

COMMONWEALTH of VIRGINIA

Joseph W. Guthrie Commissioner Department of Agriculture and Consumer Services PO Box 1163, Richmond, Virginia 23218 www.vdacs.virginia.gov

Starting a Commercial Kitchen Food Processing Business in Virginia

General Information

Thank you for your inquiry regarding starting a food manufacturing business in Virginia. The following documents are enclosed/attached, or are available at the VDACS website for you:

- VDACS Permit Application Commercial Kitchen Food Processing Operation
- Virginia Food and Drink Law
- 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- How To document for completing this application and preparing for your inspection
- Other information pertaining to your food business

If, after reviewing the application and other materials, you have any questions, please contact the VDACS Food Safety Program at 804-786-3520 or <u>foodsafety@vdacs.virginia.gov</u>.

Please be advised that pursuant to section 3.2-5130 of the Virginia Food and Drink Law, it is unlawful to operate as a food manufacturer, food storage warehouse, or retail food establishment until it has been inspected and has been issued a permit for the operation of the food establishment. An inspection of your operation will not be conducted until all of the necessary information requested in the permit application has been reviewed by the VDACS Food Safety Program office. You will be notified when this has been completed.

Also, there is a \$40.00 annual fee for operating a food processing business. You will not be required to pay this fee at the time of your initial inspection; however, you will receive a bill during our next billing cycle.

Sincerely,

Parmela Millo

Pamela Miles Program Supervisor Food Safety Program Office of Dairy & Foods Virginia Department of Agriculture & Consumer Services



<u>www.vdacs.virginia.gov</u>

VDACS Food Safety Program PO Box 1163 Richmond, VA 23218-1163 (804) 786-3520 foodsafety@vdacs.virginia.gov

DEPARTMENT USE ONLY					
DATE RECEIVED					
APPLICATION # _					
FIRM ID #					

Permit Application for a Commercial Kitchen Food Processing Operation

NOTE: THIS APPLICATION IS FOR FOOD MANUFACTURERS OPERATING IN A SHARED KITCHEN THAT IS NOT WITHIN A PRIVATE RESIDENCE. AN INCOMPLETE APPLICATION WILL BE RETURNED FOR CORRECTION

DOWNLOAD THIS APPLICATION TO YOUR COMPUTER AND OPEN IN ADOBE READER FOR FULL FUNCTIONALITY

Business Name:						
Owner Name:						
Owner Phone:	Owner Phone: Owner Email:					
Name of Commercial	Kitchen:					
Commercial Kitchen A	Address:					
County or City (LIST TH	E COUNTY OR	CITY WHERE THE COMMERCIAL KITCHEN IS LO	DCATED):			
Your Business Mailing	g Address:					
Water Supply:	Water Supply: Public Private*; Type (drilled, bored, etc.)					
	*FC	DR A PRIVATE WATER SUPPLY, ATTACH A CURRENT	WATER TEST REPORT SHOWING ABSENCE OF COLIFORM BACTERIA			
Sewage Disposal: Public Private*; Type (septic tank, etc.) *FOR A PRIVATE SEWAGE DISPOSAL SYSTEM, ATTACH DOCUMENTATION THAT YOUR SYSTEM IS APPROPRIAT FOR YOUR PLANNED FOOD OPERATIONS (SEE ITEM #7 OF THE APPLICATION INSTRUCTIONS ON PAGE 2)						
Number of employees, including owner: Days and Hours your business will operate at the kitchen:						
Percentage of ingredients received from out of state suppliers:			Percentage of products sold retail:			
Percentage of products sold to out of state customers:			Percentage of products sold wholesale:			

