

LAND O'LAKES, INC.

Food Safety and Quality Expectations Manual

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Version 1.0

Our Product Safety and Quality Heritage

Land O'Lakes, Inc., since its formation in 1921, has been known for and committed to the production and delivery of safe, high-quality products – a commitment that stretches across all of our businesses, from farm to fork.

Land O'Lakes is one of the largest cooperatives in the United States, with approximately 10,000 employees, 3,900+ direct producer-members, 750 member-cooperatives, doing business in more than 50 countries.

Your Role as a Supplier or Service Provider

As a supplier of materials, finished goods or services to Land O'Lakes, you play an important part in helping us maintain the trust that our consumers and customers have in us. The quality and safety of the products you provide can significantly affect both our reputation and yours. It is essential that we both choose suppliers and service providers who have strong, prevention-based product safety and quality programs, combined with a passion for doing the right thing.

Scope of this Document

This document outlines the requirements for suppliers of materials, finished goods and services who work with Land O'Lakes. It includes industry programs and practices we expect to see in place when we visit facilities. Some elements may be more critical than others, depending on the type of product produced and the nature of the relationship with Land O'Lakes. This document, along with Land O'Lakes' specifications and contracts, provides guidance for being or becoming an approved supplier of goods and services.

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CUSTOMER AND CONSUMER RELATIONS REQUIREMENT

Statement of Intent: To ensure a process is in place to capture, respond to and evaluate customer and consumer contacts (e.g., complaints, inquiries, compliments).

CUSTOMER AND CONSUMER CONTACT PROGRAM

1. Each facility must have a documented program in place regarding customer and consumer complaints. This program must include:
 - A process for receiving, reviewing, and tracking complaint data;
 - Communication on trending and Corrective Action activity;
 - Complaint reduction initiatives captured in the management review.
2. All customer and consumer contact (e.g., verbal or written complaints, compliments, inquiries, unsolicited suggestions) must be directed to a defined team that handles customer and consumer contacts.
 - All customer and consumer requests (e.g., questionnaires, samples, audits, surveys, supplier information) must be sent to a defined team that handles customer and consumer requests.
 - Product donations must:
 - Be properly labeled for sale;
 - Meet all applicable quality specifications;
 - Maintain traceability;
 - If product does not meet these requirements, Land O'Lakes Corporate Quality (LOLCQ) must be contacted for approval.
3. Customer contact team must ensure documentation is complete and appropriate parties are notified of an incident. This includes incidents that get escalated. Continued monitoring must take place to ensure timely responses and resolution.

DOCUMENT AND RECORD CONTROL REQUIREMENT

Statement of Intent: To ensure product safety and quality documents and records (e.g., requirements, programs, procedures, forms) are managed within a controlled system.

DOCUMENT AND RECORD CONTROL

1. Facility must have a document control program and maintain a master document and record list.
2. Documents must be created to demonstrate compliance with product safety and quality policies. Documents must include the following legible attributes:
 - Supersede date/version control;
 - Effective date;
 - Document owner;

- Document identification;
3. Facilities must have a documented review process that requires review at least every three (3) years or whenever process or program modifications require document changes. Document change control for active documents must include:
 - Document reviewer;
 - Revision history.
 4. Facilities must have a documented approval process.
 5. Records must be:
 - Completed electronically or in ink;
 - Dated with month, date, and year;
 - Legible;
 - Complete and accurate:
 - Missing required data must be investigated and/or explained;
 - Authenticity:
 - Filled out at the time of, not in advance of, the observation/test;
 - Traceable to the person performing the activity and to the facility at which the activity was performed;
 - Traceable back to the product, process, or production period;
 - Corrections to non-electronic records must be documented with a single line through the error, initials of person making Correction, date of Correction, and justification (if necessary) for Correction and the updated information. White-out and Correction tape must not be utilized.
 6. Documents and records must be stored in a secure manner and be readily available for review.
 7. Obsolete documents and completed records must be retained according to the state or federal regulations regarding record retention.
 8. Facilities must have a documented record destruction process.

EXTERNAL BUSINESS PARTNER REQUIREMENT

Statement of Intent: Ensure product safety, quality, and regulatory requirements are reviewed and met in selecting, approving, managing, and monitoring External Business Partners.

CO-MANUFACTURERS

1. Co-manufacturer quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of co-manufacturers.
 - All Co-manufacturer facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Co-manufacturer facilities/locations.

- The Land O'Lakes (LOL) Co-manufacturer business management team will select suitable Co-manufacturers for review and engage Land O'Lakes Corporate Quality to evaluate those Co-manufacturers for suitability.
- All Co-manufacturer facilities/locations must be assessed prior to completing a Co-manufacturer agreement
- Ongoing Co-manufacturer evaluations must be conducted with risk-based frequency.
- Disqualification criteria must be defined, and records kept when Co-manufacturers are disqualified.

JOINT VENTURES

1. Joint Venture quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Joint Ventures.
 - All Joint Venture facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Joint Ventures facilities/locations.
 - The LOL Joint Venture business management team will select suitable Joint Ventures for review and engage Land O'Lakes Corporate Quality to evaluate those Joint Ventures for suitability.
 - All Joint Venture facilities/locations must be assessed prior to completing a Joint Venture agreement.
 - Ongoing Joint Venture evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and records kept when Joint Ventures are disqualified.

LICENSEES

1. Licensee quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Licensees.
 - All Licensee manufacturing facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Licensee facilities/locations.
 - The LOL Licensee business management/operations team will select suitable Licensees for review and engage Land O'Lakes Corporate Quality to evaluate those Licensees for suitability.
 - All Licensee facilities must be assessed prior to completing a Licensee agreement for products and services.
 - Ongoing Licensee evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and records kept when Licensees are disqualified.

INGREDIENTS SUPPLIERS

1. Ingredient Supplier quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Ingredient Suppliers.
 - Ingredient Supplier facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Ingredient Supplier facilities/locations.
 - The LOL Ingredient Supplier business management team will select suitable Ingredient Suppliers for review and engage Land O'Lakes Corporate Quality to evaluate those Ingredient Suppliers for suitability.
 - All Ingredient Supplier facilities/locations must be assessed prior to procuring products.
 - Ongoing Ingredient Supplier evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and Records kept when Ingredients Suppliers are disqualified.

MERCHANDISED MATERIALS SUPPLIERS

1. Merchandised Materials Supplier quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Merchandised Materials Suppliers.
 - Merchandised Material Supplier facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Merchandised Material Supplier facilities/locations.
 - The LOL merchandising business management team will select suitable Merchandised Material Suppliers for review and engage Land O'Lakes Corporate Quality to evaluate those Merchandised Materials Suppliers for suitability.
 - All Merchandised Material Supplier facilities/locations must be assessed prior to procuring products and/or services.
 - Ongoing Merchandised Material Supplier evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and records kept when Merchandised Material Suppliers are disqualified.

PACKAGING SUPPLIERS

1. Packaging Supplier quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of product contact and non-contact Packaging Suppliers.

- All Packaging Supplier facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Packaging Supplier facilities/locations.
- The LOL sourcing/R&D business management team will select suitable Packaging Suppliers for review and engage Quality Land O'Lakes Corporate Quality to evaluate those Packaging Suppliers for suitability.
- All Packaging Supplier facilities/locations must be assessed prior to procuring products and/or services.
- Ongoing Packaging Supplier evaluations must be conducted with risk-based frequency.
- Disqualification criteria must be defined, and records kept when Packaging Suppliers are disqualified.

