# INITIAL STATEMENT OF REASONS

## SUMMARY OF PROPOSAL

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

The proposed regulations will:

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

## POLICY STATEMENT OVERVIEW

**Problem Statement:** The Department is required to license manufacturers of cannabis products, to set manufacturing standards for cannabis products, and to set packaging and labeling standards for such products.

**Objectives (Goals):** The objective of these proposed regulations 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.

## 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 license and regulate cannabis cultivators and oversee the State track-and-trace system.

- **Bureau of Cannabis Control** (Bureau) in the Department of Consumer Affairs, which will license and regulate retailers, distributors, testing labs, and microbusinesses.

- **California Department of Public Health** (CDPH), which will license and regulate cannabis product manufacturers. The Department is also required to develop standards for the production and labeling of all adult-use and 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 allowed 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 allowed 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 statewide licensure and regulation of medical marijuana. The primary portion of MMRSA was 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 Medical Cannabis Regulation and Safety Act (MCRSA).

Prior to the enactment of the MMRSA, California had no regulatory oversight of 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. AUMA was codified in separate code sections from the MCRSA. In June 2017, the Governor signed SB 94 (Cmte on Budget and Fiscal Review, Chapter 27, Statutes of 2017), a budget trailer bill to combine AUMA and MCRSA into a single, unified law known as the Medicinal and Adult-Use Cannabis Regulation and Safety Act (Act)

*History of Regulatory Proposal*

The Department initially released a rulemaking package in April 2017 (published April 28, 2017, in the Regulatory Notice Register) under the authority provided in MCRSA. Upon repeal of the MCRSA, the Department withdrew its rulemaking package.

However, the package had already been through a 45-day public comment period and hundreds of public comments were submitted. The Department reviewed and considered all comments and made revisions to the text, as appropriate. The revised text, which also incorporated rules and requirements for adult-use cannabis, was released as emergency regulations in November 2017 and became effective December 7, 2017.

Previous to the adoption of emergency regulations, the Department of Consumer Affairs formed the state's new Cannabis Advisory Committee under the Bureau of Cannabis Control. The Committee was formed under authority from Business and Professions Code Section 26014. The Committee's members were announced on October 4, 2017, and meetings began on November 16, 2017. The Committee has met six times since the adoption of the emergency regulations and has made a series of recommendations to the agencies responsible for cannabis licensing. These recommendations come from subject specific subcommittees, which include subcommittees on Enforcement, Microbusiness, Public Health and Youth, Retailers, Testing Laboratories, Cultivators, Distributors, Equity, Licensing Application, and Manufacturers.

*Establishment of Permanent Regulations*
This proposed rulemaking action will make the emergency regulations permanent. Some revisions to the emergency text have been made as a result of public comments received, as well as clarifications needed indicated by a number of questions received.

The Act, in Business and Professions Code (BPC) §26011.5, establishes protection of the public as the primary concern of regulatory agencies. 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 resources in an effective way. The Cole 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.

This memo was rescinded by Attorney General Jeff Sessions on January 4th, 2018 in his Memo on Marijuana Enforcement ("Sessions Memo"). The Sessions Memo directed all U.S. Attorneys to enforce the Controlled Substances Act laws, but leaves discretion of said enforcement up to the Attorneys themselves. Many have chosen to continue the hands-off approach directed by the now-rescinded Cole Memo.

When developing the initial regulatory package released in April 2017, the Department heavily considered this list of federal priorities. Although the Cole Memo has since been

rescinded by the Trump Administration, the priorities included within it align with the priorities of the Department and the Act. The Department has used 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. 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 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 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 cannabis products would choose to remain in the underground market. One step the Department has taken to create equity in access to the legal cannabis market is the creation of Type S licenses. These licenses allow for the shared use of certain licensed spaces, such as industrial kitchens or manufacturing floors, to allow for smaller businesses to operate without the cost associated with large-scale manufacturing facilities. The license fees for said space are also lower, allowing for equity in access to the consumer market. Such shared spaces work as a diversion against black market manufacturing by opening up previously unavailable spaces to manufacturers with less economic power.

*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.[1] It further requires that license fees be set on a scaled basis, dependent on the size of the business.[2]

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 and pay the manufacturing industry's share of the track-and-trace database[3].

Based on information provided by the Humboldt Institute for Interdisciplinary Marijuana

[1] Business and Professions Code section 26180.
[2] Business and Professions Code section 26180.
[3] Required by Business and Professions Code section 26067.

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 it will issue approximately 3,000 cannabis manufacturing licenses.

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

### I. Add Subchapter 1: General Provisions and Definitions

### Add Article 1. Definitions.

**Adopt Section 40100. Definitions.** This section 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 industry in order to effectuate the purposes of the enabling statute.

The emergency regulations contained all of the definitions in this section. As necessary definitions continued to be added, the definition section became increasingly lengthy and was not user-friendly. All of the definitions solely related to good manufacturing practices have been moved to the relevant subchapter to provide for greater ease of use.

Subsection (a): Adopt the term "A-license" to mean a license issued for commercial cannabis activities involving cannabis and cannabis products that are intended for individuals 21 years of age and older and who do not possess physician's recommendations. This is a statutory definition and is included in order to provide clarity to the regulated industry.

Subsection (b): Adopt the term "Act" to mean the Medicinal and Adult-Use Cannabis Regulation and Safety Act. This definition is included in order to provide clarity to the regulated industry.

Subsection (c): Adopt the term "adult-use market" to mean products intended for sale at an A-licensed retailer or microbusiness to individuals 21 years of age and older and who do not possess physician's recommendations. This is needed to ensure that THC and

other cannabinoid levels are within the acceptable parameters for adult use versus higher levels for medical use. This definition is necessary in order to provide clarity to the regulated industry.

Subsection (d): Adopt the term “adulterated” or “adulteration” to mean a product that meets the conditions of section 26131 of the Act. This definition is necessary in order to provide clarity to the regulated industry.

Subsection (e): Adopt the term “allergen” to mean a major food allergen including any of the following: (1) Milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. (2) A food ingredient that contains protein derived from a food specified in (1), except the following: Any highly refined oil derived from a food specified in (1) and any ingredient derived from such highly refined oil. This definition is reasonably necessary to inform the regulated industry of 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.

Subsection (f): Adopt the term “applicant” to mean the owner who is applying on behalf of a commercial cannabis business for a license to manufacture cannabis products. This definition is consistent with statute and included for clarity.

Subsection (g): Adopt the term “batch” or “production batch” to mean (1) an amount of cannabis concentrate or extract produced in one production cycle using the same extraction methods and standard operating procedures; or (2) an amount of a type of cannabis product produced in one production cycle using the same formulation and standard operating procedures. . As further provisions of the regulations specify requirements for each product batch, this definition is necessary to provide clarity to the regulated industry.

Subsection (h): Adopt the term “Bureau” to mean the Bureau of Cannabis Control in the Department of Consumer Affairs. This definition is necessary to provide clarity to the regulated industry.

Subsection (i): Adopt the term “cannabis concentrate” to mean cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product’s potency. “Cannabis concentrate” includes, but is not limited to, the separated resinous trichomes of cannabis, whether crude or purified (including dab, wax, or shatter), tinctures, capsules, suppositories, extracts, and vape cartridges. This

definition further clarifies the types of products that the Department considers to be a "concentrate," including tinctures, capsules, suppositories, vape cartridges, and inhaled products (such as shatter, dab, or wax). This provision is necessary to distinguish "concentrates" from "edibles" so that the public and the regulated industry can follow the appropriate requirements for each product. This change has been made at the request of stakeholders for their ease of understanding.

Subsection (j): Adopt the term "cannabis product" to mean cannabis that has undergone a process whereby the plant material has been transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical product containing cannabis or concentrated cannabis and other ingredients. This is a statutory definition and is necessary to provide clarity to the regulated industry.

Subsection (k): Adopt the term "cannabis product quality," "quality cannabis product," or "quality" to mean that the cannabis product consistently meets the established specifications for identity, cannabinoid concentration (as specified in Section 5724 of Title 16 of the California Code of Regulations), composition, and limits on contaminants (as specified in Section 5718 to 5723, inclusive, of Title 16 of the California Code of Regulations), and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and misbranding. This provision is necessary to ensure the safety of cannabis products for public consumption and to ensure the regulated industry and consumers create and receive quality products.

Subsection (l): Adopt the term "cannabis waste" to mean waste that contains cannabis or cannabis products, but is not otherwise a hazardous waste. This definition is included to provide clarity to the regulated industry.

Subsection (m): Adopt the term "CBD" to mean the compound cannabidiol. This definition is included in order to provide clarity to the regulated industry.

Subsection (n): 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 necessary to provide clarity to the regulated industry.

Subsection (o): Adopt the term "Department" to mean the State Department of Public Health. This definition necessary to provide clarity as to which licensing authority is being referred to in the proposed regulations.

Subsection (p): Adopt the term “distribution” to mean the procurement, sale, and transport of cannabis and cannabis products between licensees. This is a statutory definition and is included for ease of reading.

Subsection (q): Adopt the term “edible cannabis product” to mean a cannabis product that resembles traditional foods or beverages and cannabis products that dissolve or disintegrate in the mouth. This definition is necessary to provide clarity and to address products that could potentially be ambiguous as to whether they are considered an edible, such as mouth strips, lozenges, and tinctures. Requirements for edible products differ from other cannabis products; this definition is necessary for the regulated industry to understand which requirements apply to which products.

Subsection (r): 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 industry.

Subsection (s): Adopt the term “finished product” to mean a cannabis product in its final form to be sold at a retail premises. This definition is necessary to provide clarity to the regulated industry.

Subsection (t): Adopt the term “harvest batch” to mean a specifically identified quantity of dried flower or trim, leaves, and other cannabis plant matter that is uniform in strain, harvested at the same time, and, if applicable, cultivated using the same pesticides and other agricultural chemicals, and harvested at the same time. This is a statutory definition and is included for ease of reading.

Subsection (u): Adopt the term “informational panel” to mean any part of the cannabis product label that is not the primary panel and that contains required labeling information. Further provisions of the regulations contain requirements for the informational panel. This definition is necessary to provide clarity to the regulated industry.

Subsection (v): Adopt the term “infusion” to mean a process by which cannabis, cannabinoids, or cannabis concentrates are directly incorporated into a product formulation to produce a cannabis product. The cannabis manufacturing process includes all aspects of the infusion process. This definition is necessary to provide clarity to the regulated industry.

Subsection (w): Adopt the term “infused pre-roll” to mean a pre-roll into which cannabis concentrate or other ingredients have been incorporated. This definition is necessary to clarify the difference between a “pre-roll,” which is not considered a manufactured cannabis product, and an “infused pre-roll,” which is a manufactured product.

Subsection (x): 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 necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Subsection (y): Adopt the term “kief” to mean the resinous trichomes of cannabis that have been separated from the cannabis plant. This definition corresponds to terminology used in the industry and definitions used by CalCannabis. It is necessary to provide clarity on terms.

Subsection (z): Adopt the term “labeling” to mean any label or other written, printed, or graphic matter upon a cannabis product, or upon its container or wrapper, or that accompanies any cannabis product. Further provisions of the regulations contain specific labeling requirements for cannabis products. This is a statutory definition included to provide clarity to the regulated industry.

Subsection (aa): Adopt the term “limited-access area” to mean an area in which cannabis or cannabis products are 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 necessary to provide clarity to the regulated industry.

Subsection (bb): Adopt the term “M-license” to mean a license issued for commercial cannabis activity involving medicinal cannabis. This is a statutory definition and is included for ease of reading.

Subsection (cc): 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 included to provide clarity to the regulated industry.

Subsection (dd): Adopt the term “manufacture” to mean to compound, blend, extract, infuse, or otherwise make or prepare a cannabis product. This definition further defines what is and is not included under the “manufacture” definition. 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.

Subsection (ee): 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. Manufacturing does not include relabeling of cannabis products, the creations of pre-rolls, or the collection of kief incidental to cultivation activities. This definition is necessary to provide clarity to the regulated industry.

Subsection (ff): Adopt the term “MCLS” to mean the Manufactured Cannabis Licensing System, the online license applications system available on the Department’s website. Further provisions of the regulations provide for submission of applications and information through MCLS and this definition is necessary to clarify how to access the system.

Subsection (gg): 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 and ethanol used for extraction. Further provisions of the regulations contain requirements for license Type 6, which involves the use of nonvolatile solvents. This definition is necessary to provide clarity to the regulated industry.

Subsection (hh): Adopt the term “orally-consumed concentrate” to mean cannabis concentrates that are consumed by mouth and are not otherwise considered edibles. Further provisions of the regulations specify requirements for orally consumed concentrates; this definition is necessary to clarify the requirements to which products must adhere.

Subsection (ii): Adopt the term “package” or “packaging” to mean any container or wrapper that may be used for enclosing or containing any cannabis products. The term “package” does not include any shipping container or outer wrapping used solely for the transportation of cannabis products in bulk quantity to another licensee or licensed premises. Further provisions of the regulations contain requirements for packaging of cannabis products. This definition is necessary to provide clarity to the regulated industry.

Subsection (jj): 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. This definition is necessary to provide clarity to the regulated industry.

Subsection (kk): Adopt the term “person” to mean any individual, firm, partnership, joint venture, association, corporation, limited liability company, estate, trust, business trust, receiver, syndicate, or any other group or combination acting as a unit, and the plural as well as the singular. This is a statutory definition and is included for ease of reading.

Subsection (ll): Adopt the term “pre-roll” to mean any combination of flower, shake, leaf, or kief rolled in paper. Pre-rolls are a common and popular item sold, and the term is a term of art commonly used in the cannabis industry. However, it is necessary to distinguish pre-rolls that contain only parts of the cannabis plant from pre-rolls that are infused with concentrate or other ingredients. The Department developed this definition in conjunction with the Bureau and CDFA in order to ensure conformity of terminology in the regulated industry.

Subsection (mm): Adopt the term “premises” to mean the designated structure (s) and land specified in the application that is owned, leased, or otherwise held under the control of the applicant or licensee where the commercial cannabis activity will be or is conducted. This definition is included to provide clarity to the regulated industry by making specific what is meant by “premises” in the context of these regulations.

Subsection (nn): Adopt the term “primary panel” to mean the part of a cannabis product label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. This definition necessary to clarify which

portion of the label is the primary panel so that the regulated industry can properly understand and follow labeling requirements.

Subsection (oo): Adopt the term “product identity” or “identity of the product” to mean the generic, common, or usual name of the product by which it is most commonly known. This definition is necessary so that the regulated industry can properly understand and follow labeling requirements.

Subsection (pp): Adopt the term “quarantine” to mean the storage or identification of a product to prevent distribution or transfer of the product. This definition necessary to provide clarity to the regulated industry.

Subsection (qq): Adopt the term “serving” to mean the designated amount of cannabis product established by the manufacturer to constitute a single unit. This definition is needed as the Department has set a maximum amount of cannabinoids per serving in edible products for both the medical and adult-use market. This definition is necessary to provide clarity to the regulated industry.

Subsection (rr): Adopt the term “tablet" to mean a solid preparation containing a single serving of THC or other cannabinoid that is intended to be swallowed whole, and that is not formulated to be chewable, dispersible, effervescent, orally disintegrating, used as a suspension, or consumed in a manner other than swallowed whole, and that does not contain any added natural or artificial flavor or sweetener. This definition necessary to provide clarity to the regulated industry and to differentiate between concentrates in tablet form meant to be swallowed whole and dissolving or flavored tablets, which are a greater risk of being mistaken for products that are attractive to children such as lozenges and mints and are therefore classified as edibles.

Subsection (ss): 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 necessary so that the regulated industry can properly follow labeling requirements.

Subsection (tt): Adopt the term “topical cannabis product” to mean a cannabis product intended to be applied to the skin rather than ingested or inhaled. This definition necessary to provide clarity to the regulated industry.

Subsection (uu): Adopt the term “track and trace system” to mean the program for reporting the movement of cannabis and cannabis products through the distribution

chain established by the Department of Food and Agriculture in accordance with section 26067 of the Act.

The Act requires the CDFA, in consultation with the Bureau, to establish a track and trace program for reporting the movement of cannabis products throughout the distribution chain. Further provisions of the regulations include specific track and trace requirements for manufacturer licensees. This definition necessary to provide clarity to the regulated industry.

Subsection (vv): Adopt the term "UID" to mean the unique identifier for use in the track-and-trace system established by the Department of Food and Agriculture in accordance with section 26069 of the Act. This definition is included to provide clarity to the regulated industry.

Subsection (ww): Adopt the term "universal symbol" to mean the symbol established by the Department pursuant to paragraph (7) of subdivision (c) of section 26130 of the Act to indicate a product contains cannabinoids. Further provisions of the regulation require the use of the universal symbol. The definition is necessary to provide clarity to the regulated industry. The image is included in these regulations in Section 40412.

Subsection (xx): 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, as defined in Health and Safety Code 11362.3(b)(3). Examples of volatile solvents include, but are not limited to, butane, hexane, or propane. The Act requires that the Department establish two manufacturer license types based on the type of solvent (volatile and non-volatile) used. This definition is necessary to provide clarity to the regulated industry.

**Adopt Section 40101. Applicability.**
Subsection (a) clarifies that the regulations apply to the manufacturing of adult-use and medicinal cannabis products.

Subsection (b) clarifies the specific regulatory sections that are applicable to microbusinesses. This provision is necessary to clarify which Department regulations microbusinesses, which are licensed by the Bureau, must follow.

**Adopt Section 40102. Owners and Financial Interest Holders.** The Act establishes two levels of disclosure for individuals participating in the commercial cannabis industry. The highest level of disclosure is for "owners," which is defined in BPC §26001(al),

followed by “financial interest holders,” which are defined in this regulatory proposal. “Owners” are defined as:

- Any person that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in a commercial cannabis business of 20 percent or more;
- The chief executive officer of a commercial cannabis business;
- If a non-profit entity, each member of the Board of Directors;
- Any individual that will be participating in the direction, control, or management of the licensed commercial cannabis business.

“Owners” are required to submit their fingerprints to the Department of Justice for purposes of a criminal history background check.

In contrast, “financial interest holders” are required to be disclosed on the application, but do not need to undergo a background investigation. BPC §26051.5(d) requires the applicant to “provide a complete list of every person with a financial interest in the person applying for the license,” and, among other exclusions, specifically excludes “persons whose only interest in a licensee is an interest in a diversified mutual fund, blind trust, or similar instrument.” The proposed regulation clarifies the distinction between owners and financial interest holders, and is necessary to provide clarity to the regulated industry. In addition, the requirements of this section were developed in conjunction with the Bureau and CDFA so that all aspects of the commercial cannabis industry are subject to the same requirements.

Subsection (a) specifies an owner shall mean the following:

Paragraph (1): any person that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in a commercial cannabis business of 20 percent or more;

Subparagraph (A) clarifies that if the owner identified in subsection (a)(1) is an entity, then the chief executive officer and members of the board of directors of the entity shall be considered owners.

Paragraph (2): the chief executive officer of a cannabis business;

Paragraph (3): if a non-profit entity, each member of the Board of Directors; or

Paragraph (4): any individual participating in the direction, control, or management of the commercial cannabis business, including:

Subparagraph (A): Each general partner of a commercial cannabis business that is organized as a partnership;

Subparagraph (B): Each non-member manager or managing member of a limited liability company for a commercial cannabis business that is organized as a limited liability company; and

Subparagraph (C) Each officer or director of a commercial cannabis business that is organized as a corporation.

Subparagraph (D) Any individual that assumes responsibility for the licensee.

Paragraph (5) The Trustee(s) and all persons that have control of the trust and/or the commercial cannabis business that is held in trust.

The Department has chosen these entities based on the requirements in Business and Professions Code. These entities have direction, control, and/or management of a cannabis business. These provisions are necessary so that the Department can fulfill its mandate to assess the background of cannabis business owners.

Subsection (b) specifies that persons that hold an ownership interest of less than 20 percent are considered financial interest holders that need to be disclosed on the application. This subsection also specifies that “financial interest” means an agreement to receive a portion of the profits of a commercial cannabis business, investment into a commercial cannabis business, a loan provided to a commercial cannabis business, or any other equity interest in a commercial cannabis business. This provision is necessary to clarify for the regulated industry what responsibilities fall to owners and financial interest holders in cannabis businesses.

