

REDUCED OXYGEN PACKAGING AT RETAIL INDUSTRY GUIDANCE

Section 3-502.12, 2017 FDA Food Code and Section 5K-4.0050, Florida Administrative Code (F.A.C.)

Reduced oxygen packaging (ROP) of Time/Temperature Control for Safety Food (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.

Due to the increased risks associated with ROP of TCS food, an accepted Hazard Analysis and Critical Control Point (HACCP) plan is required. These documents only apply to foods that are considered TCS. The applicant may be required to provide scientific data that their food item is non-TCS. Under some instances where the product or method differs from that of section 3-502.12 of the 2017 FDA Food Code, an additional Special Process Application (SPA) will be required along with further scientific documentation.

All ROP products are limited to a shelf life of 30 calendar days from the date of packaging if not served for on-premises consumption or consumed if served or sold for off-premises consumption. The day it is packaged is counted as day one.

Types of ROP:

- ROP with Two Barriers
 - Requires the food under vacuum packaging to be held at 41° F and have one other barrier to protect against *Clostridium botulinum*. You may select from one of the following:
 - Provide laboratory documentation for product pH or water activity (A_w);
 - The meat or poultry is raw;
 - The meat or poultry is produced is cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21 and received in an intact package.
- Modified Atmosphere Packaging (MAP)
 - This 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.



- Controlled atmosphere Packaging (CAP)
 - The atmosphere of a package of food is modified so that until the package is opened, its composition is different from air. 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.
- Cook Chill
 - Cooked food is hot-filled into an impermeable bag which has the air expelled and is then sealed or crimped closed. The bagged food is cooled and refrigerated. This product is not for resale in bagged form.
 - Raw food is placed into an impermeable bag whereby it is then vacuum sealed, cooked, cooled and stored for later service. The product is reheated in the bag before opening. This product is not for resale in bagged form.
- Fish (raw or cooked)
 - Except for fish that is frozen before, during and after packaging, a retail food establishment may not package fish using ROP.
 - All ROP fish must be labeled, “KEEP FROZEN UNTIL TIME OF USE.”
 - Fresh fish may be considered for ROP only if the fish is packaged using a 10K bag and scientific documentation is submitted with the SPA application.
- Cheese
 - Most types of cheese may be packaged using ROP so long as they meet the Code of Federal Regulations Standards of Identity under the Title 21 sections as listed below:
 - 133.150 Hard Cheeses
 - 133.169 Pasteurized process cheese
 - 133.187 Semisoft cheeses
 - Soft cheeses such as Brie, Camembert, Ricotta and Cottage are examples of cheese which may not be vacuum packaged in a retail food establishment.
- Raw Fruits and Vegetables (excluding cut tomatoes)
 - ROP of fresh cut fruits and vegetables may be vacuum sealed without prior approval so long as the product is in a raw state (no heat-treatment applied).
 - If the fruits and vegetables have been heat-treated, they are considered TCS and must gain acceptance prior to being placed into ROP.

If the process you are seeking to perform is not specifically addressed and differs from what is stated above, the Department requires a SPA application be completed and submitted in addition to the information required below. Additional scientific documentation may be requested as part of the application. All other applicable laws and rules apply.



Documentation Requirements:

- **HACCP plan:** Provide an adequate HACCP plan with copies of potential monitoring records.
- **Food Process Flow Diagram:** This will illustrate the flow of food throughout the process. It must include the food ingredients and their amounts as well as their CCP points.
- **Standard Operating Procedures (SOPs):** Step-by-step description of the entire process from start to the finished food product. Include ingredients/amounts, each preparation step, method(s) of storage/distribution and display for sale, labels (include use by date, etc.), lot identification code system and how you track each lot, and calibration of applicable instruments.
- **Sanitation Standard Operating Procedures (SSOP):** These are the cross-contamination strategies and sanitation practices for your operation. State how things will be cleaned, how often, with what sanitizer and at what concentration, etc. Be careful to include all surfaces (tables, cutting boards), as well as all pieces of equipment and utensils required for making the product.
- **Food employee and supervisory training plan:** This is a document which outlines how those involved in this special process will be trained in all procedures and plans associated with this process.
- **Floorplan:** Layout of the processing area; include equipment placement involved in the process. Does not have to be professionally created but should be as accurate as possible.
- **Any other pertinent, applicable documentation to ensure the safety of the finished product.**

Please submit required materials to the Retail HACCP Coordinator: RetailHACCPspa@FDACS.gov

If after review all submitted materials are acceptable, the operator will receive written notification from the Department stating the HACCP documents has been accepted. These documents must be kept on site where reduced oxygen packaging is taking place and made available to the regulatory authority upon request. The inspector will review the documentation and ensure the establishment is implementing the accepted plans/procedures and retaining monitoring records as required to document proof of control.

A HACCP plan is not required for ROP product if **all** the following criteria are met:

- Labeled with the production time and date,
- Held under cold storage at 41° F or colder,
- Removed from the packaging in the food establishment within 48 hours after packaging.

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