WAREHOUSING PROVIDERS

1. Warehousing Provider quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Warehousing Providers.
 - All Warehousing Provider facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of services from approved Warehousing Provider facilities/locations.
 - The LOL warehousing team will select suitable Warehousing Providers for review and engage Land O'Lakes Corporate Quality to evaluate those Warehousing Providers for suitability.
 - All Warehousing Provider facilities/locations must be assessed prior to shipping products to them for storage.
 - Ongoing Warehousing Provider evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and records kept when Warehousing Providers are disqualified.

TRANSPORTATION PROVIDERS

1. Transportation Provider quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of Transportation Providers.
 - Transportation Providers must be qualified through a documented and implemented risk-based program to ensure use of services from approved Transportation Providers.
 - The LOL transportation and logistics team will select suitable Transportation Providers for review and engage Land O'Lakes Corporate Quality to evaluate those Transportation Providers for suitability.
 - All Transportation Providers must be assessed prior to completing an agreement for services.
 - Ongoing Transportation Provider evaluations must be conducted with risk-based frequency.

- Disqualification criteria must be defined, and Records kept when Transportation Providers are disqualified.

OTHER GOODS AND SERVICES PROVIDERS

1. Other Goods and Services Providers (providers that do not fit the categories above) quality, food safety and/or product integrity requirements must be managed through a documented program. The program must include guidance for the selection, assessment, and management of those Other Goods and Services Providers.
 - All Other Goods and Services Providers facilities/locations must be qualified through a documented and implemented risk-based program to ensure procurement and use of products and services from approved Other Goods and Services Providers.
 - The company will select suitable Other Goods and Services Providers for review and engage Land O'Lakes Corporate Quality to evaluate those Other Goods and Services Providers for suitability.
 - All Other Goods and Services Providers must be assessed prior to completing an agreement for services.
 - Ongoing Other Goods and Services Providers evaluations must be conducted with risk-based frequency.
 - Disqualification criteria must be defined, and records kept when Other Goods and Services Providers are disqualified.

MANAGEMENT COMMITMENT REQUIREMENT

Statement of Intent: To ensure the development, implementation, maintenance and continuous improvement of the processes and programs supporting the product safety and quality policy in order to ensure that risk is managed throughout the organization.

MANAGEMENT RESPONSIBILITY

1. Facility management is responsible for ensuring compliance with quality management systems (QMS), and a focus on continuous improvement.
 - A quality plan must be developed and implemented at each facility. The plan must include the following specific and measurable goals:
 - Key performance indicators (KPI);
 - Plant-specific quality goals and initiatives;
 - Measurement parameters for goal completion;
 - Actual results.

2. The facility must define and maintain a clear plan for the development and continuous improvement of product safety and quality culture.
3. Adequate resources (human, financial, technical and training) must be provided to implement, maintain and make improvements at each facility to support the quality management system.
4. Procedures that support compliance with the QMS must be documented.
5. Documentation of a management responsibility requirement must be maintained through a meeting dedicated to management review of product safety and quality conducted with the facility's management staff. These meetings must be conducted at least quarterly.
 - The management review of product safety and quality meeting agenda must include:
 - Previous management review action plans and timelines for completion;
 - Progress of quality plan objectives;
 - Plant operations and resources evaluation;
 - Non-conforming product review;
 - External auditing findings;
 - Corrective Action and Preventive Action (CAPA) program status.
 - Documented minutes of the management review of product safety and quality meetings must include:
 - Attendance at the meeting;
 - Discussion topics and status of topics/projects;
 - Meeting output and communication of meeting outcomes;
 - Follow up actions, assignments and agreed timelines for completion.
6. The facility must conduct and document self-assessments on an annual basis to evaluate adequacy and effectiveness of meeting the QMS programs.
 - Self-assessments must be led by trained facility employees.
 - Corrections or Corrective Actions for self-assessment findings must be completed and documented.
 - Human food facilities must maintain a schedule for their self-assessments.
7. Facility must have a Corrective Action/Preventive Action (CAPA) program to address findings when failures are found in the QMS (e.g., self-assessments, housekeeping, pest control, etc.).
8. If any area is not in compliance with the QMS, the facility must document the situation assessment, risk assessment to mitigate potential product safety, regulatory and business risks, and CAPA.
9. If there is a change in a process or to a product, the facility must have a process to evaluate and address any potential impact to product safety or quality.

PRODUCT SAFETY AND QUALITY EVENT MANAGEMENT

1. Each manufacturing facility must have documented procedures for managing events where product safety, product quality, human safety, public relations, security, or environmental conditions (e.g., fire, natural disaster, water disruption, etc.) may put the business and/or operations at risk (e.g., a facility incident management team). Procedures must include:
 - Identification of a facility incident management team;
 - A key contact list that includes plant, corporate, regulatory, and emergency services;
 - A communications plan that addresses the different types of incidents/crises listed above. The communication plan must include who may communicate to customers, consumers, and regulatory, and how this information may be communicated.
2. Product safety and quality events must be documented and communicated per the facility's communication plan.
3. On an annual basis the product safety and quality event management procedures must be reviewed and tested to Verify effectiveness.

MERGERS, ACQUISITIONS & DIVESTITURES

1. A merger and acquisition team must develop and implement a detailed pre-acquisition due diligence plan to investigate and decide whether to execute a potential transaction.
2. A merger and acquisition team must integrate the target company through a comprehensive integration plan.
3. Divestiture tasks must be handled by a trained team with a detailed divestiture plan.

QUALITY MANAGEMENT SYSTEM (QMS) GOVERNANCE

1. Facilities must have a method of governing quality-system-driven initiatives.

QUALITY MANAGEMENT SYSTEM (QMS) VERIFICATION

1. Verification activities must be designed and conducted to assess compliance and effectiveness of the QMS as a basis for continuous improvement.
2. Verification activities must have a defined purpose and scope.
3. Verification activities must be conducted by qualified, trained, and calibrated auditors.
4. Verification activities must be conducted at a risk-based frequency and/or to comply with a certification, license or approval. Audits are either internal audits or external audits.
 - Internal audits or first-party audits must be conducted within the company for internal organizational purpose.
 - External audits, second-party audits, or third-party audits must be conducted by an individual or entity from outside the company.

5. Verification activities must be conducted using defined methods and reporting processes.
 - The methods used in Verification must be determined based on the type, purpose, and scope of the assessment/audit.
 - Reporting of Verification activities must be documented.
6. Verification activities identified as requiring Correction must follow documented CAPA processes.

PERSONNEL TRAINING, EDUCATION AND QUALIFICATIONS REQUIREMENT

Statement of Intent: To ensure all employees, contractors, temporary workers and visitors have appropriate training, education and qualifications to ensure product safety and quality.

TRAINING AND EDUCATION PROGRAM

1. Employee training and education (in appropriate languages where needed) must be provided to support the QMS requirements.
 - Facility must create a training matrix per job function. This training matrix must be kept current and list required training frequencies.
2. Product safety, quality and regulatory training must be provided, relevant to the task being performed, to contractors and visitors.
3. All training activities must be documented and training records for all personnel must be maintained.
 - Verification of training effectiveness must be documented for employees. Examples include written tests, interviews, observations in work area, etc.
4. There must be documented confirmation that the trainers/educators are qualified (having met qualifications based on training, education, or professional experience).

PRODUCT INTEGRITY REQUIREMENT

Statement of Intent: To protect products and processes from the initial design and throughout manufacturing, so that the products and processes meet safety, quality, regulatory, business and customer requirements.

