FSC 36 SAFE FEED SAFE FOOD CHECKLIST

The checklist for FSC36 Safe Feed/Safe Food (Version 6.0) is shown below. The checklist includes the Element (Clause) number and name, the description of the element, and an area to provide supporting compliance information. For "Implementation Guidance" and "Auditor Guidance", please see the FSC36 Safe Feed/Safe Food Guidance Document. For exceptions and additional information pertaining to rendering plants, see "Implementation Guidance" and "Auditor Guidance" in the NRA-APPI COP Companion Guidance for FSC36.

Updated: December 2014

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1.1 Management Policy (M)	1) Management shall prepare and implement a policy statement that outlines at a minimum: a) The organization's commitment to provide quality and safe feed. b) The methods used to comply with its customer and regulatory requirements and continually improve its quality and feed safety system. c) The organization's commitment to establish and review animal food safety objectives. 2) The policy statement shall be signed by management, made available in a language understood by all staff, and displayed in a prominent position and effectively communicated to all staff.	
1.2 Management Responsibility (M)	1) The organizational reporting structure describing those who have responsibility for quality and feed safety shall be defined and communicated within the organization. 2) The management shall ensure adequate resources are available to achieve the desired animal food safety objectives and support the development, implementation, maintenance and ongoing improvement of the quality and feed safety system.	
1.3 Responsibility, Authority and Communication (M)	1) The management leader or team shall designate a quality and feed safety practitioner (also known as the Practitioner) for each site. The Practitioner will be responsible for and have authority to oversee the development, implementation, review and maintenance of the quality and feed safety system, including: animal food safety fundamentals outlined in Element 8.1, and the animal food safety plan outlined in Element 8.2; to take appropriate action to ensure the integrity of the quality and feed safety program; and communicate to relevant personnel all information essential to ensure the effective implementation and maintenance. 2) The Practitioner shall be employed by the Supplier as a company employee on a full-time basis, hold a position of responsibility in relation to the management of the quality and feed safety system, and understand the FSC36 requirements relevant to the Supplier's scope of certification. Although HACCP certification by the Practitioner is not required, the Practitioner should have a grasp of the principles of HACCP and command the ability to identify hazards and develop preventive controls to reduce or prevent potential animal food safety risks. 3) All staff shall be informed of their responsibility to report animal food safety problems to personnel with authority to initiate action.	
1.4.1 Management Review Process	1) Management shall be responsible for reviewing the quality and feed safety system and documenting the review procedure. 2) Any changes to the animal food safety plan shall be reviewed during management review meetings. 3) The management shall establish processes to improve the effectiveness of the quality and feed safety program to demonstrate continuous improvement. 4) A documented procedure shall be maintained that describes management review and its process. It shall include frequency, expected attendees, general overview of information to be reviewed and expected actions to be taken.	
1.4.2 Management Reviews Inputs and Outputs	1) Management review of inputs shall include information about the quality management system effectiveness. This may include (but not limited to) the following: a) Customer complaints or customer satisfaction. b) Any failures in the quality and feed safety program. c) Nonconformities identified from audits (internal and external) completed since last meeting. d) Corrective and preventive actions taken for continuous improvement. e) Changes within processes or at location that may impact product quality and feed safety. f) Changes to the animal food safety program. g) Regulatory changes that may impact the quality and feed safety program. h) Industry news or activities relevant to the quality and feed safety program. 2) The management is required to assess the effectiveness of the quality management system. This shall include (but not limited to) the following: a) Recommendations to improve customer service or satisfaction. b) Continuous improvement to the quality and feed safety system. c) Sufficient resources to implement an effective quality and feed safety program and desired outcomes.	
1.4.3 Records for Management Review	1) Records of management reviews shall be maintained. This shall include a running list of recommended actions and their current status. 2) Information shared during a management review shall be kept with the management review records.	
2.1 General Requirements - Quality & Feed Safety Management System	1) The Supplier shall establish, document, implement and maintain a quality and feed safety system and continually improve its effectiveness. 2) A quality and feed safety manual shall be maintained. 3) The Supplier shall determine the processes needed for the quality and feed safety system and their application throughout the organization. 4) Quality and feed safety policies may be used to provide insight into the practices that drive the implementation and procedures for the quality and feed safety program. Quality and feed safety policies may include descriptions of the following: a) Management commitment. b) Management review. c) Scope of the quality and feed safety system and FSC36 certification. d) Processes critical to ensuring the quality and feed safety of products. e) Animal food safety plan and processes to implement.	
2.2 Quality and Feed Safety Manual (M)	1) The Supplier shall establish and maintain a quality manual that includes: a) The scope of the quality and feed safety system, including exclusions from the FSC36 Safe Feed/Safe Food Certification Program. b) Documented procedures that have been established for the quality and feed safety system. 2) Polices that impact the quality and feed safety system shall be documented within the manual and maintained in either electronic and/or hard copy form. 3) The manual shall be readily available to personnel. 4) The manual may include (but not limited to) the following: a) Quality and feed safety policy statement b) Organization chart c) Quality and feed safety policies implemented by the location d) A description of how the animal food safety plan will be achieved or maintained e) The scope of the certification and a list of the products covered f) Processes and procedures that ensure the implementation of the quality and feed safety policies	
2.3 Document Control (M)	1) The methods and responsibility for maintaining document control shall be maintained. 2) The Supplier shall ensure staff has access to current documents. 3) Proper training for document control is needed to ensure records are as accurate as possible.	
