

LAND O' LAKES, INC.

Animal Food Safety and Quality Expectations Manual

6/26/20

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;

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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, 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.

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- 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.
 - 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, 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.
 - 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, 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.

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- 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 program in place.
 - The plan must be developed and overseen by a qualified individual(s) trained in preventive controls (PCQI).
 - The 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) including:
 - Annual documented Verification with approval signatures and dates
2. Facility must have a documented Hazard Analysis evaluating biological, chemical (including radiological), physical hazards for all steps identified on the process flow diagram.
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.

MEDICATION CONTROL

- 3.1. Drug classification, facility registrations and Feed Mill License (FML)
 - Facilities using any of the following drugs must have a Feed Mill License (FML), must follow the regulatory requirements associated with these drugs, and must perform routine analysis per FDA requirements:
 - Category II Type A drugs;
 - Category I and II drugs used in the manufacturers of medicated free choice feeds and medicated blocks;
 - Category I and II drugs used in manufacturing liquid feeds not requiring agitation.
 - Facilities manufacturing feed under a Veterinary Feed Directive (VFD) must follow the requirements in Veterinary Feed Directive (VFD).

- The following registrations are required to be on file where applicable. These registrations vary due to physical location of the plant and drugs used.
 - State product registration;
 - State Company/Plant Facility License;
 - FDA Bio-terrorism Facility Registration;
 - FDA Feed Mill License (FML) and FDA registration of drug;
 - FDA registration of drug establishment can be located at:
<http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>

3.2. Drug records for receipt, usage, inventory and drug assays

- Employees handling drugs in the manufacturing process and warehousing must follow facility procedures on drug receipt, usage, lot control, storage and record Keeping.
- Drug Inventory
 - A daily inventory of the drugs used in manufacturing must be conducted and include the following:
 - Comparison of actual to theoretical values;
 - Drug inventory discrepancy calculated and compared to allowable limits. If larger than allowed limit, a documented investigation must be performed.
 - All drugs associated with shipping and receiving activities and all Category II-Type A Drugs stored in the warehouse for sale must have a documented inventory at least daily and compared to system/ledger inventory quantities.
 - A confirmatory drug inventory must be taken of all drugs a minimum of once per month. A physical count of all drugs and associated drug lots, expiration date, including partial bags/odd pounds, must be conducted, compared, and reconciled to system/ledger inventory quantities.
- Feed Drug Assay Requirements
 - FDA CGMP drug assay requirements only apply to medicated feeds containing a drug or drug combination requiring an FDA Feed Mill License. Each facility using drugs meeting this requirement must maintain assay records for each drug or drug combination for the current and previous year available for FDA review. The facility must comply with requirements, including:
 - Initial drug assays for first time use of drug or drug combination;
 - Annual drug assay requirements for medicated feeds containing a FDA controlled drug or drug combination;
 - Assay sampling procedures.

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- Label requirements
 - Medicated labels must be proofread referencing the master label and/or formula, initialed, dated and maintained in a file.

3.3. Record Keeping for FDA CGMP (Current Good Manufacturing Practice) Compliance

- Facility must maintain the following records that are available for regulatory review:
 - Master Record File (MRF) – is comprised of the following records:
 - Product name and code;
 - Master formula – formula issued from formulation system;
 - Process Control Batching System Formula – actual mixing record of batch/run of product;
 - Product label;
 - Manufacturing and control procedures posted in the mixing room.
 - Production Records which capture the following:
 - Product identification;
 - Reference to the specific formula used;
 - Date of production;
 - Quantity and name of drug components used;
 - Endorsement by each operator;
 - Theoretical and actual quantity of medicated feed produced;
 - Equipment clean out (sequencing, flushing, visual inspections, physical clean-out);
 - Evidence that a responsible individual has reviewed the records daily indicating that all procedures for that item are in compliance with applicable corporate quality and FDA medicated and cGMP requirements.
 - Distribution records for medicated feeds and VFD drugs – shipping record and label
 - Facility VFD records must be kept for two years following date of distribution.
 - Medicated complaint record
 - Medicated feed complaints related to the intended functionality of the drug must be kept in a medicated complaint file that is separate from all other complaints.

YIELD VARIANCE

- 3.4. Facilities must have a program to calculate production yield variance to measure manufacturing accuracy and usage, to determine the salability of feeds and to track operational efficiencies. The program must include:
- Calculation of percent (%) yield variation;

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- Established tolerances and limits. Investigation and corrective actions when discrepancies occur;
- Release requirements;
- Monitoring records of bin stocking if applicable;
- Final screened finished product variance, when applicable.