PRODUCT AND PROCESS DESIGN AND DEVELOPMENT

1. Facilities must have a documented program for product and process design and development. A Stage Gate-type evaluation process must be used to guide product design, development and commercialization.
 - A Design Hazard Analysis Process must be used during product and/or process development.

PRODUCT INTEGRITY

1. Facilities must have a HACCP/Product Safety Plan in place.
 - The Product Safety Plan must be developed and overseen by a qualified individual(s) trained in preventive controls (PCQI).
 - The Product Safety Plan must establish and include a HACCP/Product Safety team that is multi-disciplinary.
 - The HACCP/Product Safety Plan must include the product description, intended use, and distribution.
 - Process flow diagrams (PFDs) must be documented, including preventive controls (if applicable).
 - When creating a HACCP/Product Safety Plan, PFDs must be verified on-site before completing the Design Hazard Analysis Process, and must be approved, signed, and dated by the HACCP/Product Safety Plan team leader.
2. Facility must have a documented Hazard analysis evaluating biological, chemical, physical and radiological Hazards for all steps identified on the PFD.
3. Preventive controls (PCs)/Critical Control Points (CCPs)/control measures (if any) must be identified, monitored, Verified, Validated (if applicable), and Corrective Actions must be documented.

ALLERGEN AND SENSITIZING AGENTS

- 3.1. Facilities must have a documented allergen and sensitizing agent program that consists at a minimum:
 - A review, at least annually, of all ingredients to identify those that contain allergens and/or sensitizing agents listed in section 3.2 below:
 - This review should include any processing aids (which includes food-grade lubricants);
 - A list of the products produced in the facility and the allergens and/or sensitizing agents listed in Section 3.2 below that they contain.
 - A review of the operation to determine which ingredients/products/processing aids (e.g., allergens and/or sensitizing agents) are handled/processed in a manner that could lead to cross-contact and/or improper labeling:
 - This review should consider modes of failure such as incorrect ingredients/formula, incorrect rework, mislabeled product, Sanitation issues, and cross-contact.
 - The methods/procedures/etc. that will be used to control the allergen and/or sensitizing agent (e.g., Sanitation, production scheduling, dedicated line, label modifications, storage requirements, or handling requirements), including those required in sections 3.3-3.7 below.
- 3.2. The following allergens and sensitizing agents must be considered:

- Allergens - The human food allergen list below is in alignment with the U.S. Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004:

Fish (each type of fish species is considered a separate allergen and must be labeled and controlled separately);	Tree Nuts (each type of tree nut is considered a separate allergen and must be labeled and controlled separately);
Crustacean (each type of crustacean is considered a separate allergen and must be labeled and controlled separately);	Milk;
Wheat;	Soy;
Peanuts;	Eggs;

By-products or derivatives of these allergens are also typically considered allergens. In the United States, an oil of an allergen that is refined, bleached, and deodorized (RBD), is not usually considered an allergen and will be labeled accordingly;

- Sensitizing agents - The items below represent the current human food list of sensitizing agents that apply to all facilities:

Sulfites	FD&C colors
Monosodium glutamate	Hydrolyzed protein
Autolyzed yeast (when used as an ingredient)	Gluten when a “gluten-free” claim is being made on finished product: Must assure there is no gluten from a prohibited grain (wheat, rye, barley, or a crossbred hybrid of these), from ingredients that are derived from a prohibited grain that has not been processed to remove gluten, or from cross-contact with a prohibited grain

Sensitizing agents will be labeled per applicable regulations:

- Added sulfites ≥ 10 ppm or 10 mg/kg must appear on finished product label per 21 C.F.R. 101.100 (a)(4) (a level < 10 ppm sulfite allows for the proper use of sulfites as processing aids and in boiler treatment without affecting labeling or facility operations);
- Products with “gluten-free” claims must meet the FDA requirements for gluten-free labeling of foods (21 C.F.R. 101.19);
- Additional sensitizing agents may be added to a specific facility’s program to meet customer requirements.

- 3.3. Material Receiving, Handling, and Storage - Ingredients, packaging material, processing aids, work in process (WIP), rework, and finished products containing an allergen and/or sensitizing agent must be identified, handled, and stored in a manner to prevent cross-contact.
- The facility must clearly identify and segregate ingredients, packaging material, processing aids, WIP, rework, and finished products that contain allergens and/or sensitizing agents.
 - Segregation procedures/practices in warehouses must be implemented and adequately monitored.
 - Product contact utensils/tools must be controlled to reduce the potential for cross-contamination.
 - Instructions shall be provided to all relevant staff involved in the receipt and/or handling of raw materials, WIP, rework and finished product on how to identify, handle, store and segregate raw materials containing allergens and/or sensitizing agents.
- 3.4. Production (including cleaning) must consider proper sequencing of allergen-containing and/or sensitizing agent-containing products to reduce the opportunity for cross-contact.
- A changeover matrix based on allergen and/or sensitizing agent content is required to assist in production scheduling.
 - If all products produced at the facility contain the same allergen and/or sensitizing agent, a changeover matrix is not required (e.g., milk is in all products at the facility and is the only allergen in all ingredients and products at the facility).
 - The control step between products must be clearly defined. If rinsing or flushing is used as a means of control, the amount of water/product used to rinse/flush must be documented.
 - A Sanitation Preventive Control is required between:
 - A product that contains an allergen and a product that does not contain an allergen;
 - Products that contain unlike allergens.
- 3.5. Cleaning Validation
- If cleaning is determined to be a mechanism for allergen control, the procedures must be Validated for effectiveness in removing the allergenic substance.
 - Verification of the effectiveness of each allergen cleaning must be documented after each instance where a Sanitation Preventive Control is used to control an allergen.
 - Validation or re-Validation of the cleaning effectiveness is required when:
 - A new allergen is introduced to the facility;
 - A process is modified, and it affects ingredient additions or cleaning effectiveness;
 - A plant trial that includes a new allergenic ingredient or alters the process in a way that may affect cleanability.

- 3.6. Rework - Product containing allergens and/or sensitizing agents must only be reworked into products containing the same allergens and/or sensitizing agents.
- 3.7. Allergen and/or Sensitizing Agent Labeling
 - Finished products, byproducts, or derivatives which contain or may contain (by way of ingredients received with precautionary labeling) any of the allergens identified in section 2 above must have the allergen(s) and sensitizing agents labeled in accordance with FALCPA.
 - Products that are intended for export from the United States must conform to the allergen and/or sensitizing agent regulations of the country or countries where they are to be sold (e.g., sesame seeds and sulfites are regulated as allergens in Canada, and celery is an allergen in European Union countries). Country-specific allergen and/or sensitizing agent labeling must be considered.
 - Facilities must have a documented process for ensuring allergens and/or sensitizing agents are correctly labeled in finished products.
4. HACCP/Product Safety Plan must be approved at least annually, and a review must take place anytime there are changes to ingredients, products, food contact packaging, or equipment/processes that could have an impact on product safety.

