

Manufactured Food Establishment Permit Application Guide

This guidance document provides information on completing the [Permit Application for a Food Manufacturer or Food Storage Warehouse](#), how to prepare for a food safety inspection, and additional information related to manufactured food establishments. Questions may be directed to foodsafety@vdacs.virginia.gov.

Table of Contents

I. Jurisdiction5

1. Catering5

2. Farmers Markets/Events5

3. Pet Food/Animal Feed6

II. Completing the Application6

1. Application Instructions.....6

2. General Information and Requirements6

3. Establishment Information7

4. Business Information8

5. Appendix A: Floor Plan9

6. Appendix B: Training and Records9

7. Appendix C: Preventing Allergen Cross-Contact..... 10

8. Appendix D: Requirements and Exemptions for 21 CFR 117 Subparts C & G 10

9. Appendix E: Preventing Contamination in the Home 12

10. Appendix F: Product Information 12

11. Appendix F-1: Product List..... 13

12. Appendix F-2: Product Recipe..... 13

13. Appendix F-3: Product Label..... 13

14. Application Checklists 14

15. Specialized Food Processing Checklists 14

16. Attestation 14

III. Permit Application Review Process Overview 15

IV. Reminders	15
V. Home Food Processing Exemptions	16
VI. Preparing for Inspection.....	16
1. Foodborne Illness Risk Factors.....	16
2. Items Needed	17
3. Thermometers.....	18
4. Food Temperatures	18
5. Handwashing Sinks	19
6. Two- or Three-Compartment Warewashing Sink	19
7. Sanitizer and Sanitizer Test Strips	20
8. Food, Equipment, and Utensil Storage	21
9. Chemical Labeling and Storage	21
10. Lighting	21
11. Floors, Walls, and Ceilings	21
12. Toilet Rooms.....	22
13. Pest Control	22
14. Refuse Storage	22
15. Service/Mop Sink.....	22
16. Plumbing	23
17. Traceability Lot Codes	23
18. Approval from Other Regulatory Authorities	23
VII. Labeling.....	24
1. Statement of Identity/Common Name of the Food.....	24
2. Net Content Statement	24
3. Ingredient Statement	25
4. Allergens	25

5.	Name and Address of Manufacturer, Packer, or Distributor	26
6.	Nutrition Facts Panel	26
7.	Label Format	27
8.	Labeling Claims.....	28
9.	Labeling Time/Temperature Control for Safety Foods	31
10.	Product Label Examples	32
VIII.	Specialized Food Processing/Products	35
1.	Acidified Food	35
2.	Baby Food	36
3.	Bottled Drinking Water	36
4.	Dairy/Frozen Desserts	37
5.	Dietary Supplement.....	37
6.	Edible Hemp.....	38
7.	Fermented Food	39
8.	Food Containing Alcohol.....	40
9.	Food Containing Botanicals	40
10.	Food Containing Meat or Poultry.....	41
11.	Juice	42
12.	Low-Acid Canned Food	43
13.	Sea Moss.....	43
14.	Seafood	44
15.	Sprouts	45
IX.	VDACS Food Safety Program Contact Information.....	46

I. Jurisdiction

A **Food Manufacturer** is an establishment that manufactures, packages, labels, or stores food and beverages for sale or distribution to other businesses (wholesale) and/or directly to the end consumer (retail).

Examples of manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

A **Food Storage Warehouse** is an establishment that only stores food or beverages and does not modify them in any way.

Manufactured food establishments such as Food Manufacturers and Food Storage Warehouses are permitted by the Virginia Department of Agriculture and Consumer Services (VDACS) in accordance with the Virginia Food and Drink Law and Title 21 of the Code of Federal Regulations. There are certain types of establishments, processes, and/or products that may be under shared jurisdiction between the VDACS Food Safety Program and another program/agency or be under primary jurisdiction of another program/agency. Common examples are briefly outlined below and in [Section VIII Specialized Food Processing/Products](#) of this document. This document does not cover all the nuances that may apply. Please contact the VDACS Food Safety Program or the appropriate program/agency for additional information.

1. Catering

A Food Manufacturer/Food Storage Warehouse permit does not allow manufactured food establishments to cater or conduct other food service. Catering and other food service operations/food establishments are under the Virginia Department of Health (VDH)'s jurisdiction. Contact your [local Health Department](#) for assistance.

2. Farmers Markets/Events

A Food Manufacturer/Food Storage Warehouse permit allows you to manufacture and/or warehouse packaged and labeled manufactured food products at the permitted location and sell those products at other locations, including at farmers markets and events. Ensure you have a copy of your permit with you at any events you attend. In accordance with the [Retail Food Service Memorandum of Understanding](#) (MOU) in place between VDACS and VDH, food establishments permitted by VDACS generally do not need to obtain a Temporary Food Establishment (TFE) permit from VDH to sell their products at farmers markets and events unless they are conducting food service at the farmers market or event. Examples of onsite food service that requires a VDH TFE permit include, but are not limited to, assembling dishes or products, preparing and serving beverages, and cooking/reheating/hot holding foods. TFE permit requirements may also vary by locality. Please refer to the MOU and/or contact your [local Health Department](#) or the VDACS Food Safety Program for additional information.

Manufactured food products are typically sold packaged and labeled. If you plan to sell your manufactured food products unpackaged at farmers markets/events, you must have a card, sign, or other method of notification available onsite with the required labeling information (common name of food, ingredient statement, major food allergens, and nutrition labeling). See [Section VII Labeling](#) of this document for additional information.

If you plan to offer samples of your products, prepare your samples at your permitted location and ensure that all products are held at appropriate temperatures during transportation and for the duration of the event. See the [Guidelines for Providing Safe Food Samples at the Market guidance document](#) for additional information.

3. Pet Food/Animal Feed

A Food Manufacturer/Food Storage Warehouse permit is for food and beverages intended for human consumption. The VDACS Food Safety Program does not regulate food and beverages intended for animal consumption, such as pet treats, pet food, and animal feed. Contact the VDACS Agricultural Commodities for assistance at (804) 786-3515 or feed@vdacs.virginia.gov.

II. Completing the Application

1. Application Instructions

Take care to read and follow the application instructions on Page 1 carefully, in addition to reviewing this guidance document. Failure to follow the application instructions may result in a returned application and/or a delay in the review and approval of your application.

2. General Information and Requirements

- [Virginia Food and Drink Law](#): you must meet the requirements of this Law.
- [21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food](#): you must meet the requirements of these regulations.
- [21 CFR 101 Food Labeling](#): you must meet the requirements of these regulations.
- [FDA Food Labeling Guide](#): the Food and Drug Administration's food labeling guidance for industry.
- [Basic Labeling Guidance](#): packaged food products, including those packaged onsite at the establishment, must comply with labeling requirements. See [Section VII Labeling](#) of this document for additional information.
- [Employee Health Policy Form 1B](#): documentation that covers reportable illnesses and symptoms. This documentation is required to be kept onsite at the establishment.
- [Allergen Control Plan Guidance](#): guidance for creating and implementing an allergen control plan.
- [VDACS Food Safety Program Website](#): the VDACS Food Safety Program's website.

3. Establishment Information

- **Did you review the [Manufactured Food Establishment Permit Application Guide](#)?** Check Yes or No. This is referring to the document you are currently viewing. Reviewing this document in its entirety is strongly recommended.
- **This application is for a:** new firm/relocation or change of ownership. Check which applies to your establishment.
- **Establishment Name:** enter the full legal name of your business, including, if applicable, the “Doing Business As” (DBA) name.
- **Water Supply:** check whether the establishment has a public or private water supply.
 - Public water supply – provided by the locality. Your establishment’s water supply is public if you receive a water bill in the mail. You may be requested to provide proof of a public water supply.
 - Private water supply – provided by private facilities, such as a well. **If your establishment water supply is private, you must provide a current water report from within the past year showing the results for total coliform. [Total coliforms must be absent.](#)**
- **Sewage Disposal:** check whether the establishment’s wastewater is disposed of into a public or private system.
 - Public sewage disposal – connected to the locality.
 - Private sewage disposal – connected to private facilities, such as a septic tank. **If you have a private sewage disposal system, you must provide documentation that your system is appropriate for your planned food operations.** Documentation must be obtained from your [local Health Department](#) and/or from a licensed On-Site Soil Evaluator. **This is not the same as the initial sewage disposal record of inspection received when your establishment’s building was first constructed.**
- **Establishment Phone Number:** enter the phone number that can be used to contact your establishment.
- **Establishment Email Address:** enter the email address that can be used to contact your establishment.
- **Establishment Physical Address:** enter the full physical address of your establishment.
- **City/County:** enter the name of the city or county in which your establishment is located. This is the locality that assesses the real estate tax for the establishment’s physical address.
- **Establishment Mailing Address:** enter the full address that can be used to mail food safety-related correspondence, such as permits and letters, to your establishment. If the mailing address is the same as the physical address, you may choose to indicate that by entering a brief note like “same as above” or “same as physical address” in this field instead of retyping the full address.
- **Establishment Ownership Name:** enter the name of the business entity that legally owns the establishment.
- **Ownership Type:** check the applicable ownership type for the establishment’s legal ownership.
- **Virginia State Corporation Commission Business Entity ID:** enter the Business Entity identification number for the establishment’s legal ownership as provided by the [Virginia State Corporation Commission](#).
- **Ownership Billing Address:** enter the full address that can be used to mail billing-related correspondence, such as the annual inspection fee invoice, to your establishment. If the billing address is the same as the physical or mailing address, you may choose to indicate that by entering a brief note like “same as above”, “same as physical address”, or “same as mailing address” in this field instead of retyping the full address.
- **Names, Titles, and Contact Information for Persons Comprising the Ownership:** enter the name, title, phone number, and email address for the individuals involved in the establishment’s ownership. Attach a list of this information to your application if needed.

