

State of California—Health and Human Services Agency California Department of Public Health



FREQUENTLY ASKED QUESTIONS (FAQ) - WHEN MAY A RETAIL FOOD ESTABLISHMENT (RFE) NEED A LICENSE FROM THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)

1. When is a CDPH Cannery License required?

Making shelf-stable (non-refrigerated) hermetically sealed (airtight) foods that are low-acid or acidified will likely require a Cannery License issued by CDPH. Examples of low-acid or acidified foods include, but are not limited to sauces, salsas, pickled vegetables and peppers, marinades, and certain beverages. Fruit butters, jams, and jellies **that comply with 21 CFR 150 do not** require a Cannery License. However, other types of fruit butters, jams and jellies require evaluation (see below).

The University of California Laboratory for Research in Food Preservation (UCLRFP) contracts with CDPH to evaluate acidified and low-acid foods to determine whether the products could support the growth of Clostridium botulinum, the organism that causes botulism. All manufactures of shelf-stable hermetically sealed acidified or low-acid foods must have their products evaluated by the UCLRFP. Once the evaluation is complete, CDPH will issue an Official State Process Letter (S-Letter) for each product indicating whether the product requires a Cannery License or not. It is important for the food manufacturer to retain the S-Letter for future reference. When a RFE cans food into a shelf-stable product but refrigerates the product instead, a reduced oxygen packaging (ROP) approved HACCP plan from CDPH is required.

UCLRFP submissions

Use this form for acidified foods found here. Submit a separate form for each product. Use this form for low-acid foods found here. Submit a separate form for each product. Local environmental health agencies note: The UCLRFP may contact the manufacturer to request submission of product samples or additional information.

Instructions for submitting the forms, general information about the CDPH Cannery Program, and applicable laws and regulations can be found <u>here</u>. If you



have questions, local environmental health agencies contact CDPH's Cannery Program Specialist at Anthony.Garcia@cdph.ca.gov

For convenience, the chart below identifies all of the fruit and their allowable categories from the 21 CFR 150. Fruits not listed and all vegetables may not be used without an S-Letter from CDPH.

Allowable fruits by category from 21 CFR 150:

Fruit Butter	
Apple	
Apricot	
Grape	
Peach	
Pear	
Plum and Prune	
Ouince	

Fruit Jelly				
Apple	Fig	Pineapple		
Apricot	Gooseberry	Plum		
Blackberry	Grape	Pomegranate		
Boysenberry	Grapefruit	Prickly Pear		
Cherry	Guava	Quince		
Crabapple	Loganberry	Raspberry		
Cranberry	Orange	Strawberry		
Dewberry	Peach	Youngberry		

Fruit Preserves and Jams				
Group I			Group II	
Blackberry	Loganberry	Apricot	Guava	
Blueberry	Orange	Cranberry	Nectarine	
Boysenberry	Pineapple	Currents	Peach	
Cherry	Raspberry	Fig	Plum	
Crabapple	Rhubarb	Gooseberry	Quince	
Dewberry	Strawberry			
Elderberry	Tangerine			
Grape	Tomato			
Grapefruit	Youngberry			
Huckleberry				

2. When is a CDPH Processed Pet Food License required?

Pet Food means food that is heated, dried, semi-dried, or canned during the manufacturing process and intended for household pets, including dogs, cats, birds, fish, reptiles, and other animals kept strictly for companionship. Processed Pet Food includes a special diet, health foods, supplements, treats, and candy. Manufacturing includes operations such as packing, re-packing, and labeling.

A RFE, including Cottage Food Operations (CFO), cannot manufacture processed pet food under a permit or registration issued by the local environmental health department due the California Retail Food Code not including pet food.

All manufacturers of processed pet food must operate under a Pet Food Processor License issued by CDPH. Use of a commercial kitchen is necessary because home kitchens cannot meet the requirements of the Pet Food Processor License. The Pet Food Processor License application can be found here. General information about CDPH's Pet Food Program, including applicable laws and regulations, can be found here. If you have questions, local environmental health agencies contact CDPH's Processed Pet Food Specialist at Melissa.Vasquez@cdph.ca.gov

If the processed pet food is labeled "organic", or if any ingredient is identified as "organic" in the ingredient list on the product label, the manufacturer must also operate under an Organic Processed Product Registration (OPPR) issued by CDPH, refer to FAQ #4e for information about the OPPR.

