



MARYLAND  
Department of Health

## **Reduced Oxygen Packaging at Retail**

The following guideline is provided in response to requests from local food programs for clarification on the preparation of foods using reduced oxygen packaging procedures in the retail setting.

Reduced oxygen packaging (ROP) is a packaging procedure which results in a reduced oxygen level in a sealed food package and decreases the amount of competing spoilage bacteria normally found in certain foods. ROP is used to extend the shelf life, as well as retard and control microbial growth in foods. Additional benefits include preservation of flavor, food product aesthetics, and prevention of water loss, which leads to product shrinkage.

Reduced oxygen packaging presents a public health risk in that it can allow the growth of two serious foodborne illness causing pathogens – *Clostridium botulinum* and *Listeria monocytogenes*. 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.

### **A. Defining Reduced Oxygen Packaging**

“Reduced Oxygen Packaging” (ROP) means:

1. 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 ambient atmosphere (which is typically at 21% oxygen content, ROP would therefore be less than 21% oxygen), and
2. A process that involves a food for which the hazards of *Clostridium botulinum* and *Listeria monocytogenes* require control in the final packaged form.

Typical applications for ROP include:

“Vacuum Packaging” (VP) in which air is removed from a package of food, and the package is hermetically sealed so that a vacuum remains inside the package.

“Modified Atmosphere Packaging” (MAP) in which the atmosphere of a package of food is modified so that its composition is different from air, but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging

includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

“Controlled Atmosphere Packaging” (CAP) in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from ambient air with continuous control of the atmosphere, using oxygen scavengers or a combination of total replacement of oxygen, non-respiring food, and impermeable packaging material.

“Cook-Chill Packaging” (CC) in which cooked food is hot filled into impermeable bags (usually as part of a total system), where the air is expelled and the bags are then sealed or crimped closed. The bags are rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic (capable of surviving in a cold environment) pathogens.

“Sous Vide Packaging” (SV) in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, served or rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

## **B. Concerns about ROP**

- Facultative bacteria (most food borne pathogens) grow under aerobic & anaerobic conditions.
- Most spoilage organisms are no longer “indicators” for temperature abuse (MAP modifies spoilage conditions allowing *Clostridium botulinum* to grow and produce toxin before signs of spoilage occur).
- Extended shelf life could allow bacteria that are “slow growers” to reach high numbers under refrigerated conditions.
- Secondary barriers, or hurdles, such as low pH or  $A_w$  (water activity) are not always possible with cook chill and sous vide packaging.
- Potential for temperature abuse at retail and in the home is great.
- Cooking and fermentation destroy most vegetative cells but spore forming organisms like *C. botulinum* survive.

## **C. The Primary ROP Barrier Against Food Borne Illness is Refrigeration**

- All potentially hazardous food (temperature control for safety food) requires refrigeration.
- Few treatments reliably destroy all pathogenic microorganisms in food except heat sterilization and irradiation.

- Other inhibitory factors or hurdles (pH or  $A_w$ ) used in combination with refrigeration can be equally effective at preventing spoilage and growth of foodborne illness pathogens.

#### **D. Acceptable Foods**

Foods placed in reduced oxygen packaging should be restricted to those which will not support the growth of *Clostridium botulinum* or *Listeria monocytogenes*. This would include but not be limited to:

- Foods with a water activity ( $A_w$ ) below .91.
- Foods with a pH (acidity) of 4.6 or less.
- Meat and poultry products (including cured products) produced and packaged at a food processing plant regulated by the USDA. Such products should be received and retailed in an intact package.
- Foods with high levels of non-pathogenic competing organisms (harmless bacteria) such as raw meat, raw poultry, or raw vegetables.
- Natural hard and semi-soft cheeses, and pasteurized processed cheeses. Examples, Cheddar, Gruyere, Parmesan, Reggiano, Romano, Blue, Edam, Gorgonzola, Gouda, and Monterey jack. *Also see page 8.* Soft cheeses such as Brie, Camembert, Ricotta, Cottage, and combinations of these cheeses with other ingredients such as vegetables, meat, or fish at retail **MAY NOT** be packaged under reduced oxygen without an approved variance because of their ability to support the growth of *L. monocytogenes* under modified atmosphere conditions.
- Commercially frozen foods, which do not meet the above criteria, provided they are conspicuously labeled "Keep Frozen Until Use."
- Commercially packed controlled atmosphere packages which maintain a reduced level of oxygen sufficient to control the growth of *Clostridium botulinum*. Written certification or independent laboratory analysis indicating the process and parameters for storage should be maintained with the product.

Except fish and fish products that are frozen before, during and after packing, fish (and seafood) may not be packaged using reduced oxygen packaging at retail. (This includes cook-chill and sous vide packaging of fish and fish products.)

Meat or poultry products which are smoked or cured at retail cannot be packaged using reduced oxygen packaging unless the review (and approval) has been conducted by the approving authority.

Product purchased for the purpose of repackaging should include stringent written product purchase specifications for the *Clostridium botulinum* control parameter, i.e. pH, water activity, nitrites, viable competing microbes, etc., which the original manufacturer of the product should meet.

## E. ROP Procedures

Reduced oxygen packaged foods packed at retail must be maintained at a temperature of 41°F or below. Retail packages should be prominently and conspicuously labeled “Keep refrigerated.”

Access to the reduced oxygen packaging equipment should be restricted to persons who have been trained on the equipment, the procedures and the concepts required for safe reduced oxygen packaging.

