



THE DAIRY PRACTICES COUNCIL®

**GUIDELINE FOR
FOOD SAFETY
MODERNIZATION ACT (FSMA)
PREVENTIVE CONTROL
GUIDANCE**

Publication: DPC089

JULY 2023

Prior Version – None

**APPROVED COPY
EXCEPTIONS FOR INDIVIDUAL STATES NOTED IN TEXT OR
FOOTNOTES**

Additional Guidelines may be ordered from:

<https://www.dairypc.org>

evp@dairypc.org



Guideline Preparation and Review Process

Guideline development within Dairy Practices Council (DPC) is unique and requires several levels of peer review. The first step in the process of guideline development starts with a Task Force subcommittee comprised of individuals from industry, regulatory and education interested in and knowledgeable about the subject to be addressed. Drafts, referred to as ‘white copies,’ are circulated until all members are satisfied with the text. The final white copy may then be distributed to the entire Task Force, DPC Executive Vice President and whoever the Task Force Director feels would add to the strength of the review. Following final white copy review and correction, the next step in the process requires a yellow cover draft that is circulated to the member Regulatory Agency representatives that are referred to as “Key Sanitarians.” The Key Sanitarians may suggest changes and insert footnotes if their state standards and regulations differ from the text. After final review and editing the guideline is distributed in the distinctive DPC green cover to people worldwide. These guidelines represent the state of the knowledge at the time they are written.

Disclaimer

The DPC is not responsible for the use or application of the information provided in this Guideline. It is the responsibility of the user to ensure that the information addresses their needs and that any action taken complies with appropriate regulations and standards.

DPC is a Registered Trademark of the Dairy Practices Council®

Reproduction or use in whole or in part of any text or graphic content without written permission from the DPC is prohibited.



TABLE OF CONTENTS

Cover Page	i
Guideline Preparation and Review Process	ii
Disclaimer	ii
TABLE OF CONTENTS.....	1
INTRODUCTION	3
DEFINITIONS.....	3
GUIDELINE CONTENT	4
Hazard Requiring a Preventive Control	4
Preventive Control Requirements	5
Program Key Elements.....	6
Supplier Management.....	6
Foreign Supplier Verification.....	7
Recall Plan.....	7
Allergen Control.....	9
Sanitation.....	12
Process Control.....	13
Good Manufacturing Practices	13
Product Traceability	14
Food Defense/Intentional Adulteration	14
Training	15
Pathogen Monitoring.....	17
Calibration	18
Record Review	19
Verification and Validation	20
Corrective and Preventive Action	21
Monitoring.....	22
Visitor & Contractor Management.....	23
Premises Preventive Maintenance.....	24
Equipment Preventive Maintenance.....	24
Management of Pests and Vermin.....	25
Foreign Material Control.....	27
Temperature Management of Raw, In-Process, & Finished Product.....	30
Shipping, Receiving, and Warehouse Controls.....	31
Chemicals	32
Internal Audits.....	33



Complaint Management	34
Document Control/Record Control	34
Crisis Management/Business Continuity	35
Rework	36
Identity Preserved Foods	36
REFERENCES	37
APPENDIX.....	38
Appendix A: Hazard Tables	38
Appendix B: Hazard Analysis Table and Preventive Control Summary Table Examples	40
Appendix C: Contract Manufacturing Ingredient Scenarios	44
Appendix D: DMI Slide of Supplier Assessment Criteria	45
Appendix E: Overview	46
Appendix F: Preventive Controls Checklist.....	47
CURRENT ACKNOWLEDGEMENTS	51
Officers.....	51
Task Force Director.....	51
Lead Author(s)	51
Contributor(s)	51
HISTORICAL ACKNOWLEDGEMENTS	51



INTRODUCTION

This guideline has been developed to help companies evaluate their food safety programs for gaps covering FSMA regulations, but it is strongly encouraged for companies to read the actual Food Safety Modernization Act (FSMA) law CFR 117. It is also recommended that each facility re-evaluate their food safety program from start to finish to ensure that all aspects of the FSMA law are incorporated.

DEFINITIONS

Preventive Control (PC) – Those risk-based reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing or holding at the time of the analysis.

Critical Control Point (CCP) – A step in your process at which a control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. This step will likely be preventive control.

Control Point (CP) – A step in your process at which a control can be applied to aid in the reduction or elimination of a food safety hazard.

Hazard – A biological, chemical (including radiological) or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Reasonably Foreseeable Hazard – Biological, chemical (including radiological) or physical hazard that is known to be or has the potential to be associated with the facility or the food.

Corrections – Steps taken to timely identify and correct a minor, isolated problem that occurs during food production.

Corrective Action – Actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce.

Preventive Controls Qualified Individual (PCQI) – An individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified Individual – A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Validation – Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazard.

Verification – Application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.



Standard Sanitation Operating Procedures (SSOP) – A procedure followed routinely that describes in detail the steps to be taken including the supplies needed, safety precautions to follow, chemical concentration checks (if applicable), responsibility, etc.

Pre-Requisite Programs (PP) – Procedures including Good Manufacturing Practices which address operational conditions that provide the foundation of the Food Safety Plan.

Food Safety Controls – Programs such as Pre-Requisite Programs and Preventive Controls that have been put in place to help manage identified food safety hazards.

Food Safety Plan – Policies and procedures implemented and trained to meet regulatory requirements and build a food safety culture. Programs include Good Manufacturing Practices, Pre-Requisite Programs and Standard Operating Procedures designed to maintain batching, processing, manufacturing, and storage areas in a clean and safe environment for manufacturing food products.

GUIDELINE CONTENT

A Preventive Controls Checklist was created and incorporated into this guideline to help companies determine if they are required to be FSMA compliant as well as whether they have all the steps and elements to be considered compliant.

Hazard Requiring a Preventive Control

A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system. The chart in Appendix A can be used to help determine whether the hazard would require a Preventive Control.

After conducting the hazard analysis, controls to mitigate or reduce the hazard will either be controlled using a Preventive Control (PC) or a Pre-Requisite Program (PP). The chart in Appendix E is a visual representation of how the PC's and PP's can be categorized. Preventive Controls would be grouped into one of the following categories: (example forms are provided in Appendix B)

1. Processing Preventive Control
2. Sanitation Preventive Control
3. Allergen Preventive Control
4. Supply Chain Preventive Control
5. Recall Plan



Preventive Control Requirements

- Hazard Analysis (HA) – This includes the identification of hazards that may occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain. The hazard analysis must include the following elements:
 - Severity and probability of the hazard occurring.
 - Processes and programs implemented to minimize the risk of occurrence down to an acceptable level.
- Preventive Control Food Safety Plan – These are measures that are required to ensure that hazards requiring preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan. The plan elements include a chart indicating:
 - Preventive Control – Step in the process where a program has been implemented to minimize the hazard.
 - Description of the hazard that is being controlled by the preventive control.
 - Parameters established to determine what is required to control the hazard.
 - Monitoring responsibilities that describe what is being monitored, who is doing the monitoring, how it is being monitored and at what frequency.
 - Corrective Action program describing what actions will be taken when the preventive control is found outside the established parameters.
 - Verification activities described stating what will be verified, at what frequency and the qualified individual who will be doing the activity.
 - Records listed that will be used to show the monitoring and verification activities.
- Monitored according to the plan to provide assurance that the preventive controls are consistently performed.
- Corrective Actions or corrections that will be taken.
- Verified according to the plan.



Program Key Elements

The following programs should be evaluated as part of the hazard analysis process and a determination based on risk of whether the program should be considered a Preventive Control or Pre-Requisite Program. Some preventive controls are required, and these are identified above in the section Hazard Requiring a Preventive Control. The chart found in Appendix A can be used to help determine if the risk of the hazard is significant enough to require it to be a Preventive Control.

Supplier Management

*Required if the Hazard Analysis indicates a PC is needed

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. Risk Based (i.e., PC not needed if the controls are applied at a subsequent entity such as a Customer or Processor) <ol style="list-style-type: none"> a. Risk Assessment b. Letter of Assurance 2. Approved Suppliers or unapproved only on a temporary basis with verification activities required. Verification activities may include, but are not limited to: <ol style="list-style-type: none"> a. Third Party Audit requirement and review b. Review of documents such as COA, Letter of Guarantee, etc. c. Product Testing d. Conduct a survey/questionnaire e. Audit 3. Documentation explaining the control needs to be on file 4. Foreign Supplier Verification Program (if applicable – refer to Program) 	<ol style="list-style-type: none"> 1a. Risk assessment completed including HA of food, the entity that will be controlling the hazard, and supplier performance. Refer to Appendix D for hazards that could be associated with the supplier. 1b. Food controlled by a subsequent entity should state “not processed to control (identified hazard)” and a letter of assurance from the controlling entity stating the controls that will be applied shall be on file. Letter must be renewed annually. 2a. Verification activities can be done by the facility or a broker/distributor, but the facility is ultimately responsible for verifying that the hazards are controlled. 2c. Testing requirements for incoming raw materials shall be based on the risk assessment of the raw material, the supplier, and regulatory requirements. Testing requirements shall be documented. Testing shall be done using an approved testing methodology. 3. All documentation must be maintained according to the record retention program. 4. Refer to Foreign Supplier Verification Program (refer to Appendix B for example form. Appendix C is a chart that may be used to help determine who owns the responsibility when dealing with co-manufacturers).



