject to inspection by the Department and is necessary to allow the Department to conduct investigations and sampling if needed to protect public health and safety.

Subsection (e) requires licensees to render cannabis waste unusable and unrecognizable before disposal via incorporation with a non-consumable, non-cannabis product. This requirement is similar to the United States Drug Enforcement Agency's (USDEA) requirements that controlled substance pharmaceuticals be rendered non-retrievable so as to prevent diversion of the substance.

Subsection (f) requires the rendering process to be conducted under video surveillance. Conducting the activities under video surveillance is necessary in order to ensure that the waste has actually been destroyed and has not been diverted.

Subsection (g) specifies the requirements the licensee must comply with if the waste is to be composted at a compostable materials handling operation.

Subsection (h) requires that the cannabis waste be disposed of at either a (1) manned and fully permitted solid waste landfill; (2) a manned compostable materials handling operation or facility; or (3) a manned in-vessel digestion operation or facility. This subsection is necessary to ensure that cannabis waste is disposed of in accordance with state waste management laws and is not diverted.

Subsections (i), (j), (k), and (l) require that the licensee use the track-and-trace database and on-site documentation to ensure the waste materials are identified, weighed, and tracked. These provisions is necessary to maintain the integrity of the track-and-trace system and to prevent diversion

Adopt Section 40292. Consent to Sample Collection. This section is adopted in order to establish the requirement that a licensee must allow the Bureau to collect samples of cannabis product at a distributor under specified conditions. The Bureau licenses testing laboratories. To enforce the provisions of the testing-laboratory regulations and to ensure licensed testing laboratories are reporting accurate results, the Bureau will need to, on occasion, collect "split samples" from a manufactured cannabis batch or lot at the same time as the sampling agent from the licensed testing laboratory collects samples for analysis for the official, state-mandated testing. The Bureau will collect samples in the same amount as the testing laboratory does (according to the weight of the lot) and will analyze the samples and compare the results with the results from the licensed testing laboratory. The Bureau will perform these analyses to ensure the testing laboratory reported accurate results.

**V. ADD SUBCHAPTER 4. PRODUCTS.** In addition to licensing of manufacturers and setting standards for manufacturing, the Department, in this regulation package, will be setting standards for the quality of the finished product under its implied statutory authority.

Business and Professions Code section 19347.6 defines situations and characteristics under which a product will be considered adulterated, including:

- It has been produced, prepared, packed, or held under insanitary conditions [subsection (a)(1)];
- It consists in whole or in part of any filthy, putrid, or decomposed substance [subsection (a)(2)];
- It bears or contains a substance that is restricted or limited under the statute or regulations and the level of substance in the product exceeds the limits specified by statute or regulation [subsection (a)(4)].

The Act provides the Department with the authority to determine a cannabis product is adulterated and can order recall, segregation, embargo, or destruction of a product (Bus. & Prof. Code §19347.7). Finally, Business and Professions Code section 19347.4 authorizes the Department to notify the public regarding any cannabis product if the Department deems it necessary for the protection of the health and safety of the consumer or for the consumer's protection from fraud.

These sections, in combination with the Department's authority to administer the provisions of the Act related to and associated with the manufacturing of medical cannabis,<sup>21</sup> can reasonably be construed to authorize the Department to set standards for product quality as necessary to protect the health and safety of the consumer.

Add Article 1. Cannabis Product Standards

Adopt Section 40300. Prohibited Products. This section is added to establish the types of cannabis product that are *not* permitted to be manufactured. This section is necessary for the Department to protect public health through the prevention of unsafe products.

Subsection (a) prohibits infusion of alcoholic beverages, as defined by section 23004 of the Business and Professions Code. 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.<sup>22</sup> This has the potential of altering the intended dosage of medical cannabis products as well as increasing the level of psychological impairment of medical cannabis users, in addition to the well-documented adverse health effects of alcohol alone. This restriction is necessary to protect the health of the consumer.

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<sup>21</sup> Business and Professions Code section 19302.1, subdivision (f) .

<sup>22</sup> Meier, A review of the additive health risk of cannabis and tobacco co-use (Sept. 1, 2016) 166 Drug Alcohol Depend., pages 6-12.

Although using alcohol and cannabis together is very common, there is increasing evidence that co-use substantially increases risk to the user. For example, a review of the presence of alcohol and other drugs, including marijuana, in persons killed in fatal motor vehicle crashes showed that the risk of fatal crash was doubled in persons with alcohol and another drug (including marijuana) over those with alcohol only.<sup>23</sup> Restricting the combination of alcohol and cannabis in a single product is necessary to protect public health.

Subsection (b) prohibits the addition of any non-cannabinoid additives that would increase potency, toxicity or addictive potential including nicotine and caffeine. A review of the scientific literature examining additive health risk of cannabis and tobacco co-use discusses mechanisms of co-use which reinforces the use of tobacco and cannabis products.<sup>24</sup> The recommendation that caffeine not be allowed as an additive comes from the FDA determination that caffeine (stimulant) in certain alcoholic (depressant) beverages is an “unsafe food additive” due to the unpredictable negative effects of the two substances. The mixing of stimulants with depressants may lead to dangerous cardiac events.

A similar lack of definitive information exists as well for the safety of caffeine as an additive to cannabis.

Subsection (c) prohibits edible products from being made from potentially hazardous foods. Potentially hazardous foods are those that require time/ temperature controls because the food product is capable of supporting the growth of infectious or toxigenic microorganisms when held at temperatures above 41 degrees Fahrenheit. Paragraphs (1) – (8) provide the list of foods that the Department considers potentially hazardous for purposes of this restriction.