PRODUCTION SEQUENCING

- 3.5. Facility must have a sequencing program in place to prevent cross contamination from materials that may be a risk to the animal or to humans that consume the animal or products from the animal. The program must include the following:
- Production sequencing control measures
 - Production sequencing control measures (sequential production, flushing, visual inspection and physical clean-out), including documentation, must be reviewed for compliance, and signed off daily by a qualified individual other than the person who performed the sequencing tasks.
 - Flushing of production processes
 - Ingredients used for flush materials must not to be used as original ingredients;
 - When using a flush, the facility must record the material used, amount used, and disposition of the flushed material on the production records;
 - Facility must document and implement a site-specific flushing program that identifies equipment or process where flushing is an acceptable means of mitigating cross-contamination. Program is to include:
 - Type of flush material;
 - Quantity of flush material;
 - Verification of flush effectiveness;
 - Visual inspection and physical clean-out
 - Bulk delivery inspections prior to unloading
 - Bulk delivery trucks and rail cars must be inspected for cleanliness prior to loading.
 - Facility must establish a program to address the following:
 - Documented Verification of truck cleanliness before loading;
 - Vehicles are loaded with consideration for appropriate sequencing at unloading;
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 to 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/work in process, 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;

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

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- 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 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.
 - 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).
4. Each facility must have a documented and implemented label control process.
5. If rework is used, the facility must develop, document and Verify their internal rework program.
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.

NON-CONFORMING MATERIAL

1. Facility must have a documented and implemented non-conforming material program that includes the following:
 - Persons responsible for the program;
 - Procedures for identification of material on hold, classification (including reprocessed material (RPM)), segregation, hold/quarantine, inventory and disposition.

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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, which includes:
 - Material placed on hold in the system (electronic or manual);
 - Segregation (e.g. wrapped in caution tape, stretch-wrap, designated area);
 - Conduct a physical inventory of all material on hold monthly. Any inventory discrepancies must be investigated.
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, food-contact packaging, in-process materials, and finished product (as applicable).
 - Where applicable, finished products must not be released until all CCP and preventive control verification reviews have been completed and 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. Including where applicable:
 - Formula use;
 - Salt use;
 - Ingredient substitution use;
 - Micro storage, weighing and use;
 - Mixing;
 - Pelleting;
 - Ingredient processing;
 - Packaging and labelling;
 - Finished product sampling;
 - Raw material sampling.

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. Buildings must be designed and maintained to prevent pests (e.g., rodents, birds, insects) from entering, harboring, and infesting.
4. Animal Food facilities must have shatterproof or shielded lighting at a minimum in open product areas.
 - 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.
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 (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 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;

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- 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.

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/feed, ingredients, packaging, or raw materials.
5. All chemical handling, application procedures, and usage must be per label instructions and plant chemical control program.

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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 housekeeping program includes at a minimum for each area:
 - Responsibility for cleaning and maintaining assigned to a person or position;
 - Frequency of cleaning and maintaining;
 - Methods of cleaning and maintaining;
 - Documentation that assigned person (or position) performed required cleaning and maintaining tasks/duties.
2. Areas to be cleaned and/or maintained must encompass the entire facility (e.g., locker rooms, break rooms, restrooms, office, outside grounds).
 - Walls, ceilings, and equipment must be kept free from foreign material (e.g. loose paint, rust, dust, dirt, condensation) which could contaminate the process/product flow.
 - The area above 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.
 - Operational tools and cleaning equipment must be stored off the ground and in an orderly manner to prevent risk of product contamination;
 - Use of compressed air must be managed as to not present a product contamination risk;
 - Air hoses and nozzles must be in good condition, kept off the floor or ground when not in use;
 - Spills, floor sweepings must be cleaned up and disposed of in a timely manner;
 - Housekeeping must be maintained in a manner to avoid pest attraction and harborage;
 - Condensation must be eliminated or controlled in manufacturing and warehouse areas.
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.
 - In animal food facilities, H1 Lubricants (Lubricants that could have incidental food contact) can be used on product contact areas.
 - 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:
 - 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.
 - Verification must occur of raw material and finished product to receiving paperwork (e.g., to the Bill of Lading (BOL), order details).
 - Each facility must perform a documented inspection confirming acceptability of conveyance, raw materials, and finished product before unloading including:
 - Previous haul of bulk ingredient shipments, other than rail;
 - Conveyance maintained to prevent damage to or contamination of products;
 - Verification that product safety and/or quality has not been compromised and meets specifications as applicable (e.g. mycotoxin requirements, temperature requirements, COA verification, Ionophore status: medication, ionophore and other plant status categories);
 - Initial discharge for bulk ingredients;
 - Security seal inspection as applicable.
2. Storage Conditions - Finished products and raw materials must be managed to prevent contamination and damage. Management practices include:
 - Materials must be stored according to specification requirements; minimum requirements include storage in a clean, dry environment with temperature controls as necessary;
 - Kept off the floor by storing on a pallet, slip sheet, or on racks;
 - Open containers of packaging materials are covered or cleaned prior to use;
 - Finished products and raw materials maintain an 18-inch perimeter from walls;
 - Ensuring wood pallets in good condition;
 - Broken packages that cannot be addressed in a timely manner must be temporarily repaired (i.e. taped);
 - Finished products and raw materials must not be stored with the following, unless such articles are approved for use in feed manufacturing:
 - Dog, cat and fish feeds;
 - Prohibited ruminant by-product ingredients;
 - Food plot seed;
 - Fertilizers;
 - Herbicides and pesticides;
 - Insecticides and rodenticides;