- **Zoning/Building Department Approval Obtained:** check Yes or No. You are responsible for ensuring your establishment and planned food operations are approved by the locality's Zoning/Building Department as applicable. Localities may have restrictions for certain types of manufactured food establishments, such as home kitchen-based food operations.
- **Anticipated Date of Establishment Opening and/or Construction Completion:** enter the anticipated date your establishment will be ready to open. **The permit application must be submitted at least sixty (60) calendar days prior to this date.**

4. Business Information

- **Operational Hours**
 - **Open Year-Round/Open Seasonally:** check whether your establishment is open year-round or open seasonally. If your establishment is open seasonally, specify which months your establishment will be open.
 - **Operational Hours:** enter the days and hours of operation for your establishment.
 - **Number of employees:** enter the number employees, including owners and managers, for the food establishment.
- **Business Distribution**
 - **Percentage of ingredients received from out-of-state suppliers:** enter the percentage of food ingredients and packaging that comes into direct contact with your manufactured food products that originated in another state, territory, or country. For example, you purchase flour for your baked goods at the local supermarket. You check the label and see that it was distributed by a company in California. Since that flour was made in a different state, you would count that into the percentage of ingredients from out-of-state suppliers even though you purchased it in Virginia.
 - **Percentage of products sold to out-of-state customers:** enter the percentage of products that are distributed to customers in other states, territories, or countries.
 - **Percentage of products sold wholesale:** enter the percentage of products sold wholesale (i.e. to other businesses and/or for resale).
 - **Percentage of products sold retail:** enter the percentage of products sold retail (i.e. directly to the end consumer). Retail includes direct-to-consumer transactions, such as you selling your product directly to your individual customers at the farmers market or online through your own website.
 - **NOTE:** percentage of products sold wholesale and percentage of products sold retail must add up to 100%. If you do not know the exact retail or wholesale percentages, please include what you believe to be your projected percentages.

- **Example:**

Percentage of products sold wholesale:	70%	100% total
Percentage of products sold retail:	30%	

- **Establishment Size**
 - Select the corresponding Establishment Size in relation to your Projected Gross Annual Sales. Your Establishment Size helps determine the regulatory requirements that are applicable to your business as established in Title 21 of the Code of Federal Regulations Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food.

- **Manufactured Food Establishment Type**

- This section lists the types of manufactured food establishments permitted by the VDACS Food Safety Program. Check all the type(s) that apply to your establishment, and submit the appendices required for that establishment type.
- **Shared-Use Facility:** check whether you are operating in a shared-use facility. A shared-use facility provides shared space and equipment for multiple businesses to use for food preparation/processing and storage. Examples may include church kitchens, commercial kitchens, commissary kitchens, community canneries, and restaurant kitchens. If the answer is yes, provide the name of the shared-use facility.
- **Description of the Food Products Manufactured and/or Warehoused:** provide a brief description of the food and beverages you intend to manufacture and/or warehouse.
- **NOTE:** Manufactured food establishments that also operate as a retail food establishment need to be permitted for both operational aspects. A [Permit Application for a Retail Food Establishment](#) is required in addition to the [Permit Application for a Food Manufacturer or Food Storage Warehouse](#) if you are retailing food or beverages (i.e. have a storefront, tasting room, etc.) and are NOT a home operation. A home operation cannot operate as a retail food establishment.

- **Specialized Food Processing**

- This section provides common types of specialized food processing for manufactured food establishments. Check all the types that apply to your establishment. If your establishment processes and/or warehouses seafood/seafood products, you must also check the applicable sub-types for that establishment. If your establishment type and/or sub-type is not listed, use the “Other” fields to describe your establishment.
- Specialized processes have additional requirements necessary for approval prior to processing those food products. See [Section VIII Specialized Food Processing/Products](#) of this document for additional information. Provide the required documentation outlined in the Specialized Food Processing Checklists on pages 16-17 of the permit application as applicable to your establishment.

5. Appendix A: Floor Plan

- Provide a simple floor plan of the manufactured food establishment that is clearly labeled with the locations of all handwashing sinks, three-compartment sink, service/mop sink, food preparation areas, food storage areas, restrooms, etc. The floor plan can be drawn using computer software or drawn by hand.

6. Appendix B: Training and Records

- Provide your training record and training certification. All employees and persons in charge involved in food operations must complete food safety training, including single-employee businesses where the owner is the only employee and warehouses that only store food products.
- Adequate training covers principles of food hygiene and food safety, as appropriate to your manufactured food establishment and the duties of each employee. A Food Handler Certification does not meet these training requirements.
- Completed training must be documented. You may use the training record template provided in the permit application or create your own.

- **Example Training Courses (not an all-inclusive list):**

- ANSI Approved Certified Food Protection Manager Courses
 - <https://www.foodprotect.org/Certification>
 - Accredited courses through the Conference for Food Protection (CFP). List maintained by the American National Standards Institute (ANSI).
- Institute for Food Safety at Cornell University
 - <https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/>
 - (315) 787-2288
- NC State Food Safety Education & Training
 - <https://units.cals.ncsu.edu/foodsafety/good-manufacturing-practices-in-food-safety/>
 - (919) 513-2065

7. Appendix C: Preventing Allergen Cross-Contact

- Provide your written plan for preventing allergen cross-contact. Allergen cross-contact is the unintentional incorporation of a food allergen into a food product. A food allergen is a specific food or ingredient that can cause a potentially life-threatening immune system reaction. The nine major food allergens are: **Crustacean shellfish, egg, fish, milk, peanuts, tree nuts, sesame, soybeans, and wheat.**
- You should conduct a food allergen ingredient analysis, which considers all nine major food allergens. If your analysis identifies food allergens that will (or may be) in your products, you must have controls in place that prevent allergen cross-contact that includes all the products you manufacture for sale. A statement on your product label such as “may contain [peanuts], [milk], [fish]...” is NOT an adequate control for preventing allergen cross-contact.
- A plan for preventing allergen cross-contact helps protect the health of consumers with food allergies and helps protect the financial health and reputation of your company. If your products contain any of the major food allergens, you must have controls in place to prevent allergen cross-contact.
- **NOTE:** If you operate in a shared-use facility, you must also consider foods that they prepare and store.
- **Allergen Control Resources (not an all-inclusive list):**
 - [Allergen Control Plan Guidance](#)
 - [FDA – Allergen Cross-Contact Prevention](#)
 - [FDA – What You Need to Know about Food Allergies](#)
 - [Food Allergy Research and Resource Program – Components of an Effective Allergen Control Plan](#)
 - [Food Safety Magazine – Putting Together an Effective Allergen Control Plan](#)

8. Appendix D: Requirements and Exemptions for 21 CFR 117 Subparts C & G

- Review the requirements and exemptions for 21 CFR 117 Subparts C & G and select whether your establishment is exempt from those requirements.

- The FDA Food Safety Modernization Act of 2011 (FSMA) aims to better protect public health by adopting a preventive, risk-based approach to food safety regulation. 21 CFR 117 is divided into seven subparts: A through G.
 - Subpart C establishes a food safety plan that includes an analysis of hazards and implementation of risk-based preventive controls. Establishments subject to Subpart C must have and implement a Food Safety Plan. The Food Safety Plan must be overseen by a Preventive Controls Qualified Individual (PCQI) and include the following:

▪ Hazard analysis ▪ Monitoring procedures ▪ Preventive controls ▪ Corrective action procedures	▪ Supply chain program ▪ Verification procedures ▪ Recall plan
---	--
 - Preventive Controls Qualified Individual (PCQI)
 - A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience.
 - Additional information and upcoming PCQI training may be found on the [Food Safety Preventive Controls Alliance \(FSPCA\)'s website](#).
 - Subpart G establishes the supply chain requirements for managing risks from suppliers. The safety of your manufactured food products depends on both the controls you implement at your establishment and the controls implemented by your suppliers or customers. Known hazards for your ingredients or products need to be controlled, whether at your establishment, your suppliers' establishment, or at another step in the supply chain. If you decide that the hazard will not be controlled at your establishment, then you should identify a supply chain control in your hazard analysis and implement a supply-chain control.
- Not all establishments are required to comply with Subparts C & G, as there are certain exemptions that may apply.
- **A Manufactured Food Establishment is NOT subject to the requirements of Subparts C & G if the business:**
 - Operates within a private residence (i.e. home operations)
 - Conducts 51% or more of sales directly to the end-consumer (retail)
 - Conducts 50% or more of sales to other businesses (wholesale) **AND** averages less than \$1,000,000 in sales of human food per year for three (3) years, [adjusted for inflation](#)
 - This is considered a “very small business” that **MUST** file an [attestation with the FDA](#) to be exempt from Subparts C & G
 - See the [FDA's Qualified Facility Attestation website](#) for additional information and instructions
 - Exclusively manufactures or warehouses seafood, juice, dietary supplements, or alcoholic beverages
 - If your establishment manufactures or warehouses any of the above **AND** other commodities, then you are still subject to Subparts C & G for the other commodities unless one of the other exemptions applies
 - Exclusively warehouses unexposed, packaged food
 - **NOTE:** your establishment's exemption status may change over time. Non-exempt establishments must comply with the requirements of Subparts C & G.

- **Food Safety Plan Resources (not an all-inclusive list):**

- [FDA – FSMA Final Rule for Preventive Controls for Human Food](#)
- [FDA – Draft Guidance for Industry, Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
- [Food Producer Technical Assistance Network](#)
- [Food Safety Preventive Controls Alliance](#)

9. Appendix E: Preventing Contamination in the Home

- **Appendix E Preventing Contamination in the Home** is only applicable for home operations. If your establishment is NOT a home operation, select “Not Applicable – my establishment is not a Home Operation”. If your establishment IS a home operation, answer both sections of **Appendix E**.
- **Preventing Contamination from Pets:**
 - If you have pets in the home, describe how pets will be excluded from all food processing and storage areas on this page or as part of floor plan for **Appendix A Floor Plan**. Pets must be excluded from these areas AT ALL TIMES, not only when you are actively processing/preparing your manufactured food products. These areas must be fitted with a solid hinged door(s) that can be latched/closed shut. Installing “baby gates” or placing pets in closed rooms in other areas of the home while operating your manufactured food business DOES NOT satisfy this requirement.
 - If you do not have pets in the home, select “Not Applicable – I do not have any pets in my home”
- **Preventing Contamination from Personal Belongings:**
 - Provide your written plan for preventing contamination from personal belongings while operating your manufactured food business. Personal belongings are any items that are not used in the manufacturing of your foods that will be offered for sale to the public.
 - The regulation states that clothing or other personal belongings cannot be stored in areas where food is exposed or where equipment or utensils are washed.
 - In addition, the regulation also states that eating food, chewing gum, drinking beverages or using tobacco cannot occur in areas where food is exposed or where equipment or utensils are washed. This means that during the hours that your home is used as a manufactured food establishment, all areas must have first been cleaned and sanitized and that all personal belongings must be removed from the countertop, tables, etc. where food will be manufactured. All production areas must be cleaned and sanitized, and all personal belongings must be removed from the countertop, tables, etc. where food will be manufactured.

