

What is Reduced Oxygen Packaging and What are the Food Safety Concerns & Controls?

By
Shirley B. Bohm, MPH
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

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Reduced Oxygen Packaging

- Considerations:
 - What is ROP
 - Benefits and concerns for ROP
 - Microbiology & pathogens of concern for ROP
 - Gases associated with ROP and their uses
 - ROP packaging materials & equipment
 - Barriers, hurdles & controls for pathogens
 - How to conduct an ROP inspection



ROP Changes in the 2005 Food Code

(Definition) “Reduced Oxygen Packaging” 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 surrounding, 21% oxygen atmosphere, and
- (ii) A process as specified in the Subparagraph (a)(1) of this definition that involves a food for which the hazards of ***Clostridium botulinum*** and ***Listeria monocytogenes*** require control in the final packaged form. *(new)*



ROP Changes in the 2005 Food Code

Vacuum packaging, 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, 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; and



ROP Changes in the 2005 Food Code

Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, non-respiring food, and impermeable packaging material.



ROP Changes in the 2005 Food Code

Cook chill packaging, 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. (new)

Sous vide packaging, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens. (new)



ROP Changes in the 2005 Food Code

- In 3-501.12 Reduced Oxygen Packaging, Criteria* (New)
 - Both *Clostridium botulinum* and *Listeria monocytogenes* must be considered as hazards of concern
 - Criteria for cook chill and sous vide packaging without a variance added
 - Criteria for packaging certain cheeses under reduced oxygen without a variance added



Benefits of ROP

- Extends shelf life of packaged food
- Reduces need for skilled labor
- Provides more consistent quality
- Takes less time for preparation
- Results in less mess, fewer dirty utensils
- Takes less time to prepare
- Portion control problem eliminated



Concerns about ROP

- Facultative bacteria (most foodborne pathogens) grow under aerobic & anaerobic conditions
- Most spoilage organisms are no longer “indicators” for temperature abuse
- Extended shelf life could allow “slow growers” to reach high numbers under refrigerated conditions
- Secondary barriers such as low pH or a_w 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 formers survive



General Controls for ROP Hazards

- Additional controls built into the Code:
 - Minimize bacterial load with HACCP & SSOPs
 - Use the “hurdles” or barrier concept with refrigeration
 - Store cook chill and sous vide products at 34°F if no other hurdles are present
 - Cannot sell cook chill or sous vide bagged product to customers
 - ROP fish only if frozen before, during and after ROP
 - Place 14 or 30 day “use by” dates on labels to limit shelf life



ROP Pathogens of Concern

- *Clostridium botulinum* – spore former, obligate anaerobe, is a concern with ROP foods.

– Minimal growth requirement for *C. botulinum*

<u>Property</u>		<u>Group I</u>		<u>Group II</u>
		Proteolytic	Non-Proteolytic	
		Type A, B, F		Type B, F, E
Inhibitory pH	4.6	5.0		
Inhibitory NaCl		10%		5%
Minimum a_w		0.94		0.97
Temp. optimum		98°F		86°F
Temp. range		50 -118°F	38 -113°F	
Toxin production		≥ 50°F		≥ 38°F



ROP Pathogens of Concern

- *Why is Listeria monocytogenes* a concern in ROP?
 - **Conditions for LM growth:**
 - $\leq 10\%$ salt
 - 5-10 % O₂
 - pH 4.1 – 9.6
 - a_w 0.90 - 0.93
 - 28°F - 122°F
 - **LM can survive months in a moist environment - steam from cooking, dishwashing machines, pressure sprayers.**
 - **LM competes well with other organisms, especially at refrigeration temperatures**
 - **LM is more heat resistant than most vegetative pathogens – a concern with lightly cooked foods**



Gas Component(s) of ROP

- Normal atmosphere – 21% O₂, 0.03% CO₂, (remainder is N₂, trace gases, water vapor)
- Back flushing with CO₂, N₂, O₂, CO
 - CO₂ is antimicrobial, 5-10% inhibits spoilage organisms, anaerobes unaffected
 - O₂ speeds growth, ripening, aging, inhibits anaerobes, is necessary for spoilage indicators
 - N₂ is inert, a filler gas, decreases rancidity
 - CO protects color, is GRAS, no labeling required, no CO remains after opening package



ROP Absorbents & Packaging

- Absorbents (Scavengers)
 - Easily oxidizable compound, used in CAP
 - Absorbs O₂, ethylene, moisture, etc.
 - Contained in sachet, label or packaging materials
- Packaging
 - Non-transmissible to O₂
(at 10-100 cc O₂/m²/24hrs)
 - Hermetic seal
 - Layered for different properties (strength, flexibility, moisture control, etc.)



