LAND O'LAKES, INC.

Quality Expectations Manual for Packaging Suppliers

9/1/20

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 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 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 CONTACT PROGRAM

1. Each facility must have a documented program in place regarding customer 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 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 requests.
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.

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.
     - LOL requires notification in writing a minimum of 60 days prior to implementation of any changes to manufacturing /packaging location(s). At such time Land O'Lakes, Inc. will determine what, if any, additional qualifications or acceptance testing may be required.
   - The LOL sourcing/R&D business management team will select suitable Packaging Suppliers for review and engage LOLCQ 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.

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.
7. Packaging Facilities must be audited by an accredited third-party audit company with satisfactory resolution of key issues identified. Use of a Global Food Safety Initiative benchmarked audit scheme is recommended.

8. Facility must have a CAPA program to address findings when failures are found in the QMS (e.g., self-assessments, housekeeping, pest control, etc.).
9. 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.
10. 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.

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 be conducted at a risk-based frequency and/or to comply with a certification, license or approval.
3. Verification activities must be conducted using defined methods and reporting processes.
4. 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 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.
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.

   - 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.
   - LOL requires notification in writing a minimum of 60 days prior to implementation of any changes to material specifications. At such time Land O'Lakes, Inc. will determine what, if any, additional qualifications or acceptance testing may be required.
2. Facilities must ensure raw materials meet specifications.
3. Finished products must meet specifications and the label declaration (e.g., formula, finished product, package, label) established by product owners.
4. If rework is used, the facility must develop, document and Verify their internal rework program.
5. 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
2. When nonconforming material is identified, the facility must ensure that all nonconforming product is visually distinct and accounted for to prevent accidental release.
3. Disposition of nonconforming product must be documented and traceable. Documentation must include details of the disposition and who authorized it.

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).

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.

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.

PACKAGING PRINT CONTROL

1. Each facility maintains reference source information for the current and approved printed labels. The source documents include Product name, Product item/SKU, Product UPC, Allergen/Safety/Legal Labeling, and copy of label. Electronic color copies are acceptable.
2. Each facility maintains a documented system to confirm and communicate the proper label/printing to run.
3. A documented system is maintained to test printed materials/labels for identification errors and sorting of the packaging from acceptable printed materials/labels.
4. An assessment of the print process and handling of printed/labeled packaging materials is conducted to identify risk of loss to essential information, legibility, odor, quality, and mixing of printed products.
5. Printing plates, media, and other equipment are fully traceable and appropriately stored.
6. Any unused printed materials/labels are accounted for, documented, and properly disposed of, or alternatively, properly stored.

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 drainpipe design must prevent product contamination.
     - Equipment and process waste piping must be arranged so that waste liquids go directly to a drain.
     - Drains and drainpipes 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;
    - 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.

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:
   - Safety Data Sheets (SDS) and EPA registration numbers, where applicable.

- A defined process for selecting vendors and chemicals;

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.
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.
4. A housekeeping inspection 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.
    - 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.
        - 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.
2. Storage conditions - Finished products and raw materials must be managed to prevent contamination and damage.
3. Each facility must have a documented program in place for shipping, including a documented inspection prior to loading.

EMPLOYEE PRACTICES

1. Facility must have a program defining expectations around personal hygiene and employee practices based on risk to materials.
2. Employees must maintain clean and proper personal hygiene.
3. Work wear must be fit for purpose and not pose a contamination risk in areas where exposed products and/or materials are handled.
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;
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;
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.
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.
4. Program deviations which impact food safety or quality must be documented, and Corrective Actions identified and implemented.

DEFINITIONS

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.

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

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: 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.