**Two Barrier ROP HACCP Plan Requirements Guideline**

A two barrier process is one in which raw or ready-to-eat foods are placed into oxygen impermeable bags that are then sealed to complete the oxygen barrier. Food stored in a bag in this manner is in a Reduced Oxygen Package (ROP). This type of ROP creates an anaerobic environment that prevents the growth of most spoilage organisms, and without these, the normal signs that the food is no longer fit for consumption (such as off-odors, slime, texture changes, etc.) will not occur. In addition, the ROP environment can allow for the growth of anaerobic bacteria such as *Clostridium botulinum* and *Listeria monocytogenes* which are pathogens of concern that must be controlled.

Per the 2013 FDA Food Code 3-502.12, as a high hazard process, the Department requires a HACCP plan to be submitted and approved prior to practicing reduced oxygen packaging. A waiver is required unless the growth of the toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled for as specified under the Food Code 3-502.12. If following 3-502.12 with no deviation, a waiver for this process is not required. If you plan to waiver from the specified process, a waiver and alternate approval will be required.

The first barrier will always be holding the packaged food at 41°F or less. The second barrier must be one of the following: water activity of 0.91 or less, pH of 4.6 or less, a meat or poultry product cured at a food processing plan regulated by the USDA utilizing substances specified in 9 CFR 421.21 and receive in an intact package or is a food with a high level of competing organisms such as raw meat, raw poultry or raw vegetables.

The purpose of the HACCP plan is to show processing controls compliant with regulatory requirements and that industry standards are being met to control identified hazards.

This guideline is to assist you in creating a two barrier HACCP plan.

1. **Preliminary HACCP Steps**

□ Assemble the HACCP team. Select people with specific knowledge and expertise about the process and product who will be responsible for planning, developing and implementing the HACCP plan. It is important to include personnel who routinely make the product(s).

□ Develop a complete list of ingredients and raw materials used in the product(s).

□ Develop a complete list of equipment and material that will be used to produce the product(s).

1. **Process Flow Diagram**

□ Include all steps of the process [i.e. receiving, cold holding before reduced oxygen packaging (ROP), bagging, cold holding of ROP at processing facility, transport to outlets (if applicable), cold holding of ROP at outlets (if applicable), removal from bag, etc.

□ Label all critical control points (CCPs). See below for the minimum required CCPs.

1. **Hazard Analysis Worksheet**

By identifying the food safety hazards in your process, control measures and CCPs can be determined. The following organisms are common hazards that may be required to be controlled depending on ingredients used.

* + *Listeria monocytogenes*
  + *Campyloboacter jejuni*
  + *Yersenia enterocolitica*
  + *Salmonella*
  + *Staphylococcus aureus*
  + *Clostridium perfringens*
  + *Clostridium botulinum*
  + *Bacillus cereus*
  + *Shigella* spp.
  + E. coli O157:H7
  + *Hepatitis A*
  + *Norovirus*
  + *Crytosporidium*
  + *Trichinella* (if pork is included in the plan)

1. **HACCP Worksheet**

The HACCP Worksheet must include details for all designated CCPs from the Process Flow Diagram. The following chart includes details of necessary information for the minimum required CCPs on the HACCP Worksheet. Note: CCPs are dependent on the facilities process; therefore, additional CCPs may be required.

1. **Employee Health Policy**

□ Ensure to include symptoms of food borne illness and pathogens known to cause food borne illnesses, such as *E. coli 0154:H7*, *Shigella*, *Salmonella*, *Hepatitis A*, and *Norovirus.*

1. **SOPs**

In order for a HACCP system to be effective, a strong foundation of procedures that address the basic operational and sanitation conditions within an operation must first be developed and implemented. These prerequisite programs or Standard Operating Procedures (SOPs) must be in place to ensure that processing controls are met.

Ensure the following SOPs are included and address the following common errors:

* + **All SOPs**
    - All SOPs must include details of instructions, monitoring, corrective actions, record keeping and verification.
    - Ensure details of log verification and maintenance are consistent with all documents in the plan (HACCP Worksheet, instructions on logs, etc.)
  + **Eliminating Bare Hand Contact SOP**
    - Ensure that the SOP includes instructions, monitoring, and corrective action specific to eliminating Bare Hand Contact with **ROP** foods.
    - Clarify that bare hand contact with food that will be placed in ROP is not permitted even while washing fruits and vegetables.
  + **Cleaning and Sanitizing Food Contact Surfaces SOP**
    - The SOP must include details of how to wash rinse and sanitize food contact surfaces. Note: it does not have to be specific to each type of equipment.
    - Include instructions to ensure an appropriate contact time with the chemical sanitizer (i.e. according to the manufacturer’s instructions).
    - Include instructions to clean and sanitize continuous in use equipment every four hours or at a frequency determined by the temperature in the facility.
    - The use of single service items in lieu of a 3-compartment sink is a contingency plan which can only used with prior approval. Ensure to remove any instructions or corrective actions specifying the “use disposable single service/single-use items if a 3-compartment sink is not available”.
  + **Washing Hands SOP**
    - Ensure to specify that hands must be rubbed together vigorously for at least 15 seconds after the application of soap.
    - Specify that single-use paper towels must be used to dry hands.
  + **Date Marking / Labeling SOP**
    - Ensure to include instructions, monitoring, corrective actions and verification and record keeping for date marking **ROP** food.
    - Include details of all applicable dates (packaging, expiration, freezing, thawing, etc.)
    - Ensure to reflect an accurate shelf life for ROP foods (i.e 30 day shelf life from time of packaging for 2 barrier ROP food). Note: Ready-to-eat foods do not need to be included in the submitted SOP. If ready-to-eat foods are included ensure to distinguish between ready-to-eat and ROP shelf lives.
    - Ensure that the shelf lives are consistent throughout the plan (SOPs, HACCP Worksheet, etc.)
  + **Cold Holding SOP** 
    - Address shelf life for ROP products in cold holding.
    - Provide details monitoring temperatures and shelf life.
  + **Cooling SOP (required for 2 barrier ready-to-eat plans)**
    - Include details of monitoring cooling temperatures of bagged products. Ensure to specify how temperatures will be checked (i.e. probing the bag through thermocouple tape, placing a probe thermometer between two bags, etc.).
  + **Personal Hygiene SOP**
  + **Transporting SOP (required if transporting to holding outlets)**
  + **Thermometer Use and Calibration SOP**

Ensure the frequency of monitoring refrigeration temperatures is accurate and consistent throughout the plan.



Flathead City-County Health Department

Environmental Health Services

11035 1st Avenue West

Kalispell, MT 59901

www.flatheadhealth.org

406.751.8130