ROP in Food Establishments

Cook Chill Packaging

- Hot filling bags by hand



ROP in Food Establishments

Cook Chill Packaging

- Seal-a-Meal machine used to make the hermetic seal



ROP in Food Establishments

Cook Chill Packaging

- Rapid chilling in a tote with ice water



ROP in Food Establishments

Cook Chill Packaging

- Storage in the walk-in cooler at 38°F



ROP in Food Establishments

Cook Chill Packaging

- Rethermalizing or reheating bagged product in hot water



ROP in Food Establishments

Cook Chill Packaging

- Cook Chill Packaging – High Capacity Feeding



ROP in Food Establishments

Cook Chill Packaging

- Tumble Chiller to drop product temperature rapidly



ROP in Food Establishments

Cook Chill Packaging

- Tumble chiller cools 200+ bags (1 gal.) to 39°F in 1 hr.



ROP in Food Establishments

Cook Chill Packaging

- Cook Chill Packaging – Labeling Bags



ROP in Food Establishments

Cook Chill Packaging

- Cook chill packaging – warehouse storage of bagged product at 29°F



ROP in Food Establishments

Vacuum Packaging

- Vacuum Packaging in a Pouch – Table Top Machine



ROP in Food Establishments

Vacuum Packaging

- Vacuum Packaging – Placing Filled Pouch in the Machine



ROP in Food Establishments

Vacuum Packaging

- Vacuum Packaging – Sealing the Pouch



ROP in Food Establishments

Vacuum Packaging

- Vacuum packaged fish – must be frozen before, during and after vacuum packaging



ROP Controls in Food Establishments

- The Primary ROP Barrier 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 (hurdles) used in combination with refrigeration can be equally effective at preventing spoilage and growth of foodborne illness pathogens.



ROP Controls in Food Establishments

- Secondary barriers or hurdles with refrigeration at $\leq 41^{\circ}\text{F}$ (“Hurdle Effect”)
 - pH or acidity ≤ 4.6
 - Natural
 - Acidification
 - Fermentation
 - Water activity (a_w) ≤ 0.91
 - Dried products (jerky, dry fermented sausage)
 - High salt or sugar concentration
 - Cured meat or poultry products
 - Salt added at 3.5%
 - Nitrite (inhibits spore germination and toxin production by *Clostridium botulinum*)



ROP Controls in Food Establishments

- Freezing (required for fish)
 - Surveillance sampling showed 21.7 - 66.7% of fish samples are contaminated with ***Clostridium botulinum*** (A, B, E or F)
 - Normal spoilage tells consumers not to eat product (too old, temperature abused, etc.), BUT
 - MAP modifies spoilage conditions to allow ***Clostridium botulinum*** to grow and produce toxin before signs of spoilage occur.

ROP Controls in Food Establishments

- Live competing organisms
 - Spoilage organisms
 - grow faster than pathogens
 - out compete for nutrients
 - Fermentation by lactic acid bacteria
 - Metabolic products inhibit
 - Starter cultures give “jump start”
 - Effective against *E. coli*, *Salmonella*, *Clostridium botulinum*, *Listeria*, *Staphylococcus aureus*



ROP Controls in Food Establishments

- **Intrinsic factors present in certain cheeses (hard, semi-soft and pasteurized process cheese)**
 - Lowered pH
 - Organic acids
 - Hydrogen peroxide
 - Natural antibiotics or bacteriosins (nisin)
 - Salt (added during processing)
 - Lower water activity
 - Added preservatives (pasteurized process cheese)
 - Live competing cultures
 - Low redox potential (Eh)
- **Extrinsic factors (certain cheeses)**
 - Temperature at 41°F or less
 - ROP including VP, MAP



ROP Controls in Food Establishments

- Cook Chill/Sous Vide products must remain under control of Food Establishment
 - Used On the premises
 - Satellite operations owned solely by operator
- Why home storage temperatures are in doubt
 - Audits International data
 - **25% of home refrigerators are above 45 ° F**
 - **10% are above 50°F**
 - Van Garde & Woodburne
 - **27% of home refrigerators are above 50°**



ROP Controls in Food Establishments

- Written HACCP plan and SSOPs (prior approval not required)
 - HACCP plan
 - Hazards (both *Clostridium botulinum* and *Listeria monocytogenes* must be considered)
 - Critical control points (refrigeration & secondary barrier)
 - Critical limits
 - 41°F , secondary barrier 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 (2006 CFP)
 - Monitoring (temperature continuously electronically monitored)
 - Corrective actions (appropriate for safety)
 - Verification (if unable to verify, must discard)
 - Record keeping (held 6 months for CC & SV records – for cooking, cooling, refrigeration)



