

**Reduced Oxygen Packaged (ROP), Cured TCS/PHF Food (3-502.11)
Variance/ HACCP Submission Checklist**

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

- Completed and signed Variance Application (**attached**)
- Completed and signed Variance Procedures for Reduced Oxygen Packaging (ROP) at Retail (**attached**)
- Signed Prerequisite Program Agreement (**attached**)
- A categorization of the types of potentially hazardous foods that will be both cured and ROP
- A list of ingredients used in each product (including commercial cure brand, sausage casings, etc.)
- Label(s) of any pre-mixed cure used by the firm
- Cure recipes for standard batch of product: include the weights of ingoing meat, cure mix, and any other ingredients such as binders and accelerants)
- Equipment Specifications (e.g. vacuum package machine, grinder, 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**)
- Batch records to include scale accuracy measurements (**example batch record – 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 variance/ HACCP request.

Facility DBA _____ Owner Name _____

Owner Signature _____ Date _____



Oregon
Department
of Agriculture

Food Safety Program Variance Application

Website: <http://www.oregon.gov/oda/programs/foodsafety>

Please send the completed variance application form to the Oregon Department of Agriculture's Food Safety Program. Please submit a separate application form for each variance request, using additional pages if necessary.

Date: _____

Name of Applicant / Owner/ Operator: _____

Name of Establishment: _____

Mailing: _____

Physical Address: _____

Statewide Chain Establishment: _____ Independent: _____

Telephone: _____

Email: _____

Signature: _____

Product or Process Requested: _____

Request for Variance: (OAR 603-25-0030 Section 8-103.11):

1. Describe the proposed Code variance being requested, citing the relevant Code section numbers.
2. Explain specifically how your proposed procedure will adequately control the public health hazards addressed in the Code. Please include supporting documentation.
3. Include a HACCP plan if required as specified under OAR 603-25-0030 Section 8-201.13(A), including the information specified under OAR 603-25-0030 Section 8-201.14.

OAR 603-25-0030 Food Code Website:

<http://www.oregon.gov/ODA/shared/Documents/Publications/FoodSafety/FoodCode.pdf>

Oregon Department of Agriculture
Food Safety Program
635 Capitol Street NE, Salem, OR 97301-2532
Phone:(503) 986-4720 and Fax: (503) 986-4729

Variance Procedures for Reduced Oxygen Packaging (ROP) at Retail



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 (2013 ODA Food Code - 3-502.12). 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 the form below, and provide to the Regulatory Authority with the completed variance packet prior to implementation:**

- (1) Firm Name & Name of Contact
- (2) The ROP packaged food shall meet the criteria below and requires variance and HACCP:
 - (a) Part of a special process in 2013 ODA Food Code 3-502.11(D) Variance Requirement.
These products must be cured (nitrate/nitrite to USDA standards) and can be raw or ready to eat (RTE).
 - (b) Raw meat with added ingredients and without cure (nitrate/nitrite to USDA standards).
These products must be kept frozen before, during, and after packaging, with a continuous monitoring device.
*If these products with added ingredients without cure are kept refrigerated or do not meet the criteria of (b) above, then validation that these products are safe must be included in the variance submission.
- (3) 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.
- (4) Include operational procedures that:
 - (a) Prohibit contacting 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.

- (5) 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

Statement: I hereby certify that the above information is correct and I fully understand that any deviation from the above without prior permission from this Regulatory Authority may nullify final approval.

License Holder or Person-in-Charge **Signature/Title** **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

