



Small Michigan dairy plant owner regarding the Food Safety Modernization Act: "What do I have to do to be in compliance that is different than I am doing today?"

GOAL: To create a self-assessment tool for small to medium sized Michigan dairy processors to use while preparing to meet the new requirements under FSMA.





Introduction

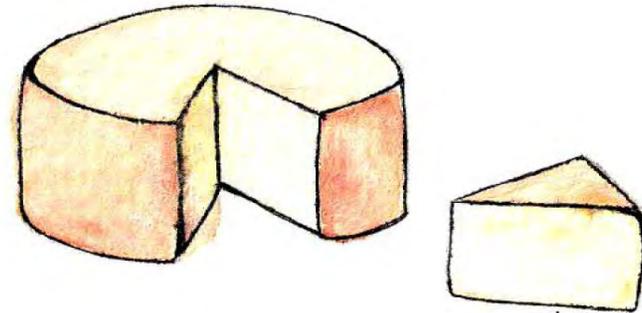
Welcome to the Food Safety Risk Self-Assessment Tool for Dairy Processing Plants. MDARD is pleased to introduce this tool to small and medium dairy plants in the state of Michigan. This tool was designed to help our state's artisan dairy facilities comply with the FSMA (Food Safety Modernization Act) rules and regulations. This tool enables the producer to assess the risks associated with dairy food production.

This is a comprehensive and proactive program for Michigan's dairy processing facilities to gain FSMA compliance. The practices described in this tool and the appendices are based on available technology and scientific research to promote sound food safety practices.

Processors who complete the assessment will be able to determine what management, structural, or equipment changes (if any) will be needed to comply with the FSMA rules.

How does the tool work?

- 1.) Select all relevant sections for your plant.
- 2.) Answer the risk questions by selecting the statement that best describes conditions in your plant.
- 3.) Indicate the risk level in the column to the right.
- 4.) After completing each section of the risk questions, list the practices that present a high risk. This will be your Plant Food Safety Improvement Action Plan.
- 5.) In your Plant Food Safety Improvement Action Plan, list:
 - Alternative practices, structures or equipment that are planned to implement or install that will help reduce risks to food safety.
 - Sources of technical and financial assistance.
 - Target dates for accomplishing the changes.



Disclaimer

The information provided by MDARD is for guidance purposes only. MDARD is not your attorney and cannot provide you with legal advice. The Food Safety Self-Assessment Tool for Dairy Processing Plants is intended as a device to assist companies in complying with FDA Food Safety Modernization Act (FSMA) preventive controls regulation, however, following this guide does not ensure compliance with the law or FDA's regulations.

MDARD does not guarantee the accuracy, adequacy, applicability, or completeness of any information provided in this tool and is not responsible for any errors or omissions or for any results obtained while using the tool.

General Questions

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
<u>1. Is your plant registered with FDA under Section 415 of the FD&C Act?</u>	Yes, my plant is registered and I renew the registration annually.	I registered a couple of years ago but haven't renewed annually.	My plant is not registered with FDA.		Register plant with the FDA. See Appendix A for the FDA registration/renewal form.
<u>2. Does your plant have a person designated to implement and oversee a food safety program?</u>	The designated food safety person has attended an FSPCA Participant Course or has equivalent experience.	We have a designated Food Safety person but they haven't attended the required course.	We do not have a designated Food Safety person for our facility.		Designate a food safety person for your dairy plant and document it in the Food Safety Plan. See Appendix B for how to sign up for the FSPCA Participant Course.
<u>3. Does your plant have a food safety program that is followed to reduce the risk of foodborne illness?</u>	A written food safety plan exists and is being implemented. We plan to review it at regular intervals.	Food safety practices are generally followed, but a written document needs to be developed.	A food safety plan is not available.		Create a Food Safety Plan for your dairy plant. See Appendix C for an explanation of how to get started creating a food safety plan.

Food Safety Plan

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
1. Have you defined the essential characteristics of your product?	I have described the product(s) produced in my plant in my Food Safety Plan.	Yes, but the written document needs to be developed.	I have not defined my product.		Define the product that you manufacture at your plant. See Appendix C for instructions on how to define your product.

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
<u>2. Have you identified hazards that are likely to occur in your plant?</u>	I have identified the hazards that might occur in my plant in my Food Safety Plan.	Yes, but the written document needs to be developed.	I have not identified the hazards that may occur in my plant.		Identify the hazards that might occur in your plant. See Appendix C for instructions on how to identify hazards.
<u>3. Have you identified the Process Preventive Controls (PPC) for these hazards?</u>	I have identified the process preventive controls for potential hazards in my Food Safety Plan.	Yes, but the written document needs to be developed.	I have not identified the process preventive controls in my plant.		Identify the Process Preventive Controls for the hazards in your plant. See Appendix C for instructions on how to identify process preventive controls.
4. Do you have a plan to mitigate the hazards - to significantly minimized or prevented them?	I have installed monitoring procedures and corrective actions for my process.	I have SOPs in place for everyday production but no corrective procedures.	I have no plans in place.		Install a plan to mitigate hazards in your plant. See Appendix C for instructions on how to identify critical control points and learn how to minimize and prevent them.
<u>5. Have you begun documenting Process Preventive Controls at each production run?</u>	I have validated, monitored, and verified my process.	I have a documented process but have not validated, monitored, or verified them.	I'm not sure what you mean by process controls.		Implement a plan to validate, monitor, and verify your process with recordkeeping. See Appendix C for an example and instructions.
<u>6. Have you identified food allergen controls?</u>	I have identified and implemented a food allergen control plan.	I have trained my employees on allergen control but have not documented a plan or the training.	I do not have an allergy control plan for my facility.		Implement and document the use of an Allergen Control Plan. See Appendix D for guidelines on how food processors plan for allergens.

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
<u>7. Have you identified sanitation controls?</u>	I have identified sanitation controls and documented SSOPs and employee training.	I have taught each of my employees to effectively clean and sanitize the equipment.	We tell the employees to clean and sanitize the equipment after each use. What is an SSOP?		Implement and document Standard Sanitary Operation Procedures (SSOP). When employees are trained, also document the training. See Appendix E for guidelines on sanitation controls.
<u>8. Have you documented a plan in the case of a recall?</u>	I have created a recall plan for my dairy plant.	I have the websites for information on what to do in case I have a recall.	My dairy inspector will know what to do if I have a recall. I have no recall plan.		Develop a Plant Recall Plan. See Appendix F for a model Recall Plan.
9. Do you conduct mock recalls?	I will conduct a mock recall at regular intervals and document the results.	We plan to conduct mock recalls but have no specific timeline.	We have no plans to conduct mock recalls.		Plan for a Mock Recall at regular intervals.
<u>10. Is your food safety plan re-evaluated every three years?</u>	I have a food safety plan that is evaluated every three years	I have a food safety plan but I don't recall the last time that it was evaluated.	I do not have a food safety plan.		Put in place a Food Safety Plan and evaluate it every three years.
<u>11. Has your plant implemented a Supply Chain Control Program?</u>	I have created a Supply Chain Control Program for my facility.	My facility has discussed quality issues with our suppliers.	We have never considered the supplies that we use.		Create and use a Supply Chain Verification Program. See Appendix I for an example Supply Chain Control plan.

Current Good Manufacturing Practices (CGMP)					
Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
1. Is there a policy in place concerning employee illness?	I have a policy concerning employee illness in the plant policy manual.	I have told my employees to stay home if they are sick.	My workers are dedicated and come to work even if they are sick.		Create an employee manual and include a policy concerning illness. See Appendix J for an Employee Health Plan
2. Is there a policy in place concerning employee hygiene?	I have a policy concerning employee hygiene in the plant policy manual. I provide uniforms and foot wear for my employees.	I have told my employees to clean up before they come to work. My employees appear to wear clean clothes from home.	I feel uncomfortable telling my employees that they need to wear clean clothes.		Create a management practice that includes the use of uniforms, smocks, aprons, or lab coats when working in the dairy plant.
3. Is there a program in place to educate employees in Current Good Manufacturing Practices (CGMPs)?	I use the FDA guidance documents to train and document training in Current Good Manufacturing Practices.	I have my employees look at the FDA guidance documents on CGMPs but I do not document their training.	I'm not sure what to use as a resource for CGMPs.		Train and document the training of employees in CGMPs. Use the FDA guidance documents at http://www.fda.gov/food/guidanceregulation/cgmp/
4. Is the building and surroundings kept in a condition that will protect against contamination?	The plant and its surroundings are kept neat and clean.	We work hard to keep the plant and surroundings neat but sometimes it gets away from us.	It too hard because the dairy is next door to the plant.		Keep the building and surroundings neat and clean to protect against contamination.
5. Is your plant constructed and designed for sanitary operations? Are airflow and plant traffic considered?	Our building was constructed with food manufacturing in mind.	Our building has been retrofitted with food safety in mind.	Our building is old and there's not much that we can do with it.		When designing new facilities or additions, design for food safety. When using older facilities, renovate with food safety in mind. See Appendix G for an example floor plan with traffic flow.

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
6. Is general plant maintenance current?	I stay up-to-date with general and preventative maintenance.	I fix equipment when it breaks.	Sometimes it's hard to keep up with routine repairs.		Stay up-to-date with general and preventive plant maintenance.
7. Are substances used for cleaning and sanitizing appropriate and properly stored?	I work directly with my chemical rep to choose chemicals specifically designed for dairy soils and pathogenic microorganisms.	I use food grade cleaners and sanitizers.	I use products from the local grocery store for cleaning and sanitizing.		Use cleaners and sanitizers specifically designed for cleaning dairy soils and killing pathogenic microorganisms. See Appendix E for a Model Sanitation Control Plan.
8. Is a pest control plan used?	I have a pest control company visit the plant routinely.	I set and routinely check my food safe rodent and insect control traps.	I don't have a rodent or insect plan.		Use routine pest control and document their use.
9. Are food contact surfaces cleaned and sanitized as frequently as necessary to protect against food contamination?	I clean and sanitize all food contact surfaces before, during (between product runs), and after production.	I sanitize my equipment just prior to production and clean and sanitize it after production.	I sometimes wait until the day after production to clean up but I always sanitize my equipment just prior to use.		Clean and sanitize food contact surfaces routinely and as frequently as practicable. See Appendix E for a Model Sanitation Control Plan
10. Are the sanitized utensils and equipment identified and stored properly?	I use a color-coded system of utensils for raw, pasteurized, allergenic product and non-product contact surfaces. I hang them to air dry when not in use.	I have a color coded system for my utensils for raw and pasteurized product.	I have one set of utensils that I use for everything but I sanitize them between uses.		Identify sanitized utensils and equipment and store them properly. See Appendix E for a Model Sanitation Control Plan

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
11. <u>Is the plant water adequate and sanitary?</u>	My inspector tests my water every 6 months. I have an approved well and proper water protection devices installed.	My inspector tests my water every 6 months but my well is old.	My inspector tests my water every 6 months but my water is hard and I have low water pressure.		Assure that your plant has a safe and adequate water supply.
12. Is the plumbing of adequate size and design?	My plumbing is of adequate size and design. Backflow prevention has been installed.	My plumbing suits my plant needs. I'm not sure whether backflow prevention is up to code.	My plumbing is old but OK.		When designing new facilities, make sure that the plumbing is of adequate size and design. When planning additions to older facilities, plan for adequate plumbing.
13. Are the toilet facilities adequate and readily accessible?	I have one toilet on the raw milk intake side of my plant and one toilet on the pasteurized side.	I have one toilet for all of the employees.	I have one toilet that isn't conveniently located.		Toilet facilities should be adequate and readily accessible. A sign should be posted for all employee to wash their hands.
14. Are hand-washing facilities adequate and readily accessible?	I have adequate hand-washing facilities in each area of the plant.	I have adequate hand-washing facilities but employees must cross over production areas to use it.	I have one hand - wash sink for my plant.		Provide hand washing-sinks for every area of production.
15. Is trash stored and removed to minimize the potential for it becoming a harborage for insects and rodents?	I remove the trash from the plant after every day. I wash and sanitize the can to eliminate any residue.	I remove the trash after each production day.	I remove the trash when it is full but I keep it covered when not in production.		Remove trash daily. Wash and sanitize cans.

Plant Food Safety Question	High Food Safety – 3 (recommended/ <u>required</u>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
16. Are the plant's equipment and utensils designed to be cleanable?	All the equipment and utensils in my plant meets the 3-A Sanitary Standards.	I have some older equipment and utensils but I clean them thoroughly. Some of my equipment meets the 3-A sanitary standards.	I have trouble cleaning some of the cracks and crevices in my equipment. What are 3-A sanitary standards?		Use 3A approved equipment and utensils designed for food or dairy use. See Appendix H for examples of sanitary design.
17. Are raw materials and other ingredients handled and stored under conditions that will protect against contamination?	I have a separate storage area for ingredients and packaging. The room is clean and dry. Opened containers are re-sealed tightly when opened.	I have a separate storage area for ingredients and packaging but sometimes I forget to re-seal containers and the room is cleaned but not routinely.	I have storage for ingredients and packaging but I have to walk in and out of the plant to get the items that I need. The items are stored together.		Store all raw materials, ingredients, and packaging in conditions that will protect against contamination.
18. Is the storage and transportation of finished food conducted under sanitary conditions?	My finished product cooler is monitored for temperature daily and we deliver our product in a refrigerated truck.	My finished product refrigerator is monitored for temperature and I use ice when delivering product.	My finished product cooler has thermometer but is rarely checked. I store other products than my finished products in the cooler.		Store and transport finished product in a safe and sanitary manner.
19. Are there position descriptions for employees?	Each of the tasks has a job description. Each employee has his/her own set of job descriptions so that they understand what is expected of them.	I have written down the steps that need to be followed for each phase of production but they have not been assigned to employees.	My employees do it all. They are a "Jack of all trades".		Write a job description for each facet of production. Assign each employee the jobs, along with the description.

Plant Food Safety Question	High Food Safety – 3 (recommended/ <i>required</i>)	Medium Food Safety – 2	Low Food Safety -1	Food Safety Risk Score	Plan of Action
20. Does your facility have a mission statement?	My facility has a mission statement. It is posted in the lunch area.	My facility has a mission statement in the employee handbook.	My employees know that the mission is to produce a quality product but it's not posted anywhere.		Create a mission statement that describes the aims and values of the organization. Post it somewhere that all the employees will see it.
21. Do you have an environmental sampling program in place?	I have an environmental sampling program in place for pathogenic organisms.	I have sampled in the past.	I have never environmentally sampled our plant.		Institute an Environmental Sampling Program. See Appendix K for instructions on environmental sampling.



Appendices

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FSMA Compliance Deadlines

Find your facility with the definitions below to determine when you will need to be in compliance with FSMA.

- **Is your facility a “Small Business”?** - You have fewer than 500 full-time equivalent employees and average more than \$1 million/year in annual sales of human food manufactured, processed, or packed. Your deadline: 8-30-17*
- **Is your facility a “Very Small Business”?** - You have fewer than 500 full time equivalent employees and average less than \$1 million/year in annual sales of human food manufactured, processed, or packed. Your deadline: 8-30-18**

*If your plant is a Grade A facility (subject to the Pasteurized Milk Ordinance) the compliance dates have been extended to allow time for changes to the PMO. Your deadline has changed to 8-30-18.

**If your plant is a “Very Small Business” it may be considered a “Qualified Facility”. A business that meets the definition of a “Qualified Facility” will be subject to modified requirements. Facilities that qualify for modified requirements are still required to complete the following: facility registration (Appendix A), preventive controls (Appendix C), recordkeeping, good manufacturing practices (as outlined in the Food Safety Risk Self-Assessment), and training.

If you are a “Very Small Business”, and you think that you may be a “Qualified Facility”, these modified requirements can be met by submitting a form to FDA. The draft guidance, “Qualified Facility Attestation Using Form FDA 3942a (for Human Food)” explains how to determine whether your business meets the definition of “Qualified Facility” and how to submit the FDA form attesting to its status as a “Qualified Facility”. (Human food facilities are required to submit their first attestation to FDA by December 17, 2018.)

Quick Reference

Appendix A - Registering with FDA

Appendix B - Becoming FSPCA Certified

Appendix C - Hazard Analysis and Process Controls

Appendix D - Allergen Plan

Appendix E - Sanitation Control Plan

Appendix F - Recall Plan

Appendix G - Plant Floor Plan

Appendix H - Sanitary Equipment Review

Appendix I - Supplier Verification

Appendix J - Employee Health

Appendix K - Environmental Sampling

Appendix L - References



Open Letter to Michigan Dairy Product Manufacturers,

Hello. We are Bess and Ted Crocker. We are the owners of Calico Creamery - - - makers of Cheese and other good things to eat. We are located in beautiful Northern Michigan. Please join us on our journey to create a food safety plan for our business.

As you are aware by now, the first risk-based objective was to register our plant with FDA on the Food Facility Registration Form. There are two ways that you can accomplish this:

1). Register on-line by going to this link ---

Go to:

<http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm088860.htm> (to register)

2). Fill out the form and mail it to FDA.

Regardless of how you accomplish the task, we have attached the FDA form so that you can see how we did it. It took approximately 30 minutes to complete this form. We have also left a blank copy for you to fill out.

Please remember that your registration needs to be updated annually, even if it is just to let them know that there has been no changes. Here is a handy reference for the update link ---

Go to:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm084379.htm> (to update)

Good luck to all of our fellow dairy processors!

Bess and Ted Crocker

Owners

Calico Creamery

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration DHHS/FDA FOOD FACILITY REGISTRATION (If entering by hand, use blue or black ink only.)	FDA USE ONLY
Date (mm/dd/yyyy) 02/14/2017	

Section 1 – TYPE OF REGISTRATION

1a.	<input type="checkbox"/> DOMESTIC REGISTRATION	<input type="checkbox"/> FOREIGN REGISTRATION
1b.	<input checked="" type="checkbox"/> INITIAL REGISTRATION	<input type="checkbox"/> UPDATE OF REGISTRATION INFORMATION
1c.	<input type="checkbox"/> BIENNIAL REGISTRATION RENEWAL	
If update or biennial registration renewal, provide the Facility Registration Number and PIN <i>FDA will mail this number and pin to you when they've received your completed form.</i>		Facility Registration Number PIN
For update of registration information: Check all that apply and further identify changes in the applicable sections		
<input type="checkbox"/>	Facility Name Change	<input type="checkbox"/> United States Agent Change - Foreign facilities only
<input type="checkbox"/>	Facility Address Change (See instructions)	<input type="checkbox"/> Seasonal Facility Dates of Operation Change
<input type="checkbox"/>	Preferred Mailing Address Change	<input type="checkbox"/> Type of Activity Change
<input type="checkbox"/>	Parent Company Change	<input type="checkbox"/> Type of Storage Change
<input type="checkbox"/>	Emergency Contact Change	<input type="checkbox"/> Human Food Product Category Change
<input type="checkbox"/>	Trade Name Change	<input type="checkbox"/> Animal Food Product Category Change
<input type="checkbox"/>		<input type="checkbox"/> Operator or Agent in Charge Change

1d. ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? Yes No
 If "Yes," provide the following information, if known.

Previous owner's name	Previous owner's registration number
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Section 2 – FACILITY NAME/ADDRESS INFORMATION

Facility Name
Calico Creamery, Inc.

Facility Street Address, Line 1
1066 Barnstormer Lane

Facility Street Address, Line 2

City Boon Town	State (If applicable; if not, skip to Province/Territory) Michigan
Province/Territory (If applicable) —	ZIP or Postal Code 49618
Country USA	Phone Number (Include Area/Country Code) 496-184-9618
FAX Number (Optional; Include Area/Country Code) 46-184-9619	E-Mail Address calicocreamery.com

DHHS/FDA FOOD FACILITY REGISTRATION

Section 3 – PREFERRED MAILING ADDRESS INFORMATION

- Complete this section only if different from Section 2 Facility Name/Address Information (OPTIONAL)

Name

Street Address, Line 1

Street Address, Line 2

NOTE: Our home address is the same as our plant address - we don't need to fill this section out.

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

Section 4 – PARENT COMPANY NAME/ADDRESS INFORMATION

(If applicable and if different from Sections 2 and 3)

If information is the same as another section, check which section: Section 2 Section 3

Name of Parent Company

Street Address

NOTE: We don't have a parent company. We won't fill out this section either.

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

Section 5 – FACILITY EMERGENCY CONTACT INFORMATION

Optional for foreign facilities; FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

Individual Name (Optional)

Bess or Ted Crocker

Title (Optional)

Owners

E-Mail Address (Optional)

calicocreamery.com

Emergency Contact Phone Number (Include Area/Country Code)

496-184-9618

DHHS/FDA FOOD FACILITY REGISTRATION

Section 6 – TRADE NAMES - If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as").

Alternative Trade Name #1

NOTE; Calico Creamery is the only name that we manufacture cheese under. This is another section that we will leave blank.

Alternative Trade Name #2

Alternative Trade Name #3

Alternative Trade Name #4

Section 7 – UNITED STATES AGENT - To be completed by facilities located outside any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico

Name of U.S. Agent

Title (Optional)

NOTE: Not applicable to Calico Creamery.

Address, Line 1

Address, Line 2

City	State	ZIP Code
U.S. Agent Phone Number (Include Area Code)		Emergency Contact Phone Number (Include Area Code)
FAX Number (Optional; Include Area Code)		E-Mail Address

Section 8 – SEASONAL FACILITY DATES OF OPERATION (OPTIONAL)

Optional - Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis.

Dates of Operation (Optional; mm/dd/yyyy)

NOTE: Calico Creamery doesn't have a seasonal dry-off for the cows--- We'll leave this one blank too.

Section 9 – TYPE OF STORAGE (for facilities that are primarily holders) (OPTIONAL)

Ambient Storage (neither frozen nor refrigerated)

Refrigerated Storage

Frozen Storage

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION; and
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

<p>To be completed by all food facilities. Please see instructions for further examples.</p> <p>IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.</p>		<p align="center">TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.</p>									
		Warehouse/ Holding Facility <i>(e.g., storage facilities, including storage tanks, grain elevators)</i>	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator <i>(Recondi- tioner)</i>
<input type="checkbox"/>	1. ACIDIFIED FOODS (AF) [21 CFR 114.3(b)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	8. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	a. Soft, Ripened Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	b. Semi-Soft Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	c. Hard Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	d. Other Cheeses and Cheese Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	9. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	10. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	11. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	12. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	13. DIETARY SUPPLEMENT CATEGORIES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	b. Vitamins and Minerals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	c. Animal By-Products and Extracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	d. Herbals and Botanicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	14. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and
GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.									
		Warehouse/ Holding Facility <i>(e.g., storage facilities, including storage tanks, grain elevators)</i>	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator <i>(Recondi- tioner)</i>
<input type="checkbox"/>	15. FISHERY/SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fin Fish, Whole or Filet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Shellfish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Ready to Eat (RTE) Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	d. Processed and Other Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh Cut Produce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Agricultural Commodities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other Fruit and Fruit Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	21. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. LOW ACID CANNED FOOD (LACF) PRODUCTS [21 CFR 113.3(n)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY
and GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.									
		Warehouse/ Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator (Recondi- tioner)
<input type="checkbox"/>	27. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	28. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Nut and Nut Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Edible Seed and Edible Seed Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	29. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	30. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Chicken Egg and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Other Eggs and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	31. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	32. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	33. SOUPS [21 CFR 170.3 (n) (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	34. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	35. VEGETABLE AND VEGETABLE PRODUCT CATEGORIES [21 CFR 170.3 (n) (19), (36)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh Cut Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Agricultural Commodities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other Vegetable and Vegetable Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	36. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	37. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	38. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	39. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10b – GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION; and
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.							
		Animal Food Manufacturer/ Processor	Warehouse/Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/Low Acid Food Processor	Contract Sterilizer	Packer/ Repacker	Labeler/ Relabeler	Salvage Operator (Reconditioner)	Other Activity Conducted
<input type="checkbox"/>	1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. AMINO ACIDS OR RELATED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. ANIMAL-DERIVED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. BREWER PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. CHEMICAL PRESERVATIVES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	8. CITRUS PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	9. DISTILLERY PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	10. ENZYMES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	11. FATS OR OILS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	12. FERMENTATION PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	13. MARINE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	14. MILK PRODUCTS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	15. MINERALS OR MINERAL PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. MOLASSES OR MOLASSES PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. NON-PROTEIN NITROGEN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. PEANUT PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. RECYCLED ANIMAL WASTE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: Calico Creamery uses the whey from cheese production as fertilizer. We agronomically spread it on our fields. If we sold it as animal feed, we would need to check these two boxes.

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10b – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and
GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION (cont.)**

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.							
		Animal Food Manufacturer/Processor	Warehouse/Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/Low Acid Food Processor	Contract Sterilizer	Packer/Repacker	Labeler/Relabeler	Salvage Operator (Reconditioner)	Other Activity Conducted
<input type="checkbox"/>	21. SCREENINGS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. VITAMINS OR VITAMIN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. YEAST PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MIXED FEED (E.G., POULTRY, LIVESTOCK, EQUINE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. PET FOOD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. PET TREATS OR PET CHEWS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	27. PET NUTRITIONAL SUPPLEMENTS (E.G., VITAMINS, MINERALS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	28. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 11 – OWNER, OPERATOR, OR AGENT-IN-CHARGE INFORMATION

Name of Entity or Individual Who Is the Owner, Operator, or Agent-in-Charge

Provide the following information, if different from all other sections on the form. If the information is the same as another section of the form, check which section.