Livestock or poultry **slaughter** for pet food **and** pet food manufacturers that prepare **fresh or frozen raw meat** pet food products fall under the California Department of Food and Agriculture (CDFA) jurisdiction. CDFA's website can be accessed <u>here</u>. It contains information about licensing, applicable laws and regulations, and contact information.

3. When is a CDPH Processed Food Registration (PFR) required?

A PFR is required for manufacturing, packaging, or holding (storing, warehousing) of processed food in California. Manufacturing includes re-packaging and labeling. Information about the PFR program and the PFR application form can be found on CDPH's website here. Questions about the PFR program can be sent to FDBfood@cdph.ca.gov.

If the processed food, or any ingredient, is identified as "organic" on the product label, an Organic Processed Product Registration (OPPR) is also required. Local environmental health agencies refer to FAQ #4e. Information about CDPH's organic program and the OPPR application can be found at here. Questions can be submitted to CDPH's Organic Program Specialist at Organic@cdph.ca.gov.

The law provides some exemptions for retail food from the PFR. The California Retail Food Code requires food to be dispensed or sold directly to the consumer. Distribution is not a function of retail food. Distributing or selling food **indirectly** to the consumer, via other businesses or organizations, is considered **wholesale** and **requires a PFR** unless specific requirements are met, as specified in the law. To qualify for an exemption from the PFR, the RFE must meet **each** of these criterions:

First the RFE must have a valid retail food permit issued by the local environmental health agency, and

- a. Gross annual wholesale sales of processed foods do not exceed 25% of the total food sales, [HSC 110480(a)(3)(A)], and.
- b. <u>Processed foods are only sold within the jurisdiction of the local</u> environmental health agency that permits the RFE, [HSC 110480(a)(3)(B)] and
 - i. Note: A RFE that makes food in one local jurisdiction and dispenses or sells **direct to the consumers** in a second jurisdiction does not need a PFR but may need additional permitting, such as a Temporary Food Facility permit, issued by the second local environmental health agency.
 - ii. The processed food sold **direct to the consumer** does not require nutritional labeling as described in 21 Code of Federal Regulations Part 101 found here.

- c. Processed food requires nutritional labeling described in 21 CFR 101. When nutritional labeling is required a PFR is also required. The federal code 21 CFR 101.11 regulates all food labeling requirements. A RFE that packages food is exempt from nutritional labeling if food is dispensed or sold directly to the consumer and sales limits are not exceeded. Compliance with the nutritional labeling is required for any nutritional or health claims made on a label. [HSC 110480(a)(3)(C)], and
- d. The wholesale or distribution of food by the RFE does not include fresh or frozen seafood or raw (fresh or frozen) shellfish [HSC 110480(a)(3)(D)], and
- e. The RFE does not salvage processed foods for sale anywhere other than at the retail food facility. HSC 110480(a)(3)(E)

A RFE that does not qualify for a PFR exemption may need to operate under **both** a RFE permit **and** a PFR. Types of RFEs that may require a PFR in addition to a retail food permit include, but are not limited to

- a. A RFE operating under a local environmental health agency permit processes food and moves the food to a second business location owned by the same owner for direct to the consumer sales. This is distribution and may require a PFR
- b. Central School Kitchens School kitchens that prepare food and distribute the food to other locations for dispensing require a PFR. If a central school kitchen also serves food directly to students, that facility also needs a retail permit issued by the local environmental health agency.

A RFE that only dispenses or sells food **directly to the consumer** does **not** need a PFR. Such operations fall under the jurisdiction of the local environmental health department except for specific types of food commodities as identified in this FAQ (see CDPH Cannery License – FAQ #1 and CDPH Processed Pet Food License – FAQ #2).

Is a RFE allowed to transport food offsite for sale without a PFR?

