

LAND O' LAKES, INC.

Warehousing Quality Expectations Manual

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Version 1.0

Our Product Safety and Quality Heritage

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

Land O'Lakes (LOL) 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 LOL, 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 LOL. 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 LOL. This document, along with LOL's specifications and contracts, provides guidance for being or becoming an approved supplier of goods and services.

CONTENTS

Customer and Consumer Relations Requirement	2
Customer and Consumer Contact Program.....	2
Document and Record Control Requirement	2
Document and Record Control.....	2
Management Commitment Requirement	3
Management Responsibility.....	3
Product Safety and Quality Event Management.....	3
Personnel Training, Education and Qualifications Requirement	4
Training and Education Program.....	4
Product Integrity Requirement	4
Foreign Material Control.....	4
Lot Control and Traceability.....	5
Nonconforming Material.....	5
Regulatory Compliance Requirement	6
Domestic and International Compliance.....	6
Regulatory Inspection:.....	7
Site Management Requirement	7
Site Infrastructure.....	7
Chemical Control.....	8
Housekeeping.....	8
Maintenance and Calibration.....	8
Materials and Warehouse Management.....	9
Employee Practices.....	11
Pest Control.....	12
Definitions.....	14

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.

DOCUMENT AND RECORD CONTROL REQUIREMENT

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

DOCUMENT AND RECORD CONTROL

1. Facility must have a document control program and maintain a master document and record list.
2. Documents must be created to demonstrate compliance with product safety and quality policies. Documents must include the following legible attributes:
 - Supersede date/version control;
 - Effective date;
 - Document owner;
 - Document identification;
3. Facilities must have a documented review process that requires review at least every three (3) years or whenever process or program modifications require document changes. Document change control for active documents must include:
 - Document reviewer;
 - Revision history.
4. Facilities must have a documented approval process.
5. Records must be:
 - Completed electronically or in ink;
 - Dated with month, date, and year;
 - Legible;
 - Complete and accurate:
 - Missing required data must be investigated and/or explained;
 - Authenticity:

Warehousing Quality Expectations Manual

- Filled out at the time of, not in advance of, the observation/test;
 - Traceable to the person performing the activity and to the facility at which the activity was performed;
 - Traceable back to the product, process, or production period;
 - Corrections to non-electronic records must be documented with a single line through the error, initials of person making Correction, date of Correction, and justification (if necessary) for Correction and the updated information. White-out and Correction tape must not be utilized.
6. Documents and records must be stored in a secure manner and be readily available for review.
 7. Obsolete documents and completed records must be retained according to the state or federal regulations regarding record retention.
 8. Facilities must have a documented record destruction process.

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.
2. 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.
3. Procedures that support compliance with the QMS must be documented.
4. 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.
5. The facility must conduct and document self-assessments on an annual basis to evaluate adequacy and effectiveness of meeting the QMS programs.
6. 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.

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. Trainers must be qualified through training, education, or professional experience for the topics on which they are training.

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.

FOREIGN MATERIAL CONTROL

1. Facilities must have documented program(s) to identify potential sources of foreign material and mechanisms to prevent, detect and control such sources. The program should include potential sources from raw materials, facility environment (e.g., ceilings, walls, floors), processing and packaging equipment design, utensils, personnel sources, and other operations such as Sanitation, contractor work, construction, rework/WIP, maintenance or repair of equipment, and historical information of types of foreign material previously found or reported by consumers.
 - The program must include a procedure for the control of glass, brittle or hard plastic, ceramics, or other similar materials when the use of these items cannot be avoided. This procedure must be documented and include:

Warehousing Quality Expectations Manual

- 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.

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.
 - 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 twice per year.
 - If the mock trace does not meet the requirements, investigation and Corrective Actions must be implemented and documented.