FOREIGN MATERIAL CONTROL

1. Facilities must have documented program(s) to identify potential sources of foreign material and mechanisms to prevent, detect and control such sources. The program should include potential sources from raw materials, facility environment (e.g., ceilings, walls, floors), processing and packaging equipment design, utensils, personnel sources, and other operations such as Sanitation, contractor work, construction, rework/WIP, maintenance or repair of equipment, and historical information of types of foreign material previously found or reported by consumers.
 - The program must include a procedure for the control of glass, brittle or hard plastic, ceramics, or other similar materials when the use of these items cannot be avoided. This procedure must be documented and include:
 - A list detailing location, number, type and condition of such materials. This list must be audited at a risk-based frequency, but at the least, annually;
 - Actions required in the event of broken glass, brittle or hard plastic, and/or ceramic located near the product processing/packaging areas.
2. Foreign material control equipment must be in place and operated such that it identifies foreign material in product. Protective devices must:
 - Be designed and installed to not contribute foreign material to the product stream;
 - Have defined normal operating limits;

- Be placed prior to equipment that can be damaged by foreign material in the manufacturing process;
- Be placed after equipment that can introduce foreign material to the product stream in the manufacturing process and facilitate foreign material investigations;
- Be identified on the facility PFD;
- Have a documented inspection at an appropriate frequency.
- Metal detector or x-ray must effectively and reliably detect and reject metal within the product stream without false rejects. When x-rays or metal detectors are used as a protective device:
 - Product characteristics and aperture size must be considered when establishing control limits;
 - A fail-safe mechanism must be in place so that the line will not run if the CCP metal detector/x-ray or reject mechanism is turned off or disabled;
 - A reject mechanism must stop the line or divert product flow or must have an audible or light alarm to alert the operator. The reject mechanism must be capable of diverting affected product. This process must be Verified and documented daily, unless a documented risk assessment justifies a different frequency;
 - At a minimum, annual Validation of the system, including timing of the reject mechanism, must be completed;
 - Foreign material (metal or non-metal) detection Verification must include use of certified ferrous and non-magnetic stainless steel (e.g., 316) test standard. Non-ferrous must be done as required by specific customers;
 - X-rays employed to detect non-metal foreign material must be calibrated to a certified standard for that material and the capability must be documented;
 - Final product metal detectors and/or x-rays must be located as far downstream on the manufacturing line as possible while maintaining maximum detectability.
- Magnets must be used to protect products and equipment. The magnets must not introduce dust or collected metal back into product stream during inspection process. Magnets must:
 - Be monitored for pull strength to ensure minimal magnet degradation at a set frequency;
 - Be placed as close to the point of potential contamination as possible;
 - Be positioned to enable easy inspection and must be inspected on a documented frequency.
- Sifters/shakers must be designed to have as small a mesh size/opening as possible while maintaining product quality and screen integrity without impeding product flow.
 - Human Food: Sifting/filtering/shaking materials for ingredients and in-process materials must be one of the following:

- One-piece perforated stainless steel;
 - Pliable polypropylene/nylon;
 - Magnetic stainless-steel mesh followed by a magnet.
- Routine inspection of sifter and changing of screens must be part of a preventive maintenance program.
 - Human food facilities must have a documented program for inspecting tailings for physical contaminants.
- Filters and Strainers
 - Must be placed so that all liquids are strained prior to introduction into product manufacturing process.
 - Must be designed to have smallest mesh or opening size without impeding the ingredient or product flow.
 - All in-line filtering devices must be secured in place. If a bypass is employed, a filtering device is required to control the bypass material.
 - A documented risk assessment must be completed to determine if a package Hazard control device is required prior to filling open-formed containers (e.g., poly-tubs, metal cans, glass jars, composite containers). Package Hazard control devices include washers, vacuum devices, anti-static devices, air blower systems, container twists which invert the package, deionizer.
3. When foreign material is removed by a protective device:
- Investigation must be conducted to identify the source or cause of all unexpected materials;
 - Results of unexpected materials must be documented.
4. In the event of potential product contamination with foreign material, the following process must be completed:
- Stop process, identify cut-off point, and report to appropriate facility personnel;
 - Quarantine the affected area or equipment;
 - Identify, quantify, and document the contaminate(s) and product(s) affected;
 - Investigate to determine the source of the contaminate(s);
 - Identify all materials affected and place them on hold:
 - Complete a documented risk assessment for materials on hold;
 - Determine and document disposition of the affected product(s).

LOT CONTROL AND TRACEABILITY

1. All products (finished goods, ingredients –including bulk, rework, food contact packaging, processing aids and samples) must be coded or identified with lot and date information.
 - A production lot must not run for more than 24 hours.

- The legible lot code must be applied to every consumer/customer package, shipper/case, and bulk unit.
 - All lot code information within a pallet must match, including, but not limited to, consumer unit, case/shipper, and pallet tag.
 - A split pallet must list the number of units by different codes;
 - Multi-pack products must be appropriately lot coded with traceability to all lots.
2. Each facility must have a procedure to ensure product traceability.
- All manufactured products must be traceable to the first customer, including carrier used.
 - 100% of the finished product must be traced with a possible +0.5% within four (4) hours.
 - 100% of ingredients, including bulk, and product contact packaging must be traced within four (4) hours.
 - Inventory adjustments, returns, disposals, or other discrepancies must be justified and, when needed, Corrective Action must be documented.
 - Must have a documented retrieval team including roles, contact information and back-ups.
3. Trace effectiveness must be evaluated by conducting a documented mock trace at least twice per year.
- The mock trace must include a mass balance/reconciliation to account for raw materials used and finished product produced.
 - If the mock trace does not meet the requirements, investigation and Corrective Actions must be implemented and documented.

SPECIFICATION COMPLIANCE

1. Facility must have a documented product specification use and compliance program. Raw materials and finished products must have approved and current specifications, accessible to relevant stakeholders, which are reviewed on regularly determined intervals.
- Each facility must test ingredients, in-process products, and finished products according to specifications.
 - Each facility must have a documented process to ensure that the current specifications are being used.
2. Facilities must ensure raw materials meet specifications.
- Facilities must Verify that ingredients and product contact packaging are from an approved supplier and manufacturing location.
3. Finished products must meet specifications and the label declaration (e.g., formula, finished product, package, label) established by product owners.
- Finished product packaged weight tolerances must be established and weight data must be reviewed on a documented frequency to evaluate the process.

- Weight tolerances must be based on industry expectations and government regulations (e.g., NIST Handbook 133 or other applicable local, state, or federal net weight requirements).
 - A documented program must be in place to ensure compliance to all claims (e.g., Kosher, Halal, gluten-free, organic, rBST-free, Grade A, non-GMO).
 - The facility must develop a list of products that require claims.
 - Manufacturing procedures (e.g., ingredient control, sequencing, specific equipment requirements, Sanitation requirements) must be in place to ensure claim compliance.
 - Each facility must manage appropriate approvals, audits, and inspections (e.g., non-GMO, rabbinical visits).
 - Each facility must demonstrate the ability to access claims certificates where applicable.
 - A documented process specification (including the packaging process) must be completed and approved prior to the production of a finished product.
 - For processes listed in the specification and defined by a target and/or a range, the process must be controlled to run at target or within the stated range during the production run.
4. Each facility must have a documented and implemented label control process.
- A process must be implemented to confirm and communicate the proper label to run for the formula being produced. This process must include at a minimum:
 - Matching the formula/label information with the information in the specification;
 - Documenting the label used on each line at startup, once per shift, product changeovers, and at the end of the run.
5. If rework is used, the facility must develop, document and Verify their internal rework program.
- Facilities must evaluate rework flows and incorporate a break in the rework cycle on a periodic basis.
 - Current specifications for the type and amount of rework to be used must be followed.
6. Any raw material, in-process product, or finished product found to be noncompliant must follow the nonconforming material program described below.

LABORATORY MANAGEMENT AND TESTING PROGRAM

1. Internal laboratories must be designed, located, and operated to prevent contamination of products and produce accurate results.
2. Testing facilities must utilize good laboratory practices.
3. Testing ingredients, in-process samples and finished products must follow approved sampling, holding, and test methods (e.g., rapid screening test) performed by trained, qualified individuals.
 - Pathogen testing may not be done on-site.
 - Facility laboratories must participate in annual Verification.