A RFE can transport food offsite without a PFR to sell directly to the consumer. If the facility that prepared the food is the same as the facility selling the food this would be an extenuation of retail food and is allowed without a PFR. It is common for this type of sales to have additional local environmental health agency permits for the off-site sales.

Can a RFE package foods, without a PFR, for direct to the consumer onsite or offsite sales?

A RFE is allowed to package and transport food offsite for sale or dispensing directly to the consumer without a PFR. Examples of operations that may do this include catering establishments, mobile food facilities, pushcarts that use a commissary kitchen, and restaurants that sell packaged food using a Temporary Food Facility permit at a community event or a farmers' market. If packaging is a shelf-stable hermetically sealed acidified or low-acid foods or processed pet food, please refer to FAQ # 1 and #2 for information about CDPH licenses that affect these food

commodities. Retail sales of organic products must register with the California Department of Food and Ag found <u>here</u>.

Online sales are addressed in FAQ under Specialized PFR Programs #4c.

4. What are Specialized PFR Programs?

There are several PFR programs that are specialized they include dietary supplements, juice processing, interstate commerce, olive oil, organics, seafood and shellfish. Below are brief descriptions of each program.

a. Does the manufacturing of a Dietary Supplements require a PFR?

A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. Dietary ingredients may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular, and metabolites.

Manufacturing, packing, or holding (warehousing, storing) processed food for wholesale requires a PFR. Dietary supplements are processed foods. An Organic Processed Product Registration (OPPR) is also required if the dietary supplements, or any ingredient, are identified as organic on the product label. (FAQ #4e).

Dietary supplement manufacturers must comply with the Dietary Supplement Good Manufacturing Practices in 21 CFR Part 111. Information and links to applicable laws and regulations can be found on CDPH's Dietary Supplement webpage found here. Questions can be directed to CDPH's Dietary Supplement Specialist at Melissa.Vasquez@cdph.ca.gov. Applications for the PFR and OPPR can be found here.

A RFE that manufactures, packs, or holds dietary supplements only for dispensing or sale **direct to the consumer** does **not** need a PFR. If nutritional value claims or health claims are made on the package or in the menu nutrient labeling is required.

Nutritional Value and Health Claims

Common Nutritional Value Claims include but are not limited to calorie-free; fat-free or sugar-free; gluten-free, no gluten, free of gluten or without gluten; good source of (vitamin or nutrient); healthy; high fiber; light or lite; low calorie; low sodium; natural; reduced

Health Claims must contain the elements of a substance and a disease or health-related condition; are limited to claims about disease risk reduction; cannot make claims about the diagnosis, cure, mitigation, or treatment of disease

There are two types of claims "Authorized" and "Qualified". Authorized are already recognized health claims while qualified must be approved by the FDA

Cottage food operations are not allowed to use dietary supplements in their products. Cottage food must be nonhazardous and present the lowest risk possible. According to the FDA there are potentially negative side-affects from taking dietary supplements including but not limited to rashes, shortness of breath, diarrhea, severe joint pain, slurred speech, blood in the urine, and other possible adverse effects. These effects can vary from less serious to life-threatening preventing dietary supplements from inclusion in the program.

b. When does Juice Processing require a PFR?

Juice is defined as the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portion of one or more fruits or vegetables, or any concentrates of such liquid or puree [21CFR 120.1(a)].

Manufacturing, packing, or holding (warehousing, storing) of juice in California requires a PFR. Juice is a processed food. Information about the PFR program and the PFR application can be found on CDPH's website here. Questions about the PFR program can be sent to FDBfood@cdph.ca.gov

Juice manufacturers must comply with the Juice HACCP Regulation in 21 CFR Part 120. Information and links to applicable laws and regulations can be found on CDPH's Juice webpage found here. Questions can be directed to FDBfood@cdph.ca.gov.

If the juice, or any ingredient, is identified as "organic" on the product label, an Organic Processed Product Registration (OPPR) is also required. Please refer to FAQ #4e for information about CDPH's Organic Program and the OPPR application can be found at here. Questions can be submitted to CDPH's Organic Program Specialist at Organic@cdph.ca.gov.