Foreign Supplier Verification

*If applicable

Requirements	Example Programs/Records:
<p>Must understand the scope of the organization's Supplier Management Program to determine if this applies. If it applies, the program must include the following elements:</p> <ol style="list-style-type: none"> 1. Hazard Analysis (based on experience, illness data, scientific reports, etc.) on each supplier and raw material. This should include, but is not limited to formulation, condition of manufacturing facility, ingredients being used, transportation practices, harvesting/manufacturing/processing practices, packaging and labeling activities, storage, distribution, intended use, and sanitation, including employee hygiene. 2. Evaluation of Food Risk and Supplier Performance 3. Supplier Verification 4. Corrective Actions 5. Exemptions and Modified Standards 6. All Foreign Suppliers must be registered with the FDA. 	<p>Written program needs to be created that outlines what activities the facility will do to verify Foreign Suppliers. List should be risk based and follow the hazard analysis, consider the supply being purchased, the supplier and any known entities about both. Things to consider include formulation, condition of manufacturing facility, ingredients being used, transportation practices, harvesting/ manufacturing/ processing practices, packaging and labeling activities, storage, distribution, intended use, and sanitation, including employee hygiene.</p> <p>Proof of FDA registration is required to ensure they meet FSMA requirements.</p> <p>Monitoring activities need to be spelled out and include the frequency. These need to be documented and corrective actions taken for any deficiencies.</p>

Recall Plan

*Required

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. A Recall plan must be written. 2. The written Recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: <ol style="list-style-type: none"> a. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected. b. Notify the public about any hazard presented by the food when appropriate to protect public health. c. Conduct effectiveness checks to verify that the recall is carried out; and 	<ol style="list-style-type: none"> 1. Written program needs to be on file and follow the FDA's requirements that can be found on the FDA's website (noted below). The procedure should list how a potential problem could be found, lab testing, employee, customer complaint or regulatory notification. How to initiate a recall and how to notify the FDA which will include a copy of the label, individual package label and case label and directions of use. Product identification numbers, lot numbers with an explanation of your lot number, expiration or use by date and UPC code. Have a list of who is on the recall team and what they are responsible for



<p>d. Appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food).</p>	<p>handling. Team and their contact information should be updated regularly to ensure the most up to date information is available. The type of recall, recall strategy and its elements, depth of the recall; wholesale level, user level, retail level, consumer level, urgent recall letter, public warning and effectiveness checks need to be recorded. Keep records of recall status reports, all records from customer contacts, how much product was returned/destroyed and what was done with the product. Destruction of the product shall be documented, and this can be done with pictures and/or affidavit from the destruction company. Test the recall plan at least yearly to confirm you have everything in place. Keep an updated customer list with the plan.</p> <p>2a. Create an urgent recall letter to notify the customer of what the issue is and remove the product from use and notify their customers of the issue and to do the same. Record who, when and how you notified them.</p> <p>2a. If the product goes out to the public (retail), send out a public warning letter notifying them of the issue. Record how and when.</p> <p>2a. In both letters notify them what you want done with the product. Copy the FDA on all letters sent.</p> <p>Email address that you will need if you have to recall product: Food Safety and Inspection Service (FSIS) Index of local offices and phone numbers: https://www.fsis.usda.gov/wps/portal/food/ome</p> <p>Reportable Food Registry https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry</p>
--	---



Allergen Control

*Required if the Hazard Analysis indicates a PC is needed

Requirement:

1. Prevent cross-contact.
2. Ensure accurate labeling on finished food products.

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. A Company Standard or Allergen Control Policy 2. A list of all allergens in the plant 3. Allergen line Assessment 4. Specific food allergen controls are determined through the hazard analysis process which results in appropriate control points in the food safety plan. 5. Allergen Cleaning – Procedures and checklists specific to lines or areas where product changeovers between allergen and non-allergen occur. Employing sanitary design principles like the GMA or DMI checklist for any new equipment. (Refer to links under program examples) 6. Facilities shall follow GMPs and employ other control strategies to prevent cross contact. These include but are not limited to: <ol style="list-style-type: none"> a. Storage and Processing b. Ingredient Receiving, Storage and Handling (Ingredient risk assessment is part of Supply Chain Quality) – Proper identification of allergen and color coded. c. Segregation – dedicated facilities, processes, lines, specific pieces of equipment - if they are hard to clean and storage areas. d. Separation – use of barriers or space to contain or isolate allergenic materials. e. Traffic flow – describe traffic flow and restricting employees, materials and or products when entering or leaving an allergen area in the facility. Can include maps. f. Uniform/Shoe Control – specific policies and standards that describe employee practices when entering/working in an allergen area in the facility. 	<p>1-4. A written Allergen Control Program shall be created, trained, and implemented that covers all allergens in the plant and the controls implemented to ensure no cross contamination. A list of allergens shall be created, and all existing and new ingredients reviewed to ensure there are no new allergens introduced. An annual allergen assessment shall be conducted that includes a review of the overall program, the list of allergens in the facility, and the verification of the allergen controls. Allergen controls can include, but are not limited to: scheduling of production, cleaning, verification of cleaning, storage and segregation of raw materials and finished product, rework controls, labeling of in-process and finished product, traffic flow, etc. Allergen controls shall be established as either Preventive Controls or Pre-Requisite programs based on the evaluation of the hazard analysis using the chart found in Appendix A.</p> <p>5. Allergen cleaning shall be done between different allergens and before a non-allergen product is run. A cleaning matrix that outlines what cleaning and sanitizing is required between each product shall be created as part of the SSOP. The SSOP shall include what steps need to be taken at changeover to ensure the line is cleaned prior to running a new product. A checklist shall be created to ensure all changeover steps are completed. Verification of cleaning needs to be conducted on a regular basis. Verification can include, but is not limited to, CIP verification (time, temperature, etc.), allergen swabs, visual inspection of changeover practices, micro testing, etc. Cleaning procedures</p>



<p>g. Sanitation (refer to Sanitation Program)</p> <p>h. Scheduling – production planning that takes allergenic materials into consideration with the intent to reduce the frequency of allergen changeovers and potential cross-contact.</p> <p>i. Product and ingredient tracking – proper labeling and record keeping that timely identification and traceability of allergen containing ingredients, in-process materials and finished products.</p> <p>j. Rework management – proper identification of allergenic rework and utilization back into like-product.</p> <p>7. All employees, contractors, and visitors (appropriate to their need) shall be properly trained on allergens and allergen controls to prevent cross contact.</p> <p>8. Packaging Control – assuring the right label is used on every product is critical to protecting allergic consumers and preventing a recall. Based on the HA of the line and product on the line an Allergen Label Review may be required for the preventive control at this process step and can be a CCP or it can be managed as part of an Allergen Control Plan. Label handling procedures and workflow documentation.</p> <p>9. Changeovers and Cleaning (Refer to Sanitation Program).</p> <p>10. A standard that explains that an ingredient/product shall be rendered non-compliant due to cross contact with a piece of equipment that has processed any allergen unless that equipment has been cleaned according to a validated cleaning procedure (SSOP) for allergen changeovers.</p> <p>Program Management Elements</p> <ol style="list-style-type: none"> 1. Monitoring 2. Corrective Actions 3. Verification Activities 4. Validation (Validation of allergen cleaning is not required but is highly recommended) 	<p>shall be validated, as well as the process used, at least annually and documented.</p> <p>6a-c. Storage of raw materials and in-process allergen products needs to be done in a way to prevent cross contact and contamination. Containers and utensils shall be clearly labeled or color coded. Examples of proper storage include never storing an allergen containing product above a non-allergen containing product. Another example of good storage practices includes pictures of the allergen being added to the outside of containers for easy identification of the allergen within.</p> <p>6e-f. Traffic flow and uniforms in allergen areas need to be designated as much as possible to prevent cross contact. Restricted traffic may not be feasible, but all care should be taken to ensure employees entering the area cannot transfer an allergen to a non-allergen area of the facility.</p> <p>6g. Refer to #5 above.</p> <p>6h. Allergens shall be scheduled with like allergens or in a manner that they will not pose a threat of cross contact. A production matrix outlining the run and cleaning process should be created for all products.</p> <p>6i. Refer to Product Traceability Program.</p> <p>6j. Refer to Rework Program.</p> <p>7. Refer to Visitor & Contractor Management Program.</p> <p>8. All labels need to be stored in a way that they are easily identifiable and controlled. All allergens in the product shall be noted on the label per regulatory requirement.</p> <p>9. Refer to #5 above.</p> <p>10. Refer to #5 above.</p> <p>Program Management Elements</p> <ol style="list-style-type: none"> 1. Monitoring – Changeover procedures, inspections, and checklist documentation. 2. Corrective Actions – In the event that an allergen cross contact event has occurred, an investigation is conducted, and the incident is documented. Any finished product, rework, ingredient, or packaging
--	---



	<p>materials that are affected (as determined by the investigation) are dispositioned to stock feed, landfill, or other appropriate use by QA. A CAPA plan is developed and documented as part of the incident report.</p> <ol style="list-style-type: none"> 3. Verification Activities – Visual inspections, ATP swabs, allergen swabs, and/or testing of flush material are documented including frequency. Other examples are audits and inspections, consumer complaints, review of incidents. 4. Validation – If validation is used; a documented program to describe details of initial validations of new products/changeovers or lines. It should also include additional validations such as an annual validation. Detailed procedures for how much sample is collected, what frequency, how the samples are to be labeled, what test and which lab. Procedures for holding product until results are received and Records of Finished product testing. <p>Program Management Elements are details in the Requirements section. Refer to Appendix B for example form.</p> <p>Innovation Center for US Dairy: http://sites.usdairy.com/FoodSafety/Pages/supplychain.aspx</p> <p>Commercial Food Sanitation: http://www.commercialfoodsantiation.com/documents/</p>
--	---



Sanitation

*Required if the Hazard Analysis indicates a PC is needed

Requirements	Example Programs/Records:
<p>Sanitary Operations:</p> <ol style="list-style-type: none"> 1. General Maintenance – building, fixtures and other physical facilities must be kept in a sanitary manner that will protect against adulteration. 2. Substances Used for Cleaning – must be adequate under conditions of use, in compliance with all requirements, and stored in a controlled manner. 3. Pest Control – effective measures must be taken to exclude pests from manufacturing, processing, packing, and holding areas. 4. Sanitation of Food Contact Surfaces – must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. 5. Sanitation of Non-Food Contact Surfaces – cleaned in a manner as frequently as necessary to protect against allergen cross-contact and against contamination of food, food contact surfaces and food packaging materials. <p>Sanitary Facilities and Controls: Each plant must be equipped with adequate sanitary facilities including programs for: water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal.</p> <p>Equipment and Utensils: All equipment and utensils must be designed to be cleanable and maintained to protect against allergen cross-contact and contamination.</p>	<p>Sanitary Operations:</p> <ol style="list-style-type: none"> 1. Sanitation Standard Operating Procedures (SSOP's) need to be written for all cleaning activities. A Master Cleaning schedule, including daily, weekly, monthly, etc. activities, needs to be written that describes the equipment/building area that needs cleaning, what supplies are needed and how to clean. Records of cleaning activities need to be maintained and verified as well as verification of the cleaning activity. 2. Cleaning compounds shall meet FDA requirements for food contact and must be approved for the equipment or area being cleaned and used at the manufacturer's recommended strength. Verification of cleaning activities must be part of the process. 3. Refer to Pest Control section of the chart. 4. Refer to #1 and #2 above. 5. Refer to #1 and #2 above. <p>Sanitary Facilities: Water must be at a suitable temperature to clean effectively and at an adequate pressure. When possible, sanitary facilities need to be hands free.</p> <p>Equipment and Utensils: All equipment and utensils should be made of cleanable materials and have no seams or pits that make it not cleanable. All items need to be on the Master Sanitation Schedule and have an SSOP for how to clean. Equipment should be stored in a manner to maintain its cleanliness.</p> <p>Refer to Appendix B for example form.</p>



