REDUCED OXYGEN PACKAGING REQUIREMENTS

Definitions

Aerobic organism means any organism that requires oxygen for growth. Many spoilage organisms are aerobic.

Anaerobic organism means any organism that does not require oxygen for growth and may even die in its presence. *Clostridium botulinum* is such an organism; it will not grow in the normal atmosphere.

Fish
(1) "Fish" means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(2) "Fish" includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

HACCP plan means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Hermetically sealed container means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

pH means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

Water activity in foods (*a*<sub>w</sub>) is the ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding media, and the vapor pressure of distilled water under identical conditions. It is a unit of the amount of moisture available in a food to support the growth of microorganisms. Most foods have a water activity above 0.95 and that will provide sufficient moisture for the growth of bacteria, yeasts and molds. If the water activity is reduced to 0.85 or less, it creates a less optimal environment for the growth of most organisms of concern.

References:
- 2005 FDA Food Code and the 2007 supplement
- Code of Federal References: Title 21, Part 133
- Annex 6: Food Processing Criteria, FDA Food Code
Reduced oxygen packaging (ROP) of Potentially Hazardous food/Time, Temperature Control for Safety Food (PHF/TCS) is considered a high-risk process. In conducting ROP, the oxygen content of the air inside a package is reduced to less than that of air (21%) or eliminated altogether. This creates an anaerobic environment inside the package which supports the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.

If C. botulinum toxin forms in food, there is no way to recondition the food to make it safe again. C. botulinum toxin can cause severe damage, including death. L. monocytogenes may cause listeriosis, a serious disease in pregnant women and immune compromised individuals. Listeriosis is fatal in approximately 20 to 30% of the persons who contract the disease.

This document is designed to assist you in the development and implementation of an effective procedure for reducing risks associated with ROP of PHF/TCS. It refers to regulatory requirements, definitions, and pertinent code citations, as well as guidance material and an ROP checklist for your convenience.

Due to the increased risks associated with ROP of PHF/TCS, an approved Hazard Analysis and Critical Control Point (HACCP) plan is required. For additional and more comprehensive guidance information on reduced oxygen packaging and development of HACCP plans for ROP, please refer to Annex 6 of the FDA Food Code which is provided for your convenience at the end of this document.

These documents only apply to foods that are considered PHF/TCS. Operator may be required to provide scientific data that their food item is not PHF/TCS.

The Division may be contacted by email at foodinsp@FreshFromFlorida.com or by phone at (850) 245 - 5520 or by fax at (850) 245 - 5553

INFORMATIONAL SECTION

What is Reduced Oxygen Packaging (ROP)?

As written in the 2005 FDA Food Code, ROP means:

(A) 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 atmosphere (approximately 21% at sea level); and

(B) A process as specified in (A) that involves a food for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final packaged form.

Note: Your process is considered REDUCED OXYGEN PACKAGING if it involves a PHF/TCS food and any one of the bulleted items above and at least one of the two pathogens listed above are identified as a hazard.
Reduced oxygen packaging includes:

(a) 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;

[Example of Vacuum Packaging: Packaging meat where the air (including the oxygen) is mechanically sucked out of the package immediately prior to sealing so that near-perfect vacuum remains inside.]

(b) 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;

Note: Modified Atmosphere Packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action.

[Example of MAP: Cooked baby food in a container and replacing the atmosphere at packing with 25% carbon dioxide and 75% nitrogen]

(c) Controlled atmosphere PACKAGING (CAP), 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;

Note: This is an active system which continuously maintains the atmosphere within the package throughout the shelf-life. It uses an agent to bind or “scavenge” oxygen or a sachet to emit a gas.

[Example of CAP: Adding an item to the package that will continually use up the oxygen generated by the food item or oxygen transmission rate of the package such as lettuce packaged with an ethanol releasing system enclosed in a small sachet that is permeable to water vapor. Moisture is absorbed from the food by the inert powder and ethanol vapor is released and permeates the sachet into the food package headspace.]