Section 2 Section 3 Section 4 Section 7

Street Address, Line 1

Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

DHHS/FDA FOOD FACILITY REGISTRATION

Section 12 – INSPECTION STATEMENT

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 13 – CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature of Submitter

Bess Crocker

Printed Name of Submitter

Bess Crocker

Check One Box

- A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)
 B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN BELOW)

If you checked Box B above, indicate who authorized you to submit the registration.

- OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)
 _____ NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)

Address Information for the Authorizing Individual

Authorizing Individual Street Address, Line 1

Authorizing Individual Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

MAIL COMPLETED FORM FDA 3537 TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5100 PAINT BRANCH PARKWAY, COLLEGE PARK, MD 20993, OR FAX IT TO 301-436-2804

FDA USE ONLY

Date Registration Form Received	Date Notification Sent to Facility
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OMB Paperwork Reduction Act Statement

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS.

The burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DHHS/FDA FOOD FACILITY REGISTRATION
(If entering by hand, use blue or black ink only.)

FDA USE ONLY

Date (mm/dd/yyyy)

Section 1 – TYPE OF REGISTRATION

1a.	<input type="checkbox"/> DOMESTIC REGISTRATION	<input type="checkbox"/> FOREIGN REGISTRATION
1b.	<input type="checkbox"/> INITIAL REGISTRATION	<input type="checkbox"/> UPDATE OF REGISTRATION INFORMATION
1c.	<input type="checkbox"/> BIENNIAL REGISTRATION RENEWAL	

	If update or biennial registration renewal, provide the Facility Registration Number and PIN	Facility Registration Number	PIN

For update of registration information: Check all that apply and further identify changes in the applicable sections		<input type="checkbox"/> United States Agent Change - Foreign facilities only
<input type="checkbox"/> Facility Name Change		<input type="checkbox"/> Seasonal Facility Dates of Operation Change
<input type="checkbox"/> Facility Address Change (See instructions)		<input type="checkbox"/> Type of Activity Change
<input type="checkbox"/> Preferred Mailing Address Change		<input type="checkbox"/> Type of Storage Change
<input type="checkbox"/> Parent Company Change		<input type="checkbox"/> Human Food Product Category Change
<input type="checkbox"/> Emergency Contact Change		<input type="checkbox"/> Animal Food Product Category Change
<input type="checkbox"/> Trade Name Change		<input type="checkbox"/> Operator or Agent in Charge Change

1d.	ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," provide the following information, if known.
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Previous owner's name	Previous owner's registration number
-----------------------	--------------------------------------

Section 2 – FACILITY NAME/ADDRESS INFORMATION

Facility Name

Facility Street Address, Line 1

Facility Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address

DHHS/FDA FOOD FACILITY REGISTRATION

Section 3 – PREFERRED MAILING ADDRESS INFORMATION

- Complete this section only if different from Section 2 Facility Name/Address Information **(OPTIONAL)**

Name

Street Address, Line 1

Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

Section 4 – PARENT COMPANY NAME/ADDRESS INFORMATION

(If applicable and if different from Sections 2 and 3)

If information is the same as another section, check which section: Section 2 Section 3

Name of Parent Company

Street Address

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

Section 5 – FACILITY EMERGENCY CONTACT INFORMATION

Optional for foreign facilities; FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

Individual Name (Optional)

Title (Optional)

E-Mail Address (Optional)	Emergency Contact Phone Number (Include Area/Country Code)
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DHHS/FDA FOOD FACILITY REGISTRATION

Section 6 – TRADE NAMES - If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as").

Alternative Trade Name #1

Alternative Trade Name #2

Alternative Trade Name #3

Alternative Trade Name #4

Section 7 – UNITED STATES AGENT - To be completed by facilities located outside any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico

Name of U.S. Agent

Title (Optional)

Address, Line 1

Address, Line 2

City	State	ZIP Code
U.S. Agent Phone Number (Include Area Code)		Emergency Contact Phone Number (Include Area Code)
FAX Number (Optional; Include Area Code)		E-Mail Address

Section 8 – SEASONAL FACILITY DATES OF OPERATION (OPTIONAL)

Optional - Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis.

Dates of Operation (Optional; mm/dd/yyyy)

Section 9 – TYPE OF STORAGE (for facilities that are primarily holders) (OPTIONAL)

- Ambient Storage (neither frozen nor refrigerated) Refrigerated Storage Frozen Storage

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION; and
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

<p>To be completed by all food facilities. Please see instructions for further examples.</p> <p>IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.</p>		<p align="center">TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.</p>									
		Warehouse/ Holding Facility <i>(e.g., storage facilities, including storage tanks, grain elevators)</i>	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator <i>(Recondi- tioner)</i>
<input type="checkbox"/>	1. ACIDIFIED FOODS (AF) [21 CFR 114.3(b)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	8. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Soft, Ripened Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Semi-Soft Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Hard Cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	d. Other Cheeses and Cheese Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	9. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	10. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	11. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	12. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	13. DIETARY SUPPLEMENT CATEGORIES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Vitamins and Minerals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Animal By-Products and Extracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	d. Herbals and Botanicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	14. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and
GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.									
		Warehouse/ Holding Facility <i>(e.g., storage facilities, including storage tanks, grain elevators)</i>	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator <i>(Recondi- tioner)</i>
<input type="checkbox"/>	15. FISHERY/SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fin Fish, Whole or Filet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Shellfish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Ready to Eat (RTE) Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	d. Processed and Other Fishery Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh Cut Produce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Agricultural Commodities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other Fruit and Fruit Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	21. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. LOW ACID CANNED FOOD (LACF) PRODUCTS [21 CFR 113.3(n)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10a – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY
and GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (cont.)**

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 39.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.									
		Warehouse/ Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/ Low Acid Food Processor	Interstate Conveyance Caterer/ Catering Point	Molluscan Shellfish Establish- ment	Com- mis- sary	Contract Sterilizer	Labeler/ Relabeler	Manufacturer/ Processor	Repacker/ Packer	Salvage Operator (Recondi- tioner)
<input type="checkbox"/>	27. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	28. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Nut and Nut Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Edible Seed and Edible Seed Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	29. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	30. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Chicken Egg and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Other Eggs and Egg Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	31. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	32. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	33. SOUPS [21 CFR 170.3 (n) (39), (40)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	34. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	35. VEGETABLE AND VEGETABLE PRODUCT CATEGORIES [21 CFR 170.3 (n) (19), (36)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	a. Fresh Cut Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	b. Raw Agricultural Commodities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	c. Other Vegetable and Vegetable Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	36. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	37. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	38. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	39. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10b – GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION; and
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (OPTIONAL)**

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.							
		Animal Food Manufacturer/ Processor	Warehouse/Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/Low Acid Food Processor	Contract Sterilizer	Packer/ Repacker	Labeler/ Relabeler	Salvage Operator (Reconditioner)	Other Activity Conducted
<input type="checkbox"/>	1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	4. AMINO ACIDS OR RELATED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	5. ANIMAL-DERIVED PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	6. BREWER PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	7. CHEMICAL PRESERVATIVES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	8. CITRUS PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	9. DISTILLERY PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	10. ENZYMES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	11. FATS OR OILS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	12. FERMENTATION PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	13. MARINE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	14. MILK PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	15. MINERALS OR MINERAL PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	16. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	17. MOLASSES OR MOLASSES PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	18. NON-PROTEIN NITROGEN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	19. PEANUT PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	20. RECYCLED ANIMAL WASTE PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DHHS/FDA FOOD FACILITY REGISTRATION

**Section 10b – TYPE OF ACTIVITY CONDUCTED AT THE FACILITY and
GENERAL PRODUCT CATEGORIES - FOOD FOR ANIMAL CONSUMPTION (cont.)**

To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28.		TYPE OF ACTIVITY CONDUCTED AT THE FACILITY Optional - Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.							
		Animal Food Manufacturer/Processor	Warehouse/Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Acidified/Low Acid Food Processor	Contract Sterilizer	Packer/Repacker	Labeler/Relabeler	Salvage Operator (Reconditioner)	Other Activity Conducted
<input type="checkbox"/>	21. SCREENINGS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	22. VITAMINS OR VITAMIN PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	23. YEAST PRODUCTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	24. MIXED FEED (E.G., POULTRY, LIVESTOCK, EQUINE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	25. PET FOOD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	26. PET TREATS OR PET CHEWS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	27. PET NUTRITIONAL SUPPLEMENTS (E.G., VITAMINS, MINERALS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	28. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 11 – OWNER, OPERATOR, OR AGENT-IN-CHARGE INFORMATION

Name of Entity or Individual Who Is the Owner, Operator, or Agent-in-Charge

Provide the following information, if different from all other sections on the form. If the information is the same as another section of the form, check which section.

Section 2
 Section 3
 Section 4
 Section 7

Street Address, Line 1

Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

DHHS/FDA FOOD FACILITY REGISTRATION

Section 12 – INSPECTION STATEMENT

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 13 – CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature of Submitter

Printed Name of Submitter

Check One Box

- A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)
- B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN BELOW)

If you checked Box B above, indicate who authorized you to submit the registration.

- OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)
- _____ NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)

Address Information for the Authorizing Individual

Authorizing Individual Street Address, Line 1

Authorizing Individual Street Address, Line 2

City	State (If applicable; if not, skip to Province/Territory)
Province/Territory (If applicable)	ZIP or Postal Code
Country	Phone Number (Include Area/Country Code)
FAX Number (Optional; Include Area/Country Code)	E-Mail Address (Optional)

MAIL COMPLETED FORM FDA 3537 TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5100 PAINT BRANCH PARKWAY, COLLEGE PARK, MD 20993, OR FAX IT TO 301-436-2804

FDA USE ONLY

Date Registration Form Received

Date Notification Sent to Facility

OMB Paperwork Reduction Act Statement

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS.

The burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Appendix B -Becoming FSPCA Certified

When Calico Creamery decided to designate a person to oversee the food safety program, we became aware that the FSPCA (Food Safety Preventive Controls Alliance) offers a course. A certificate from this course is required for the designated food safety person. The FSPCA course is entitled: Preventive Controls for Human Food. It lasts 3 days.

According to FSPCA, the concepts covered in the course include:

- The basics of the Food Safety Plan using preventive controls
- Good Manufacturing Practices and Other Prerequisite Programs
- Biological, Chemical, Physical & Economically Motivated Food Safety Hazards
- Hazard Analysis Determination
- Process, Allergen, Sanitation, and Supply-chain Preventive Controls
- Verification and Validation Procedures
- Record-keeping Procedures
- Recall plan
- Resources for Preparing Food Safety Plans





At Calico Creamery, we went on-line to find an FSPCA course. Here are a few examples:



MDARD in coordination with The Right Place offers courses throughout the year. To find out about these courses follow this link: <https://www.rightplace.org/events/fspca-preventative-controls-for-human-food-training-course> \$200 per person, includes course materials and meals.



FSPCA - PREVENTIVE CONTROLS FOR HUMAN FOOD -\$795.00

755 W. Big Beaver Rd., Suite 1390, Troy, MI 48084 1-877-663-1160.



FSPCA Preventive Controls for Human Food Course

Location: Michigan State University Dairy Complex Room 1125 474 S Shaw Ln East Lansing MI 48824 Cost \$600.00

Contact: ANR Event Services at 517-353-3175

orevents@anr.msu.edu



The Food Institute will hold a two-day course developed by the Food Safety Preventive Controls Alliance (FSPCA) WeiserMazars Offices, 399 Thornall Street, Edison, NJ (Their offices are located on the third floor)

Seminar - \$1195.00

FYI – some plants choose to use consultants to be their designated food safety person.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

**Appendix C - A MODEL HAZARD ANALYSIS AND PROCESS CONTROLS
FOR A SMALL-SCALE DAIRY PLANT**

The purpose of this document is to modify the basic, generic food safety model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific product strategy for our individual plant, the food safety plan can be more effective.

NOTE: This information, provided by MDARD, is for guidance purposes only. MDARD does not guarantee the accuracy, adequacy, applicability, or completeness of any information provided in this tool and is not responsible for any errors or omissions.



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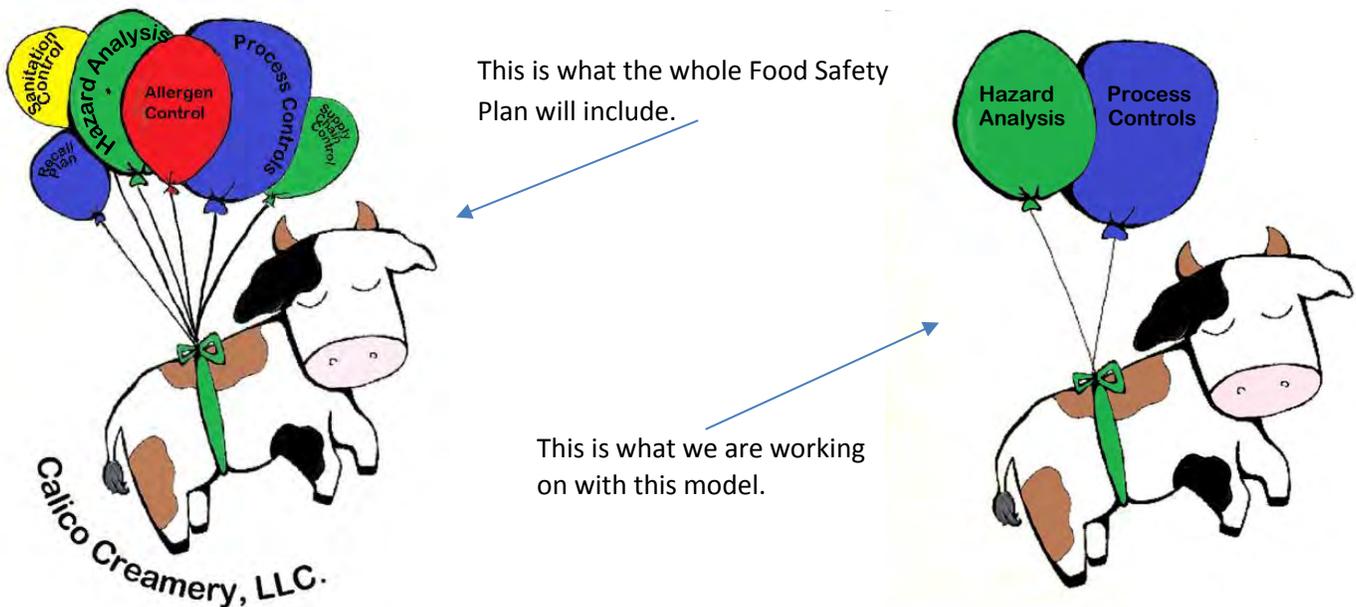
1. Introduction:

The Calico Creamery is a small-scale dairy plant in Northern Michigan. We have 8 full-time and 3 part-time employees. We also have a Grade A dairy farm that has been in our family for 3 generations. Because of a multigenerational interest in the farm, our family decided to create a value-added product from the milk production. 8 years ago, when Calico Creamery began making cheese, we never dreamed that it would be such a success. Now the creamery needs to expand to include the manufacture of other dairy products.

The creamery is an old building which was restructured when the cheese making equipment was installed. Now that expansion is underway, we would like to include an effective Hazard Analysis and Preventive Process Control system to ensure safe and superior products. This is just the beginning of our food safety plan. We will take on the task of creating an Allergen Safety Plan, a Sanitation Control Plan, Supply Chain Program, and a Recall Plan in other documents.

Figure 1.1: Food Safety Plan

Here's another way to look at it: The Food Safety Plan for Calico Creamery will eventually become our logo. This specific plan will help us identify the hazards and process controls inherent in our specific manufacturing process.





The way we got started was to create a product and process description of the cheese that we make at Calico Creamery.

2. Product description:

This part of the model document is the description and characteristics of our product. This information will be used to define the preventive controls during manufacturing. It will also be useful information for the consumers.

Table 2.1: Describing our Product

WHO are you?	Calico Creamery, LLC.
WHAT is the name of your product; what are the important product characteristics (moisture, pH, salt, preservatives...)?	Calico Cheddar Cheese; Hard cheese Moisture%:30-39% Milkfat content: 50-55% pH: 5.2-5.4 Salt: 1.56 -1.8% Using only pasteurized milk in production
WHERE will your product be sold?	On-farm kiosk and retail stores
WHEN it is to be used - Shelf life?	Ready to eat. Shelf life is 3 months to two years prior to packaging/one month from the packaging date under refrigeration
WHY have controls during distribution?	Refrigerated shipping to retail outlets to maintain cool temperatures
HOW is it going to be packaged; labeling instructions?	Vacuum seal; keep refrigerated, allergen (milk)

3. Process description:

This is one of the most difficult but important steps in developing an effective food safety plan. Describing our process at Calico Creamery will be the basis of identifying Hazards and Process Controls. The procedure to make cheddar cheese at Calico Creamery is as follows:

1. Raw milk storage - Raw milk is stored in a refrigerated bulk tank (on the farm) until being needed in the plant. It can only be held in the tank for 72 hours.
2. Raw milk receiving – We receive raw milk from our own farm on production days. It is pumped over to the plant through a sanitary stainless steel pipeline.
3. Pasteurization - our cheese is produced from milk that has been pasteurized. At Calico Creamery, we vat pasteurize at 145 °F for 30 minutes.
4. Filling – After pasteurization, the milk is cooled to 90 °F and the cheese vats are filled at that temperature.
5. Culturing – The starters for our cheddar are commercially prepared, freeze dried mesophilic, homo-fermentative cultures of Lacto coccus lactis subsp. Lactis and cremoris. They are added when the milk has cooled to 86 °F and we allow the cheese milk to ripen for 30-60 min depending upon the type of starter that we add.



6. Protein coagulation - During cheese production, commercially sourced rennet is stirred into the milk. We do not stir for more than 5 minutes. The cheese milk will then turn into a solid curd. We strictly regulate the temperature of milk at 85-87 °F for approximately 1 hour.
7. Cutting – Curd is cut at the appropriate time using wire cheese knives (harp). At Calico Creamery, we determine the appropriate time by using the “clean break” method.
8. Cooking, stirring & draining- After cutting, the curd is gently stirred in the whey, and the temperature is raised from 86 to 100.5°F over a period of 45-60 min. The whey is drained to a storage tank when the pH of the curd is 6.0.
9. Cheddaring - The curds are piled along the sides of the vat for 15 minutes following complete whey removal. A curd shovel is used to form two trenched curd columns. These two piles are then cut at intervals of approximately 10 inches. The curd blocks are spaced at about 1 inch apart. We allow these blocks to rest for 15 minutes, and then turn them over. This is repeated twice at 15 minute intervals. It is important to collect loose curds and distribute under the formed blocks. Individual blocks are stacked two to a pile and turned over every 15 minutes so that new surfaces are exposed.
10. Milling –Milling is done using a mechanical curd milling machine when a pH 5.2-5.4 is reached as measured in the draining whey.
11. Salting – Our cheddar cheese is salted with non-iodized dry salt. 1.5-2.0% salt is spread manually over the milled curd.
12. Filling molds - The salted cheese is scooped into the molds.
13. Pressing - Calico Creamery cheese is pressed overnight with low pressure initially and then gradually increasing the pressure to 11psi.
14. Ripening - The wheels of cheese are moved to the “cave”. Our cheddar is ripened at 40-45°F and 85% humidity for 3-24 months. It is rotated and flipped periodically.
15. Cutting and Packaging -The cheese is cut and vacuum sealed. The packages are sent through a metal detection tunnel. Immediately after packaging, the retail stock is stored in the finished product cooler (33 - 40 °F).
16. Metal detection- All finished packages are passed through a metal detection tunnel with an indicator light and buzzer for notification of metal.

4. Process Flow Diagram that includes ingredients:

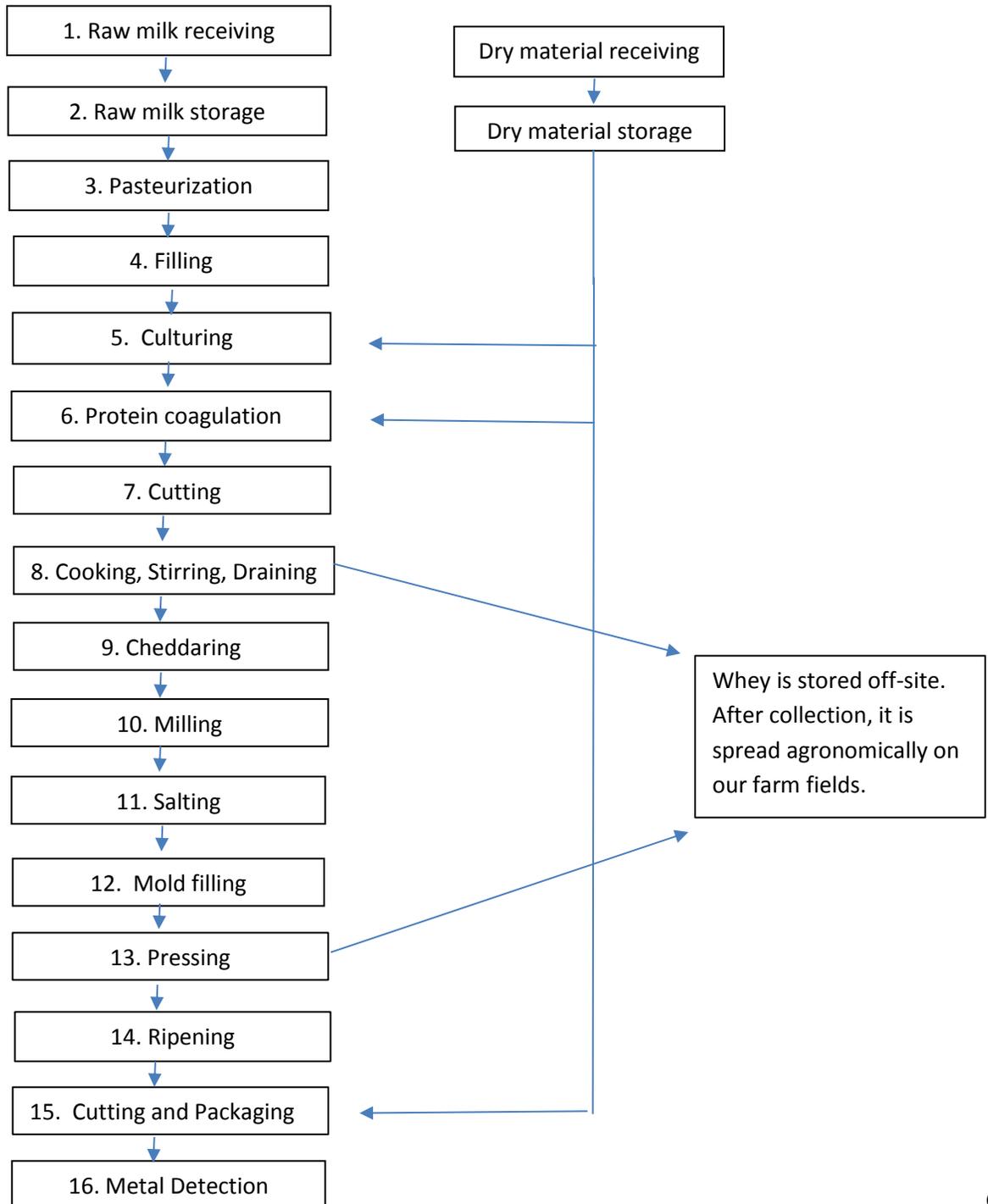
To visualize the process at Calico Creamery, we developed a flow diagram. This is an important tool because it combines the following:

- All ingredients and packaging used
- All the process steps within our control
- Receiving and finished product storage
- Rework
- Diverted by-product
- Where product is diverted to waste



Figure 4.1: Flow Diagram

If we use the information from the process description above as the starting point for our process flow diagram, much of what we need to include will be easy to document.





5. Identification of hazards:

At Calico Creamery, we understand that with the proper preventive controls, food safety is maximized. We know that hazards are seldom created by themselves in processing. Hazards are created when we have improper processing or from the ingredients and incoming materials. For example, the raw milk contains harmful bacterial such as *Brucella* spp., *Campylobacter* spp., Shiga-toxin producing *Escherichia coli*, *Listeria monocytogenes*, *Mycobacterium bovis*, *Streptococcus* spp., *Yersinia enterocolitica* and *Salmonella* spp. that could contaminate the end-product. This list represents the “biological” hazards (**B**) – for one ingredient – milk. We need to take a close look at all our ingredients.

