

# Application for Manufacturer of an Industrial Hemp-Derived Extract Intended for Human Consumption



Date of Application:		County (or city) in which the business is located:	
<b>Industrial Hemp Processor Registration Number:</b>			
Business Name:			
Owner Name:			
Phone:			
Email Address:			
Processing Location Address:			
Business Mailing Address:			
Water Supply:	Public	Private	Type (drilled, bored, etc)
Sewage Disposal:	Public	Private	
Pets (if operating in the home):	Yes	No	
Number of employees, including owner:			
Hours of operation:			

## Checklist of Required Information

	Documentation of zoning approval to operate a food processing business on the property
	Documentation that the hemp-derived extracts intended for human consumption are produced from industrial hemp grown in compliance with federal or state law.
	Documentation that the hemp-derived extracts intended for human consumption have a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent.
	Provide a certificate of analysis as documentation that the hemp-derived extract does not contain a level of any contaminant that exceeds the criteria established in 2VAC-595, and that confirms the amount of cannabinoid or phytochemicals claimed on the product label.
	Diagram of processing and storage areas.
	If private water supply is used, a copy of water test results showing Coliform bacteria are "absent".
	Documentation that the private sewage disposal system is adequate for intended use.
	Documentation of employee training.
	If operating in the home, provide written explanation of how contamination with personal belongings will be prevented.
	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. Please do not submit your application without any of the required information as it will not be reviewed without it. Submit all of it together at the same time.
  - Note about pets in the home: If you marked “Yes”, areas where food is prepared, or stored, where packaging material is stored and where equipment is cleaned and stored must be completely enclosed/separated from the rest of the home in order to be considered for home based food manufacturing. Pets must be excluded from these areas at all times by solid doors and walls.
  - Note on hours of operation: inspections are unannounced and unscheduled. Provide a list of the weekdays and times that operation would normally occur. The inspector will visit for inspection during these hours.
3. Provide written documentation that you have approval from the locality’s zoning office to operate a food processing business on the property. Alternatively, if you are using a community kitchen, provide written documentation that you have the operator’s permission. Any verifiable documentation is acceptable, such as email correspondence, official letter or other.
4. Provide a diagram of the food processing and storage areas.
5. If the property is using a private water supply (e.g. well), you must provide evidence that the water is potable. A recent copy (less than six months old) of lab results showing that Coliform bacteria were “absent” in a sample of your well water is required. 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](#)
6. If private sewage disposal is used, obtain documentation from an Alternative Onsite Soil Evaluator (AOSE), Professional Engineer (PE) or Virginia Department of Health that your system is adequate for the intended use of your business. Please see <https://drive.google.com/open?id=1nIVtqik9hDqAfzsaJX8J35dnknIG3Svl&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).
7. As a food manufacturer, you and any employees of your business must be trained, and you must provide documentation of said training. Provide documentation that you and any employees have received training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to your food products, your facility and the employee’s assigned duties. A list of suggested courses is provided within this application, but you may obtain training elsewhere as long as it is adequate. Also provided is a template you may use to document employee training. Even if the owner is the only employee, a training record needs to be maintained.
8. Provide a list of all products you plan to make, as well as the planned location of distribution.
9. Provide a list of all of the ingredients you will be using, and the source of those ingredients.
10. Complete a Product Information Sheet for each product you plan to make. Mark “Trade Secret” if your formulation/process is confidential. We will not share your process, but you must provide it.
11. Provide a copy of the label for each product (mock labels are acceptable if actual labels have not yet been made). Labels must comply with the labeling regulations, 21 CFR 101.
12. Submit applications to the VDACS Food Safety Program. An incomplete application will cause delay in it being processed. Hand-written applications will not be accepted.
  - Submit by email (preferred): [foodsafety@vdacs.virginia.gov](mailto:foodsafety@vdacs.virginia.gov)
  - Submit by mail: ATTN: Food Safety, PO Box 1163, Richmond VA 23218
13. 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 the initial inspection.