Paragraph (1) – any product that must be held at or below 41° F to keep it safe for human consumption. The FDA has developed a method by which food processors may determine if their product needs to be held below 41° F. A manufacturer can use this guidance to determine whether the product will need to be kept cold. If so, the product cannot be infused with cannabis.

Paragraph (2) – any low-acid product with a pH greater than 4.6 and water activity ( $a_w$ ) greater than 0.85 that is vacuum packed; and Paragraph (3) – any canned product. 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 (pH above 4.6) can support the growth of the microorganism.<sup>25</sup> Botulism has

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<sup>23</sup> Guohua, et al., “Drug use and fatal motor vehicle crashes: A case-control study.” (2013) 60 Accident Analysis and Prevention, pages 205-210

<sup>24</sup> Hatsukami, et al.

<sup>25</sup> USFDA, Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).

a high mortality rate and is especially concerning for immunocompromised individuals. It is necessary to prohibit the manufacture of canned or low-acid, vacuum packed products because of the potential public health threat.

Paragraph (4) – any juice, defined as the liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetable, or any concentrates of such liquid or puree. 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*.<sup>26</sup> Fruits and vegetables, including juices, that 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.

Paragraph (5) – perishable bakery products (i.e. any products that need to be refrigerated to maintain the safety of the product), including, but not limited to, cream- or custard-filled pies; pies or pastries which consists in whole or in part of milk or milk products, eggs, or synthetic fillings; or meat-filled pies or pastries. Eggs and egg products can become easily contaminated and will support the growth of spoilage and pathogenic microorganisms. Temperature control of shell eggs, followed by thorough cooking and proper handling, are essential in assuring safety. The principal human pathogens of concern in eggs and egg products are of the genus *Salmonella* (primarily *Salmonella enteritidis*).

Paragraph (6) - dairy products of any kind. Milk is an excellent growth medium for many kinds of microorganisms as it provides rich nutrients for microbes, is high in moisture, and has neutral pH. Due to these factors, it is subject to microbial spoilage from the moment it is secreted from a healthy animal. Milk is exposed to the potential for microbial contamination during collection, storage, transportation, and processing. The principal pathogens of concern associated with milk and processed milk products are *Salmonella* spp., *L. monocytogenes*, *S. aureus*, enterohemorrhagic *E. coli*, *Campylobacter jejuni*, *C. botulinum*, and *B. cereus*.

Paragraph (7) – meat products of any kind. 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.

Paragraph (8) – seafood products of any kind. Seafood is more perishable than other high-protein products due to the high level of soluble nitrogen compounds in

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<sup>26</sup> Evaluation and Definition of Potentially Hazardous Foods.

the tissue. Because of the potential public health threat, seafood products of any kind are prohibited.

Subsection (d) prohibits the manufacture of products set for in Division 15 of the Food and Agriculture Code. Division 15 governs the creation of butter. The prohibition against butter is a statutory restriction and is included here for clarity. It should be noted that this subsection does not prohibit a licensee from using commercially-available butter as an extraction method, but instead prohibits a licensee from taking raw ingredients and using them to create butter for sale.

Subsection (e) prohibits a licensee from applying cannabis extract to a commercially manufactured snack food or candy. This provision is intended to prevent confusion with non-cannabis products.

Adopt Section 40302. Prohibited Ingredients and Components. This section requires that product ingredients and components must be approved by the USFDA for use in food processing. This provision is necessary to ensure that the final product is safe for human consumption.

Adopt Section 40305. Edible Products – Serving Size. There is very limited scientific data on safe THC limits. The Department believes that this lack of human safety data, combined with what is known from experience about the actual and potential toxicity of unintentional ingestion of high levels of cannabis containing products, demonstrates the need to set THC limits for cannabis products in order to protect the public's health and safety. In setting such limits, the Department has sought to balance protecting the public's health and safety with consumer need to access medical cannabis.

Subsection (a) limits edible cannabis products to no more than 10 mg of THC per serving and no more than 100 mg of THC per package of finished product. 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 protects children and reduces the risk of accidental overdose and injury while balancing consumer needs. The recommended THC concentration limits would align the Act with the AUMA by requiring a serving size of no more than 10 mg of THC per serving and 100 mg THC per package for all edible cannabis products. The AUMA limits the THC content per serving for all manufactured products to 10 mg THC/serving.

A survey of other legal cannabis state programs was conducted to determine the rationale behind setting THC concentration limits in other states. The following states were queried: Washington, Oregon, Alaska, Hawaii, Nevada, and Colorado. Both medical and adult-use cannabis are legal in the states of Washington, Oregon, and

Colorado with Nevada voters approving adult-use cannabis in November 2016. Nevada does not currently have adult-use cannabis regulations. Also, Nevada does not limit THC concentrations in medical cannabis products. Rather, Nevada imposes a limit on the quantity of edible cannabis product and cannabis-infused products sold in a single sales transaction during a 14-day timeframe to an amount equal to 2 ½ ounces of usable cannabis. Similarly, Colorado has a single sales transaction limit on all cannabis products, as well as limits on THC concentration of adult-use edible cannabis products to 10 mg THC per serving and 100 mg THC per package. In the development of these limitations, Colorado convened a special working group to address the balance between public safety and industry impact.<sup>27</sup> The working group recommended each edible cannabis product serving size should be 10 mg THC or less and be physically demarked. The workgroup also recommended heightened packaging and labeling requirements.

A common theme across all states in the survey was concern about attractiveness to minors, accidental ingestion by children, and overconsumption by novice consumers. For both adult-use and medical edible cannabis products, the states surveyed had THC concentration limits ranging from 5 mg THC per serving (Alaska) to 10 mg THC per serving (Washington and Colorado) while Oregon had a limit of 5 mg THC per serving on the adult-use side and no limit on THC per serving on the medical side. The state of Hawaii has not legalized adult-use and does not allow edible cannabis products under their medical cannabis program. No states allow more than 100 mg THC per package.