To identify potential “chemical” hazards (**C**), we need to consider chemicals occurring naturally, chemicals used during processing, and chemicals that could be unintentionally or incidentally present during the processing of the product. Allergens are a chemical hazard. As Calico Creamery only produces their signature cheddar cheese at this location, it is assumed that milk will be in every product and that due to the limited ingredient list in the cheese, this will be the only allergen hazard in the facility. Allergens will be covered in a different model safety plan.

“Physical” hazards (**P**) include foreign objects like glass, plastic, wood, or stones.

All the ingredients and the possible biological (**B**), chemical (**C**), and physical (**P**) contamination or hazards will be listed in Table 3.1.

Calico Creamery has looked at each of the ingredients in our cheddar cheese. The possibility of microbiological, chemical, and physical hazards in the raw material and the preventative measures for the hazards has been reviewed and preventive controls have been listed.

B = Biological hazards including bacteria viruses, parasites and environmental pathogens

C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, decomposition and unapproved food additives.

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

As you will see in the following chart, Calico Creamery will review all the potential hazards that have been identified in their process and note any Preventive Process Controls (PPC).



Table 5.1: Hazard Analysis

Ingredient/processing step	Q1. Is there a hazard in this process step or ingredient? What is it? (Biological, Chemical, Physical)	Q2. Are there any potential food safety hazards?	Q3. Justify your decision for column 3	Q4. What prerequisite programs or control measure(s) can be applied to significantly minimize or prevent the food safety hazard? (CCP, Allergen, sanitation, Supply Chain, other)	Q5. Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level? (If yes then is a PPC)
Dry material receiving	Biological-Spoiled or contaminated items Chemical – Wrong item or damaged item Physical-Damaged item or foreign material issue	Y Y Y	Ingredients could be from unsafe source or past use by date Wrong item or soiled Items come in common carrier	Supplier approval and receiving program Supplier approval and receiving program Supplier approval and receiving program	N
Dry material receiving – Packaging	Biological – Environmental Contamination Chemical - None Physical – None	Y	Packaging comes bagged and sealed in outer box		N
Dry material receiving – Rennet	Biological - None Chemical - None Physical – Foreign material	Y	Items come in common carrier	Supplier approval and receiving program	N
Dry material receiving – Salt	Biological - None Chemical - None Physical – Foreign material	Y	Items come in common carrier	Supplier approval and receiving program	N
Dry material receiving – Culture	Biological- Contaminated items Chemical- None Physical- None	Y	Ingredients could be from unsafe source or past use by date	Supplier approval and receiving program	N
Dry ingredient storage	Biological- None Chemical-None Physical-Damage and Foreign materials	Y	Items may become soiled in storage area	Sanitation program, Product and Ingredient storage program, cGMP's	N
1.Raw milk receiving	Biological – Vegetative pathogens Chemical – Antibiotics Physical- Foreign materials	Y Y Y	Raw milk has a history of association with Salmonella, Listeria, Ecoli. Antibiotics are known to be used in production of milk Many pieces of equipment used in manufacture of milk	Pasteurization Appendix N testing Supplier approval and receiving program Sanitation program, cGMP's, Screens, metal detection	N



Ingredient/processing step	Q1. Is there a hazard in this process step or ingredient? What is it? (Biological, Chemical, Physical)	Q2. Are any potential food safety hazards?	Q3. Justify your decision for column 3	Q4. What prerequisite programs or control measure(s) can be applied to significantly minimize or prevent the food safety hazard? (PPC, Allergen, sanitation, Supply Chain, other)	Q5. Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level? (If yes then is a PPC)
2.Raw milk storage	Biological – Vegetative pathogen Chemical – Soap & Sanitizers Physical-None	N Y	Time of storage too short to be reasonably likely. Sanitation utilizes chemicals	Sanitation program, Product and ingredient storage and transport program Sanitation program, Product and ingredient storage and transport program	N
3.Pasteurization	Biological- Vegetative pathogen Chemical – None Physical - None	Y	Proper pasteurization is required	None	Yes - PPC-1
4. Filling	Biological – Cross contamination Chemical - None Physical – None	Y	Recontamination is possible	Sanitation Program, cGMP's	N
5.Culturing	Biological – Cross contamination Chemical - None Physical – None	Y	Recontamination is possible	Sanitation Program, cGMP's	N
6.Protein Coagulation	Biological- Environmental contamination with pathogens Chemical - None Physical - None	Y	Contamination may occur from environment	Sanitation Program, cGMPs	N
7.Cutting	Biological - None Chemical - None Physical - Metal may break from knives	Y	Cheese knife design is prone to breakage	Metal detection	N
8. Cooking. Stirring & Draining	Biological – Environmental contamination Chemical - None Physical – None	Y	Product is exposed to environment	Sanitation Program, cGMP's	N
9.Cheddaring	Biological – Environmental Contamination Chemical - None Physical – None	Y	Product is exposed to environment	Sanitation Program, cGMP's	N
10.Milling	Biological – Environmental Contamination Chemical - None Physical – Metal	Y Y	Product is exposed to environment Milling machine has metal on metal contact	Sanitation Program, cGMPs Metal detection	N



Ingredient/processing step	Q1. Is there a hazard in this process step or ingredient? What is it? (Biological, Chemical, Physical)	Q2. Are any potential food safety hazards?	Q3. Justify your decision for column 3	Q4. What prerequisite programs or control measure(s) can be applied to significantly minimize or prevent the food safety hazard? (CCP, Allergen, sanitation, Supply Chain, other)	Q5. Is the step specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level? (If yes then is a PPC)
11. Salting	Biological - None Chemical – Wrong product used Physical – None	Y	Product may be iodized or contaminated	Supplier approval and receiving program	N
12. Mold filling	Biological – Environmental Contamination Chemical - None Physical – None	Y	Product is exposed to environment	Sanitation Program, cGMPs	N
13. Pressing	Biological – Environmental Contamination Chemical - None Physical – None	Y	Product is exposed to environment	Sanitation Program, cGMPs	N
14. Ripening	Biological – Environmental Contamination Chemical - None Physical – None	Y	Product is exposed to the environment	Sanitation Program, cGMPs	N
15. Cutting & Packaging	Biological - None Chemical - None Physical – Metal	Y	Cutting is done with a metal on metal device	Metal detection	N
16. Metal detection	Biological - None Chemical - None Physical – Metal	Y	Several processes use metal on metal steps	None	Yes - PPC-#2
Signature of Food safety team leader:			Date issued & reviewed:		

6. Identification of Process Preventive Controls (PPC)

Now that the ingredients have been reviewed for possible hazards, the model calls for Calico Creamery to evaluate our Process Preventative Controls (PPC) that were identified.

1. The time and temperature of the pasteurizer is the most critical control point in the cheese making. Most of the pathogens are eliminated or reduced to the safety level.
2. Metal detection after packaging is also a preventive process control. Metal fragments could cause injury or choking.

We take these two Process Preventive Controls and look more closely at their requirements.



Table 6.1: Process Preventive Control forms

Process Preventive Control Description

(1) Process Control Point	(2) Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective Actions	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Pasteurization PPC - 1	Vegetative pathogens: E.coli O157 H7, Salmonella , Listeria	Product and air space >145F ≥30 minutes	Product and airspace temp. >145F ≥30 minutes	Calibrated and sealed thermometers	Continuous recording chart. Operator of pasteurizer will monitor during operation and prior to ending heat treatment cycle.	Vat pasteurizer operator while in process. Post process record review by QC mgr. or their designee.	In process: Pasteurization cycle will be extended to meet standard. Post processing: product will be disposed of.	Review of pasteurizer chart. Review of corrective action log and verification records within 7 days. Daily accuracy check of recording chart vs. sealed thermometer. Quarterly MDARD equipment checks.	Pasteurizer chart by QC mgr. Corrective action records by QC mgr. Yearly review of verification records including related validation studies for pasteurization.
Signature of Company PCQI official:			Date:						



Process Preventive Control Description

(1) Critical Control Point	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective Actions	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Metal detection PPC - 2	Metal inclusion	Metal detector present and operating	All of the product passes through an operating metal detector	Visual examination that the detector is on and detect notification is working	Beginning, middle and end of cut and wrap shift	Wrap room leader	If the product is processed without metal detection, hold it for metal detection. Correct operating procedures to ensure that the product is not processed without metal detection.	Pass X mm ferrous and Y mm non-ferrous and stainless standard wands though detector at required frequency. (column 6) Review of metal detector log and Corrective Action and Verification within 7 working days.	Metal Detector log Manufacturer's Validation Study that determined detector settings and sensitivity standards. Corrective action records.
		No metal fragment that would cause injury or choking are in the product passing through the metal detector	Metal detection notification is functioning when metal is present in product	Notification that metal is present in the product is functioning	When product is rejected.	Wrap room leader.			
Signature of Company PCQI official:			Date:						

7. Documentation of Process Preventive Controls

Process preventive controls make up the part of the Calico Creamery food safety plan that focuses on the controls that were identified in this appendix (pasteurization and metal detection). These process steps are critical for the safety of the cheese. To that end, Calico Creamery will validate and verify their Process Preventive Controls.

- *Validation* is obtaining evidence that control measures managed by the Food Safety Plan and by the operational prerequisite programs are capable of being effective.
 - a) Identify the control mechanisms that can mitigate the hazard
 - b) Identify how to confirm that control mechanisms are operating
- *Verification* is confirmation by providing objective evidence that specific requirements have been fulfilled.
- *Monitoring* is conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Calico Creamery has implemented the control mechanisms and the monitoring systems.



If you recall, two Process Preventive Controls (PPC) were found when the hazard analysis and process controls were developed in Appendix C. The number two PPC was metal detection. The following example for metal detection illustrates the interrelationship of validation, verification and monitoring. It illustrates the process control for this Critical Control Point:

- Validation: the metal detector at Calico Creamery was designed for optimum performance specifically for our application. The aperture is sized for our product because the sensitivity of the detector is measured at the center of the cheese wedges. The sensor was chosen based on the finished product size, type, and packaging. The sensitivity settings for the metal detector are password protected.
- Monitoring: At Calico Creamery, we have begun using a worksheet to monitor our metal detector.

Figure 7.3: Metal Detection Record

PRODUCT: Calico Creamery Cheddar Cheese	PAGE _____ of 150 Issue Date 1/14/17 Revision Date _____																														
<p>Metal Detection Log</p> <p>Hazard: Metal inclusion</p> <p>Parameters, values or critical limits:</p> <ol style="list-style-type: none"> 1) All of the product passes through an operating metal detector and 2) No metal fragments that would cause injury or choking are in the product passing through the metal detector <p>Procedure: Pass X² mm ferrous and Y mm non-ferrous and stainless standard wands through detector at start-up, middle, end of shift and when any product change occurs to assure equipment is functioning.</p> <p>Corrective action:</p> <ol style="list-style-type: none"> 1) If the product is processed without metal detection, hold it for metal detection. Correct operating procedures to ensure that the product is not processed without metal detection 2) If metal is found in product, segregate product, inspect back to the last good check, rework or discard product depending on metal type and prevalence. Identify source of the metal found and fix damaged equipment if relevant <p>Date: _____</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 10%;">Time</th> <th style="width: 20%;">Product</th> <th style="width: 15%;">Lot Number</th> <th style="width: 15%;">Detector present and on (Yes/No)</th> <th style="width: 20%;">Detector rejects ferrous, non-ferrous, and stainless standards (Yes/No)</th> <th style="width: 20%;">Line Operator (Initials)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> <p style="margin-top: 10px;">Verification Reviewer Signature: _____ Date of Review: _____</p>		Time	Product	Lot Number	Detector present and on (Yes/No)	Detector rejects ferrous, non-ferrous, and stainless standards (Yes/No)	Line Operator (Initials)																								
Time	Product	Lot Number	Detector present and on (Yes/No)	Detector rejects ferrous, non-ferrous, and stainless standards (Yes/No)	Line Operator (Initials)																										

- Verification: Verification is performed 3 times during each production run. Calico Creamery also has routine maintenance conducted on the machine where sensitivities are also verified.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

**Appendix D - A MODEL ALLERGEN CONTROL PLAN FOR A SMALL-SCALE
DAIRY PLANT**

The purpose of this document is to modify the generic allergen control model for dairy production based on actual conditions in a small-scale artisan dairy plant. It is important to pay attention to the potential for allergens in dairy production which could cause hazards to human health. Food safety is most effective when it is plant-specific and product-specific.

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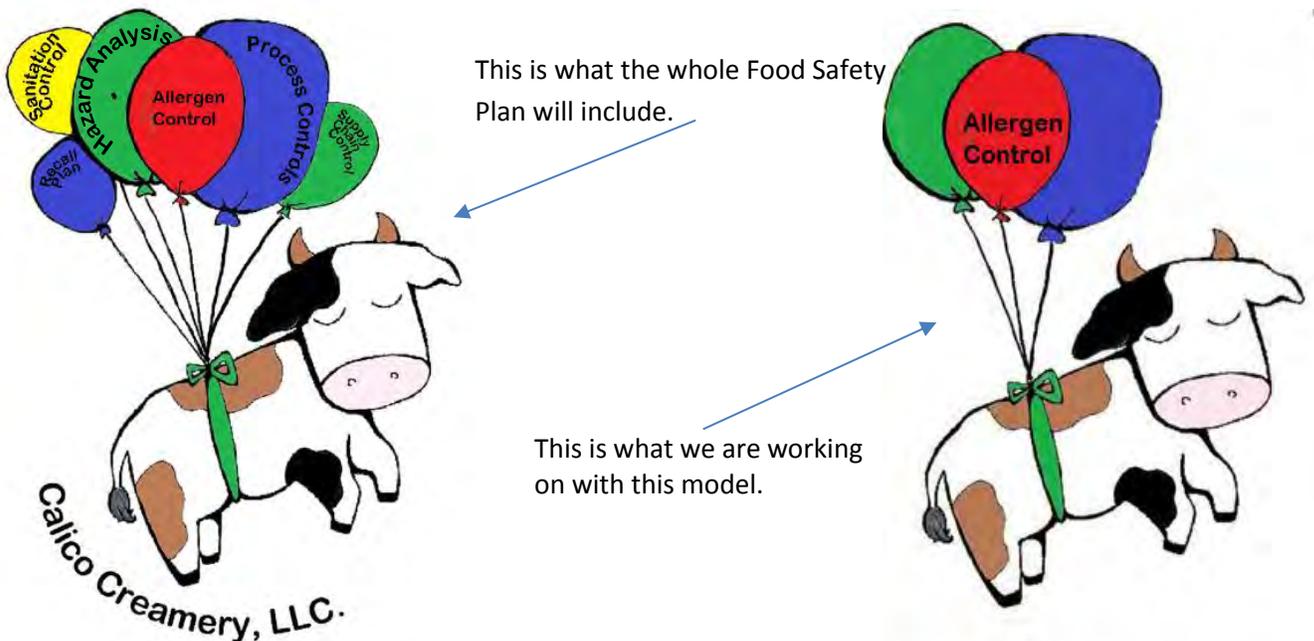
1. Introduction

Calico Creamery is thinking of expanding production to the processing of spreadable soft cheeses, one of which will contain pecans. This presented the opportunity to create an allergen control plan prior to the addition of this allergenic ingredient.

For us to create an effective Allergen Control Plan, we formed a team of people who are representative of all appropriate departments. In our example, Calico Creamery only has eight employees who each perform almost all the duties in the small plant so forming a team was easy. The team consists of three people who regularly perform; manufacturing, quality, labeling, and sanitation.

Here's another way to look at it: The Food Safety Plan for Calico Creamery will eventually become our logo. This specific plan will help us create an allergen control plan inherent in our specific manufacturing process.

Figure 1.1: Food Safety Plan Logo



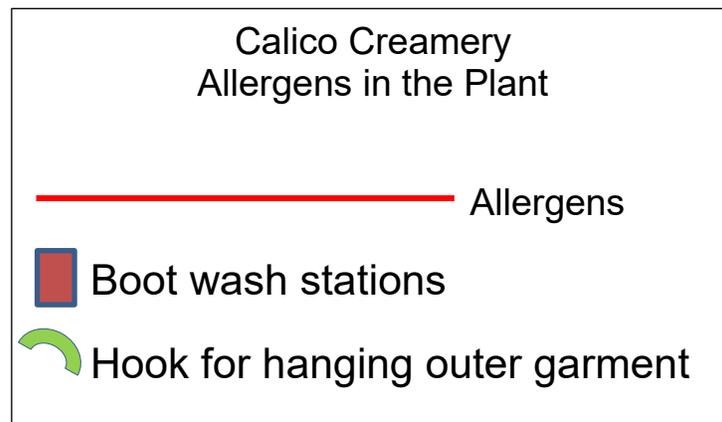
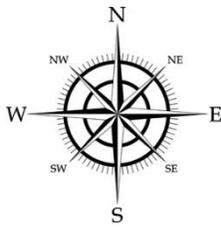
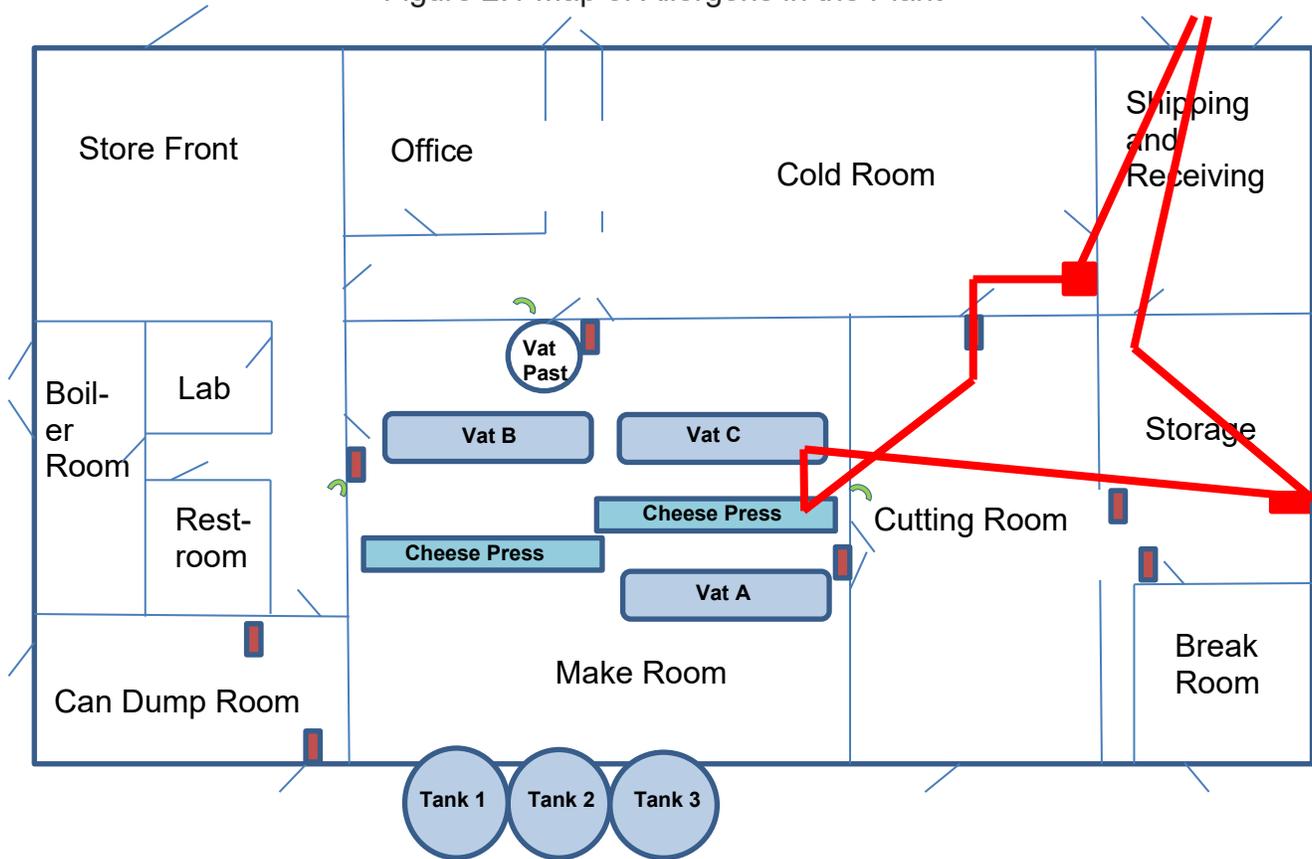
The team first reviewed the regulatory definition of an allergen. The Food Labeling and Consumer Protection Act of 2004 established the 'big eight' food allergens. The eight are: wheat (i.e. modified food starches, flour), crustacean shellfish (e.g. shrimp, crab, lobster), eggs, fish (e.g. bass, flounder or cod), peanuts, milk (i.e. cheese, non-fat dry milk, sodium caseinate, whey protein), tree nuts (e.g. almonds, pecans, walnuts), and soybeans (i.e. soy protein concentrate). These allergens cause approximately 90% of all allergic reactions associated with foods.



2. Allergen Map

The Calico Creamery Allergen Team developed an “allergen map” to visualize where the nuts would exist in the plant and where they are introduced into the process. When developing this map, the team was aware of where the nuts would be received, stored, processed into cheese, packaged, and stored prior to shipping. It was also important for them to use (whenever possible) tools and equipment that is dedicated solely to allergenic product. At any of these areas there is the potential for cross-contamination with other non-allergenic products.

Figure 2.1 Map of Allergens in the Plant





3. Allergen “to do” list

The team made a “to do” list for allergen control that included:

- Review the Allergen Control Plan regularly and update if needed -
 - 1.) If new ingredients are added
 - 2.) If processes or protocols are changed
 - 3.) If new products or equipment are introduced into the plant
 - 4.) At least annually if no other changes/modifications have been made
- Only add allergens to new products when they make a noticeable difference in the taste, texture, appearance, or utility of the product.
- Question ingredient suppliers on the function or need of allergens in their recipe
- Understand the existing allergens or lack of allergens in the manufacturing facilities when formulating new products
- Create an allergen plan for new/additional products in the manufacturing facility prior to ordering ingredients and start up

4. Receiving, storage, handling, and processing

Calico Creamery decided to segregate allergenic foods or Ingredients during receiving, storage, handling and processing. Below is a list measures that they were willing to put into place in their manufacturing facility:

Figure 4.1 Example of a label that can be used on in-coming allergens prior to storing them in the receiving area.





- **Receiving**
 1. Review the labels of incoming materials for the allergen information or any changes. An easy way to make sure you are receiving the same products that you have ordered in the past is to take a photo of the label (original) and keep it in a file. Each time you receive a new shipment of product, compare the label on the new shipment to the photo.
 2. Tag each case/pallet/bag. Identify the allergens as they are being received so that it doesn't get forgotten or overlooked.
 3. Use color coding (red tags) to identify the allergenic ingredients.
 4. If there are any damaged containers of foods that contain allergens handle them appropriately and immediately. This will minimize cross-contact at receipt.
- **Storage**
 1. At Calico Creamery, the team decided to store allergens separately.
 2. They used dedicated clean totes for storing open bags.
 3. They documented a clean-up procedure for spills or damaged containers of allergens so that the employees would be aware and consistent.
 4. They used clearly designated storage areas for allergenic foods and ingredients.

Figure 4.2 Example of Allergenic Ingredient Sign that can be used for storage areas.





- **Handling**

1. Even though Calico Creamery is a small plant the team evaluated traffic patterns of ingredients, equipment, packaging, and employees. They wanted to be sure that the manufacture of allergen containing products and would not lead to cross-contact.
2. Employees were directed to rotate inventory properly and with care.

- **Processing**

1. Calico Creamery decided that they would be using dedicated utensils for the allergenic product. These are color-coded green. The larger equipment (vat, shrink-wrapper) would be cleaned, with allergens in mind, immediately after use.
2. To minimize the allergen risk, Calico Creamery decided to add physical barriers to separate allergenic and non-allergenic vats.
3. Employees will be instructed to work on only the cheeses that they are assigned. There would be no cross-over between lines when allergenic ingredients are being used.
4. The production runs at Calico Creamery are timed so that the allergenic product is packaged and stored on the equipment last.

- **Supplier Control Programs for Ingredients**

Calico Creamery will be instituting a supplier control program (in a later appendix) but it should be noted that allergens will be also be addressed to vendors in that program.

5. Making Cheese with Allergens

The next topic that the team wanted to document was how to handle the allergens during production: specifically, the prevention of cross-contact.

- **Scheduling of cheeses with allergens**

1. The team decided to schedule cheese making with no allergens before processing cheeses with allergens.
2. Sanitation will be scheduled immediately after production of foods containing allergenic ingredients.
3. Calico Creamery will add allergenic ingredients as late in the process as possible.

- **Maintenance and engineering**

1. When the team reviewed the plant floor plan, they were able to design traffic patterns in the production facility to prevent allergen cross-contact.
2. Airflow through the plant was also taken into consideration. The team assessed the risk of migration of allergenic dust to non-allergen product lines during processing.
3. If any maintenance was required during a processing run, efforts would be made to prevent or eliminate cross-contact to non-allergen containing products/equipment – both during operations and during preventive maintenance.



