



TULSA HEALTH  
Department

**Food Protection Service**

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SUBJECT: Reduced Oxygen Packaging Regulations

Dear Owner/Manager:

The Oklahoma State Department of Health has regulations concerning the preparation and storage of foods in reduced oxygen packaging (ROP). The ROP process reduces, replaces or controls the amount of air inside a package by mechanically pulling a vacuum and sealing the food within a bag so that there is less oxygen in the package than normal air. Once sealed, whether a vacuum seal or a metal crimp is used, the bags used to cool and store food keep oxygen from getting inside thus creating an anaerobic environment (without air). The oxygen transmission rates (OTR) of the packaging material used during vacuum packaging does not change this designation.

ROP can create an environment that prevents the growth of spoilage organisms that are responsible for off-odors, slime, and texture changes, which are signs of spoilage. ROP also prevents color deterioration in raw meats caused by oxygen.

A reduced oxygen atmosphere provides the potential for growth of several foodborne pathogens. The two pathogens of most concern are *Listeria monocytogenes* (listeria), which can survive and grow slowly at temperatures near the freezing point of foods and *Clostridium botulinum* (botulism), which can survive, multiply, and form a toxin if time/temperature parameters are not strictly controlled.

Food establishments that package Time/Temperature Control for Safety (TCS) Food using ROP methods must implement a HACCP plan.

A HACCP plan is not required for ROP of Non-TCS Food or TCS Food that is always packaged:

- a. Labeled with production time and date,
- b. Held at 41°F or below during refrigerated storage, and
- c. Removed from ROP package in the food establishment within 48 hours after packaging.

The regulations described below, when properly implemented, prevent the growth and formation of bacteria or spores in reduced oxygen packaging environments. The three most common reduced oxygen processes and their requirements are described below.

### ***Reduced Oxygen Packaging for Cured Meat, Raw Meat, and Raw Vegetables, or Acidic Foods***

Without air, oxidation cannot occur, and it protects against spoilage. This is ideal storage and packaging for cured meats, cheeses, and individual portions of raw meats. In order to be approved for this process, the following requirements must be met.

1. Implement a HACCP program and operational procedures.
2. Cold hold packaged foods at 41°F or below **plus one of the following barriers:**
  - pH of 4.6 or less;
  - water activity ( $a_w$ ) of 0.91 or less water activity (amount of available moisture);
  - Cured meat or poultry products that are received in intact packages from a food processing plant regulated by the USDA and that contain substances specified in CFR 424.21 – Use of food ingredients and sources of radiation; or
  - Raw vegetables, raw meat, or raw poultry.
3. Refrigerated shelf life of no more than 30 days except the time the product is frozen. The 30 day shelf life cannot extend beyond the original manufacturer's "sell by" or "use by" date.
4. Can be sold retail for off-site consumption if labeled properly. Labels on bags must include instructions for storage at 41°F or below, and have a statement printed in bold font on a contrasting background to discard the food within 30 days of packaging if not served or consumed.

### ***Sous vide***

This is a specialized cooking process in which raw or partially-cooked food ingredients are placed in a ROP bag (typically vacuum sealed) then cooked. Once the food has been sealed in the ROP environment, one of the following must happen: (1) food is cooked and properly cooled, (2) cooked and immediately served, or (3) cooked and held hot.

### **Requirements**

1. Must provide a HACCP plan before implementation.
2. The raw or undercooked food must be cooked in the bag to heat all parts of the food to a temperature and for a time as specified for that product.
3. Must be protected from contamination before and after cooking.
4. After the initial cooling process if the intended storage period is for over seven days and up to 30 days, the food must be further cooled to 34°F within 48 hours of reaching 41°F and then held at 34°F until consumed or discarded within the 30 day period after packaging. If frozen, no shelf life restriction until thawed.
5. Cold held at 41°F or below until consumed or discarded within 30 days after the packaging date. If frozen, no shelf life restriction until thawed.
6. Cannot sell sous vide bagged products to customers or other businesses for off-site consumption, must be maintained within the same business entity.
7. Refrigeration must be equipped with an electronic system that continuously monitors time and temperature and is visually examined twice daily.
8. Individual bags must be labeled with product name and the date packaged.

### **Cook-Chill Process**

This technique involves the full cooking of food, followed by rapid chilling and storage. If the intent is to store this food in a ROP environment, the food must be placed in the ROP bag while it is still hot (before reaching a temperature below 135 °F) then sealed with either a heat seal or metal crimp.

