LAND O'LAKES, INC.

Crop Inputs Quality Expectations Manual

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Version 2.0

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 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 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 lists.
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, 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, product 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, product 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, product 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, product 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.
        - 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 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, product 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, product 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 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, product 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.

OTHER GOODS AND SERVICES PROVIDERS

1. Other Goods and Services Providers (providers that do not fit the categories above) quality, product 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 annually.
   - 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. 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.
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.
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

CONTAMINATION PREVENTION

1. Contamination Review Assessment
   - Conduct and document a Contamination Risk Assessment (CRA) for each qualifying occurrence, as listed below.
   - Situations requiring a CRA
     - Preparing to manufacture a new product (product that does not have identical ingredients to a current product and no existing CRA)
     - Ingredient change or replacement in the formula of a current product
     - Contamination Event

- A CRA will be conducted on each manufacturing process at minimum every 5 years.
- CRA Considerations for all material (Raw/ In-process/Formulation/Packaging materials)
    - **EQUIPMENT SHARING BETWEEN PROCESSES**
    - **ADJACENT AREA PRODUCTION**
    - **EQUIPMENT CLEANING CAPABILITY**
    - **OVERHEAD SOURCES OF CONTAMINATION**
    - **RAW, IN-PROCESS, AND FINISHED MATERIAL HANDLING AND STORAGE**
    - TLI matrix review
    - Simultaneous/non-simultaneous production determination
    - Segregation matrix determination review
    - Ingredient vendors must be evaluated to determine if PAI's are produced at the vendor's site, and if so, ensure that phytotoxic contamination is controlled adequately at the vendor's location.

2. Phytotoxicity-Isolation Matrix for Simultaneous Production

   Each facility will develop and abide by a separation matrix for determining the amount of Isolation/Separation needed for simultaneous production of PAI and/or non-PAI containing products for each processing area within the facility.

3. Phytotoxicity-Isolation Matrix for Non-Simultaneous Production

- A Phytotoxicity/Biological data matrix for trace level impurity limits within various crop families must be generated using the (EPA Rule 96-8 for FIFRA limits, Crop Injury Matrix for in-house limits, research and/or customer requirements/recommendations)
- Non-herbicides must not be produced in the same equipment as herbicides, unless re-dedication of equipment using stringent verification of cleanliness which can be confirmed and documented, and approval is given by the Facility Manager and the Contamination Prevention Officer (CPO) of the facility.
- Use these rules for determining allowable TLI (Trace Level Impurities), these rules are listed in the order of priority of which rule should be considered/used first; and, at minimum two rules must be used for each TLI determination:
    - EPA Rule 96-8
    - Crop Injury Calculation
    - Crop Injury Matrix
    - Customer specific information – generally regarded as the best source, if given by a multinational crop protection company, for TLI's based on phytotoxilogical activity, but involves the sharing of other PAI's and/or non-PAI's produced in the same system/equipment.

- Researching application use(s) and rates of the products, and their constituents, that share all or part of the same process and/or equipment. Along with calculating the no effect cleanout concentration is regarded as the 2nd best approach if 3.3.4 cannot be used.
- If, for confidentiality purposes, reference 3.3.4 cannot be used to determine the TLI's, then reference 3.3.2 and 3.3.3 must be used together.

- All information used in determining the TLI's being placed in the Matrix(ces) will be documented and retained
- TLI's can be lowered by Division or Plant management based on past history for the performance of the cleanout, solubility of the product being cleaned, and other factors including the length of the time between cleanouts, etc.
- When a label change or an additional label is added to a product line the TLI's must again be reviewed.