6.) Product Label

- Calico Creamery packages cheese and their labels fall under the Federal Food, Drug and Cosmetic Act. These labels must comply with the Food Allergen Labeling and Consumer Protection Act of 2004. For these requirements, Bess Crocker visited www.cfsan.fda.gov/~dms/algact.html.
- She noted that companies cannot arbitrarily add “may contain” or other precautionary labeling because in 1996, FDA advised that “because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, precautionary labeling should not be used in lieu of adherence to GMP.” (<http://www.cfsan.fda.gov/~lrd/allerg7.html>).
- The allergen team decided to ensure that the label approval process was in place for their new products (or changes to current products). MDARD has a label approval form (see figure 6.1).
- Review incoming labels (from your printer) prior to receipt for accuracy. Keep a copy of the original label on file and check the received labels against the original approved label each time a new shipment comes in.
- Examples of changes that should be reflected on the label include product specification and formulation changes.
- Monitor, the correct label at all changeovers in packaging as they occur.
- Get rid of any old labels to avoid mis-labeling.
- Implement proper packaging inventory control.
- Make sure that packaging materials are staged according to policy.
- Have a Validated Allergen Cleaning Program (routinely sample the equipment for presence of allergens after a sanitation cycle has occurred).



Figure 6.1: Label Review Request Form

LR-01
(REV 5/2015)

Michigan Department of Agriculture & Development
Food & Dairy Division
P.O. Box 30017
Lansing, MI 48909


 Michigan
 Department of
AGRICULTURE
 & Rural Development

LABEL REVIEW REQUEST FORM

Please submit this form after carefully reviewing the [Food Labeling Guide](#).
A label review specialist will review this submission as department resources allow, typically within 90 days.

Submitter's Name:		Submitter's Title:	
Firm's Name:		License Number:	
Business Mailing Address:	City:	State:	Zip:
Contact Information:		Phone Number(s):	
E-Mail Address (If not submitted by E-Mail):			

LABELS MUST BE COMPLETE-- (All panels. Indicate actual size(s) below.)

1) **Check List (Please check that these are included on the label. Each explained in Food Labeling Guide):**

- A. Statement of Identity
- B. Name and Address
- C. Quantity Declaration (Metric included?)
- D. Ingredient List (If more than one ingredient. Complete?)
- E. Allergen Labeling (If contains below allergen(s))

2) **List Allergens (If Any):**

<input type="checkbox"/> Milk	<input type="checkbox"/> Eggs	<input type="checkbox"/> Peanuts	<input type="checkbox"/> Tree Nuts (Walnuts, Almonds, Pecans, etc.)
<input type="checkbox"/> Soybeans	<input type="checkbox"/> Wheat	<input type="checkbox"/> Fish	<input type="checkbox"/> Shellfish (Crab, Lobster, Shrimp, etc.)

3) **Intended Distribution:**

<input type="checkbox"/> Wholesale	<input type="checkbox"/> Retail	<input type="checkbox"/> Internet	<input type="checkbox"/> Farm Market/Craft Show
------------------------------------	---------------------------------	-----------------------------------	---

4) **Is This Label Currently In Use?**

YES NO

5) **Proposed Opening Date (If not currently in operation):** 

6) **Describe Method of Code Dating (Sell-by-date required, if shelf-life 90 days or less) and/or Production Coding Information:**

Page 1 of 2



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- 7) Specifications of the container's dimensions; including the size of the front display panel or, if the container is round, its circumference and height (type size cannot be properly reviewed if not included):

- 8) Actual label(s) size(s), i.e. Height and Width or Diameter, if round:

- 9) How will the label be applied to the container?

- 10) Ingredient List (In order of greatest quantity) as it will appear on label:

Submit copies to: Your Local Inspector

Joni Thompson ThompsonJ15@Michigan.gov

Brandon Verhougstraete VerhougstraeteB2@Michigan.gov

Submit to Brandon & Joni

The Michigan Department of Agriculture and Rural Development does not approve food labels, and a label review should not be considered such an approval. It is the responsibility of the firm to ensure labels are in compliance with regulations.



7. Document Allergen Training

The Calico Creamery allergen team decided that allergen training would be a priority for two reasons:

- So that all jobs would be performed with the same level of precautions by each employee and new employees would go through the same training.
- So that it could be documented that the creamery made efforts to process cheese with allergens responsibly.

Figure 6.1: Example Training Log



Calico Creamery Training Log:
This training was provided for:

Allergen Awareness

NAME	DATE COMPLETE	AREA OF TRAINING	TRAINER
<i>Suzie Que</i>	<i>8/4/16</i>	<i>Packaging</i>	<i>Bess Crocker</i>
<i>Suzie Que</i>	<i>9/17/16</i>	<i>Production</i>	<i>Bess Crocker</i>
<i>Suzie Que</i>	<i>10/20/16</i>	<i>Receiving</i>	<i>Bess Crocker</i>
		<i>Sanitation</i>	
		<i>Storage</i>	
<i>Suzie Que</i>	<i>1/15/17</i>	<i>Maintenance</i>	<i>Ted Crocker</i>

NOTE: It is the goal of Calico Creamery to train/re-train employees annually.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix E - A MODEL SANITATION CONTROL PLAN FOR A SMALL-SCALE DAIRY PLANT

The purpose of this document is to modify the basic, generic plant sanitation model for dairy production based on current and future conditions in our small scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific product strategy for our individual plant, the food safety plan can be more effective.

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1. Introduction

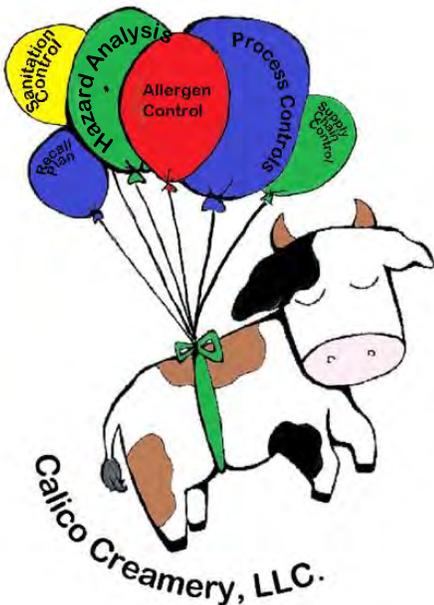
At Calico Creamery, we have always had the philosophy that proper cleaning and sanitizing is the key to producing high quality, safe dairy products. A well-informed and trained staff provides the foundation for safe food processing.

The purpose of cleaning is to remove solids, milk residues, and any other debris or soil from equipment, utensils and the environment. Soils and residues can serve as nutrients for bacteria and can be a source of microorganisms that may contaminate future production.

The key concepts of sanitation controls include knowing what to clean, what soils are present, best practices for cleaning steps and washing factors, and understanding how to handle cleaning chemicals safely.

Figure 1.1: Food Safety Plan

Here's another way to look at it: The Food Safety Plan for Calico Creamery will eventually become our logo. This specific plan will help us identify a sanitation control plan for our specific manufacturing process.



This is what the whole Food Safety Plan will include.

This is what we are working on with this model.





We use the following guide for our employees at our plant for cleaning and sanitizing.

Figure 1.2 Cleaning and Sanitizing Guide

Cleaning and Sanitizing

KEY CONCEPTS ● ○ ● ○ ●

<h2 style="text-align: center;">THE STEPS</h2> <hr/> <ol style="list-style-type: none">① Pre-rinse② Wash③ Post-rinse (acid)④ Sanitize	<h2 style="text-align: center;">WASHING FACTORS</h2> <hr/> <ol style="list-style-type: none">① Time② Action (mechanical force)③ Concentration④ Temperature
<h2 style="text-align: center;">THE DETAILS</h2> <hr/> <ol style="list-style-type: none">① Follow SSOPs② Use the right supplies③ Fill out records④ Take pride	<h2 style="text-align: center;">CHEMICAL SAFETY</h2> <hr/> <ol style="list-style-type: none">① Correct chemical use② Chemical properties③ Protective equipment④ Accident and spill response

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PENNSTATE
 College of Agricultural Sciences
Department of Food Science



2. Cleaning and Sanitizing at Calico Creamery

Food contact surfaces, the outside of equipment, the environment, and personnel hygiene are all elements of maintaining a sanitary environment for cheese processing. Note: Personnel hygiene (hand washing, uniforms) has been addressed with the Good Manufacturing Practices (GMPs) for our facility, and is not part of this Sanitation Control plan.

3. The Types of Soils at Calico Creamery

The table below shows the six basic food soil residues left on processing equipment. Depending upon the food product being manufactured and the process equipment used, varying degrees of food soil will be deposited on the equipment during production. These dairy soils will require complete removal during the cleaning process and will affect the cleaning compound used, along with the method of cleaning.

Table 3.1: Common Dairy Soils

Deposit	Solubility	Removal	Process Heat Effects
Sugars	Water Soluble	Easy	Caramelization makes removal more difficult.
Fats	Water Insoluble	Difficult	Polymerization makes removal more difficult.
	Alkaline Soluble		
Proteins	Water Insoluble	Very Difficult	Denaturation makes removal more difficult.
	Alkaline Soluble		
	Slightly Acid Soluble		
Minerals	Water Soluble	Easy to Difficult	Reaction with other soils.
	Acid Soluble		
Microorganisms	Water Soluble		
Biofilms	Mechanical Force	Easy	Effectively kills
		Very Difficult	Ineffective



4. Cleaning Steps

The specific steps used to clean and sanitize equipment and environmental areas are unique to Calico Creamery. We have written Sanitation Standard Operating Procedures (SSOPs) that provide step-by-step instructions on cleaning equipment, processing lines, environmental areas, and master sanitation schedules. Different types of equipment and different areas of the plant require different types of cleaning and different cleaners. Below is a summary for the factors that influence cleaning, methods of cleaning, and a basic cleaning procedure.

Table 4.1: Factors Influencing Cleaning

There are four interrelated factors which affect the overall cleaning process. When designing cleaning procedures these factors need to be carefully considered.

FACTOR	EFFECT ON CLEANING PROCESS
Time	The longer a cleaning solution remains in contact with the equipment surface, the greater the amount of food soil that is removed. Increasing time reduces the chemical concentration requirements.
Temperature	Soils are effected to varying degrees by temperature. In the presence of a cleaning solution, most soils become more readily soluble as the temperature is increased.
Chemical Concentrations	Chemical concentrations vary depending upon the chemical itself, type of food soil, and the equipment to be cleaned. Concentration will normally be reduced as time and temperature are increased.
Mechanical Force	Mechanical force can be as simple hand scrubbing with a brush or as complex as turbulent flow and pressure inside a pipeline. Mechanical force aids in soil removal and typically reduces time, temperature, and concentration requirements.

Table 4.2: Methods of Cleaning

The six methods of cleaning that are typically found in dairy plants depending on the equipment being cleaned and the chemicals being used.

METHOD	REASON FOR USE
Foam	Foam is produced through the introduction of air into a detergent solution as it is sprayed onto the surface to be cleaned. Foam cleaning will increase the contact time of the chemical solutions, allowing for improved cleaning with less mechanical force and temperature.
High Pressure	High pressure cleaning is used to increase the mechanical force, aiding in soil removal. In high pressure cleaning, chemical detergents are often used along with increased temperature. This method creates aerosols so it is not recommended.
Clean in Place (CIP)	CIP cleaning is used to clean interior surfaces of tanks and pipelines of liquid process equipment. A chemical solution is circulated through a circuit of tanks and/or lines then returned to a central reservoir allowing for reuse of the chemical solution. Time, temperature, and mechanical force are manipulated to achieve maximum cleaning.
Clean Out of Place (COP)	COP cleaning is used to clean tear down parts of fillers and parts of other equipment which require disassembly for proper cleaning. Parts removed for cleaning are placed in a circulation tank and cleaned using a heated chemical solution and agitation.
Manual	Manual cleaning normally involves the use of a brush either by hand or a machine such as a floor scrubber. Mechanical cleaning uses friction for food soil removal.
Low pressure	Low water volume (sometimes in the form of steam) and pressure are used for surfaces.



Table 4.3: Fundamental Cleaning Procedure

The following is the typical procedure used when cleaning food-processing equipment. The factors that influence cleaning (time, temperature, chemical concentration, and mechanical force), the method of cleaning, and the food soils to be removed will ultimately determine the cleaning procedures selected for use.

CLEANING STEP	PROCEDURE
Pre-Rinse	Soiled equipment surfaces are rinsed with warm water to remove the gross amounts of loose food soils.
Cleaning Cycle	Removal of residual food soils from equipment surfaces through manipulation of the four basic cleaning factors and the method of cleaning. Typically alkaline chemical solutions are used for the cleaning cycle.
Rinse	Rinsing of all surfaces with cold to hot water, depending upon the temperature of the cleaning cycle, to thoroughly remove all remaining chemical solution and food soil residues.
Acid Rinse	A mild acid rinse of the equipment neutralizes any alkaline residues left and removes any mineral soil present.
Sanitize	All equipment surfaces are rinsed or flooded with a sanitizing agent. Time and concentration are critical for optimum results.

5. The Chemicals we use at Calico Creamery

The selection of cleaning and sanitizing chemicals for use in Calico Creamery were chosen in coordination with our chemical supplier. We have evaluated each area and considered the following when determining how to clean:

- type of soil
- type of surface
- whether the equipment is to be COP, CIP, or manually cleaned
- water quality

Note about chemical safety - Chemicals are used in this dairy processing plant. We use demonstrations when conducting chemical safety training to educate employees how to properly mix chemical solutions, label chemical containers, wear the correct personal protective equipment (PPE) for the task at hand, and clean up spills. We document the training session (date of the session, topics covered, employees present) and place it in the training section of our Food Safety Plan. We have emergency Material safety Data sheets and contact numbers easily accessible and have spill kits accessible and use procedures in place.



Table 5.1: Identifying and Troubleshooting Dairy Solids on Equipment

The selection of chemicals may differ occasionally if the build-up of milk solids is noticed. The following table can serve as a guide to identify and clean problem areas.

	Fats	Protein	Mineral
Identification	Heavy deposit produces soft water film. Light buildup dulls surface, causes water to bead. "Greasy"	Heavy buildup produces yellow varnish-like appearance or slimy gelatinous film like applesauce. Light buildup will give a blue or rainbow cast to stainless steel. Causes water to bead.	1. Chalky – white to gray water spots and film 2. "Bluish" cast to stainless steel
Cause	Improper pre-rinse (cold water) temperature. Weak alkaline detergent solution (pH below 10.0). Low initial or outlet H ₂ O temperature. Rinsing only; not washing after each use. Using acid washes only.	Use of non-Cl detergent or detergent low in chlorine (chlorine level below 50 ppm). Rinsing only; not washing after each use. Using acid washes only. Improper pre-rinse (hot-water) temperature.	1. Use of detergent with inadequate sequestering capacity to "tie up" minerals during washing. Not acid rinsing after each use. Not employing alternate acid wash 2. Acid rinsing with hot water (in excess of 120°F).
Removal	Mix chlorinated alkaline detergent at twice the recommended dosage to insure proper pH and detergency. Insure H ₂ O temperature of 160°F and maintain above 120°F for duration of wash cycle. Follow with acid rinse at twice the recommended dosage.	Mix chlorinated alkaline detergent at twice the recommended dosage and add liquid or powdered chlorine at 1 oz. for each 5 gallons of wash solution. For manual brush surfaces, prepare a paste of 4 ozs. Cl alk. det + 1 oz. liq. Chlorine. Pour on surface. Allow to stand for 2 minutes. Brush thoroughly. Rinse. Repeat as necessary	1. Mix acid cleaner at recommended dosage in 140°F water. Circulate for a minimum of 10 minutes. Repeat as necessary.
Prevention	Analyze water and prescribe proper detergent at proper concentration. Insure pH above 10.0 and temperature above 120°F at the end of wash cycle. Check for proper wash volume, velocity, contact time, and drainage. Insure that the proper water temperatures are obtained during the pre-wash rinse (95-110°F)	Analyze water and prescribe proper detergent at proper concentration. Insure proper pH, solution temperature, volume, velocity, contact time, and drainage. Check for proper rotation and/or storage of Cl-alkaline detergent. Insure that the pre-wash rinse is performed with the correct water temperature (95-110°F)	1. Analyze water and recommend H ₂ O softener to remove hardness minerals. Use acidification rinse after each use. 2. Insure acid rinsing in temperature below 120°F. Use acidification rinse daily.



6. What is an SSOP?

An SSOP is simply a Sanitary Standard Operating Procedure. At Calico Creamery, we use them to monitor employees, train new ones, and outline all the materials and equipment needed to perform everyday tasks and duties.

7. Monitoring and Recording the Cleaning and Sanitation

The details of the Sanitation Control Plan summarize the requirements for effective cleaning and sanitizing in our plant.

- Follow SSOPs; Calico Dairy has developed Sanitation Standard Operating Procedures (SSOPs) specifically for equipment and environmental areas to meet the needs of our facility. These SSOPs include step-by-step directions on how to clean, and how often to clean, specify the correct chemicals, times, temperatures and processes to use.
- Use the correct supplies, including:
 - correct chemicals and concentrations
 - appropriate Personal Protection Equipment (PPE)
 - color-coded brushes and buckets
 - the correct wash tanks
- Fill out sanitation records and logs. This helps to ensure adherence to the Food Safety Plan through monitoring and verification records. If it wasn't documented, it wasn't done.
- Employees will also conduct pre-operational inspections to assure that proper sanitation is completed and that the equipment is in good repair.

8. Ensuring effective SSOPs

Calico Creamery SSOPs will be written as follows:

- There are written SSOPs and a master cleaning schedule for each type of equipment, utensil, and the facility itself.
- Employees are properly trained with an emphasis on why cleaning and sanitizing is necessary and the procedures involved.
- Our plant uses a color-coded brush system to prevent contamination from raw to pasteurized products, and from non-food contact and environmental surfaces to food contact surfaces.
- If our procedure changes, the SSOP will be updated
- The SSOPs will be reviewed annually with the Food Safety Plan

In the specific example on the following page, we have included three SSOPs that our employees use for operations.



Cleaning and Sanitizing Wood Boards for Cheese Aging Calico Creamery (last update 8/7/16 – version 3)

At Calico Creamery, we believe in the use of wood boards for aging our cheddar cheese. This has a longstanding tradition in cheese manufacture. The wood provides a natural wicking that helps to cure the rind of our cheese but we also understand that the boards can become sites for bacterial to grow and multiply. At Calico Creamery good sanitation practices are the key to successful wheel aging.

Practices for using wood aging boards at Calico Creamery

- We use boards that are made of wood that is safe for foods
- We use boards that are of that are in good condition, free of knots and surface pits
- We have a series of racks for the boards that make it easy to clean and inspect them
- We clean, sanitize, and inspect the boards in our cave each time the wheels graduate to a new area of the cave (by age). We look for damage and discoloration
- When using buckets for sanitizing, we make sure the buckets are thoroughly clean before mixing the sanitizer. If the sanitizer appears cloudy, it is no longer effective and should be replaced
- When the boards become discolored or damaged they are replaced
- Periodically, the cave is environmentally sampled (including the aging boards)

Cleaning and sanitizing procedures for wood aging boards

- Wood boards are cleaned and sanitized in the cave
- The minimum cleaning conditions are:
 1. Wash and scrub boards with 140°F soapy water for 3 minutes on each side. Use the Nifty brand soap
 2. Rinse boards with 140°F water for two minutes on each side
 3. Sanitize boards with 200 ppm chlorine solution
 4. Boards are placed on a clean rack to air dry
 5. The clean boards are flipped after 24 hours to assure complete drying where they rest on the rack
 6. Boards are stacked on a clean rack until the next rotation
 7. Fill out the cleaning and sanitizing record = the Daily Cleaning Log

The following person is responsible for this SSOP Bess Crocker- Food Safety Coordinator

Date: 1/15/17



Cleaning and Sanitizing Cheese Process Equipment

Calico Creamery (last update 8/7/16 – version 3)

At Calico Creamery, the cheese process equipment includes the bulk tanks, vats, sanitary stainless pipelines, valves, pumps, draining tables, utensils, and molds used during the manufacture of cheese. Cleaning and Sanitizing Schedule - Processing equipment is sanitized immediately prior to use and cleaned at the end of each processing day.

- Manual Cleaning and Sanitizing (in a sink)
 1. Tear down the equipment to be cleaned while rinsing the parts with warm water
 2. Fill the triple wash sinks with the cleaning, clear water, and sanitizing solutions. Mix chemicals according to the manufacturer's instructions and wear the appropriate personal protection equipment
 3. Wash the equipment using the proper color-code brush making sure to wash all surfaces
 4. Rinse thoroughly with warm water
 5. Submerge parts in the sanitizer solution allowing adequate contact time
 6. Visually inspect parts for cleanliness and damage while arranging/hanging to air dry

- Cleaning the Vat Pasteurizer:
 1. Pre-rinse the vat with warm water (100 -120°F)
 2. Make the detergent solution according to manufacturer's instructions. Note: wear appropriate personal protection equipment (gloves, eye protection)
 3. Sample the detergent solution; test the chemical concentration and verify it is in the correct range. Record the results on the Cleaning-Chemicals Test Log
 4. Wash the vat using a [cleaning-color] brush, making sure to wash all surfaces and parts
 5. Rinse thoroughly with warm water to remove any detergent residue
 6. Make the sanitizer solution according to the manufacturer's instructions. Again use appropriate personal protective gear
 7. Sample the sanitizer solution; test it to verify it is in the correct range. Record the results on the Cleaning-Chemicals Test Log
 8. Rinse all parts with the sanitizer solution
 9. Drain the sanitizer solution
 10. Record the cleaning of the vat pasteurizer on the Pasteurization Chart each day, in addition to recording on the Daily Cleaning Log
 11. Manual cleaning of the cheese vat, tables and equipment is recorded on the Daily Cleaning Log

The following person is responsible for this SSOP Bess Crocker- Food Safety Coordinator

Date: 1/15/17



Sanitation SOP for Milk Storage Tank that is CIP-Cleaned and Sanitized

SSOP to Wash and Sanitize Product Tank # 4 (last update on 11-17-16)

A. Objectives:

1. What (tank) is being washed and sanitized?
2. Frequency = when do we perform this procedure?
3. Who = what shift and what individual is responsible for the wash?
4. Chemicals and Concentrations = identify these.
5. Procedure = what are the steps to follow and verify?
6. Recording Chart = where is the wash procedure recorded?
7. Equipment and Tools needed = what are they?

B. The Main Events:

1. Manual cleaning of Exterior of the Tank; and non-C I P (Clean-in-Place) Tank Parts.
2. C I P, which includes the following stages:
 - Rinse = warm water at 110 F° / 10 min
 - Alkaline Wash = chlorinated alkaline detergent (at recommended concentration) for 20 minutes at 160 F°
 - Rinse = warm water 110 F° / 5 min
 - Acid Rinse Cycle = Mandate (at recommended concentration) at 90 F° for 15 min

C. Procedure = Follow and Verify these Steps:

1. Prepare the chemical solutions = for C I P; and manually cleaned parts
2. Lock out the agitator
3. Remove manually cleaned parts, and brush wash
4. Rinse and store parts to drain
5. Check refrigeration is turned off
6. Connect CIP lines; turn on agitator
7. Run CIP
8. At completion of the CIP: turn off agitator; close CIP system; check that the tank is clean
9. After wash is complete, reassemble the tank and brush-cleaned parts
10. If tank is not used within 4 hours, re-sanitize before using again

The following person is responsible for this SSOP Bess Crocker- Food Safety Coordinator

Date: 1/15/17



Calico Creamery Training Log:
This training was provided for:

Sanitation

1. NAME	DATE COMPLETE	AREA OF TRAINING	TRAINER
<i>Suzie Que</i>	<i>8/4/16</i>	<i>COP</i>	<i>Bess Crocker</i>
<i>Suzie Que</i>	<i>9/17/16</i>	<i>CIP</i>	<i>Bess Crocker</i>
<i>Suzie Que</i>	<i>10/20/16</i>	<i>Manual Cleaning</i>	<i>Bess Crocker</i>
		<i>Chemical Safety</i>	
		<i>Storage of clean items</i>	
<i>Suzie Que</i>	<i>1/15/17</i>	<i>Sanitary Preventative Maintenance</i>	<i>Ted Crocker</i>



Calico Creamery Monthly Chemical Evaluation Log

Chemical Evaluation Log: MONTH =

DATE	ppm Sanitizer = spray hoses	ppm Floor Sprayers	ppm Detergent = Manual Wash	ppm Sanitizer = Manual	ppm Detergent = CIP	ppm Acid = CIP	ppm Sanitizer = CIP	ppm Drain Wash	Corrective Action/Notes	Analyst
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
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29										
30										
31										

NOTE: Calico Creamery works with their chemical dealer for appropriate test kits and target ranges.