#### Requirements

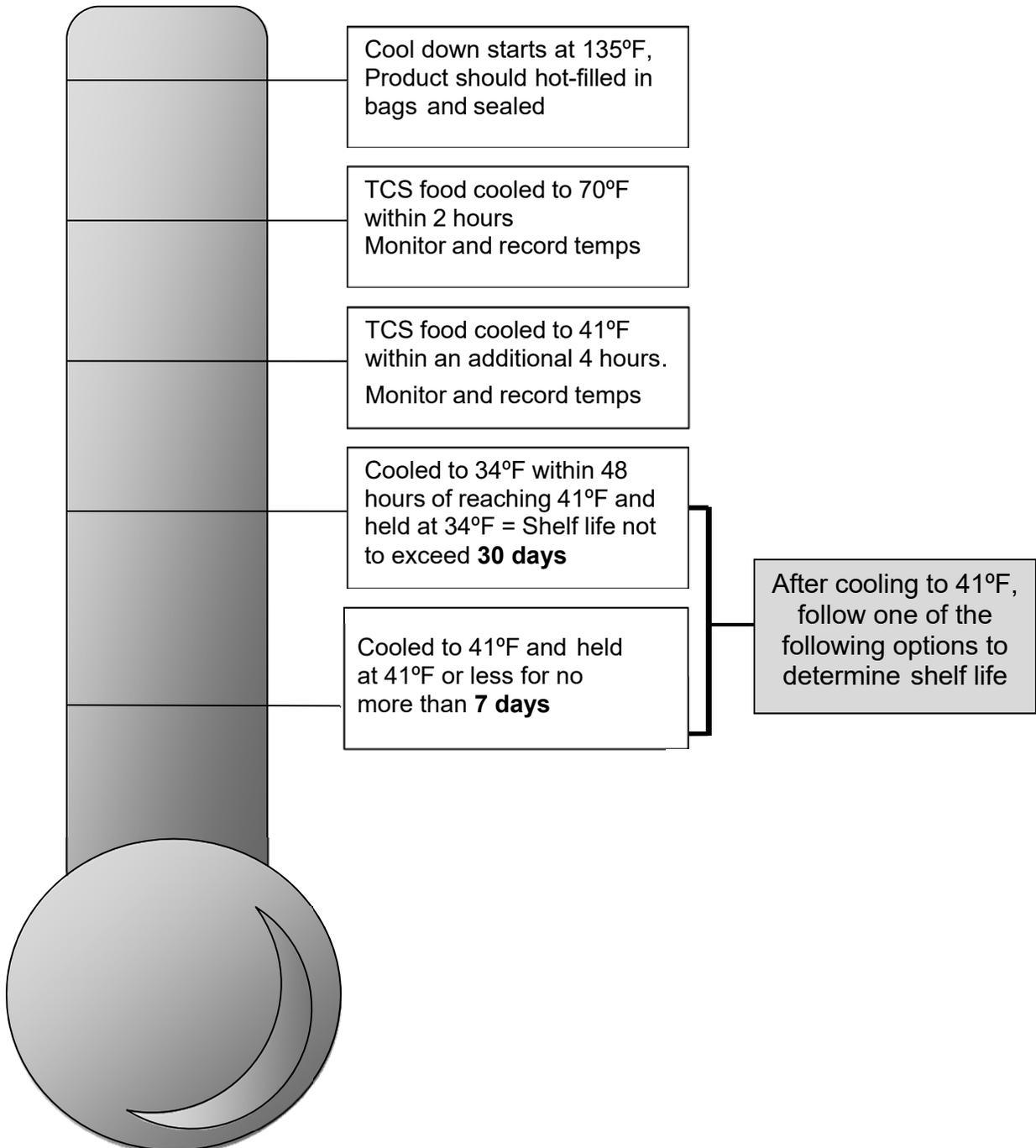
1. Must provide a HACCP plan before implementation.
2. After sealing the ROP bag, it must be rapidly cooled in the bag to 41°F within a total of 6 hours (meeting required time/temperature parameters).
3. After the initial cooling process if the intended storage period is for over seven days and up to 30 days, the food must be further cooled to 34°F within 48 hours of reaching 41°F and then held at 34°F until consumed or discarded within the 30 day period after packaging. If frozen, no shelf life restriction until thawed.
4. Cannot sell cook-chill bagged products to customers or other businesses for off-site consumption, product must be maintained within the same business entity.
5. Refrigeration must be equipped with an electronic system that continuously monitors time and temperature and is visually examined twice daily.
6. Individual bags must be labeled with product name and date prepared.

