

Allergen Guidance

What is an allergy?

An allergy is an immune response to a foreign substance. Allergies can be triggered by exposure through consumption, skin contact, or respiratory exposure.

A food allergy is an immune response to a food triggered by the body's immune system. Food allergies occur when the body's immune system reacts to certain proteins in food. Food allergies can cause mild symptoms (e.g., hives, itching, gastrointestinal issues), but in rare cases can trigger a severe and life-threatening reaction known as anaphylaxis.

Properly identifying and labeling allergens in cannabis products and preventing allergen cross-contact are important factors in ensuring the safety of consumers who suffer from food allergies.

What are the major food allergens?

The Department of Cannabis Control (DCC) follows federal law that recognizes nine major food allergens: Milk, Eggs, Tree Nuts, Wheat, Peanuts, Soybeans, Sesame, Fish, and Shellfish. (Cal. Code Regs., tit. 4, §15000, subd. (c).)

What is allergen cross-contact?

DCC regulations define allergen cross-contact as the unintentional incorporation of a food allergen into a cannabis product. (Cal. Code Regs., tit. 4, §17207, subd. (a).) For example, allergen cross-contact can occur when multiple products with different allergen profiles are produced using the same equipment and the equipment is ineffectively cleaned between production runs or through the generation of dust containing an allergen.

DCC regulations and allergens

To protect those with food allergies and sensitivities, DCC regulations require that licensees who handle allergens establish and implement a written allergen control program as part of the Product Quality Plan to prevent both labeling mistakes and allergen cross-contact between product types. (Cal. Code Regs., tit. 4, §17214, subd. (d)(3).) Licensees must implement an allergen control program that is appropriate for their specific manufacturing activities.



Key elements of an allergen control program include:

- Accurately listing all major allergens present in the cannabis product on the ingredient list of the product labeling.
- Providing accurate allergen warnings on the cannabis product label in the form of a contains statement – the word “contains” followed by a list of the allergens contained in the cannabis product.
- Implementing good manufacturing practices (GMPs) and other allergen controls during manufacturing to prevent allergen cross-contact between product types and labeling mistakes.

DCC regulatory requirements & example practices for an allergen control program

Regulatory Requirement:

Licensees are required to implement a Quality Control Program to ensure cannabis products are not adulterated or misbranded. (Cal. Code Regs., tit. 4, §17208, subd. (a).) This includes preventing allergen cross-contact during manufacturing because products with undeclared allergens may be considered adulterated or misbranded.

Example Practices:

Schedule production with allergens to minimize potential for cross contamination

- Consider scheduling production of allergen-containing products on their own day, or at the end of a shift. This minimizes the chances of allergen cross-contact between products.

Implement thorough cleaning protocols

- After production of allergen-containing products, follow an established written protocol to clean and sanitize equipment before producing the next batch of cannabis products.
- Document when cleaning and sanitizing is performed.

Designate and label equipment and utensils for use with allergens or allergen-containing ingredients

- If possible, use dedicated equipment, processing lines, and utensils for allergens and allergen-containing products
- Identify equipment and utensils for use with allergens (e.g., color coding).



Regulatory Requirement:

Licensees are required to train employees in the licensee’s manufacturing specific quality control procedures, product quality plans, and cleaning and maintenance requirements, and document these trainings. (Cal. Code Regs., tit. 4, §17211.1, subd. (a)(2)(B), (a)(2)(C) and (a)(2)(F).)

Example Practices:

Staff training

- Train staff on the importance of allergen controls.
- Manufacturing staff should know:
 - The nine major food allergens.
 - All allergens present in your facility.
 - The allergens present in each cannabis product.
- Manufacturing staff should understand the hazards of allergen cross-contact and the allergen controls they are responsible for implementing.
- Ensure training is documented and refreshed annually.

Regulatory Requirement:

Licensees are required to store raw materials and components under conditions that prevent against allergen cross-contact, including using containers to protect against allergen cross-contact, and identifying components and raw materials that are or contain food allergens. (Cal. Code Regs., tit. 4, §17212, subd. (b)(2), (b)(6) and (b)(8).)

Example Practices:

Properly store allergens and allergen-containing ingredients

- Have a designated, labeled storage area for each allergen and allergen-containing ingredient.
- Label each allergen and allergen-containing ingredient clearly with the name(s) of the allergen(s).
- Use containers with lids to prevent spills during storage and transport.
- Store allergens and allergen-containing ingredients below other ingredients to prevent spills onto non-allergen ingredients or components.

Regulatory Requirement:

Licensees are required to accurately label cannabis products with the ingredients, sub-ingredients, and allergens they contain, including an allergen warning in the form of a “contains” statement, followed by a list of the allergens. (Cal. Code Regs., tit. 4, §17406, subd. (a)(5) and (a)(6).)



Example Practices:

Correctly label cannabis products containing allergens

- Ensure ingredients and sub-ingredients (ingredients within another ingredient), especially allergens, are accurately declared in the ingredient list on your cannabis product's labeling.
- Review the ingredient lists on each of your ingredients. List those ingredients (especially allergens), and any sub-ingredients they contain on the label of your cannabis product.
- E.g. If milk chocolate is one of your product ingredients, you must list all of its ingredients and declare its allergens "(cocoa butter, milk powder, sugar, cocoa powder);" "contains milk."
- When receiving packaging and labeling for cannabis products that contain allergens, review a sample label to ensure the allergens are accurately listed and declared on the label.
- Implement additional cannabis product label reviews during packaging and labeling of allergen-containing products to ensure the correct labels are applied to the correct cannabis product.
- Consider documenting these checks in the Batch Production Record.

