

REDUCED OXYGEN PACKAGING (ROP) POLICY AND PROCEDURES

Reduced oxygen packaging (ROP) is a packaging procedure which results in a reduced oxygen level in the sealed food package and decreases the amount of competing spoilage bacteria normally found in certain foods. The resulting package is a more aesthetically pleasing product to the consumer and in many cases will extend the shelf-life of the food. Types of processes considered as ROP include modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), Sous Vide (SV) and vacuum packaging (VP). However, by reducing the oxygen normally found in the package, and the consequent reduction in normal food spoilage bacteria, an environment could be created conducive to the growth of more dangerous pathogenic food microorganisms such as *Clostridium botulinum (Cb)* and *Listeria monocytogenes (Lm)*. Ensuring the safest possible product to the consumer is the ultimate responsibility of each food establishment. Food packaged in a reduced oxygen atmosphere may not exhibit normal taste or odor spoilage signs, but may still be unsafe; therefore it is critical that food establishments adhere to the food safety principles outlined below. ALL ROP processes must be reviewed and approved by the Department Regional Sanitarian or Regulatory Authority before implemented.

SAFETY BARRIERS

Refrigeration is the primary safety barrier. **Each food must possess one or more of the following secondary barriers:**

1. Water activity .91 or less
2. Acidity (pH) 4.6 or less
3. High levels of non-pathogenic competing organisms that prohibit the growth of pathogenic bacteria, such as found in raw meat/poultry.
4. Food maintained frozen before, during or after production. (See seafood below)
5. Meat or poultry product is cured in one of the following manners: (Note: Meat/poultry processing should follow guidelines/regulations/standards of FSIS/USDA, and CFR's when creating a 2nd barrier, such as a curing agent. Some references include 9 CFR 424, 21CFR 172.170 & 172.175. FSIS web sites: www.fsis.usda.gov)
 - a. At a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21 and is received in an intact package OR
 - b. Cured in the Retail Food Facility using a commercially manufactured cure which uses USDA approved substances specified in 9 CFR 424.21, and following manufacturer's procedures to meet USDA established curing levels. No 'in-house' produced cures may be used. Documentation- Letters of Guarantee, that cure meets the USDA established levels of approved substances from supplier for each lot of cure used by the facility, must be kept on site, and should be included as a CCP in the HACCP plan.
6. Foods containing any combination of factors scientifically proven to provide a complete secondary barrier. Such foods shall not be packaged without specific scientific documentation or evidence to demonstrate the safety of the factors equating to produce a complete barrier.

Except for foods processed and reduce oxygen packed under USDA Supervision, which are exempt from testing requirements - it is the responsibility of the processor/packer to monitor and verify the second barrier through laboratory testing (e.g.; microbiological challenge study) or other required documentation.

All food ingredients must be from an approved source and packaging materials must be acceptable to the Department.

REFRIGERATION

All reduced oxygen atmosphere foods must be maintained at an internal temperature of 41°F or below if refrigerated, and in a frozen state if frozen. (Except as stated below for seafood/fish.)

LABELING

Refrigerated foods **MUST** be labeled with a **“Keep Refrigerated”** statement and a **“Use By”** date statement. The “Use By” date shall not exceed 30 days from the date of packaging or the original manufacturer’s sell-by-date of the food, whichever is first (except as specified below for certain products). At the end of the expiration date food shall be disposed, except, if frozen prior to the expiration date, the food shall be maintained frozen and must be labeled ‘Keep Frozen’.

Frozen *foods that are frozen before or immediately after packing, and remain frozen until use, **MUST** bear a **“ Keep Frozen, use within 4 days after thawing”** statement. Note: *Specific labeling requirements for fish and seafood are detailed below.

CONTAMINATION

All equipment, utensils, and food contact surfaces used for processing ROP food shall be cleaned and sanitized immediately prior to packaging and after every four hours of use. Cleaning and sanitizing procedures shall also be followed when cooked ROP food is to be processed after raw ROP food. Only unopened packages of commercially processed foods shall be reduced oxygen packed, and if processing is interrupted for more than thirty minutes the remainder of the unprocessed food shall be disposed of or used for other applications. Any foods in leaking or otherwise compromised packages shall be disposed.