A recently released study by the National Academies of Sciences, Engineering, and Medicine noted that “state-based legalization of cannabis is associated with a subsequent increase in pediatric cannabis exposures in those states.” The study notes a similar trend when comparing states in which cannabis is legal and those in which it is not. Cannabis-related pediatric exposure is associated with serious symptoms, such as respiratory depression or failure, tachycardia and other cardiovascular symptoms, and temporary coma, symptoms not typically associated with adult cannabis exposure.<sup>28</sup>

Subsection (b) requires that edible products containing more than a single serving be scored, delineated, or otherwise similarly marked to indicate one serving. Unlike other forms of cannabis products, the effects of edible cannabis products may be delayed by up to two hours. Delineating or scoring edible products into standardized

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<sup>27</sup> The working group consisted on representatives from the cannabis industry, State and local governments, law enforcement, and Children’s Hospital Colorado. The group issued its findings in a January 2015 report titled, “House Bill 14-1366 Marijuana Edibles Work Group Report.”

<sup>28</sup> National Academies of Sciences, Engineering, and Medicine, The, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017). The National Academies Press, page 9-14..

sizes together with product label warnings minimizes the risks associated with over consumption in novice consumers.

Adopt Section 40306. Finished Cannabis Products – Maximum THC Content. The states surveyed were also asked about THC concentration limits in products other than edible cannabis products. The range of THC concentration limits varied greatly among the states surveyed. A common theme across all states surveyed, however, was the desire to balance public health and safety with consumer need. Manufactured cannabis products that are not edibles (such as capsules, tinctures, and topicals), are less attractive to children but curious pets may ingest a product, leading to veterinary hospital emergency visits.<sup>29</sup> The recommended THC concentration limits are intended to minimize the risk of accidental ingestion and injury if a human or pet were to accidentally ingest a product while providing consumers with a higher mg THC per package (1000 mg THC per package) for these more traditional medical delivery mechanisms. The Department is pursuing this approach to protect public health and safety.

Adopt Section 40307. Uniform Distribution. This section requires cannabinoids to be uniformly distributed throughout the product. Inconsistent distribution can lead to consumers ingesting a higher concentration of cannabinoids than intended, which is a threat to their health and safety.

Adopt Section 40310. Contaminants. This section establishes standards regarding contaminants.

Subsection (a) prohibits cannabis product from exceeding contaminant levels set in the Business and Professions Code section 19344 or adopted by the Bureau pursuant thereto. The Bureau will be developing regulations related to testing laboratories and the maximum levels of contaminants that a product cannot exceed in order to be permitted to enter the commercial market. This provision is necessary to provide manufacturer licensees with notification of the product standards with which they are required to comply.

Subsection (b) provides that cannabis products that contain contaminant levels that render the product adulterated cannot be mixed with other cannabis products to decrease the contaminant level to an acceptable range. This requirement is adopted from the USFDA food manufacturing regulations and is necessary to protect public health and safety.

## **VI. ADD SUBCHAPTER 5. LABELING AND PACKAGING REQUIREMENTS.**

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<sup>29</sup> From January 1998 to January 2002, 213 incidences were recorded of dogs that developed clinical signs following oral exposure to cannabis, with 99% having neurologic signs, and 30% exhibiting gastrointestinal signs. (Janczyk et. al., Two Hundred and Thirteen Cases of Marijuana Toxicoses in Dogs, (2004) 46 Veterinary Human Toxicology, p. 19-21.).

The Act tasks the Department with both establishing standards for the labeling of all manufactured medical cannabis products,<sup>30</sup> as well as specifying the requirements that all packages of manufactured cannabis must meet.<sup>31</sup> This subchapter is added to Chapter 13 to establish the labeling and packaging requirements to which manufactured cannabis products must adhere. This provision is necessary to comply with the Department's mandate under the Act.

Add Article 1. General Provisions. The labeling requirements will be grouped under this article to provide the labeling requirements as required by the Act. This provision is reasonably necessary to provide clarity to the regulated public by including all statutory and regulatory requirements in a single location.

Adopt Section 40400. Applicability. This section is provided in order to clarify that the requirements in Section 40400 only apply to products intended for sale at a dispensary, not to products that are being transferred between licensees for further processing. The labeling requirements have been developed with consumer protection and education as the goal. It would be overly burdensome on the manufacturing industry, with no corresponding increase in public health and safety, to label and package products intended for further processing to this standard.

Adopt Section 40401. Release to Distributor as Finished Product. This section clarifies that a licensee may only release finished cannabis products to a distributor. This provision is necessary to protect the product from contamination.

Add Article 2. Labeling Requirements.

Adopt Section 40403. General Provisions. This section provides the basic requirements for labeling.

Subsection (a) requires all information required to be listed on the label to be in English. This is necessary to ensure that consumers and enforcement officials can read and understand the label.

Subsection (b) requires the label to be unobstructed and conspicuous. Labels provide important information to consumers that may prevent hazards such as overconsumption of THC and, as such, protect the public health. Therefore, labels should not be hidden by other materials and should be prominent enough to be easily identified and read by consumers. This provision is necessary to fulfill the Department's obligation to protect public health.

Subsection (c) similarly requires all required labeling information to be unobstructed and conspicuous. For reasons provided in subsection (b), above, to fulfill the Department's obligation to protect public health.

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<sup>30</sup> Business and Professions Code section 19341.

<sup>31</sup> Business and Professions Code section 19347.

Adopt Section 40405. Primary Panel Labeling Requirements to describe the requirements of the label's "primary panel." The "primary panel" is defined in Section 40100 as the part of the label that is most likely to be shown to the customer under conditions of retail sale (i.e. the "front" of the product package). The primary panel contains the basic information the consumer will need to make informed decisions capable of affecting their health and safety. Therefore, this provision and all its paragraphs, subparagraphs, and subsections, is reasonably necessary so that the Department may carry out its mandate in accordance with section 19341 of the ACT.

