

Bulletin #3107, Reduced Oxygen Packaging (ROP): Requirements and Guidelines in Maine for Food Service

Reduced Oxygen Packaging (ROP): Requirements and Guidelines in Maine for Food Service

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Photo by Stephen Ausmus

Many food service and commercial food processors have begun using Reduced Oxygen Packaging (ROP) (e.g. vacuum packaging) to help extend the shelf life of food products. The use of these packaging technologies has several benefits but it is essential to know the serious food safety risks and Maine Food Code requirements associated with this type of packaging.

Benefits associated with ROP products

The removal or reduction of oxygen prevents the growth of most spoilage organisms. These microorganisms are responsible for off-odors and texture changes that occur when food spoils. Reducing oxygen also reduces fat oxidation and rancidity. These are the characteristic changes that allow the consumer to determine if a food is still edible. Therefore, ROP technologies can prolong quality and extend the shelf life of refrigerated and frozen foods. However, there are very serious food safety risks if ROP food products are not handled and stored correctly.

Terms related to ROP products

Aerobic Conditions – The environment contains oxygen.

Anaerobic Conditions – The environment does not contain oxygen.

Vegetative cells – A state in which bacteria can reproduce/grow and, in particular, bacteria produce toxins.

Spore Forming Bacteria – Bacteria that is capable of forming spores, thick walled formations that can protect the bacterial cell against unfavorable or hostile environmental conditions (e.g. high acid, high temperature, drying, freezing) thus allowing survival. Once a spore, the cell cannot reproduce or grow until it enters a vegetative state.

Canning – Canning is a method of preserving food in which the food contents are heat processed and sealed in an airtight container. Examples: Dilly Beans, Acidified Pickles, Hot Sauces, BBQ sauces.

Sanitation Standard Operating Procedure (SSOP) – Procedures that will be used to accomplish sanitary food handling and general hygiene practices. They also document how monitoring and corrective actions will be accomplished and who is responsible.

Potentially Hazardous Foods (PHF) / Temperature Controlled for Safety (TCS) – The Food Code defines PHF/TCS as a natural or synthetic food that requires temperature control because it is capable of supporting:

- The rapid and progressive growth of infectious or toxigenic microorganisms, **or**
- The growth and toxin production of *Clostridium botulinum*, **or**
- In raw shell eggs, the growth of *Salmonella enteritidis*.

Curing – Meat or poultry to which some combination of salt, sugar, nitrite and/or nitrate is added for the purposes of preservation.

- If you are adding nitrate and/or nitrites, then you are curing.

Types of Reduced Oxygen Packaging

Vacuum Packaging – The air is removed from a food package and hermetically sealed (closed so no air/oxygen can enter) and the vacuum inside the package remains until the seal is broken.

Cook Chill – Cooked food filled into bags/packaging while still hot, causing the air to be expelled from the bags/packaging. They are sealed or crimped with a metal or plastic closure while the food is still hot. The bags are then rapidly chilled and stored under refrigeration or are frozen.

Sous Vide – Raw or partially cooked foods are placed in a bag, vacuum packed, and hermetically sealed. In general they are then cooked in the bag, rapidly chilled, and held under refrigeration.

Modified Atmosphere Packaging (MAP) – The air/atmosphere inside the package is altered so that the new composition is different from normal aerobic conditions (21% oxygen concentration) — usually

adding nitrogen and/or carbon dioxide and lowering or removing the oxygen. The package atmosphere does not have to maintain these conditions and may change over time due to the respiration of the food or permeability of the packaging materials.

Controlled Atmosphere Packaging (CAP) – The air/atmosphere inside a sealed package is altered so that the new composition is different from normal aerobic conditions (21% oxygen concentration) and continuous control of that air/atmosphere is maintained. This air/atmosphere can be controlled and maintained by use of non-respiring food, impermeable packaging or use of oxygen scavenging products.

Food safety concerns with vacuum packaging or ROP products

Clostridium botulinum is a very dangerous bacterium that can thrive in anaerobic conditions if certain precautions are not taken. The danger lies in its ability to form a spore to protect itself in adverse conditions. As a spore there is no danger, but if there is improper handling of a susceptible product, then conditions in the food package can become favorable for spores to transform into vegetative cells where they can grow, reproduce, and form a deadly neurotoxin. This is a heat stable toxin and very small quantities — nanograms — of this heat stable neurotoxin can cause paralysis and death. When in the spore form, this bacterium can be dormant for years and survive extreme conditions including freezer and refrigerator temperatures, boiling water (212°F), drought, high moisture, and aerobic and anaerobic conditions. *C. botulinum* is present everywhere, and any food can be contaminated with it and should be treated to prevent or control growth and toxin formation.