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- Finished product and ingredient inventory stored in a warehouse must be rotated on a "First-In, First-Out" basis.
- 3. Each facility must have a documented program in place for shipping, including a documented inspection prior to loading.
 - Shipping Protocol for bulk load out: Facility must have a documented program for Bulk Load-Out operations that includes:
 - Persons responsible for the program;
 - Directions for inspection of trailer before loading;
 - Directions to verify product is loaded and labeled correctly;
 - Directions for product sequencing compliance;
 - Inspection, testing, and sampling requirements for products;
 - Yield and liquid variance calculation requirements;
 - Record review.
 - Bulk delivery finished product or ingredient trailers must follow product sequencing requirements.
 - Shipping protocol for packaged product shipping: Facility must have documented programs for packaged product shipping operations that includes:
 - Persons responsible for the program;
 - Directions for vehicle inspection and trailer seals, as applicable;
 - Directions to verify correct product is being picked and loaded;
 - Directions for documenting and verifying lot codes;
 - Record review.
 - Packaged fertilizer must be separated from packaged finished product or ingredient during transportation. Acceptable separation method:
 - Fertilizer pallets not stacked on top of product pallets, and product pallets not stacked on top of fertilizer pallets;
 - Fertilizer pallets stretch wrapped when shipped side by side with finished product and ingredient during transportation.
 - Dog, cat and fish feeds must be separated from ruminant feeds during transportation. Acceptable methods of separation include:
 - A slip sheet placed between the dog/cat/fish feed and the ruminant feed products on the same pallet;
 - Dog, cat and fish pallets stretch wrapped when shipped side by side with ruminant feed products.

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.
 - Handwashing must be performed to mitigate risk of contamination.
 - Personnel must wash hands immediately after using the restroom;
 - Handwashing signs must be posted in restrooms.
3. Work wear must be fit for purpose, and not pose a contamination risk in areas where exposed products and/or materials are handled.
 - Shoes for use in processing areas must be fully enclosed;
 - Where required, personal protective gear and captive uniforms (including shoes), must be designed to prevent product contamination and be maintained in an acceptable condition;
 - Personal items that may adversely affect product safety or quality (e.g., jewelry, cosmetics, and accessories) must be prohibited in production areas;
 - No items (e.g., pens, pencils, tools, utensils) may be carried above the waist.
 - Jewelry (e.g., earring, necklaces, watches, rings, visible body piercings, etc.) is prohibited.
4. Smoking, vaping, chewing, eating, and drinking must be confined to designated areas. Spitting is prohibited in any part 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;
 - Tools must be inspected for damage and lost tools or components must be reported and investigated.
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;

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- 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 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 must 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.

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- 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.

CLEANING AND SANITIZING

1. Each facility must implement and maintain a cleaning and sanitizing program.
 - The cleaning and Sanitizing program must assure and document that where appropriate, equipment and tools be cleaned in a manner that effectively removes soil and contaminants, and where appropriate, sanitizes critical areas and equipment. The program must outline requirements necessary to address product safety and/or quality risk.
 - General cleaning and Sanitizing of equipment requirements:
 - Cleaning/Sanitizing tools must be designed and maintained in a condition that does not present a potential source of extraneous matter;
 - Sponges, reusable cloth towels and wooden handled tools must not be used for cleaning. Wire brushes or scouring pads are considered high risk and must be avoided or properly controlled;
 - Scoops and shovels must be free of buildup, kept clean, and in good condition;
 - Hoses used for the transfer of bulk ingredients must be kept clean, maintained in good condition, and capped when not in use. Hoses should be off the ground during storage.
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.
 - Verification of the cleaning and Sanitizing program must be performed, and must include:
 - Where clean in place (CIP) or Sanitizing is required, a review of the soils present at the site to ensure cleaning is targeting these soils;
 - Where CIP or Sanitizing is required, appropriate parameters (chemical concentrations, time and temperature, rinse vs. no rinse, etc.) must be documented and verified for each piece of equipment and each kind of sanitizer used.
 - Where applicable, validation must be performed on procedures that are critical to product safety, including the parameters which are critical to these procedures.
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. The program must:
 - Include a procedure for taking samples as per industry standard
 - Have an annual approval which must include a map of 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.
 - Positive environmental swabs must be investigated and recorded on the facility/equipment map.
 - Documentation of the investigation must include investigational swab locations, results, and corrective actions.
 - Results of the environmental monitoring program must be used to measure and report the effectiveness of the 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.

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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.

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Revision History:

6/26/20: Added the requirement to notify LOL 60 days prior to implementation of any changes to an ingredient specification and/or supplier manufacturing/packaging location.