LAND O'LAKES, INC
PURINA ANIMAL NUTRITION

ANIMAL FOOD SAFETY & QUALITY EXPECTATIONS MANUAL FOR EXTERNAL BUSINESS PARTNERS

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Our Product Safety & 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 9,000 employees, 1,200 dairy producers, and 800 retail owners doing business in all 50 states and more than 60 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 or applicable than others, depending on the type of product(s) produced and the inherent risks of those products.

This document, along with Land O'Lakes' specifications, contracts, and Expectations Resource Guide provide guidance for being or becoming an approved supplier of goods and services. The Expectations Resource Guide, which has expanded information on industry best practices, programs, and implementation elements will be made available upon request.

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Customer and Consumer Relations

External Business Partners must ensure a process is in place to capture, respond to, evaluate, and track customer and consumer contacts (e.g., complaints, inquiries, compliments).

Document and Record Control

External Business Partners must ensure product safety & quality documents (e.g., requirements, programs, procedures, forms, Records) are managed within a controlled system.

- 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
- Documents and Records must be stored in a secure manner and be readily available for review
- Electronic Records have controlled access and are backed up to avoid loss

External Business Partner Management

External Business Partners must ensure product safety, quality, and regulatory requirements are reviewed and met in selecting, approving, managing, monitoring, and disqualifying External Business Partner's suppliers that affect Land O'Lakes Products.

Management Commitment

External Business Partners senior management must demonstrate commitment to the development, implementation, maintenance, and continuous improvement of the processes and programs supporting product safety, quality, and regulatory requirements.

- Adequate resources (human, financial, technical and training) must be provided to implement, maintain and make improvements that support the quality management system at each facility
- Facilities must hold regular documented management meetings discussing Corrective Actions of non-conformances, resources, complaints, audits, and system continuous improvement.
- Each facility must conduct and document self-assessments on an annual basis to evaluate adequacy and effectiveness of meeting the quality management system programs
- Each facility must have a Corrective Action/Preventive Action (CAPA) process to address non compliances (e.g., self-assessments, housekeeping, pest control, etc.)
- 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 and quality

Product Safety and Quality Event Management

Each manufacturing facility must have documented procedures for managing events that may put the business and/or operations at risk.

Personnel Training, Education and Qualifications

External Business Partners must ensure all employees, contractors, temporary workers and visitors have appropriate training, education and qualifications to ensure product safety and quality.

Food Safety Plan

External Business Partners must have an effective Food Safety Plan based on the requirements outlined in the Preventive Controls for Animal Food regulations.(FSMA 507 Subpart C)

1. Facilities must have a Food Safety Program in place
    - The Food Safety Plan must be developed and overseen by a qualified individual(s) trained in preventive controls (PCQI), and a Product Safety team that is multi-disciplinary
    - The Food Safety Plan must include
        - Product description, intended use, and distribution
        - Process flow diagrams (PFDs) must be documented, including preventive controls (if applicable)
            - Ingredient and Process Hazard Analysis
            - Documented Verification with approval signatures and dates
            - A review of the Hazard Analysis must take place anytime there are changes to ingredients, products, food contact packaging, or equipment/processes that could have an impact on product safety or at a minimum every 3 years (best practice annual Verification)
2. Facility must have a documented Hazard Analysis evaluating biological, chemical (including radiological), and physical Hazards for all steps identified on the process flow diagram
3. Preventive Controls (PCs) and control measures (if any) must be identified, monitored, verified, Validated (if applicable) and Corrective Actions must be documented

Mycotoxin Program Management

External Business Partners must have a mycotoxin program that includes effective systems for monitoring, analyzing and maintaining mycotoxin data for local and imported raw materials. Collect and analyze crop-specific and regional data for each crop year. Out of tolerance mycotoxin results detected in incoming ingredients or finished feed must have a documented and effective corrective action plan.

The mycotoxin management program shall be included in the facility's animal food safety plan and ingredient Hazard Analysis. External Business Partners shall identify mycotoxin risks based on the completed Hazard Analysis.

Facilities manufacturing Purina branded products shall conduct weekly on-site mycotoxin testing until analysis of crop-specific and regional data for each crop year has been completed.

- Testing frequency may be adjusted accordingly, more often or less often, as mycotoxin test data indicates level of risk.
- Mycotoxin testing will be performed by a trained employee through an approved method or by a certified third-party laboratory.

Current Good Manufacturing Practices for Medicated Feeds / Medication Control

External Business Partners must manage all aspects of medicated feed production to meet 21 CFR 225 Current Good Manufacturing Practice for Medicated Feeds.

- Medications must be controlled through receipt, storage, usage, and reconciliation to meet regulatory requirements

Yield Variance

External Business Partners must calculate a yield variance for all production runs. The yield variance calculation is used to determine discrepancies between actual and theoretical yields before product is released. Each facility must conduct a product yield variance review against established tolerance limits before Land O'Lakes products are released.