Subsection (c) clarifies that the following persons are not considered to be owners or financial interest holders:

Paragraph (1) A bank or financial institution whose interest constitutes a loan;

Paragraph (2) Persons whose only ownership interest in the commercial cannabis business is through an interest in a diversified mutual fund, blind trust, or similar instrument;

Paragraph (3) Persons whose only financial interest is a security interest, lien, or encumbrance on property that will be used by the commercial cannabis business; and

Paragraph (4) Persons who hold a share of stock that is less than 5 percent of the total shares in a publicly traded company.

The Department has determined that the persons specified in subsection (c) do not have sufficient holdings within a cannabis business to warrant the same scrutiny as an owner or investor, and therefore, they are not subject to the background investigation requirements, nor is an applicant required to disclose them on the annual license application.

**Adopt Section 40105. Premises Diagram.** This section specifies the information that must be included on the premises diagram required to be submitted as part of the licensing application.

Subsection (a) requires that the premises diagram required pursuant to Section 26051.5(c) of the Act shall meet the following requirements:

Paragraph (1) The diagram shall be specific enough to enable ready determination of the bounds of the property and the proposed premises to be licensed;

Paragraph (2) The diagram shall be to scale;

Paragraph (3) If the proposed premises consists of only a portion of a property, the diagram shall be labeled to indicate which part of the property is the proposed premises and identifying what the remaining property is used for.

The Department has determined that these provisions are necessary in order to assess the proposed manufacturing premises and to maintain consistency with other regulatory agencies.

Subsection (b) states that the premises diagram shall include:

Paragraph (1) All boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, and doorways.

Paragraph (2): The areas in which all commercial cannabis activities will be conducted. Commercial cannabis activities that shall be identified on the diagram include the following, as applicable to the business operations: infusion activities, extraction activities, packaging activities, labeling activities, and transportation activities such as loading and unloading of cannabis and cannabis products.

Paragraph (3): The limited-access areas, areas used for video surveillance monitoring and surveillance system storage devices, and all security camera locations.

Paragraph (4): Areas used for disposal of cannabis waste.

The Department has determined that these provisions are necessary in order to assess the proposed manufacturing premises and to maintain consistency with other regulatory agencies.

Subsection (c) requires that if the proposed premises consists of only a portion of a property that will contain two or more licensed premises, the diagram shall clearly show any entrances and walls under the exclusive control of the applicant or licensee. The diagram shall also show all proposed common or shared areas of the property, including entryways, lobbies, bathrooms, hallways, and breakrooms. This subsection is necessary to include as space for manufacturing of cannabis products can be costly, and large manufacturing buildings are frequently shared by several licensed manufacturers.

Subsection (d) states that the diagram shall be used by the Department to determine whether the premises meets the requirements of the Act and this chapter. This is necessary in order to ensure all licensed manufacturing premises are in line with state and local ordinances, laws, and regulations.

**Add Article 2: General Provisions**

**Adopt Section 40115. License Required** to clarify that manufacturing licenses are needed for specified activities.

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 (Business and Professions Code section 26053(d)).

Subsection (b) states that no person shall manufacturer cannabis products without a valid license from the Department. This is a statutory requirement and is included in this regulation to clarify that manufacturing activities are required to hold a manufacturing-specific license.

Subsection (c) states that licenses are not transferrable. The Department is mandated to review the qualifications of applicants and ensure that licenses are only held by qualified persons. Allowing licenses to be transferred will circumvent the Department's obligation. This provision is necessary so that the Department can comply with its statutory responsibility.

**Adopt Section 40116. Personnel Prohibited from Holding Licenses**. This section will clarify that specified individuals who have law enforcement responsibilities are prohibited from holding licenses issued by the Department. In order to maintain the integrity of the oversight of the cannabis industry, it is necessary to ensure that those who are responsible for enforcement of the laws are not in a position to benefit from enforcement or lack thereof.

Subsection (a) specifies the enforcement personnel prohibited from holding a license to be those that have responsibility over enforcement of cannabis laws.

Subsection (b) includes persons employed in the State of California Department of Justice as a peace officer, in any district attorney's office, in any city or county attorney's office, in any sheriff's office, or in any local police department in the prohibition on holding a license.

Subsection (c) states that personnel listed in subsections (a) and (b) are also prohibited from holding ownership interest in a commercial cannabis business.

Subsection (d) states that this section does not apply to any person who holds a license in the capacity of executor, administrator, or guardian.

**Adopt Section 40118. Manufacturing License Types**. The Act establishes two license types for manufacturers – Type 6 for manufacturers using nonvolatile solvents and Type 7 for manufacturers using volatile solvents (BPC §26050). BPC §26012 authorizes the Department to create additional license types as needed. This section specifies additional license types created by the Department.

Subsection (a) specifies that a manufacturing license may be issued for either the adult-use market or the medicinal-use market.

Paragraph (1) implements the statutorily mandated Type 7 license for manufacturing conducting extractions with volatile solvents. This section further clarifies in subparagraphs (A)-(D) that Type 7 licensees can also conduct extractions with

nonvolatile solvents, infusions (provided that the infusion operations and product types are noted on the application form), packaging and labeling manufacturing activities, and register and operate a premises as a shared-use facility. This provision is necessary to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity.

Paragraph (2): implements the statutorily mandated Type 6 license for manufacturers conducting extractions with nonvolatile solvents. This section further clarifies in subparagraphs (A)-(C) that Type 6 licensees can also conduct infusions, packaging and labeling manufacturing activities, and register and operate a premises as a shared-use facility. This provision is necessary to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity.

Paragraph (3): creates a new license category of “Type N” for manufacturers that produce cannabis products other than extracts or concentrates that are produced through extraction. This section further clarifies in subparagraphs A and B that Type N licensees can also conduct packaging and labeling manufacturing activities and register their licensed premises as shared-use facilities in accordance with Article 6 of Subchapter 2. Establishing a new license type for infusion-only is reasonably necessary for the Department to appropriately oversee licensing operations and to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity.

Paragraph (4): creates a new license category of “Type P” for manufacturers that only engage in the packaging and labeling 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 to for the Department to fulfill its mandate under the Act to license and regulate manufacturers.

Paragraph (5): creates a new license category of “Type S” for manufacturers that allows a Type S to conduct Type N or P manufacturing activities at a shared-use facility. During the pre-regulatory stakeholder meetings, the Department heard from numerous individuals who expressed a need, due to a lack of real estate in their area or for economic reasons, to conduct manufacturing activities in a shared-use space. This

license is necessary to assist these manufacturers and address equity concerns raised during public workshops. This provision is reasonably necessary for the Department to fulfill its mandate to issue manufacturing licenses.

**Adopt Section 40120. Additional Activities.** This section clarifies that a licensee may also roll and package pre-rolls and package dried cannabis. Pre-rolls and cannabis flower are not considered manufactured products and the existing emergency regulations were not clear as to whether manufacturers could conduct such activities. This provision is necessary to clarify the activities that manufacturers are allowed to conduct under a manufacturing license.

## II. Add Subchapter 2: Manufacturing Licenses

### Add Article 1: Applications for Licensure

**Adopt Section 40126. Temporary Licenses.** This section establishes a system for temporary licenses. Temporary license authority is provided to the Department in Business and Professions Code section 26050.1, along with the basic requirements. Due to the time constraints created by SB 94 (which became law on June 27, 2017), the Department would have been unable to meet its statutory mandate to issue licenses beginning January 1, 2018 if it needed to both promulgate complete regulations and review license applications before January 1, 2018. A temporary license process was thus necessary because it allowed the Department to issue licenses on an accelerated schedule, minimizing disruption in the medicinal cannabis market and allowing the adult-use cannabis market to begin as intended by California voters. This section adopts subsection (a)-(f) previously adopted via the emergency regulations of 2017, and the re-adoption of those subsections in May of 2018. The statute allows the Department to issue temporary licenses until January 1, 2019, but is silent as to what happens to licenses after that date. This section clarifies that any temporary license with an expiration date on or after January 1, 2019, will be valid for entire term of the license, but that such licenses will not be extended.

**Adopt Section 40128 Annual License Application Requirements.** This section specifies the information and documentation that an applicant for an annual manufacturing license must submit to the Department. This section 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 authority under the Act.

Subsection (a) establishes the information that an applicant must submit on behalf of the commercial cannabis business in order to apply for a license, as follows:

Paragraph (1) a complete licensing application form prescribed by the Department, or through MCLS. 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 purposed of this chapter, a complete licensing application is one which includes all of the following information:

Subparagraph (A) The business information specified in Section 40129;

Subparagraph (B) The owner information specified in Section 40130;

Subparagraph (C) Manufacturing premises and operations information as specified in Section 40131.

Paragraph (2): a non-refundable application processing fee with the application package. Business and Professions Code section 26180 authorizes the Department to establish an application fee.

Paragraph (3): Evidence of compliance with or exemption from the California Environmental Quality Act.

Paragraph (4): The limited waiver of sovereign immunity, if required.

Subsection (b) requires the applicant to sign the application form under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate, as mandated by Business and Professions Code section 26051.5(a)(4) and to the following attestations:

Paragraph (1) the applicant is authorized to act on behalf of the commercial cannabis business. The Department has a regulatory interest in assuring that he applicant has the authority to act on behalf of the business.

Paragraph (2) if the applicant entity has 20 or more employees, the applicant entity will enter into and abide by a labor peace agreement as soon as reasonably practicable, as required by Business and Professions Code section 26051.5(a)(5)(A). The applicant shall also provide the Department with a copy of the page of the labor peace agreement

that contains the signatures of the union representatives and the applicant or applicant entity. This provision is necessary to comply with the statutory requirement.

Paragraph (3) the commercial cannabis business is operating in compliance with all local ordinances, as required by Business and Profession Code section 26055. Cannabis businesses are required to abide by any applicable local ordinances. Requiring applicants to attest that they are operating in compliance with local ordinances will ensure that applicants are aware of this requirement.

Paragraph (4) the proposed premises is not within a 600-foot radius of a perimeter of a school, day care, or youth center, unless a different radius is otherwise specified by local ordinance. This is a statutory requirement (Business and Professions Code section 26054(b)).

Subsection (c) allows the Department to request additional information as necessary to determine the applicant's qualification. This provision is necessary so that the Department can fulfill its statutory mandate to only issue licenses to qualified applicants.

**Adopt Section 40129. Annual License Application Requirements—Business Information.** This section outlines the information that must be submitted to the Department in order to apply for a commercial cannabis license.

Subsection (a) requires the following information to be submitted in order for the Department to meet its statutory obligation to issue licenses only to qualified applicants:

Paragraph (1) Legal business name;

Paragraph (2) the federal tax identification number;

Paragraph (3) the name(s) under which the business will operate if applicable. This information is necessary so that the Department may maintain accurate records in accordance with its role as a licensing authority;

Paragraph (4) the business'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;

Paragraph (5) the name, title, phone number and email address of the primary contact person for the commercial cannabis business. This provision is necessary to ensure

that the Department can contact the business if needed;

Paragraph (6) the seller's permit number issued by the California Department of Tax and Fee Administration or notification from same that the business is not required to have a seller's permit. This provision is necessary to comply with the statutory requirement that licenses only be issued if the applicant has a seller's permit;

Paragraph (7) the business structure of the commercial cannabis business as filed with California Secretary of State (e.g. limited liability company, partnership, corporation). A commercial cannabis business that is a foreign corporation shall include in its application the certificate of qualification issued by the Secretary of State of California. This provision is necessary to allow the Department to verify that the appropriate owners have submitted owner applications;

Paragraph (8) a list of the owners, as defined in Section 40102 of these regulations. This provision is necessary so that the Department may verify that the owners have submitted their owner applications;

Paragraph (9) a list of financial interest holders, as defined in Section 40102. This includes disclosure requirements for financial interest holders who are individuals (subparagraph A) and those who are entities (paragraph B). Disclosure of financial interest holders is required by statute;

Paragraph (10) proof of having obtained a surety bond in the amount of $5,000, payable to the State as oblige. Business and Professions Code §26051.5(a)(10) requires all applicants to provide proof of a bond to cover the costs of destruction of cannabis or cannabis products if necessitated by a violation of licensing requirements. Discussions with other states indicated that cannabis businesses had difficulty obtained surety bonds, and that if the requirement was set any higher than $5,000, businesses would not be able to comply;

Paragraph (11) the license type applied for and whether the application is for medicinal or adult-use manufacturing, or both. This information is required for proper processing of the application;

Paragraph (12) business formations documents, including, but not limited to, articles of incorporation, operating agreements, partnership agreements, fictitious business name statements, and copies of trust documentation if the company is held in trust. This information is necessary to the Department to clarify owners and financial interest

holders.

Paragraph (13) requires that all documents filed with the California Secretary of State are also included with the application. The section is necessary for the Department to ensure that cannabis businesses are registered with the State.

Subsection (b) establishes the process by which the Department will confirm the validity of a local license, permit, or other authorization voluntarily submitted by an applicant in accordance with Business and Professions Code §26055(e). The statute permits the Department to presume that an applicant that voluntarily submits a local license, permit, or other authorization is in compliance with local ordinances. However, local jurisdictions expressed concerns to the Department that invalid authorizations may be submitted and requested the opportunity to confirm the document's validity. In order to accommodate the request, the Department added a process for confirmation that parallels the confirmation process for temporary licenses.

**Adopt Section 40130. Owner Applications.** This section specifies 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 and so that it may provide clarity to the regulated public.

Subsection (a) specifies each owner shall submit the following:

Paragraphs (1)-(6) contact and identifying information, including name, title or position held, phone number, mailing and email address, date of birth, and social security number or individual tax payer identification number. An owner's social security number is required in order to match applicants with the results from the Department of Justice criminal history background check.

Paragraph (7) a copy of Department of Justice form BCIA 8016 that was used to submit the applicant's fingerprint images for purposes of a background check. The form contains important information that will enable the Department to contact the Department of Justice about a specific owner's background record if necessary (i.e., if results do not get properly transmitted to the Department).

Paragraph (8) requires disclosure of any of the following specified conditions, including a description of the circumstances if applicable. Business and Professions Code section 26057(b)(4) 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 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. Business and Professions Code section 26057 allows, but does not require, the Department to deny a license application if an owner has been convicted of specified offenses or any offense substantially related to the qualifications, duties, or functions of a manufacturer. This provision is reasonably necessary for the Department to implement Business and Professions Code section 26057(b)(4).

Subparagraph (B) requires the applicant to disclose any civil proceedings, administrative citations, or penalty or license sanction that is substantially related to the qualifications of a manufacturer as identified in Section 40162 of these regulations. This is a statutory requirement under BPC §26057(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 is a statutory requirement under BPC §26057(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 is a statutory requirement under BPC §26057(b)(7).

Subparagraph (E) requires the applicant to disclose any suspension or revocation of a cannabis license by a licensing authority or a local jurisdiction within the 3 years preceding the date of the application. This is a statutory requirement under BPC §26057(b)(7).

Subparagraph (F) requires the application to disclose any administrative orders or civil judgements for violations of labor standards within the three years immediately preceding the date of the application. Stakeholders expressed concern regarding labor violations such as wage theft and occupational safety hazards in the cannabis market pre-regulation. The Department determined that said issues were relevant to an applicant's qualifications for licensure and has therefore included the requirement to disclose an owner's labor violations with the application for licensure. Labor violations within the three years preceding the application for licensure are sufficiently close in time to be relevant to an owner's current qualification for licensure and ability to maintain a safe and compliant premises. The Department is also requesting disclosure

of such sanctions that may have been assessed against the owner individually or against a business in which the owner was an officer or owner because such sanctions may have been taken against the business entities rather than the individual.

Subsection (b) requires the owner application form be signed by the owner under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate. This section is necessary to ensure all information provided in applications is true and attested to be true.

Subsection (c) requires an owner disclosing any criminal convictions or other penalties or sanctions pursuant to subsection (a) paragraphs (8)(A) and (B) shall submit evidence of rehabilitation for consideration by the Department. The statement of rehabilitation shall be written by the owner, contain evidence for the Department's consideration on fitness for licensure, and supporting evidence if desired. This section is necessary to assure applicants that a previous conviction for certain crimes is not prohibitive to receiving a license.

**Adopt Section 40131. Annual License Application Requirements—Manufacturing Premises and Operations Information.** This section specifies the information applicants must submit in regards to their manufacturing premises and operation information when applying for an annual license. It outlines all the information that must be included in the application as indicated in the subsections below.

Subsection (a) requires the physical address of the manufacturing premises. This section is reasonably necessary as the premises is where the manufacturing activities is licensed and enforced.

Subsection (b) requires the applicant to indicate whether the premises manufactures medicinal-use, adult-use, or both cannabis products. This section is reasonably necessary since a manufacturer may choose to make one or both cannabis product types.

Subsection (c) requires the type of activity conducted on the premises.
This section is reasonably necessary so the Department is aware of what activities are being conducted (i.e., extractions, infusions, packaging and labeling) for enforcement purposes.

Subsection (d) requires the types of products that will be manufactured, packaged, or labeled, including a product list. This section is reasonably necessary for enforcement

purposes.

Subsection (e) requires the name, title, email address, and phone number of the on-site individual who manages the operation of the premises. This section is reasonably necessary to ensure the Department has the contact information of the appropriate contact person at the premises.

Subsection (f) requires the name, title, email address, and phone number of an alternate contact person for the premises, if applicable. This section is reasonably necessary.

Subsection (g) requires the number of employees at the premises. This section is reasonably necessary in order to meet the requirements of Business and Professions Code section 26051.5(a)(5)(A), which requires a licensee with 20 or more employees to enter into a labor peace agreement.

Subsection (h) requires the gross annual revenue from products manufactured at the premises. Section 40150 establishes licensing fees based on a licensee's gross annual revenue. This section is reasonably necessary to provide clarity to the regulated industry.

Subsection (i) requires a premises diagram as specified in Section 40105. Business and Professions Code section 26051.5 (c) requires an applicant to submit a premises diagram.

Subsection (j) requires the following:

Paragraph (1) 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 26051.5(b)(4), and to comply with the intent of the Cole Memo. While rescinded, the Department has chosen to work under the guidelines of the Cole memo for the purposes of this regulation. 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) 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 BPC §26051.5(b)(5).

Paragraph (3) 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 BPC §26051.5(b)(3).

Paragraph (4) 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 BPC §26051.5 (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) a description of the cannabis waste disposal procedures that comply with Section 40290, or a copy of the standard operating procedure addressing cannabis waste management. This provision is reasonably necessary to ensure licensees follow state and local waste management laws.

Subsection (k) requires a written statement signed by the owner of the property or their agent, identifying the physical location of the property and acknowledging and consenting to the manufacture of cannabis products on the property. This must also include the name, address, and contact phone number for the owner or owner's agent. This section ensures that owners are aware of and responsible for the risks associated with cannabis manufacturing.

Subsection (l) requires a copy of the signed closed-loop system certification and a document evidencing approval of the extraction operation by the local fire code official, if required pursuant to Sections 40223 or 40225. This section is necessary to ensure public safety in the case of volatile solvent use.

Subsection (m) states any manufacturer submitting operating procedures and protocols to the Department pursuant to the Act may claim such information as a trade secret or confidential by clearly identifying such information as "confidential" on the document at the time of submission. Any claim of confidentiality by a manufacturer must be based on the manufacturer's good faith belief that the information marked as confidential constitutes a trade secret as defined in Civil Code section 3426.1(d), or is otherwise exempt from public disclosure under the California Public Records Act in Government Code section 6250 et seq. This section is necessary to differentiate public information

from confidential business data.

**Adopt Section 40132. Annual License Application Requirements – Compliance with CEQA.**

Subsection (a) requires an applicant to provide evidence of exemption from or compliance with CEQA. The Act requires cannabis businesses to demonstrate compliance with all state and local laws and this regulation is necessary so cannabis businesses demonstrate compliance with CEQA.

Subsection (b) specifies the manner in which an applicant may demonstrate compliance or exemption, and the below subsections are necessary for the Department to know how applicant has complied with CEQA.

Paragraph (1) a copy of the local license, permit, or other authorization, if the local jurisdiction has adopted an ordinance, rule, or regulation pursuant to BPC §26055(h). Since compliance with CEQA is typically addressed by a local jurisdiction, a local license or permit is indicative that CEQA requirements have been met;

Paragraph (2) a copy of the Notice of Determination or Notice of Exemption and a copy of the CEQA document from the local jurisdiction. This regulation is necessary because if an applicant has not provided a local license, permit, or other authorization, the Department will need to examine the documents required by the regulation to determine compliance with CEQA;

Paragraph (3) any other permit or local authorization issued by the local jurisdiction in compliance with CEQA to demonstrate compliance. This regulation is necessary to allow the applicant to demonstrate compliance using various forms of documentation.