A HACCP plan submitted for ROP also requires detailed standard operational procedures that:

1. Prohibit contacting Ready-To-Eat (RTE) food with bare hands
2. Identifies a designated work area and the method by which:
  - a. Physical barriers or methods of separation of raw food and RTE foods minimize cross contamination, and
  - b. Access to the processing equipment is limited to responsible trained personnel familiar with ROP guidelines and potential hazards
3. Explains cleaning and sanitizing procedures for food contact surfaces
4. Describes the employee training program that ensures employees responsible for the ROP operation understand the:
  - a. Concepts required for a safe operation,
  - b. Equipment and facilities, and
  - c. Standard Operating Procedures and Food safety concerns involved

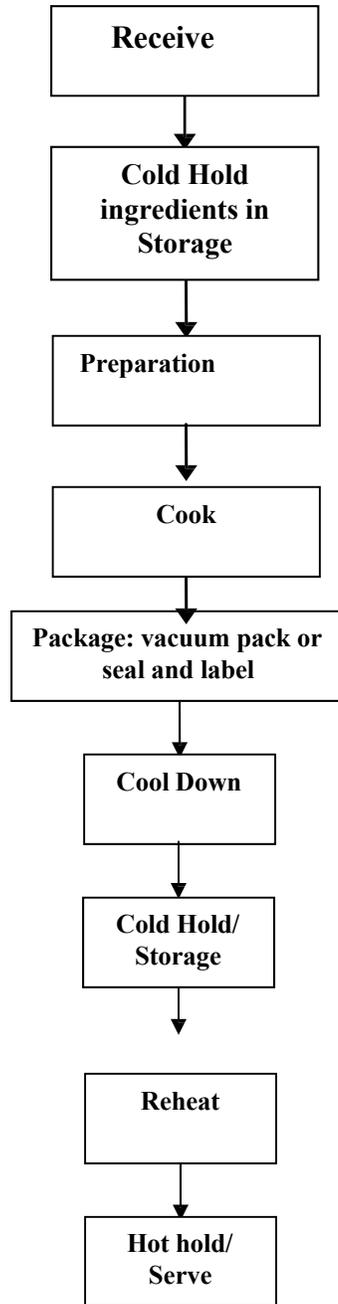
The objective of ROP regulations is to protect the health of your customers. Please contact your Tulsa Health Department Sanitarian who will be happy to assist you in meeting the requirements. If your process varies from these requirements, a request for variance must be submitted. The Tulsa Health Department appreciates your cooperation in this matter and your continuing commitment to food safety.

## Summary of Cool Down Process and Shelf Life for Cook-Chill or Sous Vide



**NOTE:** Cook-chill process requires that product is bagged and sealed while above 135°F. Sous vide process requires that raw food is bagged and sealed and then cooked in bag, and either served immediately or cooled for later service.

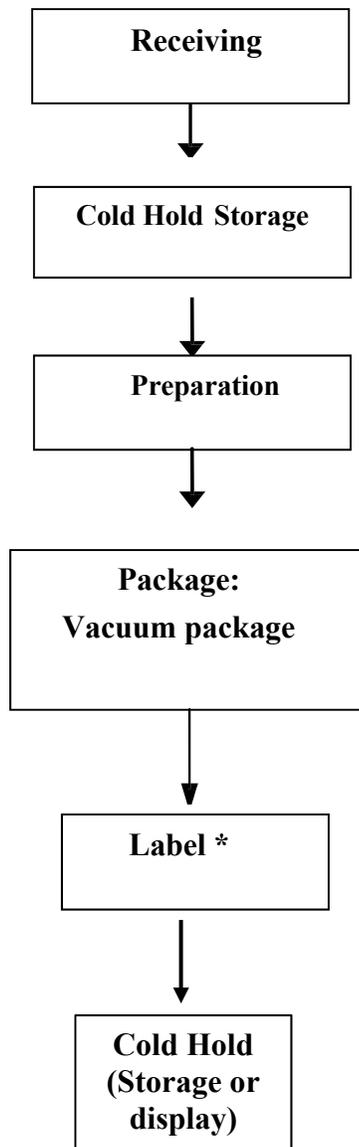
# Example of Cook/Chill ROP Process Flow Diagram



**Critical Control Points (CCP)** - defined as a step in the process that if not followed can result in an illness or injury.  
**Control Points (CP)** - defined as a step that must be followed to ensure food safety.  
**Critical Limits (CL)** - is the maximum or minimum requirement that must be met to ensure food safety.