(d) 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 psychotrophic pathogens;

[Example of Cook-chill: Pasta sauce is cooked, then placed in a bag while hot then bag is closed/sealed, (the heat generated from within the closed bag will expel the air), then quickly chilled at proper temperatures until ready for use.] or

(e) 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 psychotrophic pathogens.
Example of Sous vide: Partially cooked pasta, placed in a sealed bag, then cooked while in
the sealed bag, then rapidly chilled at proper temperatures until ready for use.

Note: Sous Vide is a specialized process of ROP for partially cooked ingredients alone or
combined with raw foods that require refrigeration or frozen storage until the package is
thoroughly heated immediately before service.

The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to
make the food shelf stable. The process involves the following steps:

- Preparation of the raw materials (this step may include partial cooking of some or all
  ingredients);
- Packaging of the product, application of vacuum, and sealing of the package;
- Pasteurization of the product for specified time/temperature and monitored;
- Rapid and monitored cooling of the product at or below 3 °C (38°F) or frozen; and
- Reheating of the package to a specified temperature before opening and service.

Note: Cook chill or Sous vide product CAN NOT BE SOLD to another business
establishment or to the public in bagged/packaged form

What is a Potentially Hazardous Food (Time/Temperature Control for Safety Food) as defined in
the Food Code?

(1) "Potentially hazardous food (time/temperature control for safety food)" means a food that
requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or
toxin formation.

(2) "Potentially hazardous food (time/temperature control for safety food)" includes:

(a) An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of
  raw seed sprouts, cut melons, or garlic-in-oil mixtures that are not modified in a way
  that results in mixtures that do not support pathogenic microorganism growth or toxin
  formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a food that because of the
  interaction of its (water activity) \( a_w \) and \( \text{pH} \) values is designated as Product Assessment
  Required (PAR) in Table A or B of this definition:
### Table A. Interaction of pH and a\textsubscript{w} for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged

| a\textsubscript{w} values | pH values |  
|--------------------------|-----------|-----------------|-----------------|-----------------|
|                          | 4.6 or less | > 4.6 - 5.6 | > 5.6 |
| <=0.92                   | non-PHF*/non-TCS food** | non-PHF/non-TCS food | non-PHF/non-TCS food |
| > 0.92 -.95              | non-PHF/non-TCS food | non-PHF/non-TCS food | PAR*** |
| > 0.95                   | non-PHF/non-TCS food | PAR | PAR |

* PHF means Potentially Hazardous Food  
** TCS food means Time/Temperature Control for Safety food  
*** PAR means Product Assessment Required

### Table B. Interaction of pH and a\textsubscript{w} for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged

| a\textsubscript{w} values | pH values |  
|--------------------------|-----------|-----------------|-----------------|-----------------|
|                          | < 4.2 | 4.2 - 4.6 | > 4.6 - 5.0 | > 5.0 |
| <=0.88                   | non-PHF*/non-TCS food** | non-PHF/non-TCS food | non-PHF/non-TCS food | non-PHF/non-TCS food |
| 0.88 – 0.90              | non-PHF/non-TCS food | non-PHF/non-TCS food | non-PHF/non-TCS food | PAR*** |
| > 0.90 – 0.92            | non-PHF/non-TCS food | non-PHF/non-TCS food | PAR | PAR |
| > 0.92                   | non-PHF/non-TCS food | PAR | PAR | PAR |

* PHF means Potentially Hazardous Food  
** TCS food means Time/Temperature Control for Safety food  
*** PAR means Product Assessment Required
(3) "Potentially hazardous food (time/temperature control for safety food)" does not include:
(a) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;
(b) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
(c) A food that because of its pH or aw value, or interaction of aw and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;
(d) A food that is designated as Product Assessment Required (PAR) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
   (i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,
   (ii) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or
   (iii) A combination of intrinsic and extrinsic factors; or
(e) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Does a business need to get approval before conducting ROP? If so, what type of approval is needed?
YES, a business must always obtain approval BEFORE conducting ROP of a PHF/TCS food. A HACCP plan is required in all cases. FOR A BUSINESS to conduct ROP in accordance with Section 3-502.12 of the Food Code it is only required to obtain approval for the HACCP plan before beginning to process ROP. If A BUSINESS DOES NOT INTEND to conduct ROP in accordance with Section 3-502.12, then you must also obtain a Process Alternative (PA) from the Division.