Process Control

*Required if the Hazard Analysis indicates a PC is needed

Requirements	Example Programs/Records:
<p>Process preventive controls make up the part of your Food Safety Plan that focuses on controls required at process steps that are critical for the safety of food.</p> <p>These controls require:</p> <ol style="list-style-type: none"> 1. Documentation of parameters for critical limits associated with control. 2. Monitoring procedures 3. Corrective actions 4. Verification 5. Validation that the process controls the hazard 	<p>These steps are identified through your Hazard Analysis. It includes steps identified as a CCP and other steps which are Safety Control Points. Pre-requisite programs (PP) may also be identified as some elements of these PP's may be considered Safety Control Points.</p> <ol style="list-style-type: none"> 1. Hazard Analysis Forms 2. Food Safety Control Point Plan Forms <ul style="list-style-type: none"> • Process Step • Hazard Critical Limits • Monitoring – What, How, Frequency, Who • Corrective Action • Verification • Validation • Records 3. Documentation of Records <p>Refer to Appendix A and Appendix B for example forms to aid in determining if the hazard requires a Preventive Control, and if yes, then documenting the required elements of the Preventive Control.</p>

Good Manufacturing Practices

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Good Manufacturing Procedures (GMP's) need to be documented and trained on an annual basis. GMP's need to include:</p> <ul style="list-style-type: none"> • Personnel • Plant and Grounds • Sanitary Operations • Sanitary Facilities and Controls • Equipment and Utensils • Processes and Controls • Warehousing and Distribution • Natural or Unavoidable Defects 	<p>Refer to DPC008, <i>Good Manufacturing Practices for Dairy Processing Plants</i>.</p>



Product Traceability

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Procedure for tracing raw materials including ingredients, packaging supplies, chemicals and in-process product through the system needs to be written, trained, and implemented. Tracing of raw materials can be done using either an internal or supplier provided lot number.</p> <p>System should be tested using a mock recall at least annually and depending on the complexity of the system more often. Refer to Recall Plan Program.</p>	<p>Program must include the ability to identify raw materials or in-process product, including rework using the following identifiers (some may not be applicable): supplier, date of manufacture, time of manufacture, batch, lot number (internal or external), amount received, made, or shipped, current location (including finished product, in-process, or in storage if a raw material). Mock recalls to test the system shall include all the above information and also include date of mock recall, date of production, product recalled, amount produced, description of problem (if a mock scenario is used), how much may have gone to rework, amount still in house versus how much has been shipped, where the product was shipped. Reconciliation of mock recall shall include the time it took to complete the mock recall, how much was found (both raw material and finished product), and root cause analysis and corrective action for any issues resulting in the inability to recall 100% of the product.</p>

Food Defense/Intentional Adulteration

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Facility must prepare and implement a written Food Defense Plan which must include the following written elements:</p> <ul style="list-style-type: none"> • A vulnerability assessment, including required explanation of vulnerabilities and actionable process steps; • Mitigation strategies with explanation; • Procedures for monitoring of the implementation of the mitigation steps; • Procedure for corrective actions; and • Procedures for verification. 	<p>Food Defense Plan must be written and include vulnerabilities from both internal and external threats.</p> <p>A vulnerability assessment shall be conducted and can be done internally or externally but needs to address all aspects of the facility including the possibility of employee tampering. A procedure for monitoring actable process steps needs to be part of the program and corrective actions put into place to reduce the risk or threat. Verification of the corrective actions shall be done and documented. FDA has created a free software application that can help with this process and can be found on the FDA's website at the following link:</p>



Training

*GMP, HACCP, Sanitation, Allergens, Pathogen Control, Food Defense, Food Regulation, Chemical Use, etc.

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>The management of an establishment must ensure that all Qualified Individuals (QI) who manufacture, process, pack, or hold food subject to follow Current Good manufacturing Practices and an approved supplier program are qualified to perform their assigned duties.</p> <p>The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject are qualified to perform their assigned duties. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:</p> <ol style="list-style-type: none"> 1. Be a qualified individual as that term is defined i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties; and 2. Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual’s assigned duties. Supervisors responsible for ensuring compliance by individuals with the requirements of this part must have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food. <p>Preventive Controls Qualified Individuals (PCQI) must have additional training. The PCQI is responsible for overseeing and maintaining the Food Safety System.</p>	<p>A training program needs to be created covering all required programs to assist in maintaining Qualified Individual status.</p> <p>A New hire orientation which includes all safety and quality programs will be completed at time of hire.</p> <p>A training register exists and is maintained to show what is being trained, when the training is to occur and who is responsible for the training. Dates of actual training are documented with the employee’s name.</p> <p>A schedule will be created on an annual basis to show the necessary training required and a timeline for when the training should be completed.</p> <p>Annual training is planned, scheduled, and documented. Training in GMP, HACCP, sanitation, allergens, pathogen control, food defense, food regulation, and HAZCOM (chemical use) are some of the necessary trainings.</p> <p>Training provided must coincide and support the FDA requirements and the maintenance of Food Safety and Food Quality Programs.</p> <p>A training skills register is used for all training on site.</p> <p>Training materials and the delivery of training are provided in a language understood by all staff.</p> <p>Schedule shall include all tasks critical to meeting customer specifications, the maintenance of food safety, quality, and process efficiency. The schedule will also include safety training.</p> <p>Training materials will be provided along with an attendance list of who attended the training and will be maintained for a minimum of two years plus the current year. The attendance list will include participants’ names, a description of what was trained, the date of the training, and who provided the training.</p>



<p>Records. Records that document training required must be established and maintained.</p>	<p>Informal trainings can include an observation of an employee performing a task with the supervisor or responsible employee signing a description of what was observed.</p> <p>QI (qualified individual) is a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.</p> <p>A PCQI is an individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.</p>
---	--



Pathogen Monitoring

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>An environmental monitoring program must be developed and implemented based on the hazards identified in your facility. An environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include <i>Listeria monocytogenes</i>, <i>E. coli</i> and <i>Salmonella</i> spp. but do not include the spores of pathogenic spore forming bacteria.</p> <p>Environmental monitoring is required. Procedures for environmental monitoring must:</p> <ol style="list-style-type: none"> 1. Be scientifically valid; 2. Identify the test microorganism(s); 3. Identify the location(s) from which a sample(s) will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective. 4. Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective. 5. Identify the test(s) conducted, including the analytical method(s) used. 6. Identify the laboratory conducting the testing; and 7. Include the corrective action procedures. 	<p>The program should focus on your facility's environment to identify and prevent harborage sites for pathogens.</p> <p>The program should also confirm that the exposed finished product environment to pathogen found in the Preventive Controls for Human Foods Draft Guidance Appendix 1 (examples include: <i>Listeria</i>, <i>E. coli</i> and <i>Salmonella</i>) are not potentially contaminating product through cross-contamination from harborage sites onto food-contact surfaces.</p> <p>Validate and verify product processes and handling through environmental sampling. The program should document and summarize the procedures and basic testing protocols for verifying that the pathogen containment and control programs are effective.</p> <p>Follow-up actions must be taken for all presumptive positive and positive test results including vectoring and identifying the source of the contamination. A review of test results must be completed by each facility on a scheduled basis, and if necessary, modifications to the sampling plan (e.g. – frequency/locations) made with appropriate approvals from the PCQI. Additionally, based on the review, if pathogen test results show trends that have a >2.0% positive rate, the facility will form an action plan using a cross-functional team under the direction of the PCQI.</p> <p>Utilize FSIS Directive 10240.4: Verification Activities for the <i>Listeria monocytogenes</i> (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program to create your <i>Listeria monocytogenes</i> and <i>Salmonella</i> monitoring Programs, this will cover all aspects that you need to cover in your program.</p> <p>Other dairy related pathogens you may want to consider while doing your hazard analysis may include:</p>



	<i>Listeria monocytogenes</i> <i>Salmonella</i> <i>Pathogenic E. coli</i> <i>Cronobacter sakazakii</i> <i>Staphylococcus aureus</i> <i>Bacillus cereus</i>
--	---

Calibration

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Documented procedures shall be established, implemented, and maintained to control, calibrate, and maintain inspection, measuring, and test equipment used by the location to demonstrate that the product being produced meets the specified requirements. Inspection, measuring, and test equipment includes those instruments (and associated test software) used by manufacturing, laboratories, or other areas to take measurements that can affect product safety or quality.</p> <ol style="list-style-type: none"> 1. Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision. 2. Identify all inspection, measuring, and test equipment used to measure parameters that can affect product safety and quality, and calibrate and adjust them prior to use and at prescribed intervals, against certified equipment having a known, valid relationship to internationally or nationally recognized standards. Where no such standard exists, the basis for calibration shall be documented. The method establishing the intervals between calibrations shall be defined. 3. Define the process for calibration of inspection, measuring and test equipment including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to take when results are unsatisfactory. 4. Identify inspection, measuring, and test equipment with a suitable indicator or 	<p>Calibrated instruments that measure a critical limit parameter are an effective way to conduct monitoring. Examples of calibrated instruments include thermometers, pH meters, water activity meters, chart recorders, etc.</p> <p>Examples:</p> <ul style="list-style-type: none"> • Thermometer <ol style="list-style-type: none"> 1. Periodic Calibration – A dial thermometer is checked against a NIST standardized thermometer for two or more temperatures. 2. Routine Accuracy Check – Thermometer used to monitor cold temperatures measures correct temperature of an ice slurry (32°F (0°C)). • Metal Detector <ol style="list-style-type: none"> 1. Periodic Calibration – Detector is adjusted by manufacturer to detect and reject standardized metal pieces. 2. Routine Accuracy Check – Detector rejects products with metal standards. <p>Verification Activities: Activities include, but are not limited to:</p> <ul style="list-style-type: none"> • Auditing of calibration records to verify compliance to schedule by trained individual. Schedule should be based on how often equipment is used, regulatory requirements, and on manufacturer recommendations. • Auditing of calibration tasks against established protocols/procedures by trained individual. <p>Validation Activities: Activities include, but are not limited to:</p>



<p>approved identification record to show the calibration status.</p> <ol style="list-style-type: none"> 5. Maintain calibration records for inspection, measuring, and test equipment. 6. Review previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration, and address the disposition of product produced since the last valid calibration. 7. Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and test being carried out. 8. Ensure that the handling and storage of the inspection, measuring, and test equipment is such that the accuracy and fitness for use are maintained. 9. Safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting; and 10. Ensure only qualified individuals will be responsible for calibrating this equipment. 	<ul style="list-style-type: none"> • Reviewing monitoring and audit records to ensure the equipment was not out of calibration at the time it was checked. • Follow equipment manufacturers schedule and recommendations for validation using known standards or methods. • Use of standard industry and accepted industry methods and tools. <p>Engage an outside certified contractor to confirm proper calibration if necessary.</p>
--	--

