

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/or 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, Appeals, and Licensing (DIAL) to vary from the provisions in the food code. You will need to provide information on how you will ensure food safety

What is a Variance?

A “Variance” is a written document issued by the Regulatory Authority that authorizes a modification or a waiver of one or more requirements of the [Iowa Food Code](#) or [FDA Food Code](#), if in the opinion of the Regulatory Authority, a health hazard or nuisance will not result from allowing the activities detailed within the modification or waiver. The decision to grant or deny a variance request will be based on the best available information and science submitted by the applicant or sought out by the **Iowa Department of Inspections, Appeals, and Licensing Food Safety Bureau** at the time the decision is made.

8-103.10 Variances Modifications and Waivers

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

When is a Variance Required?

A “Variance” is required, and should be requested, when the retail food establishment Standard Operating Procedure (SOP) goes outside the requirements of the [Iowa Food Code](#) or [FDA Food Code](#) as detailed in the sections 8-103.11 and 8-103.12, or when the retail food establishment conducts an operation that is not addressed by the FDA Food Code as referenced in section 3-502.11.

Code 8-103.11 Documentation of Proposed Variance and Justification.

Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY’S file on the FOOD ESTABLISHMENT includes:

- (A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;
- (B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and
- (C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.

Code 8-103.12 Conformance with Approved Procedures.

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

- (A) Maintain the APPROVED VARIANCE at the FOOD ESTABLISHMENT; and
- (B) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; and
- (C) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;
 - (1) Procedures for monitoring the CRITICAL CONTROL POINTS,
 - (2) Monitoring of the CRITICAL CONTROL POINTS,
 - (3) Verification of the effectiveness of the operation or process, and
 - (4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

What Types of Food and/or Processing Methods Require a Variance?

Specialized food processing methods are not allowed by the food code unless certain criteria is met. Code section 3-502.11 states the food processing methods that are not allowed by the Food Code without an approved variance request.

3-502.11 Specialized Processing Methods 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:

- (A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;
- (B) Curing FOOD (which 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).
- (C) Using FOOD ADDITIVES (which means using chemical or microbiological means such as food additives) or adding components such as vinegar:
 - (1) As a method of FOOD preservation rather than as a method of flavor enhancement, or
 - (2) To render a FOOD so that it is not TIME/TEMPERATURE CONTROL OF SAFETY FOOD;
- (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. (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.);
- (E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;
- (F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT;
- (G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or
- (H) Sprouting seeds or beans (which 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).

In addition, certain raw or undercooked animal foods as described in Code 3-401.11(D) - (Serving raw animal foods to a Highly Susceptible Population) also require a variance.

What Types of Processes Require a HACCP Plan and NOT a Variance?

Certain specialized food processing methods, such as Reduced Oxygen Packaging, require an approved variance as well as an approved HACCP Plan, while other processing methods (including some foods processed using reduced oxygen packaging) require only a HACCP Plan and not an approved variance.

What is HACCP?

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards. It consists of a seven step process that a food producer or establishment operator can use to address hazards introduced or controlled by a process.

HACCP Principles are:

Conduct a food safety **HAZARD ANALYSIS**.
Identify **CRITICAL CONTROL POINTS**, also called "CCP's".
Establish **CRITICAL LIMITS** for preventive measures.
Establish **MONITORING PROCEDURES** for control points.
Establish **CORRECTIVE ACTIONS**.
Establish an effective **RECORD KEEPING/DOCUMENTATION** system.
Establish **VERIFICATION PROCEDURES** to ensure the HACCP Plan is working.

A **HACCP Plan** is a written document that describes the Food Establishment's formal procedures of following HACCP principles. It is a system for managing food safety by following a strict method of preparation that prevents hazards of a biological, chemical, or physical nature. Producing food using a specialized food processing method may require a HACCP Plan in addition to a variance approval.

Code 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.

Required Contents of a HACCP Plan

The FDA Food Code has specific criteria for the contents of a HACCP Plan. HACCP Plans must be submitted to the Iowa Department of Inspections, Appeals, and Licensing for approval prior to implementing the plan.