10. Appendix F: Product Information

- Provide information regarding ALL the food and beverage products you intend to manufacture using **Appendix F-1 Product List**. Then select up to three (3) products from this list and provide recipes and labels for those products using **Appendix F-2 Product Recipe** and **Appendix F-3 Product Label**. Your reviewer may request additional recipes and labels from your product list during the application review process.
- It is your responsibility to ensure your product labels comply with regulatory requirements. After you receive your permit, product recipe/label reviews will primarily occur during routine inspections, and you will generally not need to submit new products for recipe/label review. However,

there are some instances in which a review may be necessary before you can sell those products. Examples of such instances include, but are not limited to, introducing new allergens, adding/changing product types, and/or conducting specialized processing. Please contact the Food Safety Program if you have questions about adding new products.

11. Appendix F-1: Product List

- List of ALL the food and beverage products you intend to manufacture and the planned distribution channels (i.e. where you plan to sell them). Check the “Recipe & Label Provided” box next to each product that you’re submitting recipes and labels for.
- Then select up to three (3) products from this list and provide recipes and labels for those products using Appendix F-2 and Appendix F-3. Your reviewer may request additional recipes and labels from your product list during the application review process.

12. Appendix F-2: Product Recipe

- Provide Product Recipe sheets for the products you selected on **Appendix F-1 Product List**. Your reviewer may request additional recipes and labels from the list during the review process.
- **Business Name:** enter the name of your business/establishment.
- **Date:** enter the date you completed the product recipe sheet.
- **Product Name:** enter the name of the product this recipe is for.
- **Trade Secret:** check this box if your product is a trade secret/confidential. Note that you still need to provide all required information for your products whether or not this box is checked. Trade secrets are excluded from disclosure in accordance with the [Virginia Freedom of Information Act](#).
- **Description of Product Packaging:** provide information regarding how your product is packaged. For example, whether it is packaged in a plastic pouch, glass bottle, vacuum-sealed package, aluminum can, etc.
- **Method of Storage/Distribution:** provide information regarding how your product will be stored and distributed. For example, whether it will be held or distributed at ambient/room temperature, refrigerated, frozen, etc.
- **Ingredients:** list each ingredient used in your product’s recipe, including the amount of each ingredient. Listing ingredient amounts in weight using the same unit of measurement (i.e. ounces, grams, etc.) is preferred, although using other units of measurement such as teaspoons, cups, gallons, etc. is acceptable.
- **Step-by-Step Instructions:** describe each step needed to make your product. Ensure to include information such as cleaning and sanitation, ingredient mixing and preparation, baking/cooking times and temperatures, cooling times and temperatures, packaging steps, storage instructions, shelf life/expiration dates, etc.

13. Appendix F-3: Product Label

- Provide Product Label sheets for the products you selected on **Appendix F-1 Product List**. Your reviewer may request additional recipes and labels from the list during the review process.

- Labeling is mandatory for all packaged foods. Accurate food labels are an important aspect of food safety, both for your customers and for your business. Undeclared allergens on food labels are the leading cause of food recalls in the U.S. Incorrect product labels may also delay your permit application's review and approval process. See [Section VII Labeling](#) of this document for additional information.

14. Application Checklists

- Use the checklists provided to ensure all required information and supporting documentation is included in your application. Ensure you use the checklists that correspond with the Manufactured Food Establishment Type that you selected on page 4 of your permit application. Submitting an incomplete application may result in a returned application and/or a delay in the review and approval of your application.

15. Specialized Food Processing Checklists

- Use the checklists provided to ensure all required information and supporting documentation is included in your application. Ensure you use the checklists that correspond with the Specialized Food Processing that you selected on page 4 of your permit application. Submitting an incomplete application may result in a returned application and/or a delay in the review and approval of your application.

16. Attestation

- Enter your signature, printed name, and the date of signature to attest to the accuracy of the information provided and agree to comply with the Virginia Food and Drink Law, the Current Good Manufacturing Practice Regulations, and other applicable state, local, and/or federal regulations. You also agree to allow the regulatory authority access to the establishment at any reasonable time to inspect, conduct investigations, or collect samples as required.

III. Permit Application Review Process Overview

Submit your completed application with all required information and supporting documentation to the VDACS Food Safety Program by email at foodsafety@vdacs.virginia.gov **at least sixty (60) calendar days before the establishment's anticipated opening date.**

Your submitted application will be assigned an Application Number and forwarded to a Checklist Reviewer. The Checklist Reviewer evaluates the submitted application in accordance with the appropriate Application Checklist to ensure the required application and supporting documentation has been received. Incomplete applications will not proceed in the permitting process until all required documentation has been received. A Checklist Reviewer will contact you to confirm receipt of your application, provide your Application Number, and inform you of next steps, typically within one (1) week of receiving the application.

The Checklist Reviewer will move your application to the next step of the process after they receive all required application documentation. An Application Reviewer will conduct a full review of your application for correctness, accuracy, and compliance with regulatory requirements. The Application Reviewer will contact you if additional information and/or revisions are needed for your application, typically within eight (8) weeks from when the checklist review step has been completed. Incorrect applications will not proceed in the permitting process until all requested information or revisions have been received and approved. After the Application Reviewer approves your application, an inspector will contact you to schedule a preoperational inspection of your establishment. See [Section VI Preparing for Inspection](#) of this document for additional information. You will receive a food safety permit and approval to operate following the successful completion of this inspection.

IV. Reminders

- Permits are not transferable. A new permit application must be submitted prior to the establishment moving to a new location or changing ownership. Otherwise, permits are automatically reissued every year around the month of June, and you do not need to reapply for a permit.
- There is a \$40 annual inspection fee for operating a retail food establishment, unless the establishment is exempt. You will not be required to pay this fee at the time of your inspection; however, you will receive an invoice during the next billing cycle, which is typically in the fall of each year.
- Remodels/Renovations: contact your current inspector or your VDACS Food Safety Program Regional Office to discuss changes to your establishment and what may be needed to remain compliant with regulatory requirements.
- Private water supply: in addition to providing a current water report from within the past year showing the results for total coliform with your application, you are required to conduct this testing on a regular basis and maintain test results onsite.
- A [Permit Application for a Retail Food Establishment](#) is required if you are retailing food or beverages (i.e. have a storefront, tasting room, etc.) and are NOT a home operation. A home operation cannot operate as a retail food establishment.
- Changes to your product list such as introducing new allergens, adding/changing product types, and/or conducting specialized processing may require additional approval before you can sell those products. For example, you are permitted to manufacture baked goods and want to start manufacturing pickles. Please contact the Food Safety Program if you have questions about adding new products.

V. Home Food Processing Exemptions

Manufactured food establishments, including home food processing operations, that manufacture, process, package, label, or store food for introduction into commerce (i.e., sale or distribution) are subject to the Virginia Food and Drink Law and other applicable regulations administered by the Virginia Department of Agriculture and Consumer Services (VDACS) Food Safety Program. These establishments are required to be inspected, have a permit to operate, and pay an annual inspection fee of \$40.

[Section § 3.2-5130](#) of the Virginia Food and Drink Law includes exemptions from inspection, permit, and fee requirements for home food processing operations that process certain low risk foods, acidified vegetables, and/or honey in compliance with the exemption provisions. If your home-based manufactured food establishment meets the exemption provisions, you may operate in accordance with the exemption and do not need to submit a permit application. You will NOT receive a manufactured food establishment permit or an invoice for the \$40 annual inspection fee.

If you want to sell products not listed in the exemption, sell/deliver products beyond what is allowed by the exemption, and/or your operations change such that your home-based manufactured food establishment no longer meets the exemption provisions, you must complete and submit a [Permit Application for a Food Manufacturer or Food Storage Warehouse](#). See the [Virginia's Home Food Processing Exemptions Frequently Asked Questions guidance document](#) for additional information.

VI. Preparing for Inspection

After your application has been approved, an inspector will contact you to schedule a preoperational inspection of your establishment. You will receive a food safety permit and approval to operate following the successful completion of this inspection. Although the preoperational inspection is scheduled, routine and other inspections are unannounced and unscheduled.

The last page of the [Permit Application for a Food Manufacturer or Food Storage Warehouse](#) is a Preoperational Inspection Checklist. This is a reference tool and does not need to be submitted with your permit application. This section of the Permit Application Guide works in tandem with the Preoperational Inspection Checklist to highlight information on multiple common inspectional items to assist you in preparing for inspection.

1. Foodborne Illness Risk Factors

The U.S. Centers for Disease Control and Prevention (CDC) has identified the top five (5) risk factors contributing to foodborne illness outbreaks as:

- Poor personal hygiene
- Contaminated equipment/cross-contamination
- Improper holding times and temperatures
- Food from unsafe sources
- Inadequate cooking temperatures

Understanding these risk factors can help you reduce the risk of foodborne illness, protect your customers, and protect your business. Steps you can take to manage/minimize the prevalence of these risk factors in your establishment include:

- Proper handwashing
- Implementing an Employee Health Policy
- Avoiding bare-hand contact with ready-to-eat food
- Holding food at the proper temperature and for the appropriate amount of time
- Cooking food to the proper temperature
- Cleaning and sanitizing food contact equipment
- Obtaining food from approved sources and suppliers

2. Items Needed

This list highlights the most common items that a retail food establishment may need to operate in compliance with regulatory requirements. This list does not cover everything that may/may not apply to your establishment. Please contact the VDACS Food Safety Program for additional information.