Paragraph (1) of subsection (a) requires the identity of the product to be printed on the label. Identity of the product is defined in Section 40100 as the name by which the product is most commonly known. Further provisions of this regulation require opaque packaging of edible products. Correct identification of a product ensures public health and safety by providing consumers with accurate information on what the package contains.

Paragraph (2) of subsection (a) requires the words "cannabis-infused" to be printed immediately above the product identity and in a larger text size than the product identity. This provision is intended to make it obvious to the consumer that the product contains cannabis and is not a traditional food product. Differentiation between traditional food products and products containing cannabis is necessary in order to protect public health and safety by preventing any unintentional consumption of a cannabis product by consumers.

Paragraph (3) of subsection (a) requires that the label include the cannabis product symbol, which is defined in Section 40412. The cannabis product symbol provides another method of informing people that the product contains cannabis and helps to protect public health and safety as discussed in paragraph 2 of subsection a, above.

Paragraph (4) of subsection (a) requires the label on a cannabis product to provide the net weight or volume of the contents of the package. This is a standard requirement in food manufacturing so that consumers can verify the contents of the package are in accordance with what is has been purchased.

Paragraph (5) of subsection (a) requires the content of THC and CBD contained in a cannabis product be printed on the primary panel of the label. Business and Professions Code section 19347(a)(2)(l) requires THC and/or CBD content to be printed on the label. Because THC and CBD content is one of the primary elements consumers will look for when purchasing a cannabis product, prominently displaying content levels on the primary panel of a label will ensure that this information is easily accessible to the consumer. The following subparagraphs specify the manner in the THC and/or CBD content is required to be included on the primary panel:

Paragraph (6) of subsection (a) requires the content of THC and/or CBD per serving, expressed in milligrams per serving. As a package may contain more than one

servings, both the total amount of THC and/or CBD per package and the amount per serving are valuable information for the consumer and will enable them to make a safe and informed choice. This provision is a statutory requirement of the Act<sup>32</sup> and is included here for the clarity to the regulated industry and public.

Paragraph (7) of subsection (a) allows the content of other cannabinoids or terpenes to be printed on the label if the information has been verified by a licensed testing laboratory. Many familiar with cannabis attribute certain effects to specific terpenes, and some consumers (but not all) are interested in knowing the specific terpenes in the product. Because there are over 100 known terpenes and a strain of cannabis could contain multiple terpenes, the Department is concerned that requiring a full listing of the terpenes in the product could negatively impact the readability and effectiveness of the product label. However, in the interest of truth in labeling, if specific terpenes are claimed to be present that information must be validated by an independent laboratory.

Subsection (b) of subsection (a) establishes the minimum size for the text of a label's primary panel as 6 point font or no less than 1/12 of an inch. Product information will not be effective if it is too small to read. Food manufacturing regulations set the minimum text size as 1/16 of an inch, roughly the equivalent of 4.5 point font. Due to the nature of cannabis products, this provision is intended to ensure that information can be easily read by the consumer and any other individual who may have access to the product, in order to mitigate instances of unintended consumption that pose a threat to public health and safety.

Adopt Section 40408. Informational Panel Labeling Requirements to specify the information that needs to be included on the remaining portion of the label, known as the "informational panel." The informational panel is defined in Section 40100 as the remaining portions of the label that are not the primary panel. The following paragraphs establish the information that needs to be included on the informational panel:

Paragraph (1) of subsection (a) requires the name of the licensed manufacturer and a contact number or website address. For purposes of product complaint, consumers must be able to contact the manufacturer of a product.

Paragraph (2) of subsection (a) requires the date of manufacture. This is a statutory requirement<sup>33</sup> and is included here so that all cannabis product labeling requirements can easily be found by the public or the regulated industry.

Paragraph (3) of subsection (a) lists the mandated statements that are required to be included. Except for subparagraph (D) all of the statements are required to be

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<sup>32</sup> Business and Professions Code section 19347(a)(2)(l).

<sup>33</sup> Business and Professions Code section 19347, subdivision (a)(2)(A).

included by statute<sup>34</sup>. The list is included here so that all cannabis product labeling requirements may be easily be found by the public and the regulated industry. Subparagraph (D) of paragraph (3) requires the warning statement “IF PREGNANT OR BREASTFEEDING, CONSULT A PHYSICIAN PRIOR TO USE.” The safety of cannabis use while pregnant or breastfeeding has not been established. This statement is intended to inform the consumer that such actions should be discussed with a physician.

Paragraph (4) of subsection (a) requires all product ingredients to be listed in descending order of predominance by weight or volume. While the listing of ingredients is a statutory requirement under Business and Professions Code section 19347(a)(2)(I), the Department has further specified that ingredients be listed in descending order of predominance as is a commonly accepted standard for food-product labeling. This provision is intended to provide clarity and ease of access to ingredient information to the public in order that they may make safe and informed choices regarding the consumption of cannabis products.

Paragraph (5) of subsection (a) requires major food allergens included in the product to be listed. This is a statutory requirement.<sup>35</sup> This provision is further necessary in order to clarify that any ingredient, flavoring, coloring, or incidental additive containing a major food allergen must also be noted on the information panel. Allergic individuals may react to allergens used as both primary and/or component ingredients in a cannabis product, necessitating that the Department clarify that *all* potential sources of food allergen must be considered and listed on the informational panel in order to protect the health of the consumer.

Paragraph (6) of subsection (a) requires the names of artificial food colorings used in the product. As some individuals are sensitive to artificial food colorings; this requirement is necessary to protect the health of the consumer.