## Requirements for Manufacturers of Industrial Hemp Extracts

In order to produce a hemp-derived extract intended for human consumption a registered hemp processor:

- Must be able to provide documentation that the hemp-derived extracts intended for human consumption are produced from industrial hemp grown in compliance with federal or state law.
- Must be able to provide documentation that the hemp-derived extracts intended for human consumption have a total tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent.
- Shall meet the standards stated below, which are standards that are included in the regulations promulgated by the Virginia Board of Pharmacy for the production of the cannabidiol oil product that it regulates.

Microbiologicals			
Microbiological		Acceptable criteria	
Total Aerobic Microbial Count		< 1,000 cfu/g or cfu/ml	
Total Combined Yeast and Mold Count		< 100 cfu/g or cfu/ml	
Escherichia coli		Absent in 1g or 1ml	
Mycotoxins		Heavy Metals	
Aflatoxin B1	<20 ug/kg of Substance	Arsenic	<10 parts per million (ppm)
Aflatoxin B2	<20 ug/kg of Substance	Cadmium	<4.1 ppm
Aflatoxin G1	<20 ug/kg of Substance	Lead	<10 ppm
Aflatoxin G2	<20 ug/kg of Substance	Mercury	<2 ppm
Ochratoxin A	<20 ug/kg of Substance		
Residual Solvents			
A hemp-derived extract intended for human consumption shall not contain more residual solvent than the amounts listed as acceptable for residual solvent content in 2VAC-595			

- Only residue from pesticides that meet the following requirements may be present in a hemp-derived extract intended for human consumption:
  1. The active ingredient is exempt from the requirements of a pesticide tolerance on all food crops (i.e., auxins, select biopesticides, copper, cytokinins, gibberellins, petroleum oil, phosphorous acid, pyrethrins, soap, sulfur, common consumer food commodities, edible fats, and oils). Information regarding food tolerances for pesticide ingredients may be found on the [U.S. Environmental Protection Agency's \(EPA\) website](https://www.epa.gov/); and
  2. The label has directions for use on unspecified food crops (e.g., bedding plants); and
  3. The pesticide is registered by EPA or exempted from registration; and
  4. The pesticide is registered by VDACS; and
  5. The label language is sufficiently broad to include hemp and does not specifically prohibit its use on hemp.
- Must be able to provide a certificate of analysis if the label states that any amount of cannabinoids are present in the finished product.
- Comply with the food laws and regulations pertaining to food manufacturing, including 21 CFR Part 117, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMP).
- Comply with Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (21 CFR 111) *if the industrial hemp-derived extract product appears to be labeled or marketed as a Dietary Supplement.*