There are several strains of *C. botulinum*. *C. Bot* type E and non-proteolytic types B and F are associated with fish and fishery products and can grow and produce toxin in temperatures as low as 38°F (3.3°C). As vegetative cells, *C. Botulinum* type A and proteolytic types B and F can grow and produce toxin at temperatures as low as 50°F (10°C) and are associated with many commodities, i.e., red meat, poultry, pork, vegetables, etc.

If present, and proper processing, handling, and storing are not in place, *C. botulinum* could potentially grow, produce toxin, and render an ROP food toxic. Under ROP conditions, most competing spoilage microorganisms cannot grow, therefore allowing *C. botulinum* to grow unimpeded. Foods that contain *C. botulinum* toxin generally look, smell, and taste normal.

Normal cooking (e.g. pasteurization or sous vide) does not destroy *C. botulinum* spores. In order to destroy *C. botulinum*, foods must be heat-treated to commercial sterility — such as with canned foods. If this is not possible, then *C. botulinum* must be controlled with refrigeration (41°F or 4.4°C or below) with the exception of *C. bot* type E present in most fish and fisheries products, which should be held at 38°F (3.3°C) or below. In addition to these low temperatures, *C. botulinum* will **not** grow in food with a low pH (4.6 or less), or low water activity (Aw 0.935 or less for type A and proteolytic Type B and F **OR** Aw of 0.97 or less for type E and non-proteolytic type B and F).

Because of the high mortality rates and lack of warning signs when contaminated with *C. botulinum* toxin, foods held in anaerobic conditions are strictly regulated. Therefore, PHF or TCS foods packed in ROP packages are required to employ multiple barriers to prevent the growth of *C. botulinum* and must be manufactured and/or packed under a HACCP plan.

Hazard Analysis Critical Control Plan (HACCP)

HACCP is a food safety management system, which identifies and controls biological, chemical, and physical food safety hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product. There are seven principles that must be addressed in HACCP including:

- Principle 1 — Conduct a Hazard Analysis (HA)**
- Principle 2 — Identify the Critical Control Points (CCPs)**
- Principle 3 — Establish Critical Limits (CLs)**
- Principle 4 — Monitor CCP**
- Principle 5 — Establish Corrective Action (CA)**
- Principle 6 — Verification**
- Principle 7 — Recordkeeping**

HACCP was developed in the 1960s to ensure the safety of food for the space program and since the mid 1990s HACCP has become the foundation of our food safety system for all commodities in the US and countries worldwide.

Regulations (2013 Maine Food Code)

2013 Maine Food Code lists 2 Sections:

1. **Section 3-502.12 — Any PHF products that are allowed to be packed under ROP *Without a Variance* must meet the criteria in 3-502.12 (low water activity, low pH, USDA cured, raw meat, raw poultry, and/or raw vegetables). HACCP plan required.**
2. **Section 3-502.11 — Any PHF products that do not meet the criteria listed in 3.502.12 will require a Variance and a HACCP plan.**

1) Section 3-502.12 — Any PHF products that are allowed to be packed under ROP *Without a Variance* must meet the criteria in 3-502.12 (low water activity, low pH, USDA cured, raw meat, raw poultry, and/or raw vegetables). HACCP plan required.

Products that meet these criteria **have a barrier to prevent C. Bot growth and toxin formation.** *Strict temperature control will provide the second barrier.*

If packaged on site at the eating establishment, a **HACCP plan and recordkeeping** is required and a shelf life of 14 days is allowed.

Minimal HACCP plan and CCP requirements for these products:

- If held at refrigerated temperatures:
 - Continuous temperature monitoring to ensure product is stored at 41°F or lower.
 - Written processing procedures, SSOP, and ongoing records to show that product is not temperature abused during processing and vacuum packing.
 - Labeling “**Important — Must be kept refrigerated at 41°F (5°C) or below**” and date coding for a shelf life of 14 days.
- If frozen:
 - Written processing procedures, SSOP, and ongoing records to show that product is not temperature abused during processing and vacuum packing.

- Labeling “Important — Must be kept frozen,” or “Important, keep frozen until used, thaw under refrigeration immediately before use” or “Important, keep frozen until used, break seal prior to thawing.”
 - Once removed from freezer to thaw, the product must have date coding for a 14-day shelf-life.
- Written procedure for thawing:
 - Break the seal prior to thawing — **OR** —
 - Thaw ROP product under continuous monitoring
- **Best Practices** (*not required*)
 - Continuous monitoring (*preferred option*) — **OR** —
 - Periodic Temperature records (*example: record temperature of cooler every 4 hours*)

Fish and seafood products may not be vacuum packaged at retail unless the fish is frozen before, during, and after packaging. This process still requires a HACCP plan.

