FOOD SAFETY IMPLEMENTATION GUIDE

Implementing a Food Safety System for Small-Scale and Raw Milk Cheese Plants

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Purpose and Note from the Authors

The purpose of this guide is to assist small-scale and raw milk cheesemakers in conducting Hazard Analyses of their processes to ensure they are producing the safest product possible and to meet the requirements of the Food Safety Modernization Act (FSMA).

There are many resources available on conducting Hazard Analyses and developing Food Safety Plans. It has been our experience that existing materials do not provide enough information and direction focused on small-scale dairy processors to help them write the elements of their Food Safety Plans. The production of raw milk cheese poses additional risk because there is no pathogen kill step applied to the milk, and therefore cheesemakers must manage the risk at various other steps in their process using a combination of hurdles.

The companion document for this guide is the "Penn State Extension Food Safety Plan for Raw Milk Gouda Cheese Teaching Example," which follows an example for raw milk, flavored Gouda. These two documents address the gap in materials available for the manufacture of raw milk cheese.

The original intended focus of this document was to provide tips on conducting a Hazard Analysis to accompany the Food Safety Plan example. During collaboration with cheesemakers in the development of the guides, we realized there was still difficulty in understanding how all the pieces associated with a Food Safety System fit together. We feel that it is paramount that cheesemakers understand the full scope of a properly implemented Food Safety System required by FSMA, so we included sections on Good Manufacturing Practices, Prerequisite Programs, dairy hazards, and resources in this document. Good Manufacturing Practices, hazards, and other aspects of Food Safety Systems are more thoroughly covered in other documents and classes, and our guide is intended to complement these resources, not replace them.

We thank the cheesemaker collaborators on this project. We greatly appreciate their input—they thought of things we didn't and provided a valuable cheesemaker's perspective to our academic perspective.

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Introduction to the Food Safety Modernization Act

The Food Safety Modernization Act (FMSA) was enacted by the U.S. Food and Drug Administration (FDA) in 2015 to improve the safety of the food supply and reduce the number of foodborne illnesses. This legislation affects all aspects of our food supply and all food providers. Regardless of size, all food processors are expected to take responsibility for producing safe food for human and animal consumption. A consumer does not distinguish whether their food was made by a small-scale artisanal processor or a multinational corporation when the issue is safety—they expect their food to be safe and not cause illness or injury no matter who they buy it from. All processors should be dedicated to following safe food practices.

Food safety is directly related to risk—the more risk that a food product will cause illness or injury to the consumer, the more controls are needed to eliminate, reduce, and manage that risk. The fundamental premise of FSMA is managing risk.

Because FMSA seeks to manage risk across the entire food supply, the regulations are extensive. The FDA had a big task to cover all bases while trying to make the regulations workable for the food industry, but they can be cumbersome to read and interpret.

The section of FSMA that we are addressing in this guide is compliance with the Preventive Controls for Human Food Rule, which is presented in Title 21 of the Code of Federal Regulations, Section 117 on Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR 117). This rule contains:

- Requirements that must be met by all food processors
    - Employee Training
    - Good Manufacturing Practices (GMPs)
- Requirements that must be met by larger food processors
    - Hazard Analysis
    - Risk-Based Preventive Controls
    - Record Keeping
    - Supply-Chain Program
- Modified requirements for processors meeting certain size and financial qualifications
    - Attestation of financial qualifications
    - Attestation that a Hazard Analysis has been conducted, and if hazards are identified, that appropriate Preventive Controls are implemented and monitored OR are in compliance with state, local, county, tribal, or other applicable nonfederal food safety laws
        - ★ *Note*: The management of high-risk foods is similar for small and large processors.

To reduce the industry burden of implementing the activities and documentation in these regulations, compliance dates were staggered based on company size:

- Covered facilities with more than 500 employees: September 17, 2016
- Covered facilities with 10–499 employees: September 17, 2017
- Qualified facilities: September 17, 2018
    - Attestations filed with the FDA by December 17, 2018

- Facilities operating under the Grade "A" Milk program: September 17, 2018 (to allow for an update to the Pasteurized Milk Ordinance to conform with FSMA)

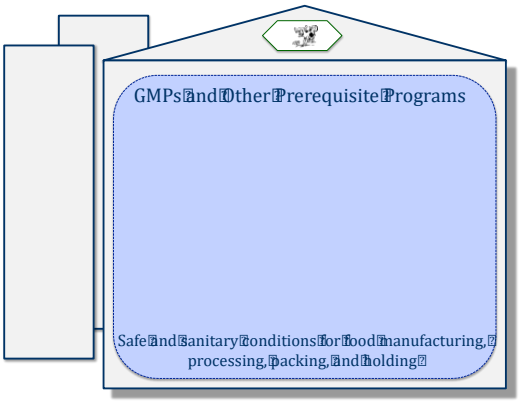
The target audience for this guide is small-scale and raw milk cheesemakers. It is likely that most of these facilities fall under the classification of qualified facilities with modified requirements for Food Safety Plans. However, it is a fact that *milk is known to be associated with pathogens and should be considered a high-risk food*. Therefore, it would be prudent for all dairy food processors to conduct a thorough Hazard Analysis to ensure they are managing all potential risks that could cause illness or injury to consumers. Processors should also be diligent with their monitoring activities and documentation to ensure the continued production of safe cheese.

An Introduction to Food Safety Systems

Most people think of "Food Safety Plans" when they think of what is required under FSMA. However, Food Safety Plans are only one element in the bigger scope of managing risk and producing safe food. This section provides definitions and a visual representation of the different elements that comprise a comprehensive Food Safety System.

A **Food Safety System** is the *outcome* of implementing the Food Safety Plan and all of its supporting elements. It is the totality of everything we do to produce safe food.

Good Manufacturing Practices (GMPs) are *practices* that provide the basic environmental and operating conditions to produce safe food in a sanitary environment. GMPs cover personnel, operational, and facility aspects. GMPs are a subset of Prerequisite Programs and are not specific to any individual food.

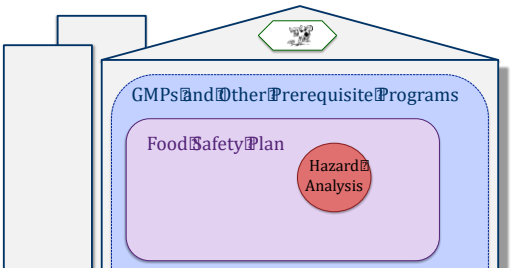


GMPs and Prerequisite Programs are the foundation of food safety in a dairy processing facility.