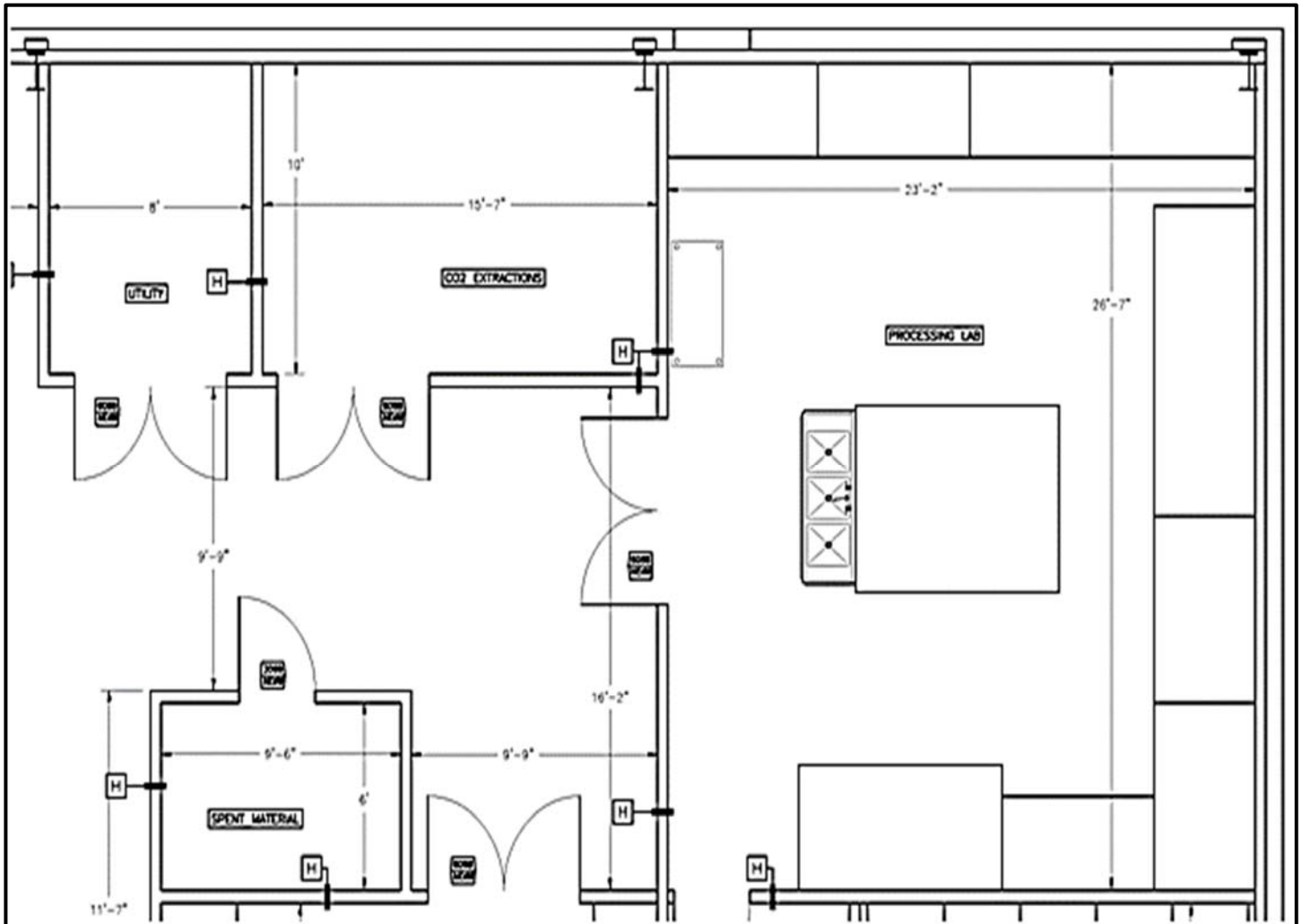
## **Zoning/Commercial Kitchen Approval**

Include your zoning approval here or on a separate sheet.

## Diagram of food processing and storage areas

The diagram may be drawn using computer software or drawn by hand. Clearly indicate or label each area used for storage of raw ingredients, packaging materials, finished products, processing area, warewashing facilities, handwashing sinks, restrooms, etc.

### EXAMPLE



## **Food Processing and Storage Area Diagram**

Include your diagram here or on a separate sheet.

## Employee Training and Records

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. **Provide documentation that training was completed on a separate sheet.**

List of available trainings:

- **360training.com, Inc.**  
Learn2Serve Food Protection Manager Certification Program:
  - Website link: <https://www.360training.com/course/ansi-food-safety-manager-principles-training-and-exam>
  - (877) 881-2235
- **AboveTraining/StateFoodSafety.com**  
Certified Food Protection Manager (CFPM) Exam:
  - Website link: <https://www.statefoodsafety.com/food-safety-manager-certification#/>
  - (801) 494-1416
- **National Registry of Food Safety Professionals**  
Food Manager Certification
  - Website link: <https://www.nrfsp.com/exam-center/training-options/>
  - (800) 446-0257
- **National Restaurant Association**  
ServSafe Food Protection Manager Certification Program
  - <https://www.servsafe.com/ServSafe-Manager>
  - (800) 424-5156
- **The Always Food Safe Company, LLC**  
Food Protection Manager Certification
  - <https://alwaysfoodsafecom.com/food-protection-manager>
  - 844-312-2011
- **Institute for Food Safety at Cornell University**  
Good Manufacturing Practices Part 117 Online Course
  - <https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/>