Note: An ingredient manufacturer and/or supplier may change their product formulation at any time - including adding an allergen, for example, switching a sub-ingredient to peanut oil. Periodically review the ingredient lists and allergen warnings on your ingredients and update your cannabis product labels' ingredient lists when necessary to prevent manufacturing a cannabis product with an undeclared allergen.

Regulatory Requirement:

Licensees are required to establish and implement a written product quality plan which includes evaluating the risk for allergen cross-contact and implementing an allergen control program (Cal. Code Regs., tit. 4, §17214, subd. (a), (c)(2) and (d)(3).)

Example Practices:

Written procedures

- Put your allergen controls in writing. Create written procedures describing the steps and actions you take to prevent allergen labeling errors and allergen cross-contact (see Allergen Control Program Checklist).



Major Food Allergens

The following are the nine major food allergens recognized by DCC and federal law. The list includes alternate names for these allergens, some common foods and ingredients that contain these allergens, and some examples of cannabis products that may contain these allergens.

ALLERGEN	ALTERNATE NAMES (ALSO KNOW AS)	INDIRECT AND THIRD-PARTY COMMERCIAL SOURCES <i>(These are examples, but not an all-inclusive list)</i>	CANNABIS PRODUCTS WHERE THIS ALLERGEN MAY BE FOUND <i>(These are examples, but not an all-inclusive list)</i>
WHEAT	<ul style="list-style-type: none"> • Semolina • Flour • Rye • Barley • Spelt • Malt 	<ul style="list-style-type: none"> • Cookie pieces • Cereals 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies, crisped rice treats) • Confections (licorice) • Non-alcoholic beers • Pretzels
PEANUTS	<ul style="list-style-type: none"> • Groundnut • Goober 	<ul style="list-style-type: none"> • Peanut butter • Peanut oil 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies, granola bars) • Chocolates (peanut butter cups, candy bars) • Infused peanut butter
TREE NUTS	<ul style="list-style-type: none"> • Walnuts • Almonds • Pecans • Cashews • Pistachios • Hazelnut (Filbert and Cobnut) • Brazil • Macadamia • Pine Nut • Coconut 	<ul style="list-style-type: none"> • Nut oils • Nut-based vegan “butter” alternatives • Nut milks/beverages • Nut butters & creams/spreads 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies, granola bars) • Chocolates (candy bars, nut-flavored chocolates) • Confections (nougat, nut clusters) • Nut butters • Infused vegan “butter” derived from tree nuts • Tinctures • Topicals • Infused oils



<p>SESAME</p>	<ul style="list-style-type: none"> • Tahini • Sesamol or sesamolina • Benne, benne seed, or benniseed • Gingelly and gingelly oil • Sim sim 	<ul style="list-style-type: none"> • Sesame seeds • Sesame oil • Cereals, such as muesli and granola • Margarine • Sauces, dips, and dressings 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies, granola bars, bagels, bread) • Sesame oil-based tinctures • Chocolates • Savory snacks
<p>MILK</p>	<ul style="list-style-type: none"> • Butter • Ghee • Casein • Whey 	<ul style="list-style-type: none"> • Butter • Cheese • Cheese powder • Cookies • Milk chocolate • Fudge • Caramel • Toffee 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies) • Chocolates • Confections (caramels) • Savory “cheesy flavored” snacks • Infused Butter/Ghee
<p>EGGS</p>	<ul style="list-style-type: none"> • Egg whites • Meringue • Albumin • Egg lecithin 	<ul style="list-style-type: none"> • Cookies • Marshmallow 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies, crisped rice treats) • Confections (nougat)
<p>SOY</p>	<ul style="list-style-type: none"> • Soy lecithin • Soybeans • Soybean oil • Soy-based vegan “butter” • Soybean protein powder • Edamame 	<ul style="list-style-type: none"> • Chocolates, baked goods and confections containing soy lecithin or soy oil • Tofu • Soy Sauce • Vegan “butter” alternatives • 	<ul style="list-style-type: none"> • Baked goods (cookies, brownies) • Chocolates • Confections • Soy oil-based tinctures • Infused Vegan “butter” cooking alternatives derived from soy •



CRUSTACEAN SHELLFISH	<ul style="list-style-type: none"> • Crab • Lobster • Shrimp • Clams • Scallops 	<ul style="list-style-type: none"> • Omega-3 Fatty Acids (derived from shellfish) • A sub-ingredient in savory seasonings, dried powder flavorings, Clamato & Bloody Mary mixes/beverages 	<ul style="list-style-type: none"> • Infused Clamato/Bloody Mary Mix • Savory snacks
FISH	<ul style="list-style-type: none"> • Fish oil 	<ul style="list-style-type: none"> • Omega-3 Fatty Acids (derived from fish) • A sub-ingredient in savory seasonings, dried powder flavoring 	<ul style="list-style-type: none"> • Fish oil-based supplements and tinctures

The Department of Cannabis Control (DCC) licenses and regulates commercial cannabis activity within California. To learn more about the California cannabis market, state licenses or laws, visit cannabis.ca.gov. Email questions to info@cannabis.ca.gov or call 1-844-61-CA-DCC (1-844-612-2322).