Paragraph (7) of subsection (a) requires that edible product labels list the amount of sodium, sugar, carbohydrates, and total fat per serving. This is a standard practice for food-related labeling and is will provide consumers with information necessary to protect their health.

Paragraph (8) of subsection (a) requires the lot number. In cases of suspected contamination or recall, the lot number will allow manufacturers, distributors, dispensaries, and consumers to identify whether they hold a product from the affected or potentially affected lot.

Paragraph (9) of subsection (a) requires instructions for use and any preparation necessary prior to use to be listed. Instructions for use or application can cover a

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<sup>34</sup> Business and Professions Code section 19347, subdivision (a)(2)(B) – (F).

<sup>35</sup> Business and Professions Code section 19347, subdivision (a)(2)(H).

wide variety of information, such as how to determine a serving for edible products, where to apply tinctures, how to prepare the skin for transdermal products, or whether the product should be shaken prior to use. Instructions for use are best provided by the manufacturer and must be included on the label so that the consumer can easily find the information.

Paragraph (10) of subsection (a) requires a “best by” date. Stability studies to determine a date by which a product retains its best quality are common and well-established in food and drug manufacturing. Although the same level of study has not been conducted on cannabis, manufacturers will be able to set a “best by” date based on the non-cannabis elements of the product. This provision is necessary to protect public health from products with degraded quality.

Paragraph (11) of subsection (a) requires the unique identifier issued by the track-and-trace system. This is a statutory requirement.<sup>36</sup> It is included here for clarity.

Subsection (b) establishes the minimum size for the text of a label’s informational panel as 6 point font or no less than 1/12 of an inch, for the same reasons as specified for the primary panel. However, because some cannabis product packaging may be too small to include all of the required information, this subsection allows that the information may be provided through supplemental labeling (such as an insert). This provision is necessary so that the consumer is provided with readable information needed to protect their health.

This subsection further requires that, if required informational panel information is provided through supplemental materials, the warning statements mandated by paragraph 3 of this section must still be printed on the package. These warning statements are critical information to protect the public and should not be separated from the package.

Adopt Section 40410. Labeling Restrictions. The Act establishes several limitations on what can be printed on the label. The required restrictions are identified here in order to provide a single location in which the public and the regulated industry can access labeling requirements and restrictions and so that the Department may comply with its mandate under the Act. Labels for manufactured cannabis products are prohibited from:

Subsection (a) claiming the manufactured cannabis or cannabis product was grown in a California county if the cannabis was not grown there. This is a statutory restriction<sup>37</sup>.

Subsection (b) including the name of a California county unless the cannabis was grown there. This is a statutory restriction.<sup>38</sup>

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<sup>36</sup> Business and Professions Code section 19347, subdivision (a)(2)(L).

<sup>37</sup> Business and Professions Code §19332.5, subdivision (c).

<sup>38</sup> Business and Professions Code §19322.5, subdivision (d) .

Subsection (c) containing any content that is designed to be attractive to individuals under the age of 21. Business and Professions Code section 19347(a)(1) requires that packages and labels of medical cannabis products not be attractive to children. In order to make specific this statutory restriction, the Department is specifying the characteristics that would make a label “attractive to children.” In making this determination, the Department reviewed the regulations of other states with legalized cannabis. Oregon regulations contained the most specific description of what is considered appealing to children. The Department has incorporated many of Oregon’s requirements here.

Paragraph (1) prohibits the use of cartoons. Cartoons are often intended to specifically appeal to children. This provision is reasonably necessary to protect public safety and keep cannabis products away from minors.

Paragraph (2) prohibits any likeness to images, characters, or phrases popularly used to advertise to individuals under age 21. Such items on the label could lead to confusion that the product is intended for children. This provision is reasonably necessary to protect public safety and keep cannabis products away from minors.

Paragraph (3) prohibits any imitation of candy packaging or labeling. Candy can be particularly appealing to children. The Department wants to ensure that cannabis products are not able to be confused with traditionally-available candy products. This provision is reasonably necessary to protect public safety and keep cannabis products away from minors.

Subsection (d) including false information. Under the Act, any product with labeling that is false or misleading is considered misbranded<sup>39</sup> and subject to embargo by the Department. The restriction is included here so that all labeling requirements and restrictions are located in one location in order to provide clarity to the regulated industry and public.

Subsection (e) making any claims of health benefits and other physical benefits. The USFDA prohibits nutritional supplements from making any claims of health benefits unless the claim has significant scientific agreement and authorization from the USFDA. As there is currently no scientific agreement of specific health benefits to cannabis, it would be misleading to make claims of such on the label.

Adopt Section 40412. Cannabis Product Symbol. This section establishes the required cannabis product symbol to be printed on the primary panel. Product symbols are a commonly used tool to provide information and guidance as to a package’s content. Oregon, Washington, and Colorado all require a cannabis-specific symbol to be placed upon the package. A cannabis product symbol provides notice to that a product is not a traditional food product. This provision is necessary to protect from unintentional consumption.

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<sup>39</sup> Business and Professions Code section 19347.5, subdivision (a)(2).

Subsection (a) provides the cannabis product symbol. The symbol was designed by the Department and is intended to provide clear notice that a package contains cannabis.

Subsection (b) requires that the symbol must be no smaller than 0.5 inch by 0.5 inch in size. A symbol that is too small to be readily seen will not serve to protect public health.

Add Article 3. Packaging. This article is added to provide a single location for the public and regulated industry to find the packaging requirements for cannabis products.

Adopt Section 40415. Packaging. This section establishes the requirements to which packaging for manufactured cannabis products must adhere.