4. External laboratories must be accredited.

NONCONFORMING MATERIAL

1. Facility must have a documented and implemented nonconforming material program that includes the following:
 - Damaged, rejected, aged, and/or expired materials;
 - Procedures around identification, classification, segregation, hold/quarantine, inventory reconciliation, and disposition of nonconforming materials.
2. When nonconforming material is identified, the facility must ensure that all nonconforming product is visually distinct and accounted for to prevent accidental release.
 - Facility must place nonconforming material on hold in the system (including electronic and/or manual logs).
 - Facility must assign nonconforming material a classification based on risk.
 - Non-hazardous holds may include quality-related holds and reprocess material.
 - Hazardous holds are for nonconforming material that may present a potential food safety threat.
 - Facility must segregate nonconforming material to prevent unintentional movement.
 - Hazardous or potentially hazardous nonconforming product must be segregated (e.g., using tape, cones, space, etc.) to avoid loss of control.
 - Facility must conduct a physical and electronic systems (if applicable) inventory on all nonconforming products to ensure product on hold is not shipped.
 - Inventory frequency for non-hazardous holds – monthly.
 - Inventory frequency for hazardous holds – daily.
 - Any inventory discrepancies must be investigated.
3. Disposition of nonconforming product must be documented and traceable. Documentation must include details of the disposition and who authorized it.
 - If destruction/reprocessing is the disposition for hazardous holds, proof of disposal/reprocessing approval is required.

POSITIVE RELEASE

1. Each facility must have a documented and implemented positive release program for ingredients, food-contact packaging, in-process materials, and finished product (as applicable).
 - The program must have defined roles and responsibilities and documentation requirements.
 - Employees who conduct positive release must receive training on facility positive release procedures. If changes are made to the program, retraining is required.
 - Finished products must not be released until all CCP and PC Verification reviews have been completed and the results are acceptable.

MANUFACTURING CONTROL

1. Facilities must have a manufacturing control plan (MCP) in place for all manufacturing processes to include all quality and product safety/integrity monitoring activities.
 - The MCP charts must contain required testing/activity for identified chemical, physical and biological Hazards, regulatory requirements and quality checks.
 - MCP charts must contain:
 - Testing/activity description;
 - Responsible person and frequency;
 - Control and operational limits if applicable;
 - Monitoring procedures (including frequency and responsibility);
 - Actions against deviations;
 - Verification procedures (including frequency and responsibility);
 - Validation procedures if applicable;
 - The MCP must include CCPs, PCs, control points (CPs) and extended run requirements.

REGULATORY COMPLIANCE REQUIREMENT

Statement of Intent: To ensure business and facility compliance with all applicable laws and regulations governing the product, manufacturing process, packaging, and service in the country of origin (where made) and country of destination (where sold).

DOMESTIC AND INTERNATIONAL COMPLIANCE

1. Business must have a program for managing domestic and international compliance.
 - Product and packaging materials must comply with applicable laws and regulations in country of origin (where made) and the country of destination (where sold).
 - Manufacturing facilities must be registered under applicable laws and regulations.

REGULATORY INSPECTION:

1. Facilities must have a documented inspection plan that contains the following elements:
 - Facility name and location;
 - List of the members, roles, and responsibilities of the facility regulatory inspection team;
 - Training schedule and documentation requirements for each member of the team;

- Product hold procedure for collecting and testing regulatory samples for pathogens or other non-routine product safety Hazards. Duplicate samples must be collected and stored.
2. Documented inspection plan must include a process to manage regulatory inspections.
 3. Communication must occur when LOL products or facilities are affected, or when production areas used for LOL products or ingredients are involved in the following scenarios, prior to public notifications: EPA, FDA RFR, or FDA 483, recalls, retrievals, and/or after samples are pulled by regulatory agencies.

PRODUCT LABELING

1. All product labels must meet applicable laws and regulations for country of destination.
2. Business must have a labeling approval process in place.

EMERGING INFORMATION

1. Business must have a process for managing emerging issues that can have an impact on product quality, safety and regulations. Actions must be documented when emerging information in legislation, regulation, scientific data, or industry practice is identified.

SITE MANAGEMENT REQUIREMENT

Statement of Intent: To prevent contamination of final product and help ensure safe conditions for the manufacture and storage of raw materials and products.

SITE INFRASTRUCTURE

1. Facility must have a documented plan in place before the installation, construction (permanent and temporary structures), modification, and destruction of buildings, grounds, equipment, utilities, and critical software that have the potential to present a product safety or quality issue.
2. Facility must have a document/map (GMP map) that identifies the controls, including physical barriers and segregation, to prevent potential cross-contamination risk for products and processes.
3. Buildings must be designed and maintained to prevent pests (e.g., rodents, birds, insects) from entering, harboring, and infesting.
4. Lighting must be shatterproof or shielded.
 - Buildings and grounds must have adequate lighting.
5. Building ventilation must limit and control condensation and mold development.
 - Where temperature, relative humidity, or air quality impacts the product or production environment, adequate controls must be implemented to achieve the necessary operating conditions.
 - Building ventilation (e.g., windows, vents, fans, pipes, louvers) must be screened and/or sealed.
6. Walls and ceilings must be constructed of materials designed to be cleanable.
7. Doors must be constructed of materials designed to be cleanable.

- Exterior doors, including dock doors, must be self-closing or kept closed and must be sealed tight to prevent pest entry. Doors, when closed, must have no visible light present around the seals.
8. Floors must be designed to drain properly to prevent standing water.
- Drains and drain pipe design must prevent product contamination.
 - Equipment and process waste piping must be arranged so that waste liquids go directly to a drain.
 - Drains and drain pipes must prevent product contamination.
9. Designated changing facilities or locker rooms must be provided for all personnel. These areas must be properly used, maintained, and inspected.
10. Facilities must have a defined specification for utilities (e.g., water, ice, steam, air, compressed air, etc.) based on their intended use.
- Wastewater and sewage must be handled in accordance with all applicable regulations and in a manner that prevents product contamination.
11. Exterior grounds must be suitably surfaced (e.g., gravel, asphalt, concrete) and drain properly to prevent standing water, pest pressure, and vegetative outgrowth.
12. Facility must have a program to mitigate risk due to waste/trash that includes:
- Identification and management of types of waste/trash applicable to specific facility (e.g., lab waste, chemical container, maintenance oils & lubricants, etc.);
 - Review of regulatory requirements for each type of waste/trash;
 - Appropriate removal frequencies of each waste/trash type;
 - Where potential for cross-contamination exists, waste/trash accumulation areas must be in a designated space separate from product handling and processing areas;
 - Procedures for how waste/trash moves through the facility prior to removal from the premises;
 - Waste/trash containers that are:
 - Acceptable for waste/trash type, and that meet all applicable regulations;
 - Clearly identified and/or labeled for intended purpose;
 - Sized appropriately;
 - Designed to be effectively emptied.
 - In human food facilities, Sanitation methods for waste/trash containers and removal equipment;
 - A documented procedure to ensure product labels, finished product packaging, and fully labeled finished product designated as waste/trash are defaced/destroyed in a manner that prevents unintended or unauthorized use.