Checklist of Required Information

Documentation of commercial kitchen approval to operate a food business on the property				
Diagram of food processing, equipment washing, and food storage areas and handwashing facility				
Copy of water test results showing Coliform bacteria are "absent" from private source water				
Documentation that the private sewage disposal system is adequate for intended use				
Documentation of employee training				
Written procedures for preventing allergen cross-contact				
If applicable, additional documentation required under Subparts C & G under 21 CFR 117				
List of all products submitted for review with planned method and place of distribution				
List of all ingredients used in your business, with the source of each				
Product information sheet for each product				
Copy of label for each product				

Application Instructions

- 1) Review the **How To** document for completing this application and preparing for your inspection.
- 2) Complete page 1, providing all of the requested basic business/owner information.
 Note on hours of operation: Your first inspection will be scheduled, but subsequent routine inspections will be unannounced and unscheduled. Provide a list of the weekdays and times that your business will normally operate. The inspector will visit for routine inspections during those days/hours.
- 3) Review General Information and Requirements (see page 3).
- 4) Provide written documentation that you have approval from the commercial kitchen you will be using. Any verifiable documentation is acceptable, such as email correspondence, official letter, signed contract, or other.
- 5) Provide a diagram of the food processing and storage areas (see page 4).
- 6) If the commercial kitchen is using a private water supply (e.g. well), you must provide evidence that the water is free of harmful bacteria. A copy of lab results showing that Coliform bacteria were "absent" in a sample of the well water is required. The water test results must be recent (less than six months old). The testing laboratory that you use must be certified by the Virginia Safe Drinking Water Program. A list of labs that are certified for water testing can be found at this link: Virginia Safe Drinking Water Certified Laboratories
- 7) If private sewage disposal is used, obtain documentation from an Alternative Onsite Soil Evaluator (AOSE), Professional Engineer (PE) or Virginia Department of Health that the system is adequate for the intended use of your business. Please see https://drive.google.com/open?id=1nlVtqik9hDqAfzsaJX8J35dnknlG3Svl&usp=sharing for additional information and to locate a service provider. NOTE: All service providers must be properly licensed through the Department of Professional and Occupational Regulation (DPOR).
- 8) Create an Employee Training Record to document your training in food safety (see page 5).
- 9) Provide a list of the products you plan to make, as well as the planned distribution (see page 6).
- 10) Develop a written plan to prevent allergen cross-contact (see page 7).
- 11) Provide a list of all of the ingredients you will be using, the source of those ingredients, and determine if any of the eight major allergens are present in each ingredient (see page 8).
- 12) Complete a Product Information Sheet for each product you plan to make (page 13). Mark "Trade Secret" if your formulation is confidential. We will not share your recipe, but you must provide it. TIP: While the number of products you submit for review is not limited, the review of your application will be more efficient for both the reviewer and for you if you will submit only a few with your application (suggest five or fewer). You may submit additional products for review at any time after your initial inspection, and the review of additional products is generally completed within a few days.
- 13) Provide a copy of the label for each product (mock labels are acceptable if actual labels have not yet been made). Incomplete labels will cause your application to be returned to you. See instructions contained within this application. More guidance on labeling is available from FDA: https://www.fda.gov/media/81606/download.
- Submit applications to the VDACS Food Safety Program. An incomplete application will cause delay in it being processed.
- 15) By email (preferred): foodsafety@vdacs.virginia.gov; By mail: ATTN: Food Safety, PO Box 1163, Richmond VA 23218
- 16) Once your application is submitted, it will be reviewed, and you will be contacted by the reviewer if there are any questions. When the application review is complete, a Food Safety Specialist will contact you to schedule your first inspection.
- 17) If you do not provide a response to the reviewer's comments within four months, your application will be discarded. A new application will need to be submitted if you wish to continue.

General Information and Requirements

The following documents are enclosed/attached, or are available at the VDACS website for you:

- VDACS Permit Application Commercial Kitchen Food Processing Operation
- Virginia Food and Drink Law
- 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- How To document for completing this application and preparing for your inspection
- Allergen Control Plan Overview and Guidance
- Additional regulations if applicable (e.g. 21 CFR 111, 21 CFR 114, 21 CFR 123)

If, after reviewing the application and other materials, you have any questions, please contact the VDACS Food Safety Program at 804-786-3520 or foodsafety@vdacs.virginia.gov.

Please be advised that pursuant to section 3.2-5130 of the Virginia Food and Drink Law, it is unlawful to operate as a food manufacturer, food storage warehouse, or retail food establishment until it has been inspected and has been issued a permit for the operation of the food establishment. An inspection of your operation will not be conducted until all of the necessary information requested in the permit application has been reviewed by the VDACS Food Safety Program office. You will be notified when this has been completed.

Also, there is a \$40.00 annual fee for operating a food processing business. You will not be required to pay this fee at the time of your initial inspection; however, you will receive a bill during our next billing cycle.

Commercial Kitchen Approval

Include your documentation of approval to use the kitchen for your business here or on a separate sheet.

Example: diagram of food processing and storage areas

The diagram may be drawn using computer software or drawn by hand.



Food Processing and Storage Area Diagram for the Commercial Kitchen Space

Include your diagram here or on a separate sheet. Clearly indicate or label each area used for storage of raw ingredients, packaging materials, finished products, processing areas, warewashing facilities, handwashing sinks, restrooms, etc.

Employee Training and Records

As a food manufacturer, you and any employees of your business must be trained, and you must provide documentation of said training, in addition to keeping a record of this training. An adequate and complete training course would include topics on employee health and hygiene, proper food storage and cooking temperatures, cleaning food contact surfaces, allergen awareness/control and any other topics specifically applicable to your particular food processing operation.

List of available trainings (this list is not all-inclusive):

NC State Food Safety Education & Training

- Good Manufacturing Practices in Food Safety
- https://units.cals.ncsu.edu/foodsafety/good-manufacturing-practices-in-food-safety/
- (919) 513-2065

Institute for Food Safety at Cornell University

- Good Manufacturing Practices Part 117 Online Course
- https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/
- (315) 787-2288

360training.com, Inc.

- Learn2Serve Food Protection Manager Certification Program:
- https://www.360training.com/
- (877) 881-2235

AboveTraining/StateFoodSafety.com

- Certified Food Protection Manager (CFPM) Exam:
- <u>https://www.statefoodsafety.com/</u>
- (801) 494-1416

National Registry of Food Safety Professionals

- Food Manager Certification
- https://www.nrfsp.com/
- (800) 446-0257

National Restaurant Association

- ServSafe Food Protection Manager Certification Program
- https://www.servsafe.com/
- (800) 765-2122

The Always Food Safe Company, LLC

- Food Protection Manager Certification
- https://alwaysfoodsafe.com/en/
- (844) 312-2011

Example template (please create a training record similar to this template and include a copy of it with your application):

Employee Training Rec	ord			
Grannie's Cookies				
111 Happy Ln				
Anytown, VA 22554				
Employee Name	Course Name	Location	Date Completed	Trainer Signature

Employee Training and Records

Include a copy of your training record and documentation here or on a separate sheet.

Product List and Planned Distribution

Product Submitted for Review	Planned Distribution
Example: Chocolate Chip Cookies	Example: Farmer's Market, local grocery stores, internet

Preventing Allergen Cross Contact

The eight major allergens in the U.S. are: milk, wheat, eggs, peanuts, tree nuts, soybeans, fish, and crustacean shellfish. Preventing products that do not contain an allergen from exposure to an allergen is critical to the safety of your food product. Cross contact occurs when an allergen from one food (walnuts, for example) is transferred to another food that does not contain the allergen (strawberry jam, for instance). You should conduct a food allergen ingredient analysis. 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. When you operate in a space that is also used for personal use, you must also consider foods that you store, prepare and consume for personal use. Including a statement on your product label such as "may contain [peanuts], [tree nuts], [fish]..." is not an adequate control for preventing cross contact.

The following resources may help you in developing a plan:

- Allergen Control Plan Overview and Guidance
- Putting Together an Effective Allergen Control Plan, Food Safety Magazine October/November 2017
- Components of an Effective Allergen Control Plan
- FDA What You Need to Know about Food Allergies
- FDA Allergen Cross-Contact Prevention

Preventing Allergen Cross-Contact

Provide your written plan for preventing allergen cross-contact here or on a separate sheet.

Allergen Control Plan - Master List of Ingredients

Business Name and Address:

Date: _____

Food Allergen Ingredient Analysis Worksheet.

	Supplier	Ingredients List for this Raw Material	Fo	od A	Aller Fo	gen rmu	Allergens in				
Raw Material Name			Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish	Supplier's Precautionary Labeling

How to Use the Chart

List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

Requirements of 21 CFR 117 Subparts C & G and Exemptions

Who is not subject to the requirements of Subparts C and G?

- A business conducting at least 50% of sales directly to the consumer (retail). This type of business will be exempt from 21 CFR 117 Subparts C and G, does not need to register with the FDA, and does not need to attest to FDA.
- Very small businesses that have attested to FDA. If 50% or more of your sales are to businesses who will resell your products (wholesale sales), and your business is one that averages less than \$1,000,000 in sales of human food per year for 3 years, then you are a "very small business" and you can file an attestation with the FDA to be exempt from Subparts C and G. Use the instructions and form 3942a at this website to submit your attestation: www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation
- Facilities who exclusively handle or manufacture seafood, juice, dietary supplements, or alcoholic beverages. To clarify, if your facility handles any of the above products **plus** other commodities, then you are subject to Subparts C and G for those other commodities.

If you do not meet any of the above exemptions you must comply with and submit the following:

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

This subpart applies to all businesses not exempt as listed above. Facilities that are subject to this subpart must have a written and implemented Food Safety Plan (FSP). The FSP must be overseen by a Preventive Controls Qualified Individual (PCQI). The FSP must include the following:

- Hazard analysis
- Preventive controls
- Supply chain program

- Monitoring procedures
- Corrective action procedures
- Verification procedures

Recall plan

Preventive Controls Qualified Individuals (PCQI)

Preventive Controls Qualified Individual means 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 to develop and apply a food safety system.

For additional information visit: https://www.ifsh.iit.edu/fspca

Subpart G: Supply-Chain Program

This subpart outlines the requirements for a supply chain program. The safety of the product you manufacture not only depends on the controls you put in place, but the controls applied by your suppliers or your customers. If a known hazard exists in your product or ingredients, it needs to be controlled, whether that be at your supplier's facility, at your facility, or by the next facility in the supply chain. If you decide that the hazard will not be controlled at your facility, then you should identify a supply chain control in your hazard analysis. If you do so, you will need to implement supply-chain control which may include using approved suppliers and conducting verification of these suppliers.

Resources for Creating Your Food Safety Plan

- Food Safety Preventive Controls Alliance: https://www.ifsh.iit.edu/fspca
- FDA: www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food
- Virginia Tech Food Innovations Program: Joell Eifert, Director foodbiz@vt.edu or (540) 231-5770

If you do not qualify for an exemption as explained above, include a copy of your Food Safety Plan and Supply-Chain Program as attachments to your application. If you are a very small business, include documentation showing that you have attested.

Example: Product Information Sheet

Product Information Sheet

Business Name: Grannie's Cookies

Product Name: Chocolate Chip Cookies

Recipe

Ingredients (Include Quantity of Each, preferably by weight in ounces or grams*):

3 ½ cup all-purpose flour (438 grams)

- 2 cup semi-sweet chocolate chips (336 grams)
- ¾ cup brown sugar (165 grams)
- ¾ cup granulated sugar (150 grams)
- 1 cup chopped walnuts (117 grams)
- 8 tablespoons butter (114 grams)
- 2 whole eggs (114 grams)
- ½ teaspoon salt (3 grams)
- ½ teaspoon baking soda (2.3 grams)
- ½ teaspoon vanilla (2.2 grams)

Step-By-Step Instructions:

- 1. Wash and sanitize utensils and preparation area.
- 2. Assemble ingredients and equipment.
- 3. Preheat oven to 375°F.
- 4. Combine flour, baking soda, and salt in small bowl.
- 5. Beat butter, granulated sugar, brown sugar, and vanilla in large mixer bowl.
- 6. Add eggs one at a time to butter/sugar mixture, beating well after each addition.
- 7. Gradually beat in flour mixture.
- 8. Stir in chocolate morsels and nuts.
- 9. Drop by rounded tablespoons onto greased baking sheet.
- 10. Bake at 375°F for 9-11 minutes or until golden brown.
- 11. Let cool for 2 minutes, then remove to wire racks to cool completely.
- 12. After cookies have cooled, place in packages.
- 13. Label packages.
- 14. Store at room temperature until distributed.

* Weights can be determined by using a Food Weight Scale. Alternatively, a useful tool for calculating weights of food per volume can be found here: https://www.aqua-calc.com/calculate/food-volume-to-weight

Date: 1-1-2021

Trade Secret: 🗸

Basic Labeling Requirements

PLEASE READ THE FOLLOWING INSTRUCTIONS CAREFULLY. These labeling components are required for <u>all</u> packaged foods. Failure to provide labels in the format described below will cause your application to be returned.

Product Name:

- Must be on the front panel
- Must be an accurate description of the product
- Must be in bold print
- Must be the largest type on the panel

Net Weight:

- Must be on the front panel
- Must be stated in both standard and metric units
- Must be in bold print
- Must be located on the bottom of the panel

Ingredients Statement: Must appear on the same panel as the name and address of your business. It must be on the front panel or the panel directly to the right of the front panel. Ingredients must be listed in order of heaviest to least heavy. Some ingredients, like chocolate chips for example, consist of multiple ingredients, and these sub-ingredients must be listed in parentheses next to the main ingredient. When one of the 8 major food allergens 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. This is called a "contains statement" and must follow the format shown below. The only words that may be used to identify the allergens are the following: Milk, Wheat, Eggs, Peanuts, Tree Nuts (name the specific type of nut), Soybeans, Fish (name the specific species of fish), and Crustacean Shellfish (name the specific species of crustacean).

Allergens* listed within the ingredients 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.

*Text does not need to appear in red.

Allergens* listed in a Contains Statement:

Name and Address of Manufacturer, Distributor, or Packer: Must appear on the same panel as the ingredient statement. It must be on the front panel or the panel directly to the right of the front panel. 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 cannot substitute.

EXAMPLE 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)

Nutrition Labeling Exemption for Small Businesses

Some businesses are exempt from the requirement that a nutrition facts panel be included on the product label. In order to qualify as a small business that is exempt from including a nutrition facts panel, you must have less than 10 full-time employees and sell less than 10,000 units of product in one year. Also, you may not have claims on the label if a nutrition facts panel is not present. Examples of claims can include: "low fat", "no added sugar", "healthy", "high in fiber" etc. In addition, your product would have to meet the definition of these claims.

If you voluntarily include a nutrition facts panel, even though you are not required to have one, it must be correct and include all the required formatting and components. Below is a graphic showing what the Standard Format looks like. All components are required. If you are interested in including a nutrition facts panel, Virginia Tech can create a panel, although you may choose to look elsewhere for this service.



This image was taken from FDA guidance. For more information on nutrition labeling visit their website here: https://www.fda.gov/media/81606/download

Product Information Sheet

Business Name:

Product Name:

Date: Trade Secret:

Recipe

Ingredients (Include Quantity of Each, preferably by weight in ALL ounces or ALL grams):

Step-by-Step Instructions:

Product Label

Include a copy of your label here or on a separate sheet.