Subsection (a) requires that the packaging protect the product from contamination and does not expose the product to any toxic or harmful substance. Protecting cannabis products against contamination between manufacturing and purchase by the consumer is the basic function of a package and helps to ensure against negative health impacts to public safety. Furthermore, an adulterated product is one whose container is composed of any poisonous or deleterious substance. This provision is reasonably necessary for the Department to ensure products are not adulterated and are safe for human use or consumption.

Subsection (b) requires that the package be tamper-evident. This provision is necessary so that the Department may comply with its mandate under the Act that packaging be “tamper proof.”<sup>40</sup> “Tamper-proof” is not a term used by the USFDA to describe packaging requirements and appears to be an uncommon usage in the context of food or drug manufacturing. The USFDA uses the term “tamper-evident,” which is defined as a package that cannot be opened without obvious destruction to the seal. Because tamper-proof is not a commonly accepted requirement of food and drug packages, and indeed, may be an impossible requirement to meet, the Department has chosen instead to use the more common term “tamper-evident.”

Subsection (c) requires the packaging to be child-resistant. A key element of public health protection is decreasing the likelihood that children or unsuspecting adults could accidentally ingest cannabis products. This is a statutory requirement<sup>41</sup> and is necessary to protect public health and safety.

Subsection (d) prohibits the packaging from imitating any package used for products typically marketed to individuals under age 21. The Act prohibits the packaging of cannabis products from being appealing to children.<sup>42</sup> If cannabis product

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<sup>40</sup> Business and Professions Code section 19347, subdivision (a).

<sup>41</sup> Business and Professions Code section 19347, subdivision (a)(1)(M).

<sup>42</sup> Business and Professions Code section 19347, subdivision (a)(1).

packaging resembles packaging commonly used for children's products, children could be confused between products at great risk to their health. This provision is reasonably necessary to protect public health and safety.

Subsection (e) requires the packaging to be opaque if the package contains an edible product. Many cannabis products resemble traditional food products that may be especially appealing to children, including cookies, brownies, candies, chocolates, and beverages, and which may be confused with traditional items if glimpsed through transparent packaging. This provision is therefore reasonably necessary in order to mitigate situations in which a child may accidentally ingest a cannabis product that looks like a traditional food product.

Subsection (f) requires the packaging to be re-sealable in a manner that preserves child-resistance if the package contains more than one serving of product. The purpose of child-resistance (see subsection (b), above) is negated if a package containing multiple servings can no longer be made child-resistant after opening. The provision is necessary to clarify the requirements of a child-resistant package.

## **VI. Add Subchapter 6. Inspections and Enforcement**

Adopt Section 40500. Inspections. This section establishes the Department's inspection authorities to enforce the Act and these regulations.

Subsection (a) establishes that the Department and its inspectors or agents may conduct an on-site inspection prior to issuing a new or renewal license. This provision is reasonably necessary because the Department and its inspectors or agents need to be able to conduct on-site inspections prior to issuing a new or renewal license to determine compliance with the provisions of the Act and these regulations.

Subsection (b) establishes the Department and its inspectors or agents' authority must have free access at reasonable times to the manufacturing premises, storage areas, records, production processes, labeling, and packaging processes, and conveyances used in the manufacture, storage or transportation of medical cannabis products so that they may determine compliance with the provisions of the Act and these regulations. Inspection shall include all pertinent equipment, raw material, finished and unfinished materials, containers, packaging, and labeling that may have a bearing on whether the medical cannabis product complies with the Act and these regulations. This provision is reasonably necessary because the Department and its inspectors or agents need to have free access to the premises used to manufacture medical cannabis products to determine compliance with the provisions of the Act and these regulations.

Subsection (c) establishes that the Department may collect a sample or specimen of any medical cannabis product or ingredient during an inspection and that the inspector will leave a receipt describing any sample obtained prior to concluding the

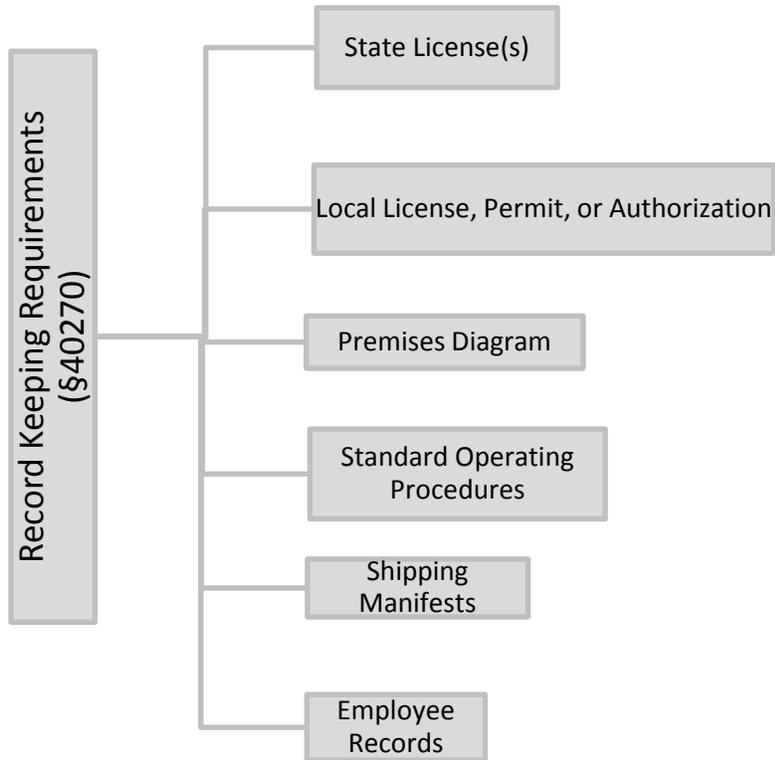
inspection. This provision is reasonably necessary because the Department may collect a sample or specimen of medical cannabis product or ingredient during an inspection to determine compliance with the provisions of the Act and these regulations.