Code 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) General information such as the name of the PERMIT applicant or PERMIT HOLDER, the FOOD ESTABLISHMENT address, and contact information;

(B) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are to be controlled under the HACCP PLAN;

(C) A flow diagram or chart for each specific FOOD or category type that identifies:

- (1) Each step in the process; Pf and

(2) The steps that are CRITICAL CONTROL POINTS; 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;

(D) The ingredients, recipes or formulations, materials and equipment used in the preparation of each specific FOOD or category type and methods and procedural control measures that address the FOOD safety concerns involved;

(E) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies:

- (1) Each CRITICAL CONTROL POINT,

(2) The significant HAZARDS for each CRITICAL CONTROL POINT,

(3) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,

(4) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the designated FOOD EMPLOYEE or the PERSON IN CHARGE,

(5) Action to be taken by the designated FOOD EMPLOYEE or PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met,

(6) 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, and

(7) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed;

(F) Supporting documents such as:

(1) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;

(2) Copies of blank records forms that are necessary to implement the HACCP PLAN;

(3) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal.

(G) Any other information required by the REGULATORY AUTHORITY.

What Types of Processes Require a HACCP Plan and NOT a Variance?

Certain specialized food processing methods, such as Reduced Oxygen Packaging, require an approved variance as well as an approved HACCP Plan, while other processing methods (including some foods processed using reduced oxygen packaging) require only a HACCP Plan and not an approved variance.

Code 3-502.12 Reduced Oxygen Packaging Without a Variance Criteria, gives specific criteria for reduced oxygen packaging processes. If these processes are followed as stated in this Code, a Variance *is not* required. A HACCP Plan however, *is* required for these processes- with the exception of 3-502.12(F) (“the 48 hour rule”) provided the establishment follows all three provisions in section (F).

Code 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.

(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:

- (1) Identifies the FOOD to be PACKAGED;
- (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:
 - (a) Has an AW of 0.91 or less,
 - (b) Has a PH of 4.6 or less,
 - (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, or
 - (d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; ([Iowa Administrative Code 481-31.1\(7\)](#) amends this 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.”)
- (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:
 - (a) Maintain the FOOD at 5o C (41o F) or below, 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;
- (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;
- (5) Includes operational procedures that:
 - (a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶3-301.11(B),
 - (b) Identify a designated work area and the method by which:
 - (i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and
 - (ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, 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,
 - (b) EQUIPMENT and facilities, and
 - (c) Procedures specified under Subparagraph (B)(5) of this section and ¶¶ 8-201.14 (B) and (D).
- (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 and bears a label indicating that it is to be kept frozen until time of use, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method.

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 information as specified under ¶¶ 8-201.14 (B) and (D);

(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,

(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),

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

(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),

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

(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

(iii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) FOOD temperature and then held at 5°C (41°F) or less for no more than 7 days, not to exceed 30 days from its date of PACKAGING, at which time the FOOD must be consumed or discarded; or

(iv) Held frozen with no shelf life restriction while frozen until consumed or used.

(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,

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure times and temperatures are monitored during transportation, and

(h) Labeled with the product name and the date PACKAGED; 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, and

(b) Hold such records for at least 6 months; 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.

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;

(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.

48 HOURS

(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.

The other instance when a HACCP Plan and Variance are not required is stated in Iowa Administrative Code 481-31 which amends code section 3-502.11 and 3-502.12 by adding:

- 31.1(7)** *Reduced oxygen packaging in meat and poultry processing plants.* Meat and poultry processing plants that are licensed and inspected by the IDALS meat and poultry inspection bureau pursuant to Iowa Code chapter 189A and that are also licensed as a food establishment are exempt from section 3-502.11, paragraphs (A), (B), (D) and (F), and section 3-502.12 if these criteria are met:
- a.* Each food product formulation has been approved by the IDALS meat and poultry inspection bureau;
 - b.* A copy of the approved formulation (T40/45) is maintained on file at the establishment and made available to the regulatory authority upon request;
 - c.* Cooked products that do not include a curing agent or an antimicrobial agent that will control *Clostridium botulinum* and *Listeria monocytogenes* that are in a reduced oxygen package are stored and sold frozen and are labeled “Keep Frozen”;
 - d.* The food products are properly labeled.

How does my Organization or Establishment request a Variance?

The *Request for a Variance* application shall be submitted to the Iowa Department of Inspections, Appeals and Licensing Food Safety Bureau. All information on the Variance Request Form must be fill out completely and all additional required information must be submitted. Request forms that are not filled out completely will be returned to the applicant.

Request a Variance:

<https://stateofiowa.seamlessdocs.com/f/VarianceGuidanceDocSpecializedProcessesApplication>

Additional information for HACCP Plans and Variance Requests:

<https://ia.foodprotectiontaskforce.com/resources1/restaurants-grocery-stores/#tab7>

How long does it take obtain an approval for a Variance request?

The variance approval process takes approximately 30 days once the request and all adequate supporting documentation is received by the Iowa Department of Inspections, Appeals, and Licensing.