A RFE that manufactures, packs, or holds juice only for dispensing or sale **direct to the consumer** does **not** need a PFR, however the local environmental health agency may require the RFE to operate under a HACCP plan. Shelf-stable packaged acidified or low-acid juices, please refer to FAQ #1 for information about CDPH's Cannery License. Retail sales of organic products must register with the California Department of Food and Ag found here.

c. Is a PFR needed to sell processed food Outside of California?

Facilities that manufacture, pack, or hold (warehouse, store) processed food for wholesale require a PFR. This includes processed foods distributed outside of California.

Information about the PFR program and the PFR application can be found on CDPH's website here. Questions about the PFR program can be sent to FDBfood@cdph.ca.gov. If the processed food, or any ingredient, is identified as "organic" on the product label, an OPPR is also required. Please refer to FAQ #4e. Information about CDPH's Organic Program and the OPPR application can be found here. Questions can be submitted to CDPH's Organic Program Specialist at Organic@cdph.ca.gov.

A RFE that manufactures, packs, or holds processed food only for dispensing or sale **direct to the consumer** does **not** need a PFR. Interstate **direct to consumer sales** are not under the jurisdiction of the California Retail Food Code. The U.S. Food and Drug Administration (FDA) has jurisdiction over interstate food sales and provides an exemption for retail food that is sold on the interstate market. However, the state receiving the food may have laws that regulate this type of retail food sales. Operators should check the requirements for themselves. Retail sales of organic products must register with the California Department of Food and Ag found here.

d. Can a RFE produce Olive Oil without a PFR?

Facilities that manufacture, pack, or hold (warehouse, store) processed food for wholesale require a PFR. Olive oil is a processed food.

Information about olive oil can be found on CDPH's website here. Information about the PFR program and the PFR application can be found on CDPH's website here. Questions about the PFR program can be sent to FDBfood@cdph.ca.gov. If the processed food, or any ingredient, is identified as "organic" on the product label, an Organic Processed Product Registration (OPPR) is also required please refer to FAQ #4e. Information about CDPH's Organic Program and the OPPR application can be found here. Questions can be submitted to CDPH's Organic Program Specialist at Organic@cdph.ca.gov.

e. When is a CDPH Organic Processed Product Registration (OPPR) required?

Processing or handling of processed products for human consumption that are sold as "organic" requires an OPPR. To handle means to sell, process, or package. Sold as organic means any use of the terms "organic', "organically grown", or grammatical variations of those terms, whether orally in writing, in connection with any product grown, handled, processed, sold, or offered for sale

in California. Sold as organic includes use of these terms in labeling or advertising of any product and **any ingredient in a multi-ingredient product.** Processed products include, but are not limited to dietary supplements, alcoholic beverages, fish or seafood, animal food, and cosmetics.

Information about CDPH's Organic Program and the OPPR application can be found at here. Questions can be submitted to CDPH's Organic Program Specialist at Organic@cdph.ca.gov.

Note: Processors or handlers of organic processed products may also need other licenses issued by CDPH or another regulatory agency. For example,

- Manufacturers of organic processed food will need a PFR. See FAQ #3 and #4e
- b. RFE that do not meet the criteria for PFR exemption, See FAQ #3
- c. Organic products regulated by the California Department of Food and Agriculture (CDFA). CDFA has jurisdiction over these products sold as organic:
 - i. Processed meat, fowl, or dairy products
 - ii. **Retailers** engaged in the processing or handling of processed products sold as "organic, except dietary supplements, alcoholic beverages, fish or seafood, pet food and cosmetics
 - iii. **Cottage Food Operations** engaging in the processing or handling of processed products sold as organic

f. When does Seafood or Shellfish processing require a PFR?