BIOSECURITY

1. Facility must have a documented and implemented biosecurity plan.

CHEMICAL CONTROL

1. Facilities must have a documented program for all non-ingredient chemicals stored and used at that facility (e.g., chemicals used for pesticides, processing aids, Sanitation, maintenance, waste, water and boiler treatment, indicators, laboratory, office, janitorial, paints, inks, and solvents). The program must include:
 - A defined process for selecting vendors and chemicals;
 - Safety Data Sheets (SDS) and EPA registration numbers, where applicable.
2. Facilities must manage chemical receiving and storage against the approved chemicals list.
 - Annually, the chemical list must be reviewed for accuracy.
 - Upon receipt, all chemicals shall be Verified against the approved supplier list.
 - Chemicals must be segregated by application categories during storage, segregated from food products by a physical barrier, and stored per label requirements.
3. Labels must be present to identify chemicals, including:
 - Primary and secondary chemical containers must be labeled and include physical or health Hazards.
4. Chemicals must not be dispensed from, or stored in, containers originally containing food, ingredients, packaging, or raw materials.
5. All chemical handling, application procedures, and usage must be per label instructions and plant chemical control program.
6. All direct or incidental food contact chemicals (non-ingredient chemicals that come in direct contact with food) must be labeled to indicate its use as direct food contact, incidental food contact, or requiring a rinse with potable water prior to food production.
7. Disposal of chemicals must follow all manufacturer requirements.
 - Empty chemical containers are to be returned to suppliers, recycled, or sent to proper disposal facilities. If containers are re-used in the plant, a process must be established to manage associated risk, including cleaning the container, defacing label, identifying use, etc.

HOUSEKEEPING

1. Each facility must establish a written master housekeeping program.
 - The facility must have a general housekeeping program covering the care, cleanliness, and orderliness of the facility.
 - Program must include identification of areas to be cleaned, methods, responsibilities, frequency, and housekeeping records.
2. Areas to be cleaned and/or maintained must encompass the entire facility, including:
 - Employee Welfare Areas;
 - Management of doorway sanitizers (foam or footbaths);
 - Walls, ceilings, and equipment kept free from foreign material and potential microbiological Hazards (e.g., loose paint, rust, dust, dirt, condensation):

- Suspended ceilings must be periodically inspected for cleanliness and pest activity.
3. Housekeeping methods and/or tools must be appropriate to complete the task, without introducing additional contamination.
 - Production, Sanitation, and janitorial tools must be maintained and stored in a sanitary manner.
 - Facilities must develop and maintain a documented color-coded tool system to indicate proper use (e.g., drain cleaning, product contact, etc.) and prevent cross-contamination.
 - Janitorial tools and cleaning supplies must be stored separately from production and tools used for Sanitation.
 - When used, compressed air must be used in a controlled way to prevent cross-contamination.
 - Air hoses and nozzles must be in good condition, kept off the floor, and cleaned and/or sanitized at an appropriate frequency and after any repairs or maintenance.
 - Spills must be cleaned promptly when they occur.
 - Transfer and Clean in Place (CIP) hoses used for bulk ingredients must always be kept off the ground (e.g., donuts on hoses, hangers), capped when not in use, and cleaned on documented frequency.
 - Condensation must be eliminated or controlled on structures above exposed product before food handling can begin and during production.
 - Tools with wood components must not be used. All tool handles must be metal or plastic and of a sanitary design (e.g., hollow handles sealed).
 - In-process containers must be properly labeled, cleaned on a scheduled basis, and stored in a sanitary manner.
 - All utensils must be cleaned and sanitized to eliminate cross-contamination during production and cleaning.
 4. Housekeeping inspections must be performed at a determined frequency, with Corrections implemented for deficiencies.

MAINTENANCE AND CALIBRATION

1. Facilities must develop and implement a documented program that covers preventive maintenance and general maintenance and repair expectations for equipment impacting product safety, quality, and regulatory compliance (e.g., production equipment, controls including traffic patterns, sanitary surfaces, Sanitation systems, and controlled environments). This program must include:
 - A priority system to address product safety/quality issues;
 - A process for incorporating new or upgraded equipment into program;
 - Records available to Verify completion of maintenance work.
2. General maintenance and repair plans must include methods to prevent cross-contamination where risks exist (e.g., assessment of adjoining lines, scheduling, equipment/tools cleaning and inspection prior to

relocating, cleanup steps and tool accountability, pre- and post-maintenance inspection measures, chemical control measures, fit for use assessment).

- A maintenance shop must be maintained in a clean and organized manner, according to risk to the products and processes. Human food facilities must include:
 - Control measures at exits to trap metal shavings and debris (e.g., bristled mats, tacky mats);
 - Restricted access.
 - Tools hazardous to products or processes must be identified and controlled. Facilities must have a program, where necessary, that define control measures (e.g., Sanitation, color-coding, traffic patterns, check-in/check-out procedure) and appropriate procedures for use.
 - Lubricants must be fit for use and managed in a way to minimize cross-contamination concerns.
 - H1 Lubricants must be used as follows:
 - Human food: Where incidental product contact is possible (refer to chemical control program). They must not contain allergens such as nut oils.
 - Lubricant application must be done in a way to minimize the risk of product cross-contamination.
3. Facilities must develop and implement a temporary repairs program, which includes a plan for permanent repair.
4. Facilities must develop and implement a documented calibration plan. The calibration plan must include:
- Identification of all equipment that requires calibration. At a minimum, this must include measurement and monitoring equipment used during manufacturing (e.g., resistance temperature detectors (RTDs), liquid meters, scales, thermometers, metal detectors, etc.);
 - The frequency of calibration, acceptable range and action against deviation (per manufacture recommendations);
 - The steps required for calibration and validation of equipment accuracy:
 - Calibration of critical equipment used for monitoring CPPs and PC points must be to certified and traceable standards, adjusted as necessary, and safeguarded where applicable from unintended adjustments (including handling, maintenance, and storage).

MATERIALS AND WAREHOUSE MANAGEMENT

1. Inbound vessels (e.g., trucks, tankers, railcars) and documentation must be inspected before unloading to determine the acceptance or rejection.
- Facilities must have documented and implemented procedures for inbound carriers including:
 - Food defense:
 - All inbound carriers, non-less than truckload (LTL), delivering ingredients or raw materials must have intact seals upon arrival. Seal numbers must match recorded numbers on the load documentation;

- Inspection to detect evidence of tampering;
 - Receiving material in compliance with specification compliance program:
 - Compliance with shipping requirements per specification;
 - Compliance with temperature requirements per specification;
 - Compliance with regulatory requirements per specification (e.g., antibiotic testing on milk);
 - Good Manufacturing Practices (GMP) inspections (e.g., pests, unsanitary conditions, odors, glass, residues from previous loads);
 - Confirmation that the materials delivered match the bill of lading (e.g., items, lot codes, and quantity).
 - Bulk dairy liquids must be received in a manner that minimizes risks associated with extraneous contamination including unloading only in areas designated and accepted by state regulation. All required testing must be completed before unloading begins.
 - Receiving records and relevant lot information must be documented for traceability.
2. Storage conditions - Finished products and raw materials must be managed to prevent contamination and damage.
- All ingredients, food-contact packaging, and finished product are to be stored according to their specification requirements and to prevent potential contamination from physical, chemical, and biological Hazards.
 - Warehouse areas must be clean, dry, well ventilated and free of pests.
 - Controlled temperature areas are to be Verified and documented.
 - Products susceptible to odors (e.g., butter, cheese, etc.), must be stored in a manner to prevent odor absorption.
 - A documented age management procedure for minor ingredients, bulk ingredients, packaging materials and finished products must be in place to ensure proper rotation and that:
 - FIFO (first in, first out)/FEFO (first expired, first out) is followed.
 - Wood pallets used in the storage areas shall be clean, dry, and in good repair.
3. Each facility must have a documented program in place for shipping, including a documented inspection prior to loading.
- Each facility must perform a documented inspection of carriers (trucks, tankers, and rail cars) and Raw Materials before loading. This inspection includes:
 - All non-less than truck load (LTL) carriers delivering products must have intact seals prior to departure:
 - Seal numbers must match recorded numbers on the load documentation;
 - GMP inspection (e.g., pests, unsanitary conditions, odors, glass, residues from previous loads);
 - Suitability of the equipment to prevent product damage;

- Compliance to shipping requirements per specification.
- Outbound carriers must meet the temperature requirements as defined in the specification, and the temperature shall be taken and documented.
- Contents must match the bill of lading (e.g., items, lot codes, and quantity).