- Allergen Control Plan
- Cleanable floors, walls, and ceilings
- Employee Health Policy
- Food Safety Plan
- Functional and cleanable food processing equipment
- Handwashing sinks
- Maintained roads, yards, parking lots
- Outdoor refuse facilities
- Pest control
- Potable water supply (water bill for public water supply or water test results for private water supply)
- Records of education and training
- Refrigeration equipment
- Sanitizer for food, equipment, & utensils
- Sanitizer test strips
- Service sink for the disposal of mop water or similar liquid waste
- Shielded/shatter-proof light fixtures in areas with exposed food and/or equipment
- Supply Chain Program
- Thermometers (ambient air thermometer, probe-type food thermometer)
- Two- or Three-compartment warewashing sink
- Toilet rooms with handwashing sink and self-closing doors
- Vomiting and diarrheal cleanup procedures

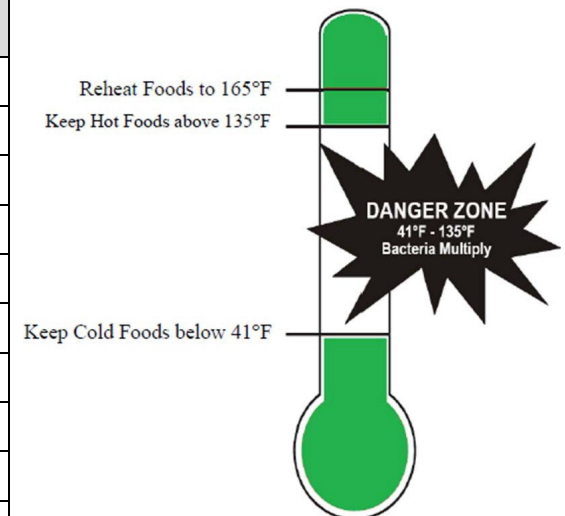
3. Thermometers

Ambient Air Thermometer	Metal Stem Probe-Type Thermometer
An <u>ambient air thermometer</u> in each refrigerator/cooler is necessary to monitor the air temperature inside the units. The air temperature should be about 38°F to hold foods at 41°F or below. Example pictured below. 	A <u>metal stem probe-type thermometer</u> that reads from 0°F to 220°F is necessary to take the internal temperature of food products. Example pictured below. 

4. Food Temperatures

- Cold Holding: 41°F or below
- Hot Holding: 135°F or above
- Frozen Foods: 32°F or below
- Cooking: see table below

Food Item	Minimum Temperature
Fruits and vegetables cooked for hot holding	135°F
Beef and pork roast, beef steaks, veal, lamb, and commercially raised game animals	145°F
Eggs cooked for immediate service	145°F
Fish and foods containing fish	145°F
Pork, including ham and bacon	145°F
Ratites and injected meats	155°F
Eggs cooked for later service	155°F
Ground or flaked meat and fish, including hamburger, ground pork, or sausage	155°F
Poultry/poultry products, including stuffing and casseroles	165°F
Stuffed meat and fish	165°F



5. Handwashing Sinks

Handwashing sinks must be provided with:
Soap
Paper towels
Trash can
Hot (85°F minimum) and cold running water on demand
Handwashing sign



- **Handwashing Sinks for a Home Operation – Personal Kitchen:** because these establishments operate within the operator’s personal home kitchen, an allowance may be provided to allow use of the nearest restroom handwashing sink instead of installing an additional handwashing sink in the personal kitchen area.
- **Handwashing Sinks for a Home Operation – Separate Kitchen:** because these establishments operate within a separate, dedicated processing area inside or attached to the operator’s home that is not the personal kitchen, the handwashing sink requirements are the same as manufacturers that are not home operations. Handwashing sinks must be provided in all food preparation and warewashing areas.

6. Two- or Three-Compartment Warewashing Sink

Two- or Three-compartment warewashing sinks must be provided with:
Detergent
Hot (110°F minimum) and cold running water on demand
Sanitizer
Sanitizer test strips
Sink drain stoppers



- To clean and sanitize equipment/utensils:
 - Pre-clean by scraping large food particles into trash can
 - Wash in hot soapy water

- Rinse soap from surface in clean water
- Submerge equipment in chemical sanitizer for the time specified on the sanitizer container
- Air dry
- **Warewashing Sink for a Home Operation – Personal Kitchen:** because these establishments operate within the operator’s personal home kitchen, an allowance may be provided to allow use of the kitchen sink instead of installing an additional warewashing sink in the personal kitchen area. You must consider how to properly wash/rinse/sanitize with this setup if your kitchen sink doesn’t have enough compartments, such as by using food-safe containers in addition to the kitchen sink or using the dishwasher to wash/rinse and the kitchen sink to sanitize.
- **Warewashing Sink for a Home Operation – Separate Kitchen:** because these establishments operate within a separate, dedicated processing area inside or attached to the operator’s home that is not the personal kitchen, the warewashing sink requirements are the same as manufacturers that are not home operations. A two- or three-compartment sink must be provided for warewashing as appropriate to the establishment’s operations.

7. Sanitizer and Sanitizer Test Strips

Sanitizers used must be approved for sanitizing food-contact surfaces and used in accordance with the manufacturer’s instructions. Two of the most common chemical sanitizers are chlorine bleach and quaternary ammonium. Sanitizer test strips are used to measure the sanitizer concentration. Sanitizer test strips are specific to the type of sanitizer that you choose. In other words, sanitizer test strips for chlorine will not work with the quaternary ammonium sanitizer and vice versa. An overview of these sanitizers and test strips is provided in the table below.

Chemical Sanitizer	Pros	Cons	Example Sanitizer	Example Test Strips	Typical Concentration	Notes
Chlorine Bleach	Easy to find, Inexpensive	Strong odor, Can bleach clothes			50-100 ppm	Do not use scented or splash-less bleach
Quaternary Ammonium	Mild odor, Available in tablet form for easy measuring	Not as easily obtained as bleach, May be more expensive than bleach			200-400 ppm	Typically found at restaurant supply companies or online

8. Food, Equipment, and Utensil Storage

Store food, equipment, and utensils in a clean and dry location where it is not exposed to splash, dust, or other contaminants.

- Store these items covered, inverted, and by maintaining your establishment in a condition that ensures insect/rodent entry points such as doors, windows, floors, walls, ceiling, and the roof are in proper working order/condition.
- Store all food products (packaged and non-packaged) at least 4-6 inches above the floor level.
- You may store food products and equipment/utensils in cabinets, on shelving, pallets, tables, etc. if they are clean and won't contaminate the food or equipment/utensils.
- If you use raw foods (eggs, meat, etc.) in your food products, store them in the refrigerator **BELOW** any other ready-to-eat food products. This will help prevent any potential leakage onto other items stored in the refrigerator.

9. Chemical Labeling and Storage

Ensure chemicals are properly labeled with the common name of the chemical and stored away from food, equipment, and utensils. Find an area to segregate your chemicals (including sanitizer, medicines, first aid supplies, etc.) to help you prevent potential contamination.

10. Lighting

Lighting

Lighting above and around food preparation/processing areas and areas where there is exposed food, equipment, or utensils **MUST** be shatterproof or have protective shields such as plastic tubing with endcaps (for fluorescent ceiling lighting) or another form of a cover. This prevents glass from falling into your food, equipment, or utensils.



11. Floors, Walls, and Ceilings

All floors, walls, and ceilings in the food preparation area(s) must be made of materials that are smooth, easily cleanable, non-absorbent, and free from open cracks, holes, exposed insulation, and flaking/peeling paint. Carpeting and unsealed wood is not allowed in these areas. Walls must be painted in a glossy paint or another smooth cleanable surface. Surfaces that cannot be easily cleaned and sanitized may lead to contamination in your establishment and products.

12. Toilet Rooms

At least one toilet must be provided that is conveniently located and accessible to employees during all hours of operation. Toilet rooms must be provided with a fully stocked handwashing sink either inside or immediately adjacent to the room. A covered waste receptacle must be provided for disposal of sanitary napkins. A supply of toilet tissue must be available at each toilet. The plumbing fixtures (sink, toilet, etc.) must be easily cleanable. Toilet rooms cannot be used for storing food, equipment, or utensils. Toilets may not be used as service/mop sinks. A toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door, except where a toilet room is located outside a food establishment and does not open directly into the food establishment.

13. Pest Control

The premises must be free of insects, rodents, and other pests. Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests. A restricted use pesticide shall be applied only by a certified applicator. Tracking pesticide powders may not be used in a food establishment.

14. Refuse Storage

An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain. An outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials. Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers. Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit. An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate. Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents. Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

15. Service/Mop Sink

Service/Mop Sink

At least one service sink or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste. Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.



16. Plumbing

A plumbing system shall be installed to prevent backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law by providing an air gap as specified or installing an approved backflow prevention device. An air gap between the water supply outlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply outlet and may not be less than one inch.

17. Traceability Lot Codes

Assigning lot codes to your products helps ensure accurate identification of the food as it moves through the supply chain. A traceability lot coding system can be very useful in events such as product recalls or foodborne outbreak investigations. Without a traceability lot coding system in place, you may have to recall all of your products instead of a smaller, specific lot of products since you may not be able to narrow down which products may be affected. An example of a simple lot code system/log is provided below. See the [FDA's Traceability Lot Code website](#) for additional information.