Record Review

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Review of records must be done within a specified timeframe, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.</p> <p>Records of monitoring and corrective actions must be reviewed within seven (7) working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds seven (7) working days.</p> <p>Records of calibration, testing (e.g., product testing, environmental monitoring), supplier</p>	<p>Record reviews must be done by a qualified individual and overseen by a Preventive Controls Qualified Individual (PCQI). A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.</p> <p>Monitoring records are all records that support the hazard analysis and the preventive controls or pre-requisite programs that have been implemented to maintain safe food.</p>



<p>and supply-chain verification activities, and other verification activities must be reviewed within a reasonable time after the records are created.</p> <p>Records must be maintained for a minimum of 2 years.</p>	<p>Records shall be accessible within 24 hours if they are stored in an offsite location.</p> <p>Records shall be permanent, recorded at the time the activity occurred, and identify the facility, date, time (as appropriate) and appropriate signatures. Facility identification can be done using the facility address, name if it is a single location, or number such as an IMS inspection number.</p>
---	--

Verification and Validation

*Required Program – not a required Preventive Control

Requirements	Example Programs/Records:
<p>Verification is an ongoing process to provide evidence that the plan is being properly implemented and operating as intended. Verification can be defined as activities that answer the question, “Is the plan being followed?”</p> <p>Verification should be conducted routinely to:</p> <ol style="list-style-type: none"> 1. Determine if the Food Safety Plan (FSP) should be modified when a change in the process, equipment, and ingredient occurs. 2. Confirm that changes are implemented correctly. 3. The recommended frequency is daily or weekly, dependent on severity and/or incident occurrence rate of CP, PC or CCP. 4. Corrective action shall be initiated if verification finds the plan is not being followed. <p>Validation can be defined as activities that answer the question, "Is the plan solving the problem and effectively controlling the issue?" It focuses on collecting and evaluating scientific and technical information to determine if the FSP plan will effectively control the hazards. It is conducted after the plan is developed both the initial validation and as needed, revalidation.</p> <p>Validation performed or overseen by a PCQI should be conducted prior to production, or</p>	<p>Verification activities include, but are not limited to:</p> <ul style="list-style-type: none"> • Confirm accuracy of the flow diagram. • Review of pre-requisite program records, control points, critical control points and preventive control monitoring records. • Review of records for deviations and corrective actions. • Review of calibration records. • Review of modifications of the FSP. • Review the FSP system to determine if facility is operating according to the plan. • Audits to check practices. • Evaluation of day-to-day compliance activities. • Sampling & testing to verify control points, critical control points and preventive controls. <p>Verification activities will be based on the record type and monitoring activity. PC monitoring records shall be reviewed prior to release of product. Other records such as calibration records would be dependent upon the frequency of the activity.</p> <p>Validation procedures may include, but are not limited to:</p> <ul style="list-style-type: none"> • Using scientific principles and data from the literature • Use of expert opinion



<p>within the first 90 days of production (for on-line validation) or a reasonable amount of time with written justification by a PCQI.</p> <p>Plans should be revalidated when changes occur in any of the following: the prerequisite programs, suppliers, raw materials, equipment, shelf life, packaging, storage conditions, processing operations, product specifications, and preparation procedures.</p> <p>*NOTE: Both Verification and Validation require documentation.</p> <p>Validation is demonstrating that following the plan will actually control the identified hazards.</p> <p>Validation – The process of obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.</p> <p>Validation is required for process controls. Validation is not required for food allergen, sanitation, or supply chain program controls, but may be useful.</p> <p>Validation is not required for the recall plan.</p>	<ul style="list-style-type: none"> • Conducting in-plant observations or tests • Challenging the process at the limits of its operation controls • Using mathematical models • Incorporating regulatory guidelines <p>The FSPCA website links to scientific information that can be used for validation studies. Other sources may include manufacturer’s websites and manuals, FDA website, state regulatory sites, etc.</p> <p>The Pasteurized Milk Ordinance (PMO) is a reference document that can be used as a scientific basis for the process preventive control of pasteurization.</p>
---	--

Corrective and Preventive Action

Requirements	Example Programs/Records:
<p>Corrective Actions and corrections are preventive control management components. Corrective actions are procedures that must be taken if preventive controls are not properly implemented and involve documentation of the specific actions taken. Corrections apply when you act in a timely manner to identify and correct a minor and isolated problem that does not directly impact product safety.</p> <p>Corrective Action Procedures must describe steps taken to:</p> <ul style="list-style-type: none"> • Identify and correct a problem with implementation. • Reduce likelihood of occurrence. • Evaluate affected food for safety. 	<p>An example of a correction could be identifying food-contact surfaces that were not properly cleaned and re-cleaning them prior to production. Many sanitation preventive control lapses can be effectively managed using corrections.</p> <p>Conversely, many process preventive control lapses require corrective action procedures. Examples include when there is a deviation from a critical limit, when unsafe product may have been produced. Predetermined corrective action procedures in your Food Safety Plan shall provide a how-to guide that describes the steps to take when a preventive control is not properly implemented.</p>



<ul style="list-style-type: none"> Prevent affected food from entering commerce if you cannot ensure the food is not adulterated. <p>Required records for Corrective actions include:</p> <ul style="list-style-type: none"> Actions taken to identify and correct the problem. Actions taken, when necessary, to reduce the likelihood that the problem will recur. Safety evaluation for all affected food. Records demonstrate that food that is potentially injurious to health did not enter commerce. 	<p>Process examples could include:</p> <ul style="list-style-type: none"> Empowering the employees to stop the line when they observe a process deviation that affects food safety, and their actions would minimize the amount of product that will be subject to review. Applying an alternate process Repairing equipment Immediate adjustment of the process <p>Product examples could include:</p> <ul style="list-style-type: none"> Hold Product Evaluate Product Determine product disposition – release, rework, or destroy product <p>Documentation is required and should include the following information:</p> <ul style="list-style-type: none"> Date of Record Date and Time of Problem Description of Problem and Root Cause Actions taken to Restore the Process Person taking action (name and signature) Amount of Product involved in Problem Evaluation of Product involved with Problem Final Disposition of Product Reviewed by (name and signature) and date
--	--

Monitoring

Requirements	Example Programs/Records:
<p>You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.</p>	<p>You must have a written plan for monitoring describing what is being monitored, who is doing the monitoring, how to monitor and the frequency it is being done. By having this plan, it provides assurance that preventive controls are consistently performed.</p> <p>Records are to be kept per the record retention plan.</p>



Visitor & Contractor Management

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. A written Contractor and Visitor program shall be created and implemented. Program shall include required training with how often the training should be renewed, how a contractor qualifies for building access, and what is done when building access is revoked. 2. A list of contractors who are used within the facility should be maintained. Contractors who are provided access to the building should be provided with more descriptive training on plant programs and procedures. Training records need to be maintained. 3. Contracts or descriptive purchase orders (PO) detailing the work to be provided shall be maintained and the work verified at some frequency. 	<ol style="list-style-type: none"> 1. Visitor/Contractor program should include a sign in/out program that details why they are at the facility and who they are there to visit. Visitors should be monitored throughout their visit when in the manufacturing building, unless provided appropriate training and undergone a documented background evaluation. This could include verification of identification, a check with their company, etc. Contractors that are given access to the building should have extensive training in the company's food safety and personnel safety requirements. Training should be provided on a regular basis to reduce the risk of contamination and injury in the plant. Monitoring of the contractor should be done periodically to ensure they are following the rules. This should be done at least annually. 2. Contractor Master List should be reviewed at least annually to ensure that the list has not changed. No one should be allowed into the facility who has not been added to the list and has undergone appropriate training. 3. Contracts should have an expiration date, or a review of the contract should be done with the contractor on an annual basis to ensure that it is appropriate and valid. If there is no contract, the PO for work on site should be descriptive so that the contractor can be held accountable for the work they are there to perform. This can be in the form of an email or work list that can be attached to the PO.



Premises Preventive Maintenance

Requirements	Example Programs/Records:
<p>A written program needs to be created and implemented that outlines all activities needed to be completed to ensure that the building and surrounding areas of the facility are maintained in a way as to not pose a threat to food safety. Program should include elements such as:</p> <ul style="list-style-type: none"> • Control of Pest and Vermin • Control of foreign material contaminants such as peeling paint, temporary fixes, rust, etc. • Protection from cross contamination from air, water, waste stream, etc. • Separation of function from raw to RTE areas. • Protection from contamination from leaks, drips, condensation, etc. <p>Records of activities must be maintained.</p>	<p>A schedule of activities needed to ensure the protection and safety of the product needs to be created and re-evaluated at least annually to ensure the frequency is adequate.</p> <p>Activities addressed as part of the Premises PM program typically include cleaning of walls and floors in non-production areas, overhead pipes and ceilings, control panels (inside and out) in non-production areas, seasonal cleaning outside the building, peeling paint, holes in walls and floors, etc.</p> <p>Activities that ensure that all utilities are under control such as maintaining chemical levels in central sanitizing stations, air, and water filters.</p> <p>Other programs outlined in this document such as Pest Control, Foreign Material Control, Sanitation, storage of toxic chemicals, Warehouse Management, etc. may also be used as guidance for Premises Preventive Maintenance.</p>

Equipment Preventive Maintenance

Requirements	Example Programs/Records:
<p>A written program needs to be created and implemented that outlines all activities needed to be completed to ensure that the equipment used in the facility is maintained in a way as to not pose a threat to food safety. This includes prevention from cross contamination and cross contact with allergens. Program should include elements such as:</p> <ul style="list-style-type: none"> • List of all equipment in the building including equipment that is out of service. • SSOP's for maintenance of all equipment which can be in the form of a PM specific to the equipment that outlines the tools, parts, etc. needed or the maintenance guide that came with the equipment. 	<p>A schedule of activities needed to ensure the protection and safety of the product needs to be created and re-evaluated at least annually to ensure the frequency of equipment maintenance is adequate.</p> <p>Activities addressed as part of the Equipment PM program typically include:</p> <ul style="list-style-type: none"> • Greasing of the machine. • Replacement of critical and non-critical parts prior to them becoming worn or requiring replacement due to a breakdown. • Re-evaluation of equipment that has been taken either permanently or temporarily out of service that is still maintained in a production environment. • Changing of water or air filters.