Calico Creamery Daily Cleaning Log

Daily Cleaning Log: Day / Date =

Equipment	? Washed Today	Manually Cleaned = rinse temp.	Man. Cleaned = chemicals OK?	CIP rinse temp.	CIP Detergent in Range?	CIP Acid in Range?	CIP sanitizer in Range?	CIP properly Recorded?	Visual OK after cleaning?	Corrective Action/Notes	Signed / Time
Raw Tank 1											
Past. Tank 2											
Vat Pasteurizer 1											
HTST Pasteurizer 2											
Lines Circuit 1											
Lines Circuit 2											
Tabletops											
Wood Boards											
Utensils											
Filler 1											
Filler 2											
Floors											
Drains											



Calico Creamery blank SSOP

Record – Cleaning SSOP	
What to be cleaned?	
How to be cleaned?	
How often?	
Detergents and sanitizers	
Equipment required for activity	
Who will clean?	



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix F - A MODEL RECALL PLAN FOR A SMALL-SCALE DAIRY PLANT

The purpose of this document is to modify the basic, generic recall model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific product strategy for our individual plant, the food safety plan can be more effective.

NOTE: This information, provided by MDARD, is for guidance purposes only. MDARD does not guarantee the accuracy, adequacy, applicability, or completeness of any information provided in this tool and is not responsible for any errors or omissions.



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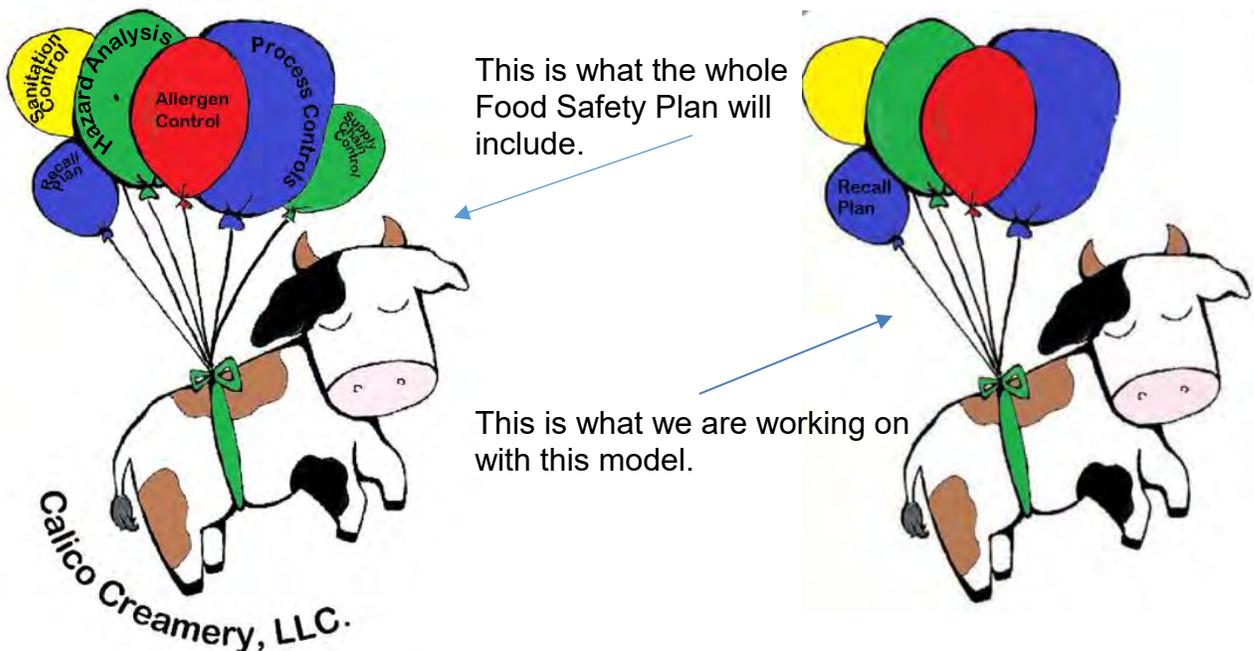


1. Introduction

At Calico Creamery we understand the need for a plant recall plan. At the creamery, we use many controls to ensure the safety of our products. This recall plan is also an effort to protect our customers. We hope to never need a recall plan but if we do, the quicker we remove our cheese from the market, the safer our customers will be.

Here's another way to look at it: The Food Safety Plan for Calico Creamery will eventually become our food logo. This specific plan will help us develop a recall plan inherent in our specific manufacturing process.

Figure 1.1 Food Safety Plan



Our food recall plan is developed to have the following goals:

- To create procedures for determining if a recall is needed
- To inform MDARD and FDA
- To formulate a recall notice as quickly as possible
- To have a proper and timely plan to remove our cheese from the market
- To retrieve as much cheese as possible for destruction or correction
- To dispose of or correct the affected product
- To evaluate the effectiveness of our recall



2. Recall Committee

At Calico Creamery, the recall committee coordinates all the actions and communications during a recall. It was important that we assigned responsibilities so that everyone would know what to do in a recall situation.

Table 2.1: Recall Committee Assignments

NAME	ROLE	RESPONSIBILITY	PHONE	TYPE
Bess Crocker	Recall Coordinator and Regulatory Agency Communication	RFR (Reportable Food Registry) is used for electronic reporting. MDARD and FDA are also notified	888-7887 777-4321 888-3456 xxx@xxx.xx	Home Office Cell e-Mail
Ted Crocker	Securing inventory of affected cheese and cheese disposition	Identifying the lots of the effected product and securing any in-house stock. Handles the disposal of effected cheese	666-1234 555-5225 666-2345 xxx@xxx.xx	Home Laboratory Cell e-mail
Jericho Jensen	Customer Notification and Effectiveness Checks	Informing customers of the specific product, quantities of affected cheese, dates the cheese was shipped and the reason for the recall. Instruct them on how to handle the effected cheese. Follow up	888-543-3245 888-8998 888-9876 xxx@xxx.xx	Home Office Cell e-Mail
Suzy Que	Information and Data Compilation	Creation and maintenance of data base to track cheese purchases from customers. Daily reconciliation of quantity recovered versus total cheese sold	231-666-6969 666-8080 666-5678 xxx@xxx.xx	Home Office Cell e-Mail
Chris Hollin	Recall initiation and documentation	Formation of the Recall Notice. Documentation of all aspects of cheese recovery and destruction	454-4554 863-2959 454-9944 xxx@xxx.xx	Home Office Cell e-Mail



3. Identifying the Need for a Recall

The first step in a recall situation is the discovery of a potential product problem. Calico Creamery will use the Recall Decision Matrix below to provide guidance for recall decisions.

Table 3.1: Recall Action Decision Matrix

Problem is reported by:	Initial Action	Decisions	Actions
Regulatory Agency believes our cheese may/is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if/what and how much product to recall. Use Evaluation Form on next page.	If no recall is needed: Document why not and actions taken
News media story on problem with the cheese we produce	Assemble recall team and review internal records		If recall is needed:
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		<ul style="list-style-type: none"> • Assign Responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of cheese • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Health Department believes our cheese is causing illness	Assemble recall team, contact appropriate regulatory agency		



Table 3.2: Calico Creamery Recall Evaluation

Explain in detail how the cheese is defective or violative.	
Explain how the defect impacts the performance and safety of the cheese, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the cheese. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the cheese to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem impacts only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none"> • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved 	
If a State agency is involved in this recall, identify Agency and contact.	



Calico Creamery will begin an investigation or inspection of the plant to identify the reason for the recall so that it may be documented, corrected, and prevented in the future.

4. Classes of Recalls

Calico Creamery’s recall committee coordinator will work with the regulatory agencies to determine appropriate course of action based on the findings or answers to the questions in table 3.2.. If there is confirmation that an actual recall issue exists with our cheese, the committee is to be reconvened as soon as possible to begin the customer notification/press release processes.

Once a recall determination has been reached and the following information has been supplied to the state and if needed federal regulatory agency, the agency will use the results of a health hazard evaluation (HHE) to determine the classification of the recall. Previously performed HHE’s may be used to assign classifications if similar in nature.

Class I Recall – the most serious and involves product that has a reasonable probability of causing serious injury, illness or death. (Listeria, Salmonella, E. coli H7:0157, undeclared allergens)

Class II Recall – may cause temporary illness that typically resolves in full recovery. For Class II recalls, death and other serious consequences are not likely. (Yellow # 5)

Class III Recall – Use or exposure to the product is not likely to cause adverse health consequences. (Excess water, adulterants presenting no safety issues)

5. Forms to fill out if Calico Creamery were to have a recall

If it is determined using table 3.2 (Calico Creamery Recall Evaluation), that a recall is required, the following three forms will be used by Calico Creamery to inform authorities.

Table 5.1 **Volume of Recalled Cheese

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
How much cheese is being quarantined.	
Estimate amount remaining in Marketplace	
<ul style="list-style-type: none"> • Distributor level • Customer level 	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	



Figure 5.1 **General Cheese Information

Cheese Name(s) (including brand name(s) and generic name(s))

TWO COMPLETE SETS OF ALL Labeling Product labeling

- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

CODES (Lot identification Numbers):

- UPC code(s) involved: _____

- Lot numbers involved *:

- Lot numbers coding system: *Describe how to read your product code:*

- Expected shelf life of the product: _____

*Lot number(s) include reviewing any re-worked or re-labeled cheese – also include any packages that may have been discarded so that these are included in the final production totals.



Figure 5.2: **Distribution Pattern

Number of Direct Accounts (customers we sell directly to) by type:

Type	Number
<ul style="list-style-type: none"> • Wholesalers/distributors • Repackers • Manufacturers • Retail • Consumers (internet or catalog sales) • Federal government • Foreign consignees (specify whether they are wholesale distributors, retailers or users. 	
Geographic areas of distribution, including foreign countries	

Commercial customers:

Name	Street Address	City	State	Recall Contact Name	Contact Phone Number	Recalled cheese was shipped?	Recalled cheese was sold?	Recalled cheese may have been shipped or sold?

** Note: Provide these lists to the State and FDA District Recall coordinators. Include US customers, foreign customers and federal government consignees.



6. Recall Notification

Once the need for a recall has been determined by the committee, customer notification will begin. Waiting for regulatory agency decision is not necessary to initiate the recall process.

Instructions for Consignee Notification from Calico Creamery -

- Letters will be sent to Calico Creamery customers by e-mail, fax, or overnight mail (whichever can be accomplished first according to the contact information available).
- Notify each customer by using the phone script. NOTE: Be prepared to provide a copy of the phone script to MDARD and FDA.
- Upload the recall notification (see example on last page) on the Calico Creamery website.
- In all cases include instructions for consignees on what to do with recalled cheese (FDA and MDARD may want a copy of final instructions).
- Consider what to do for out-of-business distributors.

The notifications should be as follows:

- MDARD
- FDA
- RFR (Reportable Food Registry) - done on-line
 - <http://www.fda.gov/Food/ComplianceEnforcement/RFR/ucm2019388.htm>
 - The Reportable Food Registry (RFR or the Registry) is an electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences.
- Customers – whether we notify by telephone, fax, email, or personal contact any/all contact must be documented. Contact should be made in the order of largest to smallest customer.
- Our employees also need to be informed of the situation and given clear instructions regarding external communications.
- Media outlets – *The need making a public press release will depend on the reason for the recall and the classification.* If a public declaration is required or deemed appropriate, Calico Creamery will use a prepared press release (see example in the back of the recall plan).



6.1: Press Release Examples

To assure that the public is aware of the recall, Calico Creamery will contact the local and/or regional Associated Press offices in the areas of Michigan/US in which the product was distributed. Additionally, written recall notification letters will be sent to each of our customers (an example of Calico Creamery's press release and recall notification letter is available below). And phone contact with each customer will be made.

Example: Allergen Press Release

**The Calico Creamery
1066 Barnstormer Drive
Boon Town, Michigan 49618**

FOR IMMEDIATE RELEASE
Bess Crocker / 231-777-4321

1/17/17

CALICO CREAMERY ISSUES ALLERGY ALERT ON UNDECLARED PECANS IN CALICO CREAM CHEESE

Calico Creamery of Boon Town, MI is recalling its 8-ounce packages of their Calico Cream Cheese because they may contain undeclared pecans. People who have allergies to tree nuts run the risk of serious or life-threatening allergic reaction if they consume this product.

The recalled cheese was sold from the Calico Creamery to the Boon Town Store and was available for purchase on the internet from the Creamery's web site. The product comes in a 8 ounce, round plastic tub marked with lot number 04505 printed in black on the side of the cup.

No illnesses have been reported to date in connection with this problem.

The recall was initiated after it was discovered that the pecan-containing product was used to fill tubs simultaneously on a line with plain cream cheese. Subsequent investigation indicates pecan cream cheese being mixed-in with the plain cream cheese products. All of the tubs were labeled as Calico Cream Cheese and no allergens other than milk are listed on the label.

Production of the product has been suspended until FDA and the Creamery are certain that the problem has been corrected.

Consumers who have purchased 8-ounce packages of the Creamery's Calico Cream Cheese are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-814-865-7535.



Example: Listeria Customer Notification Letter

**The Calico Creamery
1066 Barnstormer Drive
Boon Town, MI 49618**

1/17/17

**RE: CALICO CREAMERY RECALLS CALICO CREAM CHEESE DUE TO
POSSIBLE HEALTH RISK**

Calico Creamery of Boon Town, MI, is recalling its 8-ounce packages of Calico Cream Cheese because they have the potential to be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail, or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, listeria infection can cause miscarriages and stillbirths among pregnant women.

The recalled cream cheese was sold from the Calico Creamery to retailers and was available for purchase on the internet from the Creamery's web site. The product comes in an 8 ounce, round plastic tubs marked with lot number 04505 printed on the side of the cup.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of *Listeria monocytogenes* in 8-ounce packages of the cream cheese.

The production of the product has been suspended while MDARD and the company continue to investigate the source of the problem.

Retailers and consumers who have purchased 8-ounce packages of the Creamery's Calico Cream Cheese are urged to return them to Calico Creamery for a full refund. Retailers or consumers with questions may contact the company at 1-865-7535.



7. Emergency Contacts

Federal Food and Drug Administration (FDA)
Detroit, MI
313-259-0650
704-376-4813 Fax

Michigan Department of Agriculture and Rural Development (MDARD)
Barb Koeltzow Phone - (989) 871-3470
 Toll Free-(800) 292-3939
 Email: koeltzowb@michigan.gov

Associated Press - To assure the broadest coverage, press releases should be issued through the Associated Press. Contact the AP news desk at 202-776-9477. The facsimile number is 202-776-9570.

8. Recovering the Recalled Cheese (Recall Strategy)

Recovery and Disposal of the Product – A designated area in the receiving room will be used for the returned product. Returns will be clearly marked and segregated from other product. A dumpster will be ordered from the local landfill for disposal.

Documentation of the Recovery and Disposal of the Recalled Cheese – the amounts and locations from which the product was retrieved, along with its disposition will be documented.

- Bleach will be poured onto the cheese in the dumpster to denature it.
- If the product is to be "reconditioned", Calico Creamery will provide details of the reconditioning plan to MDARD and FDA before implementation.
 - a. All reconditioning must be conducted under any applicable GMPs.
 - b. Reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
 - c. Calico Creamery will contact MDARD and FDA prior to product destruction. MDARD or FDA will review your proposed method of destruction and may choose to witness the destruction.
 - d. You and your customers should keep adequate documentation of product destruction (and whether destruction was witnessed by an inspector).
 - e. Field corrections, like product relabeling, will be performed by Calico Creamery, or under our supervision and control.



9. Effectiveness Checks

It is our responsibility to assure that the recall is effective. Calico Creamery will conduct effectiveness checks for every recall. From these effectiveness checks (and the documents created) Calico Creamery will be able to provide updated status reports if required. The level of Effectiveness Checks assigned will depend on the classification and specifics of the recall.

- Class 1 --100 percent of the total number of consignees to be contacted
- Class 2--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 75 percent and less than 100 percent of the total number of consignees
- Class 3—At least 50 percent of the consignees.

Table 9.1: Effectiveness checks by account

When time permits, Jerico Jensen (in charge of Customer Notification and Effectiveness Checks) can fill in the consignee’s recall contact name and information ahead of time to make it easier to contact them in the event of a recall.

Consignee	Recall Contact		Date Contacted	Method of Contact				Date of response	Number of Products returned or corrected
	Name	Contact Info		Phone	Email	FAX	Letter		

Table 9.2: Effectiveness check summary

To be provided to MDARD and/or FDA periodically during recall

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of cheese on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date



Figure 9.1: Effectiveness Check Questionnaire

**The Calico Creamery
1066 Barnstormer Drive
Boon Town, MI 49618**

PRODUCT RECALL

This is (Name of Interviewer). I am calling for Calico Creamery to check on the effectiveness of the company recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE _____

1. Did your firm receive notification that (product name) products manufactured by Calico Creamery are being recalled?
YES _____ NO _____
2. Did your firm receive shipments of the product being recalled? (If no, terminate questioning and go to the closing).
YES _____ NO _____
3. Do you have any of the recalled product on hand? (Please check inventories before answering).
YES _____ NO _____
4. If the answer to question 3 is YES, do you intend to return the product to the Calico Creamery as requested?
YES _____ NO _____

Closing: Thank you for taking the time to complete this survey. It is the best way for our company to check the effectiveness of our recall.



10. Closing out a Recall

The Regulatory authority in coordination with the Recall Committee will determine when the recall is complete. The Recall Coordinator will also issue a report to the Recall Committee as to the reason for the recall and corrective action steps to prevent this from happening again. We will evaluate our recall for termination when all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.

A final status report and documentation of recalled product disposition will be provided to MDARD and FDA who will consider formal termination of the recall action.

11. Calico Creamery Recall Checklist

- Confirm that the Recall Committee information is up-to-date.
- Verify that the appropriate press release templates are available and that the person responsible knows how to use them.
- Be sure that the names and phone numbers of customers who need to be contacted are available and current.
- Identify regulators who need to be contacted and their phone numbers if the recall scenario occurred.
- Identify the problem and assess the health risks.
- Determine the products and lot numbers involved. This should include the product name, line number, UPC, and freshness code.
- Determine the production day, shifts, and all employees involved.
- Determine quantities produced.
- Determine the current inventory in-house.
- Identify any unaccounted for cheese such as lab samples, discarded product, and any product that has or will be reworked.
- Determine the amount of product in the marketplace.
- Identify the customers who have received the product.
- Generate a recall memo to be given to the media. Also develop talking points to be used with sales representatives, drivers, and other employees.
- Generate a call list for the customers to be contacted.
- Collect manufacturing sheets, pasteurizing charts, and other pertinent documentation.
- Identify which regulatory authorities should be called.
- Identify which media sources should be called.
- Outline the shortcomings in our recall plan and what corrective action will be taken. This would include taking longer than four hours to gather the information and/or not being able to potentially account for 100% of the products produced.



12. Special Note about Trace-Back and Trace-Forward

At Calico Creamery, we realize that in order to have an effective recall, our manufacturing facility needs to have an effective trace-back and trace-forward record-keeping system in place. While there are many on-line resources to accomplish this, we have developed a simple system that meets our needs.

Calico Creamery, Inc.		Invoice		
1066 Barnstormer Lane				
Boon Town, MI 49618				
Date	Invoice #			
01/29/14	1007			
Bill To:	Terms			
Boss Mouse Cheese				
Quantity	Unit	Description	Price Each	Amount
8.00	Mik Can	10 gallon milk can	35.00	280.00
<p>BULK SHIPMENT OF MILK Shipper & Hauler: Boss Mouse Cheese (M26-196) Point of Origin: Moomers Farm Creamery (M26-126) Tanker ID: (MI-0985) Whole Milk, Grade A Milk Gallons <u>80</u> Temperature <u> </u> F Date shipped <u> </u> Exp. date <u> </u></p>				
				Total Due: 280.00

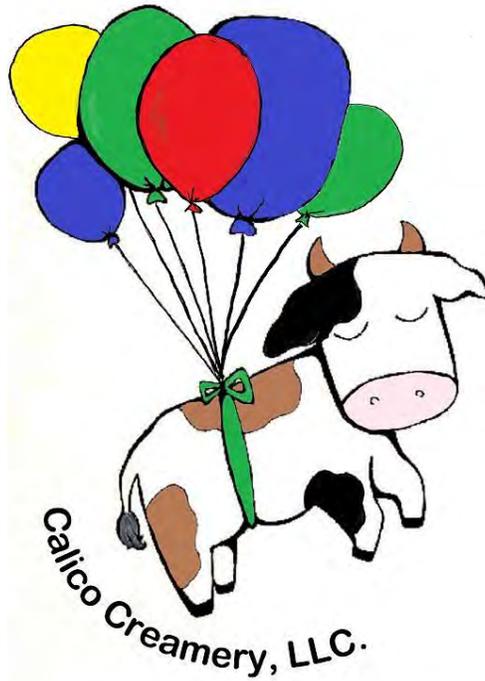
TITLE	Project No.	Book No.
From Page No.		44
2/1/14		
CHEDDAR #196		Whole wheels to Robert Starr Farms 5-8-14
CHEDDAR WHEEL # 4472027395		
GTG VEG. MENNET # CM2008		
DIAMOND KOPHER SALT # 31413A2AA7		
2/2/14		
BLUE CHEDDAR #197		2nd count (have 5-20-14) TCFM 5-29-14
CHEDDAR P. ROQUEFOLTA # L9110929598		
CHEDDAR WHEEL # 4472103038		
DIAMOND KOPHER SALT # 31413A2AA7		
GTG VEG. MENNET # CM2008		
2/2/14		
CARAWAY SWISS #198		TCFM 4-20-14
BIENA PPOA # MD303		
CHEDDAR WHEEL # 4472061508		
GTG VEG. MENNET # CM2008		
GTG CARAWAY SEED # 071A3-B		
Witnessed & Understood by me, Date Invented by Date Recorded by		

This page documents how much milk is used on a production day. A food grade grease pencil (butcher pencil) is used to mark the wheels with the date of manufacture.

This page documents the following (filled in as time progresses):

- Date of manufacture
- Type of cheese made
- Ingredients and corresponding lot numbers
- The date that the wheels were cut and packaged
- Where the wheels were sold

Chapter 15. Recall Plan in Preventive Controls for Human Food, 1st. Ed., was relied upon for several of the tables and a portion of the content. The manual is the training document for the USFDA approved course for Preventive Controls Qualified Individuals and was developed by the Food Safety and Preventive Controls Alliance (See Appendix L – References)



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix G – CONSTRUCTION AND DESIGN OF PLANT FOR SANITARY OPERATIONS

The purpose of this document is to modify the basic, generic recall model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific product strategy for our individual plant, the food safety plan can be more effective.

NOTE: This information, provided by MDARD, is for guidance purposes only. MDARD does not guarantee the accuracy, adequacy, applicability, or completeness of any information provided in this tool and is not responsible for any errors or omissions.



