

Reduced Oxygen Packaging (ROP) Without a Variance (3-502.12) HACCP Submission Checklist

Firms that are requesting a ROP HACCP review are required to submit the following documents:

- Guidance and Application for Reduced Oxygen Packaging (ROP) at Retail (HACCP Only) **(attached)**
- Signed Prerequisite Program Agreement **(attached)**
- A categorization of the types of potentially hazardous foods that will be reduced oxygen packaged
- A list of ingredients and materials used in each ROP product (e.g. marinades, spices, sausage casings, vacuum packaging bag specifications, etc.)*
- Equipment Specifications (e.g. vacuum package machine, etc.)
- Flow diagrams for each specific food or category type: either appropriately modified ODA templates or flow diagrams developed by the firm—indicate which steps in the flow diagram are critical control points (CCPs) **(example flow diagram – attached)**
- HACCP plan(s): either appropriately modified ODA templates or a HACCP plan developed by the firm **(example HACCP plan – attached)**
- Logs required by each HACCP plan: either appropriately modified ODA templates or logs developed by the firm **(example logs – attached)**
- Final labels for each item (following all CCP labeling requirements specified in the HACCP plan)

With my signature below, I acknowledge that I am submitting all the required documents listed above. I understand that failure to submit the required documents may result in the delay or rejection of my ROP HACCP plan application.

Facility DBA _____ Owner Name _____

Owner Signature _____ Date _____

*** This handout is not intended to be used as a guidance for firms proposing to use reduced oxygen packaging methods for foods with added marinades or spices. Please contact your local Oregon Department of Agriculture Food Safety inspector to discuss additional HACCP and/or variance requirements.**

Guidance and Application for Reduced Oxygen Packaging (ROP) at Retail (HACCP Only)

(2013 ODA Food Code - 3-502.12)



Oregon
Department
of Agriculture

Using reduced oxygen packaging (ROP) can create serious food safety hazards. The reduced oxygen in these packages can allow the growth of bacteria called *Clostridium botulinum*, which produces a deadly toxin, and *Listeria monocytogenes*. Some foods (raw meat, raw poultry, and raw vegetables) can be safely packaged in ROP under a HACCP plan with temperature and labeling controls, and careful attention to sanitation. Other foods and processes may require additional controls that will require a variance and a process study. A HACCP plan is required by the food code. The plan will help you to control the hazard and document the controls for the regulatory authorities. A food establishment that packages potentially hazardous food (TCS) using a ROP method **shall have a HACCP plan (2013 ODA Food Code - 8-201.14), complete items 1-7 below, and provide to the Regulatory Authority prior to implementation:**

- (1) Firm Name, Address, Name of Contact, e-mail and phone#:

- (2) Identify the food to be packaged and its intended use:

- (3) The packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the criteria, 3-502.12(B) (Circle Below):
 - (a) Has a water activity (A_w) of 0.91 or less (laboratory test required),
 - (b) Has a pH of 4.6 or less (laboratory test required),
 - (c) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, and is received in an intact package,
 - (d) Is a food with a high level of completing organisms such as raw meat or raw poultry or raw vegetables;
 - (e) Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133/169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;
 - (f) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a ROP method.

- (4) Provide a copy of the label showing how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
 - (a) Maintain the food at 5°C (41°F) or below, and
 - (b) Discard the food if within 30 calendar days of its packaging if it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first.

- (5) Include operational procedures that:
 - (a) Prohibit contacting ready-to-eat (RTE) food with bare hands as specified under 3-301.11(B),

- (b) Identify a designated work area and the method by which:
 - (i) Physical barriers or methods of separation of raw foods and RTE foods minimize cross contamination, and
 - (ii) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and
- (c) Describe cleaning and sanitization procedures for food-contact surfaces.

- (6) Describe the training program that ensures that the individual responsible for the ROP packaging operation understands the:
 - (a) Concepts required for a safe operation,
 - (b) Equipment and facilities, and
 - (c) Operational Procedures and HACCP plan

- (7) A flow diagram by specific food or category type identifying critical control points 8-201.14(B).