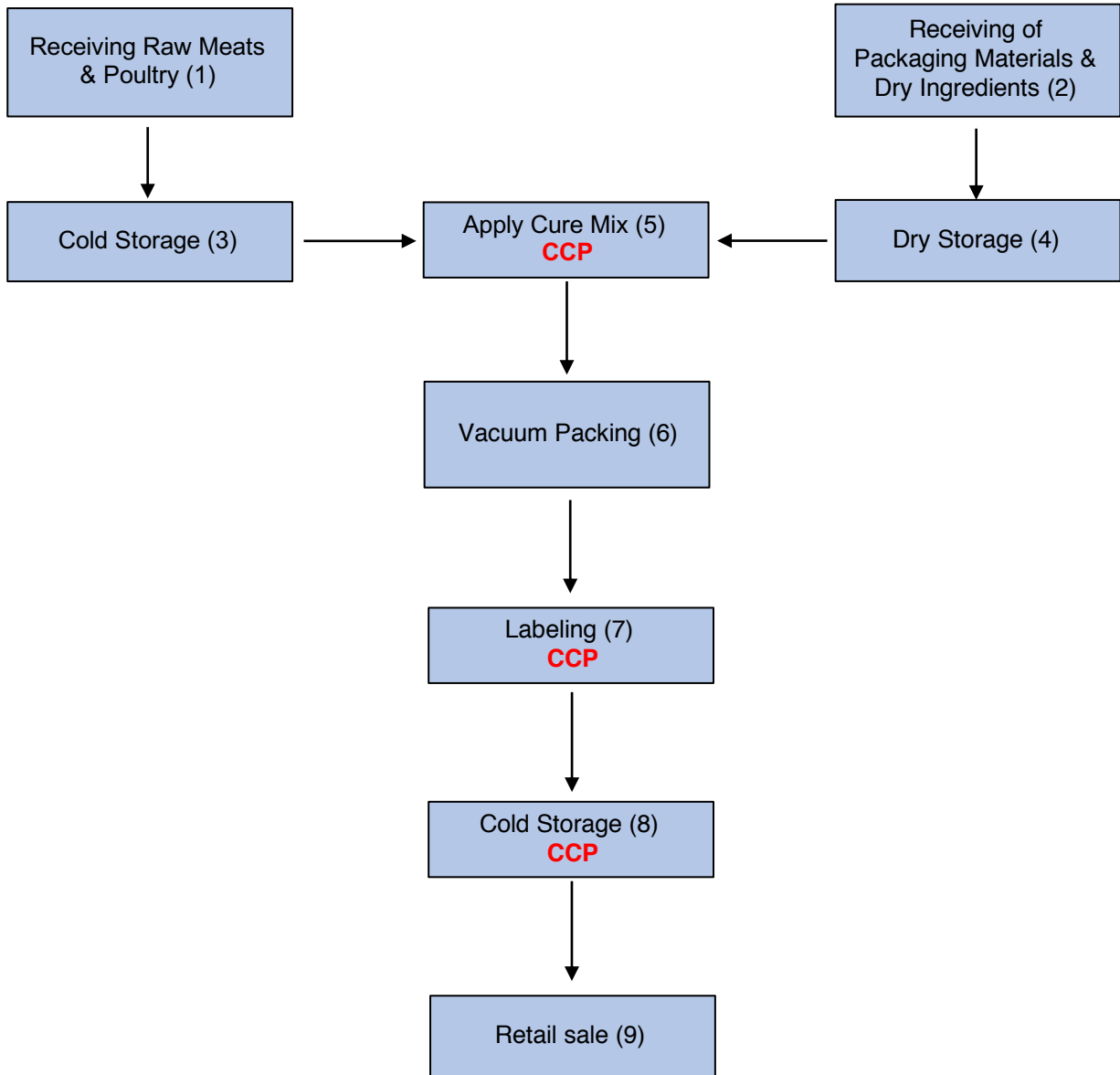
Firm agrees to develop and implement a food employee and supervisory training plan that addresses the food safety issues of concern.

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: Curing with ROP



Establishment Name & Address:

Product Name & Description:

Curing with ROP HACCP Plan

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring Procedures				Corrective Actions	Records	Verification
			What	How	Frequency	Who			
CCP 1: Curing (if Reduced Oxygen Packaging cured product)	Biological: Pathogens (<i>Clostridium botulinum</i>)	Follow Maximum and Minimum Ingoing Nitrite/Nitrate Limits (in ppm) for Meat and Poultry Products from USDA FSIS PROCESSING INSPECTORS' CALCULATIONS HANDBOOK (TABLE II) (Include Ratio Below)	Quantity and the presence of nitrite/nitrate in the mixture	Monitors weight of the curing agent & meat with a calibrated scale	Each batch	Person in Charge that is mixing the product will sign off.	- Identify and eliminate cause of deviations. - Bring CCP under control by making sure a proper amount of curing agent is in the mix. - Discard or rework the mixture.	- Weighing Log - Corrective Action Log	- Owner or designated personnel will review the weighing log weekly. - Scale Calibration Log
CCP 2: Temperature Control	Biological: Pathogens (<i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i>)	Maintain the food at 41°F or below	Refrigerator Cooler 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 the firm)	(To be completed by the 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

Establishment Name & Address:

Product Name & Description:

Curing with ROP HACCP Plan

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring Procedures				Corrective Actions	Records	Verification
			What	How	Frequency	Who			
CCP 3: 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	At time of ROP and at least daily thereafter	(To be completed by the 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(s) 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

BATCH RECORD: CURED MEAT PRODUCTS

Product:			
Batch #/Lot Code:		Date:	

CURING:

Cure Type: <small>(Specific Chemical)</small>		Lot #	
Weight:			
CCP Met?	Yes	No	
Corrective Action:			
Staff Initials:			

FOOD SCALE ACCURACY:

Food Scale Identification	Standard Weight	Scale Reading	Accurate Y/N	Corrections	Staff Initial

SMOKE/COOK:

Final Internal Temp:	°F
Control Met?	Yes No

COOLING:

Start Time:		Temp:	°F
Staff Initials:			
1st Cool from 135°F to 70°F (≤2 hours)		Temp:	°F
Staff Initials:			
2nd Cool from 70°F to ≤41°F (≤4 hours):		Temp:	°F
Control Met?	Yes	No	

VERIFICATION:

All CCPs and Controls Met?	Yes	No	
Corrective Actions:			
Verified by:		Date:	