4. Clean-out/De-contamination for non-Simultaneous Production

- Use a systematic comprehensive procedure(s) for clean-out/de-contamination of all vessels/tanks, piping, and/or packaging equipment and keep detailed records.
  - Cleaning levels must be defined, and a cleaning method generated between non-pesticide active ingredients such as micronutrients and adjuvants that are produced sequentially in the same equipment based on quality specifications and performance.
  - If a non-pesticide active ingredient is produced sequentially in the same equipment as an insecticide or fungicide, then a cleaning method and acceptable ACL matrix must be generated.
  - Cleaning of equipment in a facility that produce pesticides sequentially must be completed in a way to ensure cleaning from a PAI is at or below the TLI level specified for the next product.
  - Cleaning procedures must be reviewed for effectiveness by the CPO or their designee.
  - Cleaning will be verified by laboratory analysis for all changes between PAIs and according to the cleaning matrix developed for the equipment through the OQMS-006-P1 Contamination Prevention Policy.
  - Validated analytical methods must be available to analyze residues in wash liquids and/or analyze in the following product.
  - Sample points must be identified and at a location that will provide a representative sample for verification of the equipment being cleaned.
  - Cleaning of equipment must take place as soon as possible.
  - On non-dedicated equipment after the production has stopped not only when changing from one product to the next, but also if the equipment is left idle. This applies to all non-dedicated synthesis, formulation and filling and packaging equipment.
  - On dedicated equipment when it can affect product quality.

- Mobile and portable equipment (vacuum cleaners, flexi hoses, pumps, tools, etc.) must be dedicated for use for herbicides, unless rededication of equipment using stringent verification of cleanliness which can be confirmed and documented approval is given by the Facility Manager and the CPO of the site.
- Portable equipment and refillable containers (IBCs, ISOs, Bulk Bags, Rail cars, etc.) must be treated in the same way as chemical equipment that comes into contact with the product when used as part of the process and must comply with the contamination prevention policy and this standard.

- The cleanout procedure must include the sampling of the final flush of the system, and the concentration of previous pesticide active ingredients in the final flush sample must be below the TLI listed in the plant's TLI matrix before the system can be certified clean and before the next product can be introduced into the system.

5. Audits

- An Annual review of the entire Contamination Prevention Program will take place as initiated by the Quality Manager. The review team will consist of a minimum of those team members listed above. This review will include not only an overall policy/program review, but also detailed review of each manufacturing plant's implementation of the policies/programs.

6. Training

- The product Integrity Plan approvers, plant Quality Assurance Managers and Leaders, Plant Managers, and Contamination Prevention Officers will undergo appropriate documented training
- All plant personnel shall receive annual Product Integrity training. This training shall include an overview of the process and specific information for their facility.

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.

2. 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.

- Routine inspection of sifter and changing of screens must be part of a preventive maintenance program.

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.

LOT CONTROL AND TRACEABILITY

1. All products (finished goods, ingredients – including bulk, rework, product 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.
   - 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 once 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 ingredient 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 the label declaration (e.g., formula, finished product, package, label) established by product owners.
    - 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).
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.

NON-CONFORMING MATERIAL

1. Facility must have a documented and implemented non-conforming material program.
2. When non-conforming material is identified, the facility must ensure that all non-conforming product is visually distinct and accounted for to prevent accidental release.
3. Disposition of non-conforming 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, product -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, package 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 Land O'Lakes products or facilities are affected, or when production areas used for Land O'Lakes 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. 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.
4. Walls and ceilings must be constructed of materials designed to be cleanable.
5. 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.
6. 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.
7. Exterior grounds must be suitably surfaced (e.g., gravel, asphalt, concrete) and drain properly to prevent standing water, pest pressure, and vegetative outgrowth.
8. Facility must have a program to mitigate risk due to waste/trash that includes:
   - Identification and management of types of waste/trash applicable to your 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 must meet all applicable regulations;
     - Clearly identified and/or labeled for intended purpose;
     - Sized appropriately;

- Designed to be effectively emptied.

- Facility must have 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.

HOUSEKEEPING

1. Each facility must establish a written master housekeeping program
2. Areas to be cleaned and/or maintained must encompass the entire facility (e.g., locker rooms, break rooms, restrooms, office, outside grounds).
3. Housekeeping methods and/or tools must be appropriate to complete the task, without introducing additional contamination.
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.
   - 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, 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:

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.

DEFINITIONS

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.

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.

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.

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.