<ul style="list-style-type: none"> • Schedule of how often the equipment is required to have maintenance. <p>Records of activities must be maintained.</p>	<ul style="list-style-type: none"> • Maintenance of backflow preventers at hose stations. • Maintenance of sanitizing stations and any controls that are used at point of use somewhere in the production environment (i.e., backflow preventers, air handlers, water filters, etc.).
---	---

Management of Pests and Vermin

Requirements	Example Programs/Records:
<p>An effective pest control program shall be based on widely recognized integrated pest management procedures to identify likely pests and the best technologies to manage their presence in dairy processing plants. An evaluation of your property and program shall be conducted based on risk and completed on an annual basis.</p> <p>Pests must not be allowed in any area of a food plant. Guard, guide, or pest detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food- contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food packaging materials.</p>	<p>A written pest control program must be in place. Program at a minimum will include:</p> <ul style="list-style-type: none"> • Individual identified who is responsible for evaluation of the program, following up on findings, and signing off on reports. • Target pests need to be determined based on history, plant location, etc. • An approved pesticide list needs to be created that includes what chemicals are allowed for application. An SDS (Safety Data Sheet) needs to be available for all chemicals. Tracking of what chemicals are applied and what quantities need to be maintained. • If applying pesticides by a Pest Control Operator (PCO) or an internally licensed applicator, a written SOP needs to be created outlining what methods are used and how pesticide containers are destroyed once empty. These must meet EPA standards. • Methods need to be documented for handling situations to prevent contamination; these should include: <ul style="list-style-type: none"> • Disposal of pests once trapped • Disposal of glue boards • Disposal of droppings • Disposal of empty containers • Schedule of service shall be determined based on the risk assessment of the property. The risk assessment must be documented. The scope of service shall be documented.



- Control measures shall be established for pest entry prevention, monitoring of pests and vermin, application of chemicals in food manufacturing and storage areas, placement of light traps and insect-o-cutors (not recommended), etc. Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the raw materials, ingredients, packaging, processing equipment and finished products.
- Training records need to be maintained for all employees and PCO's associated with pest management. Pesticide applicator records need to include certifications and licenses. Training for plant employees shall be done routinely.
- An evaluation should be completed to identify potential pest risks from neighboring properties that would impact the manufacturing facility. Risks identified will have control measures implemented.
- A map locating the position of all pest control devices both inside and outside the dairy shall be maintained.
- The frequency of checking each pest control device shall be documented as part of the program and will be based on risk. Detectors and traps shall be appropriate for the target pests.
- A report after each pest control service shall be provided outlining the service and what actions were taken.
- Evaluation of data is completed after each service and reviewed as part of the assessment. Trending of data shall be done periodically to identify problematic areas.
- Exterior tamper resistant rodent bait stations shall be used and secured. Procedure shall include what employees need to do if they find a problem with a bait station. This shall include not touching the bait station and who should be contacted.



	<ul style="list-style-type: none"> • All exterior entrances and exits should be effectively fly-proofed and self-closing. • Any rodent stations used inside the dairy processing plant shall never use poison bait.
--	---

Foreign Material Control

Requirements	Example Programs/Records:
<p>The Physical Contamination Control Prerequisite Program shall protect against the risk of physical contamination. Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on the size and shape of the object, it may cause choking, injury in the mouth or other adverse health effects. The plan shall be documented.</p> <p>It shall include:</p> <ul style="list-style-type: none"> • An assessment of physical contamination risks as part of their hazard analysis to identify potential physical contamination sources. Based on the hazard analysis, controls shall be put in place to prevent, control, or detect potential contamination. • Pre-operational inspections to identify sources of potential physical contamination shall be conducted prior to starting operation of any given area or line. Inspections shall ensure equipment and the facility remain in good condition and potential contaminants have not developed. If found, potential sources of contamination shall be corrected prior to start-up. Records of these inspections and any corrective actions taken shall be documented. • When repair, construction, or maintenance activities have been conducted in production areas, cleaning, sanitation, inspection, and approval are required to mitigate maintenance work hazards prior to startup. 	<ul style="list-style-type: none"> • Materials <ul style="list-style-type: none"> • Staples and paperclips shall not be permitted in open product zones. In instances where ingredients and packaging materials include foreign-body hazards such as staples, procedures shall be put in place to prevent these hazards from entering the product stream. • Glass, hard or brittle plastics, ceramics, and similar materials shall be controlled and managed. This includes identification of the location, audits, and documentation that they are intact. • Wood should not be permitted in or over food handling/contact zones. Where the use of wood cannot be avoided, the condition of the wood shall be monitored and documented on a frequency as determined by a hazard analysis. Monitoring shall ensure the wood is in good condition and free from damage, splinters, dirt, and deterioration which could contaminate product or product contact surfaces. • Throughout the facility, the use of wooden pallets, crates, and other instances of wood shall be minimized to the greatest degree feasible by the plant. Where wood pallets are used, they shall be dedicated to a specific purpose, clean, maintained in good order, and inspected for pests, odor, and damage before entry into the facility and prior to each re-use within the facility. • Tools, knives, and utensils shall be controlled and managed to prevent or



<ul style="list-style-type: none"> • In cases of known or suspected physical contamination of ingredient, product or packaging, all affected materials shall be isolated, and an incident investigation shall be conducted. All production areas affected by a foreign material incident shall be cleaned, inspected, and cleared by a trained individual prior to the restart of production. 	<p>mitigate the risk of physical contamination.</p> <ul style="list-style-type: none"> • Employee uniforms and protective clothing shall be controlled and managed to not pose a risk of contamination to product. • In-Process Devices <ul style="list-style-type: none"> • The need for equipment that detects, screens, or removes physical contaminants shall be established by a documented hazard analysis. When devices or equipment are used as a process control in this manner, their use shall be documented in the Food Safety Plan for that line. • The frequency of testing of in-process devices shall be defined and take into consideration the specifications of the product, the specific customer or country requirements, and the facility's ability to isolate and control any affected materials should the equipment fail. • In-process devices shall not pose risk of contamination through poor sanitary design or breakdown. These devices shall be properly maintained and must comply with cGMPs for sanitary equipment. • The accuracy, strength, and other key specifications of devices used to control or mitigate physical contamination such as filters, sieves, metal detectors, magnets, optical sorting equipment, and x-ray shall be defined per device and documented. Factors that could influence the sensitivity of the equipment (e.g., temperature, location, vibration) shall be evaluated and documented when identified. • Operating instructions for the operation/testing of physical contamination control devices shall be in place and shall include responsibilities for testing of equipment, the operating effectiveness and sensitivity of the equipment and variation of this for
--	---



particular products (as necessary), the methods and frequency of monitoring the device, and the recording of the results of checks. Refer to Calibration Program.

- Personnel who have the responsibility to operate or check physical contamination control devices shall be trained in the proper operation and operating instructions for the specific device. The proper operation of devices used to control or detect physical contaminants shall be checked at their established frequency.
- Filters, sieves, and screens used for physical contamination control shall be of a specified mesh size or gauge appropriate for the product, process and hazards identified for control by hazard analysis and shall be designed to provide the greatest practical protection for the product.
- When used, metal detectors and magnets shall meet the minimum requirements established.
- Where physical contaminants are detected or removed by equipment, any unexpected, hazardous, or unusual material shall be investigated to determine its source and documented. Information shall be gathered and collected on rejected materials, this information shall be used to identify trends and where possible, implement preventive actions to reduce reoccurrence of the material.
- In the case of failure, breakdown, or flaw of an in-process device employed to control physical contaminants, corrective actions shall be implemented, and an incident investigation shall be conducted and documented.
- In-process devices shall not be used to reprocess materials that pose a foreign material risk without an approved risk assessment.

- Verification & Validation



	<ul style="list-style-type: none"> • At least annually, the Physical Contamination Control Prerequisite Program at each facility shall be verified and validated. • Verification shall be documented and include a comprehensive review of the facility’s Physical Contamination Control Plan. Examples of verification activities include records reviews (control point monitoring records, glass audit records, etc.), visual observation of equipment, and visual observation of employees operating/testing equipment, and recorded inspections of device settings. • Validation shall be documented and include evidence that demonstrates the effectiveness of the facility’s Physical Contamination Control Plan. Examples of validation activities include review of studies or conducting of studies that support the controls in place (i.e., FDA position paper), records of demonstrations of effectiveness, analysis of consumer complaint data, and analysis of incident reports and cost of non-conformance data. <p>Resources: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm</p>
--	---

Temperature Management of Raw, In-Process, & Finished Product

Requirements	Example Programs/Records:
<p>Temperature requirements that are based on food safety must be monitored on a continuous basis or be alarmed in some way to indicate when temperature is not maintained. The equipment for monitoring of temperature must be on a calibration frequency and the program must include what to do when the equipment is found to be out of calibration.</p>	<p>Calibration program must be written and include all equipment in the facility that monitors food safety. Food safety equipment must be on a continuous monitoring program or include an alarm process that indicates when the equipment is not working or when the product has deviated from the safe temperature range. Calibration program shall include a list of all equipment that needs calibration as well as the frequency, method/standard used for calibration, verification activities, and tolerance. Procedure needs to describe what is done</p>



	when equipment is found out of calibration and shall include holding affected product, investigation of the cause of malfunction, evaluation of product held, and corrective action documenting the investigation process and actions taken. Refer to Calibration Program.
--	--

Shipping, Receiving, and Warehouse Controls

*Loading, unloading, monitoring, etc.

Requirements	Example Programs/Records:
<p>All receiving, inspecting, transporting, segregating, storage and shipping must be conducted in accordance with adequate sanitation principles.</p> <p>All coolers and freezers need to be controlled for temperature and access.</p> <p>Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.</p> <p>Inspection – All incoming and outgoing trucks, trailers, etc. are to be inspected. Inspection shall include the condition of the truck and the product.</p> <p>Refrigerated products for all incoming and outgoing loads should be shipped at 40 degrees or below. At a minimum it must meet PMO requirements. Frozen products need to be kept frozen. Shelf stable products do not need to be kept refrigerated.</p> <p>Records of all incoming and outgoing shipments and inspections are to be documented.</p>	<p>All warehouse, shipping and receiving operation SOPs need to be written including what needs to be completed and where it will be documented. These areas of the building need to be in the master sanitation program.</p> <p>Each freezer and cold storage* compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature- measuring device, or temperature- recording device so installed as to show the temperature accurately within the compartment. If a non-continuous monitoring instrument is used, the frequency of recording the temperature needs to be based on risk.</p> <p>Effective measures shall be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor shall be protected against allergen cross contact and against contamination, as necessary.</p> <p>As part of your hazard analysis of incoming ingredients and approved supplier program, ingredients shall be reviewed. Some ingredients will be tested at receipt – per FDA requirements and some may have a COA delivered with the product. Outgoing product must have all required testing completed or it needs to be under your</p>



	<p>control. Required testing shall be based on your hazard analysis and shall follow the requirements of the PMO.</p> <p>All incoming trucks, trailers, etc. shall be inspected and inspection documented. Inspection shall include:</p> <ul style="list-style-type: none"> • Confirm supplier name, day, and time of delivery. • Drivers name license or company ID. • Check seals on truck compared to seals on paperwork. • Clean, good condition, no odors, load organized to prevent cross contamination. • Look at the condition of product containers, are they clean, ripped, broken, swollen containers, signs of tampering. • Check dates. • Product at right temperature, refrigerated or frozen. • Check temperature and look for refreezing of product or freezing of refrigerated product. <p>All product testing records need to be recorded at incoming and outgoing.</p> <p>Records shall be kept as required by the record retention policy.</p> <p>*Cold Storage can also include caves (i.e., aging caves), rail cars, trucks, etc.</p>
--	---

