



ROP HACCP PLAN SUBMITTAL GUIDELINES

California Health and Safety Code Section 113883 defines “reduced oxygen packaging” (ROP) as the reduction of the amount of oxygen in a package by evacuating the oxygen, displacing the oxygen, or otherwise controlling the oxygen content in a package to a level below that normally found in the surrounding atmosphere. Examples of ROP include: *vacuum packaging, cook-chill, and sous vide.*

Reduced oxygen packaging of potentially hazardous foods can create a suitable environment for the growth of hazardous pathogens such as *Clostridium botulinum*, the bacteria associated with botulism. Due to the potentially serious health risk, California Health and Safety Code Section 114419 (b)(2) requires that food facilities who utilize ROP methods submit a Hazard Analysis Critical Control Point (HACCP) plan to the California Department of Public Health (CDPH) for review and approval.

HACCP plans submitted to CDPH for review and approval must include the following information:

- 1) A flow diagram identifying the specific food for which the HACCP plan is requested. The diagram should include ingredients, equipment, and materials used in the preparation of the food.
- 2) A hazard analysis that identifies chemical, biological, and physical hazards associated with the food and the preventive measures needed to mitigate the hazards.
- 3) Identification of critical control points (CCP’s) associated with the food. A CCP is a point at which control measures are enacted to reduce the likely occurrence of a hazard to an acceptable level. CCP’s steps include cooking, cooling, holding, and reheating.
- 4) Determination of critical limits for each critical control point. A critical limit is a measurable value to which a hazard must be controlled in order to mitigate the risk. For example, chicken must be cooked to an internal temperature of 165F for 15 seconds in order to be considered safe for consumption.
- 5) Description of monitoring practices that ensure critical limits are being met and that monitoring equipment is properly calibrated.

- 6) Description of corrective actions that are to be enacted if critical limits are not met.
- 7) Description of employee training program. All employees that prepare food in accordance with an ROP HACCP plan must be trained. Training shall include the seven principles of HACCP as well as specific contents related to the ROP HACCP plan. Training records must be maintained for a minimum of two years.
- 8) Description of standard operating procedures (SOPs) needed to address hazards not controlled by the critical control points. Submit a copy of the following SOPs with your ROP HACCP plan:
 - Procedure that prevents bare hand contact with ready-to-eat food.
 - Procedure for cleaning and sanitizing food contact surfaces.
 - Procedure for preventing cross contamination
 - Procedure that ensure food items are properly rotated
- 9) Description of the recordkeeping and audit system used to verify adherence to the ROP HACCP plan. Records must be kept on site for a minimum of 90 days. Submit copies of all log sheets with your ROP HACCP plan.

In addition to the information contained in items (1-9), facilities that vacuum package food must also submit the following:

- 10) Identification of a primary and secondary barrier intended to control the growth of *Clostridium botulinum* and *Listeria monocytogenes*:
 - Maintain product at 41F or below (primary barrier)
 - Aw of 0.91 or less.
 - pH of 4.6 or less.
 - Raw meat, poultry, or vegetables.
 - Meat or poultry cured at a USDA regulated plant.
- 11) Description of how the food package will be prominently labeled with the following:
 - Maintain product at 41F or below
 - "Use by" date of no more than 14 days from the date of packaging
- 12) Fish may only be vacuum packaged if the fish is frozen before, during, and after vacuum packaging.
- 13) Cheese may only be vacuum packaged if it is commercially manufactured in a processing plant, has no added ingredients, and is one of the following:
 - Hard cheese (cheddar, parmesan, etc..).
 - Semi-soft cheese (monterey jack, provolone, etc..).
 - Pasteurized processed cheese (labeled as such).

In addition to the information contained in items (1-9), facilities that use cook-chill or sous vide food must also submit the following:

- 14) Description of how food is to be packaged immediately after cooking at temperatures above 135F.
- 15) Description of how the food is to be cooled to 41F within 6 hours as per Cal Code (Section 114002) and then:
 - Cooled to 34F within 48 hours and then held at 34F or below for no more than 30 days.
 - Cooled to 34F within 48 hours and then held at 41F for no more than 3 days.
 - Cooled to 38F within 24 hours and then held at 38F for no more than 3 days.
 - Frozen with no time restrictions while frozen.
- 16) Description of how the food package will be prominently labeled with product name, date, and time packaged.
- 17) Description of electronic monitoring device used to monitor holding temperatures of ROP products while in cold storage. Include device make and model number.

Note: Cook-chill and sous vide products prepared at retail facilities cannot be sold to consumers or other independent businesses.

Instructions for filling out the “Flow Diagram Worksheet”

- 1) Identify the facility name and the type of ROP process used.
- 2) List the food item that will undergo reduced oxygen packaging.
- 3) List all ingredients involved in the preparation of the food item.
- 4) Circle all operational steps needed to prepare the food item, starting with receiving and continuing through service.
- 5) List all the equipment and materials used during each of the operational steps.

Instructions for filling out the “Hazard Analysis Worksheet”

- 1) Identify the facility name and the type of ROP process used.
- 2) List the food item that will undergo reduced oxygen packaging.
- 3) List chemical, biological, and physical hazards associated with the food item. Visit www.fda.gov/BadBugBook for more information. Please note that *Clostridium botulinum* and *Listeria monocytogenes* must be included in the hazard analysis.

- 4) Circle all operational steps needed to prepare the food item, starting with receiving and continuing through service.
- 5) Identify potential hazards associated with each operational step.
- 6) State the preventive measures needed to mitigate the hazard.
- 7) Check all operational steps that are considered critical control points.

Instructions for filling out the “Critical Control Point Worksheet”

- 1) Identify the facility name and the type of ROP process used.
- 2) List the food item that will undergo reduced oxygen packaging.
- 3) List all standard operating procedures needed to mitigate hazards.
- 4) List all critical control points identified on the hazard analysis worksheet.
- 5) List the critical limit for each CCP.
- 6) Describe how monitoring will take place.
- 7) List the corrective action that will be taken if the critical limit is not reached.
- 8) List who is responsible for verifying the critical limits are being achieved.
- 9) List the type of records that must be maintained in order to monitor the CCP.
- 10) List employee training that is necessary to ensure critical limits are being met and that monitoring is being conducted.

All facilities are required to maintain a copy of their approved HACCP plan at the establishment for review by the local enforcement officer upon request.

Sacramento County Environmental Management Department (EMD) is not authorized to review or approve ROP HACCP plans.

For additional information contact California Department of Public Health, Food and Drug Branch at (916) 650-6500.

FACILITY NAME: _____

PROCESS: _____

Flow Diagram Worksheet

<i>Food Item</i>	<i>Operational Steps</i>	<i>Equipment</i>	<i>Materials</i>
	<i>Receiving</i>		
<i>Ingredients</i>	<i>Storage</i>		
	<i>Preparation</i>		
	<i>Cooking</i>		
	<i>Cooling</i>		
	<i>Cold Holding</i>		
	<i>Reheating</i>		
	<i>Hot Holding</i>		
	<i>Sale / Service</i>		

FACILITY NAME: _____

PROCESS: _____

Hazard Analysis Worksheet

<i>Food Item</i>	<i>Operational Step</i>	<i>Potential Hazard</i>	<i>Preventive Measure</i>	<i>CCP</i>
	<i>Receiving</i>			
Hazards	<i>Storage</i>			
Vegetative Bacteria <i>Listeria monocytogenes</i>	<i>Preparation</i>			
Spore-Toxin Bacteria <i>Clostridium botulinum</i>	<i>Cooking</i>			
Viruses & Parasites	<i>Cooling</i>			
	<i>Cold Holding</i>			
Chemical Hazards	<i>Reheating</i>			
Physical Hazards	<i>Hot Holding</i>			
	<i>Service / Sale</i>			

FACILITY NAME: _____

PROCESS: _____

Critical Control Point Worksheet

<i>Food Item</i>	<i>Critical Control Points</i>	<i>Critical Limits</i>	<i>Monitoring</i>	<i>Corrective Action</i>	<i>Verification</i>	<i>Records</i>
	<i>CCP 1</i>					
<i>Required SOP's</i>						
	<i>CCP 2</i>					
	<i>CCP 3</i>					
	<i>CCP 4</i>					
	<i>CCP 5</i>					

Required Training:

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HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) AT RETAIL



A *Hazard Analysis and Critical Control Point* system, more commonly referred to as HACCP, is a systematic approach to the identification, evaluation, and control of food safety hazards by preventing, eliminating, or reducing those hazards to safe levels.

The basic steps of a HACCP plan include:

1. A Hazard Analysis.
2. Determine the Critical Control Points
3. Establish Critical Limits
4. Critical Control Point Monitoring
5. Corrective Actions
6. Verification Procedure
7. Record-Keeping Procedures

In accordance with Article 5 of the California Retail Food Code ([CRFC](#)), food facilities may engage in any of the following activities through the use of an HACCP plan. Contact your [Local environmental health services](#) to obtain information about HACCP requirements for the following food activities:

- Smoking food as a method of food preservation rather than as a method of flavor enhancement.
- Curing food by the addition of salt or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices.
- Using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement, or to render a food so that it is not potentially hazardous.
- Operating a molluscan shellfish life support system display tank used to store and display shellfish that are offered for human consumption.
- Custom processing animals that are for personal use as food and not for sale or service in a food facility.
- Preparing food by another method that is determined by the enforcement agency to require an HACCP plan.

Certain high risk food processes require that a HACCP plan must be approved, prior to implementation, by the California Department of Public Health, Food and Drug Branch (CDPH-FDB), specifically:

- Using acidification or water activity to prevent the growth of *Clostridium botulinum*. For more information on these activities see CDPH-FDB information on [Cannery License](#) requirements.
- Packaging potentially hazardous food using a reduced-oxygen packaging (ROP) method as specified in CRFC Section 114057.1.

Foods that have been vacuum-packaged or otherwise had oxygen removed from their packaging can put foods at additional risk for growth of certain bacteria and/or toxin formation (*Clostridium botulinum* (botulism), *Clostridium perfringens*, and *Listeria monocytogenes*). Implementing a complete and comprehensive HACCP plan will help ensure that food products that are vacuum-packaged at a retail food facility are safe.

A retail food facility that is required to have a [HACCP plan](#) for reduced oxygen packaging (ROP) must include plans and specifications as set forth in CRFC Health and Safety Code Sections 113801, 114057, 114057.1, 114419.1, 114419.2, and 114419.3:

Additional food safety controls are required for utilizing sous-vide and /or cook chill ROP methods. Guidance to determine sous-vide and /or cook chill ROP controls in the HACCP plan can be found in the [U.S. FDA Model Food Code, Section 3502.12\(D\) 1-4](#).

To request a CDPH-FDB ROP HACCP plan review, submit a hard copy of the ROP HACCP plan along with a completed Retail Food Program Service Request Application and fee, to the address on the application.

To decrease delays in review and processing, please include the following items in accordance with the principles of HACCP and CRFC ROP requirements, including but not limiting to:

1. Conduct and provide a Hazard Analysis.
2. Process Flow Analysis with listed Critical Control Points.
3. HACCP control plan- including controls required for sous-vide and/or cook chill process if applicable.
4. Monitoring and Verification Procedures.
5. Correction Action Procedures.
6. Standard Sanitation Operating Procedures.
7. Employee training procedures including a list of HACCP trained personnel.
8. Vacuum packaging equipment specifications.

Complete information on the retail HACCP requirements can be found in the [CRFC](#).

Additional Information about HACCP can be found at:

[California Retail Food Code, Article 5 HACCP Exemptions](#)

<https://www.cdph.ca.gov/services/Documents/fdbRFC.pdf>

[CDPH Retail Food Program Service Request Application – HACCP review \(CDPH6801\)](#)

<https://www.cdph.ca.gov/pubsforms/forms/CtrlForms/cdph8601.pdf>

[U.S. FDA HACCP Principals and Application Guidelines](#)

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#princ>

[Examples of Questions to be Considered When Conducting a Hazard Analysis](#)

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#app-c>

[U.S. FDA Food Code – Annex 7 – Food Processing Criteria](#)

<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM188557.pdf>



**RETAIL FOOD PROGRAM
SERVICE REQUEST APPLICATION**



HACCP Plan Review Request Variance Request Resubmission

Name of Facility			Facility Operator (Name and Title)	
DBA (List additional DBAs on separate sheet if necessary.)			Contact Telephone Number	E-mail Address
Facility Address (number, street)			Health Permit Number *	
City	State	ZIP Code	County *	

* If this request applies to more than one facility and/or facilities in multiple counties, please attach a list of the facilities that will be affected.

You must include the following documentation with this application:

1. A letter signed by the applicant with a detailed description of the specific service that is requested;
2. A hard copy of the plan and/or request, and copies of supporting scientific documentation that validates the food safety efficacy of the process, procedure, or plan being proposed (which may include laboratory analyses); and
3. Payment of \$207.00 non-refundable cost-recovery fee

Fee payment is non-refundable and does not guarantee an approval by this agency.

The fee covers the first two hours of technical/scientific review of the documents submitted by the applicant. Additional fees will be required if additional time is necessary for technical/scientific review or if a field evaluation is necessary to complete the review.

**Make Checks payable to:
California Department of Public Health**

Submit Applications and required documentation to:

Department of Public Health
Food and Drug Branch, MS 7602
Cashier – Retail Food Program
P.O. Box 997435
Sacramento, CA 95899-7435

If you have any additional questions, please call (916) 650-6500.

PLEASE DO NOT WRITE BELOW THIS LINE

Date Received	Payment Type	Amount	Tracking Number
		\$	2010-