

HACCP Plan Requirements for Special Processes Without a Waiver Checklist

Some special processes which meet exemptions listed in the 2013 FDA Food Code under regulation 3-502.12 will not require a waiver by the Department. These processes include reduced oxygen packaging of cheese, fish, certain reduced oxygen packaging (ROP) processes, cook-chill processes and sous vide processes. A HACCP plan is required for these processes. If you are not specifically following the outlined procedures in section 3-502.12 of the 2013 FDA Food Code, you will need a waiver and processes authority review in addition to HACCP plans and required Standard Operating Procedures (SOP's).

Cook chill packaging is when 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 which inhibit the growth of pathogens.

Sous vide packaging is when raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of pathogens.

HACCP plans and Standard Operating Procedures (SOP's) need to be tailored to your specific process. Sample HACCP forms and SOP's for various processes are provided by the Department.

ALL HACCP PLANS REQUIRE THE FOLLOWING: (CHECK FOR ADDITIONAL REQUIREMENTS BY PROCESS)

- Provide a list of all facilities, with permit numbers (if currently licensed), that are utilizing the plan to prepare or hold foods. Additionally, provide a separate list of all facilities, with permit numbers, that are holding but not preparing foods produced using a special process.
- Provide a detailed **Process Flow Diagram** including all Critical Control Points (CCPs). Diagram must address the general preparation steps of the food(s) through the special process.
- Provide a **list of all ingredients** for each menu item used in the special process. Ingredient proportions are not necessary unless specifically asked for. Also provide detailed preparation steps for each menu item.
- Provide **specifications for the equipment** used in the special process. All equipment must meet the NSF Standard or equivalent. Specifications for equipment like vacuum packaging machines, immersion circulators, smokers etc. are necessary, but specifications for equipment like grills, cook tops, refrigeration etc. are not.

- Provide a **training plan or training program** for food handlers in the special process or processes used within the facility. The training program must demonstrate that the individual responsible for reduced oxygen packaging understands:
 - (i) concepts required for safe operation
 - (ii) equipment and facilities
 - (iii) operational procedures described in the HACCP plan and must include a training log(s).
- Provide a **Guide to Hazards Worksheet** for each special process.
- Provide a **Hazards Analysis Worksheet** for each special process.
- Provide a **HACCP Worksheet** for all Critical Control Points listed in the Process Flow Diagram.

SOPs: (REQUIRED FOR ALL PLANS) – SOPs will need to be adjusted for the specific HACCP Plan to which they apply.

- Provide a **Personal Hygiene Standard Operating Procedure (SOP)**.
- Provide a **Hand Washing Standard Operating Procedure (SOP)**.
- Provide an **Employee Health Policy**.
- Provide a **Cleaning and Sanitation Program Standard Operating Procedure (SOP)**.
- Provide an **Eliminating Bare Hand Contact Standard Operating Procedure (SOP)**. Please note that bare hand contact is not allowed when using a special process to prepare food. SOP must address this requirement.
- Provide a **Using and Calibrating a Thermometer Standard Operating Procedure (SOP)** with Log.
- Provide a **Labeling Standard Operating Procedure (SOP)**. SOP must address all required dates for special process, including labeling that must be updated due to changes in temperature like freezing or product that is out of temperature

Two Barrier (vacuum sealing) Reduced Oxygen Packaging (ROP) (If following Food Code Regulation 3-502.12 a waiver is not required)

Note: *See Two Barrier Guidance Documents for further specific requirements.*

The first barrier will always be temperature control at 41°F. Product will have a shelf life of no more than 30 days.

Note: If you are placing raw foods in ROP and you are adding ingredients to the bag like marinades or seasonings you must list this on your ingredient list. You may need to provide third party lab confirmation of the pH and/or water activity of any added ingredients. FCCHD will request the result when they are necessary or as listed below.

The second barrier will be one of the following:

- The water activity (A_w) of the product is 0.91 or less. Provide third-party laboratory confirmation of water activity of the product when submitting your plan.
- The pH of the product is 4.6 or below. Provide third-party laboratory confirmation of the pH of the product when submitting your plan.
- Provide proof that the meat or poultry product was cured at a Food Processing Establishment 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**
- Food has a high level of competing organisms including but not limited to raw meat or raw poultry or raw vegetables.