NONCONFORMING MATERIAL

1. Facility must have a documented and implemented nonconforming material program that includes the following:
 - Persons responsible for the program;
 - Procedures for identification of material on hold, classification, segregation, hold/quarantine, inventory and disposition.
2. When nonconforming material is identified, the facility must ensure that all nonconforming product is visually distinct and accounted for to prevent accidental release.
 - Identification (e.g., placard, hold tag on each pallet/package, etc.);
 - Material placed on hold in the system
 - Segregation (e.g., wrapped in caution tape, stretch-wrap, designated area, etc.);
 - Conduct a physical inventory of all material on hold. Any inventory discrepancies must be investigated.
 - Release of material off hold must be authorized by LOL Corporate Quality (LOLCQ).
3. Disposition of nonconforming product must be documented and traceable. Documentation must include details of the disposition and who authorized it.

- All returns of product will receive prior approval from LOLCQ.

Animal food warehouses only:

- Non-conforming Veterinary Feed Directive (VFD) products must not be sold as salvage.
- If material is a potential environmental concern (e.g., fertilizers, tubs, etc.) LOL Environmental, Health & Safety must be contacted for approval and disposal instructions.
- Non-conforming Ingredient: Ingredients that after receiving do not meet specifications (e.g. expired but not out of condition) must be communicated to Supplier Quality Assurance for documented approval and disposition direction. Reference SIT Procedure
- Non-conforming product or ingredient dispositioned as Salvage (Feed, Material, Compost)
 - Product with VFD medication must be trashed
 - Non-conforming product or ingredient dispositioned as Salvage (Feed, Material, Compost) must meet the requirements of the Lot Control and Traceability Program
 - Applicable waiver must be completed and signed by appropriate parties.
 - Mark invoice and shipping papers with type of salvage – salvage feed, salvage material, compost material
- Non-conforming product or ingredient dispositioned as Trash:
 - Packaged non-conforming product dispositioned as Trash must meet the following:
 - Mark 'X' through or remove label or tag
 - Cut an 'X' through the face of the bag

Human food warehouses only:

- If destruction/reprocessing is the disposition for hazardous holds, proof of disposal/reprocessing approval is required. This proof may include:
 - A photo/video by LOL employee verifying the destruction
 - An affidavit of destruction/disposal from an approved third party.
 - If product is proposed for reprocessing, contact LOLCQ for approval of the following:
 - Approval that the material is suitable for reprocessing
 - Approval of the reprocessing parameters and location

REGULATORY COMPLIANCE REQUIREMENT

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

DOMESTIC AND INTERNATIONAL COMPLIANCE

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

- Warehousing facilities must be registered under and in compliance with applicable laws and regulations (e.g. the Food Safety Modernization Act (FSMA)).

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;
2. Communication must occur when LOL products or facilities are affected, or when production areas used for LOL products or ingredients are involved in the following scenarios, prior to public notifications: EPA, FDA RFR, or FDA 483, recalls, retrievals, and/or after samples are pulled by regulatory agencies.

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. Buildings must be designed and maintained to prevent pests (e.g., rodents, birds, insects) from entering, harboring, and infesting.
3. Lighting must be shatterproof or shielded.
 - Buildings and grounds must have adequate lighting.
4. 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.
5. Walls and ceilings must be constructed of materials designed to be cleanable.
6. Doors must be constructed of materials designed to be cleanable.
7. Exterior doors, including dock doors, must be self-closing or kept closed and must be sealed tight to prevent pest entry. 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.
8. Human Food warehouses only: Designated changing facilities or locker rooms must be provided for all personnel. These areas must be properly used, maintained, and inspected.

Warehousing Quality Expectations Manual

9. Exterior grounds must be suitably surfaced (e.g., gravel, asphalt, concrete) and drain properly to prevent standing water, pest pressure, and vegetative outgrowth.
10. Facility must have a program to mitigate risk due to waste/trash that includes:
 - A documented procedure to ensure product labels, finished product packaging, and fully labeled finished product designated as waste/trash are defaced/destroyed in a manner that prevents unintended or unauthorized use.