EMPLOYEE PRACTICES

1. Facility must have a program defining expectations around personal hygiene and employee practices based on risk to materials.
 - Facility must clearly define areas where employee practices must be followed.
 - Documented plant GMP assessments must be conducted in all GMP, transitional, and warehouse areas on a monthly basis at a minimum. All other non-GMP areas of the facility (e.g., exterior grounds, laboratories) must be assessed at least annually.
 - Corrective Actions must be documented, implemented, and monitored for effectiveness.
2. Employees must maintain clean and proper personal hygiene.
 - Individuals entering a manufacturing area must have clean hands at all times. Employees are required to wash their hands:
 - Before starting work and when returning to work area (e.g., after smoking, vaping, eating, visiting restroom);
 - Before entering a production GMP or high hygiene area;
 - Whenever hands are soiled or contaminated.
 - Facilities must have hand wash and Sanitizing stations in restrooms, breakrooms, and areas where employees may contaminate product directly or indirectly.
 - Employee hands must be in a clean and sanitary condition when handling product, product-contact surfaces, and food-contact packaging. Clean and sanitized gloves must be used when touching product or product-contact equipment.
 - Employees must keep fingernails clean and properly trimmed. Fingernail polish, false fingernails and false eyelashes are not permitted.
 - No personal items (e.g., purses, tobacco, lotions, personal electronics, cell phones, reading materials, etc.) are allowed in GMP areas.
 - Employees must not hold anything in their mouth or behind their ears in GMP areas (e.g., toothpicks, pens).
 - Employees must cover mouths when coughing or sneezing and wash hands immediately after such occurrence. If excessive coughing or sneezing occurs, employee must leave GMP areas and wash hands prior to returning to work.
3. Work wear must be fit for purpose and not pose a contamination risk in areas where exposed products and/or materials are handled.
 - Uniforms must be captive and not worn outside unless specified for a certain job type or covered.

- Clean uniforms are required at the start of work and must be changed if they become soiled.
 - Clean uniform storage must be maintained in a sanitary manner.
 - Smocks or aprons should be worn over uniforms where rapid soiling or exposure to open product can occur.
 - Removable work wear (e.g., smocks, lab coats, coveralls, aprons, sleeves, gloves, head wear) must be removed and hygienically stored while using the restroom and eating/drinking in Employee Welfare Areas.
 - Product-contact gloves must be kept intact, in sanitary condition, visually distinct (e.g., color), disposable, and not stored in the pockets of a uniform.
 - Personal protective equipment (PPE) must be maintained and stored in a sanitary condition.
 - Ear protection must be secured to prevent product contamination.
 - Point-of-use work wear (e.g., cooler jackets, stocking caps, cloth gloves) must be hygienically stored and either disposable or laundered.
 - Employee footwear must be fully enclosed and comply with the following:
 - Captive (in-plant) footwear specific to the job is required. Specific requirements must be defined and documented as part of the facility uniform GMP program.
 - Footwear must be cleanable and must be maintained in a clean condition. Construction, material, tread type and depth must be considered in the selection of footwear for each job type.
 - All employees must wear a hair net in GMP areas. Hair nets must fully contain the hair, cover the ears, and be company-supplied. Open, mesh-style hair nets and beard nets must not be used.
 - Beards and mustaches must be covered by a beard net in all GMP areas.
 - Sideburns that are not completely covered by a hair net must be covered by a beard net.
 - Hair curlers, combs, and bobby pins must not be worn in GMP areas. Although discouraged, barrettes (two inches or more) made of metal, scarves, and bandannas may be worn under a hairnet.
 - Jewelry (e.g., rings, earrings, necklaces, watches, tongue jewelry, or other visible body piercings) cannot be worn in GMP areas.
4. Smoking, vaping, chewing, eating, and drinking must be confined to designated areas. Spitting is prohibited in all parts of the facility.
5. Illness, disease, blood borne pathogen, and biohazards:
- Cuts, sores, and scrapes must be covered to protect product and the employee;
 - All cuts and scrapes on exposed skin must be covered using company-issued metal-detectable bandages;
 - Employees are responsible for notifying management when they have signs of an illness that may affect product safety;
 - Employees with, or those who have come into contact with, a communicable disease or employees with boils, open sores, infected wounds, etc. are not allowed to work in areas where they could affect product safety or transmit a disease to others.

6. Employee medications are not allowed in GMP areas and may only be stored in authorized areas (e.g., first aid kits, lockers).
7. Operational tools and electronic device management control:
 - Tools, utensils, and electronic devices must be controlled to prevent a contamination threat to products;
 - Facilities must have a documented program for tool management including inspection for damage and investigation of any lost tools or components;
 - Items (e.g., pens, pencils, thermometers, tools) cannot be worn about the belt/waistline;
 - Staples, thumb tacks, twist ties, and paperclips must not be used in GMP areas. The use of other small metal items must be minimized.
8. The facility must establish a documented and implemented program for visitors and contractors.
9. The facility must have a policy or procedure defining cell phone and camera use at the plant.

PEST CONTROL

1. Facility pest control program must be documented, maintained, reviewed, and updated annually at a minimum. This program must contain the following elements:
 - Written description of the program;
 - Scope of the service agreement;
 - Pest Control Operator (PCO) information including:
 - Photocopy of the PCO applicator license;
 - Business license (where required by state);
 - Contact information for PCO and manager(s);
 - Certificate of insurance with a minimum of one million dollars of liability insurance or five million dollars minimum if fumigation services are performed;
 - Pesticide information:
 - Hard copies or electronic copies of labels and Safety Data Sheets (SDS) for pesticides approved for use must be readily available;
 - Schematic map(s) of facility (including monitoring devices identification and location);
 - Activity/trending logs (permanent and, if used, temporary devices);
 - Inspection summaries/service reports must be signed and dated by authorized personnel and PCO;
 - PCO or facility inspection findings, including trends of increased activity, must have Corrective Actions that are completed, documented, signed, and dated;
 - Program reviews to be completed annually and documented by PCO;
 - Business review conducted by PCO and facility to evaluate PCO performance and facility needs.

2. Pesticide Application and Storage: The application of a pesticide inconsistent with its label requirements is prohibited.
 - All fumigation activities must be performed by a licensed PCO.
 - Application of pesticides must be performed by a licensed PCO.
 - Pesticide usage records (pesticide usage log) must include the following information, at a minimum:
 - Pesticide name, EPA number and lot number;
 - Quantity of pesticide used;
 - Target pest;
 - Specific areas treated;
 - Method of application;
 - Percent of active pesticide material when applied;
 - Rate of application;
 - Date and time(s) of application;
 - Applicator's name, license or certification number, and signature.
 - Pesticides stored at the facility must be kept in a separate and locked storage area, away from ingredients, packaging, and products.
3. Pest control devices (where employed) must have documented and identified placement, and their activity must be monitored.
 - In the event of a facility infestation, immediate action must be taken to eliminate the Hazard.
4. Pest Control records must be kept for the period necessary to meet regulatory requirements.