What is a Process Alternative (PA)?
A PA is a written document granted by the Division that authorizes a modification or waiver of one or more requirements of the FDA Food Code or allows a high-risk process to be performed that requires stringent controls, if in the opinion of the Division, a health hazard or nuisance will not result from the process, modification, or waiver. Food Establishments must have written authority from the Division BEFORE beginning procedures that require a PA. See conditions for getting and maintaining a PA on the Application form.

How does a business request a Process Alternative (PA)?
A business may apply for a PA by completing “Application for Process Alternative for Food Establishments Involved in Specialized Processing” with required supporting documentation.
Documentation will include the requested information on the application form and any other pertinent information that may be needed to complete the application process.

If the Division grants a PA, the permit holder shall:

1- Comply with the approved HACCP plan, procedures and any conditions of the PA; and

2- Maintain on site and provide to the Division, upon request, the written PA with all supporting documentation and all documentation involved in the execution of the HACCP plan. Records must be kept for at least 2 years.
What information must my HACCP plan contain?

You must comply with a HACCP plan that contains at a minimum, the information listed on the application form.

How is ROP conducted in accordance with Section 3-502.12 of the Food Code and not have to obtain a Process Alternative?

Section 3-502.12 of the Food Code outlines several instances when ROP may be conducted without having to obtain a Process Alternative (PA) from the Division

**Instance 1. Refer to 3-502.12(A)-(B). ROP using 2 Barriers**

Per 3-502.12(A), ROP may be conducted without having to obtain a Process Alternative (PA) from the Division if at least **TWO BARRIERS** are in place to control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*. In accordance with Division policy, you must properly implement an approved HACCP plan that contains the following information:

1. Each Critical Control Point (CCP);
2. The critical limits for each CCP;
3. The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge;
4. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring CCPs;
5. Action to be taken by the person in charge if the critical limits for each CCP are not met;
6. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;
7. The specific food(s) to be packaged;
8. A requirement that the packaged food be maintained at 5°C (41°F) and have **at least one additional barrier** from the following list:
   a. A water activity level of 0.91 or less,
   b. A pH of 4.6 or less,
   c. Is a meat or poultry product cured at a food processing plan 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 or raw poultry;
   **Note:** Additional safety barrier beside refrigeration must be verified in writing for all foods processed in ROP at retail. This can be done via written certification from the product manufacturer or through independent laboratory analysis of the incoming product using a standard method of analysis.
9. A description of how the package will be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
   a. Maintain food at 5°C (41°F) or below, and
   b. Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
10. A limitation on the refrigerated shelf life to no more than 14 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;
11. Specific operational procedures that:
a. Prohibit contacting food with bare hands [all food, not just ready-to-eat (RTE) food];
b. Identify designated work areas and the method by which:
   i. Physical barriers or methods of separation of raw foods and RTE foods to
      minimize cross contamination, and
   ii. Access to the processing equipment is limited to responsible trained personnel
      familiar with the potential hazards of the operations; and

c. Delineate cleaning and sanitization procedures for food contact surfaces; AND

12. A description of the training program that ensures that the individual responsible for the ROP
operations understands the:
   a. Concepts required for a safe operation for their specific task;
   b. Pathogens of interest, especially anaerobes and psychrophilic organisms;
   c. Time/temperature control of foods;
   d. Health and hygiene of food handlers;
   e. Equipment and facilities, and
   f. Procedures specified under Item 11 above in regards to operational procedures and Items
   1 – 6 related to the HACCP plan.

(Instance 2) Refer to 3-502.12(C). ROP of Raw Fish or Fish-Containing Products

Except for uncooked fish that is frozen before, during and after packaging, a retail food establishment
may not package fish using a reduced oxygen packaging method. [May not means absolute prohibition]
No ROPing of cooked fish is allowed at retail under any circumstances.