_____ **Date:** _____
License Holder or Person-in-Charge **Signature/Title**

For ODA Use:

Date	Reviewer	Comments	Accepted

Implementation Date: _____

Prerequisite Programs, Standard Sanitation Operating Procedures (SOP), and Employee Training Program

HACCP (Hazard Analysis and Critical Control Point) is a systematic approach in identifying, evaluating and controlling food safety hazards. HACCP represents an important food protection tool supported by prerequisite programs, Standard Sanitation Operating Procedures (SSOPs), and employee training. In order to achieve active managerial control of hazards associated with foods, firms that are submitting a HACCP plan or variance request are required to agree to the development and implementation of the following:

1. Prerequisite Programs

Firm agrees to follow the establishment construction, maintenance, sanitation and product handling procedures as outlined in the ODA 2013 Retail Food Code (OAR 603-025-0030), ORS 603, ORS 619, OAR 603-028, and ORS 603-025-0200.

2. Standard Sanitation Operating Procedures

Firm agrees to monitor and comply with the following provisions of the 2013 ODA Retail Food Code:

1. Hand washing
2. Personal hygiene
3. Preventing bare hand contact with ready to eat foods
4. Employee Illness
5. Purchasing food from approved sources
6. Ensuring appropriate equipment maintenance and cleaning and sanitizing procedures for food contact surfaces
7. Cross-contamination prevention
8. Date-marking ready-to-eat, time/temperature control for safety food
9. Safety of water sources
10. Maintenance of hand-washing and toilet facilities
11. Protection from contamination
12. Proper labeling, storage, and use of toxic materials
13. Exclusion of pests

3. Employee Training Program

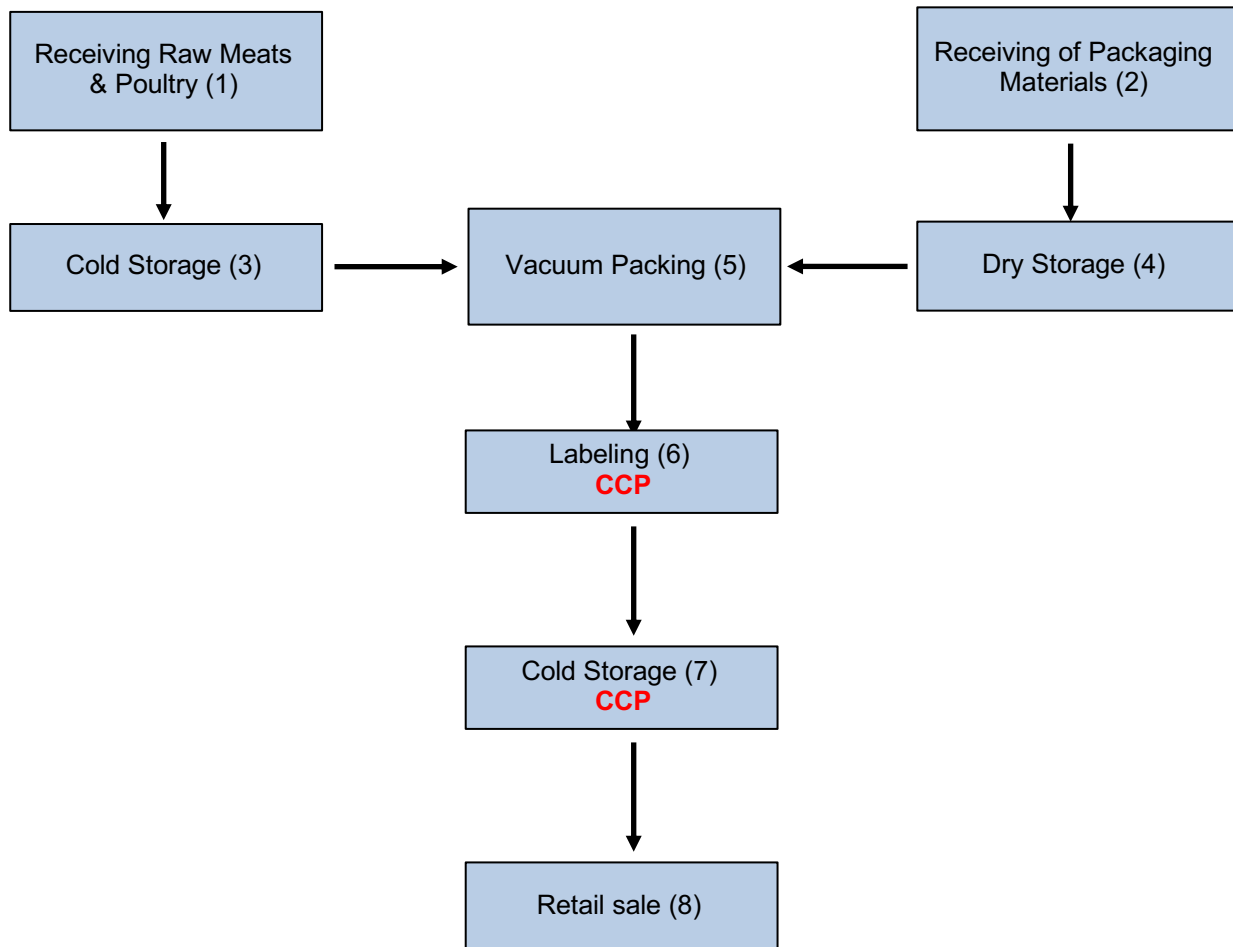
Firm agrees to develop and implement a food employee and supervisory training plan that addresses the food safety issues of concern.

