

Dairy Manufacturing Permit Application Part II

Example: product information sheet

Product Information

Sheet Business Name: Crazy Cow Creamery, 111 Happy Ln, Cowtown, VA

Date: 1-1-2020

22554 Product Name: Strawberry Ice Cream

Trade Secret:

Recipe

Ingredients:

4 cups Ice Cream Mix

1 cup strawberries

1/3 cup sugar

1 Tbsp Lemon Juice

1/3 teaspoon Vanilla Extract

Step-By-Step Instructions:

1. Wash and sanitize utensils and preparation area
2. Assemble ingredients and equipment
3. Completely combine ingredients and mix into large bowl
4. Beat with mixer to fluff
5. Place in freezer for 20 minutes
6. Pour into ice cream maker and churn for 15 minutes
7. Remove ice cream and put into containers for storage
8. After ice cream has frozen, place in packages marked for sale

Product Information Sheet

Business Name:

Date:

Product Name:

Trade Secret:

Recipe

Ingredients:

Step-By-Step Instructions:

Product List and Planned Distribution

| Products submitted for review | Planned distribution |
|------------------------------------|---|
| <i>Example:</i> Gouda-style cheese | <i>Example:</i> Farmer's Market, local grocery stores, internet |
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Basic Labeling Requirements

The following are labeling components required for all 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. Ingredients like chocolate chips, for example, have multiple ingredients in themselves, and these sub-ingredients must be listed in parentheses next to the main ingredient. When one of the 9 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, Sesame, 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: 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.

Allergens* listed 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, 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**

OR

*Text does not need to appear in red.

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. A Plant # may be used in lieu of the full physical address.

Product Code and Keep Refrigerated/Frozen statement also needs to appear on the label.

EXAMPLE LABEL

| |
|--|
| <p style="text-align: center;">CHOCOLATE CHIP COOKIES</p> <p>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, 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</p> <p style="text-align: center;">Grannie's Cookies, 111 Happy Ln, Anytown, VA 22554</p> <p style="text-align: center;">Net wt. 10 oz (283 g)</p> |
|--|

Nutrition Labeling Exemption for Small Businesses

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.

Vertical Display with Micronutrients Listed Side-by-Side†
21 CFR 101.9(d)(12)

| Nutrition Facts | |
|-------------------------------------|----------------------|
| 8 servings per container | |
| Serving size | 2/3 cup (55g) |
| Amount per serving | |
| Calories | 230 |
| % Daily Value* | |
| Total Fat 8g | 10% |
| Saturated Fat 1g | 5% |
| <i>Trans Fat</i> 0g | |
| Cholesterol 0mg | 0% |
| Sodium 160mg | 7% |
| Total Carbohydrate 37g | 13% |
| Dietary Fiber 4g | 14% |
| Total Sugars 12g | |
| Includes 10g Added Sugars | 20% |
| Protein 3g | |
| Vit. D 2mcg 10% • Calcium 260mg 20% | |
| Iron 8mg 45% • Potas. 235mg 6% | |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Annotations on the left side of the label:

- No smaller than 10 pt with 1 pt of leading
- Bold, no smaller than 10 pt ¹
- Bold, no smaller than 6 pt
- Bold, no smaller than 16 pt
- 3 pt rule
- No smaller than 8 pt with 4 pt of leading ²
- Bold, no smaller than 8 pt with 4 pt of leading ³
- ¼ pt rule centered between nutrients (2 pt leading above and below)
- Shortened rule above
- Added Sugars declaration
- No smaller than 6 pt with 1 pt of leading

Annotations on the right side of the label:

- Bold, no smaller than all other point sizes except numerical value for “Calories”
- 7 pt rule
- Bold, no smaller than 22 pt
- Bold, no smaller than 6 pt
- Bold, no smaller than 8 pt ⁴
- All labels enclosed by ½ point box rule within 3 point of text measure
- 7 pt rule
- No smaller than 8 pt with 4 pt of leading and 8 pt bullets ⁵

This image was taken from FDA’s website. For more information on nutrition labeling and formatting, please click [here](#).

Product Label

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



Outline for an Effective Recall Plan

Please review the information below which provides basic instructions for developing a recall plan for your firm. You may develop your own plan from scratch or you may follow the template provided as a model plan. Please modify the documents for your firm, customize as necessary and submit them along with the rest of the application documents to VDACS Dairy Services for review. Additional info on recall can be found [here](#).

XYZ Farmstead Cheese Company
250 Milk Run Lane
Great Falls, Virginia
Phone Number

RECALL PLAN

If **XYZ Farmstead Cheese Company** determines there is a need to recall any product or if **XYZ Farmstead Cheese Company** is notified by the Virginia Department of Agriculture and Consumer Services to recall any product based on laboratory determinations, inspection, labeling or for any other reason the **XYZ Farmstead Cheese Company** will implement its recall plan as soon as practicable and in no case later than eight hours after notification.

If **XYZ Farmstead Cheese Company** determines or is notified there is a need to recall any product the Virginia Department of Agriculture and Consumer Services will be notified by phone call to the Dairy Services Program Supervisor by calling 804-786-1452 to discuss the recall. The following information will be supplied to the Dairy Services Program Supervisor by email to dairyservices@vdacs.virginia.gov or send hard copy to the Richmond Office, Attn.: Dairy Services.

Also contact the FDA Recall Coordinator, Mr. Ruark Lanham, 215-717-3738

1. Identity of the product involved;
 - Name of the product
 - Product codes
 - Number of units of each size of product
2. Reason for the recall;
 - Date product deficiency was discovered
 - Circumstances under which the product deficiency was discovered
3. Evaluation of the risk associated with the deficiency;
4. Total amount of identified products produced and the time span of the production;
5. Total amount of identified products estimated to be in distribution channels;
6. Distribution information including the number and identity of each person dairy products were sold to;
7. Draft copy of the proposed recall communication (sample letters are available upon request);
8. Proposed strategy for conducting the recall; and
9. Name and phone number of the **XYZ Farmstead Cheese Company** representative who should be contacted concerning the recall.

After the initial notification is completed the **XYZ Farmstead Cheese Company** will immediately notify each of its affected direct accounts about the recall with a recall communication that includes:

1. The identity of the product, size, lot number(s), code(s) or serial number(s);
2. The reason for the recall and the hazard involved, if any;
3. Specific instructions on what should be done with respect to the recall product;
4. Providing a method for the recipient of the recall communication to report if the firm has any of the products;
5. A statement that distribution and use of any remaining product should cease; and
6. If the direct account should then in turn notify its customers who received the product about the recall.

During the ongoing recall the **XYZ Farmstead Cheese Company** will provide recall status reports to the Virginia Department of Agriculture and Consumer Services when requested until the recall is terminated. The recall status report will include:

1. Number of consignees notified of the recall, and date and method of notification;
2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
3. Number and identity of consignees that did not respond to the recall communication;
4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
5. Number and results of effectiveness checks that were made; and
6. The estimated time frames for completion of the recall.

XYZ Farmstead Cheese Company

| Print Name | Title | Signature | Date |
|------------|-------|-----------|------|
|------------|-------|-----------|------|

XYZ Recall Plan Annual Review Record

Date annual reviews were completed.

Details of changes – if any:

| Print Name | Title | Signature | Date |
|------------|-------|-----------|------|
|------------|-------|-----------|------|

| Print Name | Title | Signature | Date |
|------------|-------|-----------|------|
|------------|-------|-----------|------|

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 pasteurization temperatures, cleaning food contact surfaces, allergen awareness/control and any other topics specifically applicable to your particular food processing operation.

List of available trainings, with website links (this list is not all-inclusive) are listed below:

- **360training.com, Inc.**
Learn2Serve Food Protection Manager Certification Program:
 - ❑ 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:
 - ❑ Link: <https://www.statefoodsafety.com/food-safety-manager-certification#/>
 - ❑ (801) 494-1416
- **National Registry of Food Safety Professionals**
Food Manager Certification
 - ❑ Link: <https://www.nrfsp.com/exam-center/manager/>
 - ❑ (800) 446-0257
- **National Restaurant Association**
ServSafe Food Protection Manager Certification Program
 - ❑ Link: <https://www.servsafe.com/ServSafe-Manager>
 - ❑ (800) 424-5156
- **The Always Food Safe Company, LLC**
Food Protection Manager Certification
 - ❑ Link: <https://alwaysfoodsafecompany.com/food-protection-manager>
 - ❑ 844-312-2011
- **NC State Food Safety Education & Training**
Good Manufacturing Practices in Food Safety
 - ❑ Link: <https://foodsafety.ncsu.edu/GOOD-MANUFACTURING-PRACTICES/>
- **Institute for Food Safety at Cornell University**
Good Manufacturing Practices Part 117 Online Course
 - ❑ Link: <https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/>

Example template:

| Employee Training Record | | | | |
|---|-------------|----------|----------------|-------------------|
| Grannie’s Cheese, 111 Happy Ln, Anytown, VA 22554 | | | | |
| | | | | |
| Employee Name | Course Name | Location | Date Completed | Trainer Signature |
| | | | | |
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Employee Training and Records

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

Preventing Allergen Cross-Contact

The nine (9) major allergens in the U.S. are: milk, wheat, eggs, peanuts, tree nuts, soybeans, fish, crustacean shellfish and sesame. 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. [Click here to access this template in Word.](#)

| Allergen Control Plan - Master List of Ingredients | | | | | | | | | | |
|---|----------|--|--|------|-----|-------|---------------------------|-------------|-----------------------|--|
| Business Name and Address: _____ | | | | | | | | Date: _____ | | |
| Food Allergen Ingredient Analysis | | | | | | | | | | |
| Raw Material Name | Supplier | Ingredients List for this Raw Material | Food Allergens in Ingredient Formulation | | | | | | | Allergens in Supplier's Precautionary Labeling |
| | | | Egg | Milk | Soy | Wheat | Tree Nut (market name) | Peanut | Fish (market name) | |
| | | | | | | | | | | |
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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.

Preventing Allergen Cross-Contact

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?

- A business conducting at least 50% of sales directly to the consumer (retail). This type of business does not need to attest to FDA.
- Very small businesses that have attested to FDA. A very small business is one that averages less than \$1,000,000 in sales of human food per year for 3 years. Use the instructions and form 3942a at this website to submit your attestation: <https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/qualifiedfacilityattestation/default.htm>
- 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 your business model changes such that none of the above exemptions apply, you must then comply with Subparts C & G.

- Warehouses that store only pre-packaged food (more information directly below):

Subpart D: Warehouses That Store Only Pre-Packaged Food

If the warehouse holds refrigerated or frozen food then they must implement temperature controls, such as storage below 41°F, monitor the storage temperature often, calibrate or check accuracy of thermometers, and maintain temperature records. When temperature control is lost, corrective action should be taken to prevent negatively affected food from entering the food supply.

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). If you are familiar with Hazard Analysis Critical Control Point (HACCP), then this will sound familiar. 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: <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 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 on Page 14.

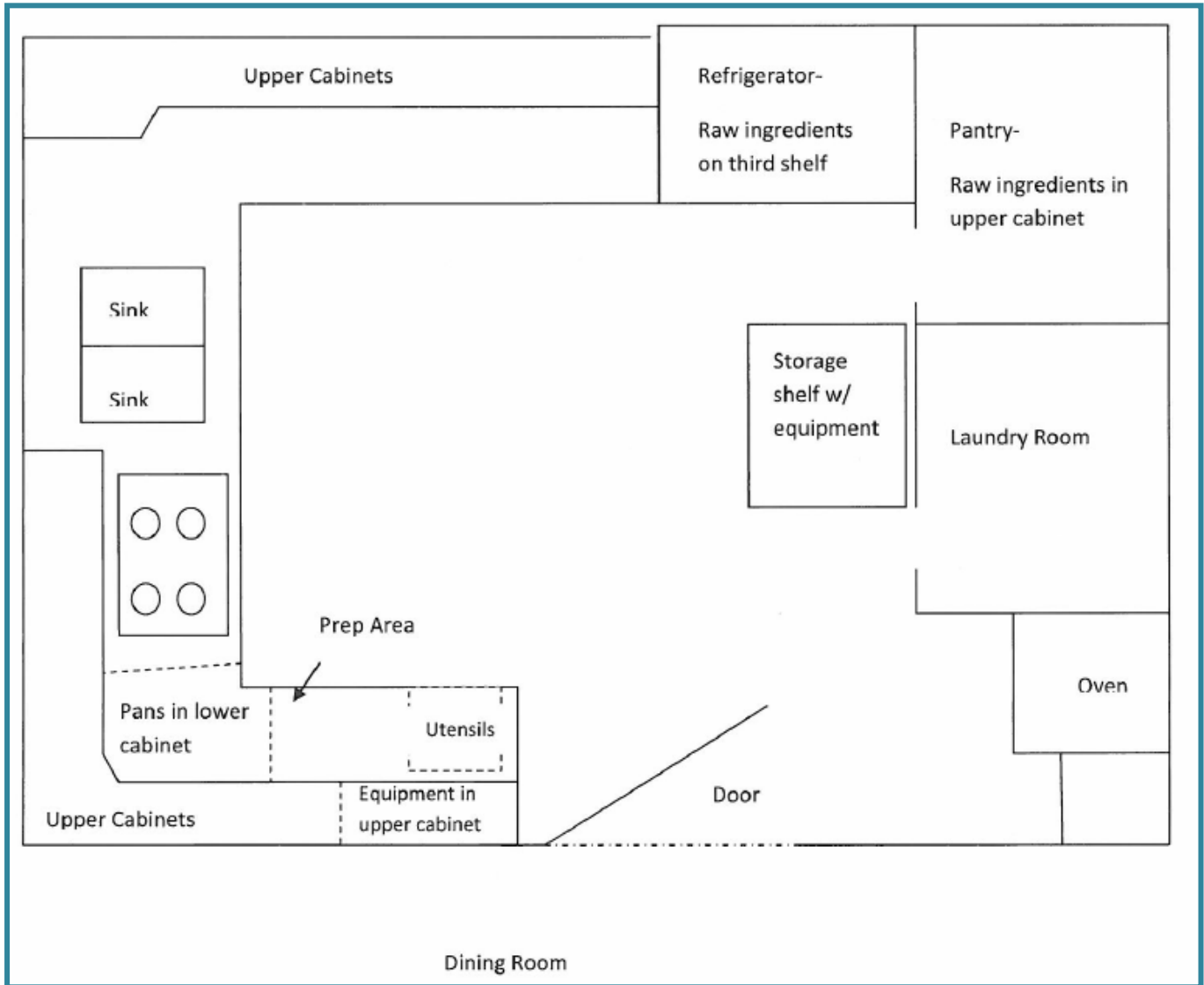
Food Safety Plan and Supply-Chain Program

If you are a very small business, include documentation you have attested.

Example: diagram of dairy processing and storage areas

The diagram may be drawn using computer software or drawn by hand. If there are pets in the home, make it clear in the diagram how the food processing and storage areas are inaccessible to pets at all times.

Please note that all dairy manufacturing equipment installed in the plant must be approved by the Regulatory Agency prior to the purchase and must be compliant with 3-A and NSF Standards.



Dairy Processing and Storage Area Diagrams

Include your diagram here or on a separate sheet.

Zoning Approval

Include your zoning approval here or on a separate sheet.

Pre-Operational Checklist for Dairy Manufacturing Establishments to assist you with regulatory compliance

- 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 semi-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 hot and cold water under pressure to areas throughout the plant
- Adequate sewage disposal system
 - Private sewage systems require approval from the Virginia Department of Health
- Refrigeration equipment
 - 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, trash 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
 - 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
 - Premises free of harborage and/or breeding places;
- 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 Dairy Regulations, 21 CFR 101, 21 CFR 133, 21 CFR 135
 - Note: Additional regulations may apply depending on the type of product you are manufacturing
- Approval from other regulatory authorities in the locality
 - Building inspector, fire marshal, etc.
- Submitted VDACS Dairy Manufacturing Permit Application