Note: HACCP plan is required to control the potential hazard of Clostridium botulinum and Listeria
monocytogenes. Minimum CCPs are Labeling and Freezer storage; depending on the species/process
there could be other CCPs. Labeling must state on separate lines the following statements:

KEEP FROZEN
Open Package Before Thawing
Must be Cooked within 4 days after Thawing

HACCP plan at a minimum must contain:
   (1) Each CRITICAL CONTROL POINT,
   (2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,
   (3) The method and frequency for monitoring and controlling each CRITICAL CONTROL
      POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE,
   (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,
   (5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each
      CRITICAL CONTROL POINT are not met, and
   (6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP
      PLAN is properly operated and managed; and

Additional scientific data or other information, as required by the REGULATORY AUTHORITY,
supporting the determination that FOOD safety is not compromised by the
proposal.
(Instance 3) Refer to 3-502.12(D). Conducting a Cook-Chill or Sous Vide Process in Accordance with the Code

A product using a cook-chill or sous vide process may be packaged without obtaining a Process Alternative (PA) if the product being packaged does not contain fish (see Food Code for complete definition of fish) and you properly implement an approved HACCP plan that contains the following information: (Same as Section 8-201.14(D), FDA Food Code)

A flow diagram of each finished product from start to finish; and
1-Ingredients, materials, and equipment used in the preparation of the food, and
2-Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

Properly implement an approved HACCP PLAN that contains:

1. Each Critical Control Point (CCP);
2. The critical limits for each CCP;
3. The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge;
4. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring CCPs;
5. Action to be taken by the person in charge if the critical limits for each CCP are not met;
6. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;
7. A description of how the food is:
   a. Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business establishment with no distribution or sale of the bagged product to another business establishment or the consumer;
   b. Cooked to heat all parts of the food to a temperature and for a time as specified under Section 3-401.11 of the FDA Food Code;
   c. Protected from contamination after cooking as specified in Part 3-4 of the FDA Food Code;
   d. Placed in a package or bag with an oxygen barrier and sealed before cooking, or placed in a package or bag 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 Section 3-501.14 of the FDA Food Code and subsequently:
      i. Cooled to 1°C (34°F) or less 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 preparation, or
      ii. 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 72 hours, at which time the food must be consumed or discarded, or
      iii. Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held at 3°C (38°F) for no more than 72 hours from 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 establishment, equipped
   with verifiable electronic monitoring devices to ensure that times and temperatures are
   monitored during transportation; and
h. Labeled with the product name and the date packaged;

8. Operational procedures that prohibit contacting food with bare hands [all food, not just ready-
to-eat (RTE) food]

9. Operational procedures that identify a designated work areas and the method by which:
   a. Physical barriers or methods of separation of raw foods and RTE foods to minimize
      cross contamination, and
   b. Access to the processing equipment is limited to responsible trained personnel
      familiar with the potential hazards of the operations;

10. Operational procedures that delineate cleaning and sanitization procedures for food contact
    surfaces; and

11. A description of the training program that ensures that the individual responsible for the ROP
    operation understands the:
    a. Concepts required for a safe operation for their specific task;
    b. Pathogens of interest, especially anaerobes and psychrophilic organisms;
    c. Time/temperature control of foods;
    d. Prevention of cross contamination;
    e. Health and hygiene of food handlers;
    f. Equipment and facilities, and
    g. Operational procedures specified under Items 8 - 10 and Items 1 – 6 related to the
        HACCP plan; and

12. A requirement that the records used to confirm that cooling and cold holding refrigeration
    time/temperature parameters are maintained and are held for 6 months and made available to
    Division personnel upon request.

Note: Cook chill or Sous vide product CAN NOT BE SOLD to another business establishment or to
the public in bagged/packaged form.