With my signature below, I agree to develop and comply with the prerequisite programs, standard sanitation operating procedures, and training program requirements. I understand that failure to comply with the requirements noted above may result in the revocation of an approved variance/ HACCP plan.

Facility DBA _____ **Owner Name** _____

Owner Signature _____ **Date** _____

FLOW DIAGRAM: ROP (Example)



Establishment Name & Address:

Product Name & Description:

ROP HACCP Plan

(1) Critical Control Point (CCP)	(2) Significant Hazard(s)	(3) Critical Limits/Factor for each Preventive Measure	(4) Monitoring Procedures				(8) Corrective Actions	(9) Records	(10) Verification
			(4) What	(5) How	(6) Frequency	(7) Who			
CCP 1: Temperature Control	Biological: Pathogens (<i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i>)	Maintain the food at 41°F or below	Refrigerator/ Freezer Temperature storing ROP product will be monitored	Monitor refrigerator temperature with a calibrated thermometer in the warmest part of the unit	(To be completed by Firm)	(To be completed by firm)	If the holding case is found to be out of temperature, PIC will check internal temperature of product. Discard product if above 41°F	- Cold holding Log - Corrective Action Log	- Daily temperature verification of the cold holding unit when there is product stored. - Thermometer Calibration Log
CCP 2: Labeling (Refrigerated)	Biological: Pathogens (<i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i>)	Label each ROP package to maintain at 41°F or below, and discard within 30 days	Each ROP package	Visual	(To be completed by firm) e.g. At time of ROP and at least daily thereafter	(To be completed by firm)	- Identify and discard products that are out of date - Label or discard if date of packaging is not known.	- Product date/label log - Corrective Action Log	- Daily verification of Product date/label log

Preparers Name and Title: _____

Preparers Signature: _____ **Date:** _____

Refrigeration / Freezer Log

Instructions: The designated employee must record the location or description of holding unit, date, time, air temperature, corrective action, and initials on this Log on a daily basis. The designated supervisor must verify that workers have taken the required temperatures by reviewing, initialing, and dating this log daily. This log shall be maintained on-site for a minimum of 6 months and at a reasonably accessible location for 2 years.

Location/ Unit Description	Date	Time	Temp	Corrective Action	Initials	Verified By

Product Date / Label Log

Instructions: The designated employee(s) must check the date and label of each vacuum packaged product and ensure they meet all labeling requirements indicated in the HACCP plan. The employee must record the date and time the product label is checked, any corrective actions, and initial the log on a daily basis. The designated supervisor must verify that workers have completed the log by reviewing, initialing, and dating it daily. This log shall be maintained on-site for a minimum of 6 months and at a reasonably accessible location for 2 years.

Location/ Unit Description	Date	Time	Label Check?	Corrective Action	Initials	Verified By

Thermometer Calibration Log

Instructions: The designated employee(s) must record the calibration temperature and corrective action taken each time a thermometer is calibrated. Thermometers intended for cold temperatures must be calibrated in an ice slurry. The designated supervisor must verify and initial that employees are using and calibrating thermometers properly. This log shall be maintained on-site for a minimum of 6 months and at a reasonably accessible location for 2 years.

Date	Time	Thermometer ID #	Method Used (Ice Slurry)	Thermometer Reading	Accurate (Yes/No)	Corrective Action	Initials	Verified By