Prerequisite Programs (PPs) are *universal programs, practices, and procedures* that provide the basic environmental and operating conditions necessary to produce safe food in a sanitary environment. PPs include GMPs, and may also include programs such as water safety for the whole facility, overall sanitation procedures, and preventive maintenance programs. Prerequisite Programs are not specific to any individual food.

A **Food Safety Plan** is a *set of written documents* including the Hazard Analysis, Preventive Controls, Supply-Chain Programs, and Recall Plan for producing a particular food or group of foods. The plan is based on the results of the Hazard Analysis. It specifies procedures for monitoring, corrective actions, and verification of the Preventive Controls to ensure the plan is working effectively to manage the hazards that are identified in the Hazard Analysis. It is common that a processor will have different Food Safety Plans for different products. For

example, the Food Safety Plan for producing cheese will be different from one for producing yogurt. A processor might use the same plan for producing different types of cheese that are similar such as Cheddar and Monterey Jack, but might have different plans for Cheddar and Blue Cheese.



The Hazard Analysis is the backbone of the Food Safety Plan and identifies and assesses hazards associated with producing a specific food.

A **Hazard Analysis** is the *process of collecting and evaluating information on hazards* present to determine which are significant for food safety and must be considered in the Food Safety Plan. The Hazard Analysis is a two-step process:

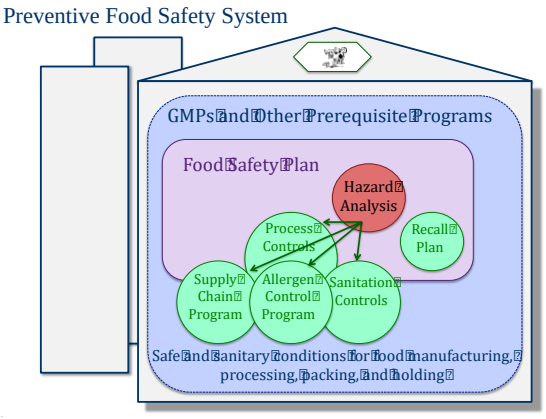
1. *Identification* of all *hazards* that may be introduced, controlled, or enhanced at each step in the production of a food.
2. *Risk-based assessment* (supported by scientific facts) of the *severity* of the hazard and the *likelihood* it will occur

Typically, a flow chart of all the steps in the manufacturing process, including all inputs and outputs, is used to conduct the Hazard Analysis. The results of the Hazard Analysis are documented on a **Hazard Analysis Summary Form**.

A **hazard** is a *biological, chemical (including radiological), or physical agent* that has the potential to cause *illness or injury* to a consumer. A hazard is a safety issue, not a quality issue. A hazard will make someone sick or cause tissue damage. Organisms that cause spoilage, tolerable levels of filth (e.g., insect parts), violations of standards of identity, or situations relating to economic fraud (e.g., adding water to milk) are not hazards—these are quality issues.

A **Preventive Control** is *a procedure, practice, or process* that is used to significantly minimize, eliminate, or manage a hazard. Preventive Controls involve monitoring, have corrective actions, and require verification to ensure they are effective at managing the hazard. Different hazards are managed in different ways.

- A **Process Control** is a *biological, chemical, or physical parameter* that is used to control a hazard during dairy processing. Process Controls are measurable and have critical limits, which are minimum or maximum values or a combination of values that must be met.
- An **Allergen Control** is *an action* used to prevent allergen cross-contact and ensure correct labeling of foods that contain allergens.



The Preventive Controls needed to manage the hazards are identified in the Hazard Analysis. This illustrates a comprehensive Food Safety System.

- A **Sanitation Control** is a *procedure* used to guide sanitation activities that addresses a specific hazard in the Food Safety Plan. Examples include cleaning of food-contact surfaces, prevention of allergen cross-contact, and monitoring for environmental pathogens when a ready-to-eat (RTE) product is exposed to the environment prior to packaging.
- A **Supply-Chain Control** is an *action or procedure* used to minimize or reduce a hazard in raw materials or ingredients that is applied by the supplier, and monitored by the food processor. It may include approving a supplier by a third-party audit or through the use of Certificates of Analysis (COAs).

Monitoring is *a planned set of observations or measurements* to assess whether a **Preventive Control** is operating as intended. A monitoring program defines what is to be monitored, how it is monitored, how often, and by whom.

A **Corrective Action** is *a procedure* that must be taken if a **Preventive Control** is not properly implemented and the food is at risk of causing illness or injury.

Verification is an *action* conducted to ensure a **Preventive Control** Is consistently implemented and effective in managing the hazard. Verification activities include:

- Calibrating process monitoring instruments, such as pH meters and thermometers
- Reviewing records

Validation is *using research* to objectively show that a Process Preventive Control works to manage a hazard or hazards.

A **Recall Plan** is *a set of procedures,* used in the case of a potential hazard reaching the consumer, to recall products from the market, determine the cause of the outbreak, assess the cause of the outbreak, and fix the problem that caused the recall.

An important concept to keep in mind is that while the FDA has specified the elements that need to be addressed in Food Safety Systems and Plans, there is no set format required of all processors. Each processor has the flexibility to use the documentation forms and formats that work best for them.

The Foundations of a Food Safety System

The foundations of a Food Safety System are concepts, procedures, programs, processes, and actions that affect the facility as a whole. These are used to ensure the entire facility is an environment that is suitable for safe food production. Three key aspects of food safety are personnel training, Good Manufacturing Practices, and other Prerequisite Programs. Sometimes hazards may be controlled through GMPs and PPs and can be used as the justification in the Hazard Analysis.

This section provides an overview of these topics and questions to help you evaluate how well your manufacturing practices contribute to food safety and help you identify areas to be

improved. If you answer "no" to a question, then consider what you can do to correct the situation and make an action plan to implement change.

FSMA Training Requirements

The Food Safety Modernization Act requires training for all employees relative to their job duties. Managers have the responsibility to see that all employees are trained. Documentation of employee training is required under FSMA.

A **Qualified Individual** is a person who works in a food processing facility and has the education, training, or experience appropriate to their job duties. For example, the sanitation crew should be trained in sanitation procedures and chemical handling, and the lab staff should know how to properly conduct lab analyses. All employees need to be trained in the principles of food hygiene and safety.

A **Preventive Controls Qualified Individual (PCQI)** is a person who has been trained to prepare a risk-based Food Safety Plan by attending a course with a standardized curriculum recognized by FDA or through appropriate experience.