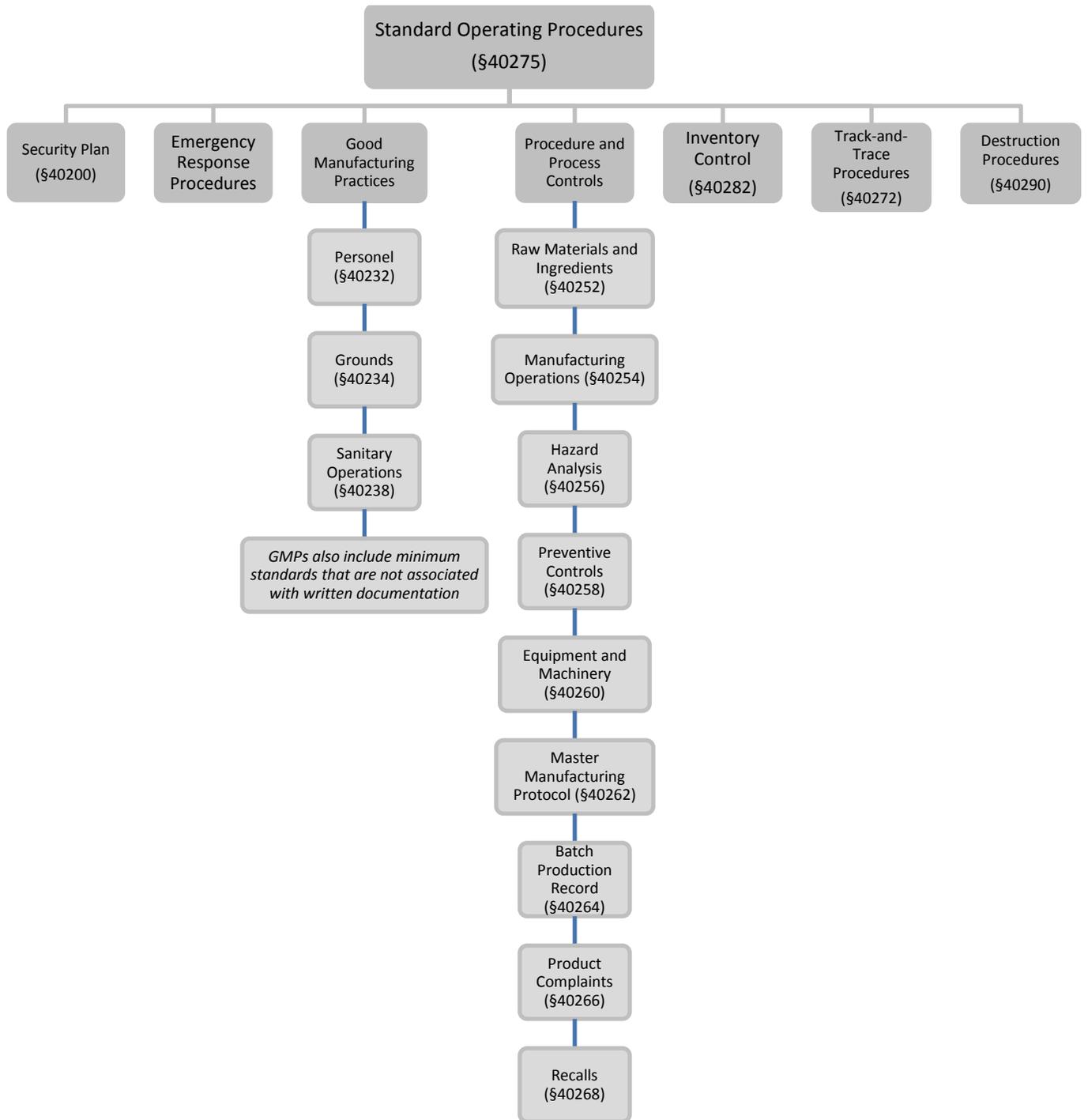
Subsection (d) establishes that the Department must provide the licensee a copy of the results of any sample analysis or determinations. This section establishes the licensee's right to know the results of any sample analysis or determinations. This provision will help the licensee comply with the provisions of the Act and these regulations.

Subsection (e) establishes that the Department may conduct investigations concerning the adulteration, misbranding, or unlicensed production of any medical cannabis product. Investigations will include entry and inspection of any place where any medical cannabis product is suspected of being manufactured or held in violation of the Act or these regulations. This provision is reasonably necessary for the Department to fulfill its mandate to protect public health.

*Written Documentation, Policies, Procedures, and Record Keeping*

Following is a visual representation of the required written documents, policies, and procedures in order to provide further clarity.





### **DOCUMENTS RELIED UPON**

The following studies, reports, and laws were used by the Department in development of these regulations: The following studies, reports, and laws were used by the Department in the development of these regulations:

- A. 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.
- B. Colorado Department of Revenue, Marijuana Enforcement Division. House Bill 14-1366 Marijuana Edibles Work Group Report. (January 30, 2015).
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- E. Mead et al., *Food Related Illness and Death in the United States* (Sept.-Oct. 1999) 5 Journal of Emerging Infectious Diseases, pages 607-625.
- F. Meier, A review of the additive health risk of cannabis and tobacco co-use (Sept. 1, 2016) 166 Drug Alcohol Depend., pages 6-12.
- G. National Academies of Sciences, Engineering, and Medicine, The, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017). The National Academies Press.
- H. Pava-Ripoll et al., *Detection of Foodborne Bacterial Pathogens from Individual Filth Flies* (Feb. 13, 2015) Journal of Visualized Experiments .
- I. United States Department of Justice, Memorandum ("Cole Memo"), (Aug. 29, 2013).
- J. United States Food and Drug Administration (USFDA), 2014 Reportable Food Registry (2014).
- K. USFDA, Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).
- L. USFDA, Compliance Policy Guidance: Filth from Insects, Rodents, and other Pests in Foods (Last updated: Nov. 14, 2002).
- M. USFDA, 21 C.F.R. Part 117. *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*.
- N. USFDA, 21 C.F.R. Part 111. *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*.
- O. USFDA Compliance Policy Guide. Foods, Adulteration Involving Hard or Sharp Foreign Objects (Last Updated: May 2005).
- P. World Health Organization (WHO), Hazard prevention and control in the work environment: Airborne dust (August 1999).
- Q. WHO, Cockroaches: Their biology, distribution and control (1999).