Subsection (c) establishes that the applicant is responsible for the preparation of the documentation required pursuant to CEQA, when applicable. This regulation is necessary because the Act does not require an applicant to submit, or even hold, a license, permit, or other authorization from a local jurisdiction before applying for a state license. The proposed regulation would clarify that applicants must provide evidence that their premises would be exempt from or in compliance with CEQA and prepare that documentation for the Department's review and approval or certification if such documentation is not available from the local jurisdiction. The regulation is necessary to clarify the applicant's role in demonstrating compliance with CEQA.

**Adopt Section 40133. Limited Waiver of Sovereign Immunity.** This section is intended to specify the rules required in order for sovereign entities, such as federally recognized tribes, to apply for and receive a license to manufacture cannabis. This is necessary to ensure that tribes or other qualifying sovereign entities can participate in the regulated cannabis cultivation in the same way as the general public. The Department is statutorily mandated to issue licenses only to qualified applicants and must be able to conduct reviews of all applications. Requiring sovereign entities to waive certain aspects of immunity will allow the Department to fulfill its mandate. Furthermore, the Department is tasked with ensuring the protection of public health through oversight of manufacturing operations. Without a waiver of immunity, the Department will be unable to properly oversee manufacturing operations located on sovereign lands, leaving those located on sovereign land unable to participate in the legal cannabis market. In order for sovereign entities to participate in the cannabis market, the Department is using its general rulemaking authority provided under BPC §26013 to require a limited waiver of immunity. The section is included based on inquiries from tribes within California expressing interest in participating in the cannabis marketplace.

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

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

Paragraphs (1) – (6) requires documentation that the applicant or licensee has lawful authority to enter into waiver, the tribal sovereignty waiver to include language that clearly states all tribal entity applicants shall conduct all cannabis business activity in full

compliance with all state laws and regulations, that the Department has access to all licensed areas, access to all records pertaining to commercial cannabis activity, and that all licensees may only sell product to other licensees and customers meeting the legal requirements to purchase cannabis goods. These provisions are necessary to ensure the Department has the ability to fully enforce all statutes and regulations related to the licensing of cannabis business activities and that all cannabis licensees are regulated with the same standards and expectations. Without this specific language, it may be unclear which regulations would be applicable to a tribal government, thus creating business and enforcement uncertainty.

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

Subsection (b) specifies that the Department will not approve an application for a state license if approval would violate the provisions of any local ordinance or regulation, which is a restatement of the BPC §26055(d), and is included to provide clarity.

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

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

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

**Adopt Section 40135. Incomplete and Abandoned 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. (BPC §§26012 (a)(3) and 26013(a))

Subsection (a) specifies that an incomplete application will not be processed, and the Department shall issue a written notice to the applicant informing them of any information missing from the application. This provision is reasonably necessary so that the Department may comply with BPC §26055(a) mandating that licensing authorities only issue licenses to qualified applicants, and in order to provide clarity to the regulated industry.

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, and application fees will not be returned. This provision is necessary in order to provide clarity to the regulated industry 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. This section is also necessary as staff costs remain in processing applications even if they are withdrawn or abandoned.

Subsection (c) states that an applicant may reapply at any time following an abandoned application, but that a new application and application fee are required. This section is necessary in order to provide clarity to an applicant regarding reapplying for a license.

**Adopt Section 40137. Application Withdrawal.**
Subsection (a) states that an applicant may withdraw an application for annual licensure at any time prior to the issuance or denial of the license. Requests to withdraw an application shall be submitted in writing to the Department or through MCLS. This section is necessary to allow applicants to withdraw their applications if they are incomplete or unable to meet the requirements for licensure.

Subsection (b) states that an applicant may reapply for annual licensure at any time subsequent to the withdrawal of an application. This section allows applicants who have

withdrawn time to correct any errors on applications or other reasons for withdrawing an application and reapply when specified corrections are completed.

Subsection (c) states that withdrawal of an application shall not deprive the Department of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground. This section is necessary in order for the Department to keep records of denials and to keep track of applicants who have a history of withdrawn applications, which may indicate unfitness for licensure for all of the licensing authorities.

Subsection (d) states that application fees paid for a withdrawn application shall not be refunded. This section is necessary as staff time is needed to review and investigate applications.

**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. (BPC §26180(c))

Subsection (a) establishes a nonrefundable application fee for manufacturer applications.

Paragraph 1 establishes a fee of $1,000 for Type 7, Type 6, Type N and Type P licenses and Paragraph 2 establishes a fee of $500 for Type S licenses.

This provision is reasonably necessary so that the Department may cover its costs is 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 28 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 $3,338,520. Dividing this number by the 3,000 licenses anticipated to be issued under the proposed regulations results in a per license application cost of $1,113, which has been rounded down to $1,000.

Type S applicants are only subject to a $500 application processing fee, rather than the $1,000 fee applicable to other applicants. Type S applications will have a reduced review workload to Department staff as many of the elements will have already been reviewed during the assessment of the primary licensee's application.

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. 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 $1,500,000 (Tier III), the fee shall be $15,000;

Paragraph (4): For a licensed premises with an annual gross revenue of $1,500,001 to $3,000,000 (Tier IV), the fee shall be $25,000;

Paragraph (5): For a licensed premises with an annual gross revenue of $3,000,0001 to $5,000,000 (Tier V), the fee shall be $35,000;

Paragraph (6): For a licensed premises with an annual gross revenue of $5,000,001 to $10,000,000 (Tier VI), the fee shall be $50,000;

Paragraph (7): For a licensed premises with an annual gross revenue of over $10,000,000 (Tier VII), the fee shall be $75,000.

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, and the Track and Trace Fees required by BPC §26067. 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.

Funding for the MCSB program for FY 2017-18 is $13.5 million, appropriated from the Cannabis Control Fund 3288, which has 63 positions.

Subsection (c) states that any fee paid in nonrefundable. Department administrative costs and licensee track-and-trace system fees are derived from license fees. These costs remain even if a licensee surrenders or abandons operations.

**Adopt Section 40152. Gross Annual Revenue Calculation.**

This section clarifies for applicants the Department's expectation for calculation of gross annual revenue. During the effective period of the emergency regulations, the Department received numerous questions regarding the process for calculating gross annual revenue if the business was essentially providing a service for other businesses, rather than manufacturing their own products. This provision is modeled after Sherman Food and Drug Act provisions for food processing firms to calculate revenue.

Applicants are required to calculate the gross annual revenue for the licensed premises based on the annual gross sales of cannabis products and, if applicable, the annual revenue received from manufacturing, packaging, labeling or otherwise handling cannabis or cannabis products for other licensees, in the twelve months preceding the date of application (subsection (a)). For new license applicants, the gross annual revenue shall be based on the gross sales and revenue expected during the 12 months following licensure (subsection (b)).

Subsections (c) and (d) provide the method by which a licensee that holds multiple licenses can determine the gross annual revenue from the manufacturing operations. The language is modeled after the requirements of the Revenue and Taxation Code.

## Add Article 4: Approval or Denial of Application for Licensure

**Adopt Section 40155. New License Approval**. This section establishes requirements for payment of a license once an application has been approved.

Subsection (a) requires the Department to notify the applicant upon approval of the license by email or through MCLS. This is reasonably necessary in order to convey that an application has been approved.

Subsection (b) specifies that the applicant has 30 calendar days to pay the license fee. Many licensees will need to pay their annual license fee in cash. Thirty days should be sufficient time for licensees to arrange to deliver cash to a cash acceptance office.

Subsection (c) clarifies that a license will not be effective until the license fee is received in full. This provision is reasonably necessary as the fees provide funding to the Department in order for it to meet the statutory obligations of the Act.

**Adopt Section 40156. Priority License Issuance.** This section is intended to implement the statutory provision of priority license issuance to businesses operating in compliance with the Compassionate Use Act as of September 1, 2016.

Subsection (a) reiterates the statutory provision of priority license issuance. Although a statutory requirement, the provision is included in this regulation to provide clarity and ease of understanding for the regulated public.

Subsection (b) provides the documentation that may be used to demonstrate eligibility for priority license issuance. The Department has determined that the specified documents, dated prior to September 1, 2106, reasonably demonstrate that a business was in operation as of the date required by statute. The acceptable documents include:

Paragraph (1) a local license, permit, or other form of authorization;

Paragraph (2) a collective or cooperative membership agreement;

Paragraph (3) tax or business forms submitted to the Board of Equalization or Franchise Tax Board;

Paragraph (4) incorporation documents;

Paragraph (5) any other business documents that demonstrate operation prior to September 1, 2016.

Subsection (c) reiterates the statutory provision that local jurisdictions may identify businesses eligible for priority review (Business and Professions Code §26054.2(b)). The provision is included in this regulation to provide clarity and ease of understanding.

Subsection (d) states that the Department may request additional documentation to verify the applicant's date of commencement of operations. This provision is necessary to clarify that the Department retains the authority to request additional information during its review.

Subsection (e) adopts the statutory sunset date of 12/31/19. This is necessary for clarity and ease of understanding of the eligibility for priority review.

**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. The Department may deny an application if the applicant has a record of performing actions that are grounds for disciplinary action.

Subsection (a) specifies that an application may be denied for any reason specified in section 26057(b) of the Act. Further, the Department may deny a new a renewal license application for any of the following reasons:

Paragraph (1) an application may be denied when the applicant, owner, or licensee has 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 Division 1.5 of the Business and Professions Code, commencing with section 480 and is included here for the clarity of the regulated industry.

Paragraph (2) an application may be denied when an owner 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. BPC §26057(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.

Paragraph (3) an application may be denied when the applicant, owner, or licensee 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 BPC §26055(d), which requires a licensee to possess both a state and local authorization in order to engage in commercial cannabis activity.

Paragraph (4) an application may be denied when the applicant, owner, or licensee has denied the Department access to the manufacturing premises. BPC §26160(e) 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. (BPC §26030.) This provision is necessary to clarify and make specific that the Department's authority under the Act.

Paragraph (5) an application may be denied if the licensee has engaged in conduct that is grounds for disciplinary action. BPC §26030 establishes the grounds for disciplinary action. This provision is reasonably necessary to ensure licensees are aware they may be denied a license in the future if they violate any of the provisions in §26030.

Subsection (b) specifies that an application shall be denied if the proposed manufacturing operation or premises would violate the applicable local ordinance. This is a statutory requirement and is included here for the clarity of the regulated industry.

Subsection (c) is adopted to clarify the meaning of the word "conviction." This definition is in accordance with the definition of conviction contained in Division 1.5 of the Business and Professions Code section 480(a)(1) and is necessary in order to clarify what constitutes a conviction under the Act.

Subsection (d) clarifies the Department, prior to the denial of a license, shall consider any evidence of rehabilitation as provided in Section 40165. This is a statutory requirement and is included here for clarity of the regulated industry.

**Adopt Section 40162. Substantially Related Acts**. This section is intended 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." BPC §26057 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." This section establishes the convictions and violations that the Department considers to be "substantially related:"

Subsections (a) – (e) identifies the specific felony convictions for which a person may be denied a license. These convictions correspond to BPC §26057.

Subsection (f) identifies violations for adulteration and misbranding related to both food and drugs. These are provisions of the Sherman Food, Drug, and Cosmetic Law making it unlawful to manufacture and sell adulterated or misbranded food and drugs.

Subsection (g) identifies violations governing Wholesale Food Processors, which includes the CA Food Sanitation Act. Because of the way the wholesale food provisions are structured, it is very difficult to only choose certain provisions as violations, thus the Department is citing the entire chapter.

Subsection (h) identifies a conviction under sections 382 and 383 of the Penal Code and is reasonably necessary as it specifies food and drug adulteration violations.

The above mentioned subsections (f)-(h) define the specific California food and drug 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 and drug safety laws when determining whether to deny a license application on the grounds of a substantially related act.

Subsection (i) specifies a violation of law identified in subsections (f) or (g) committed by a business entity in which an owner was an officer or had an ownership interest is considered a violation that is substantially related to the owner's qualifications for licensure.

**Adopt Section 40165. Criteria for Evidence of Rehabilitation.** BPC §26057(b)(4) requires the Department to consider evidence of the applicant's rehabilitation prior to a license denial due to an applicant's prior conviction of a substantially related offense.

Subsection (a) specifies the information that the Department will accept in order to conduct the statutory-required evaluation of evidence of rehabilitation. The criteria in Paragraphs (1) – (8), below, is reasonably necessary for the Department to conduct this evaluation.

Paragraph (1) the nature and severity of the act or offense, including the actual or potential harm to the public;

Paragraph (2) the owner's criminal record as a whole;

Paragraph (3) evidence of any act committed subsequent to the act or offense under consideration that could be considered grounds for denial, suspension, or revocation of a manufacturing license;

Paragraph (4) the time elapsed since commission of the act or offense listed in Section 40162, or in section 26057(b)(4) of the Act;

Paragraph (5) the extent to which the owner has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against the owner or licensee;

Paragraph (6) if applicable, evidence of dismissal under Penal Code section 1203.4, 1203.4a, 1203.41, or a similar law in another state;

Paragraph (7) if applicable, a certificate of rehabilitation obtained under Penal Code section 4852.01 or a similar law in another state; and

Paragraph (8) other evidence of rehabilitation submitted by the owner.

**Adopt Section 40167. Appeal of License Denial.** This section establishes the process by which an applicant may appeal a denial of a license.

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 BPC §26058, 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 industry.

Subsection (b) sets forth the process by which the applicant may appeal the denial of the application. Specifically, this section requires an applicant who elects to petition the Department to file the written petition within 30 days of the date of denial. The request for a hearing must be postmarked within a 30-day period or the applicant's right to a hearing is waived. This provision is necessary to implement and make specific BPC §26058 and to provide clarity to the regulated industry.

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 26058 and is reasonably necessary in order to provide clarity to the regulated industry.

**Add Article 5. General Licensee Responsibilities.**

**Adopt Section 40175. License Constraints.** This section is added to clarify the licensing constraints to which a licensee must adhere.

Subsection (a) states that a licensee shall not manufacturer products other than cannabis products, which includes packaged cannabis and pre-rolls, at the licensed premises. This provision is reasonably necessary to protect public health and safety in accordance with BPC §26011.5 by ensuring that there is no possibility of cross-contamination between cannabis products and other types of products, 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. This subsection further provides that the prohibition does not apply to products that are identical to cannabis products (except for the addition of cannabis) and are intended to be used for samples. The Department understands that it is a fairly common practice in the industry to manufacture “zero milligram THC” versions of products if needed. Because such products will remain within the cannabis market and will not be sold in the traditional food market, the Department agrees that such a practice is a reasonable business practice.

Subsection (b) prohibits a licensee from employing or retaining an individual under age 21. BPC §26140 restricts an A-licensee from employing or retaining a person under 21 years of age. The Department, in consultation with the other licensing authorities, has extended this prohibition to M-licensees as well. The statutory prohibition is intended to protect minors (the title of the relevant chapter is “Protection of Minors”). It is therefore reasonable to prohibit minors from similarly working in medicinal cannabis businesses.

Subsections (c) specifies that a manufacturer shall only use cannabinoid concentrates and extracts that are manufactured or processed from cannabis obtained from a licensed cannabis cultivator. This subsection is intended to ensure that unregulated or black market cannabis is not being used in the regulated market.

Subsection (d) specifies that a manufacturer licensee shall not manufacture, prepare, package or label cannabis products in a location that is operating as a retail food

establishment or as a processed food registrant. This subsection is necessary to prevent the cross-contamination of food and beverages that are not cannabis products.

Subsection (e) specifies a manufacturer licensee shall not manufacture, prepare, package, or label cannabis products in a location that is licensed by the Department of Alcoholic Beverage Control (ABC) pursuant to Division 9 (commencing with section 23000) of the Business and Professions Code. BPC §26200(g)(3) prohibits the sale or consumption of alcohol at a manufacturing premises. This provision is intended to provide clarity to the regulated industry that cannabis manufacturing activities are prohibited from being conducted at the same premises licensed by ABC.

**Adopt Section 40177. Change in Licensed Operations.** This section is intended to allow licensees to change the operations performed on a licensed premises, provided that the licensee informs the Department what forms of manufacturing will now take place, and that manufacturing standards are met.

Subsection (a) clarifies that at any time during the license period, a licensee may request to change the manufacturing operations conducted at the licensed premises. This section has been added to allow licensees to modify their manufacturing as needed to meet market demand or accommodate changes in business practice. The following changes require pre-approval from the Department as the rise to higher level of review by the Department:

Paragraph (1) the addition of any extraction method subject to the requirements of Section 40225;

Paragraph (2) the addition of any other extraction method that necessitates a substantial of material change to the premises;

Paragraph (3) the addition of infusion operations if no infusion activity is listed on the current license application filed with the Department;

Paragraph (4) any substantial or material alteration of the licensed premises from the diagram currently filed with the Department. This is required by BPC §26055(c) and is added for clarity for the regulated industry.

Subsection (b) for the purposes of this section, “substantial or material alterations” include: the removal, creation, or relocation of an entryway, doorway, wall, or interior partition; a change in the type of activity conducted in, or the use of, an area identified in

the premises diagram; or remodeling the premises or portion of a premises in which manufacturing activities are conducted. This section has been added to clarify what alterations must be reported by the licensee.

Subsection (c) States that in order to request approval for any change listed in subsection (a), a licensee shall submit the following:

Paragraph (1) the information required under Section 40131, and

Paragraph (2) a non-refundable $700 application processing fee to review all documents. This paragraph is necessary in order to offset staff time needed to review all applications. The Department will need to review almost all of the same documentation as submitted for the initial license application in order to ensure that all of the requirements have been met. The only documentation that will not be reviewed is the Department of Justice criminal history information. This fee is necessary to cover staff time needed to review the application documentation.

Subsection (d) states that the request for a change in licensing operations shall be evaluated on a case-by-case basis by the Department, and upon approval, the licensee may begin conducting the additional manufacturing operation. The existing license shall be amended to reflect the change in operations, but the date of expiration shall not change. This subsection is necessary as county and city rules for allowable operations is likely to evolve and shift in the future, and the Department will need to ensure that the licensee is operating under local laws and regulations.

Subsection (e) states that licensees that choose to cease operation of any activity shall notify the Department within 10 days of cessation of the activity. License fees shall not be pro-rated or refunded upon cessation of any activity. This paragraph is necessary to include for the clarity of the regulated market.

Subsection (f) states a licensee shall notify the Department through MCLS of any changes to the product list on file with the Department and provide a new list within 10 business days of making any change. This is reasonably necessary for clarity to the regulated industry, and should field inspectors go out to a premises, the product list is consistent with what is being manufactured at the premises.

**Adopt Section 40178. Add or Remove Owner(s).** This section requires the licensee to submit to the Department any changes to the ownership of a licensed cannabis manufacturing business. This section is necessary in order for the Department to

determine if the proposed owner meets the qualifications for denial as previously described. This provision is reasonably necessary in order to provide clarity to the regulated industry.

Subsection (a) requires a licensee to notify the Department of any addition or removal of an owner within ten (10) calendar days through MCLS. This section is necessary in order for the Department to determine if the proposed owner meets the qualifications for denial as previously described.

Subsection (b) requires that any new owner shall submit the information required under Section 40130 to the Department through MCLS or on a prescribed form. The Department shall review the qualifications of the owner in accordance with the Act and the regulations to determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis. This provision is reasonably necessary to provide clarity to the regulated industry that each owner is required to meet the requirements of the Act and the Department's regulations.

Subsection (c) requires an owner to notify the Department through MCLS of any change in their owner information submitted pursuant to Section 40130 within 10 calendar days of the change. This provision is reasonably necessary to provide clarity to the regulated industry.

Subsection (d) also requires a licensee to notify the Department through MCLS of any change in the list of financial interest holders within 10 calendar days. This provision is reasonably necessary to provide clarity to the regulated industry and ensure that the Department has an up-to-date list of all parties with a financial interest in the licensed business.

**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 BPC §26180 to establish a licensing scheme with an annual renewal fee.

Subsection (a) establishes that to apply for a license renewal, the licensee shall submit any changes to their current license application information on a form prescribed by the Department, or through MCLS, sign the renewal application under penalty of perjury and submit the annual license fee as specified in subsection (b) of Section 40150. This

subsection is added for the clarity of the regulated industry. This subsection further requires the licensee to submit documentation of their gross annual revenue for the preceding year, such as tax returns filed with the California Department of Tax and Fee Administration. In order to properly assess the applicant's annual license fee, which is based on gross annual revenue, it is necessary that the Department be provided with documentation.