ROP Controls in Food Establishments

- HACCP plan must contain:
 - Names of food(s) to be packaged using ROP
 - Critical control points
 - Secondary barrier in addition to refrigeration for each food
 - Labeling that identifies storage temperature and shelf life (for product sold to consumers) or product name and preparation date for SV and CC.
 - **“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**



ROP Control in Food Establishments

- Standard Sanitary Operating Procedures
 - Training for food employees engaged in ROP is critical and must identify:
 - **Procedures which must be followed**
 - **Critical limits which must be met, monitored, have corrective actions if not met and record keeping**
 - **Consequences of not meeting critical limits**
 - **SSOPs (especially hand washing, no bare hand contact with ready-to-eat foods, cleaning and sanitizing food contact equipment)**
 - **Dedicated work areas to separate raw and RTE foods**
 - Handwashing & no bare hand contact with RTE foods



ROP Controls for Cook Chill & Sous Vide

- **Cook chill and sous vide packaging require NO VARIANCE, provided Food Code criteria are met in 3-502.12(D): (new)**
 - Implementation of a HACCP plan
 - Prepared and consumed on the premises or in a satellite operation within the same business entity – no direct sale of bagged product to the public or another business
 - Cooked to the required temperature for that food
 - Protected from contamination.
 - Placed in an oxygen barrier bag just after or just prior to cooking and sealed
 - Cooled to 41°F according to time and temperature requirements, then cooled to 34°F within 48 hrs.
 - Can be removed to a 41°F cooler for no more than 3 days, or
 - Can be held for 72 hrs at 38°F after packaging (2006 CFP)



ROP Controls

for Cook Chill & Sous Vide

- **Cook chill and sous vide packaging requires NO variance, provided Food Code criteria are met in 3-501.12(D) - cont'd: (New)**
 - Refrigeration units must be continuously monitored electronically and visually examined twice daily using, for example:
 - Thermocouple data loggers
 - Recording charts
 - Temperature monitor & alarm systems to activate an alarm or dialer
 - (Nickel-sized) data loggers with software to display temperatures



ROP Controls in e Food Code for Cook Chill and Sous Vide

- **Cook chill and sous vide packaging requires NO variance, provided Food Code criteria are met in 3-501.12(D) – cont'd: (New)**
 - Bagged product transported to a satellite location must have temperature monitored using verifiable electronic monitoring
 - Maximum shelf life at 34°F (if not frozen) is 30 days after preparation
 - Bags must be labeled with product name and date packaged
 - Cooling and refrigeration temperature records must be held 6 months and made available to the regulatory authority
- Any change in the cook chill or sous vide operation that varies from the criteria provided in 3-501.12(D) will require variance approval by the regulatory authority



ROP Controls for Vacuum Packaging Cheese

- **Specific criteria to vacuum package certain cheeses are found in 3-502.12(E) in the Food Code: (New)**
 - **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 a variance.**
 - **Soft cheeses such as Brie, Camembert, Ricotta, Cottage and Teleme MAY NOT be vacuum packaged in a food establishment**
 - **A HACCP plan and SSOPs identified in 3-502.12(B) must be implemented**
 - **Label must bear a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date**
 - **Any cheese packages that are not consumed or sold within 30 days must be discarded**



Facility Inspection of ROP Process

- After review of the written HACCP plan, observe preparation of food
 - Is it in compliance with the HACCP plan?
 - Is it in compliance with the Food Code?
- Observe packaging of food
 - Clean and sanitized equipment, utensils, supplies
 - Dedicated work areas for raw and prepared foods
 - Seal is complete – no debris in seal
 - No cross-contamination
 - Labels have necessary information



Facility Inspection of ROP Process

- Storage & display of product for sale or use
 - Appropriate storage temperature (41°F, 38°F or 34°F)
 - No packages held past appropriate shelf life
 - Examine expiration dates on packages in storage and on display
 - Discarded if beyond the appropriate expiration date
 - Continuous electronic monitoring for CC/SV
 - Records kept 6 months for electronic monitoring
 - Visually examined twice daily (when? Who?)
 - **No CC/SV product sold to another business entity or to the public in bagged/packaged form**



Facility Inspection of ROP Process

- Storage of equipment, utensils, packaging materials
 - **Protected from contamination**
 - **Bags stored off the floor and protected from splash and condensation (often a source of *Listeria*)**
 - **Hoses used to pump product from kettles to filler heads in cook chill operations are stored clean, off the floor and in a self-draining position between uses**
 - **All equipment cleaned and sanitized (check hoses)**
- Ask employees who use the ROP process about their training
 - **Confirm they received training according to the HACCP plan/SSOPs**



Facility Inspection for ROP Process

- 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?