Additional required documents of ROP with two barriers:

- Provide a **Holding Cold Potentially Hazardous Foods Properly Standard Operating Procedure (SOP) with Log.**
- Provide samples of labels which show the following:
 - Prominent and conspicuous labeling on the principal display panel in bold type contrasting background, with instructions to:
 - (a) Maintain the food at 41F or less, and
 - (b) Discard the food if within 30 calendar days of packaging if it is not served for on-premises consumption or consumed if served or sold for off-premises consumption.
- Show how the shelf life is limited to no more than 30 calendar days from packaging to consumption, unless frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first.

Cook-Chill or Sous Vide Cooking (If following Food Code Regulation 3-502.12 a waiver is not required)

Note: See *Cook-Chill or Sous Vide Guidance Documents* for further specific requirements.

- Provide a signed statement that food prepared by cook chill and/or sous vide will be used within the same business entity and that no retail sales are allowed.
- Provide **Cooking Potentially Hazardous Foods Properly Standard Operating Procedure (SOP)** with log.
- Provide a **Cooling Potentially Hazardous Foods Properly Standard Operating Procedure (SOP)**. SOP must address all cooling for the special process. If foods must be cooled below 41°F, SOP must address this. SOP must be accompanied by a Cooling Log. **Note:** *ROP items held more than 7 days (not frozen) must be cooled to 34°F within 48 hours of reaching 41°F. Product must be held at that temperature until consumed or discarded within 30 days of packaging. Include SOP and logs which show how this will occur.*

- If using time as a control, provide a **Time as a Control for Potentially Hazardous Foods Standard Operating Procedure (SOP)**.
- Provide a **Holding Hot and Cold Potentially Hazardous Foods Properly Standard Operating Procedure (SOP)** with Log.
- Provide **Reheating Potentially Hazardous Foods Properly Standard Operating Procedure (SOP)** with Log.
- Provide a signed statement that one or both of the following statements is/are true.
 - Food produced under a cook chill system will be bagged while the food is above 135°F.
 - Food produced under a sous vide process will be bagged immediately before cooking.
- Provide proof of electronic monitoring on all refrigeration units holding cook chill or sous vide foods.
- Provide **Visual Examination of Electronic Monitoring System Standard Operating Procedure (SOP)** with Log. **Note:** *SOP should indicate visual examination at least twice daily.*
- If product is transported off-site to a satellite location of the same entity, the process must include verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation.
- Indicate how the product will be labeled with the product name and date it was packaged.
- All other applicable SOPs and Logs required for your plan.

Reduced Oxygen Packaging of Fish

- Provide a signed statement that fish will be maintained frozen before, during and after packaging consumption and that the bag is opened before thawing. (Waiver not required for this, but HACCP Plan is required)
- Provide **Cold Holding of Reduced Oxygen Packaged Fish Standard Operating Procedure (SOP)**.
- If a process other than that allowed in the 2013 FDA Food Code 3.502.12 (C) where fish is frozen before, during and after ROP packaging is proposed you must provide written validation of the operational procedure from a Processing Authority which utilized the national Advisory Committee on Microbiological Criteria for Foods (NACMCF) for fresh fish reduced oxygen packaged solely for the cooking process, for individual orders for immediate service to a customer.
- All other applicable SOPs and Logs required for your plan.

Reduced Oxygen Packaging of Cheese

- Product will have a 30 day shelf life.
- No additional ingredients may be added to the package. Cheese can only be portioned and packaged.
- Provide proof that the cheese(s) is / are commercially manufactured in a food processing establishment with NO ingredients added. And that it meets *CFR 133.15 Standards of Identity Hard Cheeses*, *21 CFR 133.169 Standards of Identity Pasteurized Process Cheese*, or *CFR 133-187 Standards of Identity Semi-Soft Cheeses*.
- Provide a HACCP plan which includes a product flow diagram identifying critical control points and providing information on:
 - (a) Ingredients, materials, equipment used in the food preparation and
 - (b) Procedural controls that address food safety concerns involved.
- Provide a **Holding Cold Potentially Hazardous Foods Properly Standard Operating Procedure (SOP) with Log**.
- Labels must be reviewed by FCCHD if product will be sold. (Product must be labeled with a “use-by” or “sell-by” date.)
- All other applicable SOPs and Logs required for your plan.

Using Food Additives as a Method of Preservation or to render a food Non-Temperature Control for Safety

- Provide HACCP documentation listed above (required for all plans) and all applicable SOP's/Logs for your plan.
- Provide product authority review for Aw (water activity) and pH if necessary.



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