Subsection (b) establishes that a complete application for renewal of a manufacturing license shall be submitted to the Department no later than 5:00 pm on the last business day prior to the expiration date of the current license, but not more than 60 calendar days prior to the expiration date of the currently license. A complete renewal application includes submission of all changes to the information required by Section 40128 and payment of all fees. This subsection is necessary to clarify date ranges acceptable to renew applications for the regulated industry.

Subsection (c) This subsection provides that if a licensee has not submitted a renewal application, no commercial cannabis activity can be conducted after the expiration of the license. Under statute, commercial cannabis activity cannot be conducted without a valid license. This provision is necessary to clarify this statutory restriction.

Subsection (d) 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. 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.

Subsection (e) states that any changes to owner and financial interest holder information shall be made in accordance with Section 40178. That section is reasonably necessary to clarify that owners are still subject to the requirements of 40178 for license renewals.

Subsection (f) states that the Department shall notify the applicant upon approval of the

renewal application through email or MCLS. The Department shall notify an applicant of the denial of an application in accordance with Section 40167. This section is necessary for the clarity of the regulated industry.

**Adopt Section 40182. Disaster Relief.** This section allows the Department to waive certain regulatory licensing requirements during a disaster and is necessary to ensure that licensees who have been impacted by a disaster are not deemed to have surrendered, abandoned, or quit their licenses, due to the impacts of the disaster, if their intent is to continue as a licensee. Additionally, as the Act places public safety as the top priority for licensing authorities (BPC §26011.5), the provisions allowing a licensee to move product to a location different than the original location approved by the Department is critical to public safety to ensure that cannabis and cannabis products are secured and unable to be accessed by the general public.

The Department has determined that in certain circumstances a licensee may be relieved from regulatory provisions. Additionally, Government Code section 8571 provides that during a state of emergency the Governor may suspend any regulatory statute, or statute prescribing the procedure for conduct of state business, or orders, rules, or regulations of any state agency, where the Governor determines and declares that strict compliance with any statute, order, rule, or regulation would in any way prevent, hinder, or delay the mitigation of the effects of the emergency. This section would allow licensees that have been impacted by a disaster to be relieved from rules, orders and regulations that would otherwise delay mitigation of the effects of the disaster and the ability to keep cannabis and cannabis products secured to prevent diversion in the illegal market and prevent minors from accessing cannabis or cannabis products. This section is also necessary to ensure that licensees are provided an opportunity to exercise the privileges of their license, when otherwise prohibited from doing so by forces and circumstances beyond their control, that have made compliance with the regulations so onerous that the operation under their license is not worthy of being carried out in practice.

Subsection (a) states that if a licensee is unable to comply with any licensing requirement due to a disaster, the licensee may notify the Department of its inability to comply and request relief from the specific licensing requirement. Licensees may be tempted to walk away from a business or choose not to adhere to the law when a disaster occurs. This provision is reasonably necessary to ensure businesses have an opportunity to recover and remain compliant.

Subsection (b) allows the Department to exercise its discretion to provide temporary relief from specific regulatory requirements in this chapter and from other licensing requirements when allowed by law. It is likely that some licensees will request disaster relief, but will not meet the threshold established by the Department. This provision is reasonably necessary as it provides clarity to the regulated industry, and provides the Department flexibility in determining whether a licensee should be exempted from the licensing requirements.

Subsection (c) states temporary relief from specific licensing requirements shall be issued for a reasonable amount of time in order to allow the licensee to recover from the disaster. This provision is reasonably necessary to allow a business time to recover without being subject to licensing requirements that may be incapable of being met during a disaster.

Subsection (d) specifies the Department may require that certain conditions be followed in order for a licensee to receive temporary relief from specific licensing requirements. Temporary relief of licensing requirements is not intended to suspend all statutory and regulatory requirements. Therefore, it is reasonably necessary for the Department to request a licensee to meet certain conditions in order to receive temporary relief.

Subsection (e) states a licensee shall not be subject to an enforcement action for a violation of a licensing requirement in which the licensee has received temporary relief. This provision is reasonably necessary to provide clarity to the regulated industry.

Subsection (f) defines “disaster.” This provision is reasonably necessary to provide clarity to the regulated industry on what constitutes a disaster.

Subsection (g) provides that, if a licensee needs to move cannabis or cannabis products stored on the premises to another location immediately to prevent loss, theft, or degradation of the cannabis or cannabis products from the disaster, the licensee may move the cannabis or cannabis products without obtaining prior approval from the Department if the following conditions are met:

Paragraph (1) the cannabis or cannabis products are moved to a secure location where access to the cannabis or cannabis products can be restricted to the licensees, its employees, and its contractors. This provision is reasonably necessary to reduce the potential for diversion;

Paragraph (2) the licensee notifies the Department in writing that the cannabis or cannabis products have been moved and that the licensee is requesting relief from complying with the specific licensing requirements pursuant to subsection (a) of this section within 24 hours of moving the cannabis or cannabis products. The Department has determined that 24 hours is sufficient time for the licensee to immediately secure cannabis or cannabis products while providing prompt notice of the change in location to the Department;

Paragraph (3) the licensee agrees to grant the Department access to the location where the cannabis or cannabis products have been moved. BPC §26160 (e) specifies that a licensee who refuses an inspection of the premises has committed a violation of the Act. This provision is reasonably necessary to ensure the Department can inspect the location where the cannabis product is being held;

Paragraph (4) the licensee submits in writing to the Department within 10 days of moving the cannabis or cannabis products, a request for temporary relief that clearly indicates what statutory and regulatory sections relief is requested from, the time period for which the relief is requested, and the reasons relief is needed for the specified amount of time. The Department has determined that 10 business days is the appropriate time to allow a licensee to provide the Department with a request for relief as it allows the licensee time to address the immediate effects of the disaster on the licensee's business while not allowing too much time to elapse before the Department can evaluate the proposed plan.

**Adopt Section 40184. Notification of Criminal Acts, Civil Judgments, and Revocation of a Local License, Permit, or Other Authorization after Licensure.**
This section clarifies a licensee's responsibilities in notifying the Department of any convictions or judgments made against them. This section has been added in order for the Department to fulfill its mandate under BPC §26055, which requires the licensure of only qualified applicants. It further clarifies for the regulated industry that illegal activities may cause a license to be denied or revoked.

Subsection (a) requires that a licensee shall notify the Department in writing of a criminal conviction of any owner, either by mail or electronic mail, within 48 hours of the conviction. The written notification to the Department shall include the date of conviction, the court case number, the name of the court in which the owner was convicted, and the specific offense(s) for which the owner was convicted. This section is reasonably necessary in order for the Department to implement BPC §26057(b)(4).

Subsection (b) requires that a licensee shall notify the Department in writing of a civil penalty or judgment rendered against the licensee or any owner in their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the verdict or entry of judgment, whichever is sooner. The written notification to the Department shall include the date of verdict or entry of judgment, the court case number, the name of the court in which the matter was adjudicated, and a description of the civil penalty or judgement rendered against the licensee or owner. This section is reasonably necessary in order for the Department to implement BPC §26057(b)(4).

Subsection (c) states that a licensee shall notify the Department in writing of the revocation of a local license, permit, or other authorization, either by mail or electronic mail, within 48 hours of receiving notice of the revocation. The written notification shall include the name of the local agency involved, a written explanation of the proceeding or enforcement action, and the specific violation(s) that led to revocation. Section 26200 (c) establishes a notification process for a local jurisdiction that revokes a licensee's authorization to conduct business. However, it only establishes that the local jurisdiction has to notify the state, but does not include a timeframe in which the notification has to occur. It is reasonably necessary to require the licensee to provide this information within 48 hours in order for the Department to assess whether the reason for the revocation rises to a level that should result in an immediate revocation as it poses significant public health and safety concerns.

Subsection (d) states that a licensee shall notify the Department in writing of an administrative order to violations of labor standard against the licensee of any owner in their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the order. The written notification shall include the date of the order, the name of the agency issuing the order, and a description of the administrative penalty or judgement against the licensee. Stakeholders expressed concern regarding the prevalence of wage theft and other labor violations in the cannabis market pre-regulation. The Department determined that said concerns were valid and has therefore included this section in order to ensure compliance with labor codes by applicants and licensees prior to renewal of a license. In addition, labor violations may serve as a basis for discipline pursuant to section 26030 of the Act.

## Add Article 6. Shared-Use Facilities

**Adopt Section 40190. Definitions.** This section establishes definitions for Shared-Use Facilities, as follows:

Subsection (a) defines “common-use area” as any area of the manufacturer’s registered shared-use facility that is available for use by more than one licensee, including equipment. “Common-use area” is needed in order to ensure that all parties – primary licensee, Type S licensee, and the Department – understand which areas of the manufacturing premises the Type S licensee is authorized to use.

Subsection (b) defines “designated area” as the area of the registered shared-use manufacturing facility that is designated by the primary licensee for the sole and exclusive use by a specific Type S licensee. “Designated area” is needed to ensure that all parties understand which areas of the manufacturing premises are for sole use by a specific Type S licensee.

Subsection (c) defines “primary licensee” as the Type 7, Type 6, or Type N licensee that has been approved to operate a shared-use facility. The primary licensee is given specific responsibilities in further provisions of this proposal. The definition is needed to clarify who is the primary licensee.

Subsection (d) defines “shared-use facility” as a manufacturing facility operated by a Type 7, Type 6, or Type N licensee in which Type S licensees are authorized to conduct manufacturing operations. This definition is necessary to clarify further provisions of the proposal.

Subsection (e) defines “use agreement” as a written agreement between a primary licensee and a Type S applicant or licensee that specifies the designated area of the Type S licensee, the days and/or hours in which the Type S licensee is assigned to use the common-use area(s), any allocation of responsibility for compliance pursuant to Section 40196, and an acknowledgement that the Type S licensee has sole and exclusive use of the common-use area(s) during the Type S licensee’s assigned days and/or hours. This definition is necessary to clarify further provisions of the proposal.

**Adopt Section 40191. Type S License.**

Subsection (a) establishes the requirements for applications for a Type S license.

Paragraph (1) requires that applications be made in accordance with Section 40128. Section 40128 provides the application process for all applicants;

Paragraph (2) requires the application to identify the registered shared-use facility the applicant will use. As part of its statutory mandate to ensure that manufacturing

activities take place only in licensed locations, the Department needs to ensure that that the Type S licensee is operating in an approved facility;

Paragraph (3) requires the applicant to include a copy of the use agreement signed by both the applicant and the primary licensee. The Department will need the use agreement for oversight and enforcement activities. This paragraph also specifies that the use agreement shall be considered the landlord approval required pursuant to section 26051.5(a)(2) of the Act. Because the use agreement requires signature of the primary licensee, it is reasonable to consider it as the landlord approval;

Paragraph (4) requires the applicant to include a premises diagram of the designated area to be used by the applicant pursuant to Section 40131(i). All applicants are required by statute to submit a premises diagram, which the Department will use in its evaluation of the applicant's procedures to ensure the protection of public health.

Subsection (b) limits the availability of a Type S license to applicants with a gross annual revenue of less than $1 million during the preceding license term. The intent of the Type S license is to provide a means by which smaller businesses can enter the regulated market. As the business grows in size, it can reasonably be expected to operate its own facility. The emergency regulations limited Type S licenses to businesses with no more than $500,000 in gross annual revenue. Feedback from the regulated industry indicated that this threshold was too low, given the limitations cannabis businesses face in terms of availability of locations. The Department reconsidered its decision and raised the threshold to $1 million.

Subsection (c) specifies the operational activities a Type S licensee may conduct. The Department has determined that the following activities present lower public safety risk and can therefore be performed safely in a shared facility:

Paragraph (1) infusions, as defined in Section 40100(dd);

Paragraph (2) packaging and labeling of cannabis products, and;

Paragraph (3) extraction operations using butter or food-grade oil, provided that resulting extract or concentrate is used solely in the manufacture of the Type S licensee's infused product, and is not sold to any other licensee. Extraction activities present a greater public safety risk than infusion activities because of risk of explosion. However, the Department is aware that many infused products are made by incorporating infused butter or other oil into a recipe formulation. Extractions with butter

or food-grade oil do not present the same public safety risk as other types of extractions. The Department determined that the practice was a reasonable business practice to accommodate.

**Adopt Section 40192. Registration to Operate a Shared-Use Facility.**

Subsection (a) states that a licensee may not operate as a shared-use facility without prior approval by the Department. This provision is necessary so that the Department can fulfill its mandate to oversee manufacturing activities.

Subsection (b) provides that a Type 7, Type 6, or Type N licensee can request approval to operate as a shared-use facility by submitting to the Department through MCLS:

Paragraph (1) a copy of the local license, permit, or other authorization from the local jurisdiction explicitly authorizing operation of a shared-use facility. Local jurisdictions maintain ultimate authority over the type of cannabis activities that are conducted in their locality. This provision is necessary to ensure that local jurisdictions are aware and in support of shared-use facilities;

Paragraph (2) a registration form prescribed by the Department with the following information:

Subparagraph (A) the proposed occupancy schedule that the common-use area will be available for use by Type S licensees and when the common-use area will be used by the primary licensee. The occupancy schedule shall allow for adequate maintenance and sanitizing between use by individual licensees. In order to properly oversee manufacturing operations, the Department must have a record of the operating schedule.

Subparagraph (B) a diagram indicating the below:

Clause (i) each designated area for a Type S licensee. This provision is necessary to differentiate designated areas for shared-use from other manufacturing areas.

Clause (ii) the common-use area(s), including identification of any shared equipment. This provision is necessary to clarify which areas and/or equipment can be used by a Type S licensee.

Subsection (c) requires that the Department shall notify the Type 7, Type 6, or Type N licensee upon approval of the registration to operate as a shared-use facility. Notification shall be made through MCLS. This provision ensures that primary licensees are informed in a timely manner and may begin to allow shared-use manufacturing on their premises.

Subsection (d) specifies that at least one business day prior to a Type S licensee commencing manufacturing operations at a registered shared-use facility, the primary licensee shall provide written notification to the Department. The notification to the Department shall include the Type S licensee's business name, contact person, contact phone number, and license number. The primary licensee shall also provide an updated occupancy schedule to include the Type S licensee and an updated diagram indicating the designated area of the Type S licensee. Notification may be provided by email or through MCLS. This provision is necessary to ensure accurate documentation of operating licensees and to ensure the Department's ability to oversee and inspect the use of shared facilities.

Subsection (e) states that a primary licensee that wishes to discontinue operation as a shared-use facility may cancel its registration by providing at least 30 calendar days written notice to the Department and each Type S licensee authorized to use the shared-use facility prior to the effective date of the cancellation. This provision allows time both for the Department to update the Department's records and for Type S licensees using the shared facility to have time to potentially find a new operating space and to safely remove anything from their storage space at the shared-use facility.

**Adopt Section 40194. Shared-Use Facility Conditions for Operation.**

Subsection (a) establishes the conditions of operation that a primary licensee must ensure. The below subsections are necessary to set out the minimum requirements a primary licensee must demonstrate to operate a shared-use facility.

Subsection (b) requires each Type S licensee to be assigned a "designated area" that, at minimum:

Paragraph (1): is for exclusive use by the Type S licensee.

Paragraph (2): includes secure, locked storage for exclusive use by, and accessible only to, the Type S licensee for storage of that Type S licensee's cannabis, cannabis concentrates, and cannabis products. The regulations referred to in paragraphs (1) and (2) are needed to require the primary licensee to provide a designated area and storage

space for a Type S licensee. The cannabis manufacturing activity must be done in an area occupied only by one licensee at a time. Further, a secure storage space for the Type S licensee's cannabis, cannabis concentrates, and cannabis products must be provided because the licensee will leave the shared-use facility and others will use the common-use areas.

Subsection (c) requires any part of the premises used for manufacturing activity that is a common-use area to be occupied by only one licensee at a time by restricting the days and/or hours that each licensee may use the common-use area. During the assigned days and/or hours one licensee shall have sole and exclusive occupancy of the common-use area. This regulation requires the use of a schedule for use of the common-use areas because this allows cannabis manufacturing activity to be done in a shared-use facility by different Type S licensees by providing exclusive use of a portion of the common-use area to each Type S licensee.

Subsection (d) restricts the use of the shared-use facility to the primary licensee and the Type S licensees identified in the registration and authorized by the Department to use the shared-use facility. This regulation is necessary as the documentation provided will be examined by the Department to assure the cannabis manufacturing can be done with the licensees designated to use the shared-use facility. The department must have a regulation that assures it has documentation of all the licensees using the shared-use facility, and that no person or entity will use the shared-use facility for cannabis manufacturing without Department authorization.

Subsection (e) requires any cannabis product or other materials remaining after a Type S licensee ceases operation and discontinues use of its designated area to be disposed of by the primary licensee consistent with the requirements of the Act and regulations. The regulation is needed to provide that any cannabis product or other materials left behind by a Type S licensee after its use of the common-use area is cannabis waste and cannot be used in order to prevent adulterated cannabis products.

Subsection (f) requires that the shared-use facility meet all applicable requirements of the Act and regulations. The regulation is needed to make clear to the regulated public that all licensees that use a shared-facility must meet all the requirements of the Act, and regulations promulgated under the Act, irrespective of the fact that it is a shared-use facility.

Subsection (g) requires the occupancy schedule to be prominently posted near the entrance to the shared-use facility. This provision is necessary as it further ensures

consumer protection by preventing adulteration of cannabis products by making it clear to all who enter and use the facility what is the current occupancy schedule of the shared-use facility.

Subsection (h) states that the primary licensee may conduct manufacturing activities as permitted under its Type 7, Type 6, or Type N license and may use the common-use areas during its scheduled time period. This provision clarifies activities allowed by the primary licensee to the regulated public, and that the primary licensee must also comply with the designated occupancy schedule, along with the Type S licensees, to assure that only one licensee at a time is using the common-use area for cannabis manufacturing.

**Adopt Section 40196. Shared-Use Facility Compliance Requirements.**

Subsection (a) provides that there may be an agreement between the primary licensee and the Type S licensee(s) to allocate the responsibility for providing and maintaining security devices, fire monitoring and protection, and other commonly used equipment and services, and liability for theft or violations; however, such agreement is not binding on the Department in taking any compliance or enforcement action. To properly fulfill its responsibility and mandate under the statute to protect public health and safety, the Department needs to maintain flexibility and authority to enforce the requirements of the Act and the Department's regulations.

Subsection (b) establishes that a primary licensee or a Type S licensee is liable for any violation found at the shared-use facility during that licensee's scheduled occupancy or within that licensee's designated area; however, a violation of any provision of the Act or regulations may be deemed a violation for which each Type S licensee and the primary licensee is responsible. Further, in the event of a recall or embargo of a cannabis product produced at a shared-use facility, the Department, in its sole discretion, may include any or all cannabis products produced at the shared-use facility. To properly fulfill its responsibility and mandate under the statute to protect public health and safety, the Department needs to maintain flexibility and authority to enforce the requirements of the Act and the Department's regulations. Any public health concern that necessitates a recall could potentially impact the cannabis products produced by other licensees at the shared-use facility. In order to protect public health, the Department needs flexibility to recall other cannabis products produced at the shared-use facility.

Subsection (c) states that the occupancy schedule and designated area for a Type S licensee shall not be altered without prior approval by the Department. A written request shall be submitted to the Department that includes the requested changes and

may be submitted by email or through the online licensing system. This provision is necessary so that the Department has accurate records of which licensee is using the facility at a given time.

## 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 (BPC §26051.5(b)(6)). Adequate security measures are a necessary component of preventing diversion and providing for employee safety.

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) 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 breaches of physical barriers.

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.

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. 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 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. These designated areas must be separate from the manufacturing areas.

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 (BPC §26051.5(b))

Subsection (a) requires licensed premises to have a complete digital video surveillance system with a minimum camera resolution of 1280 x 720 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. BPC §26051.5(b)(6) requires the Department to establish minimum security requirements for the storage of cannabis products at the manufacturing site.

Subsection (b) 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.

Subsections (c)(1) through (5) requires video surveillance of specific areas on the premises where cannabis or 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 (d) requires the surveillance system be capable of continuous 24 hour recording at a minimum of 15 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 (e) requires that all recording and monitoring equipment be stored in a secure room or area of the premises so that access is controlled. A secure room must have a commercial grade lock. This provision is reasonably necessary to ensure that recording and monitoring equipment is not tampered with.