### **OBJECTIVES (GOALS)**

The objective of this proposed regulation is to implement the Department's responsibility under the Act to protect public health and safety through the licensing of cannabis product manufacturers, the establishment of safety standards for cannabis products, and the establishment of minimum standards for packaging and labeling of cannabis products.

## **BENEFITS**

The benefits of the regulation, including benefits to the health and welfare of California residents, worker safety, and the state's environment, are as follows:

- The proposal increases and strengthens the health and welfare of California residents, and worker safety by providing regulatory oversight to a previously unregulated industry. The proposed regulations improve health benefits through packaging and labeling requirements, minimum facility requirements, and product standards. As a result of these regulations, the Department anticipates a cleaner and safer product that results in fewer instances of over-consumption, consumption by children, potential exposure to product contaminants, or other related harm to the consumer.
- These proposed regulations will also positively impact public safety through safety measures designed to reduce accidents involving explosions and fires.

## **PRE NOTICE MEETING WITH AFFECTED PARTIES**

In conjunction with the Bureau, the Department held eight (8) pre-notice meetings with stakeholders. The meetings were held in a variety of locations throughout California (Redding, Sacramento, Santa Rosa, Oakland, Fresno, Santa Ana, San Diego, and Los Angeles). Notice of the meetings were provided on both the Bureau's and the Department's websites and sent through both email distribution lists.

## **CONSIDERATION OF REASONABLE ALTERNATIVES**

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulatory action, or would be more cost-effective to affected private persons.

Several elements of the proposed rulemaking package have alternatives that were considered and ultimately rejected.

1. Background investigations for all employees. The Department considered requiring that all persons employed by a manufacturing operation undergo a Live Scan criminal history check, as owners are required to do. This alternative was rejected as too costly for both the industry and the Department, with no corresponding increase in public health protection.
2. Product imprints. The Department considered mandating that a warning symbol be imprinted directly on edible products. Many infused products have a surface that is conducive to printing, stamping, or marking. The Department found no evidence that product imprints reduce exposure by minors.
3. Mandatory identification badges for cannabis industry employees. The Department has decided not to mandate the use of identification badges at this time. Identification badges can pose a risk of contamination in the manufacturing process. Other provisions of the regulation require jewelry and other items to be secured or removed so that they cannot dangle or fall into ingredients or

products. Mandating the issuance of identification badges would run contrary to this provision. Nothing would prohibit a licensee from issuing identification badges if the licensee determines the use of such badges does not pose a risk of contamination and is appropriate to ensure the security of the premises.

**STATEMENTS OF DETERMINATIONS and STANDARDIZED REGULATORY IMPACT ASSESSMENT (SRIA)**

In addition to the following determinations, the Department has prepared a Standardized Regulatory Impact Analysis (SRIA), which is required for major regulations by the Administrative Procedure Act. Due to its extensive length and in the interests of ease-of-reading for the regulated public, the SRIA can be found as Attachment 1 of this document.

**Determination of Significant Statewide Adverse Impact Directly Affecting Private Persons or Businesses, Including Ability to Compete**

The Department has determined that the proposed regulatory action would have a significant economic impact on California business enterprises and individuals. This regulation is considered a Major Regulation with a statewide impact of over \$50 million. The required Standard Regulatory Impact Assessment (SRIA) is included as Attachment 1 to this document.

The Department has determined that the regulations affect the following as described:

- A. The creation or elimination of jobs within the State of California.** The proposal will positively impact the creation of jobs in California. See Attachment 1, SRIA, for further details.
- B. The creation of new businesses or the elimination of existing businesses within the State of California.** The proposal will impact the creation of new businesses or result in the elimination of existing businesses within California. See Attachment 1, SRIA, for further details.
- C. The competitive advantages or disadvantages of businesses currently doing business within the State of California.** The proposal will impact the competitive advantages or disadvantages of businesses currently doing business in California. See Attachment 1, SRIA, for further details.
- D. The increase or decrease of investment in the state.** The proposal will impact the level of investment in the state. See Attachment 1, SRIA, for further details.
- E. The incentive for innovation in products, materials, and processes.** The proposal will impact the incentive for innovation. See Attachment 1, SRIA, for further details.
- F. The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment or quality of life.** This proposal will benefit public health and safety of California residents and worker safety. See Attachment 1, SRIA, for further details.

**Determination of Local Mandate**

The Department has further determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code. Section 19315 of the Business and Professions Code explicitly provides that nothing in the Act shall be interpreted to supersede or limit existing local authority.

**Determination of Reporting Requirements**

The Department has determined that reporting requirements are necessary to meet the specific requirements of the authorizing statute to track commercial cannabis activity. The Department has further determined that imposing reporting requirements is necessary to ensure protection of public health through the use of good manufacturing practices and preventive controls.

**Determination of Mandate for Use of Specific Technologies, Equipment , and/or Proscriptive or Performance Standards**

The Department has determined that performance standards are insufficient to accomplish the goals and objectives of this proposal.