Questions to Ponder on Training

- How are employees trained to perform their jobs?
    - Do they receive verbal instruction? Demonstrations? Written resources?
- Are employees trained when they are new?
- How often are employees trained or retrained?
    - Are there follow-up training sessions for employees?
    - Are there regularly scheduled trainings?
- Do all of your employees speak the same language?
- How do you make sure that they understand all of the training materials?
- What topics are taught in training sessions?
    - Basic concepts of food safety?
    - Basic concepts of personal hygiene?
    - Tasks specific to their duties? Cheesemaking? Sanitation? Cheese aging practices?
- How is training standardized?
- Is training the responsibility of one person or is it shared?
- Who trains the trainer?
- How do you evaluate the training your employees receive?
- How is employee training documented?

Good Manufacturing Practices

Good Manufacturing Practices (GMPs) apply to the whole facility and are required for all food processors. GMPs are outlined in 21 CFR 117, Subpart B. More details for cheesemakers can be found in the American Cheese Society's (ACS) *Best Practices Guide for Cheesemakers* (2017), the Dairy Practice Council's (DPC) *Guideline for Food Safety in Farmstead Cheesemaking* (2002), and the Food Safety and Preventive Controls Alliance's (FSPCA) *Preventive Control for Human Foods Participant Manual* (2016).

Personnel Related

Personnel practices are critical to food safety—many risks can be reduced through awareness of a food safety culture in a processing facility. Making sure employees are trained in proper hygiene and food handling procedures and communicating clear expectations are essential to reducing risk.

Questions to Ponder on Personnel Practices

Employee Hygiene

- What procedures are in place to describe appropriate employee hygiene?
    - Do they include jewelry and fingernail polish?
- How are hygiene standards communicated to employees?
- How are employee hygiene standards enforced?
- Are employees trained in proper handwashing techniques?
- Are single-use towels used and discarded after handwashing?

Clothing

- What is the uniform policy?
- How is the uniform policy enforced?
- If the employee provides their own work clothes, are there standards of cleanliness for these clothes?
- What measures are in place so that clothing worn outside the manufacturing facility does not bring contamination into the facility?
- Where do employees get dressed?
- Do employees use separate footwear in the manufacturing areas?
- Are shoes worn in the make room ever worn outside?
    - How do you prevent shoes from contaminating the make room?
- Where and how are work shoes stored?
    - How and when are work shoes cleaned and dried?
- Are employees trained on how to properly wear hairnets and beard nets?
- Are employees trained on how to properly use gloves?

Health Conditions

- What happens when an employee is sick?
- What happens when an employee has an open sore, cut, or wound? Do they know what to do in order to prevent product contamination?
- Are there jobs a sick employee may perform that will not contaminate food products?

Facility Hygiene

- Are employees trained to not bring personal items into the manufacturing facility?
- Where do employees eat and drink?
- Where do employees smoke?

Facilities Related

Good Manufacturing Practices cover all aspects of manufacturing, including the physical facilities themselves. The design and construction of the cheese plant are the first line of defense against contamination by hazards. The facility must be suitable for the production of safe food. The regulations for GMPs address plants and grounds, sanitary operations, sanitary facilities and controls, processes and controls, and warehousing and distribution.

Questions to Ponder on Facilities

Walls, Floors, and Ceilings

- Are facility building materials appropriate for a dairy processing environment?
- Are building materials durable and easily cleaned, including walls and ceilings?
- Are floor drains adequately placed and floors adequately sloped to ensure proper drainage?
- Are there any areas of the facility where water pools on the floor?

Doors and Windows

- Are there windows in the make room or packaging area?
- When windows are open, what barriers are there to contamination from bacteria, insects, birds, and soil entering the facilities?
- If doors are propped open, could this contaminate the processing environment?
- Are there foot baths or a sanitation system installed by the doors?

Lighting and Ventilation

- Is there enough light in rooms to adequately perform all tasks and see soil if it exists?
- Are the lights protected by plastic (i.e., not glass) covers?
- What happens if a lightbulb breaks in the processing area?
- How are rooms ventilated?
- Is positive air pressure maintained in product packaging areas?

Coolers, Aging Rooms, and Caves

- Are coolers, aging rooms, and caves easily cleaned?
- How often are these areas cleaned?
- How is temperature monitored and maintained in temperature-sensitive areas?
    - How often is the temperature checked (monitored) and documented?
- How often are the thermometers used to monitor facility temperatures calibrated?
    - Is there a written calibration procedure and calibration log?

Changing Area

- Is there a specific place where employees change clothes and shoes?
- Where are clothes worn outside the facility stored while employees are working?

Laboratory

- Is there an on-site laboratory?
- Where are lab chemicals stored?
- How are chemical disposed?
- Are there microbiological hazards from in-house microbial testing that can contaminate dairy processing areas?
- Is the lab separated from the rest of the facility?

Traffic Flow

- Have you mapped out traffic flow during a production day using a facility floor plan?
- Do you use hygienic zoning to set hygiene requirements for different areas of the plant based on the risk of product contamination?
- What methods do you use to make sure contaminants do not transfer from nonprocessing areas into processing areas?
- Does the traffic flow plan minimize cross-contact between raw and ready-to-eat (RTE) foods?
- Does cheesemaking occur in the same space as packaging?
    - If so, how do you prevent cross-contamination?
- Is the cheese production room used for any other activities that have the potential to introduce hazards into the cheesemaking environment?

Shared Spaces

- Do you share processing space in a facility with another company?
- What processes are used to ensure your environment and equipment are not contaminated when you are not there?
- What type of food safety training do others that use the shared facility have?

Water

- What is the facility's water source?
- How often is the water tested?
- Are there compounds in the water that can affect the safety of the product?
- Are the appropriate boiler additives used?
- How is the safety of the steam evaluated?
- How are water hoses used in the facility cleaned regularly?

HVAC System

- Is the HVAC system properly maintained?
- Does the HVAC system pose a hazard to food safety?
- Is there potential for condensate to fall into the product or onto product-contact surfaces?
- How are condensate pans cleaned and kept free from microbial contamination?

Waste Management

- Are solid waste containers place away from food-contact surfaces in the production room?
- Are external waste collection areas free of pests?
- How is liquid waste stored?
- Is whey stored and disposed of in a manner that prevents it from becoming a reservoir for potentially hazardous bacteria?