Subsection (f) requires that licensees ensure that all surveillance recordings are kept for a minimum of 90 days. This provision is reasonably necessary to allow for review by the Department and/or the licensee.

Subsection (g) 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 (h) 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.

Subsection (i) specifies the conditions under which multiple licensees can share surveillance systems. If multiple licensees operate in the same building, it is reasonable to allow sharing of the systems, rather than require numerous cameras cover the exact same areas of the building. This requirement conforms with regulatory provisions of the Bureau, as the building may house both Bureau and Department licensees. Specifically, the requirements of this subsection are as follows and are reasonably necessary so that the Department can properly exercise its oversight authority:

Paragraph (1): Each applicant or licensee shall disclose on their premises diagram where the surveillance recordings are stored;

Paragraph (2): Each applicant or licensee shall include in their security operating procedures an explanation of how the video surveillance system will be shared, including who is responsible for monitoring the video footage and storing any video recordings;

Paragraph (3): All licensees shall have immediate access to the surveillance recordings to produce them pursuant to the requirements of this section;

Paragraph (4): All licensees shall be held responsible and subject to discipline for any violations of the video surveillance requirements.

**Adopt Section 40207. Notification of Theft, Loss, or Diversion.** This section is adopted to provide the method by which a licensee must notify the Department of suspected theft, loss, or diversion of cannabis or cannabis products. Licensees must report the theft or diversion to the Department and local law enforcement within 24 hours of the discovery. Notification to the Department is necessary in order for the

Department to properly exercise its oversight authority, ensure diversion does not occur, and fulfill its mandate to protect public health and safety.

**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 industry, 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 industry must comply with and/or that pose a threat to public health and safety. Protecting public health and safety is a statutory requirement. (BPC §26011.5.)

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 extraction using professional closed-loop $CO_2$ gas extraction systems, chemical extractions with volatile solvents, and any method authorized by the Department pursuant to subsection (b). These categories represent the existing methods of extraction to the best of the Department's knowledge, but leave open the possibility for as-yet unknown types of extraction, as the cannabis business is constantly innovating new methods for extraction.

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 $CO_2$ 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, $CO_2$ 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.

Paragraph (5) allow for any other method authorized by the Department pursuant to subsection (b). The cannabis industry is new and innovative, and new systems of extraction are likely to be developed as the industry grows.

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.

Subsection (c) prohibits volatile solvent extractions from occurring in an area zoned residential. This provision is necessary to protect public safety by reducing the threat of explosions to surrounding areas.

**Adopt Section 40223 Ethanol Extractions.** This section is necessary to provide clarity as to the requirements for ethanol extractions.

Subsection (a) clarifies that ethanol used for post-extraction processing shall be food-grade. This is in line with Section 40220 regarding non-volatile food-grade solvents.

Subsection (b) requires that ethanol extraction operations shall be approved by the local fire code official and shall be operated in accordance with Division of Occupational Safety and Health (Cal/OSHA) regulations and any other relevant state and local requirements.

**Adopt Section 40225. Closed-Loop Extraction System Requirements** to establish specific requirements for closed-loop systems for volatile solvent, $CO_2$, chlorofluorocarbon, hydrocarbon, or other fluorinated gas extractions. This provision is necessary because these solvents pose a public safety risk. Volatile solvents can build up vapor, leading to a risk of fire or explosion. $CO_2$ 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 extractions to be conducted using a professional closed loop system. It also 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 in paragraphs 1-4, specifically 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.

Subsection (c) clarifies the certification document required pursuant to subsection (a) shall contain the signature and stamp of a California-licensed professional engineer and the serial number of the extraction unit being certified.

Subsection (d) requires the licensee to establish and implement written procedures to document to ensure that the closed loop extraction system is maintained in accordance with the equipment manufacturer specifications and to ensure routine verification that the system is operating in accordance with specifications and continues to comply with fire, safety, and building code requirements. A failure of a closed loop system could cause serious bodily injury or have possibly fatal consequences, and could also cause severe property damage. Equipment that is not operating property could cause explosions, fires, or asphyxiation. It is of utmost importance that licensees routinely verify that the machinery is operating properly. Because of the variety of equipment in use, the Department is not mandating verification within a specified time period. Some types of equipment may need maintenance more often than other types. Rather, the Department expects that licensees will determine the frequency required to verify their specific equipment and provide evidence to the Department that the actions were performed.

Subsection (e) requires a licensee to develop standard operating procedures, good manufacturing practices, and a training plan prior to producing extracts. This subsection further requires any personnel using solvents or gases in a closed loop system to create extracts to be fully trained on how to use the system, have direct access to applicable safety data sheets, and handle and store solvents and gases safely. This subsection is necessary to minimize the potential threat to public safety posed by improperly trained personnel operating a closed loop extraction system.

Subsection (f) requires the extraction operation to be operated in an environment with

proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present, and be operated in accordance with applicable Division of Occupational Safety and Health (Cal/OSHA) regulations and any other state and local requirements. This subsection is necessary to minimize the potential threat to public safety posed by closed loop systems.

Subsection (g) prohibits closed loop extraction operations from occurring in areas zoned residential. This is necessary to protect public safety.

**Add Article 3. Good Manufacturing Practices.**

This Article establishes the requirements for 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 cannabis.[4] Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates which may be subsequently used to produce edible cannabis products (BPC §26130(c)). 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.

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

[4] Business and Professions Code section 26011.5.

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 26012(a)(3), 26011.5, and 26131.

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 . . . ."[5] 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.[6] 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.

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

[6] 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 26011.5.

- 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 26011.5. 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.[7] 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 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,*[8] while cockroaches carry pathogens responsible for a plethora of human diseases including those that cause dysentery, food poisoning, and typhoid fever.[9] Additionally, insects have a role as indicators of unsanitary conditions, for example, ants and weevils.[10] 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

[7] World Health Organization, Hazard prevention and control in the work environment: Airborne dust (August 1999).
[8] Pava-Ripoll et al., *Detection of Foodborne Bacterial Pathogens from Individual Filth Flies* (Feb. 13, 2015) Journal of Visualized Experiments.
[9] World Health Organization, Cockroaches: Their biology, distribution and control (1999).
[10] United States Food and Drug Administration, Compliance Policy Guidance: Filth from Insects, Rodents, and other Pests in Foods (Last updated: Nov. 14, 2002).

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.[11]

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.

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 40230. Definitions.** Throughout this regulatory proposal, 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

[11] 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

ensure protection of the public in accordance with the priority mandated to the Department by statute[12] for activities related to and associated with the manufacturing of cannabis products.

This section establishes the definitions necessary to understand the requirements of this Article. The definitions are identical to those included in the emergency regulations, but have been moved to this new section for ease of use.

Subsection (a): 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 industry.

Subsection (b): 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.

Subsection (c): Adopt the term "allergen cross-contact" to mean the unintentional incorporation of a food allergen into a cannabis product. This term is used in further regulatory provisions and is reasonably necessary to provide clarity to the regulated industry.

Subsection (d): 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" may 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 USFDA in 21 C.F.R. §111.3 and is necessary to provide clarity to the regulated industry.

[12] BPC § 26011.5.

Subsection (e): 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 necessary to provide clarity to the regulated industry and is modeled after the definitions used by the USFDA in 21 C.F.R. §§111.3 and 117.3.

Subsection (f): 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 necessary to provide clarity to the regulated industry.

Subsection (g): Adopt the term “hazard” to mean a 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 necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Subsection (h): 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 industry. The definition is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Subsection (i): 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. This definition is necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Subsection (j): 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 a cannabis product is contaminated with filth, or that may otherwise cause cannabis product to be adulterated. These definitions are modeled after those used by the USFDA in 21 C.F.R. §117.3, and are reasonably necessary to define what constitutes a microorganism so that the Department and the regulated industry may minimize opportunities for contamination to cannabis products via microorganisms posing a threat to public health and safety.

Subsection (k): 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. This definition is necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §117.3.

Subsection (l): 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 to clarify what constitutes a pathogen so that the regulated industry may minimize opportunities for contamination via pathogen(s) posing a threat to public health and safety.

Subsection (m): 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 necessary to provide clarity to the regulated industry as to what constitutes a pest.

Subsection (n): 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 necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Subsection (o): 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 provide clarity to the regulated industry.

Subsection (p): Adopt the term “qualified individual” to mean a person who has the education, training, or experience (or a combination thereof) necessary to manufacture quality cannabis products as appropriate to the individual's assigned duties. A qualified individual 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. This definition is necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §§111.3 and 117.3.

Subsection (q): 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 necessary to provide clarity to the regulated industry.

Subsection (r): Adopt the term “quality control operation” to mean the planned and systematic procedure for taking all actions necessary to prevent cannabis product(s) 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. This definition is necessary to provide clarity to the regulated industry

Subsection (s): Adopt the term “quality control personnel” to mean 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 necessary to provide clarity to the regulated industry, and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Subsection (t): Adopt the term “raw material” to mean any unprocessed material in its raw or natural state 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. This definition is necessary to provide clarity to the regulated industry.

Subsection (u): 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 its safety for 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. This definition is necessary to provide clarity to the regulated industry.

Subsection (v): 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 necessary to provide clarity to the regulated industry.

Subsection (w): Adopt the term “validate” to mean obtaining and evaluating of scientific and technical evidence that a control measure, combination of control measures, or quality control procedure as a whole, when properly implemented, is capable of effectively controlling the identified hazard. This definition is necessary in order that manufacturers of cannabis products can create effective hazard-prevention procedures. This definition is necessary to provide clarity to the regulated industry.

Subsection (x): Adopt the term “verification” to mean the application of methods, procedures, tests, or other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the quality control procedures.

**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, 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-contract 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. 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 contactor 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 premises. The proximity to the manufacturing premises 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 premises has the potential to affect product safety and quality and impact public health. In order to protect the public and ensure compliance with sections 26012(a)(3) and 26131 et al 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 premises. Making the grounds immediately surrounding the premises 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 dust, dirt, chemicals, or pests before entering the premises. 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 premises, either by personnel carrying dirt and dust into the facility on their clothing, or by wind blowing dirt and dust into the premises 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 premises, and contaminate the premises 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. Premises Construction and Design.** This section is adopted to establish minimum requirements of construction and design for cannabis

manufacturing premises 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 statute, 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, under paragraphs 1-3, 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 contaminated 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. §26011.5.)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 contaminates 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 is 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 26011.5, 26131(a)(1), 26131(a)(3), and 26131(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. (BPC §26011.5.)

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 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 ensuing 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.

Subsection (l) requires the sanitary operation procedures to include maintenance, cleaning, and sanitizing schedules or logs. In order to properly oversee manufacturing operations, the Department must be able to ensure that maintenance, cleaning, and sanitizing activities are performed as needed. Failure to clean and sanitize can pose a threat to public health through contamination of 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 26011.5 and 26131 of the Act 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 increases 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 26131 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 26131 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 26131 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 26131 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 minimizes 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 26131 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 26131 of the Act.

Subsection (f) Waste disposal. This subsection requires that waste disposal on a licensed premises be handled in a manner to prevent contamination cannabis products, contact-surfaces, packaging materials, water supplies, and ground surfaces. Waste must be conveyed in appropriate containers that are designated for such purpose, and which control the exposure of potential contaminates to the surrounding environment. Odors from improperly stored waste 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 waste has the potential to compromise water supplies and ground surfaces. This provision is necessary to prevent adulteration in accordance with section 26131 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 26131 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 26131 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 26131 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 section also requires that logs documenting the date and time of maintenance, cleaning, and sanitizing be maintained. 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 26131 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 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 contagions 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 cannabis products, raw materials, or other ingredients shall be either:

Paragraph (1) disposed of in a manner that protects against the contamination of other cannabis products or ingredients; or

Paragraph (2) reprocessed, if appropriate, using a method that has been proven to be effective and subsequently reexamined and found to be unadulterated.

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 industry.

Subsection (k) requires that manufacturing processes that utilize any sort of preparations that are held and used repeatedly (such as batters, breading, 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 contaminates 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 contaminates.

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 identification of controls other than those at critical control points that are appropriate for ensuring cannabis product quality. Examples of such controls include cleaning, sanitizing, and maintaining the premises and equipment (Paragraphs 1-4). Although such activities are not "critical control points," the performance of these activities is still essential to ensuring quality cannabis products.

Subsection (d) requires the control plan to establish the monitoring procedures by which the licensee will use to assess whether the control measures are operating as intended.

Using the example above, the licensee may use a pH meter to monitor whether the pH level is within established limits.

Subsection (e) 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. Actions taken shall include procedures for ensuring:

Paragraph (1) that appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

Paragraph (2) that appropriate action is taken, when necessary, to reduce the likelihood that a problem will recur;

Paragraph (3) that all affected material(s) or product(s) are evaluated for safety;

Paragraph (4) that all affected material(s) or product(s) are prevented from entering into commerce if the safety or quality of that material(s) or product(s) cannot be verified;

Subsection (f) 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 (g) 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.

Subsection (h) requires that a licensee shall conduct a re-analysis of the hazard analysis and preventive controls whenever a significant change is made in the activities conducted at the premises if the change creates a reasonable potential for a new hazard or significant increase in a previously identified hazard, and shall implement any new preventive controls as necessary to comply with this Section. This section is necessary in order to ensure quality of the product while allowing for a licensee to update or change their manufacturing processes as necessary.

**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 industry, 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): 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.

Paragraph (8) requires that the master manufacturing protocol for any given product may include the ability to adjust the amount or weight of cannabinoid-containing ingredients in order to account for the variability of cannabinoid content in harvest batches. This paragraph is required for the clarity of the regulated industry.

Subsection (c) clarifies that nothing in this chapter requires disclosure of the master manufacturing protocol to any person other than the individuals conducting activities that utilize the protocol or to the Department and its inspectors and agents. This allows the licensee to consider that master manufacturing protocol subject to trade secret protection. This subsection is necessary for the protection of the regulated industry.

**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. (BPC §26011.5)

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 UID, and if used, the batch or lot number of the finished batch of cannabis product and the UIDs 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 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 (3): 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 (4): the identification number assigned to each component (and, if applicable, to a product received from a supplier for packaging or labeling as a cannabis product), packaging, and label used if applicable. 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 (5): 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 (6): 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 (7): 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 (8): 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 (9): 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 *verifying the weight or measure of each component* 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 (10): 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 industry 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 (11): 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 (12) – 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.

Paragraph (13) the Certification of Analysis issued for the batch by the licensed testing laboratory. This provision is necessary to ensure that cannabis and cannabis products are being tested in licensed testing laboratories and appropriate documentation is created and kept.

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 a 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) – (7) 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.

Paragraph (7): If an investigation is not conducted, the licensee is required to keep records of the reasons the licensee did not investigate the complaint.

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

**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 a 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 the 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). These requirements are necessary to ensure that recalled product is not diverted.

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 5. Special Processing Requirements.**

**Adopt 40270. Juice Processing.** This section allows infused juice products to be manufactured as edible cannabis products. The original medical rulemaking package, since rescinded, prohibited the manufacture of any beverage that was not shelf-stable. Comments received during the 45-day comment period indicated to the Department that juices could be safely produced using processes specified by the FDA for the manufacture of juice. The Department revised its decision to allow juice products that have been processed in accordance with FDA requirements; this section incorporates by reference the relevant federal protocols to be followed: section 120.8 of subpart A. This section describes the elements to be considered in a juice hazard analysis plan. Cannabis manufacturers are already required to conduct a hazard analysis; the specific incorporation of section 120.8 simply provides manufacturers with further guidance on how to develop the hazard. Manufacturers will not be required to adhere to the specific federal regulatory sections that reference testing of juice products. Cannabis products are already required to be tested. No further public health protection is provided by requiring an additional testing step.

Subsection (a) states that requirement of this section shall apply to manufacturer of cannabis juice, and cannabis-infused juice or beverages.

Subsection (b) requires that manufacturers of juice or beverages shall prepare written juice hazard analysis and control plans in accordance with the requirements of 21 CFR, Part 120, subpart A, section 120.8, and subpart B, section 120.24, which is incorporated by reference.

**Adopt Section 40272. Dried Meat Processing.** This section provides the processes a licensee must adhere to in order to create dried meat products. In the April 2017 version of the regulations, meat products of any kind were prohibited. Numerous public comments were received arguing for the safety of dried meat products that are properly processed. After further research, the Department concurred with the comments and this proposal has been amended to accommodate the request. The United States

Department of Agriculture (USDA) provides guidance for traditional jerky manufacturing. This section establishes that dried meat must be processed in accordance with that guidance. This section further establishes that meat for processing must be obtained from commercially-available sources. The slaughtering process provides a significant opportunity for introduction of microbes, which is why it is so heavily regulated by the USDA. Limiting licensees to the use of commercially available meat, rather than slaughtering it, is necessary to protect public health.

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

This section requires a licensee to establish and maintain written standard operating procedures that are easily accessible to onsite personnel, which shall, at a minimum, include the following:

Subsection (a) requires that a licensee shall establish and maintain written standard operating procedures that are easily accessible to onsite personnel. The standard operating procedures shall, at minimum, include the following:

Paragraph (1) policies or procedures developed in accordance with the security plan required by Section 40200, necessary to protect the physical safety of employees and to minimize the potential for diversion.

Paragraph (2) emergency response procedures, including Safety Data Sheets for any chemicals on-site, necessary to ensure protection of individuals in the workplace.

Paragraph (3) policies and procedures regarding closed-looped extraction system requirements in accordance with Section 40225.

Paragraph (4) Policies and procedures developed in accordance with Article 3 of this subchapter (Good Manufacturing Practices), necessary to ensure the protection of the public in accordance with the safety priority mandated to the Department by statute for activities related to and associated with the manufacturing of cannabis. Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates, which may be subsequently used to produce edible cannabis products.

Paragraph (5) Policies and procedures developed in accordance with Article 4 of this subchapter (Production and Process Control), necessary to ensure product safety, quality, and that the product conforms to all specifications.

Paragraph (6) Procedures for complying with the track-and-trace requirements established in Article 2 of subchapter 6, necessary to ensure products in the supply chain are properly tracked and accounted for to prevent diversion and inversion of cannabis.

Paragraph (7) Inventory control procedures in compliance with Section 40282, necessary to track the location and disposition of all cannabis and cannabis products at a licensed premises.

Paragraph (8) Cannabis waste management procedures in compliance with Section 40290, necessary to ensure that cannabis waste is properly handled according to all local and state requirements and not diverted.

Subsection (b) requires procedures to be written in English but allows the procedures be made available in other languages as necessary for personnel. This section is necessary to ensure policies and procedures are also available to non-English speaking employees to ensure proper training of all employees.

**Adopt Section 40277. Weights and Measures**. This section is necessary to ensure the weighing devices used to weigh cannabis or cannabis products are consistent with requirements set forth in the Business and Professions Code in order to ensure accuracy of the quantity of products being tracked and sold.

Subsection (a) requires weighing devices used by a licensee to be approved, tested, and sealed in accordance with the requirements in Chapter 5 (commencing with Section 12500) of Division 5 of the Business and Professions Code, and registered with the county sealer consistent with Chapter 2 (commencing with 12240) of Division 5 of the Business and Professions Code. Approved and registered devices shall be used whenever:

Paragraph (1) Cannabis or cannabis product is bought or sold by weight or count;

Paragraph (2) Cannabis or cannabis product is packaged for sale by weight or count;

Paragraph (3) Cannabis or cannabis product is weighed or counted for entry into the track-and-trace system; and

Paragraph (4) The weighing device is used for commercial purposes as defined in section 12500 of Business and Professions Code.

Subsection (b) this subsection defines the term “count” as the numerical count of individual cannabis product units. This provision is necessary for clarity to the regulated industry.

Subsection (c) requires commercial shipments of cannabis and cannabis products to be weighed by a licensed weighmaster.

**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 is 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 caused 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 26160. 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 licenses 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, and again every 3 years during employment. 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)-(4) 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): 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 (2): documentation 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 (3): 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 (4): official documentation such as certificates or permits attesting to the successful completion of required training by personnel. This 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.

Subsection (d) clarifies that a licensee operating under a temporary license shall have applicable personnel complete training no later than 90 days after the effective date of the annual license. Added to provide a timeframe in which licensees in operation prior to the issuance of an annual license must train their existing employees. The requirement is clear for new employees, but not for existing employees. The Department selected a 90-day timeline is necessary to conform with the existing timeline to receive the food handler certification.