WRITTEN PROCEDURES (HACCP Plan)

A complete written procedure (HACCP Plan) shall be available covering the subject food from the time it is received until it is sold or disposed. A list of all foods to be manufactured and the ingredients used in ROP shall be posted. ROP areas shall be separate from other operations. A HACCP plan as outlined in the FDA Model Food Code Section 3-502.12(B) shall be acceptable to the Department.

HACCP PLAN MUST INCLUDE:

- (1) Identifies the food(s) to be packaged
- (2) Except as specified under the fish, cheese, and sous vide sections, require that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:
 - (a) Has an AW of 0.91 or less,
 - (b) Has a PH of 4.6 or less,
 - (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**OR**

(d) Cured in the Retail Food Facility using substances specified in 9 CFR 424.21. *A commercially manufactured cure which uses USDA approved substances specified in 9 CFR 424.21, and following manufacturer's procedures to meet USDA established curing levels.* No 'in-house' produced cures may be used and Letters of Guarantee, that cure meets the USDA established levels of approved substances from supplier for each lot of cure used by the facility, must be kept on site and be included as a CCP in the HACCP plan.

(e) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;

(f) Is a food that will be maintained frozen.

(3) Describes 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 it is not served for on-premise consumption, or consumed if served or sold for off-premises consumption;

(4) Limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(5) Includes operational procedures that:

(a) Prohibit contacting Ready-to-Eat food with bare hands

(b) Identify a designated work area and the method by which:

(i) Physical barriers or methods of separation of raw foods and ready-to-eat 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) Delineate cleaning and sanitization procedures for food contact surfaces; and

(6) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(a) Concepts required for a safe operation,

(b) Equipment and facilities, and

(c) Procedures specified in this guidance

(7) All other HACCP Plan requirements as listed in the FDA Model Food Code (These requirements include a flow diagram, a plan identifying critical control points, the critical limits for critical control points, the method and frequency of monitoring, the method and frequency of verification activities, copies of records to be maintained, and corrective action plans.)

TRAINING

Employees conducting ROP packaging shall be fully trained in the above procedure and shall be properly supervised. Documents should be maintained under the written procedures to verify training of employees.

CHEESE

A Food Facility that packages cheese using a ROP method shall:

(1) Limit the cheeses packaged to those that are commercially manufactured in a Food Processing Plant with no ingredients added in the Retail Food Facility 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**;

- (2) Have a HACCP Plan as specified in the FDA Model Food Code;
- (3) Labels the package on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and
- (4) Discards the ROPed cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

SEAFOOD AND FISH

Raw or processed fish and fishery products may be packaged in a reduced oxygen environment when **frozen** before, during, and after packaging AND labeled with a statement that the product must be kept frozen until use AND thawed under refrigeration immediately before use, if maintained in the vacuum packaging. ***“Keep Frozen until use. Thaw under Refrigeration and use immediately.”**

Note: If product is removed from the RO Packaging or the vacuum is broken on the product before thawing, product does not need used ‘immediately.’

Unfrozen processed fish and smoked fish may not be packaged by ROP unless from a registered food establishment (commercial processing facility) approved for the activity and inspected by the Department or other regulatory authority that has jurisdiction. Caviar may be packaged ROP from a food establishment which is approved by the Department or other regulatory authority with jurisdiction, and has an approved scheduled process established by a processing authority which is acceptable to the Department or other regulatory authority. All unfrozen fish products from approved food establishments will be labeled with **“Keep Refrigerated at 38°F or below”**. Food Establishments conducting fish and fishery product processing may use “Fish and Fisheries Products Hazards and Controls Guidance”, current edition, for guidance on ROP processing methods, and must comply with Seafood HACCP requirements.