- I. Manufacturers and distributors of **Seafood** products, including all fish and fishery products intended for human consumption, must obtain a PFR with Seafood HACCP compliance. Fish and fishery products include but are not limited to the following: finfish (i.e., fresh and saltwater), crustaceans (i.e., crabs, shrimps, and lobsters), echinoderms (i.e., sea cucumbers and sea urchins), reptiles (i.e., alligators and turtles), amphibians (i.e., frogs) and mollusks (i.e., escargot and abalones). Molluscan Shellfish is not considered a seafood product. Questions regarding seafood can be submitted to CDPH's Seafood Program Specialist Duy.Truong@cdph.ca.gov.
- II. Dealers of **Molluscan Shellfish** which includes all species of native and nonnative raw oysters, clams, mussels and whole scallops, either fresh or frozen, and either shucked or in-the-shell. Firms that process, handle, and distribute shellfish must obtain a Shellfish Handling and Marketing Certificate from FDB. Question regarding CDPH Shellfish Program can be submitted to the Shellfish Program Specialist Chrisina.Grant@cdph.ca.gov.

- i. A PFR is not required if firms exclusively manufacture, handle and distribute raw, fresh or frozen (shucked or in-the-shell) shellfish.
- ii. The Shellfish Handling and Marketing Certificate assigns a dealer's number for each certified facility and authorizes a dealer to engage in specific activities such as repacking, reshipping and shucking shellfish. The dealer's number is required to be listed on all shellfish tags and labels to indicate that the shellfish has originated from a certified facility.

III. A RFE that handles seafood or shellfish for **indirect to the consumer** distribution or sale requires the following:

- A RFE that processes both raw fresh or frozen shellfish and seafood must obtain a PFR and a Shellfish Handling and Marketing Certificate. Compliance with Seafood HACCP may also be required.
- ii. A RFE that only processes raw fresh or frozen seafood must obtain a PFR. Seafood HACCP compliance may also be required.
- iii. A RFE that only processed, handles, and distributes indirectly to the consumer raw fresh or frozen shellfish does not require a PFR, but is required to have a Shellfish Handling and Market Certificate.

Information about CDPH's Seafood and Shellfish Safety program and HACCP requirements can be found on here.

5. What is the difference between Retail Food operation and PFR operation?

Retail means the storing, preparing, serving, manufacturing, packaging, transporting, salvaging, or otherwise handling food for dispensing or sale **directly to the consumer** or indirectly through a delivery service. Foods produced under a PFR are for wholesale or indirect to consumer sales.

Information regarding CDPH's Retail Food Program can be found here. Questions can be submitted to CDPH's Retail Program Specialist at FDBRetail@cdph.ca.gov.

What types of retail food might fall under the jurisdiction of the California Department of Food and Ag?

Certain types of retail food operations may also require licensing from the CDFA. Examples are identified below. Please contact CDFA directly to obtain information. CDFA Webpage

- a. Smoking, curing, drying, or rendering of meat for sale or distribution **directly to the consumer**. Please see FAQ #3 regarding when a CDPH PFR would also be needed.
- b. A RFE that engages in custom slaughter of animals for individual customers and not for retail sale.

- c. Livestock or poultry slaughter for pet food
- d. All Retail Poultry Plants
- e. Organics Processors and handlers of processed meat, fowl, or dairy products, and retailers that are engaged in the processing or handling of processed products sold as organic, except dietary supplements, alcoholic beverages, fish or seafood, pet food and cosmetics
- f. Dairy at retail including soft-serve ice cream, dairy product production (cheese, yogurt, butter...)

6. When is a CDPH license needed for Water Operations?

CDPH licenses a variety of different types of water operations as described below. These operations do **not** fall under the jurisdiction of the local environmental health agencies nor the California Retail Food Code.

- 1. Water bottling plant A facility in which bottled water is produced
- 2. Retail Water Facility A facility where water is processed, sold, and placed into containers. The water containers may be brought by the consumer or may be sold or given to consumers by the facility.
- 3. Portable water hauler A person who hauls water in bulk (capacities of 250 gallons of water or greater) where there is a likelihood that the water will be used for drinking, culinary or other purposes.
- 4. Water vending machine A water-connected vending machine designed to dispense drinking water.
- 5. Private water source operator A privately owned source of water that is used for bottled or vended water.
- 6. Bottled water distributor A person who is not an employee of a water bottling plant that delivers bottled water directly to customers.

Information about CDPH's water program and applications for water licenses can be found at here. Questions can be submitted to CDPH's Water Program Specialist at Travis.You@cdph.ca.gov