**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. 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 products. 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 on-hand inventory of cannabis and cannabis products with the records in the track-and-trace database at least once every 30 days. 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. The April 2017 version of the regulations required reconciliation to happen every business day. Numerous comments indicated that this was an overly burdensome requirement. After further review, the Department concurred. In consultation with the other licensing authorities, the Department has amended the

regulation to require reconciliation of on-hand inventory with inventory in track-and-trace every 30 days.

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 are taken to rectify the discrepancy.

Subsection (d) requires that if the inventory reconciliation or audit conducted pursuant to subsections (b) and (c) respectively reveal a discrepancy that is more than five percent of the documented inventory, that the licensee notifies the Department within 24 hours of the discovery. This provision is necessary in order for the Department to be made aware of discrepancies quickly and in order to maintain accurate records.

**Adopt Section 40290. Waste Management.** 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 also 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 (BPC §26011.5), it is necessary for the Department to establish requirements for the proper disposal of cannabis waste.

Subsection (a) requires a licensee to have a written cannabis waste management plan in place to dispose of all waste, including cannabis waste, in accordance with all applicable state and local laws and regulations including laws regulating “organic waste” as defined in Public resources Code section 42649.8(c). This section further requires the licensee to properly determine whether waste is hazardous and ensure that hazardous waste is managed accordingly. This includes 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.

Subsection (b) requires a licensee to dispose of non-hazardous cannabis waste in a secured waste receptacle or secured area on the licensed premises. Public access to designated area or waste receptacles is strictly prohibited. This requirement is reasonably necessary to ensure that cannabis waste is not tampered with or diverted.

Subsection (c) prohibits a cannabis product from being disposed of in its packaging, and requires all cannabis waste to be unrecognizable and unusable as a cannabis product at the time of disposal. This requirement is reasonably necessary to ensure cannabis waste is not diverted in order to protect public health and safety.

Subsection (d) requires that the licensee use the track-and-trace database 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.

Subsection (e) requires a licensee to do the following if a local agency, a waste hauler franchised or contracted by the local government or a private hauler permitted by local government is being used to collect and process cannabis waste:

Paragraph (1) maintain and make available to the Department upon request the business name, address, contact person, and contact phone number of the entity hauling waste;

Paragraph (2) obtain documentation from the entity hauling the waste that indicates the date and time of each collection of cannabis waste at the licensed premises;

Paragraph (3) obtain a copy of the certified weight ticket, or documentation prepared by the entity hauling the waste confirming receipt of the cannabis waste at one, or more of the following solid waste facilities:

Subparagraphs (A-D) a manned fully permitted solid waste landfill or transformation facility, a manned fully permitted composting facility or operation, a manned fully permitted in-vessel digestion facility or operation, a manned full permitted transfer/processing facility or operation. This subsection is necessary to ensure that cannabis waste is disposed of in accordance with state waste management laws and is not diverted.

Subsection (f) requires a licensee that is self-hauling cannabis waste to one or more of the solid waste facilities in subsection (e)(3) to obtain a copy of the certified weight ticket or receipt from the solid waste facility for each delivery of cannabis waste. This section prohibits self-hauling by anyone other than the licensee or its employee. This subsection is necessary to ensure licensees that are self-hauling are properly disposing of cannabis waste in accordance with state waste management laws and to prevent diversion.

**Adopt Section 40292. Consent to Sample Collection.** 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.

This section requires a manufacturer licensee to allow the Bureau to collect samples of cannabis product at a distributor, upon request, and is reasonably necessary to verify the validity of the test results being reported.

**IV. Add Subchapter 4. Products.**

**Add Article 1. Cannabis Product Standards.**

**Adopt Section 40300. Prohibited Products**. This section provides the types of cannabis products that are prohibited due to their increased risk to public health. The Department's statutory mandate in BPC §26011.5 is to place public health and safety as the paramount factor in determining policy. The Department has determined that the following products pose a higher risk to public health, either due to the nature of the product itself or because the manufacturing process used for the product has a higher risk of contamination.

Subsection (a) prohibits infusion of alcoholic beverages, as defined by section 23004 of the Business and Professions Code, and clarifies that an alcoholic beverage does not include tinctures that meet the requirements of Section 40308. 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. This concurrent consumption has the potential of altering the effect of the intended dosage of cannabis products, as well as increasing the level of physiological and psychological impairment of cannabis users.

Furthermore, BPC §26054(a) prohibits the sale of alcoholic beverages at a licensed premises; therefore, no licensee can sell an alcoholic beverage infused with cannabis.

Finally, this subsection clarifies that tinctures meeting the requirements of Section 40308 are not prohibited. Tinctures are a very common cannabis delivery system, particularly in the medicinal market. Tinctures are made by combining cannabis plant material with a medium – typically glycerin or ethanol – to create a product that is intended to be consumed sublingually in small doses. Further discussion on tinctures is included under Section 40308.

Subsection (b) prohibits any product containing any non-cannabinoid additive that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. There is currently very limited scientific data available on the full health effects of cannabis use at various doses and frequency, and on the combination of cannabis with other psychoactive substances. It is not possible, therefore, to know with any certainty the full scope of potentially dangerous or damaging physiological and/or psychological effects that may occur with concurrent use of cannabis and other physiologically and/or psychologically active substances.

This subsection further specifies that the prohibited additives include nicotine and caffeine. The FDA has determined that caffeine (a stimulant) in certain alcoholic (a depressant) beverages is an “unsafe food additive” due to the unpredictable negative effects of the two substances. Cannabis can similarly behave as a depressant, causing the same unsafe combination with caffeine as does alcohol. In order to protect public health, the Department has made a determination to prohibit caffeine in cannabis products.

Subsection (c) prohibits any cannabis product that must be held at or below 41 degrees Fahrenheit to keep it safe for human consumption. Certain products are capable of supporting the growth of infectious or toxigenic microorganisms if held above 41$^{o}$ F. This prohibition is necessary to protect cannabis product consumers from foodborne illnesses that might cause serious illness or death. The FDA has developed a method by which food processors may determine if their product needs to be held below 41$^{o}$ F to keep it safe for human consumption. 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. Examples of such products include cream or custard-filled pies; pies or pastries which consist in whole or in part of milk or milk products, or eggs; and meat-filled pies or pastries.

There are two exceptions to the restriction on refrigerated products: juice that is processed in accordance with the requirements of Section 40270, and infused butter manufactured in accordance with subsection (f). After juice has been pasteurized, or otherwise processed to reduce microorganisms, it presents a reduced public health threat, although it may be necessary to keep the juice product at a reduced temperature. Infused butter is allowed by statute to be manufactured as a cannabis product. Without this exception, it appears as if there is a contradiction between the allowance of butter and juice and the prohibition on refrigerated products.

Subsection (d) prohibits any thermally processed low-acid cannabis product packed in a hermetically sealed container, that, if it were a food, would be subject to the manufacturing requirements of Title 21, CFR, Part 113 and subsection (e) prohibits any acidified cannabis product that, if it were a food, would be subject to the manufacturing requirements of Title 21, CFR, Part 114. The Department has chosen to use the definition in the Federal Food and Drug regulations so that manufacturers can more easily compare their cannabis product to the manner in which the FDA would regulate the identical food product. The types of products covered in this prohibition present a significant risk of botulism contamination if not properly processed. 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.[13] Botulism has a high mortality rate and is especially concerning for immunocompromised individuals. It is necessary to prohibit the manufacture of these products because of the potential public health threat.

Subsection (f) prohibits any juice that is not shelf-stable or that is not processed in accordance with Section 40270. Numerous types of microorganisms can be found on fresh fruits and vegetables, including yeasts, molds, *Pseudomonas*, *Erwinia, Salmonella* spp., *Shigella* spp, *Y. enterocolitica*, *E. coli* O157:H7, *L. monocytogenes*, *C. botulinum*, and *B. cereus.* Fruits and vegetables, including juices, that are not subjected to a type of processing that can destroy the microorganisms (such as pasteurization), can pose a significant threat to human health, especially for immunocompromised individuals.

[13] USFDA, Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).

Subsection (g) prohibits dairy products of any kind, as prohibited by subdivision (t) of section 26001 of the Act, except that butter purchased from a licensed milk products plant or retail location that is subsequently infused or mixed with cannabis may be sold as a cannabis product (as allowed by Food and Agriculture Code section 37104). The statutory prohibition on cannabis-infused dairy products is included in the regulations in order to provide clarity and ease of use by including all prohibited products in one section.

Subsection (h) prohibits meat products other than dried meat products prepared in accordance with Section 40272. 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, the Department has determined that a prohibition on meat products other than dried meat product is necessary to protect public health.

Subsection (i) prohibits seafood products of any kind. Seafood is highly susceptible to microorganism growth. Because of the potential public health threat, seafood-related cannabis products of any kind are prohibited.

Subsection (j) prohibits any product that is manufactured by application of cannabinoid concentrate or extract to commercially available candy or snack food items without further processing of the product. This subsection further clarifies that candy or snack food items may be used as ingredients in a cannabis products, provided that the candy or snack food is unrecognizable in the final product and the label does not list the candy or snack food. BPC §26130(b)(5) prohibits edible products that could be easily confused with non-cannabis candy and food. This provision is intended to reduce potential confusion for consumers and reduce the possibility of unintentional consumption.

Subsection (k) prohibits any cannabis product that the Department determines, on a case-by-case basis, is attractive to children, as defined in Section 40410;

Subsection (l) prohibits any cannabis product that the Department determines, on a case-by-case basis, is easily confused with commercially available foods that do not contain cannabis.

Subsection (m) prohibits any cannabis product in the shape of, or imprinted with the shape of, a human being, either realistic or caricature, animal, insect, or fruit. Edible products are statutorily prohibited from being designed to be appealing to children (BPC § 26130(c)). The Department has determined that products in the specified shapes are especially appealing to children. Products intended to be consumed by children, such as fruit snacks, are frequently shaped like animals, insects, or fruit. This prohibition is intended to reduce the possibility that a child may be attracted to the cannabis product. This restriction is also based on a similar restriction in Oregon.

**Adopt Section 40305. Requirements for Edible Cannabis Products.** Manufactured cannabis includes edible cannabis products, as well as cannabis extracts and concentrates which may be subsequently used to produce edible cannabis products. While the Act specifically defines cannabis products as neither a food nor a drug, edible cannabis products are typically made with conventional food products infused with cannabinoids that are intended to be consumed by members of the public. Except for the cannabis or cannabinoid component, edible cannabis products are made of the same ingredients as other regulated food products, are produced using the same manufacturing processes as regulated food products, and are consumed and taken into the body for a physiological purpose, in the same manner as regulated food, drug, and (most similarly) dietary supplement products. Thus, many of the public health risks associated with unsafe food, drugs, and dietary supplement products also exist with cannabis products.

Subsection (a) requires that product ingredients and components must be approved by the USFDA for use in food processing, either because they are Generally Recognized As Safe (GRAS) by the FDA pursuant to sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, or are included in the FDA's database titled *Everything Added to Food in the United States*. This provision is necessary to ensure that the final product is safe for human consumption and does not include ingredients that are harmful.

According to information in *Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry,* "it is impracticable to list all substances that are used in food on the basis of the GRAS provision because the use of a GRAS substance is not subject to premarket review and approval" by the USFDA. The USFDA further notes "the use of a substance is GRAS because of widespread knowledge among the community of qualified experts, not because of a listing or other administrative activity." Commonly used ingredients in food products, like eggs, or baking powder, or sugar are not contained on a list or database, because there is widespread knowledge that these substances are safe to be used in food. The USFDA provides significant resources to assist businesses in determining whether a

substance is GRAS, either because of common knowledge or because the USFDA made a specific determination. Manufacturers will be able to readily access the information if they are unsure if a substance is allowed.

Subsection (b) implements the statutory requirement that edible products be delineated or scored into standardized serving sizes if the product contains more than a single serving and is an edible product in solid form. In this proposed regulations, the Department has further defined how a product may be delineated and has applied the requirement to all edible products. Consumers need to be informed as to the amount of THC in a given amount of any edible product, not just solid edibles. To that end, the Department will require that edible products containing more than a single serving be: paragraph (1) scored, delineated, or otherwise similarly marked to indicate one serving, or paragraph (2) packaged in a manner such that a single serving is readily identifiable or easily measurable.

Subsection (c) requires cannabis products that consist of multiple serving to be homogenized to that each serving contains the same concentration of THC within the variance established by the Bureau. It is a matter of public health and safety to ensure that the amount of THC indicted per serving is an accurate reflection of the THC content in that serving. A consumer that ingests a single serving of cannabis product expecting a certain THC content would not have a basis of what to expect if that serving actually contained the entirety of the product's THC content because it wasn't homogenized.

**Adopt Section 40306. Requirements for Topical Cannabis Products.** This section specifies that topical cannabis products can only contain ingredients permitted for cosmetic manufacturing under FDA regulations. This provision is necessary to protect consumers from unsafe product ingredients.

**Adopt Section 40308. Requirements for Products Containing Alcohol.** This section specifies that any tincture or cannabis product that contains more than 0.5% alcohol by volume and is not defined as an alcoholic beverage, as defined in Business and Professions Code section 23004, shall not be sold in a package larger than two (2) fluid ounces and shall include a calibrated dropper or other measuring device. This section is added to address a potentially significant public health concern related to cannabis and alcohol. During the effective period of the emergency regulations, it came to the Department's attention that the lack of a definition of "tincture" in the Department regulations has led some manufacturers to attempt to circumvent the prohibition against cannabis-infused alcoholic beverages. The Department is aware of cannabis-infused wine offered for sale, labeled as a tincture, and sold in a standard-size wine bottle.

In order to mitigate the potential public health risk posed by cannabis-infused alcoholic beverages, the Department is proposing to limit the manner in which tinctures can be sold. The Department conducted research on tincture products currently on the market and determined that two fluid ounces was a reasonable limitation to place on the container size. The majority of tinctures available in the medicinal market appeared to meet this size limit and were also sold with a dropper, which is why this proposal includes the requirement to sell the product with a dropper in order for the consumer to be able to accurately assess his or her intake of cannabis.

**Add Article 2. Cannabinoid Concentration Limits.**

**Adopt Section 40315. THC Concentration Limits.** 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 and the intent of the California voters to allow adults to legally access cannabis.

Subsection (a) limits edible cannabis products to no more than 10 mg of THC per serving (paragraph (1), and 100 mg of THC per package (paragraph (2)). BPC §26130 establishes a limit of 10 mg THC per serving of edible cannabis product and the requirement is included here for clarity and ease of reading for the public. The 100 mg THC per package of finished product was established by the Department for the following reasons:

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 due to ingestion. Other delivery options that are less attractive to minors are available to consumers desiring 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

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. 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.[14] 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 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.[15]

Subsection (b) provides an exemption to the per package THC limitation in subsection (a). During the effective period of the Department's emergency regulations, it was brought to the Department's attention that the regulations were unclear as to the classification of orally-dissolving products. Cannabis products that dissolve in the mouth are a common delivery method for medicinal cannabis patients. Classifying such

[14] 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."

[15] 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..

products as edibles, and therefore limiting those products to 100 mg per package, does not serve the medicinal-use community well. However, because these products are consumed by mouth and can be flavored, there is still a potential for unintentional overconsumption by children. In this rulemaking package, the Department is proposing to clarify that these products are classified as edible products, but can be packaged in quantities of up to 500 mg of THC total, as long as the product consists of discrete servings of no more than 10 mg THC per piece (paragraph 1), is labeled as "FOR MEDICAL USE ONLY," (paragraph 2), and is only sold to a medicinal customer (paragraph 3). Because these products are classified as edibles, they are subject to the statutory serving size of 10 mg of THC. However, there is no general requirement for edible products to be in discrete, single servings. The Department believes that discrete servings will reduce the public health risk of consumption of the entire product. It is important to note that this provision does not prohibit the sale of orally-dissolving products in the adult-use market. Rather, orally-dissolving products to be sold to an adult-use customer are limited to 100 mg THC per package.

Subsection (c) limits a topical cannabis product or cannabis concentrate to no more than 1,000 mg THC per package. 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. [16] 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). The Cannabis Advisory Committee made recommendations to increase the amount but based on the state survey the Department has made a policy decision to remain with the current THC limits of 1,000/2,000 mgs. The Department is pursuing this approach to protect public health and safety.

Subsection (d) provides an exemption to the THC restriction in subsection (c). Subsection (d) allows a topical cannabis product or cannabis product to contain up to 2,000 mg THC if the product is only available for sale to a medicinal use customer. The

[16] 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.).

Department is aware that many medicinal patients desire access to higher THC products; this exemption is intended to serve the needs of medicinal use customers, while still providing public health and safety precautions.

**Add Article 3. Failed Product Batches.**

**Adopt Section 40330. Failed Product Batches.** This section establishes the requirements for cannabis products that fail testing requirements.

Subsection (a) requires a cannabis product batch that fails any testing requirement established by the Bureau to be destroyed unless a corrective action plan for remediating or reprocessing is approved by the Department. A product batch that fails testing requirements is considered to be adulterated. However, BPC §26110(c)(2) specifies that the Department may allow a failed cannabis batch to be transported to a manufacturer for remediation. This section further provides that corrective action plans shall be approved by the Department on a case-by-case basis. Given the variety of types of cannabis products and the range of contaminants for which the cannabis batch may fail testing, it is not feasible at this time for the Department to establish comprehensive requirements in regulation. Therefore, this section clarifies that failed product batches shall be destroyed unless:

Paragraph (1) the cannabis product can be remediated by relabeling pursuant to subsection (d).

Paragraph (2) a corrective action plan for remediation or reprocessing is approved by the Department pursuant to subsection (e). Cannabis or cannabis concentrate that failed testing requirements would not be suitable to move in the supply chain unless a remediation plan is approved by the department as it is considered adulterated. The manufacturer licensees is responsible for ensuring that they can remediate the product prior to receiving it. They would submit the plan to the Department, upon approval, accept the product to be remediated according to the plan. This section is necessary to provide an opportunity for failed cannabis batches to be retested without a licensee violating other sections of the regulations.

Subsection (b) specifies that remediation and reprocessing shall also comply with requirements and procedures established by the Bureau. The Bureau also has statutory authority in BPC §26110(c)(2) to establish requirements for remediation. This provision is necessary to inform manufacturer licensees that the Bureau may have additional requirements to be aware of.

Subsection (c) specifies that, except as provided in subsection (d), edible cannabis products that fail laboratory testing cannot be remediated. Reprocessing edible products poses a public health risk as it increases the potential for contamination to be introduced into the product. This section further 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.

Subsection (d) states that a cannabis product that is determined to be labeled with an incorrect amount of any cannabinoid or terpenoid can be remediated by relabeling the product with the correct information based on the certificate of analysis, provided that the THC limits in Section 40315 are met.

Paragraph (1) further provides that if the relabeling is to be done by the distributor, the manufacturer must notify the Department within three (3) business days. This notification shall be given to the Department via email and shall include a copy of the Certification of Analysis for the batch and the name and license number of the licensee relabeling the product. The Department needs to be informed of product batches in which cannabinoids do not conform to the intended cannabinoid content. Such discrepancies may indicate problems with the manufacturing process and in order to properly exercise its oversight authority, the Department must be notified.

Subsection (e) requires that expect as provided in subsection (d), any cannabis product batch, including edible cannabis products, that fails laboratory testing or quality assurance shall not be remediated or reprocessed unless the Department has approved a corrective action plan submitted by the manufacturer licensee. The section further clarifies that the corrective action plan must include a description of the how the product or harvest batch will be remediated. Corrective action plans regarding remediation of edible cannabis products that do not meet the standards under subsection (d) will be reviewed by the Department on a case-by-case basis.

Subsection (f) requires remediation, reprocessing, or the use of a failed harvest batch to be documented in the manufacturing records. This provision is necessary to ensure that in cases of recall, the Department has accurate information. This subsection further clarifies that remediated batches or cannabis products produced from remediated batches are required to go through full testing again. This provision is

necessary to protect public health and ensure that remediated batches or products made from remediated batches are safe for consumption.

**V. Add Subchapter 5. Labeling and Packaging Requirements.**

The Act tasks the Department with both establishing standards for the labeling of all manufactured cannabis products, as well as specifying the requirements that all packages of manufactured cannabis must meet. 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 industry 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 retailer, 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 to require a manufacturer to meet the Department's packaging and labeling requirements for cannabis products subject to further processing.

