

# Application for Variance Request with HACCP Plan

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

## Instructions

Complete one application for each type of product. For instance, if you are making fully cooked, vacuum packaged sausage and shelf-stable beef jerky, you will fill out two applications. Then if you have several different varieties of the sausage (fennel pork sausage, spicy beef sausage, and apple/sage pork sausage), complete one application, but provide the recipe/formulation (Section 3 of this application) for each variation.

Provide information in each of the sections 1-10 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](mailto:foodsafety@vdacs.virginia.gov). Once your application is reviewed, you will be contacted by email. Your request has not been approved until you receive a letter from our department stating so. Until this time, your variance request is still pending and it is considered a violation of our regulations to engage in the process.

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 or variance proposal 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.*

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.

## 1. Preliminary Product Information

### 1.1 Products to be considered for this variance

*List your product by its common name: jerky, country ham, kimchi, sushi rice, ready-to-eat meals, etc.*

### 1.2 Product description

*Describe the finished product. Consider the following: is it ready-to-eat? Is cooking required or recommended before consuming? Is the product salted, cured, smoked, fermented, fully cooked, uncooked, or partially cooked? Is it a sprouted seed or bean? Is it a custom processed animal? Include how product is packaged: vacuum packaged, wrapped tray packs, natural casing, etc.*

### 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, shelf-stable or other.*

### 1.5 Shelf-life of product

*Indicate how long until your product expires: 7 days, 1 month, indefinitely, etc.*

### 1.6 List of employees trained to perform these operations

*List the employee by name and title, include their qualifications for performing this high risk operation: are they a certified food protection manager, years of experience in special process and HACCP implementation, etc.*

**1.7 Equipment/Materials used in process**

*Include type of packaging; make, model and link to spec sheet for equipment such as thermometers, vacuum packaging machine, dehydrator, smoker, grinder, scale, pH meter, etc.*

**1.8 Ingredients used in process**

*Include each ingredient used in the formulation of your product. Any ingredient composed of multiple ingredients, list those subingredients as well.*

## 2. Written Proposed Variance

When requesting a variance from our Department, you are asking for permission to vary from what is required by the code. You may be conducting a specialized food process or you may be requesting to conduct your operation in a way that varies from the code requirements. Varying from the code may compromise public health, and an approved “variance” is required. Each variance request for a specialized processing method must be accompanied by a HACCP plan, which is described below. Once the variance has been approved or denied, you will be notified in writing of this decision. **You must obtain a variance prior to conducting a specialized process.**

As stated in the code, 2VAC5-585-3541. *Documentation of proposed variance and justification*, the following must be submitted to this Department for consideration in granting a food establishment a variance:

1. A statement of the proposed variance of the regulation requirement citing relevant regulation section numbers; AND
2. An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant regulation sections will be alternatively addressed by the proposal.

The variance request can be composed in a letter. When drafting the proposal include the following:

- State how the variance proposal deviates from what is required in the code, citing relevant code sections by number
- Explain how you, as the operator, will assure that all components of a granted variance will be carried out during operations at your food establishment
- State how the proposal addresses potential public health hazards
- Describe how the proposal is based on scientific or technological principles

# Written Proposed Variance

*Compose your variance letter here.*

### 3. Product Recipe/Formulation

*Provide a 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:**

**3.1 Ingredients:** *Provide exact ingredient amounts in terms of weight.*

**3.2 Step-by-step Instructions:** *Provide each step in the process in detail including temperatures, target pH values, cooking times, curing/brining time, end product storage requirements, length of fermentation, etc.*

## 4. 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, maintaining cleanliness of your facility, and implementing the HACCP program you created. 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.*

## 5. 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.*

## 6. 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 your 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)



## 7. 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. For your variance request to be considered, 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 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”? (Columns (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			

CCP	Significant Hazards	Critical Limits	Monitoring				Corrective Actions	Records	Verification
			What	How	Frequency	Who			

Implemented Date: \_\_\_\_\_ Person-in-charge: \_\_\_\_\_

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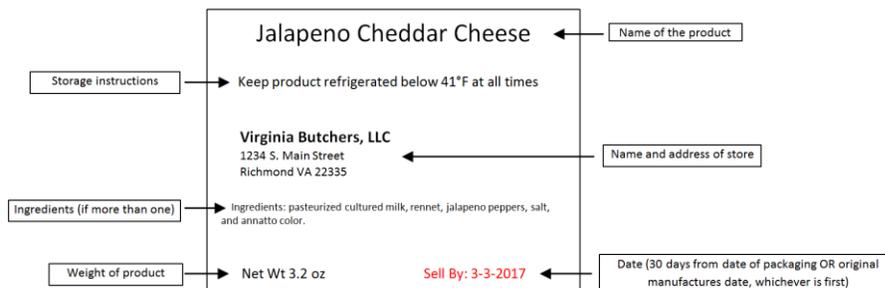
## 8. HACCP Records

*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.*

## 9. Product Label

*Attach copies of your product labels on separate sheets.*

Example label:



## 10. Additional Scientific Documentation

*Attach laboratory analysis, process authority letters, cite scholarly articles, scientific documentation from academia, industry, trade organizations, government agencies, etc. that substantiate your product will not pose an unreasonable risk to public health.*

*It is important that your product formulation and process is validated. This can be done in a couple ways, one way being consultation with a process authority. They will scientifically evaluate your process/formulation and determine if that will produce a safe food product. To do this assessment, process review and product testing may be necessary. 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](mailto:joell.eifert@vt.edu).*