Facilities must have a program to calculate production yield variance that includes:

- Documented calculation of percent (%) yield variance (calculation includes finished product produced, set off material, under & over pulls, bin hangs, fines removed, spills, etc.)
- Established tolerances and acceptable variance limits on all packaged, bulk, liquid, and bin stocked products must be documented and part of the yield variance review
- Documented investigation and Corrective Actions when discrepancies occur
- Releasing products outside of acceptable limits requires a documented review, investigation/Corrective Action, and approval from a qualified individual

Production Sequencing

External Business Partners must have a sequencing program to prevent cross contamination from materials that may be a risk to the animal, humans that consume the animal, and/or products from the animal

- Production sequencing program must include the following:
  - Production sequencing control measures for all processing steps including bins
    - 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 be reused 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:
      - Documentation of the type of flush material
      - Documentation of the quantity of flush material
      - Verification of flush effectiveness
      - Visual inspection and physical clean-out procedures and Records when equipment and/or processes cannot be flushed (bins, blenders, etc.)
  - Bulk delivery inspections prior to loading
    - Bulk delivery trucks and rail cards must be inspected for cleanliness prior to loading
    - Facility must establish a program to address the following:
      - Documented Verification of truck cleanliness before loading
      - Ensure that vehicles are loaded with consideration for appropriate sequencing at loading and unloading

Foreign Material Control

External Business Partner's Hazard Analysis must be used to identify foreign material contamination risks.

- Each facility must ensure appropriate and effective foreign material detection is in place and implemented to control, identify, and remove foreign material
- Metal detectors are required for pet, horse, and exotic species

Lot Control and Traceability

External Business Partners must ensure all materials used in manufacturing and all finished products are identified with a traceable lot identification and date code.

- All products (finished goods, ingredients - including bulk, rework, food contact packaging, processing aids and samples) must be coded or identified with traceable 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, pallet tag, and shipping documents (bill of lading / pick slips)
  - 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
- Each facility must have a documented retrieval team as well as a procedure to ensure product traceability to the first customer within 4 hours.
  - To assess trace effectiveness, perform a documented mock trace for finished product, raw material, and product contact packaging each year.

Specification Compliance

External Business Partners must ensure manufacturing processes are designed to meet product specifications (physical, chemical & microbiological) throughout the specified shelf life. Facility must have a product specification use and compliance program to ensure raw materials and finished feed meet specification.

Land O'Lakes 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.

Finished products must meet specifications consistent with 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).

Each facility must have a documented and implemented label control process that reviews labels for accuracy when they are received and again that the correct label is applied at point of application. If rework is used, the facility must develop, document and verify their internal rework program. Any raw material, in-process product, or finished product found to be noncompliant must follow the Nonconforming Material program.

Laboratory Management and Testing

External Business Partners must ensure laboratories are designed, located, and operated to prevent contamination of products and produce accurate results

- Testing facilities must utilize good laboratory practices, follow approved sampling, holding and test methods. Testing should be performed by trained, qualified individuals
- Pathogen testing may not be done on site
- If external laboratories are utilized, they must be accredited to the test being performed

Non-Conforming Material

External Business Partners must ensure ingredients, packaging materials, in-process materials, and finished products that do not meet specification or regulatory requirements are controlled to prevent accidental usage or shipment.

- Disposition of non-conforming product must be documented and traceable.
- Documentation must include details of the disposition and who authorized it

Positive Release

External Business Partners must ensure a documented positive release/critical Records review process is in place for ingredients, feed contact packaging, and finished products to prevent usage or shipment before critical information is reviewed and approved

- Where applicable, finished product must not be released until all preventive control Verification reviews have been completed and results are acceptable
- Yield variance must be reviewed prior to product being released

Manufacturing Control

External Business Partners must ensure that the manufacturing facilities have written manufacturing processes and work instructions in place for all manufacturing processes to include all quality and product safety/integrity monitoring activities.

- Examples include: formula use, salt use, ingredient substitution use, micro storage, weighing and use, mixing, pelleting, ingredient processing, packaging and labeling, raw material and finished product sampling

Regulatory Compliance and Inspection

External Business Partners must ensure the business and facility are in 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).

- External Business Partners' facilities must have a process for managing emerging issues that can have an impact on product quality, safety and regulations
- External Business Partners must ensure that the site management and employees are prepared for interacting with regulatory personnel during visits
- We require notification to us 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.
- External Business Partners must have a product hold procedure for when regulatory samples are collected and tested for pathogens or other non-routine product safety Hazards. This includes a split or duplicate sample from same product & location must be collected and stored.

Site Infrastructure

External Business Partners must ensure the buildings, utilities and equipment are designed, constructed and maintained in a manner which is appropriate to the feed safety risk of products being produced.

Facility Security / Biosecurity

External Business Partners must ensure their facility has a documented and implemented Facility Security / Biosecurity program as these are essential elements in preventing biological contamination, potential acts of sabotage, vandalism or terrorism throughout the supply chain.

Chemical Control

External Business Partners must ensure an effective non-ingredient chemical control program is in place to prevent possible cross-contamination from the time of procurement through end use and disposal of chemicals and containers.