FOOD DEFENSE

1. Each facility must have a site-specific FSMA-compliant food defense plan.
2. Each facility must have a site-specific, cross-functional food defense team.
 - Food defense team must have annual food defense job-specific training including intentional adulteration from both insiders and outsiders from the facility.

CLEANING AND SANITIZING

1. Each facility must implement and maintain a cleaning and Sanitizing program.
 - Sanitation standard operating procedures (SSOP) and work instructions must be written for all production areas, processing equipment, and other parts of the facility and must include:
 - Specific area/equipment to be cleaned;
 - Applicable critical cleaning requirements (e.g., time, temperature, concentrations {target and ranges}, flow rates, rinse hose pressure);

- Frequency of cleaning;
 - A list of parts/areas to be manually cleaned when equipment is disassembled or cleaned in place ;
 - Chemicals required and mixing instructions for manual “use” solutions;
 - Equipment and tools needed for cleaning including personal protective equipment (PPE);
 - Appropriate safety procedures;
 - Person responsible for cleaning;
 - Document control information: date of issue/revision and author’s initials.
- For all CIP systems or Assisted Cleaning Systems (ACS), the facility must manage and document the design, function, and operation of the equipment including:
 - Appropriate product PFDs;
 - SSOP reference;
 - CIP flow diagrams detailing the CIP solution flow through the circuit including all piping, valves, pumps, etc. for the equipment cleaned;
 - Programming PIN chart of control functions (e.g., programming) for each circuit;
 - Specific pulsing requirements for valve clusters;
 - Documented preventive maintenance schedule and records;
 - Recommended spare parts list.
 - For all Clean Out of Place (COP) systems, the facility must have:
 - The SSOP for each COP tank (note: multiple SSOP’s may be necessary for each COP tank depending upon the equipment and soil to be cleaned);
 - COP operating procedures.
 - A drain cleaning program (defined as cleaning of the drain pipe, receptacle and cover, and cleaning or removing debris from the basket) must be in place.
 - Dry cleaning of equipment and environment – Special considerations: When using dry cleaning (or controlled wet cleaning) techniques in a restricted or no-water-use area, care must be given to ensure the SSOPs and master Sanitation schedules (MSS) incorporate the necessary controls to prevent creating potential contamination issues from microbial harborages or niches.
2. A master cleaning and Sanitizing schedule must be in place.
 3. The cleaning and Sanitizing program must be monitored, Verified, and Validated to ensure effectiveness.
 - All facilities must have a Sanitation measurement system in place to measure the effectiveness of the facility Sanitation program.
 - A Verification audit must be completed annually for each CIP/ACS system.

4. Program deviations which impact food safety or quality must be documented, and Corrective Actions identified and implemented.

ENVIRONMENTAL MONITORING

1. Facilities must have an environmental monitoring program when microbiological Hazards have been identified as a cross-contamination Hazard through the Hazard analysis and risk assessments. This program must:
 - Include a procedure for taking samples as per industry standard;
 - Require human food facilities to evaluate the need to monitor for the presence of indicator and/or spoilage organisms (e.g., Enterobacteriaceae, yeast, mold, phage, etc.). Facilities with products that are susceptible to spoilage or issues due to the presence of organisms in the environment must include these organisms in their program;
 - Have an annual approval which must include a map of the facility and equipment layout, identified sampling areas/sites, and frequencies and history of program changes:
 - The sampling plan must follow a zone approach (taking into consideration traffic patterns) to identify potential sources and vectors and evaluate risks to determine sample sites and frequency of sampling.
 - Require positive environmental swabs to be investigated and recorded on the facility/equipment map:
 - Documentation of the investigation must include investigational swab locations, results, and Corrective Actions.
 - Require results of the environmental monitoring program to be used to measure and report the effectiveness of the environmental monitoring program.

DEFINITIONS

Assisted Cleaning System: A method of cleaning that circulates Sanitation chemicals through equipment and piping like a CIP system, but is not automatically controlled or monitored. Also known as “Pot and Pump” or “Short Circuit.”

CIP – Clean in Place: A cleaning method which uses circulation of Sanitation chemicals and water rinses to clean without dismantling the equipment. CIP systems are usually automatically controlled.

COP – Clean Out of Place: A cleaning method which requires the complete dismantling of equipment and placing the parts in a specifically designed tank. Then, by using a series of circulation of Sanitation chemicals and water rinses, the equipment is cleaned.

Co-manufacturer: Company that transforms Raw Materials into finished products for another company under a contract.

Correction: Action taken to regain control of non-conforming product or process.

Corrective Action: Action to reduce or eliminate the likelihood that a problem will reoccur; designed to address the root cause(s).

Design Hazard Analysis Process: A Hazard mitigation analysis, including identification of significant Hazards to be addressed in the product design and development, and the documentation of controls.

Employee Welfare Areas: Non-production employee spaces, including locker rooms, break rooms, smoking areas, and offices.

External Business Partner: A company who provides goods or services to or receives goods or services from Land O'Lakes.

H1 Lubricant: Lubricants that could have incidental food contact (e.g., food-grade compounds that may be used as a lubricant or anti-rust film on equipment and machine parts in locations where there may be exposure to edible products).

Hazard: A naturally occurring or intentional biological, chemical (including radiological), or physical threat that has the potential to have adverse health effects.

Ingredients Suppliers: Companies or facilities who produce and/or package materials utilized in the manufacture of finished products that are designed for human consumption.

Joint Venture: A commercial enterprise undertaken jointly by two or more parties that otherwise retain their distinct identities.

Licensee: A company that has the right under the license granted to brand their product with another company's trademark.

Merchandised Materials Suppliers: Companies or facilities who produce and/or package materials utilized in the manufacture of finished products that are designed for human or animal consumption, where there is an intermediary buying and selling the materials.

Packaging Suppliers: Companies or facilities that produce materials utilized to contain finished products. These materials can be product contact or non-product contact.

Product Safety Plan (PSP): A set of written documents based on product safety principles that incorporate Hazard analysis, preventative controls, supply-chain programs, and a recall plan, and delineate the procedures to be followed for monitoring, Corrective Actions, and Verifications.

Sanitation Preventive Controls: Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent Hazards such as environmental pathogens, biological Hazards due to employee handling, allergen Hazards, or other chemical Hazards.

Sanitation: The practice of cleaning and/or Sanitizing (does not encompass housekeeping).

Sanitizing: Adequately treating cleaned surfaces by destroying substantial numbers of vegetative cells of pathogens, substantially reducing numbers of other undesirable microorganisms without adversely affecting the product or its safety for the consumer.

Stage Gate: A project management technique in which an initiative or project (e.g., new product development, process improvement, business change) is divided into stages separated by gates. At each gate, a manager, steering committee, or other qualified individual will decide whether or not the process will continue. This decision is based on the information available at the time including the business case, risk analysis, and availability of necessary resources.

Validate: To provide documented results of effectiveness of standard operating procedure (SOP), including parameters identified as critical for the intended purpose (e.g., allergen removal, soil removal).

Verification: The application of methods, monitoring, tests, procedures, and other evaluations to determine whether a control measure is or has been operating as intended.

Warehousing Providers: Companies or facilities that store materials and finished products for later shipment to customers.