CHEMICAL CONTROL

1. Facilities must have a documented program for all non-ingredient chemicals stored and used at that facility (e.g., chemicals used for pesticides, processing aids, Sanitation, maintenance, waste, water and boiler treatment, indicators, laboratory, office, janitorial, paints, inks, and solvents). The program must include:
 - Safety Data Sheets (SDS) and EPA registration numbers, where applicable.
2. Facilities must manage chemical receiving and storage against the approved chemicals list.
3. Labels must be present to identify chemicals, including:
 - Primary and secondary chemical containers must be labeled and include physical or health Hazards.
4. Chemicals must not be dispensed from, or stored in, containers originally containing food, ingredients, packaging, or raw materials.
5. All chemical handling, application procedures, and usage must be per label instructions and plant chemical control program.
6. Disposal of chemicals must follow all manufacturer requirements.

HOUSEKEEPING

1. Each facility must establish a written master housekeeping program.
2. Areas to be cleaned and/or maintained must encompass the entire facility, including:
 - Employee Welfare Areas;
 - Walls, ceilings, and equipment kept free from foreign material and potential microbiological Hazards (e.g., loose paint, rust, dust, dirt, condensation):
 - Suspended ceilings must be periodically inspected for cleanliness and pest activity.
3. Housekeeping methods and/or tools must be appropriate to complete the task, without introducing additional contamination.
4. A housekeeping inspection must be performed at a determined frequency, with Corrections implemented for deficiencies.

MAINTENANCE AND CALIBRATION

1. Facilities must develop and implement a documented program that covers preventive maintenance and general maintenance and repair expectations for equipment impacting product safety, quality, and regulatory compliance (e.g., production equipment, controls including traffic patterns, sanitary surfaces, Sanitation systems, and controlled environments). This program must include:

Warehousing Quality Expectations Manual

- A priority system to address product safety/quality issues;
 - A process for incorporating new or upgraded equipment into program;
 - Records available to Verify completion of maintenance work.
2. General maintenance and repair plans must include methods to prevent cross-contamination where risks exist (e.g., assessment of adjoining lines, scheduling, equipment/tools cleaning and inspection prior to relocating, cleanup steps and tool accountability, pre- and post-maintenance inspection measures, chemical control measures, fit for use assessment).
- A maintenance shop must be maintained in a clean and organized manner, according to risk to the products and processes. Human food warehouses must include:
 - Control measures at exits to trap metal shavings and debris (e.g., bristled mats, tacky mats).

Human food warehouses only:

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:
- The frequency of calibration, acceptable range and action against deviation (per manufacture recommendations);

MATERIALS AND WAREHOUSE MANAGEMENT

1. Inbound vessels (e.g., trucks, tankers, railcars) and documentation must be inspected before unloading to determine the acceptance or rejection.
- Facilities must have documented and implemented procedures for inbound carriers including:
 - All inbound carriers, non-less than truckload (LTL), delivering ingredients or raw materials must have intact seals upon arrival. Seal numbers must match recorded numbers on the load documentation.
 - Padlocks should be used for inbound LTL shipments.
 - Inspection to detect evidence of tampering
 - Receiving material in compliance with BOL specifications
 - Compliance with shipping requirements
 - Compliance with temperature requirements
 - Inbound carriers must meet the temperature requirements as defined in the specification, and the temperature shall be taken and documented.
 - Compliance with regulatory requirements per specification (e.g., antibiotic testing on milk)
 - Good Manufacturing Practices (GMP) inspections (e.g., pests, unsanitary conditions, odors, glass, residues from previous loads).
 - Confirmation that the materials delivered match the bill of lading (e.g., items, lot codes, and quantity).
 - Receiving records and relevant lot information must be documented for traceability.