Chemicals

Requirements	Example Programs/Records:
<p>A program for purchase, use and storage of chemicals must be documented. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the</p>	<p>All chemicals used in the plant need to be controlled.</p> <p>All chemicals need to be on a chemical control list and secured. The only chemical allowed in the plant during production are day use amounts.</p> <p>All chemicals that could encounter food or potential food surfaces need to be approved for food contact by FDA and USDA.</p>



<p>following toxic materials may be used or stored in a plant where food is processed or exposed:</p> <ul style="list-style-type: none"> • Those required to maintain clean and sanitary conditions. • Those necessary for use in laboratory testing procedures. • Those necessary for plant and equipment maintenance and operation; and • Those necessary for use in the plant's operations. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food - packaging materials. 	<p>All new chemicals must go through a review process with a cross functional team prior to being brought into the facility. The team needs to assess how it is to be used, stored, and what safety precautions need to be implemented and what training is necessary for proper use.</p> <p>Safety Data sheets and letter of guarantees are to be kept on file.</p> <p>Reference: Non-Food Compounds Listing Directory (White Book) http://info.nsf.org/usda/psnclistings.asp</p>
---	--

Internal Audits

Requirements	Example Programs/Records:
<p>Audits must be conducted on a scheduled frequency to verify the effectiveness of the programs and procedures created and implemented to ensure food safety. Audits can include, but are not limited to:</p> <ul style="list-style-type: none"> • Facility and Equipment Inspections • Pre-requisite Programs • Process Controls • Food Safety Plans • Food Quality Plans <p>A schedule should be created to ensure that all aspects of the process are audited on a regular frequency.</p> <p>Staff conducting audits must be trained and the training documented. Records of the audits must be maintained along with the corrective actions for any findings.</p> <p>Audits must be communicated to applicable staff.</p>	<p>Audits should be done so that the person conducting the audit is looking at the process, the actual activity being completed if possible, and the supporting paperwork. The audit should be conducted so that all shifts are part of the audit process and can use multiple techniques such as observation, interviewing, etc.</p> <p>Audits should be conducted on all aspects of the business to ensure that the programs are written, implemented, and followed. Examples of audits include, but are not limited to, Training, Master Sanitation Schedule, Sanitation Records, Sanitation Verification, Pathogen Environmental Monitoring, GMP, Glass and Brittle Plastic, Calibration Records, CCP and PC documentation, Corrective Actions, Supplier Management, Peeling Paint, Documents, Foreign Material Control, Drain Cleaning, etc.</p> <p>Training of auditors should be comprehensive and include different auditing techniques such as how to ask open ended questions so that the interviewee cannot answer “yes” or “no,” what to look</p>



	for when observing an employee or an area of the plant, and how to ask questions so the employee doesn't feel threatened.
--	---

Complaint Management

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. Written complaint program that includes monitoring, investigation, cause, and resolution. 2. Trending of complaint data for investigating and analyzing purposes. 3. Corrective actions with root cause analysis where applicable. 	<ol style="list-style-type: none"> 1. Written program needs to include the different ways that consumers and customers can contact the company with their complaints. Program should include short- and long-term plans for communication with consumer/customer that outlines what investigation will be completed, in what timeframe, for specific categories of complaints. For example, serious complaints (i.e., foreign material) may require an email/phone call within 24 hours with a full investigation within 3 days. 2. Trending of complaints by category/type and month is useful in understanding the problem. Complaint trends can also show patterns that can help with root cause analysis and implementation of corrective actions. 3. Corrective actions should be implemented for all trends and serious complaints. Refer to Corrective Action Program.

Document Control/Record Control

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. Written Document Control Program needs to be implemented and trained. Program should include how to control documents, a register of documents within the facility that includes retention times, and how the records will be destroyed after the required retention. 2. Records need to be maintained in a way to keep them clean, dry, and safe. 3. Records need to be legible and maintained as legal documents. This includes, but is not limited to, written in ink, contain facts and not opinions, have no lines or ditto marks to indicate repeating information, no white out, and no scribbled out or blacked out information. 	<ol style="list-style-type: none"> 1. Program needs to include where documents are maintained on the computer (originals), in use (where stored on the floor, i.e., production office), and when completed (record retention location – i.e., storage room, warehouse pallet location) for ease of access. A register of all documents shall be maintained that includes the document number/draft and the revision date so that only the most current version is in circulation. 2. Records need to be readily available and retrievable as well as stored securely to prevent damage and deterioration. Electronic records need to be considered as part of the program. Records must



<p>4. Document review and verification activities need to be scheduled and recorded.</p>	<p>include plant identification such as company name and address.</p> <p>3. Records need to be legible to document the monitoring activity and demonstrate that the inspection, analysis, or other activity was completed as required. Employees shall be trained in acceptable and appropriate documentation.</p> <p>4. Records need to be verified on a scheduled basis. SOP's need to be reviewed at least annually to ensure there have been no changes.</p>
--	--

Crisis Management/Business Continuity

Requirements	Example Programs/Records:
<ol style="list-style-type: none"> 1. Written Crisis Management Program that has been implemented and trained. Plan should be tested on a regular basis. 2. Business continuity planning should be part of the Crisis Plan. 3. Recall plan should be either part of the crisis plan or referenced in the crisis plan. 4. Crisis plan elements include, but are not limited to: <ol style="list-style-type: none"> a. Categories of Crisis (product related, non-product related) b. Crisis Management Team c. Crisis Spokesperson d. Contact Lists (internal company contacts, customers, suppliers, etc.) e. Crisis Response Guidelines 	<ol style="list-style-type: none"> 1. Written plan should include details specific to multiple situations. For example, what should happen in the event of tornado, earthquake, fire, shooter in the building, etc. 2. If the facility was not able to produce product, who will maintain customer supply? Is there a backup plan and is it tested to ensure everyone is prepared for all eventualities? 3. Refer to Recall Plan Program. 4a. Crisis responses would be different if the crisis is a product related issue versus a building related issue. All responses should be thought out and detailed so that in the event people cannot be contacted, the facility has a plan of action to follow until contact can be made. For example, what product should be placed on hold, what customers might need immediate calls and should trucks with supplies be turned around. 4b. A complete list of internal and external (corporate) people should be created that includes both work and cell numbers. A plan of who should be contacted in each situation should also be created. 4c. Employees shall be trained on how to handle calls from the media. It is beneficial to have one person designated to take these calls and to have employees trained in who that person is and how the media can contact them.



	<p>4d. A list of suppliers and customers should be easily accessible with their contact information as well as the Crisis Team.</p> <p>4e. Guidelines should be established for each type of crisis situation. How you evacuate for a fire is very different from how you would evacuate if there was a gunman in the facility. Tests of different scenario's should be done periodically.</p>
--	--

Rework

Requirements	Example Programs/Records:
<p>A written rework program must be documented that includes:</p> <ul style="list-style-type: none"> • Where in the process rework can be generated • How rework will be identified for traceability • Where it may be included back into the process • How it will be tracked • At what percentage it may be added back into the process • What testing is required prior to use <p>Documentation showing all steps of the process and the ability to trace the product will be maintained.</p>	<p>Rework process shall be documented and the records showing each phase of the process shall be part of the written procedure. A test of the process to ensure traceability should be done at least annually.</p> <p>Examples of records that should be generated and maintained include:</p> <ul style="list-style-type: none"> • Dump sheets of what product was added to a rework containment vessel. This needs to include the code date of the product dumped as well as the quantity dumped. • Batching records showing when the rework containment vessel was added back into the process. • Lab records showing that the rework containment vessel was clean prior to use and that the product was acceptable for use when used. <p>Refer to Product Traceability Program.</p>

Identity Preserved Foods

Requirements	Example Programs/Records:
<p>Written program outlining the finished product at the facility that require special labeling and controls to maintain their preserved identity status must be documented and implemented. This includes a statement of the product's identity preserved status including all the ingredients and additives. All ingredients and finished products must be properly labeled, identified, and stored so that they maintain their preserved status. Processing of the</p>	<p>Examples of identity preserved foods includes, but is not limited to:</p> <ul style="list-style-type: none"> • Genetically Modified Organisms (GMO) • HALAL • Kosher/Kosher for Passover • rBST Free • Organic/USDA Organic • Special label claims such as Low Sodium, fortified foods, etc.



<p>finished product must be done under controlled conditions such that: 1. Ingredients are separated if not compatible with the food; and 2. Completed in a separate room, on segregated equipment, or scheduled immediately after a full clean up and prior to all other products.</p>	<p>Finished product must contain the identity preserved status and be declared in accordance with the current legal requirements.</p> <p>Testing must be conducted for special label claims to ensure that the label claim is being met.</p> <p>Audits and traceability exercises should be conducted to ensure that the written procedure is being followed and that there is no cross contact during manufacturing.</p>
---	---

REFERENCES

- DPC008, *Good Manufacturing Practices for Dairy Processing Plants*
- Food Safety and Inspection Service (FSIS) Index of local offices and phone numbers: <https://www.fsis.usda.gov/wps/portal/fsis/home>
- Reportable Food Registry for Industry: <https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry>
- Innovation Center for US Dairy: <http://sites.usdairy.com/FoodSafety/Pages/supplychain.aspx>
- Commercial Food Sanitation: <http://www.commercialfoodsantiation.com/documents/>
- Food Defense Plan Builder: <http://www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm349888.htm>
- Compliance Policy Guide for Foods, Adulteration Involving Hard or Sharp Foreign Objects: <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>
- Non-Food Compounds Listing Directory (White Book): <http://info.nsf.org/usda/psnclistings.asp>



APPENDIX

Appendix A: Hazard Tables

Figure 1. DMI Training Slide

Food Safety Hazard Table								
		Likelihood				Description of Hazard Level		
		Common (3)	Possible (2)	Remote (1)	Not Likely (0)			
Severity	Serious / Class I Recall (3)	6	5	4	3	5-6	High Hazard	H
	Major / Class II Recall (2)	5	4	3	2	2-4	Medium Hazard	M
	Minor / Class III Recall (1)	4	3	2	1	1	Low Hazard	L
	Negligible (0)	3	2	1	0	0	Insignificant Hazard	I

Class I Recall: Reasonable probability of serious adverse health consequence or death

Class II Recall: May cause temporary or medically reversible adverse health consequence or where the probability of serious adverse health consequences is remote

Class III Recall: Not likely to cause adverse health consequences (quality issue)

Directions for Use:

1. For each step in the Hazard Analysis determine the Severity of the hazards associated with that step. Severity consideration has been linked in the table with the level of a recall that would be initiated if the hazard occurred. Put the number found in the parenthesis next to the severity level in the appropriate column in the hazard analysis table.
2. For each step in the Hazard Analysis determine the Likelihood of the hazard occurring with that step. Put the number found in the parenthesis next to the likelihood level in the appropriate column in the hazard analysis table.
3. Where the two columns meet in the table gives the final hazard level. Put the final hazard level in the appropriate column in the hazard analysis table. Any final hazard level of 5-6 (highlighted in red) needs to have a Preventive Control in place. Final hazard levels between 2-4 need to have a Pre-Requisite Program or Control Point in place.