Product	Date Made	Amount Made	Lot Code	Delivery Date	Customer	Amount Delivered	Notes
Brownies	01-06-13	75	A1	01-07-13	John Brown	75	Ran out of Nestle chocolate chips mid-batch; used a mix of Nestle and Hershey
Cupcakes	04-15-13	50	A2	04-17-13	Susie Jones	50	
Lemon Bars	05-15-13	150	A3	05-16-13	Johnson Farmers Market	139	Leftovers were served at my garden club meeting on 5-17-13
Wedding Cake	06-10-13	1	A4	06-11-13	Dorine Smith	1	
Granola Bars	07-02-13	200	A5	07-03-13 07-04-13	John Jackson Mike Lawson	125 75	Strawberry crisp

18. Approval from Other Regulatory Authorities

It is your responsibility to ensure your establishment is operating in accordance with applicable regulatory authorities such as the VDACS Food Safety Program, the Virginia Department of Health, the Zoning/Building Department, Fire Department, the Virginia Alcoholic Beverage Control Authority, etc.

VII. Labeling

Labeling is mandatory for all packaged foods. Accurate food labels are an important aspect of food safety, both for your customers and for your business. Undeclared allergens on food labels are the leading cause of food recalls in the U.S. Incorrect product labels may also delay your permit application's review and approval process.

It is your responsibility to ensure your product labels comply with regulatory requirements. Ensure you pay close attention to the labeling requirements in the [21 CFR 101 Food Labeling](#) regulations. Additional information and examples of available resources that may assist in creating and revising product labels are provided below.

- [FDA Food Labeling Guide](#)
- [Food Producer Technical Assistance Network](#)
- [VDACS Basic Labeling Guidance](#)

1. Statement of Identity/Common Name of the Food



- Must be on the Principal Display Panel (Front Panel) if more than one panel is used.
- Must be an accurate description of the product.
- Must be prominent on the label.

2. Net Content Statement



- Must be on the Principal Display Panel (Front Panel) if more than one panel is used.
- Must be located on the bottom third of the panel.
- Must be stated in both standard and metric units.
- For liquid products:
 - Declared in fluid measure
 - May be preceded by "Net"
- For solid products:
 - Declared by weight
 - Must be preceded by "Net Weight" or "Net Wt."

3. Ingredient Statement

Ingredients: Enriched Corn Meal (Corn Meal, Ferrous Sulfate, Niacin, Thiamin Mononitrate, Riboflavin, Folic Acid), Vegetable Oil (Corn, Canola, and/or Sunflower Oil), Cheese Seasoning (Whey, Cheddar Cheese [Milk, Cheese Cultures, Salt, Enzymes], Canola Oil, Maltodextrin [Made from Corn], Natural and Artificial Flavors, Salt, Whey Protein Concentrate, Monosodium Glutamate, Lactic Acid, Citric Acid, Artificial Color [Yellow 6]), and Salt.

- Must appear on the same panel as the name and address of your business.
- Ingredients must be listed in order of heaviest to lightest by weight.
- Some ingredients consist of multiple ingredients; these sub-ingredients must be listed in parentheses next to the main ingredient.
 - There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.

4. Allergens

Allergens within Ingredient List*

Ingredients: all-purpose flour (bleached **wheat** flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, **soy** lecithin, vanillin, natural flavor), butter (cream (**milk**), salt), **walnuts**, granulated sugar, brown sugar (molasses), **eggs**, sodium bicarbonate, vanilla extract (vanilla bean extractives in water, alcohol), salt.

OR

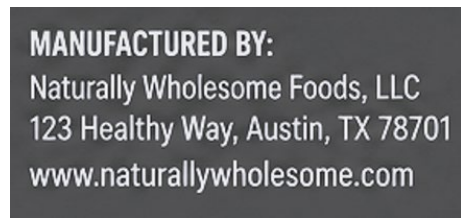
Allergens in Contains Statement*

Ingredients: all-purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), butter (cream (milk), salt), walnuts, granulated sugar, brown sugar (molasses), eggs, sodium bicarbonate, vanilla extract (vanilla bean extractives in water, alcohol), salt. **Contains: wheat, soy, milk, walnuts, eggs**

- When a major food allergen is an ingredient or sub-ingredient, it must be identified by name, either within the ingredient statement **OR** in a separate statement directly below the ingredient statement called a “contains statement”.
- The contains statement must only begin with “Contains:”.
- The only words that may be used to identify the allergens are the following:
 - Crustacean Shellfish (name the specific species of crustacean)
 - Eggs
 - Fish (name the specific species of fish)
 - Milk (specify if the milk is from another ruminant species other than cow, such as goat or sheep)
 - Peanuts
 - Sesame
 - Soybeans
 - Tree Nuts (name the specific type of nut)
 - Wheat

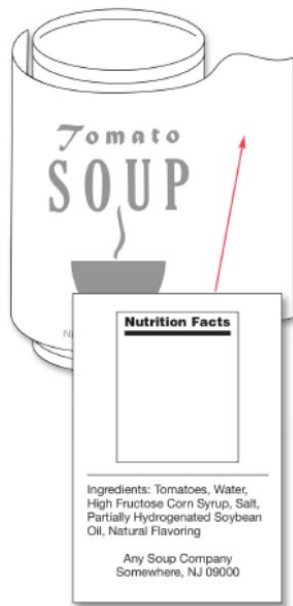
* Text does not need to appear in red

5. Name and Address of Manufacturer, Packer, or Distributor



- Must appear on the same panel as the ingredient statement.
- The address of the business must be listed in full: street name, city, state and zip. A Post Office Box number, telephone number, email address, website address, or other address cannot substitute.
 - The only exception would be if your business and address are listed in a current physical city or telephone directory.
 - In that case, you may omit the street address and list just the city, state, and zip code.
- There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.

6. Nutrition Facts Panel

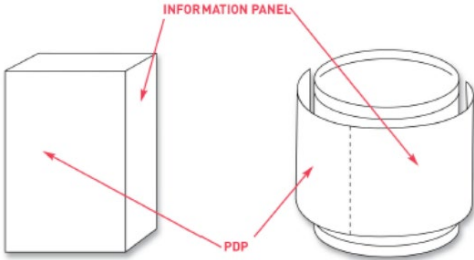
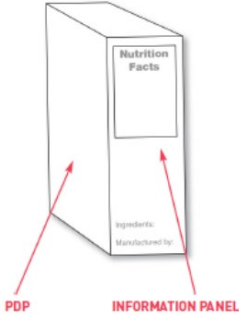


- Must appear on the same panel as the business name and address.
- Must be enclosed in a hairline box.
- Required if a Nutrient Content Claim appears on the label.
 - Examples: Low Fat, Sugar Free, Reduced Sodium
- There cannot be intervening material between the ingredient statement, business information, and nutrition facts statement.
- If you are interested in nutrition labeling, there are several options and providers you may choose from that can create a panel for you. For example, the [Food Producer Technical Assistance Network](#).
- **Nutrition Labeling Exemptions**
 - **Small Business Exemption** – this exemption applies if the person claiming the exemption employs fewer than an average of **100 full-time equivalent employees** and **fewer than 100,000 units** of that product are sold in the United States in a 12-month period. The company must file an annual notice with FDA to claim this exemption.
 - **Very Small Retailer Exemption** – this exemption applies for retailers with annual gross sales of **\$500,000 or less**, or annual sales of food directly to consumers of **\$50,000 or less**. A notice does not need to be filed for this exemption.
 - **NOTE:** these exemptions do not apply if there are nutrient content claims on the label.

7. Label Format

Your label may consist of **ONE** panel or **TWO** panels. An example of each is provided below.

One Panel Label	
CHOCOLATE CHIP COOKIES Ingredients: all purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), brown sugar (molasses), sugar, walnuts, butter (cream, salt), eggs, salt, baking soda, vanilla extract (vanilla bean extractives in water, alcohol). Contains: wheat, soy, milk, walnuts, eggs Grannie's Cookies, 111 Happy Lane, Anytown, VA 22554 Net Wt. 10 oz (283 g)	- The label must include the following: - Statement of Identity/Common Name - Net Content Statement - Ingredient Statement - Name and Address of Manufacturer/Packer/Distributor - Nutrition facts panel, if applicable

Two Panel Label		
		
Panel One	Principal Display Panel (PDP) Front Panel	- Statement of Identity/Common Name - Net Content Statement
Panel Two	Information Panel Panel to the Right of the Front Panel	- Ingredient Statement - Name and Address of Manufacturer/Packer/Distributor - Nutrition facts panel, if applicable - No intervening material between required information - Must be to the right of the PDP

8. Labeling Claims

There are three categories of claims that are defined by statute and/or FDA regulations for use on food and dietary supplement labels: health claims, nutrient content claims, and structure/function claims.

- **Health Claims**

- Health claims require a Nutrition Facts panel on the product label.
- A “health claim” has two essential components:
 - A substance (whether a food, food component, or dietary ingredient) and
 - A disease or health-related condition
- Health claims must:
 - Limit wording to disease or health-related condition risk reduction
 - Cannot suggest diagnosis, cure, mitigation, or treatment of a disease
 - Be evaluated and authorized by the FDA
- Information on authorized health claims may be found on the [FDA's Authorized Health Claims That Meet the Significant Scientific Agreement Standard website](#).
- Examples:
 - “Eating at least 3 oz. of whole grains per day may reduce the risk of heart disease”



- **Nutrient Content Claims**

- Nutrient content claims require a Nutrition Facts panel on the product label.
- A “nutrient content claim” characterizes the level of a nutrient in a food using terms such as “free”, “high”, “lite”, “low”, or “reduced”.
- Nutrient content claims must:
 - Describe the level of nutrients in the product
 - Meet the nutritional criteria for that statement or a disclosure statement must be used if the claim is quantitative
 - Be authorized by the FDA
 - Be provided with a Daily Value if core descriptors are used (i.e., low sodium)
- Unless specifically authorized, nutrient content claims cannot be used for food intended for infants.
- Examples of the conditions for several nutrient content claims are provided below (RACC = Reference Amounts Customarily Consumed; ARF = Appropriate Reference Food). Additional information on nutrient content claims may be found in Appendix A and B of the [FDA Food Labeling Guide](#).