Pests

- Are facilities designed to be an effective barrier against pests?
- Are there areas inside and outside the facility that could harbor pests?
- Are racks and shelves at least 18 inches away from the wall to facilitate cleaning and inspection for dirt and pests?
- Is the lowest shelf on any rack at least 6 inches off the ground?
- Are there visible signs of pests, such as ants, flies, or mice?
- What is your pest management program?

Equipment and Utensil Related

Equipment used in dairy processing must be made of cleanable and nontoxic, food-safe materials. Equipment and utensils should be maintained in good condition. Visible rust, scratches, and missing pieces are good indicators that equipment no longer meets these standards and may pose hazards.

Questions to Ponder on Equipment and Utensils

Design and Maintenance

- Is equipment made of materials appropriate for dairy processing?
- Are the equipment and utensils designed to be easily cleanable?
    - Can all parts be reached easily?
- Is there any visible damage on equipment and utensils?
- How often are equipment and utensils checked for damage?
- Are utensils replaced in a timely manner if they are damaged?
- If wooden shelves are used in cheese aging, how often are they inspected for damage? How are they cleaned and sanitized? How frequently?
- Is there a master equipment maintenance schedule?

Cleaning

- Are there written standard sanitation operating procedures (SSOPs) for each piece of equipment?
- What cleaning procedures and chemicals are routinely used for cleaning?
- Are clean-in-place and clean-out-of-place systems used properly?
- Are chemicals tested for concentration and documented regularly?
- Does water pool on or in equipment after cleaning?
- How are equipment and utensils dried?

Sanitary Operations

Sanitary operations refer to not just cleaning procedures but also the practices you use throughout the food manufacturing process. Having a company-wide culture of paying attention to sanitary concepts from personnel behaviors, such as handwashing, to handling utensils to the finished products greatly contributes to the production of safe dairy products.

Questions to Ponder on Sanitary Operations

- Are people trained in sanitary practices in all aspects of their job?
- Do utensils that contact food ever contact the floor or other nonsanitary surfaces?
- Do hoses and spray handles contact the floor or other nonsanitary surfaces?
- Are there written cleaning and sanitizing procedures for equipment and utensils?
- Are there written cleaning and sanitizing procedures for cleaning ceilings, walls, coolers, and aging rooms?
- Are cleaning and sanitizing documented regularly?
- Is a colored brush program used for cleaning and sanitizing?
- If squeegees are used, how do you avoid splashing onto equipment and food-contact surfaces?
- Do you sanitize equipment directly before use? How do you document this?
- How often do you clean areas of the facility that are not cleaned daily?
- How and how often are drains cleaned?
- Do you have a drain cleaning SSOP?
- Are foot baths or floor sanitation systems properly maintained to prevent contaminants from entering the facility?
- Is there a master sanitation schedule for the facility?
- Are food-contact surfaces used to store supplies, packaging, and other products that may cause contamination?
- Are storage areas cleaned regularly?
- If you do not make cheese for several days, do you do a full wash of all the equipment before use?
- Are cleaning chemicals stored to prevent contamination of food-contact surfaces or dairy products?
- Are old cleaning products discarded regularly?

Prerequisite Programs

Prerequisite Programs (PPs) are practices that apply to the whole facility. Prerequisite Programs include GMPs, but may have a broader scope. Programs mentioned in the GMP section above, such as an SSOP, preventive maintenance program, or pest control program, may be a way to manage hazards that are identified in a Hazard Analysis. Examples of other Prerequisite Programs that may be used to manage hazards include:

- Employee training procedures and documentation
- Receiving and storage procedures
- Water safety (for the whole facility)
- Calibration procedures and logs

- Routine cleaning and sanitizing of equipment and utensils
- Proper storage of cleaning chemicals
- Preventive maintenance programs for equipment, cheese knives, aging boards, etc.
- Periodic sanitation schedules for cleaning of drains, coolers, storage rooms, walls, tops of light fixtures, etc.
- Visitor policy
    - Sign-in sheet and instructions for visitors
    - Required clothing
    - Photography policy

Prerequisite Programs are written programs that usually define the scope of the program, the tasks performed, monitoring procedures and logs, and corrective actions. Not all Prerequisite Programs will fall neatly into this type of documentation, such as a visitors policy. Remember that the FDA does not have defined forms and formats that need to be used; food processors are able to use what works best for them.

Hazards

The more risk that a dairy product will cause illness or injury to the consumer, the more controls are needed to eliminate, reduce, and manage that risk. This section presents an overview of general hazards encountered in dairy processing and those of concern in cheesemaking. More information about hazards can be found in the DPC *Guideline for Food Safety in Farmstead Cheesemaking* (2002) and the FSPCA *Preventive Control for Human Foods Participant Manual* (2016).

Types of Hazards

Hazards are agents that have the potential to cause illness or injury to a consumer. They are a safety issue, not a quality issue.

Biological Hazards

Biological hazards can cause *infections*, where consumption of the live organism causes illness, or they can cause *intoxications*, where the organism produces a toxin which causes the illness. Biological hazards can originate from animals, humans, and the environment. All biological agents need a source of nutrients and water, but different agents have different temperature and pH ranges for growth and survival.

Pathogens are bacteria that cause illness. Examples of potential bacterial hazards are:

- Bacteria that cause infections
    - *Listeria monocytogenes*
    - *Escherichia coli* (pathogenic)
    - *Salmonella*
    - *Campylobacter jejuni*
    - *Yersinia*
    - *Shigella*

- Bacteria that cause intoxications
    - *Bacillus cereus*
    - *Staphylococcus aureus*
    - *Clostridium perfringens*
    - *Clostridium botulinum*

Other biological agents that could be pose hazards are the Hepatitis A virus from an infected employee, or the parasites *Giardia* and *Cryptosporidium* from contaminated water.

Biological hazards are controlled by keeping them out of the dairy processing facility (Supply-Chain Controls) and away from contact with food (GMPs), reducing the potential for their growth and survival (GMPs, Process Controls), or killing them through means such as pasteurization (Process Controls).

Chemical Hazards

Chemical hazards can cause illness and injury by allergic reactions or consumption of toxic chemicals. Chemical hazards can originate in raw materials, from external contamination, or by accident. Examples of chemical hazards are:

- Allergens (milk, peanuts, tree nuts, eggs, soy, wheat, shellfish, fish)
- Drug residues (antibiotics from animal care)
- Pesticides (from incoming ingredients or improper pest control programs)
- Mycotoxins (in the milk from moldy feed)
- Cleaning, sanitizing, and other toxic chemicals (cross-contamination)
- Radiological hazards (in areas near nuclear power plants)

Chemical hazards are controlled by ingredient control (Supply-Chain Control), proper storage and handling (Allergen Controls, GMPs), and proper use of chemicals (Sanitation Controls, GMPs).