Written Hazard Analysis and Critical Control Point (HACCP) plan and Standard Sanitary Operating Procedures (SSOPs) must be developed, adhered to and monitored. These procedures should include steps to minimize opportunities for product adulteration and cross-contamination and should include the following components:

HACCP plan:

1. Hazards (both *Clostridium botulinum* and *Listeria monocytogenes* hazards must be considered)
2. Critical control points (refrigeration & secondary barrier such as appropriate Aw or pH)
3. Critical limits –
  - 41°F, secondary barrier (pH or Aw) and 30 day shelf life
  - 41°F, no secondary barrier and 7 day shelf life
  - 34°F, no secondary barrier and 30 day shelf life
  - Frozen with no shelf life restriction
4. Monitoring (except when used within 48 hours) - temperature continuously monitored electronically for cook-chill and sous vide products
5. Corrective actions (appropriate for safety)
6. Verification (if unable to verify, must discard)
7. Record keeping (held 6 months– for cooking, cooling, refrigeration)
  - Names of food(s) to be packaged using ROP
  - Critical control points documentation
  - Secondary barrier documentation in addition to refrigeration documentation for each food
8. Labeling
  - Storage temperature and shelf life (for product sold to consumers), or
  - Product name and preparation date for non-consumer packages
  - “Keep Refrigerated at 41°F or below” statement
  - “Use by” date of no more than 30 days from packaging, except the time the product is maintained frozen, or the original manufacture’s “sell by or “use by” date, whichever occurs first
  - Other required labeling – per COMAR 10.15.03.12, product name, ingredients in descending order, company name and address, net weight

## Standard Sanitary Operating Procedures

Training for food employees engaged in ROP is critical and must identify:

Procedures which must be followed;

1. Critical limits which must be met, monitored, have corrective actions if not met and record keeping;
2. Consequences of not meeting critical limits;
3. SSOPs (especially hand washing, no bare hand contact with ready-to-eat foods, cleaning and sanitizing food contact equipment); and
4. Dedicated work areas to separate raw and RTE foods.

\*\*Note, the HACCP plans and SSOPs must be submitted and approved prior to beginning ROP processing.

## Planning, Placement & Equipment

1. Equipment placement, effective use, care (cleaning and sanitizing) must follow the manufacturer's instructions.
2. Equipment uses should be designed to operate within the requirements of the establishment and, if applicable, should meet industry standards such as NSF or equivalent.

## Food Specific Requirements -

### Cook-Chill and Sous Vide packaging

1. Food must be cooked to heat all parts to a time and internal temperature specified in COMAR 10.15.03.10. (Note – Under-cooking is not permitted unless cooking times and temperatures are scientifically proven to the Department to be as effective at killing foodborne pathogens as those specified in the regulation.);
2. Food must be protected before and after cooking;
3. Food must be cooled in the sealed package to 41°F per the required cooling parameters (COMAR 10.15.03.11), and held at 41°F or less for no more than 7 days, or cooled to 34°F within 48 hours of reaching 41°F, and held at that temperature until consumed or discarded within 30 days after the date of packaging;
4. Refrigeration units must be continuously monitored electronically and visually examined twice daily;
5. Bagged product transported to a satellite location must have temperature monitored using verifiable monitoring;
6. Maximum shelf life after preparation -- 41°F for 7 days, 34°F for 30 days, or if held frozen with no shelf life;
7. Bags must be labeled with product name and date packaged;
8. Cooling and refrigeration temperature records must be held 6 months and made available to the regulatory authority;
9. Review is required if the process deviates from the approved process; and

10. Product must be prepared and consumed on premises, or prepared and consumed off premises but within the same business entity. The distribution or sale of packaged cook-chill and sous vide foods to another business or consumer is prohibited.

#### Vacuum Packaged Cheeses

1. Only cheeses that meet the Standard of Identity for hard cheeses (21 CFR 133.150), semisoft cheeses (21 CFR 133.187) and pasteurized process cheeses (21 CFR 133.169) may be vacuum packaged in food establishments;
2. Soft cheeses such as Brie, Camembert, Ricotta, Cottage and Teleme **MAY NOT** be vacuum packaged in a food establishment;
3. A HACCP plan and SSOPs must be implemented;
4. Label must bear a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date; and
5. Any cheese packages that are not consumed or sold within 30 days must be discarded.

**\*\*Note** - A HACCP plan, as detailed above, and SSOPs are not required when a food establishment uses a reduced oxygen packaging method to package potentially hazardous food (time/temperature control for safety food) that is always:

1. Labeled with the production time and date,
2. Held at 41°F or less during refrigerated storage, and
3. Removed from its package in the food establishment within 48 hours after packaging.

The HACCP plan must, however, comply with COMAR 10.15.03.33.

#### **F. Facility Inspection of ROP Process Inspection**

1. Review of the written HACCP plan;
2. Confirm staff has received training according to the HACCP plan/SSOPs;
3. Observe preparation of food;
4. Observe packaging of food;
5. Clean and sanitized equipment, utensils, supplies;
6. Dedicated work areas for raw and prepared foods;
7. Examine seal, determine if seal is complete – no debris in seal;
8. No cross-contamination;
9. Storage of equipment, utensils, and packaging material is appropriate;
10. Labels have necessary information;
11. Examine storage & display of product for sale or use;
12. Appropriate storage temperature (41°F, 34°F or frozen);
13. No packages held past appropriate shelf life;
14. Examine expiration dates on packages in storage and on display;
15. Confirm product is discarded beyond the appropriate expiration date;
16. Continuous electronic monitoring for Cook-Chill or Sous Vide, if held for more than 48 hours;
17. Records kept 6 months for electronic monitoring;
18. Confirm that product temperatures are visually examined twice daily; and

19. Records Review -

- Pick 3-4 packages from storage or display
- Choose different lots or expiration dates, if possible
- Is the required information on the label?
- Are corresponding records available for each lot?
- Has all the information required by the HACCP plan been recorded on the log sheet or on the computer records?
- Were there any instances that corrective action was required?
- Was the corrective action done?