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1.Design and Construction

At Calico Creamery, the design and construction of our manufacturing facility is important. We need to consider design for our existing, new, or renovated facilities. After drawing the existing floor plan of our plant, we considered 2 things:

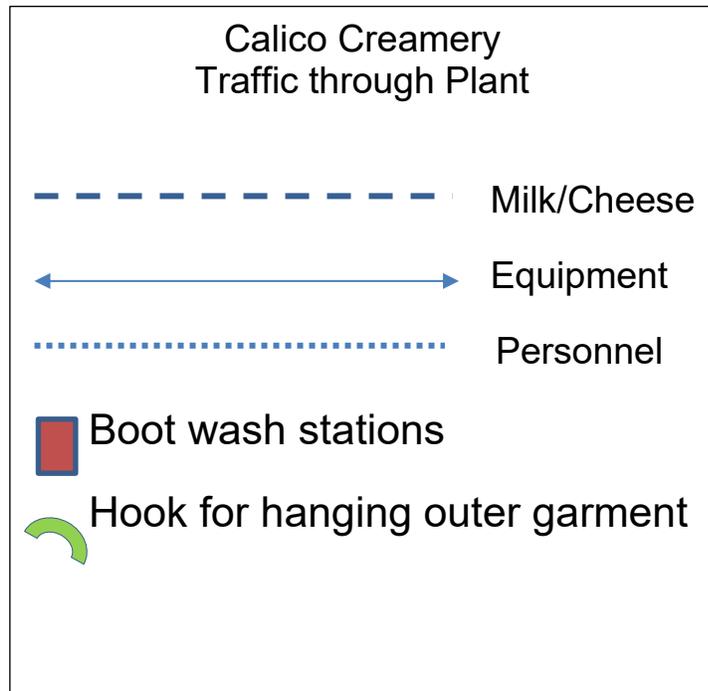
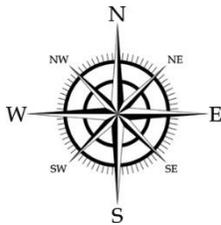
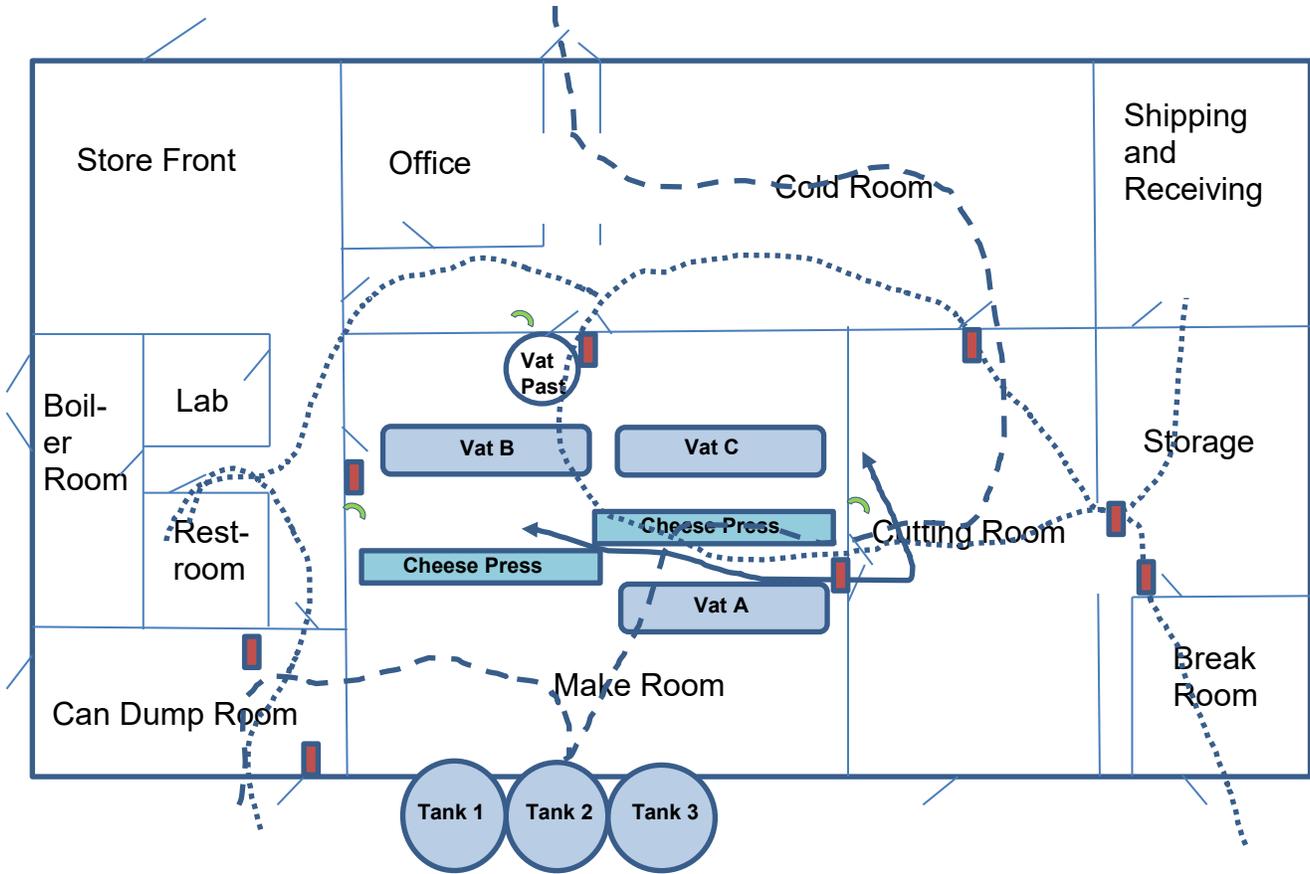
- Traffic through the plant including personnel, equipment, and product
- Airflow through the plant

Using the floor plan, we can reduce the potential for contamination. Because Calico Creamer is an existing facility, the task may be more difficult but still well worth the effort. If/when we renovate, or construct new facilities, the design will be maximized for food safety.

The floor plan on the following page is for Calico Creamery. Bess Crocker has drawn a simple map of her facility to show traffic and air flow patterns. It's important to consider the product pattern through the plant as well as personnel and equipment traffic. After creating a floor plan for our plant, we could see areas of improvement where cross-contamination can be eliminated.



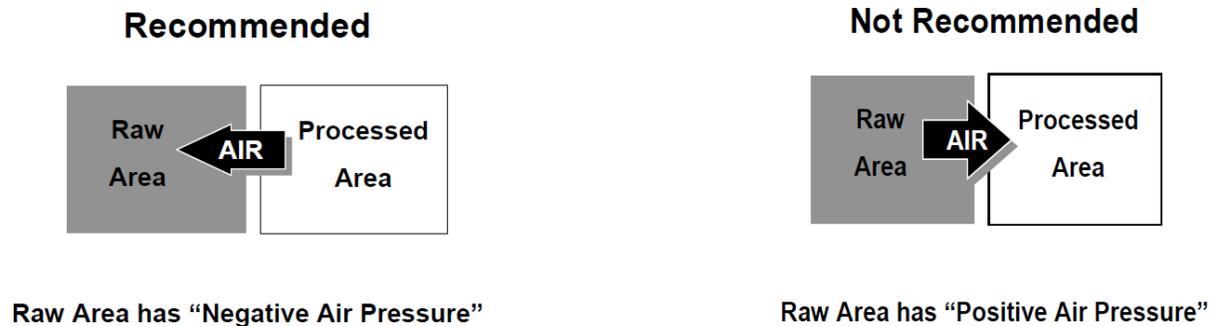
Figure 1.1: Plant Floor Plan





At Calico Creamery, we evaluated the air flow through our plant. It is recommended that air flow should have negative pressure in the raw processing area rather than in the RTE processing area.

Figure 1.2: Airflow Recommendations



2. Placement of Walls or Partitions

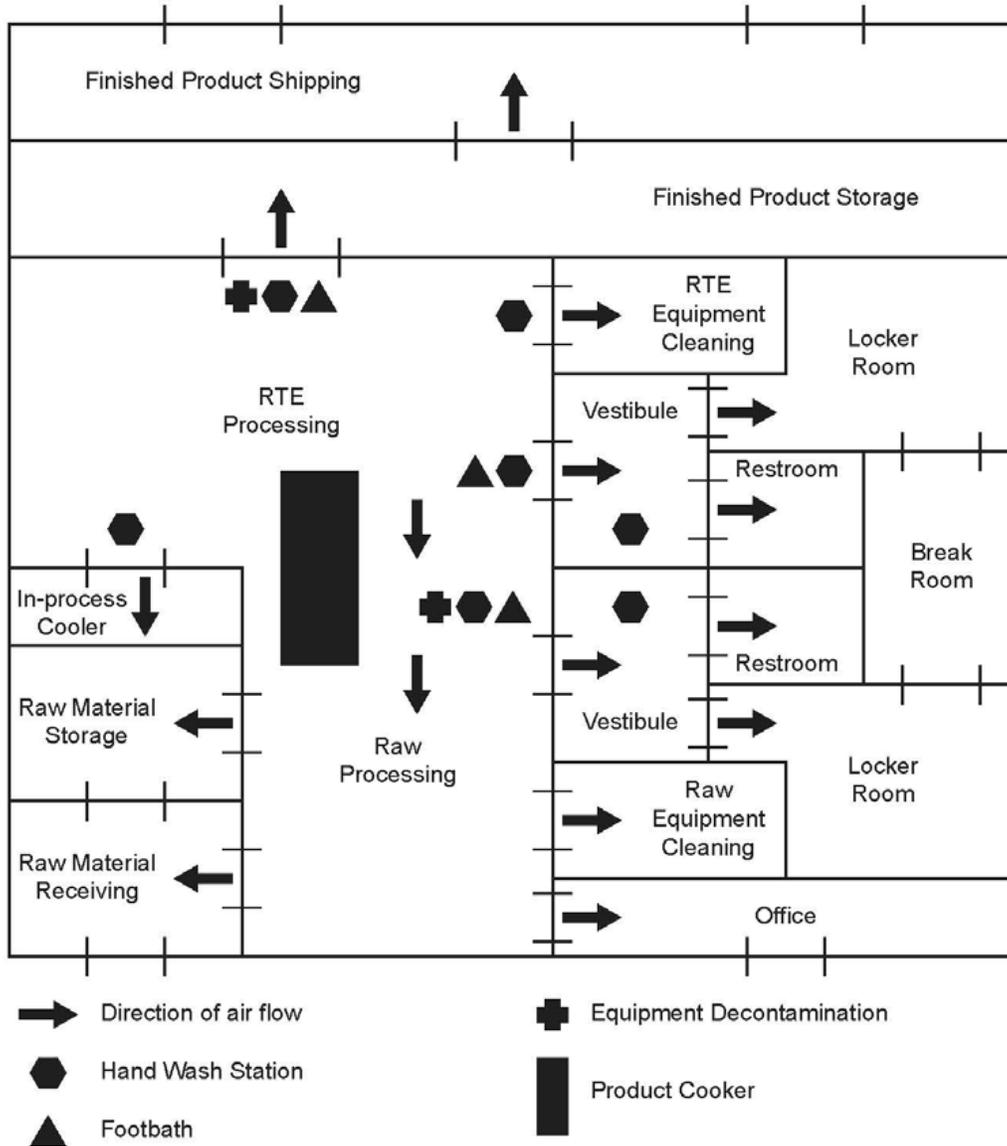
We also considered a floor plan from a document from CFSAN* (Center for Food Safety and Applied Nutrition) outlining the best scenario for airflow through a food processing plant to reduce the likelihood of contamination with *Listeria monocytogenes*. Although the floor plan is different, the airflow principals still apply.

In the following schematic, it is recommended that the plant be designed with partitions as follows:

- Between the office area and the raw processing area
- Between areas designated for receiving raw milk, storing raw milk, processing raw milk, and raw materials "in-process"
- The raw processing area and the area designated for cleaning equipment used in processing raw milk
- The raw processing area and a vestibule separating that area from rest rooms and locker rooms designated for use by employees when they work in the raw processing area
- The RTE processing area and a vestibule separating that area from rest rooms and locker rooms for use by employees when they work in the RTE processing area
- The RTE processing area and the finished product storage area
- The finished product storage area and the finished product shipping area



Figure 2.1: Airflow example



It is also recommended that the location of the air intake not be adjacent to the location of the air exhaust or other sources of airborne contamination such as waste disposal areas. This can help prevent contamination of intake air. Preventing contamination of intake air is particularly important when major construction or remodeling occurs in an existing plant. Using air-tight barriers, limiting access between construction and food production areas, and providing proper air flow can prevent introduction of contamination into the plant environment.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix H - A MODEL SANITARY EQUIPMENT REVIEW FOR A SMALL-SCALE DAIRY PLANT

The purpose of this document is to evaluate the sanitary equipment design used in dairy production in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific equipment strategy for our individual plant, food safety efforts can be more effective.

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At Calico Creamery, we asked 10 questions about the sanitary design of our equipment. These questions certainly exposed problems with our equipment but we feel it will also help us to determine which equipment to keep, which to modify, and which to replace. When purchasing used equipment, we always have concerns about sanitary design. Obtaining the user's manual and instructions for use are a must. Although there are many questions that, when asked and answered, will provide insight into the sanitary equipment decision-making process, these 10 queries are certainly among the priorities that we considered.

Question #1. Do the food contact materials meet 3A criteria for surfaces?

The picture on the right shows the two styles of sanitary stainless steel that are 3A approved.



At Calico Creamery, we want our food contact surfaces to be:

- non-reactive
- non-contaminating
- noncorrosive
- non-absorbent of any kind of liquid
- cleanable

This will ensure the prevention of biofilm formation and harborage niches for microorganisms, allergen-containing residues, or other chemical contaminants.



Question #2. Are all the welds sanitary?

At Calico Creamery, we certainly don't want improper welds on processing equipment and parts. We weren't sure how to evaluate the welds to determine if they needed repaired or replaced. Welds are the most common and problematic hurdles to good sanitation.



All three of the above butt welds are examples from sanitary stainless pipelines. The first photo shows a weld that is incomplete on the interior of the pipeline. It has a depression that is a hiding place for microbes and soils. The second picture shows a weld that was incorrectly terminated (too quickly to complete the whole weld). There is a pit that will collect milk solids. The second picture shows a weld that has not been ground and polished. It too poses some food safety risk.

We evaluated the sanitary design of our pipe welding at Calico Creamery. We found one with a lumpy surface.





We know that our clean-in-place (CIP) system won't touch it, no matter how good it is. One way to check the integrity of the interior pipe weld is to insert a borescope so you can view it. Our MDARD Dairy Inspector has a borescope available with advanced notice.

The picture below is an example of a weld that we found satisfactory. The weld isn't lumpy and there are no crevices to accumulate product.



There was one last thing that we noticed at Calico Creamery. We have seen pipelines and other stainless steel equipment become rusty. We learned that it is likely due to cross-contamination caused by grinders and polishers. Now our maintenance guys have equipment, including the stainless rods, the grinders, and polishers, dedicated to the sanitary stainless steel surfaces only.





Question #3 How are recesses and fasteners evaluated on food contact surfaces?

At Calico Creamery, we have tried to eliminate recesses. They become non-hygienic because milk solids become trapped. We found that if there is an uneven surface, it will become a holding place for dairy soils — a perfect place for bacteria to grow. We also fastened nuts on the bottom side of the product contact surface. Now we make sure that all nuts are mounted on the outside of the equipment. That way, if it vibrates loose, it won't fall into the cheese.



These are the holes on our cheese press where the jack can gain purchase and advance as more pressure is applied. We tried to keep these areas as clean as possible, but it is just a poor design.

This was the bottom side of our cheddar cutting tool. Needless to say, this was one of the first tools that we replaced. Notice also that one of the bolts isn't stainless steel... it should be.





Question #4. How do you evaluate the rolled edges on your equipment?

Sanitary Top Rim of Equipment

Acceptable:

Unacceptable:

We've got stainless steel tables in our plant where product is placed and we stuck our hand under them. We came up with a handful of glop because there is an edge underneath that is an excellent hiding place for soils and debris. Poor designs left an area that we were unable to clean and sanitize. All our equipment has been inspected for these edges. We now have tables that have structural integrity and no lip where debris can hide and settle. We stuck a picture of our mess below.





Question #5. How do you evaluate the sanitary design of equipment legs? Can you clean around them easily?

These are equipment legs and this is an example of why equipment floor supports can be unclean or hard to clean. If equipment legs are permanently mounted to the floor or elevated incorrectly, they can be almost impossible to clean. It's important to think of how to reach those nooks and crannies when selecting equipment.

Here are some photos of the types of legs to avoid:



Here are some photos of the types of legs that are sanitarily designed.





Safe and sanitary equipment also has smooth and cleanable surfaces. We took a look around our plant to determine if there were any other sources of contamination. We found paint.



Our raw milk silos are old and have peeling paint. We frequently must scrape and repaint it so that it doesn't contaminate our cheese.

Question #6. Is it easy to clean behind all of your equipment including control panels?

We didn't want anything on the walls that would be hard to clean around. (or anything for that matter, including signs, mirrors, pipes, equipment, etc.) Control panels should either be caulked or should be retrofitted to stand away from the wall.





On the previous page, the photo on the left shows that the control box is too close to the wall. The one on the right shows how a support post solves this problem, creating the space for us to see behind and underneath the control panel for effective cleaning. Also, control boxes and other switch boxes should have sloped tops to prevent moisture from settling on top of the door itself. These boxes should also be free of piano hinges, which are big dirt collection areas (See below).



Question #7. Is it easy to clean under and around our milk pumps?

Milk pumps attract both product and environmental dust. When we placed our pump on a solid base at Calico Creamery, it was easier to clean around. It was also easier to disassemble for hand-cleaning. The pumps should be elevated by mounting it on rails so that soils will fall through to the floor where we could sweep or mop them away. Below you can see a picture of our old design.

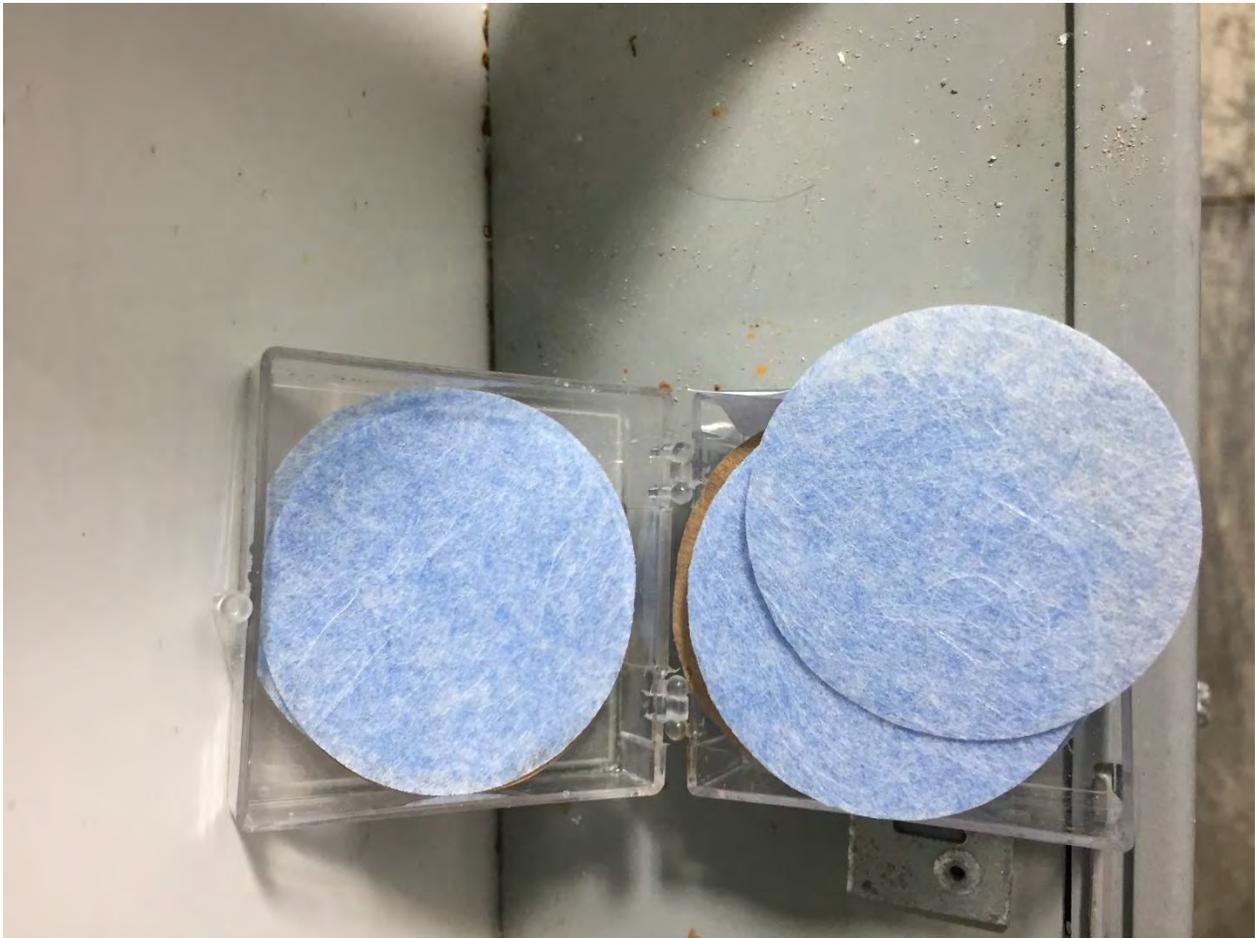




Question #8. Is the compressed air used for product or packaging zones sanitary?

At Calico dairy, we use compressed air in the bagger. This can be a sanitation problem. The compressed air lines can harbor and grow bacteria. Even though we dry the compressed air with a coalescing filter, when the line goes through a refrigerated area (like our cheese cave), then through a warm area (like the packaging area), then back into a refrigerated area, moisture will build up and bacteria will grow.

Wherever we have compressed air line that comes into product contact we ensure a 0.3 micron level at that point of use in the plant.



In addition to the point-of-use filters, we use pre-filters. As you can see from the next picture, the routine maintenance of these air filters got away from us.



It was easy to forget these pre-filters. Now we have them on our list of preventive maintenances. Here's how the filter should look.



Question #9. Are the rollers on conveyors properly designed?

Hollow roller on conveyor looks clean.



Photo: Robert L. Baker, ConAgra Refrigerated Foods, Inc.

Note organic matter in center when shaft is removed.



Photo: John Butts, Land O' Frost

The end caps allow moisture to get inside. Try to remember: whatever goes into the equipment can get out. The above photos show an example of the type of debris that can accumulate in a hollow roller.

Question #10. Are there deadlegs in the pipeline?



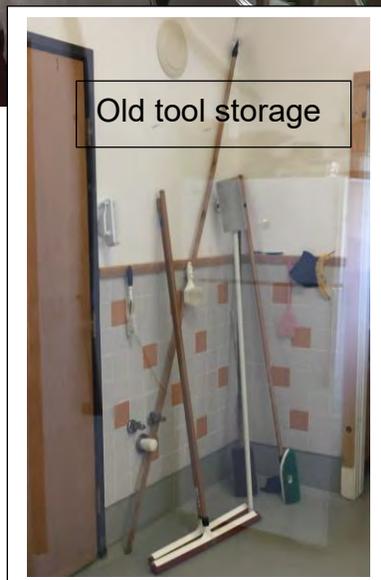
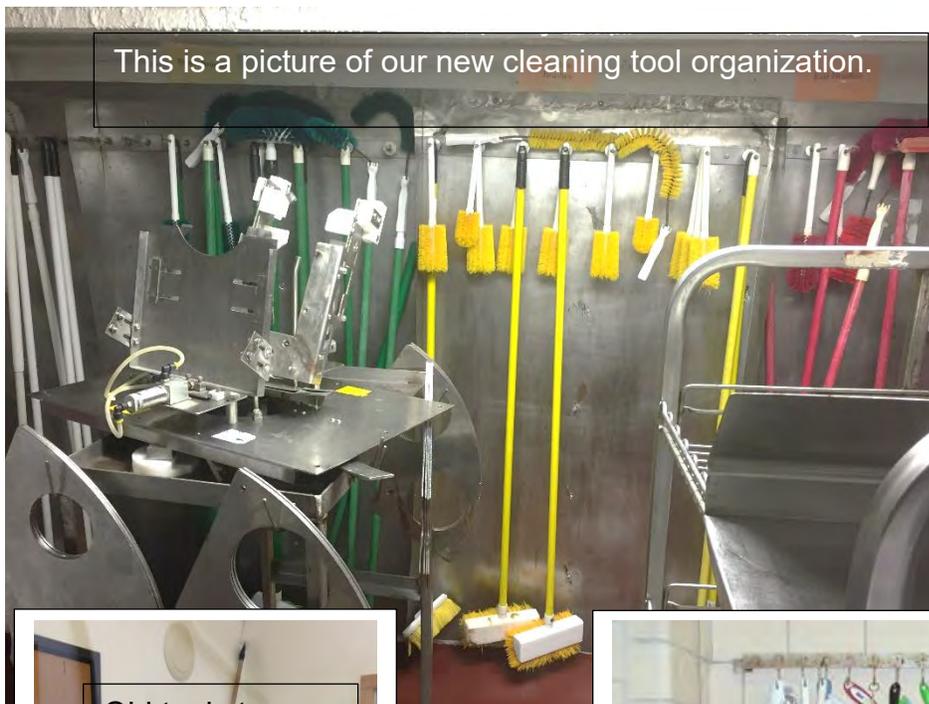
This was our sanitary water line for washing curds. It is recommended that if you cannot eliminate deadlegs, they should be no larger than two pipe diameters.



Utensils and Cleaning Tools

At Calico Creamery, we are proud of the changes that we have made to improve our food safety. We can honestly say that we were simply not aware that some of the following items were a problem because the utensils and cleaning tools “looked” clean.

These are the “before and after” pictures of our cleaning tools. As you can see in the top picture, we have color coded our tools to minimize the possibility for cross-contamination. We use red for raw, yellow for pasteurized, green for miscellaneous, and black for floor use items. Please also note that it is important to hang them up someplace that can be easily cleaned so that they can air dry between uses in a sanitary environment.





In the making of cheese at Calico Creamery, we use many tools. Here are examples of everyday cheese-making tools that needed repair or replacement.

We use our curd shovel to move curds in the vat. As you can see, the edges of the shovel become worn out over time and are very difficult to clean. We simply had these curd shovel edges ground down to a smooth and cleanable edge.



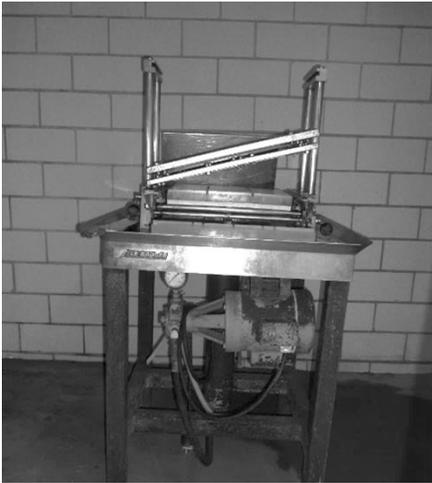


After accessing our curd strainers, we found cracks where one of our employees had been using a “C” clamp to attach it to the vat when draining whey. When we accessed the damage, there was a crack in the strainer. We ended up replacing this strainer as a weld in this area would have created its own cleaning issues. We also re-wrote the SOP for whey draining.