Housekeeping

External Business Partners must maintain a housekeeping program that assures and documents the facility environment is organized and maintained in a manner to prevent pest, dirt, dust, trash and foreign material build up.

Maintenance and Calibration

External Business Partners must develop and implement a documented program that covers preventive & general maintenance for both temporary and permanent repairs.

- H1 Lubricants must be used where there is a potential for animal food contact.
- External Business Partners must develop and implement a documented calibration plan for all measuring and monitoring equipment affecting food safety, quality, and regulatory attributes (mixer distribution, thermometers, liquid meters, scales, metal detectors, etc.)

Materials and Warehouse Management

External Business Partners must ensure incoming materials and finished products are received, stored, shipped, and managed in a manner to protect the quality and safety of the materials.

Each facility must inspect Inbound and outbound vessels (e.g., trucks, tankers, railcars) to determine conveyance acceptability before unloading raw materials or loading finished goods.

- Documentation review (bill of lading/pick/pack slips) must also be included to ensure facility receives the expected raw material and is shipping the expected finished products.

Finished product and ingredient inventory stored in the partner warehouse must be rotated (FIFO “First-In, First-Out” FEFO “First-Expired, First-Out”).

Finished product shipped non-less than truck load (LTL) must have intact seals. Seal numbers must match recorded numbers on the load documentation (BOL). Padlocks should be used for LTL shipments.

Employee Practices

External Business Partners must ensure facility and operators are operating in a hygienic (clean) condition.

- The operating facility must have a program defining expectations around personal hygiene and employee practices based on risk to the materials
- Employees must maintain clean and proper personal hygiene
- External Business Partners must establish a documented and implemented program for visitors and contractors as well as have a policy or procedure defining cell phone and camera use at the facility

Pest Control

External Business Partners must ensure the facility is effectively managing and controlling pests in the facility (21 CFR 507.19(e))

Cleaning and Sanitizing

External Business Partners must have a Cleaning and Sanitation program that assures and documents all product contact equipment be cleaned in a manner that effectively removes Soil and contaminants, and where appropriate, sanitizes critical areas and equipment

- Sanitizing is required in certain pet food / milk replacer applications
- A master Cleaning and Sanitizing schedule must be in place
- The Cleaning and Sanitizing activities must be monitored, verified and Validated to ensure effectiveness
- Program deviations which impact food safety or quality must be documented and Corrective Actions identified and implemented

Environmental Monitoring

External Business Partners must have an Environmental Monitoring Program (EMP) which actively tries to identify and eliminate pathogens in the manufacturing environment when microbiological Hazards have been identified as a cross-contamination Hazard through the Hazard Analysis and risk assessments.

- EMP is required in certain pet food / milk replacer applications

Definitions

Biosecurity: A set of practices and measures aimed at preventing the introduction and/or spread of infectious organisms (e.g. viruses, bacteria, etc.) into animals (herd or flock) in order to minimize the risk of transmission of infectious disease.
Cleaning: The removal of soil, product residue, and/or other objectionable matter
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 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
Corrective Action: Action to reduce or eliminate the likelihood that a problem will reoccur; designed to address the root cause(s)
Document: Piece of written, printed, or electronic matter that provides information. Can be revised and edited, does not act as evidence, and may be saved for a short period of time.
External Business Partner: A company who provides goods or services to or receives goods or services from Land O'Lakes, including but not limited to Co-Manufacturers, Ingredient Suppliers, Packaging Suppliers, Warehousing Providers, transportation providers, and Joint Ventures.
Facility Security: Practices and measures aimed at controlling and preventing access to facility infrastructure such that it limits potential acts of sabotage, vandalism, or terrorism in facilities that manufacture, process, pack, or hold animal food.
Food Safety Plan: A set of written Documents based on product safety principles that incorporate Hazard analysis, preventive controls, supply-chain programs, a recall plan, and define the procedures to be followed for monitoring, Corrective Actions, and Verifications.
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.
Hazard Analysis: The process of collecting and evaluating information on Hazards and the conditions leading to their presence to determine which Hazards are significant for food safety and therefore should be addressed in a Food Safety Plan.
Ingredients Suppliers: Companies or facilities who produce and/or package materials utilized in the manufacture of finished products that are designed for animal consumption.
Joint Venture: A commercial enterprise undertaken jointly by two or more parties that otherwise retain their distinct identities.
Nonconforming Material: Feed materials not suitable for normal sale or use which can include expired, out of spec feed, ingredients, set offs (including medicated screenings segregated by drug and drug level), final screenings, flushes, non-contaminated spill, crippled run, product manufacturing error, damaged packages, product contact packaging etc.
Packaging Suppliers: Companies or facilities that produce materials utilized to contain finished products. These materials can be product contact or non-product contact.
Record: Piece of evidence about the past, especially an account kept in writing or some other permanent form. Cannot be revised or edited, does act as evidence, and kept for a longer period of time.
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.
Soil: Unwanted matter on product-contact surfaces (adapted from Basic Elements of Equipment Cleaning and Sanitizing in Food Processing and Handling Operations by Ronald H. Schmidt).
Validate(d): 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.