**Conference for Food Protection**

**2012 Issue Form**

**Internal Number: 093**

**Issue: 2012 III-014**

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| **Council Recommendation:** | Accepted as  Submitted |  | Accepted as Amended |  | No Action |  |
| **Delegate Action:** | Accepted |  | Rejected |  |  |  |

*All information above the line is for conference use only.*

**Title:**

ROP 6: Updates to 2009 Food Code Annexes 2 and 3

**Issue you would like the Conference to consider:**

The Reduced Oxygen Packaging (ROP) Committee recommends adopting the ROP Committee's changes to Annex 3, Public Health Reasons as listed in the 'Supplemental Information' attachment to the 2012 CFP issue titled Report - ROP Committee (ROP 1).

The Committee further recommends inclusion of the references cited in the 'Supplemental Information' attachment to the 2012 CFP issue titled Report - ROP Committee (ROP 1).

**Public Health Significance:**

The changes to Public Health Annex 3 and references for Annex 2 as recommended in the 'Supplemental Information' attachment to the 2012 CFP issue titled Report - ROP Committee (ROP 1) to help further clarify the ROP Committee's rationale in the proposed changes to the 2009 Food Code as they relate to ROP, and also provide guidance to the regulatory authority when evaluating a food establishment's reduced oxygen packaging procedures that are conducted without a variance or prior approval.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to the FDA requesting the Annex to the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

1. include the references cited in the Committee's report into Food Code Annex 2; and
2. include the changes to the Food Code's Public Health Annex 3 as recommended by the ROP Committee and as listed below (using underlining for additions and strike through for language elimination):

FDA Food Code 2009: Annex 3 - Public Health Reasons / Administrative Guidelines - Chapter 3, Food

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cc/m2 ~~cm~~~~2~~~~/m~~~~3~~/24 hours or greater[i]. A reduced oxygen atmosphere will often result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

If packaging material OTR is to be used as a barrier to C. botulinum growth and an exemption from ROP HACCP requirements in sections 3-502.11 and 3-502.12 the operator must provide scientific evidence to the regulatory authority that the packaging, under it's intended use, maintains an oxygen atmosphere for the duration of the refrigerated shelf life. At the time of this writing, only one packaging product possesses an OTR greater than 10,000 cc/m2/24h with scientific evidence acceptable to the FDA that it maintains an aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of C. botulinum could develop[ii].

Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic C. botulinum and L. monocytogenes are able to multiply slowly ~~well~~ below 5°C (41°F). For this reason, C. botulinum and L. monocytogenes become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of C. botulinum and L. monocytogenes without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control C. botulinum and L. monocytogenes when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include aw of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. C. botulinum will not produce toxin below an aw of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of C. botulinum spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of C. botulinum and L. monocytogenes.

Non-potentially hazardous food (non-time/temperature control for safety food) as defined by interaction tables A and B (section 1-201.10) contain pH and Aw intrinsic factors that prevent the growth of both C. botulinum and L. monocytogenes. Therefore these foods are exempt from the reduced oxygen packaing HACCP requirements of 3-502.11 or 3-502.12 provided they are as received and not modified in the operation and labeled as non-potentially hazardous foods.[iii]

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of L. monocytogenes under modified atmosphere conditions.

When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as aw, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of C. botulinum and L. monocytogenes. Non-proteolytic C. botulinum spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by C. botulinum, an anaerobe, ROP foods must be held at 3°C (38°F) or less. Listeria monocytogenes is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Cooking at low temperatures below that stated in 3-401.11 (A-C) may not destroy vegetative cells and may in fact become an incubation temperature for some pathogens. Any use of these low cooking temperatures combined with ROP packaging must be approved via the variance process[iv].

Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 5°C (41°F), ~~1°C (34°F), removing product to a different refrigeration unit~~ and holding at any temperature up to 5°C (41°F) for up to 7 days ~~72 hours~~ ~~with the total storage time not to exceed 30 days~~[v]. ~~This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less~~.[vi] The third option relies on a secondary barrier, pH. When the pH is at or below 5.0 C. botulinum and L. monocytogenes cannot grow at 5oC (41oF). Therefore, 30 days storage is permitted. Note that when using pH as a barrier, a pH measurement, calibration and recordkeeping SOPs are required. ~~is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.~~[vii] The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.

Since there may not be ~~are no~~[viii] other controlling factors for C. botulinum and L. monocytogenes in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or 5°C (41°F) ~~3°C (38°F)~~ or less[ix]. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Time is also a factor that must be considered in ROP. Processes that use ROP packaging for storage less than 48h do not pose a hazard for pathogen growth when refrigerated at 5°C (41°F) or less and are exempt from the HACCP requirement of sections 3-502.11 and 3-502.12. Examples are sous vide cooking provided a proper cooking temperature is used according to 3-401.11 (A-C) followed by immediate service and enhanced cooling of foods using ROP bags. The main factors in this exemption are that the food must be date marked and consumed or removed from packaging after 48h[x]. The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process or inhibiting their growth, preventing recontamination, and then refrigerating at 34°F or less ~~with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements~~. The 7 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 5°C (41°F) or less[xi]. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.

A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. C. botulinum and L. monocytogenes are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe. It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate the scientific evidence the ROP methodology intended for use is safe[xii].

Unfrozen raw fish and other seafood are specifically excluded from ROP without a variance[xiii] because of these products' natural association with C. botulinum type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

[i] Corrects inaccurate description of OTR to that found in the US FDA Fisheries HACCP Guide.

[ii] Suggested text to clarify 10 K bag exclusion. Would require variance for all uses other than that approved by FDA Seafood HACCP Guidance for raw seafoods.

[iii] Adds text to clarify non-PHF exclusion from ROP HACCP 3-502.11 or 3-502.12.

[iv] Added text to clarify low temperature cooking processes, e.g. sous vide to obtain a variance.

[v] Changes this section to accommodate changes made to 3-502.12 (D)(2)(e).

[vi] Just deleting this text. It appears extraneous.

[vii] Corrects text to accommodate changes made to 3-502.12 (D)(2)(e)(iii).

[viii] Correct text to acknowledge that there may be other controlling factors.

[ix] The 38oF option has been deleted.

[x] This may need to be tweaked somewhat after the committee finalizes the definition change that establishes the 48 h storage point.

[xi] Clarifies this section to permit the 7 day at 41F code change.

[xii] This change was discussed by the committee and I am suggesting placing it here.

[xiii] Corrects text that implies ROP of non-frozen fish with a variance is not permitted.

**Submitter Information:**

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