COOK-CHILL OR SOUS VIDE

When food to be packaged under ROP conditions cannot reliability depend on secondary barriers time/temperature become the critical controlling factor for control of *Chlostridium botulinum* and *Listeria monocytogenes*. Both of these processes rely on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including cooking, cooling and maintaining cold storage is essential. Both of these processes DO require a HACCP Plan under the Food Code. You will also note that cooling plays an important part.

Except as specified under “fish”, a Food Facility that packages food using a cook-chill or sous vide process shall:

- (1) Implement a HACCP Plan as required in the FDA Model Food Code.
- (2) Ensure the food is:
 - (a) **Prepared and consumed on the premises**, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer,
 - (b) **Cooked to heat all parts of the food to a temperature and for a time as required**
 - (c) Protected from contamination before and after cooking
 - (d) Placed in a package with an oxygen barrier and sealed before cooking OR placed in a package and sealed immediately after cooking and before reaching a temperature below 135°F

- (e) First, cooled properly, as required, to 41°F in the sealed package/bag THEN:
 - (i) Cooled to 34°F within 48 hours of reaching 41°F AND held at that temperature (34°F) or below until consumed or discarded within 30 days after the date of packaging
 - (ii) Held at 41°F or less for no more than 7 days, at which time the food must be consumed or discarded
 - (iii) Held frozen with no shelf life restriction while frozen until consumed or used.
- (f) Held in a refrigeration unit that is equipped with an **electronic system that continuously monitors time and temperature** and is visually examined for proper operation twice daily
- (g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and
- (h) Labeled with the product name and the date packaged; and
- (3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP Plan and:
 - (a) Make such records available to the regulatory authority upon request, and
 - (b) Hold such records for at least 6 months; and
- (4) Implement written operational procedures and a training program as specified in this document

VARIANCE:

Only TCS (time/temperature controlled for safety) foods prepared under ROP methods that DO NOT control for growth of and toxic formation of Cb and Lm require a variance.

Any product, process or procedures not mentioned herein would require the operator to apply for a variance to the Food Code by the Department. Only the Department can authorize a variance to the PA Food Code, Chapter 46. Please contact the PDA Regional Food Safety Supervisor to discuss the potential for a variance and to obtain the proper forms for submittal.

PACKAGING:

ROP = Atmosphere lower than normal ambient level (21% O₂)

ROP Packaging will create an O₂ transfer rate of 10 – 100 cm²/m³/24 hrs

Non-ROP = Packaging that **will** allow transfer of O₂ has an O₂ transfer rate of 10,000 cm²/m³/24hrs or greater. Look for this guarantee from the packaging material company. If packaging has this transfer rate it is NOT ROP and would not need to comply with ROP guidelines.

EXEMPT FROM ROP:

- Non-TCS foods are exempt from ROP HACCP as long as they are not made using a ‘Specialize Process’ such as acidification, smoking/curing or similar or similar as identified in the Food Code.

- A HACCP plan is not required if all of the following are occurring: Product is labeled with production time and date, Product is held at 41°F or below AND product is removed from its package in the food facility within 48 hours after packaging.

DEFINITIONS:

Reduced oxygen packaging (ROP)-Decreases the amount of oxygen normally found in packaged food for the purpose of shelf life extension, flavor preservation and/or retardation/control of bacterial growth. The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level) and for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.

Modified Atmosphere Packaging (MAP)-a packaging method in which a combination of gases such as oxygen, carbon dioxide, and nitrogen is introduced into the package at the time of closure. (Example: lunchmeat in blister package). Most commonly used in fruit, vegetable, fish and fishery products.

Controlled Atmosphere Packaging (CAP)- a packaging method in which selected atmospheric concentrations of gases are maintained throughout storage. Gas may either be evacuated or introduced to achieve the desired atmosphere. More commonly used in fruit and vegetable packaging.

Sous Vide (SV) – a packaging method where raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Cook-Chill (CC)- a packaging method in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Vacuum Packaging (VP)-A process in which air is removed for a package of food and the package is hermetically sealed so that a vacuum remains inside the package. Carbon dioxide or nitrogen may be introduced into the container.

These guidelines are based on the most current version of the FDA Food Code and are subject to change with each publication of the FDA Food Code.