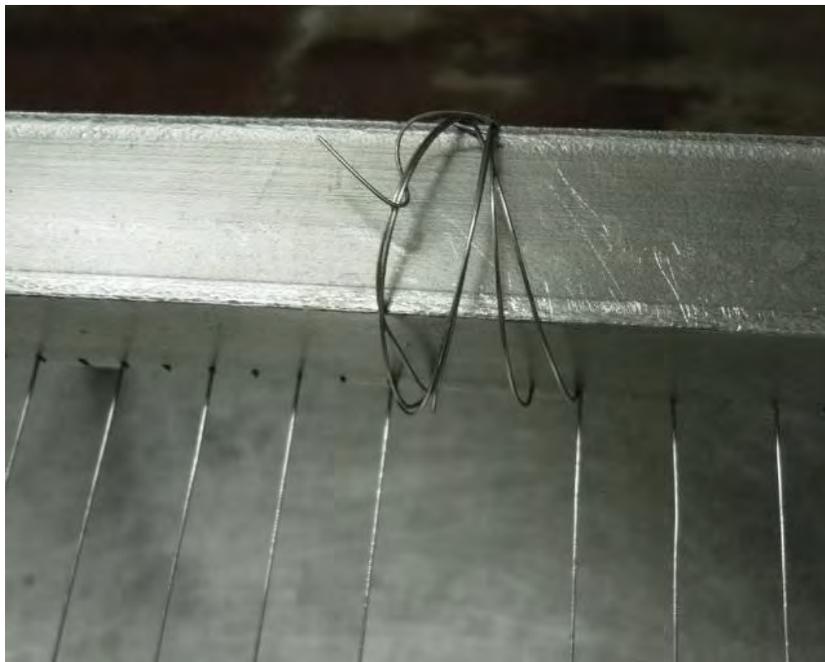




Calico Creamery has used the same cheese slicer for many years. The face plate had become cracked and we could not find replacement parts for it. We decided to have a new face plate manufactured for it using the old one as a template. The biggest hurdle in repairing this equipment was finding food safe materials to manufacture the replacement part.



Cheese harps are used to cut the curd. It is very important to keep up with maintenance on these and all the tools we use.





**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

**Appendix I - A MODEL SUPPLIER VERIFICATION PROGRAM FOR A
SMALL-SCALE DAIRY PLANT**

The purpose of this document is to modify the basic, generic supplier approval program model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific supplier strategy for our individual plant the food safety plan can be more effective.

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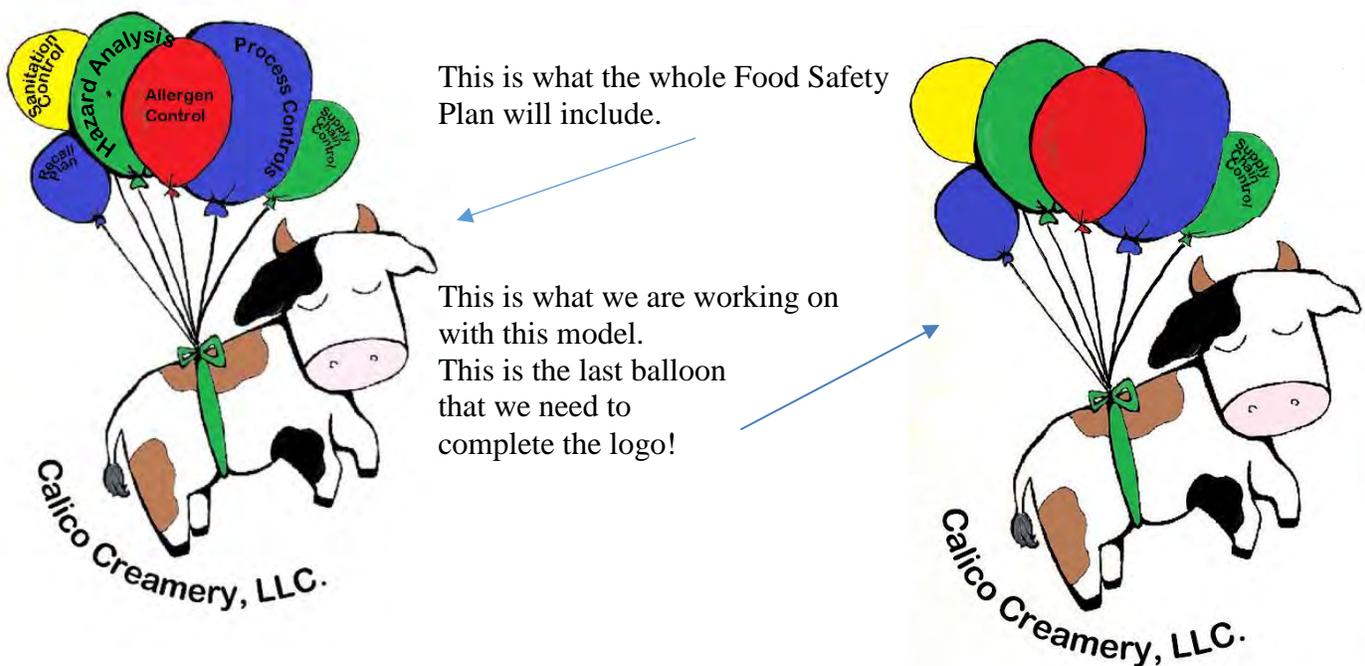


1. Introduction

When Calico Creamery needed to create a supplier verification program, Bess Crocker realized that she had never even thought about where her ingredients originated. After some confusion, she realized that she needed a simple program that assessed and confirmed that her suppliers were manufacturing their products under the same sanitary principals that were used at Calico Creamery. She soon realized that it was important to have effective quality and food safety controls in place which provided the plant with a sufficient level of 'due diligence'. Although it never occurred to her, she recognized that some products and ingredients received may pose a risk to her food safety.

Here's another way to look at it: The Food Safety Plan for Calico Creamery will eventually become our food logo. This specific plan will help us develop a recall plan inherent in our specific manufacturing process.

Figure 1.1: Food Safety Plan



The supplier approval program at Calico Creamery was developed to have the following components:

- New supplier verification
- Documenting the approval process
- Maintaining supplier documents
- Review and approval of raw materials before acceptance from suppliers



2. Procedure

- A. Calico Creamery's Food Safety Coordinator (Bess Crocker) will document all steps taken in the approval process.
- B. Bess will determine supplier compliance by:
 - a. Research of warning letters and import alerts on FDA website
 - b. Review of supplier past performance (current suppliers)
 - c. Review of references from industry partners and trade organizations
 - d. Review of supplier contact information
 - i. Purchasing/ordering contact
 - ii. Quality concerns contact
 - iii. Food safety program (PCQI contact) if different than Quality contact
 - iv. Recall coordinator (if different than Quality or Food safety contact)
 - e. Review of suppliers food safety program including:
 - i. FDA facility registration (when required)
 - ii. Food Safety Plan (if the product is processed by supplier)
 - iii. PCQI (Preventive Controls Qualified Individual) credentials when a FSMA compliant plan is required
 - f. Review of a 3rd party audit (or most recent regulatory inspection/audit)
 - g. A site visit maybe required if necessary
 - h. For any identified hazard that is controlled by supplier, Calico Creamery will require documentation showing that the hazard is minimized or eliminated

Table 2.1: Examples of documents to request from supplier

Hazard type	Microbiological	Chemical	Physical
Example of documents to request	-Certificate of analysis (COA) -Certificate of processing (e.g. Pasteurization, irradiation) -Internal/3 rd party test results	-Allergen policy -Certificate of conformance -Letter of guarantee -Certificate of analysis	-Metal detector policy -GMP procedure -Foreign material program



- C. Bess Crocker will assign all raw materials a risk level based on likelihood and occurrence of hazards.
- Risk Level A: Hazard will cause life threatening illness or injury if not controlled.
 - Risk Level B: Hazard will cause minor illness or injury if not controlled.
 - Risk Level C: Hazards are present, but not likely to cause any illness or injury.
 - Risk Level D: No hazards identified
- D. Bess Crocker will perform supplier verification activities within the first 90 days after approving supplier and thereafter at a frequency based on the risk of the product.

Table 2.2: Frequency for requesting verification

a. Risk Level A:

Verification	Frequency
Review: <ul style="list-style-type: none"> • Specification • Letter of Guarantee • Import Alert/ FDA Warning Letters • Complaints/ Corrective Actions • Certificate of Conformance • Policies/ Procedures • On-site audit and/or validation of 3rd party audit 	First 90 days/ Bi-Annual
COA Validation	Bi-Annual

b. Risk Level B:

Verification	Frequency
Review: <ul style="list-style-type: none"> • Specification • Letter of Guarantee • Import Alert/ FDA Warning Letters • Complaints/ Corrective Actions • Certificate of Conformance • Policies/ Procedures • 3rd party audit 	First 90 days/ Annual
COA Validation	Annual



c. Risk Level C:

Verification	Frequency
Review: <ul style="list-style-type: none"> • 3rd party audit • Specification • Letter of Guarantee 	First 90 days/ Annual

d. Risk Level D: No verification activities needed

E. Annual supplier assessments

- a. An annual review of all suppliers and ingredients will be conducted by Bess Crocker.
- b. Failures and problems experienced with a supplier are to be documented in production records. This information is used for reconsidering the suitability of suppliers either at the time of a failure or during a review.
- c. Potential new suppliers will be assessed initially on the recommendation of knowledgeable staff or vendors.
- d. To maintain approved supplier status, all verification activities must meet or exceed company expectations and all supplier performance issues will be addressed and documented.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix J - A MODEL EMPLOYEE HEALTH PLAN FOR A SMALL-SCALE DAIRY PLANT

The purpose of this document is to modify the basic, generic employee health model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific employee health strategy, for our individual plant, the food safety plan can be more effective.

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1. Introduction

Calico Creamery had never thought about creating an employee illness policy. The plant had always been so small that everyone knew each other... there didn't seem to be a need. After careful review though, the employees realized that there may have been times when they went to work sick. They all agreed that it would be a good idea to have an Employee Illness Policy in place. The following is a copy of the policy that went into the Employee Handbook.

Figure 1.1: Health Policy Example



Calico Creamery Employee Health Policy **(Last reviewed – June 18, 2017)**

Calico Creamery is committed to ensuring the health, safety and well-being of our employees and customers and complying with all food safety regulations. All food employees shall report if they are experiencing any of the following symptoms:

- Vomiting
- Diarrhea
- Jaundice
- Sore throat with fever
- Infected wound or pustular boil (regardless of size and located on the fingers, hand or any exposed body part)

Calico Creamery food employees must also notify whenever diagnosed by a healthcare provider as being ill with any of the following diseases that can be transmitted through food or person-to-person by casual contact such as:

- *Salmonella typhi*
- *Shigella*
- Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*
- *Hepatitis A*
- *Norovirus*

In addition to the above conditions, food employees shall notify the person in charge if they have been exposed to the following high-risk conditions:

- Exposure to or suspected of causing any confirmed outbreak involving the above illnesses,
- Exposure by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as an individual who works or attends a setting where there is a confirmed diagnosed with any of the above illnesses, or,
- Exposure by living in the same household as an individual diagnosed with any of the above illnesses.



2. Food Employee Responsibility

All Calico Creamery food employees need to follow the reporting requirements involving symptoms, diagnosis, and high risk conditions specified. All food employees subject to the required work restrictions or exclusions that are imposed upon them as specified in law, the regulatory authority, or person in charge, shall comply with these requirements as well as follow good hygienic practices always.

3. Management Responsibility

The person in charge should take appropriate action to exclude, restrict, and/or monitor food employees who have reported any of the conditions. Calico Creamery feels that it is important to ensure these actions are followed and only release the ill food employee when he/she is well.

If there were an outbreak investigation, Calico Creamery's policy is to cooperate with regulatory authorities and adhere to all recommendations provided to stop the outbreak from continuing. The person in charge will ensure that all food employees who have been conditionally employed, or who are employed, complete the food employee health questionnaire (available through MDARD – or your inspector) and sign the form acknowledging their awareness of this policy. Calico Creamery will continue to promote and reinforce awareness of this policy to all food employees on a regular basis to ensure it is being followed.

Ok, let's be honest, we took a half hour break to review the Health Questionnaire together. It was a fun way to familiarize ourselves with the kind of questions that we need to be asking. If you take the time to review it (below), you'll understand why it was important to train the employees with the questions that are on it.



Figure 3.1: MDARD Health Questionnaire

Michigan Department of Agriculture

FORM 1-A Conditional Employee and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees or Conditional Employees with Emphasis on illness due to Norovirus, *Salmonella Typhi*, *Shigella* spp., Enterohemorrhagic (EHEC) or Shiga toxin-producing *Escherichia coli* (STEC), or hepatitis A Virus

The purpose of this interview is to inform conditional employees and food employees to advise the person in charge of past and current conditions described so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

Conditional employee name (print) _____
 Food employee name (print) _____
 Address _____
 Telephone Daytime: _____ Evening: _____
 Date _____

Are you suffering from any of the following symptoms? (Circle one)

	YES / NO	If YES, Date of Onset
Diarrhea?	YES / NO	_____
Vomiting?	YES / NO	_____
Jaundice?	YES / NO	_____
Sore throat with fever?	YES / NO	_____

Or

Infected cut or wound that is open and draining, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cut, wound, or lesion not properly covered?
 (Examples: *boils and infected wounds, however small*)

YES / NO _____

In the Past:

Have you ever been diagnosed as being ill with typhoid fever (*Salmonella Typhi*)? YES / NO _____
 If you have, what was the date of the diagnosis? _____

If within the past 3 months, did you take antibiotics for *S. Typhi*? YES / NO _____
 If so, how many days did you take the antibiotics? _____

If you took antibiotics, did you finish the prescription? YES / NO _____

History of Exposure:

1. Have you been suspected of causing or have you been exposed to a confirmed foodborne disease outbreak recently? YES / NO _____
 If YES, date of outbreak: _____

a. If YES, what was the cause of the illness and did it meet the following criteria?
 Cause: _____

i. Norovirus (last exposure within the past 48 hours)	Date of illness outbreak _____
ii. <i>E. coli</i> O157:H7 infection (last exposure within the past 3 days)	Date of illness outbreak _____
iii. Hepatitis A virus (last exposure within the past 30 days)	Date of illness outbreak _____
iv. Typhoid fever (last exposure within the past 14 days)	Date of illness outbreak _____
v. Shigellosis (last exposure within the past 3 days)	Date of illness outbreak _____



Michigan Department of Agriculture

FORM 1-A (continued)

b. If YES, did you:

- i. Consume food implicated in the outbreak? _____
- ii. Work in a food establishment that was the source of the outbreak? _____
- iii. Consume food at an event that was prepared by person who is ill? _____

2. Did you attend an event or work in a setting, recently where there was a confirmed disease outbreak? YES / NO

If so, what was the cause of the confirmed disease outbreak?

If the cause was one of the following five pathogens, did exposure to the pathogen meet the following criteria?

- a. Norovirus (last exposure within the past 48 hours) YES / NO
- b. *E. coli* O157:H7 (or other EHEC/STEC (last exposure within the past 3 days) YES / NO
- c. *Shigella* spp. (last exposure within the past 3 days) YES / NO
- d. *S. Typhi* (last exposure within the past 14 days) YES / NO
- e. hepatitis A virus (last exposure within the past 30 days) YES / NO

Do you live in the same household as a person diagnosed with Norovirus, Shigellosis, typhoid fever, hepatitis A, or illness due to *E. coli* O157:H7 or other EHEC/STEC?
YES / NO Date of onset of illness _____

3. Do you have a household member attending or working in a setting where there is a confirmed disease outbreak of Norovirus, typhoid fever, Shigellosis, EHEC/STEC infection, or hepatitis A?
YES / NO Date of onset of illness _____

Name, Address, and Telephone Number of your Health Practitioner or doctor:

Name _____
Address _____
Telephone – Daytime: _____ Evening: _____

Signature of Conditional Employee _____ Date _____

Signature of Food Employee _____ Date _____

Signature of Permit Holder or Representative _____ Date _____



Figure 3.2: Employee Health Chart*

Food Employee Foodborne Illness Guidelines

Illness Symptoms Action Guidance (Food Code Sections 2-201.12, and 2-201.13)

Symptoms	Action	Return to Work Criteria for Food Employees	Local Health Department Approval
Vomiting	Exclude from retail food establishment	Symptom free for at least 24 hours or provide medical documentation that states the symptom is from a noninfectious condition	No, if not diagnosed as one of the Big Five
Diarrhea	Exclude from retail food establishment	Symptom free for at least 24 hours or provide medical documentation that states the symptom is from a noninfectious condition	No, if not diagnosed as one of the Big Five
Jaundice	Exclude from retail food establishment; call manager; Notify Health Department	Medical documentation that food employee is free of hepatitis A virus or other fecal-orally transmitted infection	Yes
Sore Throat with Fever	Restrict from food area of retail food establishment	Medical documentation stating received antibiotic therapy for >24 hours; one negative throat culture; or is free from infection from <i>Streptococcus pyogenes</i>	No
*Infected Wound or Pustular Boil	Restrict from food area of retail food establishment	*After the skin, infected wound, cut, or pustule boil is properly covered	No

* Note: Associated hands and wrists must be free of cuts or sores that are red or oozing, unless an impermeable cover is used over the sore and a single-use glove is worn over the impermeable cover. Cuts or sores on exposed portions of the arms and other body parts must be covered with an impermeable cover or tight-fitting bandage.

The Big Five are: 1. *Salmonella typhi* 2. *Shigella* 3. Shiga toxin-producing *Escherichia coli* 4. *Hepatitis A* 5. *Norovirus*
 If you have been diagnosed with, or exposed to these illnesses, they are so contagious that you must be excluded from work at a food establishment, and you cannot return to work at a food establishment until approval has been received from the Local Health Department.

Criteria for Exclusion from Work: Any food employee diagnosed with an illness due to the Big Five must report the diagnosis to the manager. The food employee must be excluded from working in the retail food establishment and the law requires the manager to notify the local health department immediately. Before a food employee is allowed to return to work, check with the local health department.

www.michigan.gov/mda

Funded by Act No. 52, of P.A. 2000, Industry Food Safety Education Fund

*We hung a copy of this poster in the break room at Calico Creamery. Our Dairy Inspector provided a copy for us but it is also available on the MDARD website.



**Prepared by: Bess Crocker - Food Safety Coordinator
For: Calico Creamery**

Appendix K - ENVIRONMENTAL MONITORING IN A SMALL-SCALE DAIRY PLANT

The purpose of this document is to modify the basic, generic environmental sampling model for dairy production based on current and future conditions in our small-scale artisan dairy plant. The formation of a basic plan, that outlines the potential contamination in our dairy production, will mitigate human health related hazards. By creating a specific environmental monitoring strategy, for our individual plant, the food safety plan can be more effective.

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1. Purpose

At Calico Creamery, we understand that environmental monitoring is an important verification tool for assessing trends as well as finding the source and dispersion of any microbiological or allergen contamination in our plant. Because the cheese-making process begins with raw milk, one microbial pathogen of concern for Calico Creamery is *Listeria monocytogenes* (Lm). *Listeria* spp. (species) is widely distributed in nature and could be present in our dairy processing environment. This could lead to a serious concern for our business. Presence of Lm in dairy products has resulted in outbreak situations, product recalls, destruction of contaminated product, extensive sanitation procedures, and major financial losses for dairy operators.

At our creamery, we have always depended on visual cleanliness to make sure that our equipment is clean. Despite its subjective nature, visually clean turns out to be an excellent approach and remains part of our standard operation approach today. But in spite of the effectiveness of looking to make sure the equipment is clean, we would like to be able to demonstrate that we have control of pathogens and allergens within the processing plant --- and those we cannot see. The goal for us is to ensure that we have taken all necessary precautions to monitor pathogens and allergen residues and prevent accidental cross contamination of products. The preventive controls rules suggest several approaches to monitor allergen residues and the effectiveness of sanitation protocols above and beyond the visually clean standard.

2. Why Monitor?

Listeria monocytogenes (Lm) grows between 31°F and 122°F. That means cold or hot, it could be at Calico Creamery. This microorganism has been isolated from plants, soil and surface water samples and has also been found in silage, sewage, milk of normal and mastitic cows and human and animal feces. The Center for Disease Control and Prevention reported that listeriosis had the second highest fatality rate (20%) and the highest hospitalization rate (92.2%) of all infections caused by foodborne pathogens. This elevated degree of severity highlights the importance of minimizing exposure, particularly among populations of high risk.

Although Lm is eliminated by pasteurization, post-processing contamination of dairy products is possible. The International Dairy Foods Association (IDFA) *Guidance for Controlling Listeria monocytogenes* recommends that establishments who environmental sample be focused on zones 2 and 3 of the processing environment. These zones are described as those adjacent to product contact surfaces, such as equipment framework (zone 2) and processing area floors, drains and walls (zone 3). The IDFA Guidance document also recommends that environmental sampling should focus on the most critical areas of the plant, which includes areas after the pasteurization step and the packaging area. To ensure the environmental sampling program is as robust and effective as possible, establishments should make it a practice to also include food contact surfaces (identified as zone 1) in their sampling plans. Doing so ensures that the product is also being monitored along with the processing environment.



3. Calico Creamery's Monitoring Program

The monitoring program at Calico Creamery includes the following information:

- Frequency of testing - once monthly
- Number of samples that will be collected - (3) non-food contacts surfaces (zones 2 and 3) and one (1) food contact surface swabs will be taken in the plant
- If the samples will be tested individually or composited – we test individually but rotate to different areas of the plant each month.
- When during operations the swabs will be taken – we swab at least three (3) hours into the production day.

Figure 3.1: Calico Creamery Environmental Sampling Worksheet

Using the plant layout map above, fill in the information for each environmental sample taken.

Date 3/12/17
 Time 3:05 pm
 Sampler's Initials J. Allen

Sample One:
 • Zone #2
 • Type of Swab used pathogen
 • Exact location of Swab the outside of vat A along the southeast side
 • Result from Lab NF On file? yes - elec 3/17/17

Sample Two:
 • Zone #2
 • Type of Swab used pathogen
 • Exact location of Swab on the rack handle of the press (west press)
 • Result from Lab NF On file? yes - elec 3/17/17

Sample Three:
 • Zone #1
 • Type of Swab used pathogen
 • Exact location of Swab on the bed of the cast press where the first hoop will sit
 • Result from Lab NF On file? yes - elec 3/17/17

Sample Four:
 • Zone #3
 • Type of Swab used pathogen
 • Exact location of Swab The floor next to the drain by silo #1
 • Result from Lab NF On file? yes - elec 3/17/17



4. Selection of Sample Sites

Food contact surfaces (FCS) are anywhere an exposed surface or object has direct contact with the unpackaged cheese. To create a good environmental sampling program, select sites in the final production or packaging areas which are exposed to both the environment and the product or where there is a higher probability of RTE product contamination. Some suggested food contact surface sites in the final production and packaging areas are:

- Slicers, dicers, shredders, etc.
- Carts and racks
- Cheese molds
- Blades of slicers
- Packaging tables, conveyor belts
- Scales
- Cutting tables
- Utensils (knives, trays)
- Packaging equipment (vacuum packaging machines, platens, etc.)
- Employee gloves/hands, aprons
- Doors, door knobs

Figures 4.1 – 4.4: Photos of Sampling



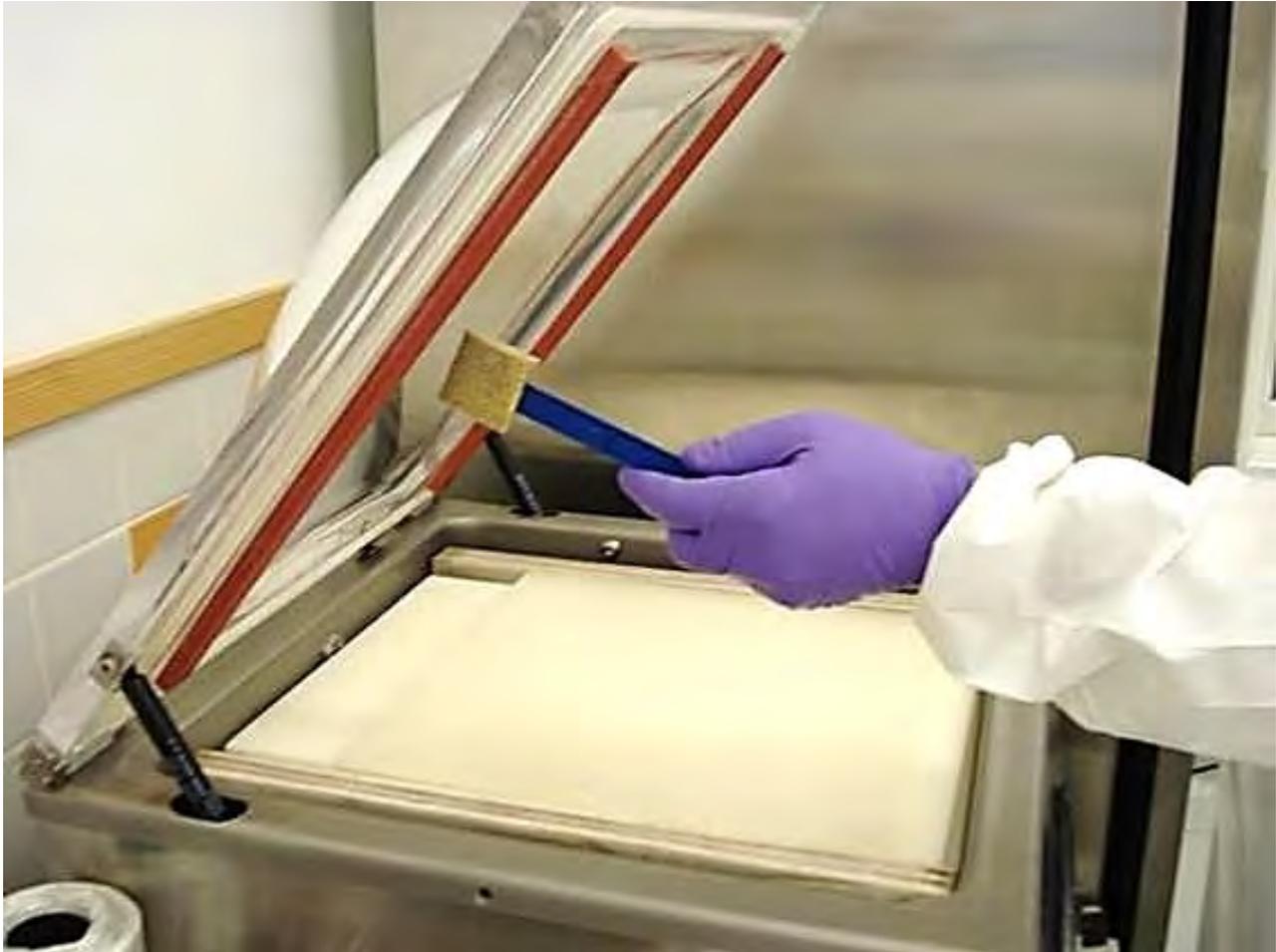
Sample pail handles



Swab knife blades and handles



Swab door handles



Swab gaskets of vacuum packaging equipment

Here at Calico Creamery, we select areas of the processing environment to sample by giving priority to the area most at risk; where the risk of post-processing contamination is higher. When/if those samples come back negative, the next month we will move onto another processing area. Prior to starting sampling, we survey the area to determine the sites to be sampled, and document them.

