

Inspection Report Item 29: Compliance with Variance, Specialized Process, Reduced Oxygen Packaging Criteria, and HACCP Plan

FDA Food Code References: 3-502.11, 3-502.12, 8-201.13, 8-201.14

Special Processes and HACCP

Certain ways of preparing food are more likely to cause foodborne illness. Hazard Analysis and Critical Control Points, known as HACCP, are a way of making sure that food will be safe to eat by following a strict method of preparation that is proven to maintain safety.

Requirements:

You will need a HACCP plan and/or variance if you wish to do special processing in your licensed kitchen. These processes include:

- Curing with nitrates/nitrites
- Smoking foods for preservation
- Acidification to prolong shelf life
- Custom processing of animals
- Reduced oxygen packaging and sous vide cooking
- Maintaining a live holding tank for shellfish
- Sprouting Seeds
- Fermentation



Acidification means lowering the pH in a food using chemical or microbiological means so the pH is less than 4.2 in foods not heat treated or heat treated but not packaged or so the pH is 4.6 or less in foods that are heat treated and packaged.

Curing refers to various food preservation and flavoring processes, especially meat, poultry or fish by the addition of a combination of salt, nitrates, nitrites, curing accelerants and flavoring.

Custom processing of animals- Holding and slaughter of animals in retail food establishments for sale or service is limited to animals that are not amenable to (or named in) USDA's Federal Meat and Poultry Products Inspection Acts.

Drying is a method of preserving meat, poultry, fish and other foods by removing moisture. Examples of drying include: Salting, dehydrating.

Fermentation, most often caused by lactic acid bacteria, is a process where bacteria and/or yeast converts carbohydrates (sugars) to organic acids or alcohols and carbon dioxide.

Reduced oxygen packaging means reducing 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.

Smoking is the application of smoke from wood, sawdust or similar materials as a method of preservation and to add flavor to meat, poultry and fish.

Sprouting is the process of seed germination and growth of the sprout for food. Sprouts which grow beyond the first set of primary leaves are considered microgreens (which are harvested above the seed).

A variance is written permission from the State of Iowa Department of Inspections and Appeals to vary from the provisions in the food code. You will need to provide information on how you will ensure food safety.

Applicable 2013 FDA Food Code Sections

Specialized Processing Methods

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under

§ 8-103.11 before: ^{Pf}

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; ^{Pf}

(B) Curing FOOD; ^{Pf}

(C) Using FOOD ADDITIVES or adding components such as vinegar: ^{Pf}

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, ^{Pf} or

(2) To render a FOOD so that it is not TIME/
TEMPERATURE CONTROL OF SAFETY FOOD; ^{Pf}

(D) Packaging TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method *except where the growth of and toxin formation by **Clostridium botulinum** and the growth of **Listeria monocytogenes** are controlled as specified under § 3-502.12;* ^{Pf}

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption; ^{Pf}

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; ^{Pf}

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; ^{Pf} or

(H) Sprouting seeds or beans. ^{Pf}

Applicable 2013 FDA Food Code Sections

Clostridium botulinum and Listeria monocytogenes Controls

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
- (6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:^{Pf}
- (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).

Fish

(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

Cook-Chill or Sous Vide

(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; ^P

(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; ^P or

(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)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section. ^{Pf}

Cheese

(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; ^P

(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; ^{Pf}

(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; ^{Pf} 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. ^{Pf}

(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is always:

- (1) Labeled with the production time and date,
- (2) Held at 5°C (41°F) or less during refrigerated storage, and
- (3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

Iowa Administrative Code 481-31 amends code section 3-502.12 by adding:

“A HACCP PLAN is not required when a FOOD ESTABLISHMENT packages raw meat and poultry using a REDUCED OXYGEN PACKAGING method and includes on the package a 30-day “sell by” date from the date the raw meat or poultry was packaged.

When do I need a HACCP Plan?

Facility and Operating Plans

8-201.13 When a HACCP Plan is Required.

(A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:

- (1) Submission of a HACCP PLAN is required according to LAW;
- (2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or ¶ 4-204.110(B);
- (3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) Before engaging in REDUCED OXYGEN PACKAGING without a VARIANCE as specified under § 3-502.12, a PERMIT applicant or PERMIT HOLDER shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY.

What does my HACCP Plan need to contain?

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY; ^{Pf}

(B) A flow diagram by specific FOOD or category type identifying CRITICAL CONTROL POINTS and providing information on the following:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, ^{Pf} and

(2) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved; ^{Pf}

(C) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern; ^{Pf}

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each CRITICAL CONTROL POINT, ^{Pf}

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT, ^{Pf}

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE, ^{Pf}

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS, ^{Pf}

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, ^{Pf} and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; ^{Pf} and

(E) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY; ^{Pf}