

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 III-034

Council Recommendation: Accepted as Submitted _____ Accepted as Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Reducing the need for HACCP Plans Under 3-502.12

Issue you would like the Conference to consider:

Re-evaluate the list of foods and activities that require a variance and Hazard Analysis Critical Control Point (HACCP) plan for reduced oxygen packaging in Section 3-502.12 of the 2013 FDA Food Code and remove foods that do not present a hazard that is likely to occur for *Clostridium botulinum* and *Listeria monocytogenes* growth.

Public Health Significance:

The removal of raw meats and raw poultry, hard and semi-soft cheeses, and shelf stable products from the list of foods that require a HACCP plan and variance will be beneficial to both the regulated food establishment and the regulatory authority, without increasing the risk of foodborne illness.

Most foodborne pathogens do not compete well with the other microorganisms. So foods such as raw meat, raw poultry and raw vegetables, that have a high level of spoilage organism do not present a significant hazard from *Clostridium botulinum* or *Listeria monocytogenes*. As identified in the Annex of the Food Code hard, pasteurized and semisoft cheeses "contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C or less...Very few outbreaks have occurred that were associated with cheese."

In foods that are shelf stable (non-time/temperature controlled for safety food) by Table B in the Food Code, *Clostridium botulinum* or *Listeria monocytogenes* are controlled by low water activities, low pH values, or a combination of lower water activities and low pH.

The USDA considers the use of reduced oxygen packaging a protective practice, one that prevents cross contamination between workers and the establishment and the food.

Foods such as raw meats, raw poultry, raw vegetables, hard cheeses, semi soft cheese, and shelf stable foods pose very low risk once they are reduce oxygen packaged at retail. Unnecessary HACCP plans and variances are cumbersome and time consuming for both

the regulatory authority and the food establishment. A reduction in the paper work resulting in stream lining of this process would allow regulators and food establishments alike to focus on higher risk activities.

If *Clostridium botulinum* or *Listeria monocytogenes* are controlled then the risk is low for reduced oxygen packaging

Recommended Solution: The Conference recommends...:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (new language is underlined; language to be deleted is in strikethrough format):

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

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.^p

(B) Except as specified under (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under 8-201.14 (B) and (D) and that:^{pf}

(1) Identifies the FOOD to be PACKAGED;^{pf}

(2) Except as specified under (C) -(E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:^{pf}

(a) Has an AW of 0.91 or less,^{pf}

(b) Has a PH of 4.6 or less,^{pf}

(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, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE,^{pf} or

~~(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables;~~^{pf}

(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:^{pf}

(a) Maintain the FOOD at 5°C (41°F) or below,^{pf} and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;^{pf}

(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;^p

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under 3-301.11(B),^{pf}

(b) Identify a designated work area and the method by which: ^{pf}

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, ^{pf} and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, ^{pf}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, ^{pf}

(b) EQUIPMENT and facilities, ^{pf}and

(c) Procedures specified under Subparagraph (B)(5) of this section and 8-201.14 (B) and (D). ^{pf}

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. ^p

(D) Except as specified under (C) and (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under 8-201.14 (B) and (D); ^{pf}

(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; ^{pf}

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under 3-401.11 (A), (B), and (C), ^p

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4, ^p

(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 57°C (135°F), ^p

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and: ^p

(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; or ^p

(iii) Held frozen with no shelf life restriction while frozen until consumed or used. ^P

(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, ^{pf}

(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, ^{pf} and

(h) Labeled with the product name and the date PACKAGED; ^{pf} 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, ^{pf} and

(b) Hold such records for at least 6 months; ^{pf} and

(4) Implement written operational procedures as specified under Subparagraph (B) of this section and a training program as specified under Subparagraph (B)(6) of this section. ^{pf}

~~(E) Except as specified under (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:~~

~~(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT 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 that contains the information specified under 8-201.14 (B) and (D) and as specified under (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;~~

~~(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 REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.~~

~~(E)(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE method to package time/temperature control for safety food that is always:~~

~~(1) Labeled with the production time and date, A FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables~~

~~(2) Held at 5°C (41°F) or less during refrigerated storage, and Cheese~~

~~(i) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT 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;~~

~~(ii) 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~~

~~(iii) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.~~

(3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING. Non-time temperature controlled for safety foods as defined in Table B (Interaction of pH and Aw for control of vegetative cells and spores in food not heat treated of heat treated but not packaged).

(i) Foods packaged limited to those that are commercially manufactured in a food processing plant with no ingredients added in the Food Establishment that would change the nature of the product.

(ii) Non-time temperature controlled for safety foods as defined by Table B, produced in the Food Establishment in accordance with a Variance submitted to the Regulatory authority in accordance with 3-502.11.

(4) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *that is always:*

(i) Labeled with the production time and date.

(ii) Held at 5°C (41°F) or less during refrigerated storage, and

(iii) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

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