2.4 Records (M)	1) Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and retained for a minimum of two years or as otherwise required by customers or regulatory compliance. 2) The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented. 3) All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed. 4) A list of records shall be maintained.	
3.1 Competence and Job Descriptions (M) - Personnel and Training	1) The Supplier shall determine the necessary competence for personnel performing work affecting the quality and feed safety of products or services. 2) Competencies shall be described within job descriptions. All personnel shall have a job description. 3) Where contractors are utilized, competency expectations shall be provided to the approved vendor providing the services or completed work. 4) The Supplier shall maintain adequate records of education, skills and experience of personnel.	

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3.2 Training and Awareness (M)	1) Where applicable, the Supplier shall provide training or take actions to achieve the desired competence for personnel. 2) Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the quality and feed safety system as well as regulatory requirements. 3) An employee training program shall be documented and implemented. A training program may include (but not limited to) the following: a) Training schedule for topics that impact the quality and feed safety program. b) Key personnel responsible for managing the training schedule and process to ensure training is completed timely, such as the human resources department. c) Training requirements for positions with responsibilities that impact the quality and feed safety program. d) Tracking of employee training needs. e) Training needs or competencies for positions impacting quality and feed safety. 4) Instructions, such as SOP's, work instructions and training manuals, shall be available to personnel to support training. 5) Training materials and the delivery of training shall be provided in language understood by staff. 6) The Supplier shall ensure that personnel are aware of the relevance and importance of their job activities and how they contribute to the achievement of the quality and feed safety objectives.	
3.3 Personnel Policies and Behavior	1) Personnel shall maintain proper hygiene relative to the employee's work area in order to ensure the safety of animal foods. This includes (but not limited to): a) Clothing and personal apparel. b) Shoes worn inside and outside of the facility. c) Dirt or filth that may be carried into the work area. 2) Personnel hygiene requirements shall be consistent with a biosecurity program to prevent the potential spread of disease or compromise the animal food safety plan. 3) The Supplier shall maintain a policy for personnel behavior that shall include (but not limited to): a) Permission for smoking, eating and chewing (e.g., gum, tobacco) in designated areas. b) Control measures to avoid hazards from jewelry. c) Permission of personal items (e.g., cell phones, smoking materials, medicines, etc.) in designated areas only. d) Maintenance of personal lockers so they are kept free of rubbish and soiled clothing. 4) Fluids provided for consumption in the manufacturing or storage areas shall be controlled to prevent the potential for contamination. 5) Personnel shall be provided adequate facilities for cleaning to prevent the potential contamination of animal foods. 6) Clothing worn by staff engaged in handling feed shall be maintained, stored, laundered and worn so as not to present a contamination risk to products. Clothing shall be appropriate for the work area. 7) Personnel shall be trained on the required hygiene and personnel policies to ensure the biosecurity of the facility and safety of animal foods.	
3.4 Personnel Facilities	1) Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as needed. 2) Changing rooms shall be available, clearly designated and maintained as necessary for animal food safety. 3) Lunch room facilities shall be available for personnel. The facilities shall be: a) Kept clean and free from waste materials and pests. b) Ventilated with adequate lighting. c) Appropriate tables and seating. 4) Restrooms shall be readily accessible without jeopardizing the animal food safety plan. 5) First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.	
3.5 Visitors	1) All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any feed processing or handling area. 2) All visitors shall be required to follow the personnel behavior policies. 3) Visitors shall be aware of the biosecurity requirements to prevent the contamination of animal feeds or feed ingredients. 4) Visitors shall enter and exit feed handling areas through the proper staff entrance points and comply with all personnel hygiene requirements. 5) Visitors shall sign in and out of facilities for biosecurity and personnel safety reasons. 6) Visitors shall be made aware of any policies, practices or requirements, where applicable, that ensure the quality and feed safety program, animal food safety plan and personnel safety requirements.	
4.1 Facility Construction and Surfaces - Infrastructure	1) Facilities and contact surfaces shall be constructed of materials that will not contribute to an animal food safety risk. 2) Floors shall be constructed of material that can be effectively cleaned, drained and is impervious to liquids. 3) In areas where water is used, floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Water shall not be allowed to pond or become stagnant. 4) Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be kept clean. 5) Wall to wall and wall to floor junctions shall be designed to be cleaned in order to prevent the accumulation of debris. 6) Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed so as to allow ease of cleaning. 7) Doors, hatches and windows and their frames shall be of a material and construction that meets the same functional requirements for internal walls and partitions. 8) Animal foods shall be processed and handled in areas that are fitted with a ceiling or other acceptable structures that is constructed and maintained to prevent the contamination of products. 9) Stairs, catwalks and platforms in feed processing and handling areas shall be designed and constructed so as not to present a product contamination risk and shall be kept clean. 10) The Supplier shall take precautions to prevent glass or plastic fragments from entering product or packaging.	
4.2.1 Equipment - Equipment and Maintenance	1) Equipment and tools shall be designed, constructed, installed and operated so as to be fit for purpose, constructed to facilitate cleaning and maintenance, and not pose a contamination threat to animal food products. 2) Installation of new equipment shall be assessed for potential risks and animal food safety plan updated. 3) Changes to equipment shall be documented. Potential risks due to the changes shall be assessed and reported.	
4.2.2 Maintenance	1) The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and carried out in a manner that minimizes the risk of product, packaging or equipment contamination. 2) Maintenance staff and contractors shall observe the following practices when undertaking maintenance and repairs in any feed processing, handling or storage area: a) Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded. b) Failures of equipment shall be documented, reviewed and their repair incorporated into the maintenance control schedule, as needed. c) Maintenance staff and contractors shall ensure materials or finished products are not contaminated during maintenance activities or pose a risk to animal food safety. d) Ensure facility supervisors are notified when maintenance or repairs are to be undertaken in any feed handling area. e) Inform the maintenance supervisor and the facility supervisor if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings and loose overhead fittings); when possible, maintenance is to be conducted outside processing times. f) Remove all tools and debris from any maintenance activity area once it has been completed; inform the area supervisor and maintenance supervisor so appropriate cleaning and inspection can be completed prior to the commencement of facility operations. 3) The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality. 4) Lubricants shall be fit for purpose, meet regulatory requirements and be food/feed grade where there is potential of direct contact with animal feed. 5) Paint used in an animal food handling or contact zone shall be suitable for use and in good condition; paint shall not be used on any product contact surface.	

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4.3 Lighting and Work Areas	1) Lighting in feed manufacturing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively. 2) Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers as to minimize a risk for contamination. 3) A suitable area with sufficient lighting shall be provided for the inspection of the product if required. 4) Adequate ventilation shall be provided in enclosed manufacturing and feed handling areas. 5) Work areas are suitable for personnel to complete required activities.	
4.4.1 Pest Management (M)	1) The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin. 2) The pest and vermin management program shall: a) Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program. b) Identify the target pests for each pesticide application. c) Outline the methods used to prevent and/or eliminate pest problems. d) Outline the frequency with which pest status is to be checked. e) Include on a site map the identification, location, number and type of bait stations set. f) List the chemicals used. g) Outline the requirements for staff awareness and training for the pest management program. h) Measure the effectiveness of the program to verify the elimination of applicable pests. 3) Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison shall not be used inside ingredient or feed storage areas or processing areas. 4) Records of all pest control applications shall be maintained.	
4.4.2 Pest Control Chemicals (M)	1) Pesticides and other toxic chemicals shall be clearly labeled, stored, handled and applied by properly trained personnel. 2) They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of feed and feed contact surfaces. 3) The Supplier shall ensure unused pest control chemicals and empty containers are disposed in accordance with regulatory requirements.	
4.4.3 Pest Management Personnel	1) Pest control contractors shall be licensed and approved by the local relevant authority. If a pest control contractor is not used, company personnel shall be licensed and approved by local relevant authority. 2) Pest control contractors, or properly licensed personnel, shall: a) Use only trained and qualified operators who comply with regulatory requirements. b) Use only approved chemicals. c) Provide a pest control management plan which will include a site map indicating the location of bait stations and traps. d) Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments. e) Provide a written report of their findings and the inspections and treatments applied.	
4.5 Cleaning and Housekeeping (M)	1) The procedures and responsibility for the cleaning and housekeeping of animal food handling and processing equipment and environment, storage areas and staff amenities shall be documented and implemented. 2) A housekeeping program shall be outlined to ensure the facility, equipment and grounds are maintained appropriately to minimize the potential of contamination. 3) If warranted, a suitably equipped area shall be designated for cleaning tools or equipment. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. 4) The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. 5) If used, detergents and sanitizers shall be suitable for use in a feed manufacturing environment. The organization shall ensure an inventory of all commercial chemicals (detergents and sanitizers) purchased and used is maintained. If considered hazardous, training of staff on proper handling, use and disposal shall be maintained. Safety data sheets shall be maintained as needed. 6) A record of cleaning and sanitation activities and verification activities shall be maintained.	
4.6 Exterior	1) The grounds and area surrounding the premises shall be maintained and kept free of waste or accumulated debris so as not to attract pests and vermin. 2) Loading and unloading areas shall be maintained so as not to present a hazard to the animal food safety operation of the premises. 3) Perimeter of facility, when possible, should be fenced for biosecurity purposes. Access to the facility shall be controlled for animal food safety purposes.	
5.1 Product Development - Product Realization	1) The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented. 2) Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by facility trials and product testing. 3) Records of all product design, process development and approvals shall be maintained.	
5.2.1 Receiving Processes for Packaging Materials	1) Packaging shall be verified that it meets the Supplier's specifications upon receipt. All packaging materials shall comply with the relevant regulatory requirements. 2) Packaging materials shall be verified to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of packaging materials may include certification that all packaging that comes into direct contact with feed meets either regulatory acceptance or approval criteria. Documentation should either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis or letter of guarantee, tests and analyses shall be conducted and records maintained to confirm the absence of potential chemical migration from the packaging to the feed contents. 3) Any printed labeling on packaging shall be verified that it complies with Supplier's specifications upon receipt. 4) All packaging materials shall be provided by approved vendors.	
5.2.2 Receiving Processes for Raw Materials and Ingredients	1) All raw materials and ingredients shall comply with the Supplier's specifications and relevant regulatory requirements. 2) Processes for receiving raw materials and ingredients shall be clearly defined and documented. 3) Personnel responsible for receiving raw materials and ingredients shall be trained on the defined processes and procedures. 4) Records shall be maintained for incoming materials to ensure raw materials and ingredients are provided by approved vendors and comply with relevant regulatory requirements. 5) Labeling for raw materials and ingredients that are received shall be verified that it complies with Supplier's specifications upon receipt.	
5.2.3 Equipment at Receiving	1) Prior to receiving or unloading raw materials or ingredients, equipment delivering the materials (typically rail cars, trucks or tankers) shall be inspected for filth or other potential sources of contamination. Rejection criteria must be established. 2) Transportation vendors must comply with regulatory requirements as well as Supplier delivery requirements. 3) Incoming rail cars and trucks should be sealed upon arrival when possible. In the absence of seals a program to evaluate the safety of the incoming ingredients shall be in place. This policy may be similar to the policy for bagged ingredients that have been opened or damaged during transport.	
5.3.1 Process Control (M)	1) Controls shall be implemented throughout the manufacturing process to ensure the quality and safety of the product. 2) The controls shall be consistent with CGMPs as authorized by the Federal Food, Drug and Cosmetic Act to complement the preventive controls required by FSMA. 3) Written procedures for the controls shall be maintained. 4) The control shall be validated to ensure the correct process has been implemented. 5) Records shall be available to verify the control has been completed and is effective.	

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5.3.2 Control of Raw Materials and Ingredients	1) Controls to minimize cross-contamination of raw materials and ingredients during processing shall be implemented to prevent an animal food safety risk. 2) Procedures shall be established and implemented to ensure regulatory requirements for handling raw materials and ingredients are followed.	
5.3.3 Product Release (M)	1) The responsibility and methods for releasing products shall be documented and implemented. 2) The procedures shall ensure the product is released by authorized personnel, once all inspections and analyses are successfully completed and documented to verify regulatory requirements and other established quality and feed safety controls have been met. 3) No product shall be released without proper approval.	
5.4.1 Finished Products Specifications (M)	1) Written finished product specifications shall be approved by the Supplier to ensure customers' requirements are met. 2) Written finished product specifications shall be accessible to relevant staff. 3) Written finished product specifications may include microbiological and chemical limits, labeling and packaging requirements. 4) A register of finished product specifications shall be maintained.	
5.4.2 Product Formulation (M)	1) Product formulations shall be developed by authorized persons to ensure they meet the designated requirements. The formulations shall include all manufacturing instructions with regard to flushing, sequencing, special instructions and cleanout procedures. 2) Procedures shall be documented and implemented to ensure that approved product formulations are used to manufacture finished products. Attention shall be paid to assuring raw materials or ingredients prohibited from use in the manufacture of animal feed are not introduced into the product. 3) All medications included in animal feed must be added in accordance with label instructions and regulatory requirements. When medications are used within a facility, the following shall be followed: a) Access to medications shall be restricted to trained and authorized personnel. b) A daily drug reconciliation inventory shall be maintained. c) Animal medications shall be subject to proper rotation based on expiration date; expired medications shall not be used. 4) Records shall be maintained to ensure products are formulated accurately and adhere to product specifications.	
5.5.1 Customer Requirements	1) The Supplier shall review customer requirements related to the product are met. 2) The Supplier shall determine: a) Requirements specified by the customer. b) Requirements not stated by the customer, but necessary for the specified or intended use (when known). c) Regulatory requirements applicable to the product. d) Any additional requirements considered necessary by the Supplier to meet the needs or expectations of the customer.	
5.5.2 Customer Communication	1) The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities shall be documented and implemented. 2) The Supplier shall determine and implement effective arrangements for communicating with customers. This includes: a) Product information. b) Enquiries, contracts or order handling. c) Customer feedback, including customer complaints. 3) Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents. 4) Records of customer complaints and their investigation shall be maintained.	
5.6 Labeling (M)	1) Finished products shall be labelled for identification. Each package shall be properly labeled. 2) If finished product is provided to the customer as bulk, a label shall be provided with shipment. 3) Labels shall comply with all federal, state and local regulatory requirements. 4) Labels shall be approved by appropriate personnel to ensure compliance with regulatory requirements.	
5.7 Nonconforming Products and Materials (M)	1) The responsibility and methods outlining how nonconforming products and materials are handled shall be documented and implemented. 2) The methods applied shall ensure: a) Nonconforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product. b) Relevant staff is aware of and trained on the organization's quarantine and release requirements applicable to product placed under quarantine status. 3) Quarantine records and records of the handling, corrective action or disposal of nonconforming product shall be maintained.	
5.8 Rework (M)	1) The responsibility and methods outlining how product is reworked shall be documented and implemented. 2) The procedure shall ensure: a) The process of reworking product is supervised by qualified personnel. b) Reworked product is clearly identified and traceable in compliance with regulatory requirements. c) Each batch of reworked product is inspected or analyzed as required before release and distribution. d) Inspections and analyses shall conform to the requirements outlined in Element 7.5. e) Release of reworked product shall conform to the requirements outlined for finished products. 3) Records of all reworking operations shall be maintained.	
5.9 Inventory Stock Rotation	1) A written procedure for ensuring effective stock rotation principles are applied shall implemented and maintained. 2) When applicable, the requirements by customers on stock rotation shall be implemented. 3) If "first in, first out" (FIFO) is not required for specific products, this shall be documented.	
5.10.1 Storage of Raw Materials and Ingredients	1) Raw materials and ingredients shall be stored in such a manner to prevent cross contamination with other raw materials or ingredients 2) Raw materials and ingredients of a similar category or function should be stored in the same area, when possible, in order to minimize the severity of contamination, should it occur. 3) Raw materials and ingredients considered high risk should be stored, when possible, in a separate area or segregated to a specific area to minimize contamination. 4) FIFO stock rotation shall be implemented and practiced, unless otherwise noted due to specific customer needs. 5) Lot numbers of raw materials and ingredients shall be easily identified for personnel to record for usage or shipment (traceability purposes). 6) Inventories for raw materials and ingredients within storage shall be easily obtained and maintained accurately. 7) Racking for storage shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin. 8) When racking is used, storage of raw materials and ingredients shall minimize the risks of contamination from one ingredient above another. 9) The storage of medications for use in feed manufacture shall be controlled and maintained in accordance with regulatory requirements or, in the absence of regulatory requirements, manufacturers' instructions.	
5.10.2 Storage of Packaging	1) Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin. 2) Lot numbers for packaging shall be easily identified for tracking and traceability purposes. 3) Outdated or nonconforming packaging shall be identified as such. These materials shall be stored separately from other packaging to avoid improper use. Nonconforming packaging shall be discarded or disposition determined in a timely manner.	

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5.10.3 Storage of Finished Products	1) Finished products should be stored separately from raw materials and ingredients, where possible. 2) All finished products shall be identified with a lot code for tracking and traceability. 3) FIFO stock rotation shall be practiced with finished products, unless otherwise noted by customer. 4) Storage areas for finished products shall be designed to enable cleaning and housekeeping practices. Storage areas shall be maintained in a manner to prevent harborage of pests or vermin. 5) When racking is used, storage of finished products shall minimize the risks of contamination from one ingredient above another.	
5.10.4 Storage of Nonconforming Materials	1) Raw materials, ingredients, packaging and finished products that are nonconforming shall be isolated in a dedicated storage area. 2) Nonconforming materials and finished products shall be labeled as nonconforming materials. 3) Nonconforming materials and finished products shall be discarded or disposition determined in a timely manner. 4) Storage area for nonconforming materials and finished products shall be designed to enable cleaning and housekeeping practices. Storage areas shall be maintained in a manner to prevent harborage of pests or vermin.	
5.10.5 Bulk Storage of Ingredients and Finished Products	1) Bulk storage shall allow separation and segregation of materials to avoid cross-contamination. 2) Bulk storage bins or silos shall allow for cleaning and housekeeping practices. Bulk storage areas shall be maintained in a manner to prevent harborage of pests or vermin, when possible. 3) Bulk storage practices that support regulatory requirements shall be implemented and maintained, when applicable. 4) Records for bulk storage shall be maintained.	
5.11.1 Hazardous Chemical Storage Process (M)	1) Hazardous chemicals and toxic substances shall be stored so as not to present a hazard to staff as well as the manufacturing of finished products. This includes packaging, product handling equipment or areas in which the finished products or ingredients are handled, stored or transported. 2) Processing tools and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances. 3) Daily supplies of chemical used for emergency cleaning of feed processing equipment or surfaces in feed contact area, may be stored within or in close proximity to a processing area provided access to the chemical storage facility is restricted to authorized personnel. 4) Pesticides, rodenticides, fumigants and insecticides shall be stored in such a controlled manner so as not to present a hazard to animal food.	
5.11.2 Hazardous Chemical Storage Area (M)	1) Hazardous chemical and toxic substance storage areas shall be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals. 2) The storage area shall be adequately ventilated and provided with appropriate signage indicating the area is a hazardous storage area. 3) The storage area shall be maintained as a restricted access only. Personnel without formal training in the handling and use of hazardous chemicals and toxic substances shall not be allowed to work in this area. 4) Instructions on the safe handling of hazardous chemicals and toxic substances shall be readily accessible to staff. 5) The storage area shall be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility. 6) Suitable first-aid equipment and protective clothing shall be available in close proximity to the storage area. 7) In the event of a hazardous spill, the storage area shall be designed such that spillage and drainage from the area is contained. 8) The storage area shall be equipped with spillage kits and cleaning equipment.	
5.12 Loading, Transport and Unloading Practices	1) The practices applied during loading, transport and unloading of animal feed or feed ingredients shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Materials and finished products shall be loaded, transported and unloaded under conditions suitable to prevent cross-contamination. 2) Vehicles (trucks/vans/containers) used for transporting feed shall be inspected prior to loading or unloading to ensure they are clean, in good repair, suitable for the purpose and free from conditions that may impact negatively on the safety of finished products or materials. 3) Loading and unloading practices shall be designed to minimize unnecessary exposure to conditions detrimental to the integrity of finished products, materials and packaging materials. 4) Procedures shall ensure incoming raw materials or ingredients comply with regulatory requirements and the Supplier's specifications, where applicable.	
6.1.1 Approved Vendors (M)	1) Raw materials, ingredients, packaging materials and services that impact on finished product safety shall be supplied by an approved vendor. 2) A written procedure defining the processes and procedures for vendor evaluation and approval shall be maintained. This shall include procedures for receiving raw materials, ingredients, packaging materials and services from unapproved vendors. 3) The responsibility for selecting, evaluating, approving and monitoring an approved vendor shall be documented and implemented. 4) A master list of approved vendors should be maintained, although this is not required. Records of inspections and audits of approved vendors should be maintained also. Supplier shall be required to demonstrate materials are received from approved vendors.	
6.1.2 Unapproved Vendors or Temporary Sourcing	1) The receipt of raw materials, ingredients and packaging materials received from unapproved vendors shall be acceptable in an emergency situation provided before use. Procedures describing the inspection and approval of temporary sourcing of raw materials, ingredients and packaging materials shall be maintained. 2) The use of unapproved vendors or temporary sourcing of incoming goods or services shall be documented. 3) Records shall be maintained showing the use of unapproved vendors and controls implemented to ensure the quality and safety of incoming goods.	
6.2 Material and Packaging Specifications (M)	1) Specifications for all materials and packaging, including (but not limited to) raw materials, ingredients, feed additives, hazardous chemicals and processing aids that impact finished product safety shall be documented and kept current. 2) The methods and responsibility for developing and approving detailed specifications shall be documented. 3) Process to provide specifications to vendors for review and approval shall be defined. A record of vendor acceptance or approval of the specifications shall be maintained and readily assessable by appropriate personnel. 4) A master list of raw and packaging material specifications and labels shall be maintained and kept current.	
6.3.1 Specifications for Contract Service Providers	1) Specifications for contract services that have an impact on finished product safety shall be documented and approved. 2) Relevant training requirements of contract personnel shall be specified and documented. 3) Training records of contract personnel shall be maintained.	
6.3.2 Contract Manufacturing	1) All finished products, "work in progress" materials and services provided by contract manufacturers shall meet the desired specifications by the Supplier. 2) Specifications for desired activities to be completed by contract manufacturers shall be maintained. 3) Records demonstrating the compliance of contract manufacturers to the desired specifications from the Supplier shall be maintained. 4) The Supplier shall verify all customer requirements are being met, ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.	
7.1 Responsibility, Frequency and Methods	1) The practitioner is responsible for ensuring validation and verification activities are completed accurately. 2) The frequency and methods used to validate and verify animal food safety fundamentals, critical limits and other animal food safety controls identified in the animal food safety plan shall be documented and implemented to meet their intended purpose. 3) Records of all validation and verification activities shall be maintained.	

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7.2 Validation Effectiveness	1) The methods shall be documented and implemented that describe the responsibility and criteria for validating the effectiveness of CGMPs and animal food safety limits. 2) The methods shall ensure that: a) CGMPs achieve the desired results. b) Animal food safety limits are selected to achieve the designated level of control of the identified animal food safety hazard(s). c) Animal food safety limits and control measures individually or in combination effectively provide the level of control required. d) Changes to processes or procedures are assessed to ensure controls are still effective. e) Ensure that CGMPs and animal food safety limits are re-validated at least annually. 3) Records of all validation activities shall be maintained.	
7.3 Equipment Calibration	1) The methods and responsibility for the calibration and re-calibration of measuring, testing and inspecting equipment used for monitoring activities shall be documented and implemented. This includes (but not limited to) CGMPs, quality and feed safety program, animal food safety plan and other process controls. 2) Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule. 3) Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the Supplier shall provide evidence to support the calibration reference method applied. 4) Mixers are tested/calibrated as follows: a) Upon installation b) On a regularly scheduled basis c) When batch results indicate the need d) After major repairs and annually thereafter 5) Calibration records shall be maintained.	
7.4 Verification Schedule and Monitoring Activities	1) A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented. 2) The methods, responsibility and criteria for verifying the effectiveness of monitoring CGMPs and animal food safety limits shall be documented and implemented. 3) Procedures shall provide actions to be taken by personnel if or when nonconformities occur during the verification process. 4) Records of the verification of monitoring activities shall be maintained.	
7.5.1 Processes for Product Sampling	1) The methods, responsibility and criteria for sampling raw materials, ingredients, finished product and work in progress shall be documented and implemented. 2) Sampling requirements of raw materials and ingredients shall be established and implemented to ensure the quality and feed safety of finished products. 3) The Supplier shall maintain sample retention times that comply with Supplier and customer requirements. 4) Work in progress materials shall be sampled as needed to ensure the quality and feed safety of finished products. 5) Samples shall be clearly labeled to identify the type of materials within the sample, lot code and date of sampling.	
7.5.2 Inspection and Analysis of Raw Materials and Ingredients	1) All raw materials and ingredients shall be inspected upon arrival to determine whether it is acceptable for use. This may include confirmation of compliance with regulatory requirements or the Supplier's specification, if applicable. 2) Testing or analysis of raw materials and ingredients shall be clearly defined. 3) Testing or analysis of raw materials and ingredients shall be completed at planned intervals to ensure the quality and safety of finished products. 4) Testing or analytical results for raw materials and ingredients shall be maintained. Results shall be reviewed at planned intervals to determine variations in raw materials. 5) Testing and analytical results shall be traceable by raw material and ingredient lot numbers. 6) Testing or analytical processes shall be validated. All analyses shall be conducted to nationally recognized methods or alternative methods, which are validated as equivalent to the nationally recognized methods. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard. 7) Records of all inspections and analyses shall be maintained.	
7.5.3 Inspection and Analysis of Finished Products	1) All finished products shall be inspected prior to release to determine whether it is acceptable for use. This may include confirmation of compliance with regulatory requirements or the Supplier's specification, if applicable. 2) Production records shall be reviewed and approved to ensure the quality and feed safety of the finished product. 3) Testing or analysis of finished products shall be clearly defined, if applicable. 4) Testing or analysis of finished products shall be completed at planned intervals to ensure the quality and safety of finished products. 5) Testing or analytical results for finished products shall be maintained. Results shall be reviewed at planned intervals to determine variations in raw materials or ingredients. 6) Testing and analytical results shall be traceable by finished product lot number and/or production date. 7) Testing or analytical processes shall be validated. All analyses shall be conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard. 8) Records of all inspections and analyses shall be maintained.	
7.6.1 Internal Audit Process	1) The Supplier shall complete internal audits at planned intervals to determine whether the quality and feed safety system: a) Conforms to the requirements established by the Supplier; and b) Is effectively implemented and maintained. 2) The internal audit schedule shall take into consideration the status and importance of the processes and areas to be audited, as well as results from previous audits. 3) The audit criteria, scope, frequency and methods shall be defined. 4) A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. 5) Records of the audits and their results shall be maintained.	
7.6.2 Internal Auditors	1) Internal auditors shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. 2) Staff conducting internal audits shall be trained in internal audit procedures. 3) Records of audit training shall be maintained.	
7.6.3 Internal Audit Corrective Actions	1) Management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without due delay to eliminate detected nonconformities and their causes. 2) Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.	
7.7 Product Identification (M)	1) The methods and responsibility for identifying raw materials, ingredients, "work-in-progress" material and finished products shall be documented and implemented. 2) The product identification system shall be implemented to ensure raw materials, ingredients, "work-in-progress" material and finished products are clearly identified during all stages of receipt, production, storage and dispatch. Finished product is labeled to the customer specification and/or regulatory requirements. 3) Product identification records shall be maintained.	

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7.8 Product Traceability (M)	1) The responsibility and methods used to trace product shall be documented and implemented to ensure finished product is traceable to the customer (one level forward). 2) The methods shall provide traceability through the process to the Supplier and date of receipt of materials, packaging and other inputs (one level backward). 3) Traceability is maintained where product is reworked. Any finished product containing rework shall be traceable to ensure that: a) Customers receiving the product can be identified; and b) Lot numbers for ingredients, including those within the rework, can be identified. 4) The effectiveness of the product trace system shall be tested at least annually. 5) Records of raw and packaging material receipt and use, and product dispatch and destination shall be maintained.	
7.9 Animal Food Defense and Biosecurity Plan	1) An animal food defense and biosecurity plan(s), with responsibility and criteria for preventing feed adulteration caused by a deliberate act of sabotage or terrorist-like incident, shall be documented, implemented and maintained. 2) An animal food defense plan shall be prepared and include: a) Name of the management person responsible for feed defense and biosecurity. b) Methods implemented to ensure only authorized personnel have access to the facility grounds, production equipment and vehicles, and manufacturing and storage areas through designated access points. c) Methods implemented to protect sensitive processing points from intentional adulteration. d) Measures taken to ensure the security of storage for materials, packaging, equipment and hazardous chemicals. e) Measures implemented to ensure materials (bulk or bagged) as well as finished product are held under secure storage and transportation conditions. f) Methods implemented to record and control access to the premises by employees, contractors and visitors. 3) The animal food defense and biosecurity plan(s) shall include processes or procedures to prevent the spread of disease to animals. This includes contact during transport or delivery to animals susceptible to disease. 4) Records for the animal food defense and biosecurity plan(s) shall be maintained.	
8.1 Animal Food Safety Fundamentals (M)	1) The property, buildings and equipment shall be located, constructed, designed and maintained to facilitate the production, manufacture, handling, storage and/or delivery of safe feed. 2) The Supplier shall ensure the relevant animal food safety fundamentals are applied or excluded according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that animal food safety is not compromised. 3) CGMPs applicable to the scope of certification that outline the means by which animal food safety is controlled and assured shall be documented and implemented.	
8.2.1 Animal Food Safety Plan Responsibility (M)	1) An animal food safety plan shall be developed, effectively implemented and maintained. The plan shall outline the means by which the organization controls and assures animal food safety. 2) An animal food safety team shall be created to develop and support the implementation and maintenance of the animal food safety plan. The team shall include personnel from various areas within operations. 3) The Practitioner shall be responsible for ensuring the animal food safety plan is developed, implemented and maintained in accordance with the quality and feed safety system. 4) Management shall approve the animal food safety plan.	
8.2.2 Process Flow Diagram	1) A process flow diagram shall be a component of the animal food safety plan. 2) The process flow diagram shall outline the processes within the receiving, storing, manufacturing and shipping of raw materials, ingredients or finished products. 3) The process flow shall be approved by the animal food safety team. 4) The process flow shall be verified annually, or when changes to the animal food safety plan are implemented, whichever is shorter.	
8.2.3 Hazard Analysis of Processes (M)	1) A hazard analysis shall be completed for each area or process within the process flow diagram. 2) The animal food safety team, or appropriate personnel, shall complete the hazard analysis for each area or process. 3) Records of the hazard analysis shall be maintained.	
8.2.4 Hazard Analysis of Materials (M)	1) A hazard analysis shall be completed for incoming raw materials, ingredients and packaging materials. 2) The animal food safety team, or appropriate personnel, shall complete the hazard analysis for incoming raw materials or ingredients. 3) Records of the hazard analysis shall be maintained.	
8.2.5 Preventive Controls (M)	1) Written procedures shall be established and implemented for controls of identified hazards where applicable. 2) The Supplier shall validate processes as appropriate for control of hazards. 3) The Supplier shall verify processes are accomplishing the desired preventive control. 4) Records from preventive controls shall be monitored on a planned basis to determine the need for continuous improvement within the process, if any. 5) Corrective actions shall be taken when a preventive control is not effective. The animal food safety plan shall be updated if warranted.	
8.3 Corrective and Preventive Actions (M)	1) The Supplier shall maintain a written procedure that describes the Supplier's processes for corrections, corrective actions and preventive actions. 2) The responsibility and methods outlining how corrections, corrective actions and preventive actions are investigated, resolved, managed and controlled shall be documented and implemented. 3) Records of all investigation and resolution of corrections, corrective actions and preventive actions shall be maintained.	
8.4 Regulatory Requirements (M)	1) The Supplier shall ensure that facility or location complies with all federal, state and local regulatory requirements. 2) The Supplier shall ensure at the time of delivery to its customer that the finished products, raw materials and ingredients comply with all regulatory requirements. This includes compliance with regulations applicable to maximum residue limits, animal food safety, packaging, product description, nutritional, additive labeling and to relevant established industry codes of practice. 3) The methods and responsibility for ensuring the organization is kept informed of changes to relevant regulations, scientific and technical developments and relevant industry codes of practice shall be documented and implemented. 4) The Supplier shall maintain defined procedures for complying with regulatory requirements. 5) Processes shall be established to ensure the facility is aware of all regulatory requirements. 6) Personnel responsible for compliance with regulatory requirements shall be trained on relevant procedures. 7) Procedures shall define individuals responsible for communicating regulatory requirements to management and site personnel. 8) If the site is subject to FDA inspections or audits, a procedure for reacting to a visit by an FDA official for an inspection or audit shall be defined. Appropriate personnel shall be trained on these procedures.	
8.5 Recall Plan (M)	1) The responsibility and methods used to withdrawal or recall product shall be documented and implemented. 2) The procedure shall: a) Identify those responsible for initiating, managing and investigating a product withdrawal or recall. b) Describe the management procedures to be implemented including sources of legal and expert advice. c) Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident. 3) Investigation shall be undertaken to determine the root cause of a withdrawal or recall. Details of the investigation and any actions taken shall be documented. 4) The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually ("mock" recall). 5) Records of all product withdrawals and recalls shall be maintained.	

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8.6 Waste Disposal	1) The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented. 2) The Supplier shall ensure portable containers, vehicles waste disposal equipment, collection bins and storage areas are maintained in a serviceable condition and cleaned regularly so as not to attract pests and other vermin. 3) The Supplier shall maintain adequate provisions for the disposal of all solid processing. Waste held on site prior to disposal shall be stored so as not to present a hazard.	
8.7 Water and Air	1) If water is used as a potential ingredient or additive within a finished product, the Supplier shall ensure the safety of the water for animal food. 2) Records shall be maintained to ensure the water used as an ingredient or additive is safe for animal use. 3) Compressed air that comes into contact with animal feed shall be clean and present no risk to animal food safety.	
9.1 Compliance with Safe Feed/Safe Food Seal Licensing Agreement	1) The Supplier shall comply with the requirements for using the FSC36 Safe Feed/Safe Food logo as described within the LICENSING AGREEMENT FOR USE OF THE SAFE FEED/SAFE FOOD SEAL. See Appendix B for an overview of the agreement. 2) The Supplier shall ensure the FSC36 Safe Feed/Safe Food logo complies with the size requirements for use on packaging. 3) The Supplier shall ensure the FSC36 Safe Feed/Safe Food logo complies with the color requirements as defined within the agreement. 4) The Supplier shall print the following in reasonably close proximity to the FSC Safe Feed/Safe Food seal or logo: “This feed was produced in a facility certified in the American Feed Industry Association’s Safe Feed/Safe Food Certification Program; for details go to: www.safefeedsafefood.org.”	