

Joseph W. Guthrie Commissioner

Department of Agriculture and Consumer Services

PO Box 1163, Richmond, Virginia 23218 <u>www.vdacs.virginia.gov</u>

Opening a Manufacturing/Warehouse Food Establishment in Virginia

General Information

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

- VDACS Permit Application Manufacturing/Warehouse Food Establishment Application
- Virginia Food and Drink Law
- 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Form 1B Employee Health Policy

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.

This application should be submitted by email at least **30 calendar days before the date planned for opening** the food establishment. 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.

Please be advised you must also comply with all other applicable state, local, and/or federal regulations. We recommend that you reach out to your locality's planning, zoning, and business license office to assure all requirements are met.

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,

Pamela Miles

Program Supervisor

Food Safety Program

Office of Dairy & Foods

Pamela Miles

Virginia Department of Agriculture & Consumer Services



www.vdacs.virginia.gov

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 Manufacturing/Warehouse Food Establishment

NOTE: AN INCOMPLETE APPLICATION WILL BE RETURNED FOR CORRECTION.

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

This application is for a	New	Establishment	New Owr	ner/Cha	inge of Ownershi	p for Existing Es	tablishment
Establishment Legal Name	:						
Doing Business As (DBA) N	ame:						
Establishment Telephone:							
Establishment Physical Add	dress:						
County or City (LIST THE COU	INTY OR CI	TY THAT ASSESSES THE I	REAL ESTATE TA	AX FOR T	HE PHYSICAL ADDRES	ss):	
Establishment Mailing Add	lress:						
Establishment Email Addre	ess:				Numl	ber of Employee	es:
Water Supply:	Public *FOR	C Private*; A PRIVATE WATER SUPPLY,	List Type (dr attach a curr		•	ING ABSENCE OF COL	IFORM BACTERIA
Sewage Disposal:	Public *FOR A	A PRIVATE SEWAGE DISPOS			IMENTATION THAT YOU ALTH DEPARTMENT FOR		
Establishment Ownership	Туре:	LLC	Corporati	on	Partnership	Individual	Other
Name of LLC, Corporation, Partnership, Individual, or Other							
Names, titles, birth dates, a	and addr	esses of persons co	mprising the	e legal c	wnership (Attach	n list if necessar	y):
NAME		TITLE	BIRTHDATE		ADDRE	ESS	
Billing Address:							
Person Directly Responsib	le for the	e Food Establishme	nt:				
NAME		TITLE	BIRTHDATE		ADDRE	ESS	
Telephone:		Email Address:					
Immediate Supervisor of P	Person D	irectly Responsible	for the Food	d Estab	lishment: ADDRE	SS	
Telephone:		_ Email Address:					

Type of Food Establish	ment:	Food M	anufacturer		Food Ware	house	
List of Food Products Manufactured and/or Warehoused:							
If Food Warehouse, do	you wareho	use seafood pr	oducts?	YES	NO		
		Dietary :	Supplements		Seafood		
If Food Manufacturer, s	Bottled Drinking Water			Fruit/Vegetable Juice			
any of these foods are	produced:	Acidified *Acidified Foods	s such as pickles,		ntaining Hem es intended to b	•	
Hours of Operation:	SUN	MON	TUE	WED	THU	FRI	SAT

Percentage of incoming ingredients received from out of state suppliers:

Percentage of products sold to out of state customers:

Percentage of products sold wholesale:

Food Processing and Storage Area Diagram: On a separate sheet, attach a copy of your food processing and storage diagram. (*see details on page 4*)

Employee Training and Records: On a separate sheet, attach a copy of any food safety training certificates, and a copy of your employee training record. (*see details on page 5*)

Allergen Control Plan: On a separate sheet, attach a copy of your allergen control plan. (see details on page 6)

If subject to Subparts C and G, Additional Required Documentation: On a separate sheet, attach a copy the additional required documentation (see details on page 8)

Product Labels: If you are a food manufacturer or repacker, please attach a copy of your product label on a separate sheet.

General Information and Requirements

The following documents are enclosed/attached, or are available at the VDACS website, or elsewhere on the web:

- VDACS Permit Application Manufacturing/Warehouse Food Establishment Application
- Virginia Food and Drink Law
- 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Allergen Control Plan Overview and Guidance
- FDA Food Labeling Guide
- Additional regulations if applicable (e.g. 21 CFR 101, 21 CFR 111, 21 CFR 114, 21 CFR 120, 21 CFR 123, 21 CFR 129)
- Form 1B Employee Health Policy

This application should be submitted by email at least **30 calendar days before the date planned for opening** the food establishment. 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 food establishment will not be conducted until all of the necessary information requested in the permit application has been reviewed and approved by the VDACS Food Safety Program office. You will be notified when this has been completed.

Please be advised you must also comply with all other applicable state, local, and/or federal regulations. We recommend that you reach out to your locality's planning, zoning, and business license office to assure all requirements are met.

Also, there is an annual \$40.00 fee for operating a food establishment. You will not be required to pay this fee at the time of your initial inspection; however, you will receive an invoice during our next billing cycle which is usually in the fall of each year.

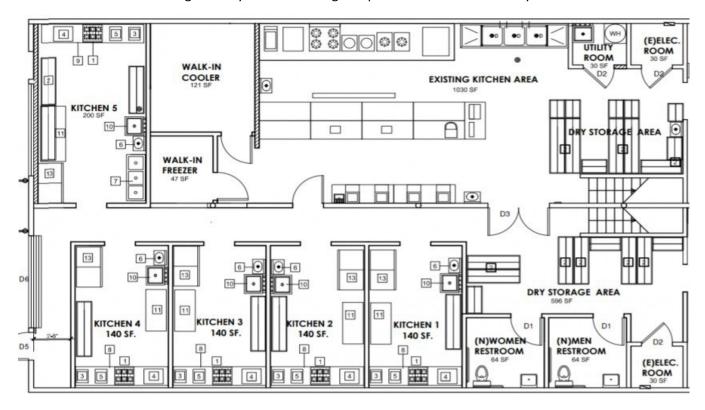
If, after reviewing the application and other materials, you have any questions, please contact the VDACS Food Safety Program at 804-786-3520 or foodsafety@vdacs.virginia.gov. Email your completed application to that same address.

I/We attest to the accuracy of the information provided, affirm to comply with the current Good Manufacturing Practices, as well as all other applicable state, local, and/or federal regulations, and allow the regulatory authority access to the establishment at any reasonable time to inspect, conduct investigations, or collect samples as required.

Printed Name(s):	Date:

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:
- https://www.statefoodsafety.com/
- **•** (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 R	ecord				
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.

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 accidental inclusion of allergens into products that should not contain them is critical to the safety of your food products. 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 other businesses, you must also consider foods that they store and prepare. 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

Example allergen ingredient analysis worksheet.

Business Name	and Address:									_ Date	::
ood Allergen Ing	gredient Analysis										
			Fo	od Al	lergen	s in I	ngredie	nt Fo	rmulat	ion	
Raw Material Name	Supplier	Ingredients List for this Raw Material	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Allergens in Supplier's Precautionary Labeling

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 needed on the finished product.

Preventing Allergen Cross-Contact

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

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
- Recall plan

- Monitoring procedures
- Corrective action procedures
- Verification procedures

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.

Pre-Operational Checklist for Manufacturing/Warehouse Establishment □ Supervisors and Employees Documentation and records of education, training, or experience necessary to perform duties Employee health policy for foodborne illness Hygienic practices: clean outer garments, personal cleanliness, hair restraints, single-use gloves, no unsecured jewelry Allergen control plan Written procedures for preventing allergen cross-contact during storage and preparation Food Safety Plan Hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures Recall plan □ Supply chain program □ Potable water supply Private water supply shall be tested annually to ensure it is safe and of adequate sanitary quality □ Adequate plumbing Installed in accordance with Plumbing Code; backflow prevention where required Carries sufficient quantities of water to areas throughout the plant Adequate sewage disposal system Private sewage systems require approval from the Virginia Department of Health Refrigeration equipment П Maintain time/temperature control for safety (TCS) foods below 41°F; keep frozen foods frozen Thermometers Probe-type thermometer capable of measuring temperatures between 0-220°F Ambient air thermometers in all refrigeration equipment where TCS foods are stored Hand washing sinks in all areas where good sanitary practices require employees to wash their hands Supplied with: hot and cold water, soap, paper towels, hand washing signage, refuse receptacles Procedures/facilities (sinks) for cleaning and sanitizing equipment Adequate sanitizer and test strips Functional toilet rooms that are accessible to employees at all times Shall be sanitary and provided with an adequate hand washing sink and self-closing door that does not open into area(s) where unpackaged food is handled/stored Shielded/shatter-proof light fixtures Required in areas where there is exposed food and/or exposed equipment Functional and cleanable food processing equipment Cleanable floors, walls, and ceilings Shall be made of non-absorbent, durable materials in food preparation and warewashing areas Coving at the floor/wall juncture □ Controls for insects, rodents, and other pests Pests not present; Premises free of harborage and/or breeding places Raw materials, packaging materials, and finished product stored at least 6" off the floor or on pallets Pallets/shelving shall not be flush to the wall Doors, windows, and other openings protected Maintained roads, yards, and parking lots around the facility No standing water, weeds, or trash Trash receptacles Trash shall be stored, conveyed, and disposed of to prevent against the contamination of food Copy of Virginia Food and Drink Law, 21 CFR 117 (Good Manufacturing Practices), and 21 CFR 101 (Food Labeling) Note: Additional regulations may apply depending on the type of product you are manufacturing/warehousing Approval from other regulatory authorities in the locality Building inspector, fire marshal, etc.

Submitted VDACS Manufacturing/Warehouse Food Establishment Permit Application