Cheese may be packaged using a reduced oxygen packaging methods without obtaining a
Process Alternative (PA) if you:

1. Limit the cheese packaged to those that are commercially manufactured in a food processing
   plant with no ingredients added in the food establishment and that meets the Standards of Identity
   as listed in the Code of Federal Regulations, Title 21, Sections 133.150 Hard Cheeses, 133.169
   Pasteurized process cheese or 133.187 Semisoft cheeses

   NOTE: Soft cheeses such as Brie, Camembert, Ricotta, Cottage and Teleme MAY NOT be
   vacuum packaged in a retail food establishment

2. Follow an approved HACCP plan that identifies:

   a. Each Critical Control Point (CCP);
   b. The critical limits for each CCP;
   c. The method and frequency for monitoring and controlling each CCP by the food
      employee designated by the person in charge;
   d. The method and frequency for the person in charge to routinely verify that the food
      employee is following standard operating procedures and monitoring CCPs;
e. Action to be taken by the person in charge if the critical limits for each CCP are not met;
f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;
g. The food to be packaged;
h. The method by which packages will be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background with instructions to maintain the food at 5°C (41°F) and a “use by” date that does not exceed 30 days or the original manufacturer’s “sell by” or “use by” date, whichever comes first;
i. Operational procedures that prohibit contacting food with bare hands [all food, not just ready-to-eat (RTE) food];
j. Operational procedures that identify a designated work areas and the method by which:
   i. Physical barriers or methods of separation of raw foods and RTE foods to minimize cross contamination, and
   ii. Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operations;
k. Operational procedures that delineate cleaning and sanitization procedures for food contact surfaces; and
l. A description of the training program that ensures that the individual responsible for the ROP operation understands the:
   i. Concepts required for a safe operation,
   ii. Equipment and facilities, and
   iii. Operational procedures specified under Items (i – k) and Items (a – f) related to the HACCP plan;
m. A requirement that the reduced oxygen packaged cheese be discarded if not sold for off–premises consumption or consumed within 30 calendar days of its packaging.

Note: The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished through written certification from the product manufacturer. Independent laboratory analysis using methodology approved by the regulatory authority is also acceptable.

ROP of fresh cut vegetables
- Determine if the product is a Potentially hazardous food (time/temperature control for safety food)
  - If not a (PHF/TCS) no HACCP plan required as there are no hazards to control specific to an anaerobic environment created by the ROP.

- If product is a (PHF/TCS) the commodity and oxygen transfer rate of bag will need to be evaluated. Contact Tallahassee headquarters for determination of HACCP requirements.

Retail - Packaging Food Item using Reduced Oxygen Packaging (ROP) Checklist
May need a Process Alternative (PA) – See Informational Section

Must have an adequate HACCP Plan and must implement the process according to the plan.

Checklist (What you must have)

- Flow diagram
- Product formulations
- Training plans
Corrective action plans
☐ HACCP Plan that contains at least two barriers to C. botulinum and the following:
☐ All items specified the same as in FDA Food Code Section 8-201.14(D)
☐ Identification of food that is to be Reduced Oxygen Packaged
☐ Limit food that does not support the growth of Clostridium botulinum and Listeria monocytogenes because it has at least one of the following:
   - Water activity level of 0.91 or less; or
   - Has a pH of 4.6 or less; or
   - Is meat or poultry product cured at a food processing plant regulated by USDA and received in an intact package; or
   - Is a food with a high level of competing organisms such as raw meat or raw poultry
☐ Specifies method for maintaining food at 41°F or less (or less than 41°F depending on the requirements for that food item)
☐ Specifies specific labeling requirements (storage temperature and use/sell/discard date within specific calendar days)
☐ Identifies a designated work area and the method by which physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation
☐ Specify operational procedures in regard to:
   - no bare hand contact of food;
   - identify the designated area where ROP will occur—how raw foods and Ready to Eat foods are separated; and state ROP equipment is limited to trained, designated individuals; and
   - cleaning and sanitation procedures
☐ Describes training program for individuals responsible for ROP operations that they understand the following:
   - Concepts required for a safe operation
   - Equipment and facilities; and
   - Operational procedures listed above as same as Section 8-201.14(D) of the FDA Food Code

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