Physical Hazards

Physical hazards cause injury to tissues by being ingested. Solid materials that are in the range of 0.25 to 1 inch can pose a choking hazard. Physical hazards can originate in equipment and utensils, from shipping and packing materials, or from the environment. Examples of physical hazards are:

- Metal
- Plastic
- Wood
- Stones
- Glass
- Rubber

Physical hazards are controlled by ingredient control (Supply-Chain Control) or Process Controls, such as filters and screens, visual inspection, or metal and X-ray detection devices.

Hazards in Cheesemaking

The cheesemaking process is at risk of hazards throughout the entire process. A thorough understanding of the potential hazards in cheesemaking, good employee training, and a dedicated culture of food safety are essential in making safe cheese.

Particular Concerns with Small-Scale and Raw Milk Cheesemaking

Small-scale cheesemakers have both advantages and disadvantages when it comes to controlling hazards in cheesemaking. Small-scale cheesemakers tend to be very dedicated and passionate, with a strong desire to make a high-quality, safe product, which infuses a food safety culture into their businesses. They can be at a disadvantage because they often have only a few employees doing multiple tasks in the cheese plant. Larger-scale cheesemakers may have separate teams dedicated to the make process, aging, sanitation, and laboratory tasks. With fewer people doing more tasks, it is possible that occasionally things can be forgotten or overlooked, or people may take shortcuts to get all the work done. Training can be more challenging in smaller plants due to time and financial constraints that can limit a cheesemaker's ability to stay up to date with new regulations and material, spare employees to send to outside courses, or bring in consultants for training. The new FSMA regulations also add a burden of time and cost to a small processor to implement new procedures, provide documentation, and conduct regular environmental testing.

Raw milk cheese poses the additional hazard of having no kill step in the process. Raw milk and raw milk cheeses are known to be associated with several pathogens. Therefore, diligence in following safe cheesemaking practices is critical. The first step is to ensure you have done everything you can to reduce the likelihood of pathogens in the raw milk supply. This can be accomplished by a strong Supply-Chain Control program, whether you are a farmstead cheesemaker using your own milk or an artisan cheesemaker purchasing milk. You want to make sure that pathogens stay out of the milk and out of your facility. During the cheesemaking process you want to make sure that the acidification process happens according to your optimized make procedure to prevent pathogens from growing in the milk and cheese, should they be present. Raw milk cheese has an aging requirement of at least 60 days at not less than 35°C. Proper temperature control and time in the aging room need to be documented. Prevention of contamination from aging shelves and the environment is crucial, which means good sanitation and environmental monitoring. Knowledge of other factors that may affect your raw milk cheese—such as high moisture and high pH, which can favor pathogen growth—should be taken into account when determining Preventive Controls and monitoring procedures. Staying aware of outbreaks associated with cheeses similar to yours and knowing how these are handled will help you be a more conscientious cheesemaker.

The environment in a cheese facility is a concern for hazards, particularly for the presence of *Listeria monocytogenes* (*L. mono*), which is a serious pathogen. *L. mono* is found in the soil and can easily find its way into processing plants, where it can live for a long time. *L. mono* can survive and grow at refrigerator temperatures and in high-salt concentrations such as cheese brines. *Listeria* is often found in moist areas, such as drains, corners of coolers, and aging rooms, and places where water pools, such as cracks in the floor and condensate pans. Cross-contamination by environmental pathogens can occur after pasteurization (if used), during the cheesemaking and aging processes, and during packaging of finished cheese. Environmental testing can be costly, but it is necessary to monitor for potential pathogen contamination. If you

find pathogens in the environment, take corrective actions to get rid of them. Good sanitation practices and regular environmental monitoring are the keys to controlling *Listeria*. Good Manufacturing Practices and proper facilities design will help prevent recontamination.

Raw Milk and Ingredients

Raw milk is known to be associated with pathogens that cause illness and death. Hazards associated with raw milk and ingredients are usually those that are introduced into the facility and the cheese. Hazards associated with raw milk and ingredients include:

- Biological hazards
  - Pathogens in raw milk
  - Pathogens in the ingredients (particularly spices)
- Chemical hazards
  - Drug residues in raw milk
  - Allergens in ingredients
  - Mycotoxins in raw milk from contaminated feed
- Physical hazards
  - Pallet splinters
  - Packaging materials
  - Stones

Cheesemaking, Brining, and Aging Processes

Hazards associated with cheesemaking processes may be introduced, such as in the case of metal from broken cheese harps, or they may be enhanced, such as pathogen growth during the aging process. Hazards associated with cheesemaking processes include:

- Biological hazards
  - Growth of pathogens due to inadequate acidification in the cheesemaking process
  - Growth of pathogens in the aging process
  - Cross-contamination from improperly cleaned equipment
  - Biofilms on equipment
  - Contaminated water
  - Contaminated brine
  - Cheese mites
- Chemical hazards
  - Allergen cross-contamination
  - Cross-contamination with cleaning and sanitizing chemicals
  - Contaminated water
- Physical hazards
  - Cheese harp and screen wires
  - Metal from equipment, knives
  - Plastic or metal from cheese molds
  - Cheese cloth pieces
  - Aging board splinters

Packaging

Packaging can be a risky operation when the finished cheese, a ready-to-eat (RTE) product, is exposed to the environment where it can be contaminated. Hazards in the packaging process are introduced into the cheese and include:

- Biological hazards
  - Pathogen contamination from improperly cleaned food-contact surfaces and utensils
  - Pathogen contamination from the environment
- Chemical hazards
  - Cross-contamination cleaning and sanitizing chemicals
- Physical hazards
  - Packaging materials
  - Pallet and aging board splinters

Environment

Environmental contamination can come from food-contact surfaces or from air in the cheese facility. Environmental monitoring programs are critical to ensuring a clean environment for cheesemaking and packaging. Environmental hazards include:

- Biological hazards
  - Pathogens living in the environment (particularly *Listeria monocytogenes*)
- Chemical hazards
  - Cleaning and sanitizing chemicals

Personnel

People can also contribute to hazards in cheesemaking by poor personal hygiene practices, improper clothing and shoes, and not being properly trained in food safety practices. Hazards associated with people include:

- Biological hazards
  - Pathogens
  - Viruses

The Hazard Analysis

The Hazard Analysis is the backbone of the Food Safety Plan. The more risk that a food product will cause illness or injury to the consumer, the more controls are needed to eliminate, reduce, and manage that risk. If hazards are identified in the Hazard Analysis as being likely to occur in the production of the food, Preventive Controls are used to manage the hazards and reduce the risk of someone getting injured or sick from consuming the food. This section addresses preparing for and conducting the Hazard Analysis.