**Adopt Section 40401. Release to Distributor as Finished Product.** This provision is included to clarify that only finished, including fully packaged and labeled, cannabis products can be released to a distributor. Under the Act, only a licensed manufactured can package, repackage, label, or relabel a cannabis product.

**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) specifies that all required labeling information shall be located on the outsider container or wrapper of the finished product to be sold at the retailer. However, if the container is separable from the outer-most packaging (such as a pill container placed inside a box), the product container shall include the information listed in Paragraphs 1 and 2. This ensures that should the consumer throws away the outer packaging, relevant information is still available to them on the inner container.

Paragraph (1) requires that an edible cannabis product, topical cannabis product, suppository, or orally-consumed concentrate product container shall also include all of the information specified in Sections 40405 and 40406.

Paragraph (2) requires that inhaled products (such as dab, shatter, and wax) shall include the universal symbol as prescribed in Section 40412.

**Adopt Section 40404. Labeling Requirements: Pre-Rolls and Packaged Flower.**
This section contains the labeling requirements for packages of pre-rolls and dried flower. Required information is divided into the primary panel and the information panel as described below. During the effective period of the emergency regulations, the Department received numerous questions regarding the requirements for packages of cannabis and pre-rolls. Based on the volume of questions received, the Department has established the following requirements that align with the requirements of the Act:

Subsection (a) requires the labeling for a package of pre-rolls or packaged flower include a primary panel information with type size of no less than 6 point font that contains the following information:

Paragraph (1) requires the identity of the product. This provision is reasonably necessary so that the flower or pre-roll 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.

Paragraph (2) requires the net weight of cannabis in the package in both metric and U.S. customary units. BPC §26120(c)(1)(B)(2) requires the listing of the net weight for dried flower.

Paragraph (3) requires the universal symbol. The cannabis product symbol provides a method of informing people that the product contains cannabis and helps to protect public health and safety by reducing the potential for unintended consumption.

Paragraph (4) requires the cannabinoid content as specified in Section 40409(b).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

Subsection (b) requires that the informational label for a package of pre-rolls of packaged flower shall include the following information in a type size no less than 6 points font and in relation to the size of the informational panel and container:

Paragraph (1) requires the unique identifier issued by the track-and-trace system. This is a statutory requirement.

Paragraph (2) requires the licensed cultivator or licensee packaging the product (either the legal business name or the registered DBA listed on the license certificate), and its contact number or website address.

Paragraph (3) requires the date of packaging for retail sale. This informs the consumer when the flower or pre-roll was packaged for sale and in turn how long it has been on the shelf.

Paragraph (4) requires the label to include the following statement in bold print: "GOVERNMENT WARNING: THIS PACKAGE CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

Subsection (c) clarifies that nothing in this section prohibits the inclusion of additional information on the label, provided that the label does not violate the requirements of Section 40410.

**Adopt Section 40405. Primary Panel Labeling Requirements: Manufactured Products** 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.

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.

Paragraph (1) 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, thereby obscuring the product from view. The product identity will ensure consumers have accurate information on the contents of the package.

Paragraph (2) 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 by reducing the potential for unintended consumption.

Paragraph (3) requires the label on a cannabis product to provide the net weight or volume of the contents of the package, listed in both metric and U.S. customary units. While BPC §26120(c)(1)(B)(2) only requires the listing of the net weight for dried flower, the Department made the policy decision that the net weight or volume should be listed for all cannabis products. 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 (4) requires the cannabinoid content as specified in Section 40409. This provision is necessary to clarify that specific information related to cannabinoid content is required to be on the primary panel of 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.

Subsection (b) 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 are interested in knowing the specific terpenes in the product—and the same can be said of cannabinoids. 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 could negatively impact the readability and effectiveness of the product label. However, in the interest of truth in labeling, if specific terpenes or other cannabinoids are claimed to be present that information must be validated by an independent laboratory.

**Adopt Section 40406. Additional Primary Panel Labeling Requirements: Edible Products.** This section includes the additional labeling requirements for edible products. This section requires the labeling to include the words “cannabis-infused” immediately above the identity of the product 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.

**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 complaints, consumers must to be able to contact the manufacturer of a product.

Paragraph (2) of subsection (a) requires the date of manufacture. This is a statutory requirement 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) specifies that the GOVERNMENT WARNING mandated by statute is required to be printed on the informational panel. This specification is necessary to provide clarity to the regulated industry as to where on the label the mandated statement is required to be printed.

Paragraph (4) of subsection (a) requires that the label include the statement "FOR MEDICAL USE ONLY" if the product meets certain specifications. BPC §26120(c)(8) requires that medicinal cannabis products sold at a retailer be labeled with the above statement. This provision makes specific that statutory requirement by establishing that products that are either (subparagraph A) the manufacturer intends the product to be sold only to medicinal customers; (subparagraph B) the product is an orally-dissolving product containing more than 100 mg of THC in the package; or (subparagraph C) the product is a topical product or cannabis concentrate and contains more than 1,000 mg THC per package. This provision is necessary to clarify which products are required to be labeled as FOR MEDICAL USE ONLY.

Paragraph 5 of subsection (a) requires all product ingredients to be listed in descending order of predominance by weight or volume. Listing ingredients in descending order of predominance is a commonly accepted standard for product labeling required by the Federal Food and Drug Administration (FDA), 21 CFR, Part 101. Subpart A. 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. This paragraph further clarifies that subingredients (for example, if chocolate chips are an ingredient in the product, the ingredients of the chocolate chips are considered subingredients) can be listed parenthetically after the ingredient (subparagraph A) or can be listed among the individual ingredients in descending order of predominance (subparagraph B).

To illustrate using chocolate chip cookies as an example:

- Subparagraph A addresses an ingredient list as: Enriched Flour (wheat flour, niacin, iron, folic acid), Semisweet Chocolate Chips (sugar, chocolate, cocoa butter, dextrose, soy lecithin), Sugar, Baking Soda, Natural and Artificial Flavor.

- Subparagraph B would permit the same ingredient list to be: Enriched Flour, Semisweet Chocolate Chips, Sugar, Baking Soda, Natural and Artificial Flavor, chocolate, cocoa butter, niacin, iron, folic acid, dextrose, soy lecithin.

Paragraph (6) of subsection (a) requires major food allergens included in the product to be listed. This is a statutory requirement. This provision further specifies 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 (7) of subsection (a) requires the names of artificial food colorings used in the product. Some individuals are sensitive to artificial food colorings; this requirement is necessary to protect the health of the consumer.

Paragraph (8) of subsection (a) requires that edible product labels list the amount of sodium, sugar, carbohydrates, protein, and total fat per serving. This is a standard practice for food-related labeling required by the FDA, 21 CFR, Part 101. Subpart A. However, this section is not intended to be used as a nutritional guide as required by the FDA for food, it will provide consumers with information necessary to protect their health.

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 wide variety of information, such as how to determine a serving for edible products, how to consume 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) allows the manufacturer to print a “best by” date on the label. Stability studies to determine a date by which a product retains its best quality are common and well-established in food and drug manufacturing, but the same level of study has not been conducted on cannabis. If a manufacturer chooses to establish a best by date, this provision specifies where on the labeling the information should be included. If the manufacturer elects not to include a best by date, consumers will still be

able to ascertain the product's freshness through the required date of manufacture printed on the label.

Paragraph (11) of subsection (a) requires the unique identifier issued by the track-and-trace system. This is a statutory requirement. It is included here for clarity. This paragraph also allows the manufacturer to include a batch number.

Paragraph (12) of subsection (a) If the cannabis product is perishable or is perishable after opening, the statement, "KEEP REFRIGERATED" or "REFRIGERATE AFTER OPENING," as applicable. This subsection is necessary in order to ensure public health through the prevention of the growth of bacteria or other adulterations or pathogens in edible cannabis products.

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, subsection (c) 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.

Subsection (d) repeats the language in Section 40405(b) for the informational panel.

**Add Section 40409. Cannabinoid Content Labeling.** BPC §26120(b)(5) specifically requires packages of cannabis and cannabis products to list "pharmacologically active ingredients, including, but not limited to, THC, CBD, and other cannabinoid content, the THC and other cannabinoid amount in milligrams per serving, servings per package, and the THC and other cannabinoid amount in milligrams for the package total." During the effective period of the emergency regulations, it was brought to the Department's attention that this statutory requirement was insufficiently clear such that licensees had difficulty determining how to implement it.

First, the phrase "pharmacologically active ingredients" is confusing when applied to plant material. "Ingredients" is a term that in general usage is typically considered to be something *added* to a product. THC and other cannabinoids are naturally occurring in a cannabis plant. Considering these compounds to be "ingredients" of a cannabis plant would be like considering chlorophyll an ingredient of a plant.

Second, listing cannabinoids in milligrams per serving is an inaccurate way to inform consumers of the strength of a package of cannabis or a pre-roll. In its dried form, most of the tetrahydrocannabinol in the plant is in the form of THCa, not delta-9 THC. Only when the plant material is heated does the THCa decarboxylate into the psychoactive THC. The rate of decarboxylation, and thus the amount of THC in dried plant material, can vary. Listing the amount of THC that the dried plant material contains at the time of testing does very little to inform the consumer of the potential THC concentration when the cannabis is consumed.

Third, the number of servings of a package of cannabis or a pre-roll is difficult to determine with any level of accuracy. Cannabis and pre-rolls are smoked, which means there will be great variability in the factors that determine serving, such as rate of inhalation, how deeply the consumer inhales, and how much time the plant material is heated without being inhaled. Given the potential variation in the number of "servings" of an inhaled plant, it would actually be misleading to a consumer for the label to state a set number.

Given these challenges, the Department was left with trying to determine a way to adhere to both the letter and spirit of the statute – list the pharmacologically active ingredients of cannabis and cannabis products while providing the consumer with meaningful information as to what they are going to consume. The following subsections describe the manner in which the Department will make specific the statutory requirements.

Subsection (a) requires each package of cannabis product to be labeled with the pharmacologically active ingredients. Cannabis product, as used in the statute and in this Chapter, refers to manufactured products, which by their nature consist of ingredients. Cannabinoids can therefore be considered an ingredient of a manufactured product. This subsection specifies that the following cannabinoids are considered pharmacologically active ingredients:

Paragraph (1): THC.

Subparagraph (A) requires that for edible products and cannabis concentrates that have serving designations, the THC must be labeled in milligrams per servicing (i.e. capsule) and milligrams per package (the total amount of THC in the package).

Subparagraph (B) requires that for topical products and cannabis concentrates that do not have serving designations, the THC must be labeled in milligrams per package.

Paragraph (2) and its subparagraphs (A) and (B) establish requirements identical to the above for CBD.

Subparagraph (A) requires that for edible products and cannabis concentrates that have serving designations, the CBD must be labeled in milligrams per servicing (i.e. capsule) and milligrams per package (the total amount of CBD in the package).

Subparagraph (B) requires that for topical products and cannabis concentrates that do not have serving designations, the CBD must be labeled in milligrams per package.

Subsection (b) clarifies that if the THC or CBD in a product is less than 2 milligrams (i.e. is negligible) per serving or per package, the label can state "<2 mg per serving" or "2 mg per package". During the emergency regulation effective period, the Department reviewed numerous testing results (Certificate of Analysis, or COA) in which the cannabinoid content, both on the label and indicated in the COA, was less than 2 mg per serving. However, if the label content and the COA were more than 10% different, the product was considered to have failed label review and would need to be relabeled. At this point in time, requiring such precision of manufacturers and testing instrumentation of very low cannabinoid content would be an unreasonable requirement. The average Limit of Quantification (LOQ) – the level at which a laboratory can reliably measure an amount – averages just under 1.9 mg for cannabinoids. In such small amounts, the cannabinoid content has very little pharmacological effect. It is therefore reasonable for the Department to allow labels to state the cannabinoid content as less than 2 mg per serving or per package, rather than requiring an exact number.

Subsection (c) states that packages of pre-rolls or cannabis flower may be labeled with the THC content expressed as a percentage. As discussed above, it is not reasonable to consider THC an "ingredient" of the plant, nor can serving sizes be reliably determined. This provision is necessary in order to provide consumers with the most meaningful information they need.

Subsection (d) provides labeling requirements for infused pre-rolls. Infused pre-rolls shall be labeled in one of two ways:

Paragraph (1) allows for infused pre-rolls to be labeled with the cannabinoid content in milligrams. As infused pre-rolls are defined as having cannabis concentrate incorporated into the product, they fall into the category of manufactured products and

are therefore required by statute to be labelled with their cannabinoid content in milligrams.

Paragraph (2) allows for the cannabinoid content of the flower to be listed as a percentage and the added cannabinoid content in milligrams. This section is in alignment with other states regulations regarding THC percentages in flower. Cannabinoid and THC content in flower is more accurately defined as a percentage rather than in milligrams.

This provision will allow the manufacturer to determine which method of listing cannabinoid content is most meaningful for consumers based on the specifics of the product.

**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. Labels for manufactured cannabis products are prohibited from:

Subsection (a) including the name of a California county unless the cannabis was grown there. This is a statutory restriction and is intended to prevent labels from misleading a consumer as to the source of the cannabis.

Subsection (b) containing any content that is designed to be attractive to individuals under the age of 21. BPC §26120(b) requires that packages and labels of cannabis and 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 those under 21 without a medical prescription.

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 those under 21 without a medical prescription.

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 those under 21 without a medical prescription.

Paragraph (4) prohibits the terms “candy” or “candies,” and any variants in spellings such as “kandy” or “kandeez.” Candy has a special appeal to children. Referring to a cannabis-infused product as “candy” would pose a threat to public health and safety and is misleading to the consumer. This prohibition is necessary to minimize the potential appeal to children.

Subsection (c) prohibits false or misleading information. Under the Act, any product with labeling that is false or misleading is considered misbranded 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 (d) prohibits any health-related statement that is untrue or misleading. This subsection further defines untrue or misleading health-statements are those that are not supported by a totality of publicly available scientific evidence and for which there is not significant scientific information. Claiming health benefits or effects that are not scientifically established is misleading to a consumer and is a threat to public health.

Subsection (e) prohibits a picture of the product, if the cannabis product is an edible product. Edible cannabis product packaging is required to be opaque in order to reduce its potential attractiveness to children. Printing a picture of the product within would negate the rationale of opaque packaging.

Subsection (f) provides that the restriction on “false or misleading information” includes any indication that the cannabis or cannabis product is organic, unless designated as such under the federal Organic Foods Product Act. BPC §26062.5 prohibits claims that cannabis or cannabis product is organic, except in accordance with the federal program. This section is necessary to clarify that the Department will consider such claims as false and misleading information, rendering the cannabis product misbranded.

**Adopt Section 40411. Statement of Characteristic Anticipated Effects.** This section allows a cannabis product to include information on the characteristic anticipated effects of the cannabis product if the manufacturer has substantiation that the information is truthful and not misleading. It further defines characteristic anticipated effect as any physiological effect that is common to or expected from the particular cannabis strain, but excludes any claim on health benefits.

BPC §26154 prohibits labels of cannabis or cannabis products from containing any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects of health of cannabis consumption; however, BPC §26130(b)(6) requires edible products to be provided to customers with sufficient information to enable the informed consumption of the product, including the potential effects of the cannabis product. This proposed regulation will provide clarity to the regulated industry as to what kind of information is required to be given to customers and what kind of information is prohibited.

**Adopt Section 40412. Universal Symbol.** BPC §26130(c)(7) requires edible cannabis products to be marked with the universal symbol, as determined by the Department. This section establishes that the universal symbol must be printed on the primary panel. This section also expands the requirement to label a product with the universal symbol to all cannabis products. In order for the symbol to become easily recognized and closely associated with cannabis products, it is reasonably necessary to require the symbol on all types of cannabis products, not just edibles.

Subsection (a) provides the universal symbol.
The Department made a policy decision to requirement the symbol to be printed in black so that it can be clearly noticed on varying backgrounds.

Subsection (b) requires that the symbol be printed in black. In order for a symbol to be universally recognized it should be standardized in form and color. However, because packages may be dark in color, this subsection provides that the symbol can be made conspicuous by printing on, or outlining the symbol with, a contrasting color. A symbol that cannot be seen on its package will not serve to protect public health.

Subsection (c) provides that the symbol must be no smaller than 0.5 inch by 0.5 inch in size and to be printed legibly and conspicuously. A symbol that is too small to be readily seen will not serve to protect public health.

Subsection (d) clarifies that the symbol cannot be altered or cropped in any way. During the effective period of the emergency regulations, the Department received numerous requests to allow certain modifications to the symbol. In order to provide universal recognition, it is necessary that the symbol not be altered in any way, other than adjusted in sizing to fit on a package. This provision is included for clarity.

**Add Article 3. Packaging Requirements.**
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 is a statutory requirement under BPC §26120(a).

Subsection (c) requires the packaging to be child-resistant as specified in Section 40417. A key element of public health protection is decreasing the likelihood that children or unsuspecting adults could accidently ingest cannabis products. Child-resistant packaging is a statutory requirement (BPC §26120(a)) and is necessary to protect public health and safety.

Subsection (d) prohibits the packaging from imitating any package used for products typically marketed to children. The Act prohibits the packaging of cannabis products from being appealing to children (BPC §26120(b)). If cannabis product 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. This section further defines an amber bottle as opaque for the purposes this subsection. Amber bottles are commonly used for medication and beer, products that are not intended for consumption by children. The Department believes that amber bottles – a packaging form that is culturally associated with adult products – will provide sufficient public health protection.

Subsection (f) provides that bottles may utilize a single, clear, vertical strip no wider than 0.25 inches for the purpose of determining serving amounts. During the effective period of the emergency regulations, the Department received numerous requests to allow for this exception to the requirement for opaque bottles. The Department determined that this exception was a reasonable allowance that will provide for greater consumer understanding, without threatening the public health protection purpose of opaque packaging requirements.

## VI. Add Subchapter 6. Compliance

**Add Article 1. Records.** This article establishes the requirements for record-keeping to which licensees must adhere.

**Adopt Section 40500. Record Keeping Requirements.** This section defines the specific records related to commercial cannabis activity that each licensee must maintain, and the requirements, including timeframes and location, for retaining these records. Licensee are required by statute to keep accurate records on the premises and record retention is fundamental to an effective regulatory oversight program. It is necessary for required records and documentation to be retained and made readily available to Department staff. In the absence of specific record retention requirements, licensees would have the discretion to dispose of or destroy business records that often serve as the primary basis for determining statutory and regulatory compliance.

Subsection (a) requires a licensee to maintain specified documents on the premises at all times and to make the records available to the Department upon request. These are statutory requirements in BPC §26160(c) and (d).

Paragraphs (1), (2), and (3): the licenses issued by the Department, other state licensing authorities, and the local jurisdiction, and further requires the Department-issued license to be prominently displayed. This protocol is widely used by licensing agencies for many types of licenses. This section is necessary to clarify the Department's expectation of a licensee to post their license and to provide regulatory bodies consistency in their ability to verify state licensure.

Paragraph (4): the premises diagram. In conducting a records review, the Department must be able to readily access the premises diagram.

Paragraph (5): the current standard operating procedures. Standard operating procedures are an important oversight tool for Department staff. When conducting an inspection, the Department will need ready access to the standard operating procedures currently in use by the licensee.

Paragraph (6): shipping manifests. This paper record trail provides an important tool to track the movement of cannabis throughout the chain and to ensure that licensees are only conducting business with other licensees.

Paragraph (7): personnel records, including training logs. Personnel records are necessary for the Department to determine whether personnel are trained in accordance with requirements.

Paragraph (8): contracts with other licensees regarding commercial cannabis activity.

Paragraph (9): Financial records related to the commercial cannabis activity. This provision is necessary so the Department can ensure that commercial activities are conducted with other licensees, and so that other oversight agencies can track that appropriate taxes are being paid.

Paragraph (10): sales invoices and receipts. This is a statutory requirement in BPC §26161 and is included here for clarity to the regulated industry.

Paragraph (11): any other documentation or record required by law to be kept by the licensee. This provision is necessary to clarify to licensees the retention requirements for all required records and documentation.

Subsection (b) requires records to be kept for a period of seven years. This is a statutory requirements (BPC §26161) and is included here for ease of the regulated

industry. This subsection further provides that outdated standard operating procedures shall be maintained in a way that onsite employees cannot mistakenly access outdated information. During the public comment period for the rescinded medical cannabis regulation package, the Department received concerns that keeping standard operating procedures for seven years could create confusion for employees. This provision has been added to clarify that the licensee must keep the records, but maintain them in a manner so that employees cannot mistakenly access them.