Nutrient	“Free”	“Low”	“Reduced/Less”
Calories	<5 calories per RACC	≤40 calories per RACC	At least 25% fewer calories per RACC than an ARF
Total Fat	<0.5g per RACC	≤3g per RACC	At least 25% less fat per RACC than an ARF
Saturated Fat	<0.5g saturated fat and <0.5g trans-fat per RACC	≤1g per RACC and ≤15% of calories from saturated fat	At least 25% less saturated fat than an ARF
Cholesterol	2mg per RACC	≤20mg per RACC	At least 25% less cholesterol than an ARF
Sodium	<5mg per RACC	Low: ≤140mg per RACC Very Low: ≤35mg per RACC	At least 25% less sodium than an ARF
Sugar	<0.5g sugars per RACC	Not Defined – Cannot be Used	At least 25% less sugar per RACC than an ARF
Other Terms Used	“zero”, “without”	“little”, “contains a small amount of”	“lower/fewer”, “modified”

- **Structure/Function Claims**

- Structure/function claims require a Nutrition Facts panel on the product label.
- A “structure/function claim” can:
 - Describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans
 - “Calcium helps build strong bones”
 - Characterize the action by which a nutrient or dietary ingredient maintains such structure or function
 - “Fiber helps maintain digestive regularity”
 - Describe a benefit related to a nutrient deficiency disease, if the statement also tells how widespread the disease is in the United States.
 - Vitamin D Deficiency is associated with weakened bone health, leading to conditions such as osteoporosis. In the United States, osteoporosis affects over 10 million adults, making adequate vitamin D intake crucial for maintaining strong bones and preventing fractures.”
- These claims focus on effects derived from nutritive value. The effects must be derived from taste, aroma, or the nutritive value of the food.
- FDA does not require conventional food manufacturers to notify FDA about their structure/function claims, and disclaimers are not required for claims on conventional foods. Additional information on structure/function claims may be found in the [FDA Small Entity Compliance Guide on Structure/Function Claims](#).

- **Non-Nutritive Claims**

- Non-nutritive claims are not considered nutrient content claims and are therefore not subject to nutrient content claim requirements if any of the following apply:
 - A claim that a specific ingredient is absent from the product regarding food allergies, food intolerance, religious beliefs, or dietary practices
 - A claim about a non-nutritive substance such as “contains no preservatives” or “no artificial colors”
 - An ingredient that is perceived to add value, i.e., “made with real butter”
- Unlike nutrient content claims, non-nutritive claims may qualify for nutrition labeling exemptions.

Common Non-Nutritive Claims	
Fresh	• The food is unprocessed, in its raw state, and has not been frozen or subject to thermal processing or other form of preservation • Can be used to describe ingredients within processed foods ○ For example: “Made with Fresh Tomatoes” on a Pasta Sauce label
Gluten-free	• To place this claim on your product label, the food must contain a gluten level of less than 200 ppm and meet at least one of the criteria below: ○ Is inherently gluten-free ○ Does not contain a gluten-containing grain ○ Is derived from a gluten-containing grain but has removed the gluten
Natural	• Product must not contain added color, artificial ingredients, or synthetic substances
No Artificial Colors, Flavors, or Preservatives	• This claim must be truthful to the product and its ingredients • Manufacturers may use “no artificial colors” or “made without artificial coloring” if the product is free from certified petroleum-based colors listed in 21 CFR Part 74
Non-GMO or GMO-Free	• The product label may highlight that either certain ingredients or the entire product is non-GMO or GMO-free • Use of the Non-GMO Project Verification logo requires product certification by that organization • You may develop your own icon for this claim if you are not verified by the Non-GMO Project
Organic	• The National Organic Program is governed by the USDA. The USDA Organic Seal can be used with the following examples: ○ 100% organic on Principal Display Panel (PDP) – composed entirely of organic ingredients ○ “Organic” on PDP – composed of at least 95% organic content • For uncertified products: ○ “Made with organic ingredients” on PDP – at least 70% organic content, may not use USDA organic seal ○ No organic claims can be made on the PDP, but may identify organic ingredients within the ingredient list or include a statement of the percentage of organic ingredients on the Information Panel

- **Disease Claims**

- Disease claims are determined by naming a disease and a substance.
- A “disease” references the damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunction (i.e., hypertension). A disease does not include diseases resulting from essential nutrient deficiencies (i.e., scurvy, pellagra).
- Disease claims can only be used for **drugs approved by the FDA**. They cannot be used for food or dietary supplements.
- Example: “treats all forms of cancer”

9. Labeling Time/Temperature Control for Safety Foods

- **Definitions**

- A “time/temperature control for safety food” or “TCS food” is a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. This includes an animal food that is raw or heat treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and a food that because of the interaction of its A_w and pH values is designated as product assessment required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_w VALUES	PH: 4.6 OR LESS	PH: > 4.6 - 5.6	PH: > 5.6
≤ 0.92	Non-TCS food*	non-TCS food	non-TCS food
> 0.92 - 0.95	non-TCS food	non-TCS food	PA**
> 0.95	non-TCS food	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w VALUES	PH: < 4.2	PH: 4.2 - 4.6	PH: > 4.6 - 5.0	PH: > 5.0
< 0.88	Non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
> 0.92	Non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

- A non-TCS food is a food that does not require time/temperature control for safety. These types of foods meet the requirements shown in Table A or B above. Non-TCS foods are safe when held at ambient temperatures after preparation. In some cases, laboratory testing is needed to determine whether a food is TCS or non-TCS. This testing can be completed by a food processing authority, which you can find by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

- **Labeling Requirements**

- Labels for TCS foods should:
 - Include a statement such as “Keep Refrigerated” or “Keep Frozen” as appropriate for that product
 - Include a “Use by” date. This date is typically seven (7) days from the date the product was made (the date the product was made counts as Day 1). Products may be reformulated and/or evaluated for longer shelf lives. This may be done in collaboration with a food processing authority
- While common examples of TCS foods are provided below, the determination of whether an ingredient or product is TCS ultimately depends on the recipe of that specific product.
 - Buttercream frosting/icing
 - Cheese
 - Cheese bread
 - Cheesecake
 - Cream cheese
 - Custard
 - Fresh salsa
 - Meringue
 - Pecan pie
 - Pumpkin pie
 - Sweet potato pie

10. Product Label Examples

One Panel Label Example – Chocolate Chip Cookies	
CHOCOLATE CHIP COOKIES Ingredients: all purpose flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), semi-sweet chocolate chips (sugar, chocolate, cocoa butter, soy lecithin, vanillin, natural flavor), brown sugar (molasses), sugar, walnuts, butter (cream, salt), eggs, salt, baking soda, vanilla extract (vanilla bean extractives in water, alcohol). Contains: wheat, soy, milk, walnuts, eggs Grannie's Cookies, 111 Happy Lane, Anytown, VA 22554 Net Wt. 10 oz (283 g)	

One Panel Label Example – Orange Juice

Orange Juice

Contains: 100% Juice

Ingredients: filtered water, orange juice concentrate.

ABC Juice Company
111 Country Road
Anytown, VA 12345

This juice is a TCS food and is clearly labeled “KEEP REFRIGERATED”

Perishable – KEEP REFRIGERATED

Net 16 fl oz (236 mL)

Fluid products use “Net” or nothing before the Net Contents Statement

One Panel Label Example – Apple Pie (Multicomponent Product)

APPLE PIE

Ingredients: Filling: apples, sugar, lemon juice, cinnamon. **Crust:** flour (bleached wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), butter (cream, salt), egg, salt.

Contains: wheat, egg, milk.

Virginia Pies LLC, 123 Main Street, Anytown, VA 12345

NET WT. 36 oz (2 lb 4 oz) 1.02 kg

Products that weigh between 1 and 4 pounds must be listed in ounces followed in parenthesis by pounds with the remainder in terms of ounces or common decimal fractions, followed by the metric equivalent.

Two Panel Label Example – Serrano Sauce (Front and Back/Side Label)

Front Label

Sally's Spicy Serrano Sauce

Hot Sauce



Net Wt 16 oz (484g)

Back (or Side) Label

We love this serrano sauce because of its sweet and fruity kick, balanced with the perfect amount of acid. Enjoy!

Ingredients: vinegar, serrano peppers, tomato sauce (tomato puree (water, tomato paste), water, less than 2% of: salt, citric acid, onion powder, garlic powder, red pepper), sugar, salt.

Sally's Spicy LLC

12121 E. Main Street, Richmond, VA 23181

Find our other spicy sauces at: sallysspicy.com

Two Panel Label Example – Serrano Sauce (Top and Side Label)

Top Label

Sally's Spicy Serrano Sauce

Hot Sauce



Net Wt 16 oz (484g)

Side Label

Ingredients: vinegar, serrano peppers, tomato sauce (tomato puree (water, tomato paste), water, less than 2% of: salt, citric acid, onion powder, garlic powder, red pepper), sugar, salt.

Sally's Spicy LLC · 12121 E. Main Street, Richmond, VA 23181 · sallysspicy.com

VIII. Specialized Food Processing/Products

Specialized processes have additional requirements necessary for approval prior to processing those products. There are certain types of establishments, processes, and/or products that may be under shared jurisdiction between the VDACS Food Safety Program and another program/agency or be under primary jurisdiction of another program/agency. Common examples are briefly outlined below. This document does not cover all the nuances that may apply. Please contact the VDACS Food Safety Program or the appropriate program/agency for additional information.

1. Acidified Food

An acidified food is a low-acid food to which acid(s) or acid food(s) are added. These foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called “pickles,” “pickled _____,” or “canned” and be in hermetically sealed packaging (i.e. in a jar with a lid). Processors must have a pH meter for monitoring the pH of their products in accordance with their scheduled process.

Acidified foods must be manufactured in accordance with the scheduled process to ensure food safety. A scheduled process is the selected process that is adequate for achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority. To ensure the safety and proper classification of your products, a processing authority must scientifically evaluate your recipe and process. You can find a processing authority by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

Regulatory Requirements

- Compliance with [21 CFR 114 Acidified Foods](#) and [21 CFR 108 Emergency Permit Control](#)
- Obtain a scheduled process from a competent processing authority
- Complete the [FDA's Establishment Registration and Process Filing](#) to register your establishment and file each product with the FDA
- Create and maintain records
- Complete Better Process Control School (BPCS) training. **Example BPCS sources:**
 - [Consumer Brands Association](#)
 - [NC State University](#)
 - [University of Tennessee](#)
 - [Virginia Cooperative Extension](#)
- Develop and maintain a recall plan

See the [FDA's Acidified and Low-Acid Canned Foods Guidance Documents and Regulatory Information](#) website for additional information.