The “Penn State Extension Food Safety Plan for Raw Milk Gouda Cheese Teaching Example” is the companion document to this section. This example contains the basic elements of a Food Safety Plan, including a flow chart and Hazard Analysis Summary that can be used to help you develop your own plan.

The Hazard Analysis Process: Step-by-Step

To help clarify the complete process of the Hazard Analysis, here's a step-by-step overview. More information and questions to help guide you through the steps are listed in the sections below.

1. Assemble the food safety team.
2. Write a product description.
3. Make a flow chart of the process.
4. Verify that the flow chart is correct by walking through of the process in your facility.
5. Write a description of the process (put the flow chart into words).
6. Conduct and document the Hazard Analysis.
    a. Identify the potential biological, chemical, and physical hazards for each step in the flow chart.
    b. Evaluate each hazard for the severity of the hazard and the likelihood it will occur.
7. Determine the Preventive Controls needed.
    a. Assess the risk of each hazard based on the severity and likelihood to occur to determine if a Preventive Control is needed.
    b. Determine the correct Preventive Control needed to manage the hazard (Process, Allergen, Sanitation, Supply-Chain).

Preliminary Steps for the Hazard Analysis

The preliminary steps to conducting the actual Hazard Analysis are listed as steps 1–5 above. These steps are not required by FSMA, but they are quite helpful with the Hazard Analysis and other parts the Food Safety Plan. Conducting a thorough Hazard Analysis without the flow chart is extremely difficult to do.

Assemble the Food Safety Team

Identify the team responsible for developing, implementing, and maintaining the Food Safety Plan. There is no set number of people that can be, or should be, on a food safety team. Larger companies can draw from different parts of the company—management, operations, quality, product development, maintenance, and marketing. Small-scale cheesemakers should try to develop a team with several people who bring different perspectives and can help share responsibilities. It is acceptable to go outside the company to find people to be on the team if needed.

Write a Product Description

A product description will help you gather your thoughts and prepare for the Hazard Analysis. It will help you identify if there are aspects of the cheese that are of concern or that can help you in other aspects of your Food Safety Plan.

Elements to include in the product description:

- Product name
- Description of the cheese
- Food safety characteristics
- Ingredients
- Packaging
- Intended use
- Labeling
- Shelf life
- Customers
- Distribution

Product Description Distribution, Consumers and Intended Use	
Product Name(s)	Pepper and Herb Raw Milk Gouda
Product Description, including Important Food Safety Characteristics	Semi-soft cheese made with unpasteurized cow milk and flavored with dried herbs and spices. Cheese is aged for a minimum of 6 months, with a final pH between 5.4 and 5.3, and final salt-in-moisture between 4.5 – 5.5%.
Ingredients	Unpasteurized milk, salt, black pepper, dried herbs, cultures, enzymes, calcium chloride
Packaging Used	Whole wheels are coated in polyvinyl acetate (PVA). Retail portions are vacuum-packaged in high density polypropylene bags, and labeled with adhesive labels.
Intended Use	Ready-to-eat product
Intended Consumers	Healthy individuals above the age of 3
Shelf Life	360 days at less than 41°F if uncut; 3-4 weeks refrigerated once cut
Labeling Instructions	Keep refrigerated. Code date. Allergen statement: Contains: milk.
Storage and Distribution	Refrigerated storage and distribution. Retail on-farm and farmers' markets in Pennsylvania. Wholesale to specialty stores and restaurants in the North East and mid-Atlantic region.
Approved: Signature: Print name: Ellie CeeCee	**Date**: 10/19/18

The description and food safety characteristics of the cheese can identify aspects such as the milk source (raw or pasteurized), texture (soft, semi-soft, hard), age, pH, addition of flavorings, and other things that may be important to identifying hazards in the cheese and the Preventive Controls needed.

The distribution section identifies where the cheese is distributed and sold and helps when writing a Recall Plan.

Questions to Ponder about the Product Description

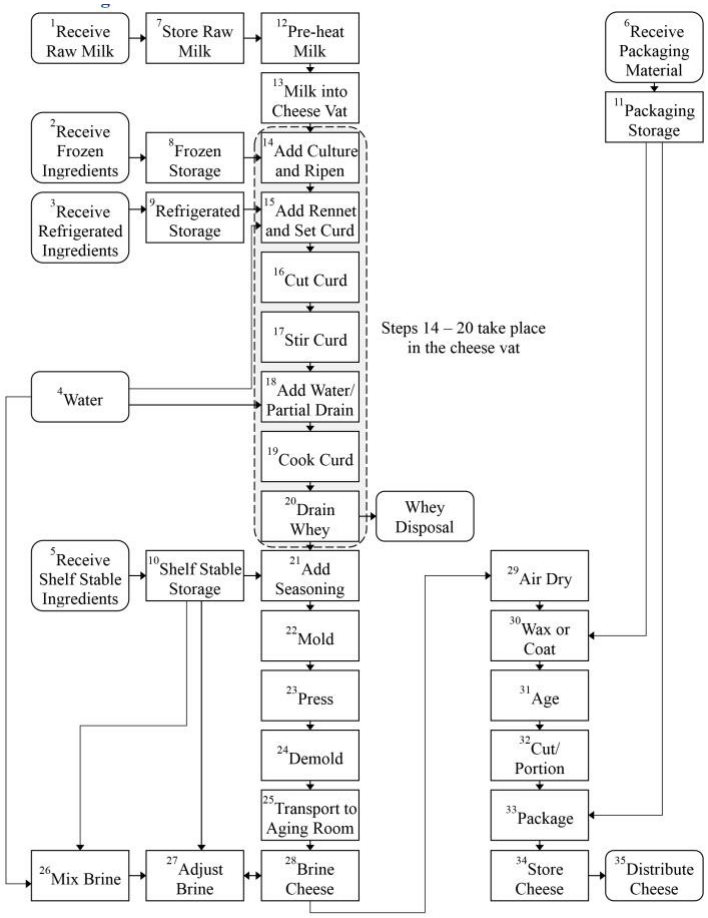
- Does this cheese have a standard of identity (see 21 CFR 133)?
- How old is the cheese at sale?
- What is the target pH at sale?
- Does the pH at the center of this cheese differ from the pH near the rind?
- What is the target moisture content of the cheese at sale?
- How much does the moisture content of the cheese vary from batch to batch?
- What is the salt, or salt-in-moisture, content?
- Does the salt, or salt-in-moisture, content vary from batch to batch?
- Will changes in the moisture and salt contents affect the safety of the cheese?
- Does this cheese have any added preservatives or cultures with antimicrobial activity?
- Will changes in cheese composition over time affect pathogen growth and survival?
- What hazards may result if the cheese composition is not controlled?
- Have foodborne illness outbreaks been associated with cheeses that are similar?
- How do you control temperature during distribution?

Make a Flow Chart of the Process

A flow chart is a diagram that identifies all the inputs, process steps, and outputs. It needs to be complete, but not overly complicated. Try to keep the terms in the boxes simple to make it easy to read. Fancy software is not needed, and there are no set shapes for the steps—a simple box is sufficient.

Making a complete flow chart may take several tries to capture everything that goes into and out of your process, in the correct order. Revise it as many times as needed to make sure it is correct and complete prior to starting the Hazard Analysis.

Numbering the boxes can make it easier to keep track of the steps throughout the Hazard Analysis.



Verify the Flow Chart

Verify that the flow chart is correct by doing a walk -through in your facility. Start at receiving raw milk and ingredients, and end when the product goes out for distribution.

Write a Description of the Process

This is a written narrative of the flow chart. It's another way to get you to think about the process and gives you an opportunity to go into more detail on steps than you can do in the flow chart.

The Hazard Analysis

The actual Hazard Analysis is the two-step process of identifying and evaluating hazards at each step in the process of a making a food, based on the flow chart. The results of the Hazard Analysis are documented on the Hazard Analysis Summary Form, which is also referred to as the *Hazard Analysis*, which can be confusing.

The specific contents of the Hazard Analysis are unique to each company for their products. The specific format of the written information is also not defined. However, there are example Hazard Analysis Summary Forms that are good templates and make the process easier. There are also many steps and hazards in common from cheese to cheese and company to company. Don't be afraid to copy information, but make sure to tailor it to your plant as appropriate. There are rarely absolute answers on how to manage a hazard, and some hazards can be handled in different ways—use what works for your company, as long as you are effective at controlling the hazard and documenting it. The important part is that you customize the information to match your product line, and can adequately justify your decisions and actions to a regulatory agent.

This is one example of a Hazard Analysis Summary Form:

Hazard Analysis Summary	Product:		Page X of Y
Plant Name		Issue Date	mm/dd/yy
Address		Supersedes	mm/dd/yy

(1) Ingredient/ processing step	(2) Identify *potential* food safety hazards* introduced, controlled or enhanced at this step		(3) Do any *potential* food safety hazards require a Preventive Control?		(4) Justify your decision for column 3	(5) What Preventive Control measure(s)** can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							

*B = biological, C = chemical, P = physical
**Process Controls include Critical Control Points, Allergen Controls, Sanitation Controls, and Supply-Chain Controls.

Hazard Identification

The Hazard Identification Process will fill in columns 1 and 2 in the example Summary Form above. Start by putting the ingredient/processing step from the first box on your flow chart into column 1. Using the same wording on the flow chart and in column 1 will help you keep track of everything.

Focus on one ingredient/processing step at time, considering only what is happening at this step, not before and not after. People have a tendency to carry over hazards from a previous step or onto the next step, which can make doing the hazard identification an unnecessary chore. For example, there is a potential food safety hazard of the *presence* of vegetative (alive) pathogens *in raw milk* at the raw milk *receiving* step, but this particular hazard is not carried through during storage of raw milk because it is addressed at receiving. Contamination by pathogens from unclean equipment or the environment is of concern at receiving and during storage and should be included in the Hazard Analysis at both steps.

Identify all potential hazards that might be associated with this step: biological (B), chemical (C), and physical (P). This includes hazards that are:

- Introduced, such as the presence of pathogens coming in with raw ingredients or contamination from improperly cleaned equipment
- Enhanced, such as the growth of pathogens during the cheesemaking process
- Controlled, such as killing pathogens with pasteurization or reducing potential pathogens during cheese aging

Feel free to add lines as needed. Keeping each hazard on a separate line will help with readability and organization later in the process. It is perfectly acceptable to have multiple lines for different biological (B), chemical (C), or physical (P) hazards in the same ingredient/processing step.

Try to be as complete as possible, but reasonable, when thinking about the potential hazards that might be associated with each step in the process. Use examples such as the "Penn State Extension Food Safety Plan for Raw Milk Gouda Cheese Teaching Example" and the "Wisconsin Food Safety Plan for Pepper Jack Cheese Teaching Example" to help you identify potential hazards.

Hazard Evaluation

The Hazard Evaluation will fill in columns 3 and 4 in the Summary Form example above. This is a science-based risk assessment of how severe the hazard is and how likely it is to occur. Hazards that are severe and likely to occur will need to be controlled to keep the cheese safe.

Determining the severity of the hazard can be done by knowing something about the particular hazard from books and classes, personal experience, knowledge of outbreaks in similar products, using example hazard guides and model Food Safety Plans, and from other resources.

Determining the likelihood of occurrence is something to assess by knowing your product, your process, the type of equipment and utensils you use, the cleaning and sanitizing practices you use, employee training, and about outbreaks in similar products.

The risk assessment and determination of the need for Preventive Controls is based on the Hazard Evaluation—that is, how likely the hazard is to occur and how severe it will be. Ask yourself, *Is this hazard severe and reasonably likely to occur given the state of my facility, operations, and product?* If the answer is yes, then it requires a Preventive Control. This gives you the "yes" or "no" answers for column 3.

You should fill in the justification that you used to make the "yes or no" decision in column 4. This decision should be backed by science, and not just because "this is how things have been done for the last 10 years with no problems" or a similar reason. Use the example hazard guides, model Food Safety Plans, trade organizations, scientific references, classes, university extension personnel, consultants, outbreaks in similar products, and other reputable sources as justification. Remember, you need to be able to justify your decisions to a regulatory agent.

Determine the Preventive Controls Needed

Once you have determined that a Preventive Control is needed to manage a hazard, you need to decide what type of control. This will fill out columns 5 and 6 in the Hazard Analysis Summary Form.

For the purpose of filling out the Hazard Analysis Summary Form, a short answer is best—a quick identification of the type of control and maybe a few words to help you identify what you need to do will keep the form readable. The types of Preventive Controls as defined in the introduction to FSMA section are:

- Process Controls
- Allergen Controls
- Sanitation Controls
- Supply-Chain Controls

The "Penn State Extension Food Safety Plan for Raw Milk Gouda Cheese Teaching Example" and other model Food Safety Plans can help determine what type of controls are needed for different hazards at different steps.

Sometimes a hazard can be effectively controlled through GMPs, employee training, or existing Prerequisite Programs. The decision about when something is a Preventive Control or Prerequisite Program can be confusing because there is no absolute way of doing things. The important part is to control the hazard to make a safe product, be able to verify that the control is effective, and make sure that the control is applied on a continual basis as specified in the control procedures.

When you determine what type of control is needed, you need to determine if it is applied to the step you are working on. All controls are not necessarily applied when they are identified. In the Raw Milk Gouda Cheese Teaching Example, at the raw milk receiving step:

- The presence of pathogens in raw milk might use a Supply-Chain Control to ensure the milk is free of pathogens at the "receiving raw milk" step. So, the answer in column 6 is "Yes," control is applied at this step.
- The presence of pathogens in raw milk might use pasteurization as a Process Control later in the cheesemaking. So, the answer in column 6 is "No," control is applied at a later step.
- Milk is an allergen that needs to be identified on the label. The allergen is a concern at raw milk receiving, but the label won't be applied until the cheese is packaged. So, the answer in column 6 is "No," control is applied at a later step.

Questions to Ponder When Conducting a Hazard Analysis

Raw Milk

- Where do you get your milk from?
- How is milk supplied or transported?
- Do the milk transfer containers have the potential to bring contamination into the processing facility?
- Is the outside of containers sanitized before milk is transferred?
- How is contamination of the milk prevented in the transfer process?
- Do you check and record the milk temperature upon arrival?
- What specifications do you have for the raw milk?
    - Do you reject milk if specifications are not met?
    - How do you ensure your suppliers are meeting these specifications?
- Do you collect documentation from your milk supplier?
- How do you monitor the microbiological safety of the raw milk?
- How is the raw milk stored before arriving at the cheesemaking facility?
- How old is the milk before reaching the cheesemaking facility?

Other Ingredients

- Do you receive a Certificate of Analysis (COA) for each batch of cultures?

- Do other ingredients (seasonings, flavorings) have the potential to be contaminated with pathogens?
- Do other ingredients (seasonings, flavorings) contain allergens?
- What specifications do you have for ingredients?
- Do you receive a COA for each batch of ingredients?
- Do you do any type of preparation of ingredients that may introduce or enhance hazards?
- Is the water used to wash curd and cheese and to make brine free from contaminants?

Receiving and Storage of Materials

- How is raw milk received and stored until cheesemaking?
- Do you have receiving and storage procedures for raw milk, ingredients, and packaging materials, including those that contain allergens?
- Are the temperatures of refrigerated and frozen ingredients checked and documented at receiving?

Cheesemaking

- Are all pieces of equipment cleaned and sanitized before use? Where is this documented?
- Are cleaning and sanitizing procedures written?
- Is the milk heated or pasteurized?
- What equipment is used to stir milk and add ingredients?
- How do you prevent equipment from contaminating milk?
- If a paddle is used to stir milk, where is it stored between stirs?
- Are parameters such as time, temperature, and pH measured and recorded regularly?
- Do you know what the target acidification profile for your cheese should be?
- What happens if the acidification schedule is off? Could it pose a hazard to the cheese?
- Are knives and cheese harps in good repair?
- Are knives and harps visually inspected regularly to determine if there is breakage and potential for metal in the cheese?
- Are molds filled with curds by hand?
- Is the press properly cleaned and sanitized before use?
- Does whey collect on the press? Does it encourage bacterial growth?
- What is done to ensure salt levels are consistent from batch to batch?
- How is brine made?
- How is brine maintained?
- If brine was found to be contaminated, would it be possible to track all cheeses that were exposed to the contaminated brine?
- How are cheeses transported to the ripening/aging rooms?
- Are cheeses exposed to outside or uncontrolled environments during transport?
- Are ripening procedures written and documented for each batch?
- Are cheeses handled or washed during ripening?
- What is used to wash or brush cheeses during ripening? Do these utensils or towels pose a food safety hazard? How are they cleaned and dried?
- Is the temperature and humidity of the aging rooms monitored regularly and documented?

- How are food-contact surfaces (shelved, tubs, mats) in the aging rooms cleaned and sanitized?
- Do you have a written sanitation and inspection program for cheese aging shelves, mats, and tubs?
- How often are wood board cleaned, sanitized, inspected, and replaced?

Packaging

- Are packaging materials free from contamination?
- Are you using any unique packaging materials (such as bark or straw) that could carry hazards with them? How are these materials treated before use to remove hazards?
- Are tamper-evident packaging features used?
- Are the food-contact surfaces used for packaging cleaned and sanitized before use? Is this documented?
- Is there an environmental monitoring program in place to prevent cross-contamination during packaging?

Writing Preventive Controls

Writing Preventive Control procedures; identifying what to monitor, how, when, and by whom; corrective actions; and record-keeping and validation procedures are beyond the scope of this document. Good resources for these activities can be found in the FSPCA *Preventive Controls for Human Food* book (2016), food safety courses, and example Food Safety Plans.

There are no set formats for writing these Preventive Controls, as long as the elements identified above are addressed. Verification of Preventive Controls is important to ensure the controls are working to manage the hazards. See the "Penn State Extension Food Safety Plan for Raw Milk Gouda Cheese Teaching Example" for examples of how to write different Preventive Controls.

Recall Plans

A Recall, or Crisis, Plan is required under FSMA when a hazard is identified in the product. Since raw milk is known to be associated with pathogens, all dairy processors should have a Recall Plan. Having a written plan in place, and testing it in a mock recall situation, can greatly reduce panic in the unfortunate event of needing to do a recall.

Writing Recall Plans are beyond the scope of this document. A good resource for Recall Plans is the FDA's website. The Industry Guidance for Recalls page (**https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm**) contains links to documents that describe how to do recalls and the necessary elements of a Recall Plan, a "Guidance for Industry: Product Recalls, Including Removals and Corrections" (**https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm**), and model press releases for common causes of recalls—all of which are helpful to have ready if needed.

Resources

American Cheese Society. *Best Practices Guide for Cheesemakers*. 2nd ed., 2017. Cheesesociety.org, 720-328-2788.

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Wisconsin Center for Dairy Research. "Food Safety Plan for Pepper Jack Cheese Teaching Example." 2016. www.cdr.wisc.edu.

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