Warehousing Quality Expectations Manual

- If unsatisfactory conditions are observed during the receiving inspection, LOL contact must be notified.
2. Storage conditions - Finished products and raw materials must be managed to prevent contamination and damage.
- All ingredients, food-contact packaging, and finished product are to be stored according to their specification requirements and to prevent potential contamination from physical, chemical (e.g., allergens), and biological Hazards.
 - Warehouse areas must be clean, dry, well ventilated, and free of pests.
 - A documented age management procedure for minor ingredients, bulk ingredients, packaging materials and finished products must be in place to ensure proper rotation and that FEFO (first expired, first out) is followed.
 - Wood pallets used in the storage areas shall be clean, dry, and in good repair.
 - Finished products and raw materials maintain an 18-inch perimeter from walls
 - The nonconforming product program must be followed for out-of-spec product including, but not limited to, damaged, rejected, aged, expired or returned materials.

Human Food warehouses only:

- Controlled temperature areas are to be Verified and documented.
 - The warehouse must record temperatures daily at a minimum.
 - The cooling equipment must be able to maintain the specified temperature range at all times.
- Products susceptible to odors (e.g., butter, cheese, etc.), must be stored in a manner to prevent odor absorption.
 - Food products (e.g., fruits, vegetables, spices, seafood, etc.) or other materials that produce strong odors shall be segregated and ventilated to avoid odor transmission.

Animal Food warehouses only:

- Broken packages that cannot be addressed in a timely manner must be temporarily repaired (i.e. taped);
 - Broken packages identified for further disposition must be segregated, identified by product, and stored in a designated area;
 - 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.
 - If finished products/raw materials and items listed above are stored in the same location, the warehouse must maintain a minimum of five feet of space or a solid wall between the finished product or ingredient and the listed items;
3. Each facility must have a documented program in place for shipping, including a documented inspection prior to loading.

- Each facility must perform a documented inspection of carriers (trucks, tankers, and rail cars) and Raw Materials before loading. This inspection includes:
 - All non-LTL carriers delivering products must have intact seals prior to departure;
 - Seal numbers must match recorded numbers on the load documentation.
 - Padlocks must be used for outbound LTL shipments;
 - GMPs (e.g. pests, sanitation, odors, glass, residues from previous loads);
 - Suitability of the equipment to prevent product damage;
 - Compliance to shipping requirements per specification.
- Contents match the bill of lading (e.g., items, lot codes, and quantity).
- If unsatisfactory conditions are observed during the inspection, the facility quality manager or designee must be notified.
- Shipping records and relevant lot information must be documented for traceability.

Human Food warehouses only:

- Outbound carriers must meet the temperature requirements as defined in the specification, and the temperature shall be taken and documented.

Animal Food warehouses only:

- Packaged fertilizer must be separated from packaged finished product or ingredient during transportation. Acceptable separation methods include:
 - 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 separation methods 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.
3. Work wear must be fit for purpose and not pose a contamination risk in areas where exposed products and/or materials are handled.
4. Smoking, vaping, chewing, eating, and drinking must be confined to designated areas. Spitting is prohibited in all parts of the facility.

5. Illness, disease, blood borne pathogen, and biohazards:
 - Cuts, sores, and scrapes must be covered to protect product and the employee;
6. Employee medications are not allowed in GMP areas and may only be stored in authorized areas (e.g., first aid kits, lockers).
7. The facility must establish a documented and implemented program for visitors and contractors.
8. The facility must have a policy or procedure defining cell phone and camera use at the plant.

PEST CONTROL

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

- Quantity of pesticide used;
 - Target pest;
 - Specific areas treated;
 - Method of application;
 - Percent of active pesticide material when applied;
 - Rate of application;
 - Date and time(s) of application;
 - Applicator's name, license or certification number, and signature.
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.

DEFINITIONS

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

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

Compost Material: A non-medicated, non-additive of concern feed material that can be used for the express purpose of use in the generation of compost. Material cannot be fed to animals or used to produce animal feed.

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

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

Salvage Feed: Damaged or expired material sold at a price substantially less than that with guaranteed analyses with direction that it is not to be resold for the purpose of human or animal consumption.

Salvage Material: A non-medicated material that can be used for the express purpose of use as a fertilizer, reprocessing, or if medicated, disposed of to appropriate landfill. Material cannot be fed to animals.

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