Sections 3-502.12 and 8-201.14 of the 2013 Maine Food Code list additional requirements for these plans. Section 3-502.12 also describes the HACCP plan and control requirements for ROP storage of Sous Vide, Cook-Chill, and Cheese Products.

2) Section 3-502.11 — Any PHF products that do not meet the criteria listed in 3.502.12 will require a Variance and a HACCP plan.

These products will require a variance and a HACCP plan. The contents of the plan will include the items listed above and may also include additional monitoring depending on what secondary barrier is used.

The adequacy of the secondary barrier will need to be evaluated by a food processing authority.

Product examples include but are not limited to:

- Unfrozen processed fish and smoked fish packed by ROP;
- Soft cheeses such as ricotta, cottage cheese, cheese mixed with meats, vegetables or fish;
- Smoked meat or cured meat and poultry cured on site.

Guidance for HACCP Plans that require Variances

1. Develop a HACCP Plan. More information at the FDA website:
<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm>
2. The licensee will need to write the HACCP plan or they can contact recognized HACCP consult (e.g., John Manoush at 207.655.7660 or go to his website at <http://www.haccpman.com/>)
3. The HACCP plans then need to be sent to Dr. Jason Bolton, at the University of Maine Cooperative Extension, who will review the process and plan and conduct sample testing of the product. Dr. Jason Bolton’s contact: 207. 581.1366, jason.bolton@maine.edu.
4. A variance will need to be approved by DHHS if selling retail out of their restaurant: contact 287.5671. If the restaurant is wholesaling, they will need to contact the Department of Agriculture, Forestry and Conservation at 207.287.3841.

3-201.12 Food in a Hermetically Sealed Container “Canning.” Code of Federal Regulations, Title 21, Parts 114 — Acidified Foods.

This includes acid, formulated acid, and acidified foods. The final pH of the product is less than 4.6. Examples include pickles, dilly beans, jams and jellies, salsas that are hermetically sealed in glass jars or bottles. You are not allowed to can low acid foods (pH 4.6 or greater), i.e., pressure canning or water bath canning of meat, poultry, seafood, vegetables, dairy, etc.

Minimal HACCP plan requirements for acidified canned products:

- Submit each product in final packaging for [Product and Process Review Testing](#).
- Follow all recommendations for process time, temperatures, critical limits/factors, procedures, calibration records, and batch pH records that are stated in Product and Process Review Testing Letter of approval.

In Summary

Steps to produce safe ROP products that meet all requirements in a restaurant/food service entity:

- If you produce a potentially hazardous ROP food that meets one or more of the following criteria: low water activity, low pH, USDA cured, raw meat, raw poultry, raw vegetables, **then** you must:
 1. Develop a HACCP Plan
 2. Submit a HACCP plan to the DHHS, if required

Health Inspection Program
Key Bank Plaza 3rd Floor
11 SHS
Augusta, Maine 04333-0011
207-287-5671

Fish and fisheries products may not be vacuum packaged at retail unless it is frozen before, during, and after packaging. This requires a HACCP plan.

- If you produce a potentially hazardous ROP food that does **not** meet the above criteria then you must:
 1. Develop a HACCP Plan
 2. Submit a variance to process authority for evaluation
 3. Submit a HACCP plan and variance to DHHS for review
- If you produce acidified canned food you must:
 1. Submit each product in final packaging for [Product and Process Review Testing](#).
 2. Follow all recommendations as stated in Product and Process Review Testing Letter of approval.
 3. Submit a HACCP plan and variance request to DHHS for review.

Additional Information

Sanitation

- **General industry-wide sanitation 101:** contact Theresa Tilton at <mailto:theresa.tilton@maine.edu> or 207.942.7396

- **Dairy Sanitation:** contact Melissa Libby at <mailto:melissa.libby1@maine.edu> or 207.581.2788

Hazard Analysis Critical Control Point Certification

- **Meat and Poultry:** contact Theresa Tilton at <mailto:theresa.tilton@maine.edu> or 207.942.7396
- **Seafood:** contact Melissa Libby at <mailto:melissa.libby1@maine.edu> or 207.581.2788

Better Process Control School

Acidified and low-acid canned food processors are required by the FDA and USDA to obtain Better Process Control School certification. Contact Melissa Libby at melissa.libby1@maine.edu or 207.581.2788.

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