Our cheese is washed rind cheddar but in other cheese processing establishments, the highest risk cheeses would include:

- Soft mold ripened cheese lines (e.g. Brie, Camembert, Blue, Gorgonzola)
- Soft and semi soft fresh cheeses (e.g. Feta, Havarti, Queso Fresco, Queso Blanco)
- Paneer, Ricotta, Mozzarella
- Washed rind cheeses (e.g. St. Paulin, Oka, Tomme)



5. Environmental Sampling Techniques

When obtaining samples from the processing/packaging environment, aseptic sampling must be used for all samples taken for microbiological purposes. It is a technique which uses sterile containers and equipment to prevent the introduction of any contamination from outside sources into either the product or sample taken. Following proper hygiene practices is also of utmost importance in maintaining aseptic sampling techniques.

When samples are taken under these conditions, it is assumed that the results of the analysis indicate the actual conditions under which the product was manufactured or handled. Cross-contamination caused by the person taking samples is avoided, if proper procedures are followed. If Lm is found in the sample, then it can be indicative that it was introduced during the manufacturing process and not by the sampler. (Canadian Food Inspection System)

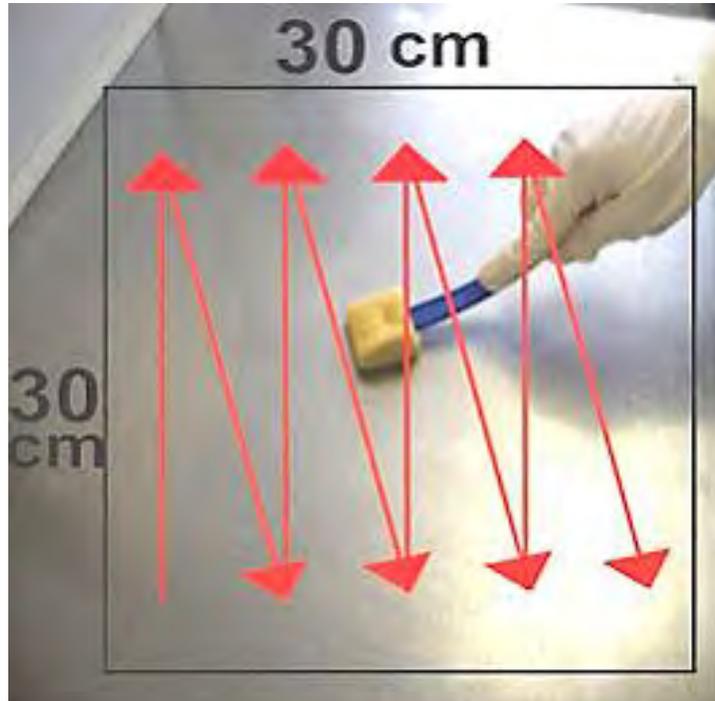
Environmental sampling kits are supplied by the laboratory you choose to send your samples to. Instructions on how to sample appropriately should be included with the kit. Upon receipt of the kits and before taking samples, review the instructions on sanitary sampling techniques and the content list supplied with the kits. Avoid contaminating the materials in the sampling kit. Any time sponges or other components of the sampling kit become contaminated during the sampling process (even if minimal and accidental), they must be discarded and not included in the sampling set. If resources permit, it is recommended that the swabbing process be completed by two individuals.

At Calico Creamery, we follow this swabbing protocol:

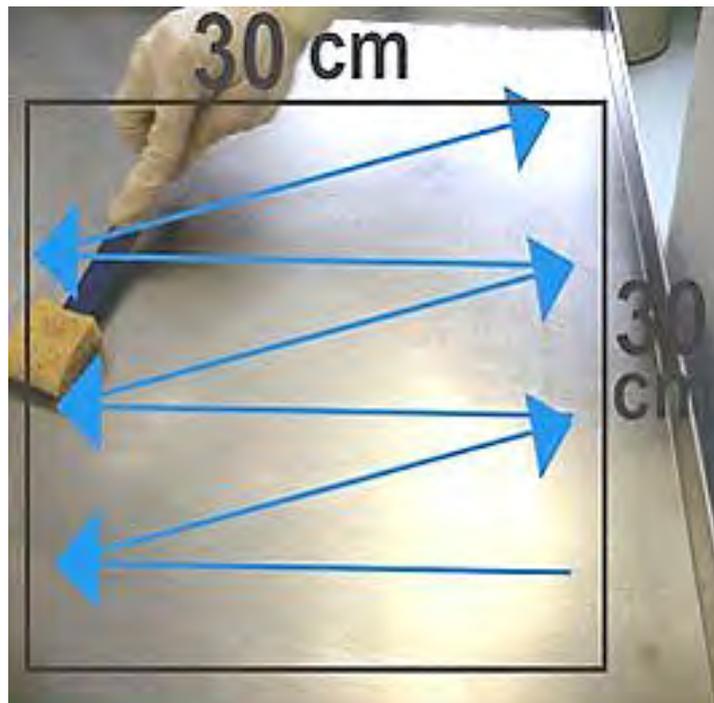
- Label the twirl-tie sample bags and record your information about the sampling site. (It is best to use a waterproof soft felt pens for labeling the bag so that you do not puncture the bag while writing)
- Thoroughly wash and dry hands
- Open the package containing the pre-moistened sterile swab, put on sterile gloves and take the sterile swab out.
- Rub the swab firmly and thoroughly over the surface to be sampled. Without lifting the swab, swab the surface area up and down until the whole target surfaced is covered. (See Figure A) Turn the swab over and swab the surface area from right to left until the whole target surface is covered.



Figures 5.1 – 5.3 Sampling Techniques



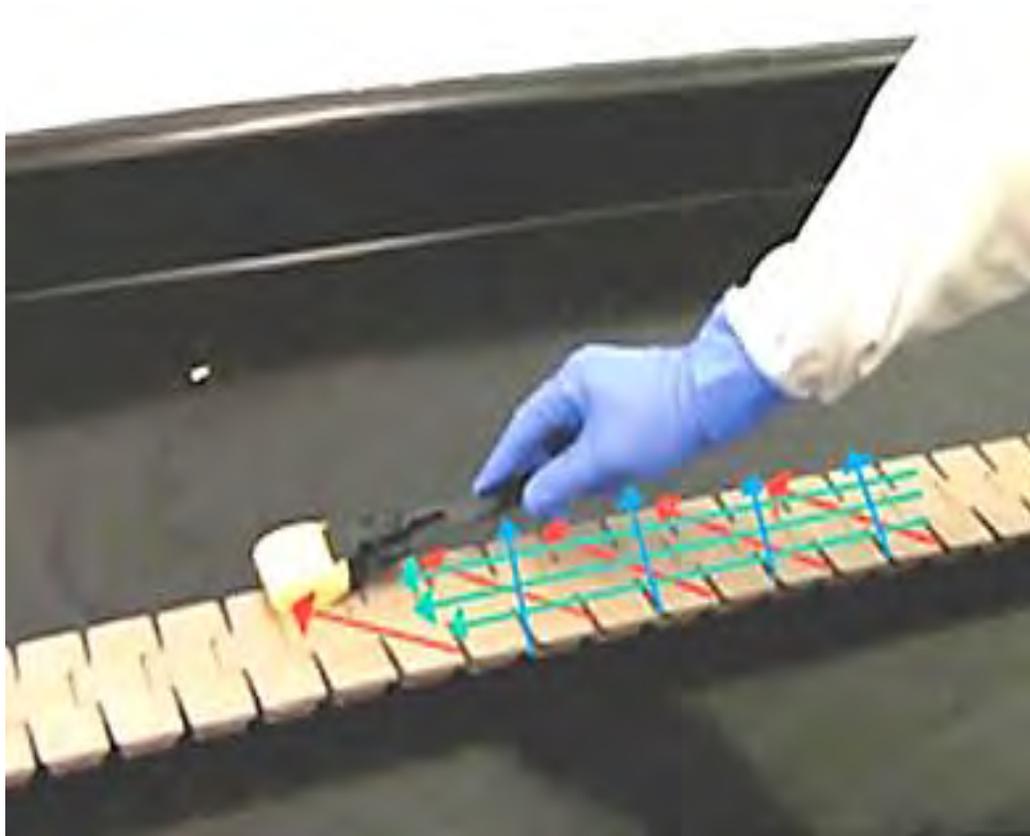
Up and Down motion



Right to Left motion



- For surfaces which are difficult to swab because of their design (such as conveyor belts), it may not be possible to swab a defined area using the above mentioned procedure. In this situation swab the area to be sampled using the same technique described (up and down/left and right). This allows the sampling of every plane of the surface that will likely come into contact with the food (see below).



Irregular surface swabbing

Once the swabbing step is complete, we follow the steps listed below:

- Release the swab into the appropriately labeled sample bag. Do not let the swab touch the outside of the bag.
- Seal the bag, making sure not to contaminate the sample.
- Place the bag into a Styrofoam box.
- Sanitize the sample site using appropriate sanitizer solution
- Change gloves for next sampling site
- Send to the lab where the samples can be composited for testing



Calico Creamery documents the following information in the records for our environmental samples (to follow FSMA recommendations):

- The name of the laboratory that will be conducting analytical testing
- Identification of the sample that was obtained (including date of sampling, initials of sampler etc. where applicable)
- Location of sampling (name of sampling site)
- Date of the test at the lab
- Target microorganism
- Analytical methods used
- Results of testing per unit volume (per gram, per cm², per ml or per analytical unit for presence/absence tests).
- Results noted as negative or not detected should also include analytical units to illustrate the sensitivity of the test.

6. Unsatisfactory Results

At Calico Creamery, we had an open and honest discussion about environmental sampling. **What would happen if we found a positive result in the creamery?** Was it better for us not to know? Who could have access to our documents? All of these questions were very unnerving for our staff. We did some research and found information from FDA on what to do with the results from this environmental testing. Bess drew up a flow chart that addressed testing results and follow-up actions for positive findings of *Listeria* spp. on non-food and food contact surfaces during sampling periods. When all is said and done, we feel much more confident in our product. We still rely heavily on our visual assessments but the environmental sampling gives us the added layer of confidence in our cheeses.

Like I said, we have found positive results in our plant... and it was frightening. We were, however, able to use the results and the flow charts below as teaching tools for the employees... and they worked! We documented everything and feel secure in our documentation of testing and corrective actions. If there were ever a customer complaint, Calico Creamery has used every tool to assure a safe product.



Figure 6.1: Flowchart for Sampling Non-food Contact Surfaces

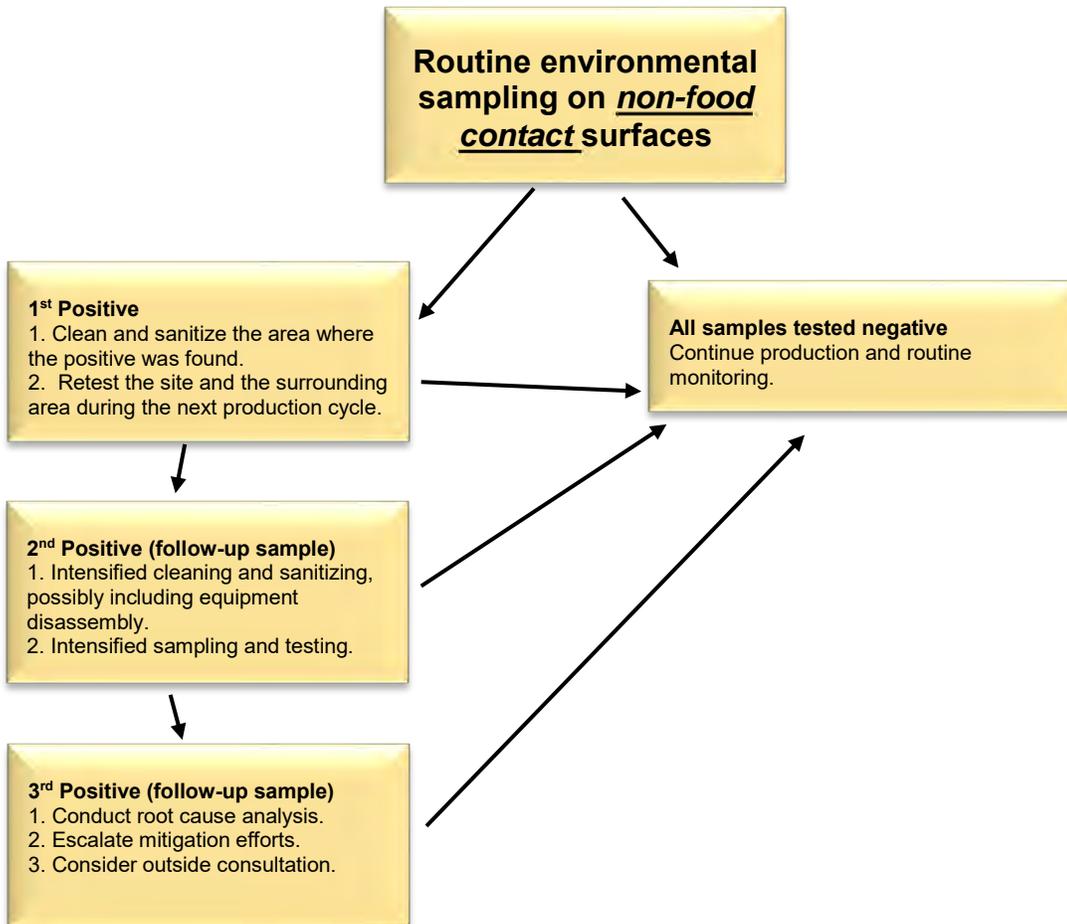
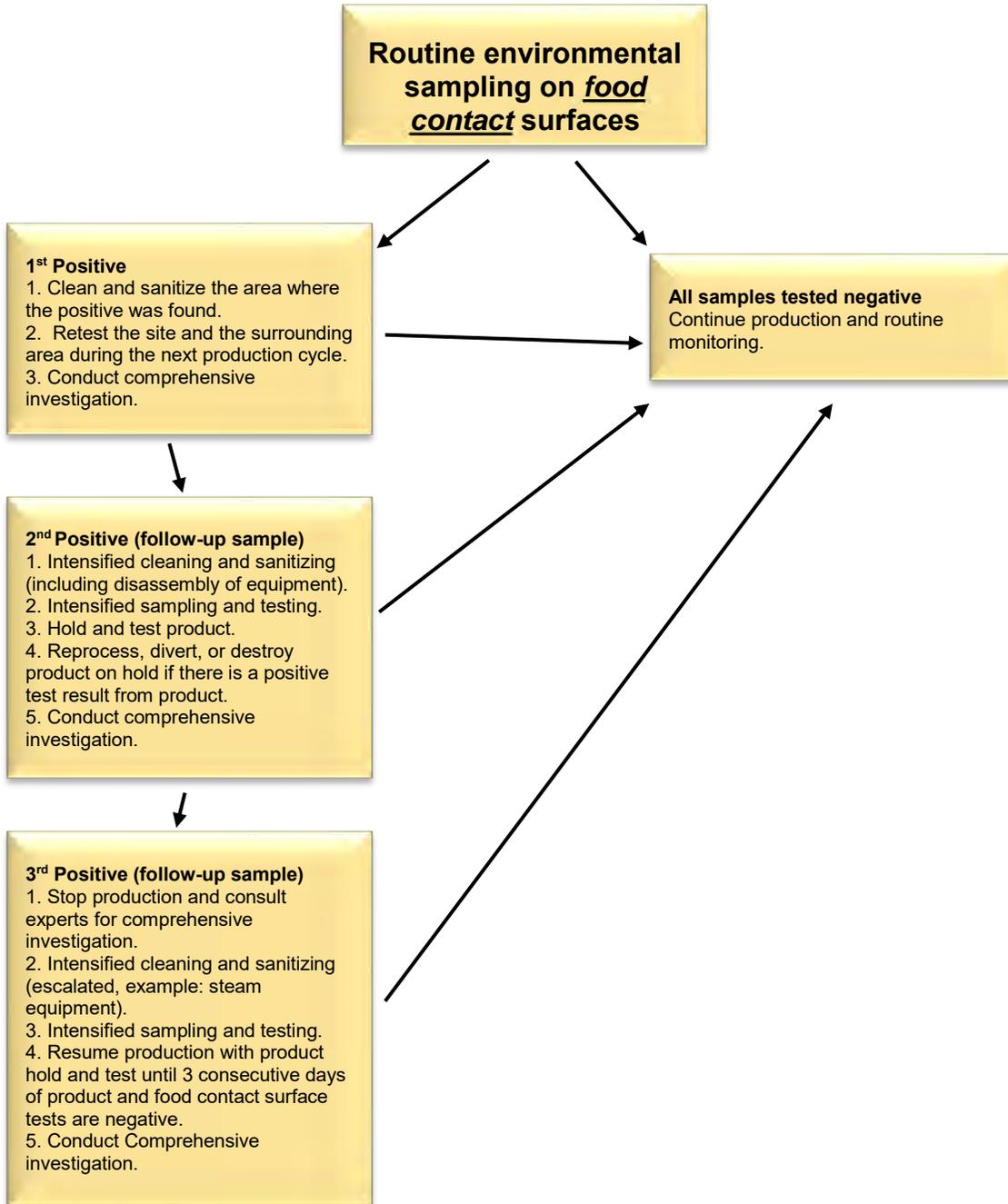




Figure 6.2: Flowchart for Sampling Food Contact Surfaces





7. Root Cause Analysis

As mentioned before, we have found positive results for *Listeria* species in our plant. When we detected *Listeria* spp. we conducted a comprehensive root cause analysis and took corrective actions immediately based on our written environmental monitoring procedures. (We also carefully documented the corrective actions.)

Here is what we did:

- Examined the equipment that yielded the positive finding and the area surrounding the positive site in all directions for potential sources of *Listeria* spp. or *L. monocytogenes*. We paid attention to possible niches that allow harborage.
- We reviewed our Food Safety Plan and its implementation to determine if there are any design or execution flaws and modified our plan as necessary.
- We conducted intensified sampling and testing of the sites that represented a potential source of the *Listeria* ssp identified in the earlier examination and collected samples several times during production to identify the source of contamination.
- We tested upstream from the positive result (in the flow of production) to help identify the source of contamination.
- We checked maintenance records for modifications or repairs to major equipment.
- We interviewed and observed our personnel to determine whether appropriate procedures were being followed.
- We reviewed production, maintenance, and sanitation procedures to determine if we should modify the procedures to prevent contamination. Then we make those modifications identified by our review.
- We reviewed traffic patterns, equipment layout, and adherence to personnel hygiene procedures; and took appropriate actions based on findings.

After conducting the root cause analysis, we found deficiencies and short cuts that were corrected. Two other tools that were particularly useful for the staff at Calico Creamery were the the potential sources of contamination (found in figure 7.1) and contamination scenarios (see figure 7.2).



Figure 7.1. Potential Sources of *L. monocytogenes*

Description	Potential Sources of <i>L. monocytogenes</i> *
Ingredients	Raw foods, such as: <ul style="list-style-type: none"> • Raw meat, poultry, and seafood • Raw milk • Raw produce
Processing materials	Compressed air Ice Brine solutions
Food contact surfaces for our cheese	Fibrous and porous-type conveyor belts Filling and packaging equipment Belts, peelers, and collators Containers, bins, tubs and baskets Slicers, dicers, shredders and blenders Utensils
Surfaces that generally do not contact our cheese	In-floor weighing equipment Cracked hoses Hollow rollers for conveyances Equipment framework Wet, rusting, or hollow framework Open bearings within equipment Poorly maintained compressed air filters Condensate drip pans Motor housings Maintenance tools (e.g., wrenches and screw drivers) Forklifts, hand trucks, trolleys, and racks On/off switches Vacuum cleaners and floor scrubbers Trash cans and other such ancillary items Tools for cleaning equipment (e.g., brushes and scouring pads) Spiral freezers/blast freezers Ice makers Aprons In-floor weighing equipment Cracked hoses Hollow rollers for conveyances Equipment framework Wet, rusting, or hollow framework Open bearings within equipment Poorly maintained compressed air filters Condensate drip pans Motor housings Maintenance tools (e.g., wrenches and screw drivers) Forklifts, hand trucks, trolleys, and racks On/off switches Vacuum cleaners and floor scrubbers Trash cans and other such ancillary items Tools for cleaning equipment (e.g., brushes and scouring pads) Spiral freezers/blast freezers Ice makers Aprons
Plant environment	Floors, especially cracks and crevices Walls Drains Ceilings, overhead structures, and catwalks Wash areas (e.g., sinks), condensate, and standing water Wet insulation in walls or around pipes and cooling units Rubber seals around doors, especially in coolers Metal joints, especially welds and bolts Contents of vacuum cleaners



Figure 7.2: Contamination Scenarios

**Reminder: Any of the following has the potential for contamination.
Please take care with our cheese.**

- Used equipment is brought from storage or another plant and installed into the process flow.
- An equipment breakdown occurs or packaging line is moved or modified significantly.
- Construction or major modifications are made to an area where our cheese is processed or exposed (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
- A new employee, unfamiliar with the operation and *L. monocytogenes* controls, has been hired to work in, or to clean equipment in, the area where our cheese is processed or exposed.
- Personnel who handle our cheese touch surfaces or equipment likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other required procedures before handling the cheese.
- Periods of heavy production make it difficult to clean the floors of holding coolers as scheduled.
- A drain backs up.
- Cheese is caught or hung-up on equipment. (Stagnant product in a system can be a major site of microbial growth during production.)
- Raw or under-processed foods are placed in an area designated for our cheese.
- Frequent product changes on a packaging line cause you to change packaging film, labels, forming pockets or molds, line speeds, etc.
- Personnel are used interchangeably for packaging raw milk and cheese.
- Increased production causes us to perform wet cleaning of lines that have been taken down from production in the same room as lines that are running cheese.
- Heat exchangers have become compromised (e.g., with pinholes).
- Equipment parts, tubs, screens, etc. are cleaned on the floor.
- Waste bins in the cheese production area are not properly maintained, cleaned and sanitized.
- Personnel handling the cheese come into contact with these items and then contaminate the foods and/or food contact surfaces.
- Re-circulating pumps and lines are not cleaned and sanitized.
- Indiscriminate use of high-pressure hoses in cleaning.
- Inappropriate use of footbaths in dry processing areas.
- Water is sprayed on wheels on transport carts when in-process cheese is stored near the wheels.



Appendix L - References

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