Step 1: A process flow chart can be used to identify each step in a reduced oxygen packaging process. Identify all CCPs, CPs, CLs, and shelf life. Then take all steps to create the Hazard Analysis Table (see attachment).

## Example of Deli Meat ROP Process Flow Diagram



**Critical Control Points (CCP)** - defined as a step in the process that if not followed can result in an illness or injury.  
**Control Points (CP)** - defined as a step that must be followed to ensure food safety.  
**Critical Limits (CL)** - is the maximum or minimum requirement that must be met to ensure food safety.

\*After ROP packaging, the refrigerated shelf life must not exceed 30 days from packaging to consumption, except for the time that the product is maintained frozen OR limit the shelf life to the original manufacturer's "sell by" or "use by" date, whichever occurs first.

## Example HACCP Monitoring Form

DATE:

PERSON RESPONSIBLE:

Receiving Record temperatures / LOT #'s:			
Product	Temp	LOT #	Corrective Action

**Receiving Critical Limits**  
 \*TCS foods received 41°F or below  
**Action:** Reject food not at proper temperature

Walk-in Cooler Temperature			
Product	Temp	Time	Corrective Action

**Cold Hold Critical Limits**  
 TCS food held 41°F or below  
**Action:** If food is out of temp for more than 4 hours discard, otherwise rapidly cool within 4 hours

Cooking Temperatures			
Product	Temp	Time	Corrective Action

**Cooking Critical Limits**  
 Poultry: 165°F  
 Ground Meat: 155°F  
 Fish, Pork: 145°F  
 Vegetables: 135°F  
**Action:** complete cooking process

Cooling Temperatures			
Product	Temp 2hr	Temp 6hr	Corrective Action

**Cooling Critical Limits**  
 TCS food cooled to 70°F within 2hrs, and to 41°F within 6hours total  
**Action:** Reheat to 165°F and start cool down process again

Reheating Date Produced:			
Product	Temp	Time	Corrective Action

**Reheat Critical Limits**  
 Reheat TCS food to 165°F within 2 hrs.  
**Action:** Discard if not reheated properly

NOTE: This is an example of a monitoring form. It should be adjusted to fit your program.

\*TCS- Time/ Temperature Control for Safety Food

Example Hazard Analysis					
Process Step	Potential Hazard B= Biological C=Chemical P=Physical	Is the Hazard likely to occur? (yes or no)	Justification for decision made in previous column?	What control measures can be applied to control hazards?	Is this step a critical control point? (CCP)
Receive	B= C= P=				
Cold Hold/ Storage	B= C= P=				
Preparation	B= C= P=				
Cook	B= C= P=				
Package	B= C= P=				
Cool	B= C= P=				
Cold Hold/ Storage	B= C= P=				
Reheat	B= C= P=				
Hot Hold/ Serve	B= C= P=				

STEP 2: This Hazard Analysis table helps to identify possible hazards in each step of the ROP process. Take each step from process flow chart and identify biological, chemical, and physical hazards. Decide what control measures can be applied to prevent hazards. Finally, decide if the step is a critical control point.

## Example CCP Description, Critical Limits, Monitoring Procedures, Corrective Action(s)

<b>Product:</b>					
Process Step	CCP Number	CCP Description	Critical Limits	Establishment Monitoring Procedures: (What/How/Frequency/Responsible Person)	Corrective Action(s)
	CCP#			What will be measured:  Where will the CL be measured?  How will the CL be measured?  Who will monitor the CL?  How often will the CL be measured?	Who is responsible for implementing corrective action:  HACCP coordinator or designee  1. Identify & correct violation  2. Bring CCP under control after corrective action is taken  3. Establish measures to prevent recurrence  4. No product that is injurious to health or adulterated enters commerce

Step 3: This table can be used to identify standards for each critical control point (CCP). There should be a table for each step in the ROP process that is indicated as being a CCP. This form will help establish who is responsible for each step and what corrective actions are approved for your process.