2. Baby Food

A baby food product is any food manufactured, packaged, and labeled in a jar, pouch, tub, or box sold specifically for babies and children younger than two years of age. "Baby food product" does not include infant formula, as defined in [§ 54.1-4300](#). To ensure the safety and proper classification of your products, a processing authority must scientifically evaluate your recipe and process. You can find a processing authority by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

Regulatory Requirements

- Compliance with the [Virginia Baby Food Protection Act](#), including testing for toxic heavy metals by a proficient laboratory at least once a month
- Making the following information publicly available on your website for the product's full shelf life plus one month:
 - The name and level of each toxic heavy metal present in the final baby food product as determined by the testing conducted under subsection C;
 - Sufficient information, including the product name, universal product code, or lot or batch number, to enable consumers to identify the final baby food product; and
 - A link to the FDA's website that provides the most recent FDA guidance and information about the health effects of toxic heavy metals on children
- Displaying the following information on the product label if the baby food product is tested for a toxic heavy metal subject to an action level, regulatory limit, or tolerance established by the FDA under [21 CFR 109 Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material](#):
 - A label that states in a clear, legible, and conspicuous form, the following: "For Information About Toxic Element Testing On This Product, Scan the QR Code."; and
 - A QR code or other machine-readable code that directs the consumers to the manufacturer's website or the baby food product information page providing (i) the test results for the toxic heavy metal and (ii) a URL to the webpage on the FDA's website that includes the most recent guidance and information about the health effects of toxic heavy metals on children

3. Bottled Drinking Water

Bottled drinking water refers to all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

Regulatory Requirements

- Compliance with [21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food](#), [21 CFR 129 Processing and Bottling of Bottled Drinking Water](#), and [21 CFR 165 Beverages](#)
- Water Source Testing
 - [Public Water Systems](#): must be tested annually for chemical contaminants and every four years for radiological contaminants

- **Non-Public Water Systems:** must be tested weekly for total coliform bacteria. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are Escherichia coli (E. coli). If E. coli is detected, the water is not considered safe for use in bottled water until appropriate corrective actions are taken
- **Treatment Processes**
 - All treatment of product water (i.e., distillation, filtration, reverse osmosis) must be performed in a manner that is effective in accomplishing its intended purpose and in accordance with [section 409 of the Federal Food, Drug, and Cosmetic Act](#)
 - Equipment used must not adulterate the bottled product
- **Sanitary Facilities and Operations**
 - Your facility must maintain sanitary conditions, including proper construction and design of buildings, adequate ventilation, and clean equipment
 - Employee areas such as locker rooms and lunchrooms must be separate from production areas and maintained in a clean and sanitary condition
- **Recordkeeping:** maintain records of water source testing, treatment processes, equipment inspections, and any corrective actions taken

4. Dairy/Frozen Desserts

The manufacture of dairy and frozen dessert products for wholesale is regulated by the VDACS Dairy Services Program and VDH. A brief overview of jurisdiction for common types of products and contact information is provided in the table below. Dairy/frozen dessert products manufactured for retail sale only may be regulated by the VDACS Food Safety Program. Contact the VDACS Food Safety Program or the appropriate program/agency for additional information.

VDACS Dairy Services Program	VDH Milk Safety Program
Manufactured Grade products, such as: butter (including ghee), cheese, cream cheese, dairy frozen desserts (i.e. ice cream), non-dairy frozen desserts (i.e. popsicles)	Grade A products, such as: buttermilk, cottage cheese, fluid milk, kefir, whey, yogurt
dairyservices@vdacs.virginia.gov Hunter.Moyer@vdacs.virginia.gov	foodsafety@vdh.virginia.gov William.Hatcher@vdh.virginia.gov
804-786-1452	804-441-0079

5. Dietary Supplement

A dietary supplement is a product intended for ingestion that, among other requirements, contains a “dietary ingredient” intended to supplement the diet. The term “dietary ingredient” includes vitamins and minerals; herbs and other botanicals; amino acids; “dietary substances” that are part of the

food supply, such as enzymes and live microbials (commonly referred to as “probiotics”); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories.

Regulatory Requirements

- Compliance with [21 CFR 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#)
- Written procedures
 - Cleaning and sanitation protocols
 - Laboratory operations
 - Master manufacturing plan
 - Pest control management
 - Product recall procedures
- Record templates
 - Batch production records
 - Customer complaints and corrective actions
 - Employee training records
 - Labeling records
 - Process monitoring logs
 - Raw material testing results

Bitters, Extracts, and Tinctures

- Bitters ARE NOT typically considered dietary supplements. They are alcoholic flavorings that are made with a mix of herbs, spices, and bittering agents, primarily for flavoring beverages or aiding digestion.
- Extracts ARE NOT typically considered dietary supplements. They are flavor concentrates made by soaking plants (or sometimes other materials) in alcohol or water, primarily used for flavoring in cooking and baking.
- Tinctures ARE typically considered dietary supplements. They are made by soaking plant material in alcohol for extraction. Used in small doses for therapeutic purposes.

6. Edible Hemp

An Edible Hemp Product (EHP) is a food for human consumption that contains ingredients from the hemp plant (hemp extract), such as THC, CBD, and many other compounds. EHPs include products that are consumed by mouth, such as gummies, other candies, tinctures, beverages, and baked goods. These products contain a Total THC concentration of no greater than 0.3% and contain no more than two (2) milligrams (mg) of Total THC per package.

Effective August 15, 2026, a product with more than 2mg of total THC per package cannot be manufactured or sold as a hemp product in Virginia. If you offer Edible Hemp Products for retail sale, submit the [Regulated Hemp Retail Facility Registration](#) and [Edible Hemp Product Disclosure Form](#) to the [Office of Hemp Enforcement](#) through July 17, 2026. After July 17, 2026, please refer to the [Virginia Cannabis Control Authority's website](#) for additional information such as requirements, registration/form submissions, and a [Compliance Guidance Handout](#).

Regulatory Requirements

- Compliance with applicable regulations, such as [2VAC5-595 Regulations Governing the Manufacturing and Sale of Products That Contain Industrial Hemp Extracts Intended for Human Consumption](#) and the [Virginia Food and Drink Law](#)
- Industrial Hemp Processor Registration from the [VDACS Industrial Hemp Program](#)
- License/Permit from the Virginia Cannabis Control Authority
- Documentation that hemp is from an approved source/compliant with applicable state or federal laws
 - You must be approved to process the hemp extract/product you are using, and/or you must purchase your hemp extract/product from a manufacturer who is inspected by the regulatory authority responsible for food safety inspection in the state where the product is made
 - A third party GMP audit is not a substitute for state regulatory inspection
-

Virginia Cannabis Control Authority	VDACS Industrial Hemp Program
hemp@cca.virginia.gov hempregistration@cca.virginia.gov	hemp@vdacs.virginia.gov
Virginia Cannabis Control Authority Website	VDACS Industrial Hemp Program Website

7. Fermented Food

A fermented food is a food or beverage transformed by the controlled growth of microorganisms, such as bacteria and yeast, which break down carbohydrates into alcohol or acids. Fermentation is the breakdown of sugars into alcohol or acids by microorganisms, such as yeast and bacteria, in a process that often requires the absence of oxygen. This ancient, natural process transforms food, preserving it and creating unique flavors and textures found in popular items like miso, tempeh, sauerkraut, pickles, and kimchi. Processors must have a pH meter for monitoring the fermentation process during and after production. To ensure the safety and proper classification of your products, a processing authority must scientifically evaluate your recipe and process. You can find a processing authority by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

8. Food Containing Alcohol

The manufacture of food products containing alcohol is regulated by the VDACS Food Safety Program and the Virginia Alcoholic Beverage Control Authority (VA ABC). Any food product (not just beverages) containing more than 0.5% Alcohol by Volume (ABV) is classified as an “Alcoholic Beverage” under Virginia law. If your product contains alcohol, testing the product’s alcohol content is necessary to ensure its proper classification. You can find a processing authority to conduct an Alcohol by Volume Analysis by using the [Food Processing Authorities Directory](#) or contacting the [Food Producer Technical Assistance Network](#).

Alcohol by Volume (ABV) Less Than 0.5%	Alcohol by Volume (ABV) More Than 0.5%
IS NOT an alcoholic beverage	IS an alcoholic beverage
May need a license/permit from ABC to use alcohol as an ingredient	May need a license/permit from ABC to sell product, unless it can be reformulated to reduce the ABV below 0.5%
foodsafety@vdacs.virginia.gov	compliance@virginiaabc.com
804-786-3520	804-213-4632

9. Food Containing Botanicals

A botanical is a plant or plant part valued for its medical or therapeutic properties, flavor, and/or scent. Food products can only contain botanicals that have been approved for use in conventional foods.

To determine whether a botanical is approved for use in conventional foods:

- Verify whether the botanical is considered Generally Recognized as Safe (GRAS) by the FDA:
 - [FDA GRAS Notices inventory](#)
 - [Select Committee on GRAS Substances \(SCOGS\) database](#)
- If the botanical is not classified as GRAS, verify whether it is an FDA-approved food additive:
 - A food additive is a substance added intentionally or unintentionally during food production, processing, packaging, or storage that affects the food’s characteristics such as taste, texture, or appearance
 - [FDA Substances Added to Food inventory](#)
- **Examples of common botanicals that ARE approved for use in conventional foods (*not an all-inclusive list*):**
 - Basil
 - Calendula
 - Butterfly Pea
 - Chamomile
 - Cinnamon
 - Dandelion
 - Elderberry
 - Marshmallow Root

- Rose Petals
- Yarrow
- **Examples of common botanicals that ARE NOT approved for use in conventional foods (*not an all-inclusive list*):**
 - Ashwagandha
 - Bee Pollen
 - Borage
 - Comfrey
 - Feverfew
 - Nettle
 - Valerian
 - Moringa
 - White Willow Bark
 - Cordyceps
 - Amanita muscaria
 - Melatonin

10. Food Containing Meat or Poultry

The manufacture of meat and/or poultry products for wholesale is regulated by the VDACS Office of Meat and Poultry Services and the VDACS Food Safety Program. A brief overview of jurisdiction for common types of products and contact information is provided in the table below. Contact the VDACS Food Safety Program or the appropriate program/agency for additional information.