Subsection (c) requires all documentation to be maintained in English. This is necessary to ensure documentation can be properly read and understood by the Department and other oversight agencies. However, the Department acknowledges that there may be a legitimate business need to keep and to provide employees information in languages other than English. This subsection is necessary to clarify that documents are allowed to be maintained in other languages as needed, provided that the documentation is also kept in English.

**Adopt Section 40505. Sales Invoices and Receipts.** Every sale or transport of cannabis or cannabis products from one licensee to another licensee must, per statute, be recorded on a sales invoice or receipt. Sales invoices and receipts may be maintained electronically and must the filed in such a manner as to be readily accessible for examination by employees of the regulating agencies. This section is necessary to prevent the diversion of product to the illegal market during transfer and to allow the opportunity for the Department, other state licensing authorities, any state or local law enforcement, and the California Department of Tax and Fee Administration to verify legitimacy of the sale and off-site movement of cannabis or cannabis products. This section is further necessary to ensure that licensees are tracking movement of product prior to their inventory being in track and trace; and that these records are retained after inventory is inputted in track and trace.

Subsection (a) requires that the licensee shall prepare a sales invoice or sales receipt for every sale, transport, or transfer of cannabis product to another licensee. Sales invoices and receipts may be maintained electronically, but shall be readily accessible for examination by the Department and its inspectors and agents.

Subsection (b) requires that each sales invoice or receipt shall include the following information so that sales can be tracked back to the point of origin:

Paragraph (1) Name, address, and license number of the seller;

Paragraph (2) Name, address, and license number of the purchaser;

Paragraph (3) Date of sale, transport, or transfer;

Paragraph (4) Invoice or receipt number;

Paragraph (5) Kind, quantity, size, and capacity of packages of cannabis or cannabis product sold, transported, or transferred;

Paragraph (6) Cost to the purchaser for the cannabis or cannabis product, including any discount or trade allowance applied to the price, which shall be recorded on the invoice;

Subsection (c) states that for purposes of this section, "discount or trade allowance" means any price reduction or allowance of any kind, whether stated or unstated, and includes, without limitation, any price reduction applied to a licensee's price list. The discounts may be for prompt payment, payment in cash, bulk purchases, related-party transaction, or "preferred-customer" status.

Subsection (d) requires that invoices and receipts for the sale, transport, or transfer of cannabis or cannabis products shall not be comingled with invoices covering other commodities.

**Add Article 2. Track-and-Trace System.**
Licensees are required by statute to utilize the track-and-trace system established and administered by CDFA. This article establishes the requirements for manufacturer licensees in their use of track-and-trace, which is designed to record the movement of cannabis and cannabis products and monitor commercial cannabis activity.

**Adopt Section 40510. Track-and-Trace System General Requirements.** This section outlines licensee requirements for using the track-and-trace system, which is designed to record the movement of manufactured products and monitor commercial cannabis activity. Licensees are responsible for the accuracy and completeness of all information they input into the track-and-trace system. Each licensee must establish one individual as their account manager who is required to complete track-and-trace system training, train other users designated by the licensee to access the system, and oversee track-and-trace system operations. All information entered into the system must be accurate and true and the department can take an enforcement action based on the data entered into the system.

Subsection (a) requires all commercial cannabis manufacturers to identify an owner in the business to be the track and trace account manager. The account manager must register for the track and trace training within 10 days of getting the notification from the Department.

Subsection (b) ensures that once a license has been issued to a license, only a trained and authenticated account manager can enter information into the track and trace system.

Subsection (c) identifies the account manager as the responsible party for all track and trace activities and categorizes what those are.

Paragraph (1) – The account manager must complete the training provided by CDFA or its designee. If they have not done so prior to licensure; they must do so within five (5) business days of receiving the manufacturing license from the Department.

Paragraph (2) – The account manager can designate other users in the system. They must ensure that those users are properly trained and adhere to all the requirements of track and trace prior to allowing them to use the system.

Paragraph (3) - The account manager must at all times have an up to date list of all the users in the system.

Paragraph (4) – Immediately cancel any track-and-trace system account manager or designated user from a track-and-trace system account if the individual is no longer a licensee representative;

Paragraph (5) – The account manager must make sure that any erroneous entries in the system are rectified within three business days of finding out the error.

Paragraph (6) - Obtain Unique Identifier (UID) tags from the Department of Food and Agriculture, or its designee, and ensure that there is a sufficient supply of UIDs available at all times;

Paragraph (7) Ensure that all inventory is tagged and entered in the track-and-trace system as required by Section 40512;

Paragraph (8) Monitor all notifications from the track-and-trace system and resolve all issues identified in the notification. The notification has to be addressed by an account manager until the issue(s) identified in the notification have been resolved.

Subsection (d): If the account manager changes, the applicant or licensee is responsible for notifying the department of the change in forty-eight (48) hours.

Subsection (e) holds the licensee and applicant responsible for all entries into track and trace made by designated users in the system.

Subsection (f) Mandates that no designated users shall intentionally misrepresent or falsify information entered into the track-and-trace system and that the Department considers track-and-trace as the system of record. It holds the licensee responsible for the accuracy and completeness of all of the data and information entered into the system and that an enforcement action can be taken against the licensee if incorrect information is not corrected in the system. This provision is reasonably necessary to ensure that the track-and-trace system is accurately maintained so that it can serve its statutory purpose to prevent diversion.

**Adopt Section 40512 Track-and-Trace System Reporting Requirements.** The track-and-trace system is a real-time inventory management system; it is a critical tool for state licensing agencies to monitor and track cannabis and cannabis products from seed to sale, and to protect against inversion and diversion from the commercial cannabis supply chain. The system will allow licensed manufacturers to identify their product, improve supply chain efficiency at the cultivation level, and provide flexibility in managing supply in response to changes in market conditions or inventory.

Subsection (a): requires certain activities to be logged within 24 hours of occurrence. In order to ensure that information is accurately recorded, it must be entered into the system quickly after occurring. The following activities correspond to the requirements of the track-and-trace system developed by CDFA:

Paragraph (1) – receipt of cannabis material.

Paragraph (2) – transfer of cannabis material to another manufacturer.

Paragraph (3) – any changes in the disposition of cannabis or cannabis product, including:

Subparagraph (A) Processing of cannabis or further processing of a manufactured cannabis product; and

Subparagraph (B) Packaging and labeling of the cannabis products or repackaging or relabeling of the cannabis products.

Paragraph (4) – the use of the cannabis for internal quality control testing or product research and development.

Paragraph (5) - The transfer of cannabis products to a distributor.

Subsection (b) requires the inclusion of specified information in the track-and-trace system records. These requirements correspond to the requirements of the track-and-trace system developed by CDFA.

Paragraph (1): the licensed entity name from which the cannabis material or product was received.

Paragraph (2): the name and license number of the distributor that transported the cannabis material;

Paragraph (3): a description of the type of cannabis material or cannabis product that was received, processed, manufactured, packaged, or transferred. This will serve to ensure that there was no cannabis product inversion and/or diversion from the commercial cannabis during the transfer;

Paragraph (4): the weight or count of the cannabis material or cannabis product received, processed, manufactured, packaged, or transferred to ensure that there was no cannabis product inversion and/or diversion from the commercial cannabis during the transfer;

Paragraph (5): the date and time of receipt, processing, manufacturing, packaging, or transfer;

Paragraph (6): the UID assigned to the cannabis material or cannabis product;

Paragraph (7): any other information required by other relevant licensing authorities.

**Adopt Section 40513 Track-and-Trace System – Loss of Access.** Because the track-and-trace system is an online system, it is reasonable to expect that there will be times in which the system is unable to be accessed by licensees. This section provides the requirements that a licensee must follow if access to the track-and-trace system is temporarily lost.

Subsection (a) requires the licensees to track and keep comprehensive records detailing all required inventory tracking activities conducted during the loss of access.

Subsection (b) requires the licensee to enter all the manual records back into the system within three (3) business days. This timeframe is necessary to ensure that records are accurately added and are not otherwise lost or forgotten.

Subsection (c) requires that the licensee document the date and time when access to the track-and-trace system was lost and when it was restored and what caused the loss of access. This will assist the licensing authority if there is a reoccurring pattern of loss of access and to ensure there was no inversion or diversion of cannabis or cannabis products during that time.

Subsection (d) prohibits licensees from transferring cannabis or cannabis products to another licensee until access to the track-and-trace system is restored and all information is recorded into the track-and-trace system. This will assist the licensing authority if there is a reoccurring pattern of loss of access and to ensure there was no inversion or diversion of cannabis or cannabis products during that time.

**Adopt Section 40515 Track-and-Trace System –Temporary Licenses.** For temporary licensees all sales or transport of cannabis or cannabis products is required by statute to be recorded on a sales invoice or receipt. This requirement is necessary to prevent the diversion of product to the illegal market during transfer and to allow the opportunity for the Department, other state licensing authorities, any state or local law enforcement, and the California Department of Tax and Fee Administration to verify legitimacy of the sale and off-site movement of cannabis or cannabis products. This section outlines licensee requirements for the use of a signed sales invoice or receipt for every sale or transfer of cannabis or cannabis product to another licensee.

Subsection (a) – defines what specific information is required to be included on the invoice or receipt for temporary licensees, including:

Paragraph (1) –the name, address, and license number of the seller of the cannabis or cannabis product;

Paragraph (2) –the name, address, and temporary license number of the purchaser,

Paragraph (3) –the date of sale or transfer of the cannabis or cannabis product and the invoice number of the sale being made;

Paragraph (4) –a description of the cannabis or cannabis product; or type of cannabis or cannabis product;

Paragraph (5) – the weight or count of the cannabis or cannabis product sold or being transferred via the sales receipt;

Paragraph (6) – the cost the purchasing party will be paying for the cannabis or cannabis product.

Subsection (b) allows licensees that have annual licenses to continue to conduct business with temporary licensees as long as all the conditions of section (a) are met. It also clarifies that any commercial cannabis activity conducted between annual license holders shall be recorded in the track-and-trace system.

Subsection (c) – states that the provisions of this section shall expire on July 1, 2019 based on the statutory sunset date of temporary licenses.

**Adopt Section 40517 Track-and-Trace System –UID Tag Order.** Consistent and proper application of UIDs are the primary mechanism for executing the traceability requirements outlined in statute, which require full transparency of all commercial cannabis activities. This section outlines the licensee requirements for the use and application of the Department-issued track-and-trace system UID tags. It also states the time requirements for entering UID data into the track-and-trace system and defines how, when, and where UIDs must be affixed. Licensees are required to use Department-issued UIDs only, maintain a sufficient UID supply, and retire UIDs in the track-and-trace system upon destruction or disposal of any cannabis products.

Subsection (a) requires licensee to order UID tags within five (5) business days of receiving access to the track-and-trace system. The receipt of the UID tags will be recorded in the track-and-trace system within three (3) business days of receipt of the tags.

Subsection (b) requires a licensee that is in operation to input all inventory into the track-and-trace system within 30 calendar days after receipt of their UID tags. Use of the track-and-trace system is a mandated responsibility. This subsection is reasonably necessary to ensure that licensees properly upload all of their existing cannabis and cannabis products. Because existing inventory may be extensive, the Department, in conjunction with the other licensing authorities, determined that 30 days should be a reasonable amount of time to enter it all into the system.

**Add Article 3. Advertising and Marketing.**

**Adopt Section 40525. Advertising and Marketing.** This section implements requirements to ensure that licensees comply with the requirements of chapter 15 (commencing with section 26150) of the Act regarding advertising and marketing.

Subsection (a) requires licensees to ensure that the advertising and marketing of its products meet the requirements of chapter 15 (commencing with section 26150) of the Act and additionally requires licensees to ensure that any health-related statements used in the advertising and marketing of its products meet the requirements established by the Department in Section 40410 of the regulations which requires health-related statements to be supported by scientific evidence. This provision is reasonably necessary because it identifies the basic requirements for advertising and marketing under the Act and these regulations.

Subsection (b) requires licensees to accurately and legibly include its license number on advertising and marketing as required by section 26151 of the Act and in addition requires the licensee to accurately and legibly include its name on advertising and marketing. This provision is reasonably necessary to implement section 26151 of the Act because it provides an additional and more readily notable method to identify the licensee responsible for advertising and marketing to ensure compliance with advertising and marketing requirements.

Subsection (c) requires licensees to keep records to establish that the advertising and marketing of its products meet the requirements of chapter 15 (commencing with section 26150) of the Act. This provision is reasonably necessary to ensure that licensees are documenting its compliance with advertising and marketing requirements and to provide the Department with a mechanism to establish a licensee's compliance with the provisions of the Act and these regulations.

Subsection (d) requires that a licensee shall remove or discontinue advertising or marketing if the Department determines it violates the provisions of the Act or these regulations or if the licensee fails to provide records to the Department upon request that establishes the advertising and marketing meets the requirements of the Act and regulations. This requirement is in line with both consumer protection and the Department's requirements that licensees adhere to all regulations in this package.

**Add Article 4. Inspections.**

**Adopt Section 40550. 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 to 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 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 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 cannabis products to determine compliance with the provisions of the Act and these regulations.

Subsection (c) states that the Department may inspect any record or document that has a bearing on whether the labeling, advertising, or marketing of a cannabis product complies with the requirements of BPC §26150. If a licensee claims a health benefit, the claim must be supported as described in other provisions of this proposal. This subsection is necessary to clarify that the Department may inspect those documents to ensure compliance.

Subsection (d) establishes that the Department may collect a sample or specimen of any 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 cannabis product or ingredient during an inspection to determine compliance with the provisions of the Act and these regulations.

Subsection (e) 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 (f) establishes that the Department may conduct investigations concerning the adulteration, misbranding, false or misleading advertising or marketing, or unlicensed production of any cannabis product. Investigations will include entry and inspection of any place where any 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.

**Adopt Section 40551. Notice to Comply.** This section establishes a process for the Department to issue a Notice to Comply in furtherance of its authority to enforce the Act and these regulations.

Subsection (a) establishes that the Department may issue a notice to comply to a licensee for violations of the Act or regulations observed during an inspection. This provision is reasonably necessary because it provides the Department with a mechanism to seek compliance with the Act and regulations that is an alternative to formal enforcement action pursuant to the Department's citation and fine authority under BPC §26134.

Subsection (b) establishes that the notice to comply shall be in writing and describe the nature and facts of each violation and a reference to the statute or regulation violated. This provision is reasonably necessary to establish the content of the notice to comply in order to provide reasonable notice to the licensee of the facts and circumstances of the violation to enable the licensee to correct the violation.

Subsection (c) establishes that the Department may serve the notice to comply on an owner, manager, or other individual on the premises designated by the licensee, prior to leaving the premises or may serve the notice to comply on the licensee by mail within 15 calendar days of the last date of inspection. This provision is reasonably necessary

to specify the manner and a reasonable timeframe for the Department to serve, and the licensee to receive, the notice to comply.

Subsection (d) establishes that the Department must specify a reasonable timeframe in the notice to comply for the licensee to correct the identified violation(s), and for the licensee to notify the Department of the corrective action taken for each violation and describe how compliance was achieved. This provision is reasonably necessary to ensure that violations are corrected in a timely manner but allows for a flexible timeframe dependent on the nature of the violation(s). The provision is also reasonably necessary so that the Department is notified of the corrective actions taken by the licensee so that the Department can ensure violations are corrected to ensure the quality of cannabis products and to protect public health.

Subsection (e) establishes that the Department may take further enforcement action or disciplinary action if the licensee fails to correct a violation identified in the notice to comply. This provision is reasonably necessary for the Department to ensure a licensee is in compliance with the requirements of the Act and the regulations and to fulfill the Department's mandate to protect public health and to notify licensees that additional enforcement action may be taken if the licensee fails to correct a violation.

**Add Article 5. Suspensions and Revocations of a License.**

**Adopt Section 40570. Emergency Decision and Order.** This section provides the circumstances under which the Department may issue an emergency decision and order for temporary, interim relief. Government Code §§11460.10 through 11460.80 allow state departments to establish emergency procedures to prevent or avoid immediate danger to the public health, safety, or welfare. This section is necessary to specify the circumstances under which the Department may exercise its authority in order to fulfill the mandate of BPC §26011.5 (protection of public health and safety).

Subsection (a) states that the Department may issue an emergency decision and order for temporary interim relief to prevent or avoid immediate danger to the public health, safety, or welfare. There are situations in which continued operation of the cannabis manufacturing premises may present an immediate danger to the public – for instance, if the closed loop extraction system is faulty (potential for explosions or fire) or an event has occurred that would contaminate cannabis or cannabis products (a sewer pipe bursts in the cannabis facility). Alternatively, there may be circumstances under which continued operation of a manufacturing facility may allow the operator to destroy evidence to avoid detection of improper manufacturing practices or illegal activity.

This subsection incorporates circumstances under which the federal Food, Drug and Cosmetic Act allows for suspension of a license (21 USC 350d(b)(1)). Specifically, this subsection includes, but is not limited to, the following circumstances:
Paragraph (1): The Department determines that a cannabis product manufactured, processed, packed, or held at the licensee's premises has a reasonable probability of causing serious adverse health consequences or death.

Paragraph (2): The Department determines that insanitary or other conditions at the licensee's premises exist that could lead to the adulteration of finished cannabis products, and has a reasonable probability of affecting the safety of finished cannabis products.

Paragraph (3): The Department observes or has information that conditions at the licensee's premises exist that present an immediate risk to worker or public health and safety.

Paragraph (4): To prevent illegal diversion of cannabis or cannabis products, or other criminal activity at the licensee's premises.

Paragraph (5): To prevent the destruction of evidence related to illegal activity or violations of the Act.

Subsection (b) establishes the various forms of temporary, interim relief that may occur. The Department will exercise its authority on a case-by-case basis to fulfill its statutory mandate to protect public health and safety.

Paragraph (1): temporary suspension of a license.

Paragraph (2): An order to segregate or isolate specified cannabis products.

Paragraph (3): An order prohibiting the movement of cannabis products from the premises or the receipt of cannabis or cannabis products at the premises.

Paragraph (4): An order to cease some or all manufacturing operations at the premises.

Paragraph (5): An order prohibiting the sale of specified cannabis products.

Paragraph (6): An order for the recall of cannabis products.

Subsection (c) requires the Department to include a brief explanation of the factual and legal basis for the emergency decision. This provision consistent with the requirements of Government Code section 11460.50 and is necessary so that the licensee is aware of the reasons for which the action is being taken.

Subsections (d), (e), and (g) establish the procedures for issuance, hearing, and judicial review of the decision. These sections are consistent with Government Code §§ 11460.40, 11460.60, 11460.80 and are standard administrative procedures necessary to protect the licensee's due process rights.

Subsection (f) provides for the appeal of a final administrative decision to the Cannabis Control Appeals Panel as provided by BPC §26043. This is an additional administrative procedure afforded licenses by the Act to protect the licensee's due process rights.

Subsection (h) clarifies that the emergency decision and order provisions in this section are in addition to, and does not preclude the Department's additional authority for the recall of products pursuant to BPC §26132, to embargo products pursuant to BPC §26133, and to take any other action available to it under the Act.

## 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).
C. Guohua, et al., "Drug use and fatal motor vehicle crashes: A case-control study." (2013) 60 Accident Analysis and Prevention, pages 205-210.
D. Janczyk et al., "Two Hundred and Thirteen Cases of Marijuana Toxicoses in Dogs." (2014) 46 Veterinary Human Toxicology, pages19-21.
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).
R. Cannabis Advisory Committee Recommendations, minutes from March 15, 2018, Committee meeting, available at: http://bcc.ca.gov/about_us/meetings/materials/20180517_cac.html
S. USFDA, Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry. (October 2016). https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM525233.pdf.

## 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.

In addition, the Cannabis Advisory Committee held several meetings during the effective period of the emergency regulations. Committee members, as well as members of the public, provided input on the emergency regulations. The Department took these comments and recommendations into account when developing this proposal.

Finally, the Department has considered comments received during the public comment periods of the emergency regulations, as well as feedback received during the effective period of the emergency regulations.

## CONSIDERATION OF REASONABLE ALTERNATIVES

The Department has determined 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 interest of ease-of-reading for the regulated industry, 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. The Act explicitly provides that nothing 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. Cannabis product manufacturers that conduct extraction operations using specified types of chemical solvents are required to use a closed-loop extraction system. The specification for a closed-loop system is necessary for the protection of public health and safety.