Figure 2.

	Likelihood/Frequency	Common	Known to Occur	Could Occur	Do Not Expect to Occur	Practically Impossible
	Consequence/Severity	A	B	C	D	E
A	Fatality	1	2	4	7	11
B	Serious Illness	3	5	8	12	16
C	Product Recall	6	9	13	17	20
D	Customer Complaint	10	14	18	21	23
E	Insignificant	15	19	22	24	25

Note: Highlighted areas indicate the need to control a quality threat through the use of a "Control Point (CP)" or a "Critical Control Point (CCP)".

	Hazard(s) Addressed by a CP in a plant prerequisite program(s), SOPs, WI
	Hazard(s) Addressed by a CCP
	Hazards may be addressed by either plant prerequisite program(s) preventive control, or a CCP depending on science, plant history & related information



Appendix B: Hazard Analysis Table and Preventive Control Summary Table Examples

Table 1. Hazard Analysis

Process Hazard Analysis									
Plant Name: _____			Process Description: _____						
Plant Address: _____			Revision Date: _____			Supersedes : _____			
_____			Authorization Signature: _____			Date: _____			
Step #	(1) Per the process flow diagram, list each processing step	(2) Identify potential food safety hazards that are: introduced, enhanced, or controlled at this step: Biological (B) Chemical (C) Physical (P)	Severity Score	Likelihood Score	Final Score	(3) Do any potential food safety hazards require a Preventive Control? Yes or No	(4) Justify your decision for column (3)	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? [Process – (including CCP's), Allergen, Sanitation, Supply-chain, Other preventive control]	(6) Is the preventive control applied at this step? Yes or No
<i>Science Based Consider Severity & Likelihood</i>									
		B							
		C							
		P							
		B							
		C							
		P							
		B							
		C							
		P							
		B							
		C							



Table 3. Allergen Preventive Control

Food Allergen Preventive Controls PLANT NAME [REDACTED] ADDRESS [REDACTED]			ISSUE DATE				PRODUCT DESCRIPTION		
			TRAINING EXAMPLE [REDACTED]				PAGE 1 of 1		
			SUPERSEDES [REDACTED]						
Allergen Control	Hazard(s)	Parameters	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			

Approved By: [REDACTED] _____
(Signature)

Print Name: [REDACTED] _____

Date: [REDACTED] _____



Table 4. Sanitation Preventive Control

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	
Sanitation Preventive Controls		
Location		
Purpose		
Frequency		
Who		
Procedure		
Monitoring		
Corrections		
Records		
Verification		Date



Appendix C: Contract Manufacturing Ingredient Scenarios

Contract Manufacturing Ingredient Scenarios

	Brand Owner Purchases All Ingredients	Brand Owner & Co-Man both purchase ingredients	Co-Man purchases All Ingredients but from Brand Owner's Suppliers	Co-Man purchases All Ingredients from their own suppliers	Brand Owner Purchases a Finished Good from Co-Man
Who Owns Hazard Analysis?	Co-man with input from brand owner	Co-man with input from brand owner	Co-man with input from brand owner	Co-man	Co-man
Who Owns Supply Chain Program?	Brand Owner	Brand Owner and Co-man respectively	Co-man	Co-man	Co-man
Documentation Maintained by Brand Owner	Supplier verification determination, audit records, supplier guarantees	Supplier verification determination, audit records, supplier guarantees for ingredients brand owner buys	No documents related to supply chain program	No documents related to supply chain program	No documents related to supply chain program
Documentation Provided to Co-Man by Brand Owner*	Written FSMA compliant SC Program; Ingredient Specifications	Written FSMA compliant SC Program; Ingredient Specifications	Ingredient Specifications	Ingredient Specifications	Finished good specifications
Documentation Maintained at Co-Man	Written SC Program including Brand Owner SC Program Verification; Receiving programs/COAs	Written SC Program including Brand Owner SC Program Verification; Receiving programs/COAs	Written SC Program including own determination of supplier verification activities; Receiving programs/COAs	Written SC Program including own determination of supplier verification activities; Receiving programs/COAs	Written SC Program including own determination of supplier verification activities; Receiving programs/COAs

*if Brand Owner is also a supplier to the Co-Man, they may need to provide supplier verification documentation to the Co-Man (3rd party audit, etc)

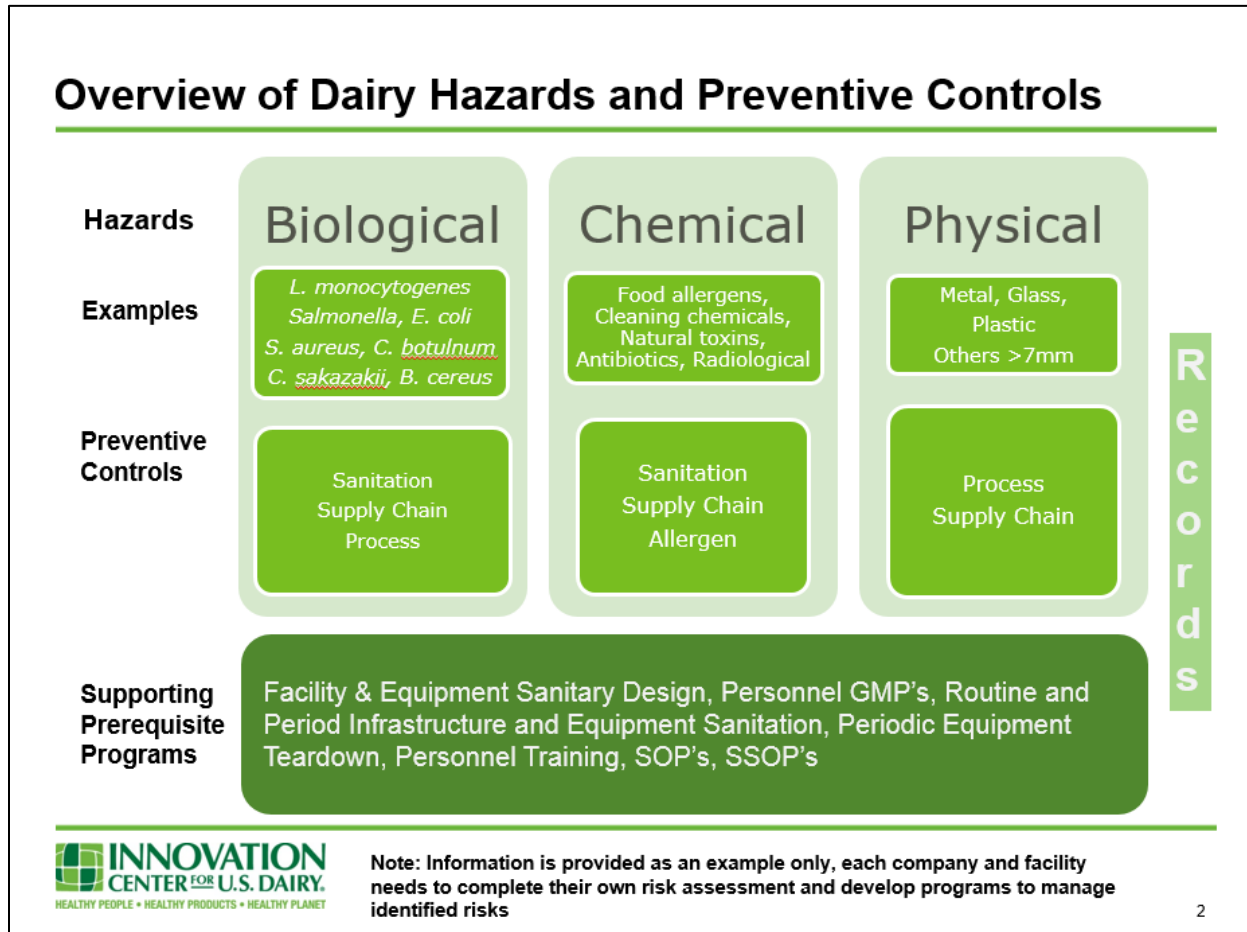


Appendix D: DMI Slide of Supplier Assessment Criteria

Material	Supplier Type	Audit/Regulatory History	Business
Low = 1 Material Risk = Nominal	<p>Pre-Pasteurized Product</p> <p>Item has low risk of tampering</p> <p>Item comes in primary and secondary packaging, or is non-food contact packaging</p> <p>Item is manufactured with hands-free process</p> <p>Broker or importer if sourced from approved manufacturer</p>	<p>GFSI Certified</p> <p>No 483 or Regulatory Findings</p> <p>No recall or withdrawals in the past 2 years</p> <p>Current with required documents, including strong HACCP plan</p> <p>Manufacturer has strong security practices and measures in place</p> <p>Supplier has aggressive Environmental Monitoring programs in place</p> <p>Supplier cooperative in sharing data to assure Food Safety</p> <p>No negative supplier product food safety related complaint history</p>	<p>Other sources of supply available and qualified</p> <p>Positive improvement or no change in credit worthiness</p> <p>Suppliers product/service is far removed from our customer</p> <p>Supplier has history of stable labor relations</p> <p>Supplier has technical resources to implement and sustain Food Safety programs</p> <p>Supplier facility has sophisticated equipment/process to control Food Safety</p> <p>Supplier facility is of appropriate construction, layout, and design to promote Food Safety</p>
Medium = 2 Material Risk = Moderate	<p>Item has only one level of packaging, or is food contact packaging</p> <p>Product is stored in third party warehousing</p> <p>Item has minimal post pasteurization exposure</p> <p>Manufacturing Complexity (allergens, etc) as to increase risk</p>	<p>3rd party audit in the last year</p> <p>Plans to become GFSI Certified in the next 9 months</p> <p>1 FDA 483 or regulatory audit finding</p> <p>Supplier is moderately cooperative in sharing data to assure Food Safety</p> <p>Minor supplier food safety related complaint history</p>	<p>Single qualified source</p> <p>No change or slight decline in credit worthiness</p> <p>Supplier's product/service is indirectly related to our customer</p> <p>Supplier facility is of moderate construction, layout, and design to promote Food Safety</p>
High = 6 Material Risk = Significant	<p>Foreign sourced material</p> <p>Broker or importer if sourced from unapproved manufacturer (or second transfer)</p> <p>Material with regulatory requirements (e.g. glycerin, diethylene glycol, etc.)</p> <p>Post pasteurization</p> <p>And/or post pasteurization exposure (e.g. brine)</p> <p>Item has greater risk of tampering</p> <p>Supplier make riskier items in same plant (i.e. raw milk cheese)</p>	<p>Never audited by any agency or 3rd party, or last audit on file is older than 5 years</p> <p>No plans to become GFSI certified or plans to implement in greater than 9 months</p> <p>2 or more FDA 483 or regulatory audit findings</p> <p>Recall or 2 Withdrawals in the last 24 months</p> <p>Manufacturer has weak security practices in place</p> <p>Supplier has weak or unknown Environmental Monitoring programs in place</p> <p>Supplier is uncooperative in sharing data to ensure Food Safety</p> <p>Significant supplier food safety related complaint history</p>	<p>Supplier is sole source</p> <p>Material exclusively made for us</p> <p>Supplier facility lacks appropriate construction, layout, and design to promote Food Safety (unrefrigerated docks, lack of vestibules, poor allergen separation, etc.)</p> <p>Slight to significant decline to credit worthiness</p> <p>Supplier's product/service is critical to, or required by, our customer</p> <p>Supplier has history of unstable labor relations</p> <p>Supplier lacks technical resources to implement and sustain Food Safety programs</p> <p>Supplier lacks sophistication in equipment/process to control Food Safety (e.g. artisan)</p> <p>Supplier presences in multiple plants (10 or more)</p>