VDACS Office of Meat and Poultry Services	VDACS Food Safety Program
Products under the United States Department of Agriculture (USDA), such as: beef broth; canned beans containing more than 2% meat; dehydrated chicken broth; lard; meat, poultry, and frozen, dried, or liquid eggs; open-faced sandwiches (i.e., one slice of bread) containing meat or poultry; pepperoni roll where meat is on top of the bread; pizza with meat and cheese; soups containing more than 2% meat; spaghetti with meatballs and sauce	Products under the Food and Drug Administration (FDA), such as: chicken broth/stock, closed-face sandwiches (i.e., two slices of bread) containing meat or poultry, dehydrated beef broth, pepperoni rolls where meat is mixed in with dough, products that contain less than 2% cooked meat or poultry or 3% raw meat or poultry, soups not regulated by the USDA
omps@vdacs.virginia.gov	foodsafety@vdacs.virginia.gov
804-786-4569	804-786-3520

Products Containing Non-Amenable Species

- Amenable species include meat such as beef, swine, sheep, goat, and quines, and poultry such as chickens, turkeys, ducks, geese, guineas, ratites (emu, ostrich, rhea), and squab

- Any species of meat and/or poultry that do NOT appear on the lists above are considered to be non-amenable and therefore are not subject to USDA/OMPS regulations, nor are they included in the USDA/OMPS inspection process
 - Examples of non-amenable species include reindeer, elk, deer, antelope, buffalo, bison, rabbits, pheasant, and quail
 - Finished products of these species are not required to, nor may they bear the federal or state mark of mandatory inspection, when introduced into commerce
 - Processors of non-amenable species may elect to go under voluntary inspection with OMPS/USDA
- Sales to or at Retail Establishments/Restaurants: vendors/processors who wish to slaughter, process, and sell the meat of non-amenable species at or to restaurants or retail stores must contact VDACS OMPS for assistance
- Sales from the Home or Farmers Market:
 - Vendors/processors may sell raw, cut meat of non-amenable species from their home or at farmers markets directly to the end consumer without inspection/permit from the VDACS Food Safety Program
 - Vendors/processors who wish to conduct secondary processing (i.e. smoking, curing, sausage-making, cooking, salting, or preparing jerky) using non-amenable game animal meat, must have the slaughter of that meat overseen by VDACS OMPS/USDA through voluntary inspection and the secondary process (curing, smoking, jerky, cooking, etc.) overseen by the VDACS Food Safety Program

11. Juice

The manufacture of juice products for wholesale is regulated by the VDACS Food Safety Program. Juice refers to the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

Regulatory Requirements

- Compliance with [21 CFR 120 Hazard Analysis and Critical Control Point \(HACCP\) Systems](#)
- Complete Juice HACCP Training. Example sources:
 - [Cornell University Juice HACCP Certification](#)
 - [eHACCP Certified HACCP Principles and GMPs for Pure Juice Industries](#)
 - [International Food Protection Training Institute Juice HACCP Plan Development](#)
 - [Registrar Corp Juice HACCP Plan Development Training](#)
- Develop and implement a Hazard Analysis and Critical Control Point (HACCP) Plan that includes a validated process that demonstrates an at least 5-log reduction in pathogens of concern, such as *E. coli* and *Salmonella*
- Recordkeeping: maintain records of HACCP plan implementation, monitoring, and corrective actions
- Daily sanitation monitoring for the eight critical sanitation areas within the establishment

Retail-Only Juice Sales

If you only sell your juice retail (i.e. direct to the end consumer), you are not required to comply with 21 CFR 120. However, your product label must include the following warning statement:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

-
- The word “**WARNING**” must be in all caps and bold font. The entire statement must be set off in a box with hairline borders to clearly distinguish it
- The warning statement can appear on either the principal display panel (front) or the information panel (side) of your product label

See the [FDA's Juice HACCP](#) website for additional information.

12. Low-Acid Canned Food

A low-acid canned food (LACF) is a food, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85. These foods may be in hermetically sealed packaging (i.e. in a jar with a lid). The VDACS Food Safety does not permit establishments solely processing LACF products; the FDA has primary responsibility for these establishments in Virginia. Review the [FDA's Acidified and Low-Acid Canned Foods Guidance Documents and Regulatory Information](#) and [FDA's Establishment Registration and Process Filing](#) requirements for additional information.

13. Sea Moss

Sea moss is a type of red seaweed that is rich in minerals, vitamins, and antioxidants. It is commonly used as a food supplement, a thickening agent, or can be prepared into a gel for consumption.

Regulatory Requirements

- Scientific name of the sea moss. Common examples provided below:
 - Chondrus crispus
 - Eucheuma cottonii
 - Eucheuma kombu
 - Eucheuma nori
- A copy of the Certificate of Analysis (COA) for each product
 - If the sea moss is obtained from a permitted Virginia operator, then a copy of the COA does not need to be included, but you must provide the name and address of the permitted Virginia sea moss manufacturer

- All sea moss products must meet the following criteria:
 - The algae are sourced from reputable growers/distributors that sell types of algae known to be used safely as or in food
 - A reputable grower must harvest from an area free from contaminants (heavy metals, agricultural or industrial chemicals and microorganisms associated with septic waste, which are commonly associated with runoff water from populated and industrial areas). An approved harvester/producer of the sea moss must be able to provide a letter to the processor attesting that their harvesting practices meet this requirement. This letter should be included with the application
 - The algae are of an appropriate food grade
 - The algae are prepared and handled as a food ingredient

Intended Use

Conventional Food	• If the sea moss is received dried and sold dried, it would be classified as a conventional food
Dietary Supplement	• If the product labeling states a health claim, the manufacturer must meet the requirements under 21 CFR Part 111 • If the product is a tincture or is in capsule form, it will automatically be categorized as a dietary supplement • See Section VIII-8 Dietary Supplement for additional information
Juice	• If the sea moss is added to juice and the finished product is sold wholesale, the manufacturer must meet the requirements under 21 CFR Part 120 • If the juice is untreated and sold strictly retail, the manufacturer must label the product with the following warning statement: “WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.” • See Section VIII-11 Juice for additional information
Low-Acid Food or Acidified Food	• If the sea moss is turned into a gel, the product must meet the requirements under either: ○ 21 CFR Part 113 – see Section VIII-12 Low-Acid Canned Food for additional information ○ 21 CFR Part 114 – see Section VIII-1 Acidified Food for additional information
NOTE: A Consumer Information Statement is highly recommended for finished labels. A commonly used statement includes: “Sea moss is naturally rich in iodine and consumption of excess iodine could have an adverse effect on thyroid function.”	

14. Seafood

The manufacture of seafood/seafood products for wholesale is regulated by the VDACS Food Safety Program. Seafood/fish refers fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption. Seafood product/fishery product refers to any human food product in which fish is a characterizing ingredient.

Regulatory Requirements

- Compliance with [21 CFR 123 Fish and Fishery Products](#)
 - This regulation applies only to:
 - Products that contain fish or fishery products where the fish is a defining ingredient of the product
 - Warehouses that store seafood products at ambient or refrigerated temperatures
 - For example:
 - Crab cakes: contain fish or fishery products (crab meat) and would fall under Seafood HACCP
 - Worcestershire sauce: may contain anchovies (a fishery product), but since the anchovies are not a defining ingredient, this product is not regulated under Seafood HACCP
- Complete Seafood HACCP Training
 - Example source: [Seafood HACCP Alliance](#)
- Develop and implement a Hazard Analysis and Critical Control Point (HACCP) Plan
- Recordkeeping: maintain records of HACCP plan implementation, monitoring, and corrective actions
- Daily sanitation monitoring for the eight critical sanitation areas within the establishment

See the [FDA's Seafood HACCP](#) website for additional information.

15. Sprouts

Sprouts (irrespective of seed source) are considered a common fresh produce. They represent a distinct food safety concern because the conditions under which sprouts are produced (i.e., temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens. Because the distinctive practices and conditions for growing sprouts present unique risks, sprout-specific requirements were established in Subpart M (Sprouts) of the Produce Safety Rule. The requirements in the Produce Safety Rule are directed specifically to covered farms that grow, harvest, pack or hold sprouts and are referred to in the Produce Safety Rule as “sprout operations”.

Regulatory Requirements

- Registration: all farms within Virginia that grow, harvest, pack or hold produce intended for human consumption and for sale need to register their business with the Virginia Department of Agriculture and Consumer Services (VDACS) Produce Safety Program
 - This registration process is intended to verify who is and who is not covered under [21 CFR 112 Produce Safety Rule](#)
 - Online Registration: [Virginia Produce Safety Grower Portal](#)
 - Mail-In Registration: [Virginia Produce Safety Farm Registration](#)
- Inspections: sprout inspections are conducted by FDA/VDACS. Inspections are mandatory for any covered farm/operation that grows, harvests and packs covered produce under the rule

Additional Information

- [FDA Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption](#)
- [Food Safety Modernization Act Final Rule on Produce Safety](#)
- [Sprout Safety Alliance](#)
- [VDACS Produce Safety Program \(VAProduceSafety.com\)](#)

VDACS Produce Safety Program
produce.safety@vdacs.virginia.gov
804-786-4003

IX. VDACS Food Safety Program Contact Information

- Email Address: foodsafety@vdacs.virginia.gov
- Phone Number: (804) 786-3520
- Mailing Address: PO Box 1163, Richmond, VA 23218-1163
- [VDACS Food Safety Program Regional Contact Map](#)
- [VDACS Food Safety Program Website](#)