
MEMORANDUM

TO: FOOD PROGRAM
FROM: FRANK GREENE, DIRECTOR, DIVISION OF FOOD & STANDARDS
SUBJECT: POLICY COMPLIANCE GUIDELINES FOR REDUCED OXYGEN PACKAGING AT RETAIL
DATE: APRIL 26, 2011

A. Defining Reduced Oxygen Packaging

“Reduced Oxygen Packaging” (ROP) means:

(i) 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

(ii) 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” (CCP) in which cooked food is hot filled into impermeable bags (usually as part of a total system), where the air 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 pathogens, and,

“Sous Vide Packaging” (SVP) 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 aW (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 aW) 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*. This would include but not be limited to:

- ❖ Foods with a water activity (aW) below .91.
- ❖ Foods with a pH (acidity) of 4.6 or less.

- ❖ Meat products produced and packaged under the auspices of the USDA's Meat Inspection Program in a USDA regulated establishment. 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 fermented natural hard and semi-soft cheeses containing live starter culture organisms. (Ricotta, cottage cheese, cheese spreads and combinations of cheese and other ingredients such as vegetables or meat are examples of cheese products which should not be packaged.)
- ❖ 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*.
- ❖ Certification or independent laboratory analysis in writing indicating the process and parameters for storage (should be maintained with the product).

Fish and fish products (except frozen product) should not be packaged in reduced oxygen containers at retail. In addition, meat or poultry products which are smoked or cured at retail should not be packaged in reduced oxygen containers unless a review has been conducted by either Consumer Protection or the local health department. Such product should be date marked and either sold or discarded in conformance with guidance specified in the most current FDA Model Food Code www.fda.gov/food/foodsafety/retailfoodprotection/foodcode.

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 should 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) should 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 14 day shelf life
 - ❖ 34°F, no secondary barrier and 30 day shelf life
 - ❖ 38°F, no secondary barrier and 72 hr. shelf life
4. Monitoring (temperature continuously monitored electronically)
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 14 days after packaging (or 30 days for certain cheeses)
 - ❖ Other required labeling – 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:

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

Planning, Placement & Equipment

1. Care should be taken with respect to placement of the product in the context of the manufacturer's recommendations and effective use, cleaning and sanitizing of the equipment,
2. Equipment uses should be designed to operate within the requirements of the establishments and if applicable should meet industry standards such as NSF or equivalent,

Food Specific Requirements -

Cook chill and sous vide packaging

1. Refrigeration units must be continuously monitored electronically and visually examined twice daily
2. Bagged product transported to a satellite location must have temperature monitored using verifiable monitoring
3. Maximum shelf life at 34°F (if not frozen) is 30 days after preparation
4. Bags must be labeled with product name and date packaged
5. Cooling and refrigeration temperature records must be held 6 months and made available to the regulatory authority
6. Review is required if the process deviates from the manufacturer's system

Vacuum Packaged Cheeses

1. Only cheeses that meet the Standard of Identity for hard cheeses (21 CFR 133.150), semi-soft cheeses (21 CFR 133.187) and pasteurized process cheeses (21 CFR 133.169) may be vacuum packaged in food establishments without prior review.

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
5. Any cheese packages that are not consumed or sold within 30 days must be discarded

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, packaging materials is appropriate
10. Labels have necessary information
11. Examine storage & display of product for sale or use
12. Appropriate storage temperature (41°F, 38°F or 34°F)
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
17. Records kept 6 months for electronic monitoring

18. Confirm that product temperatures are visually examined twice daily

19. Records Reviews -

- ❖ 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

G. Enforcement

Failure to adhere to the foregoing guidelines may result in a Department of Consumer Protection determination that the product in question is adulterated and in violation of the Connecticut Uniform Food & Drug.