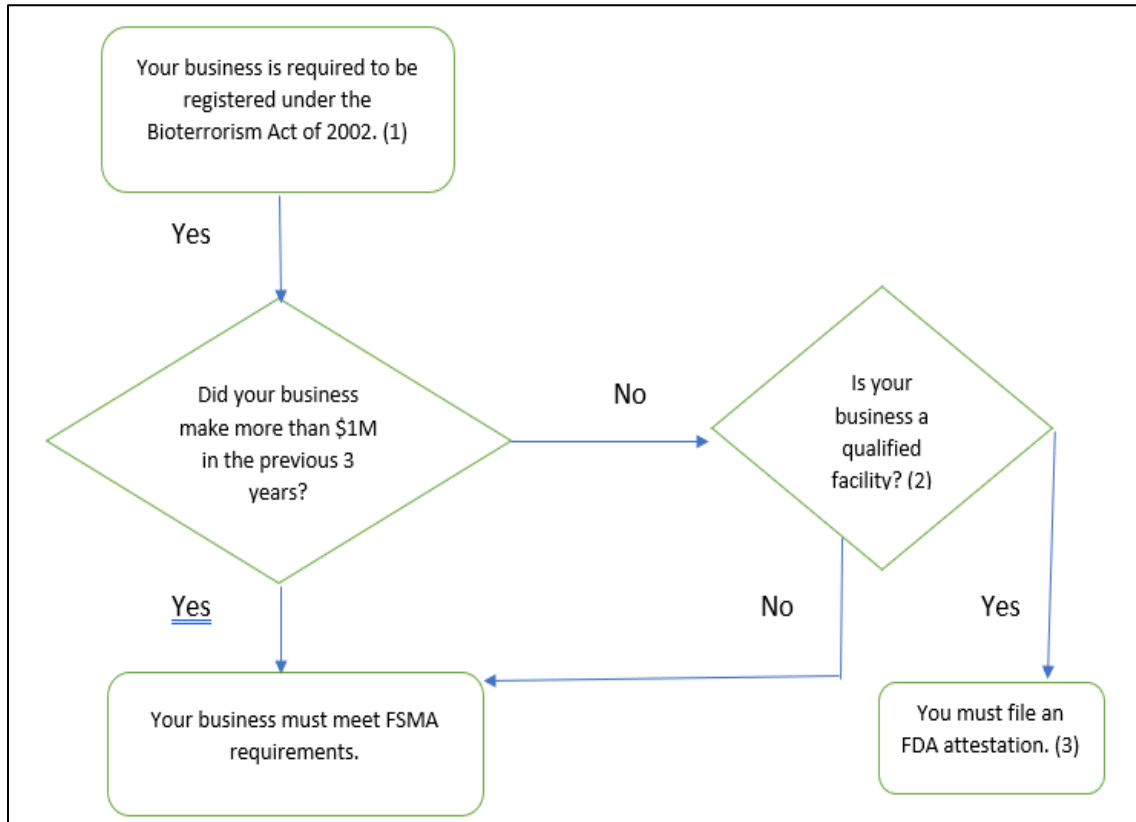
Appendix E: Overview



Appendix F: Preventive Controls Checklist

Step 1: Determining if your business needs to meet the Food Safety Modernization Act requirements.

Decision Chart



1. Refer to the following guidance: Guidance for Industry: Questions and Answers Regarding Food Facility Registration – <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>
2. Refer to the following material to determine your business status: Guidance for Industry: Determination of Status as a Qualified Facility – <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>
3. Complete and submit an attestation with the FDA at: <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm>

Step 2: Preventive Controls Checklist

Use the checklist provided to review your current programs to determine whether or not the facility has all of the elements required for FSMA Preventive Controls for Human Food compliance.

Section 1 – Food Safety Plan (21 CFR 117.126)

- The facility's Food Safety Plan is documented in writing.
- The facility's Food Safety Plan is prepared or its preparation is overseen by one or more Preventive Controls Qualified Individuals (PCQI).
- The owner, operator or person in charge of the facility has signed and dated the Food Safety Plan upon completion and whenever modifications are made.
- Reanalysis of the entire Food Safety Plan is conducted at least once every 3 years.
- Reanalysis of the applicable portion of the Food Safety Plan is conducted due to a change in a hazard, new information of a hazard, an unanticipated food safety problem, or ineffective preventive control(s). (21 CFR 117.170)
- Any reanalysis of the facility's Food Safety Plan has been performed or overseen by a PCQI.

Section 2 – Food Safety Plan Required Elements

- Facility has a written recall Plan.
- Facility has a written hazard analysis for each type of food manufactured, processed, packed or held at the facility.
- Facility has written Preventive Controls, as appropriate, for each identified hazard.
- Facility has a written Supply Chain Program, as appropriate, for each identified hazard.
- Facility has written procedures for monitoring the implementation of the preventive control(s), as appropriate, for each identified hazard.
- Facility has Corrective Action Procedures appropriate to the hazard(s) and the preventive control(s).
- Facility has written Verification Procedures appropriate to the nature of the preventive control(s).

Section 3 – Recall Plan (21 CFR 117.139)

- Written procedures include how to directly notify a customer of the food products being recalled, including how to return or dispose of the affected food products and assigning responsibility for taking those steps.
- Written procedures include how to notify the public about any hazard associated with the recalled products.
- Written procedures include how to conduct effectiveness checks to verify that the recall is carried out effectively.
- Written procedures include how to dispose of the product.

Section 4 – Hazard Analysis (21 CFR 117.130)

- Facility has identified known or reasonably foreseeable hazards that include Biological, Chemical (including allergen and radiological) and Physical hazards.



___ Facility has identified other known or reasonably likely hazards that may occur naturally, unintentionally or intentionally (i.e., food defense or food fraud).

Section 5 – Preventive Controls (21 CFR 117.135)

___ Includes written preventive control(s) at critical control point(s) for the identified hazard(s) (processing).

___ Includes written preventive controls, other than those at critical control points that are also appropriate to food safety (allergen, sanitation, supply chain).

Section 6 – Supply Chain (21 CFR 117 Subpart G)

___ Documented that a supplier of the ingredients has a functional and written food safety program that addresses hazards to include food allergen management.

___ Written program for approval of suppliers to include: supplier verification activities and their frequency; conducting and documenting supplier verification activities before using raw materials; written procedures for receiving raw materials; and documentation that those procedures are being followed.

___ Facility has taken and documented prompt action when a supplier is not controlling a hazard.

Section 7 – Monitoring (21 CFR 117.145)

___ Written monitoring procedures including the frequency they are performed, are established, implemented and consistently performed for monitoring the preventive control(s) for the identified hazard(s).

___ Monitoring records are being reviewed, dated and signed or initialed by or under the oversight of a PCQI within 7 working days after the records are created.

Section 8 – Corrective Action (21 CFR 117.150)

___ Established and implemented corrective action procedures that shall be taken if preventive controls are not properly implemented for the identified hazard(s).

___ Established and implemented written corrective action procedures that are taken to address the presence of pathogen or appropriate indicator organisms in ready-to-eat product.

___ Established and implemented written corrective action procedures that shall be taken to address the presence of pathogens or appropriate indicator organisms detected through environmental monitoring.

___ Corrective action records are being reviewed, dated and signed or initialed by or under the oversight of a PCQI within 7 working days after the records are created.

Section 9 – Verification and Validation (21 CFR 117.155 & 117.160)

___ Verification that the preventive control(s) is/are consistently implemented, effective and significantly minimize or prevent the identified hazard(s)

___ Validation that each preventive control identified and implemented is adequate to control the identified hazard(s).

___ Validation has been performed or overseen by a PCQI.



Section 10 – Qualification of Individuals (21 CFR 117.4)

___ The owner, operator or person-in-charge of the facility has ensured that all individuals who receive, handle, process and package food products are qualified to perform their assigned duties.

___ Each individual has received training in the principles of food hygiene and food safety, including the importance of employee health and personnel hygiene.

___ Supervisory personnel have the necessary education, training, experience or combination thereof, and ensure compliance by individuals who report to them.

___ Training records are established, maintained and retained at the facility for at least 2 years after the date the training was given.

Section 11 – Records (21 CFR 117.301)

___ Facility has established and is maintaining the required records documenting the implementation of the Food Safety Plan for preventive controls (i.e. monitoring, verification, and corrective action).

___ Required records are identified with the name and location of the facility or their facility code, dated and the signature or initials of the person performing the activity. Records show that they were verified.

___ The Food Safety Plan is maintained on site.

___ Preventive Control records are available on site within 24 hours. This includes monitoring, verification and corrective action records.

___ Records that support the preventive control(s) required in the facility's Food Safety Plan are retained for at least 2 years after the date they were created.



CURRENT ACKNOWLEDGEMENTS

**This guideline was developed by contributors who are of experienced individuals in a related field(s). The acknowledged persons are included with their professional affiliations and may be contacted via a DPC Officer(s) and/or Task Force Director(s) for questions or concerns.*

Officers

Name	Position
Keith Hay	President
Wendy Landry	Vice President
Mary Wilcox	Executive Vice President

Task Force Director

Melinda Davis, Task Force IV Regulatory Issues and Food Safety

Lead Author(s)

Amy Rhodes, HP Hood LLC
Greg Leach, Losurdo Foods Inc.
Rona Robertson, The Hershey Company

Contributor(s)

None.

HISTORICAL ACKNOWLEDGEMENTS

Version(s)

None.

