

Application for Reduced Oxygen Packaged Foods

Date of Application:			
County in which business is located:			
Business Name:			
Owner/Operator Name:		Title:	
Phone:		Email Address:	
Business Address: (If multiple locations, attach on separate sheet)			
Mailing Address:			

Instructions

Complete this application if you are using a reduced oxygen packaging method on foods. For instance, if you are vacuum packaging raw beef or USDA cured ham, you will fill out this application. Several different types of foods can be grouped on one application.

Provide information in each of the sections 1-8 and each field within each section. Be as descriptive as possible. Text in red is intended to help you provide the information we are looking for. Attach required information on separate pages as necessary.

Submit the completed application to: foodsafety@vdacs.virginia.gov. Once your application is reviewed, you will be contacted by email.

All information that you provide in your variance request is maintained confidential.

VDACS is not able to develop or assist in the development of a HACCP plan beyond what is given in this document. One exception being that sample HACCP Plans for select operations have been created for your use and will be provided upon request. It is suggested that you work with a consultant or process authority to develop your HACCP plan if you are unable to do so independently. To find a process authority, visit this [website](#). The process authority in the state of Virginia is Virginia Tech and they have resources that can assist you with completing this application. We strongly recommend you reach out to Virginia Tech or another process authority to assure your application is submitted accurately. They can be contacted at 540-231-2483 or joell.eifert@vt.edu.

The [Retail Food Establishment Regulations for Enforcement of the Virginia Food Laws \(2VAC5-585\)](#) are used by VDACS' Food Safety Program to regulate retail food operations. This regulation will be referred to as *the code* throughout this document.

Discussion about reduced oxygen packaged products

A reduced oxygen package (ROP) food means that there is a reduction of the amount of oxygen in the package, either by removing oxygen or replacing oxygen with another gas. A reduced oxygen packaged food will have an oxygen level of less than 21%. This can include vacuum packaging, where all air is removed from the package; modified atmosphere packaging, where the air inside the package is replaced with a gas such as carbon dioxide or nitrogen; controlled atmosphere packaging, where the use of an oxygen scavenger provides continuous control of the air inside the package; cook chill, where a package is filled with hot food, expelled of the air and sealed closed; or sous vide, where food is vacuum packaged and cooked and cooled in the package.

When oxygen is removed from a packaged food, it creates the ideal environment for certain pathogenic bacteria to grow. In order to use ROP, the operator must control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*. In addition to refrigeration below 41°F, the food product has to meet at least one of the following criteria in order to be ROP:

- water activity below 0.91,
- pH less than 4.6,
- meat or poultry cured in a USDA food processing plant,
- have a high level of competing organisms (raw meat, raw poultry or raw vegetables),
- hard, semi-soft or pasteurized process cheese

Once food is ROP, it must be labeled with 1) a statement instructing the consumer to keep it refrigerated below 41°F and 2) labeled with the sell by date that does not exceed 30 days from packaging or the manufacturer's sell by date, whichever comes first. If the ROP product is not served or sold by the sell by date, it shall be discarded.

ROP foods must be handled according to Standard Operating Procedures (see Section 3. Standard Operating Procedures and Employee Training) and employees must be trained on these procedures. In order to ROP food products, operational procedures must be in place that address the following:

- Prohibit contacting ready-to-eat food with bare hands;
- Identify a designated work area that provides separation of raw and ready-to-eat foods and is accessible only to trained personnel; and
- Delineation of cleaning and sanitizing procedure for food contact surfaces.

Employees that engage in ROP must understand the concepts required for this high risk operation, the equipment and facilities used for ROP and the SOPs and HACCP plan for conducting ROP.

1. Preliminary Product Information

1.1 Products to be reduced oxygen packaged

List your product by its common name: lunch meat, raw pork, raw vegetables, cheddar cheese, etc.

1.2 Product description

Describe the finished product. Consider the following: is it ready-to-eat, cooking required or recommended before consuming, fully cooked, uncooked, partially cooked? Include how product is packaged: vacuum packaged, modified atmosphere packaged. Provide pH or water activity of product, if known.

1.3 Intended use

Describe how your product will be used by the end consumer: off-site consumption, to be reheated, to be fully cooked, to be eaten without cooking, etc.

1.4 Storage of product

Indicate if your product is stored frozen, refrigerated, or other.

1.5 Shelf-life of product

Indicate how long until your product expires: 7 days, 1 month, etc. ROP foods have up to 30 days as a refrigerated product.

1.6 List of employees trained to perform these operations

List the employee by name and title, include their qualifications for performing the operation of ROP.

1.7 Equipment/Materials used in process

Include type of packaging; make, model and link to spec sheet for equipment like vacuum packaging machine, grinder, scale , etc.

1.8 Ingredients used in process or included in product

Include each ingredient used in the formulation of your product or if you are simply packaging a prepared food, list the ingredients in that food.

2. Product Recipe/Formulation

Provide detailed recipe or formulation for each different product. Complete only one page per product and attach additional products or variations on separate sheets.