**Example template:**

Employee Training Record				
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 Contamination from Personal Belongings\***

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. You need to ensure that you can meet this requirement in your home kitchen. Personal belongings are any items that are not used in the manufacturing of your foods that will be offered for sale to the public. 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 food manufacturing facility, 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. Compliance with these requirements will be verified by the inspector.

*\*This section is only required if you are processing in your home.*

**Provide your written explanation describing how you will comply 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:

- <https://www.foodsafetymagazine.com/magazine-archive1/december-2003january-2004/writing-and-implementing-an-allergen-control-plan/>
- <https://farrp.unl.edu/3fcc9e7c-9430-4988-99a0-96248e5a28f7.pdf>
- <https://www.fda.gov/media/129670/download>

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

# Requirements of Subparts C & G and Exemptions

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

- Very small businesses that have attested to FDA. You may attest here using the Qualified Facility Attestation module: <https://www.access.fda.gov/>
- 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.
- Home food processors

*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 in the list above, which is the vast majority of food manufacturers. 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	● Monitoring procedures
● Preventive controls	● Corrective action procedures
● Supply chain program	● 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: <https://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](mailto:foodbiz@vt.edu) or (540) 231-5770

**Include a copy of your Food Safety Plan and Supply-Chain Program here or on a separate sheet. If you are a very small business, include documentation you have attested.**

## Basic Labeling Requirements

The following are labeling components required for all packaged foods. Failure to provide labels as described below will cause your application to be returned. Refer to the labeling regulation 21 CFR 101 for complete details.

**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. If any ingredient is made of two or more ingredients, these “sub-ingredients” must be listed in parentheses next to the main ingredient. When one of the eight 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 in ingredient statement:

Ingredients: Hemp Seed Oil, Coconut Oil, Full Spectrum Hemp Extract.

OR

Allergens\* listed in contains statement:

Ingredients: Hemp Seed Oil, Coconut Oil, Full Spectrum Hemp Extract. Contains: Coconut

**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 PO Box, telephone number, email address, website address or other cannot substitute.

**No claims can be made on the product label to the product’s suggested use or potential health benefits unless you intend to comply with the dietary supplement regulation, 21 CFR 111 (in addition to 21 CFR 117). No claims can be made suggesting the product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, as statements indicating such use would cause the product to be classified as a drug rather than a food. Please be aware that labeling includes statements or images on the product packaging, business website or social media, flyers, newsletters or any other printed material not explicitly mentioned here.**

### EXAMPLE LABEL

<p style="text-align: center;"><b>Full Spectrum Hemp Extract</b></p> <p>Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract.</p> <p style="text-align: center;">Grassy Fields Hemp Company LLC 14740 Country Road Somewhere, VA 24019</p> <p style="text-align: center;"><b>1 fl oz (30 ml)</b></p>
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**Note: If your product will be a dietary supplement, additional labeling requirements will be applicable. Please contact VDACS Food Safety for more information.**

## Product List and Planned Distribution

Products submitted for review	Planned distribution

## Ingredient List and Source

Ingredient Name	Ingredient Source

# Product Information Sheet

<b>Business Name:</b>		<b>Date:</b>	
<b>Product Name:</b>		<b>Trade Secret:</b>	
<b>List of Ingredients:</b>			
<b>Processing Procedures from raw ingredients to finished product:</b>			

## **Product Label**

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