Recipe for:

2.1 Ingredients: *Provide exact ingredient amounts in terms of weight. In many cases, no additional ingredients are added to products that are ROP.*

2.2 Step-by-step Instructions: *Provide each step in the process in detail.*

3. Standard Operating Procedures and Employee Training

Standard Operating Procedures (SOPs) are written procedures used to accomplish the requirements in the code. They describe the steps employees and managers should follow for sanitary food handling and maintaining cleanliness of your facility. Employees trained on these SOPs are invaluable to ensuring your HACCP plan is implemented effectively.

Attach your SOPs and employee training procedures on separate sheets. See page 2 for details on what needs to be included.

4. Flow Diagram

Start your flow diagram when the food is received into your facility and end when food is purchased by the consumer. Attach your flow diagram on a separate sheet.

5. Hazard Analysis

A hazard is any biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of control(s). Hazards affect the safety of your food products. Some food safety hazards are associated with the product. These hazards are introduced outside your food establishment and are inherent to the product. Other food safety hazards are associated with the way in which the product is processed. With this in mind you need to conduct what is called a Hazard Analysis to decide where each food safety hazard will be controlled, eliminated or reduced.

To use the Hazard Analysis Worksheet (blank copy on next page), record each of the processing steps from you flow diagram in column (1) to start. Use column (2) to identify the product and/or the process related food safety hazards for that step. Include potential biological, chemical and physical agents. In column (3), decide if the hazards you identified are significant, and justify this thinking in column (4). If you answer No in column (3), then you don't need to fill in columns (5) or (6). If Yes is answered in column (3), describe the control measure for preventing the hazards. In column (6), decide whether this step needs to be a critical control point (CCP). Each step that is identified as a CCP will end up on your HACCP plan (explained in following pages).

Complete your Hazard Analysis on the table below.

Hazard Analysis for

(1) Ingredient/ Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What control measure can be applied to prevent the significant hazards?	(6) Is this step a Critical Control Point? (Yes/No)

6. HACCP Plan

What is HACCP and why is it important? The term HACCP is an acronym for Hazard Analysis Critical Control Point. HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical food safety hazards from raw material receipt, product handling, manufacturing, storage, distribution and consumption of the finished product by the end consumer. If properly designed and implemented, a HACCP plan can prevent the occurrence of potential food safety hazards. **Before engaging in reduced oxygen packaging, an operator shall submit their HACCP plan for approval.** To meet this requirement, you must create a HACCP plan with all of the following components:

1. Each **critical control point** (CCP)
This will be each step in your process that, without control, will produce an unsafe product. Not every step in a process will be a CCP. (Column (1))
2. The **significant hazards** that are to be controlled
Conducting a hazard analysis will help in identifying the hazards in your process. Hazards can be biological, chemical or physical. Biological hazards can be pathogen growth and/or toxin formation, parasites and/or viruses and may include *Clostridium botulinum*, *Bacillus cereus*, *Staphylococcus aureus*, *Listeria monocytogenes*, Hepatitis A, Norovirus, etc. Chemical hazards can include undeclared food allergens, food additives used in excess like sodium nitrate or sulfites or cleaning compounds that are unintentionally introduced. Physical hazards can be anything from glass to metal shards from the working environment. (Column (2))
3. The **critical limits** (CL) for each CCP
This is the maximum or minimum limit that, if not met, could produce an unsafe product. The limit must be based on scientific or industry information and it must be measurable. (Column (3))
4. The **monitoring** actions for each CCP
Monitoring addresses four parts: What, How, Frequency and Who. Ask yourself the following questions when filling in each section: “*What* is being monitored to control the CL”; “*How* is the CL being monitored”; “*At what frequency* is the CL being monitored”; and “*Who* is monitoring the CL”? (Column (4, 5, 6, 7))
5. **Corrective actions** (CA) to be taken if the critical limit is not met
This includes two parts: 1) taking control of the product—ensuring the negatively affected product does not reach the customer, and 2) taking control of the process—correct the root cause that lead to the CL deviation. (Column (8))
6. The method and frequency for **verification** of each CCP being controlled
Describe the verification procedures and the frequency of verification that will ensure the HACCP plan is controlling the food safety hazards. Review of monitoring records each week should, at a minimum, always be a verification activity. (Column (9))
7. **Record** system that documents monitoring and control of each CL
Records are written documents showing the effectiveness (or ineffectiveness) of the HACCP plan. Records are generated from monitoring activities, corrective actions and verification activities. The record template must include space to record values determined in the critical limit. (Column (10))

Using the information from your hazard analysis, complete the HACCP Plan worksheet (blank copy on next pages). First, enter the critical control points from column (6) of your Hazard Analysis into column (1) of the HACCP plan. Next, enter the hazards from column (2) of your Hazard Analysis into column (2) of the HACCP plan. Proceed with completing the remaining columns (3-10) as described in the previous discussion.

HACCP Plan for

Firm Name and Address					Intended Use by Consumer				
List of Products					Method of Storage and Distribution				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CCP	Significant Hazards	Critical Limits	Monitoring				Corrective Actions	Verification	Records
			What	How	Frequency	Who			

Implemented Date: _____ Person-in-charge: _____

7. HACCP Records

You should have a document where you record that each critical limit was met for each batch of product. You can combine them on one form or make a log for each CCP. Provide a copy of your record templates on separate sheets.

8. Product Label

Attach copies of your product labels on separate sheets.

Example label:

