Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

Purpose
The purpose of this guidance document is to provide feed and ingredient manufacturers with recommendations that may be used to develop a biosecurity plan to control the potential spread of animal diseases through feed and feed ingredients. Each facility, location or business should develop a biosecurity plan based on the potential hazards and risks of occurrence within their processes. Procedures should be developed to ensure the plan is implemented and remains effective as situations change.

There are numerous hazards that feed and ingredient manufacturers need to control or prevent, including physical, chemical and biological hazards. The scope of this guidance document is focused on the development of biosecurity practices for feed and ingredient manufacturers to control biological hazards that may contribute to the spread of animal diseases.

Introduction
Controlling diseases associated with animal production continue to be of significant importance in order to protect animal health, prevent economic hardship and ensure livelihoods for animal handlers. Numerous foreign animal diseases have been identified at the global level and although feed is seldom a carrier, preventing entry and transmission of disease is the goal for a biosecurity program (FAO, 2010, APHIS Animal Diseases, 2015). Today, due to ever-increasing global travel and international trade of feed ingredients, the concerns for biosecurity and spread of animal diseases, particularly those of foreign origin, are high within animal agriculture. Therefore, biosecurity programs are an important tool to reduce the likelihood of the introducing pathogens into the feed chain. Guidelines for developing a biosecurity plan for foreign animal diseases are available from the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS 2011).

The success of a biosecurity plan to control the spread of animal disease through feed or feed ingredients depends upon the following:

1) Identification of reasonably foreseeable animal disease hazards
2) Assessment of the risk of potential hazards and developing a biosecurity plan according to the risk assessment process outlined below
3) Communication of the biosecurity plan, which includes management commitment as well as education and training of personnel to implement the plan
4) Verification of plan implementation including effective corrective actions for deviations to ensure the degree of biosecurity desired
# Table of Contents

<table>
<thead>
<tr>
<th>Content</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Hazard Identification and Risk Assessment</td>
<td>3</td>
</tr>
<tr>
<td>Manufacturing Processes</td>
<td>3</td>
</tr>
<tr>
<td>Animal Feed Contamination</td>
<td>4</td>
</tr>
<tr>
<td>Recommended Biosecurity Practices</td>
<td>5</td>
</tr>
<tr>
<td>Supplier Verification</td>
<td>5</td>
</tr>
<tr>
<td>Ingredient Receiving</td>
<td>6</td>
</tr>
<tr>
<td>Employees, Visitors and Drivers</td>
<td>8</td>
</tr>
<tr>
<td>Manufacturing Area</td>
<td>9</td>
</tr>
<tr>
<td>Shipment of Customer Deliveries</td>
<td>9</td>
</tr>
<tr>
<td>Education and Communication</td>
<td>12</td>
</tr>
<tr>
<td>Management Commitment</td>
<td>12</td>
</tr>
<tr>
<td>Education and Training</td>
<td>12</td>
</tr>
<tr>
<td>Continuous Improvement</td>
<td>12</td>
</tr>
<tr>
<td>Communication</td>
<td>12</td>
</tr>
<tr>
<td>Summary</td>
<td>13</td>
</tr>
<tr>
<td>Reference Citations</td>
<td>14</td>
</tr>
<tr>
<td>References for More Information</td>
<td>15</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>18</td>
</tr>
</tbody>
</table>
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

Hazard Identification and Risk Assessment

The Food Safety Modernization Act requires facilities to develop and maintain a food safety plan that assesses reasonably foreseeable hazards and implements controls to prevent or minimize the impact of such hazards.

Every facility is different and a biosecurity plan to control the spread of animal disease must be specific for the location. A team should be created to ensure the appropriate procedures and processes are implemented. Responsibilities of the team include the following:

- Identifying areas of reasonably foreseeable hazards for the spread of an animal disease;
- Developing a site-specific biosecurity plan for animal disease;
- Increasing biosecurity awareness and ensuring compliance with policies;
- Ensuring proper training is maintained and completed; and
- Keeping management informed of potential animal disease risks and updating the biosecurity awareness plan as needed.

Manufacturing processes: Feed contamination with a disease-causing pathogen can be introduced at numerous points throughout the manufacturing process including through the use of contaminated ingredients, during receiving at the feed manufacturing site, cross contamination within the feed manufacturing facility, delivery vehicles (both incoming and outgoing) and by delivery personnel. Potential hazards should be identified, evaluated and prioritized. Appropriate risk mitigation steps should be implemented.

An overview of potential sources of animal disease contamination within the feed and ingredient manufacturing processes is shown in Figure 1. The process flow is divided into pre-manufacturing, manufacturing and post-manufacturing steps.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

Sources of potential hazards are listed under each processing step. For pre-manufacturing, the potential exposure of raw materials to animal disease pathogens should be assessed. This includes the potential for pathogen exposure, or animal disease, contamination during harvest, further processing, shipment and storage of ingredients. Supplier verification programs should be incorporated into the hazard analysis process to assure the feed manufacturer that processes are in place to prevent pathogen contamination of purchased ingredients. An effective supplier verification program will minimize the risks from animal diseases entering the manufacturing processes. During post-manufacturing, risks of exposure to pathogens are primarily from contaminated transfer equipment, vehicles, storage equipment and personnel. These processes may or may not be under the control of the feed manufacturer, i.e., customer pick-up or third-party feed delivery.

Animal feed contamination: Pathogens may be transmitted through a variety of ways. As outlined by APHIS (2011), there are numerous routes of transmission that may vary depending on the specific diseases. These include the following:

- Airborne transmission;
- Direct animal to animal contact;
- Semen;
- Human contact including dirty boots, clothing or hands; zoonotic diseases (those that are communicable between animals and humans) can also be included in this group;
- Vectors including rodents, feral animals and insects;
- Vehicles and other fomites;
- Feed, including water; and
- Animal manure and soiled bedding.

The feed manufacturer is responsible for biosecurity of the feed chain, which includes selecting, receiving and processing of ingredients into the complete feed through to final feed delivery or until the livestock producer takes possession of the feed.

The biosecurity plan should be science-based. However, the plan should be flexible enough to allow some modification depending on circumstances. For example, additional safeguards may be introduced immediately following the recognition of a new foreign animal disease before additional safeguards have been researched and validated. As additional information is gathered, the biosecurity plan should be updated with more effective actions or processes.

Development of a biosecurity plan begins by assessing biosecurity risks. The first step is to identify and prioritize the pathogenic agents of greatest concern to the facility. Once the disease agents of concern for the facility are identified, quality personnel should become familiar with their pathogenesis, ecology and epidemiology, paying special attention to factors such as routes of transmission, susceptible species and age groups, and environmental factors favoring transmission. The next step is to conduct an assessment of the facility to understand how facility features such as the layout, traffic patterns, geography and staffing can increase the risk of disease transmission.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

In addition, consulting with a local veterinarian or a regional veterinary diagnostic laboratory can be helpful in the identification of potential feed borne pathogens. A list of National Animal Health Laboratories is available ([NAHL List, 2015](http://example.com)).

**Recommended Biosecurity Practices**

The potential risk of exposure to pathogenic agents can be managed through the use of biosecurity measures to reduce the risk of disease introduction and transmission. By understanding the routes of disease transmission and targeting biosecurity measures to those particular routes of transmission, a biosecurity plan effective against multiple disease agents can be developed.

The following practices at various stages of feed and ingredient manufacturing may be implemented within a biosecurity plan to reduce the risk of spreading animal diseases.

**Supplier verification**: The goal of supplier verification is to insure the supplier has an adequate program to control contamination of the ingredient they are supplying. If the supplier does not have an adequate biosecurity program, then it is the responsibility of the feed manufacturer to develop an adequate testing program or risk mitigation procedures at the supplier location or as part of its production processes, if this supplier is used. Steps that feed and ingredient manufacturers should take to ensure risks from incoming ingredients or raw materials are controlled include the following:

- Determining the potential risk associated with each ingredient. For example, L-lysine purchased directly from a manufacturer may have a lower risk of pathogen contamination than wheat isolate purchased from a broker sourcing the ingredient from an unidentified manufacturer located in another country.
  - Depending on the relative risk of the ingredient, developing an appropriate supplier verification program and purchasing from approved suppliers.
  - Developing a testing and risk mitigation program if ingredients are sourced from a supplier that does not implement an adequate biosecurity program.

- Maintaining ingredient specification requirements for feed or ingredients including the requirements for biosecurity; ensure suppliers understand ingredient specifications including biosecurity requirements.

- Establishing a validation program ensuring suppliers maintain appropriate biosecurity programs; this may include supplier site visits, a review of their quality programs and/or procedures to control potential hazards, including the potential spread of animal diseases; third-party certifications such as Safe Feed/Safe Food Certification
Ingredient receiving: Ingredients and their delivery represent a potential for introduction of a pathogen(s) into the feed chain. It is important to implement preventive controls for reasonably foreseeable hazards. Consider the following:

- Establishing the relative risk associated with the ingredient delivery method. For example, bulk ingredients received in an open top vessel may represent a greater risk of environmental contamination compared to bagged, palletized and/or shrink-wrapped ingredients delivered in a dedicated sealed truck.
  
  o Developing biosafety procedures to insure each type of ingredient is delivered properly; communicating these procedures/expectations to the Freight Company and auditing to insure compliance with biosecurity procedures.
  
  o Discussing the potential hazards for ingredients with differing risk profiles and verifying the supplier has procedures in place to control reasonably foreseeable hazards.
  
  o Verifying containers are properly cleaned before loading. Ensuring no hazardous ingredients are hauled prior to, or in combination with, feed or ingredients.
  
  o Verifying the ingredient is from an approved supplier from the facility’s approved supplier list.

- Documenting that transportation vehicles and their conveyance equipment are clean and in good working order before allowing entry into the receiving area; this includes removing debris from underneath the vehicle; documenting that vehicles are acceptable; and rejecting vehicles that do not meet the facility’s clean criteria.

- Receiving area and/or unloading pit includes the following:
  
  o Inspecting the unloading pit and cleaning (as appropriate) between use.
  
  o Protecting the unloading pit between uses to prevent contamination.
  
  o Protecting the bulk ingredient during unloading from any of the following:
    
    - Contamination with material falling from the undercarriage of the delivery vehicle.
    
    - Spills onto the ground and accumulating on the ground around the unloading pit during unloading.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

- Accumulation of ingredients on tracks or roadways during receiving.
  - Do not allow debris to accumulate in the unloading pit area; measures should be considered (such as cover pit) to avoid debris from entering the receiving pit during movement of transportation vehicles in or out of the receiving area.

- Trucks delivering ingredients should be sealed as follows:
  - Sealing loads for delivery immediately after loading and intact seals should be verified upon arrival; rail car hatches and discharge gates should be sealed prior to arrival; recording and verifying the seal numbers on the bill of lading; ensuring seals have not been tampered with or broken.
  - Inspecting all receiving shipments for potential contamination and assess the potential risk for the spread of animal disease; conditions that could result in rejection/quarantine should be identified before receipt (determining if a load is contaminated with an animal disease is difficult).

- In the case of soft-top trailers, assessing whether the ingredient or raw material was contaminated from the environment during transit or from unauthorized persons.

- Maintaining a receiving log for all receipts with batch or lot number for traceability purposes; include rejected items on receiving records.

- Developing processes and procedures to prevent contamination during unloading of bulk ingredients; this includes pest control, housekeeping and other preventive control measures.

- Collecting and inspecting samples for all incoming raw materials and ingredients, as follows:
  - Collecting retained samples prior to and during unloading. For example wet feed ingredients can be contaminated with mold or bacterial pathogens while feed ingredients contaminated with fecal material can be contaminated with either bacterial or viral pathogens.
  - Developing a program for disposal of contaminated ingredients.
  - Inspecting bagged products for integrity of packaging and/or potential contamination including surface contamination.
    - Developing programs for cleaning of surface contamination.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

- Developing programs for disposal of material determined to be contaminated, if determined it cannot be cleaned.

- Personnel flow in the receiving area should include the following:
  
  o The receiving area represents an area exposed to potential outside contamination. Vehicle traffic and outside suppliers are arriving from unsecured areas. Foot traffic from the receiving area represents a potential for bringing pathogens into the feed manufacturing plant. The goal is to develop procedures that prevent the pathogens from entering the manufacturing area, such as restricting personnel movement from the receiving area into the manufacturing area.

  o Restricting driver movement; establishing cleaning protocols for personnel when moving from the receiving area to other areas within the feed plant including foot baths, hand washing stations, etc.

Employees, visitors and drivers: Employees, visitors and drivers arriving to the feed mill from unsecured locations and can carry pathogens into the feed mill on their person, soiled clothing and dirty footwear. Processes and procedures should be implemented to control the access of people throughout a facility as follows:

- Posting appropriate signage alerting personnel when they are entering restricted areas.

- Establishing wash stations including hands and boot wash at entry points.

- Biosecurity awareness should be instilled in all employees, starting with top management; everyone must vigilantly monitor the activities of visitors, customers, service providers and fellow employees; restrict access to manufacturing areas, particularly for non-employees.

- Train employees to recognize and report suspicious individuals or abnormal activities, security breaches, and suspicious ingredients or devices.

- Establish a personnel hygiene policy that reduces the likelihood of spreading animal disease. As an example, employees who own or come in contact with livestock should shower prior to reporting to work and wear clean, laundered clothes clean, dedicated footwear should be worn at work.

- All visitors and contractors should check-in with a designated company representative; procedures should protect against unwanted visitors and account for all persons during an emergency.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

- Maintaining a record of individuals’ names and companies, arrival and departure times, and purposes for the visit; such activities signal that your company takes the biosecurity plan seriously.

- Using visitor badges, identification cards or some other method to clearly identify visitors.

- Prohibiting visitors, including delivery personnel, contract providers and service support, to wander the premises unaccompanied. A company representative should serve as an escort at all times.

- Maintaining proper signage and directions for visiting drivers to ensure biosecurity procedures are followed as personnel represent a potential threat to the spread of animal disease.

- Prohibiting livestock and livestock trailers on the premises unless they have been thoroughly cleaned prior to arrival.

**Manufacturing area:** Although a facility may have systems in place to ensure that biosecurity risks from incoming ingredients are controlled, the facility should also implement processes and procedures to prevent feed contamination with animal disease organisms during manufacturing as follows:

- Ensuring housekeeping practices maintain a clean and safe work environment.

- Ensuring the integrity of stored materials (ingredients, intermediate materials or finished products) is maintained during storage.

- Establishing processes to review the facility’s compliance with its biosecurity plan and other procedures that act as barriers for animal diseases entering the property.

**Shipment of customer deliveries:** Transporting finished products or ingredients from a secure facility can increase the risk for potential contamination and spread of animal disease. The exposure of finished products to an uncontrolled environment such as contaminated vehicles, storage bins and/or people exposed to animal disease may result in feed contamination and should be controlled as follows:

- Ensuring batch or lot numbers are recorded as traceability of materials is required by the U.S. Food and Drug Administration (Bioterrorism Act, 2002).

- Ensuring equipment is clean and in proper working order prior to loading; cleaning or repairing equipment as needed.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

- Securing truck trailers, both bag and bulk, once loaded.

- In the case of soft-top trailers, measures should be taken to prevent environmental contamination or unauthorized persons from accessing and adulterating the shipments.

- Cleaning tarps (or covers) before using as follows:
  - Establishing cleaning protocols to follow if covers are determined to be dirty.
  - Ensuring tarps (or covers) are in good repair, are not torn and sealed properly when used.

- Establishing and maintaining a disease status log for livestock production locations where feed is delivered as follows:
  - Establishing a hierarchy for feed delivery locations based on the disease status of the location; hierarchy should consider the following:
    - The biosecurity level of the production unit, i.e., for example a gilt multiplier may have a higher biosecurity need compared to a commercial finishing location.
    - The disease that may be present at the location, i.e., porcine epidemic diarrhea disease virus (PEDV) may represent a greater risk of contaminating a delivery truck and being transferred to another production unit than porcine reproductive and respiratory syndrome (PRRS).
    - Veterinarians may be helpful in establishing guidelines for establishing the hierarchy.
  - Consulting the hierarchy routinely before scheduling deliveries or entry onto a customer’s premises.
  - Completing deliveries to customers according to the hierarchy.
  - Establishing cleaning procedures including down time, as appropriate, consistent with the disease risk hierarchy for feed deliveries.
  - Using dedicated vehicles for specific customer deliveries when possible in accordance with previously established customer disease hierarchy.
  - Routing deliveries to avoid contact with “infected or controlled areas.”
Guidance for Developing Biosecurity Practices
for Feed and Ingredient Manufacturing

- Establishing a protocol for unloading feed at the livestock production site. Suggested guidelines are available, such as those provided by the National Pork Board (Biosecurity Guide, 2002) as follows:
  - Using clean disinfected footwear by drivers before exiting of the truck. For example, using disposable foot protection or clean disinfected boots.
    - Maintaining a sealable trash bag to dispose of foot protection or to store boots for subsequent cleaning and disinfection.
  - Following customer biosecurity processes and procedures; making every reasonable effort to accommodate special needs; developing a decision-making process for special biosecurity requests from customers to determine mutually agreeable protocols.

- If delivery trucks do come in contact with livestock waste, establishing appropriate cleaning procedures to ensure pathogens are not brought to the feed manufacturing site. Suggested truck cleaning protocols are available (Truck Wash Procedures, 2013) as follows:
  - Not using customer equipment to unload deliveries.
  - Following a preventive cleaning or washing program consistent with disease risk hierarchy of the livestock production location.
  - Prohibiting drivers from entering a building where animal(s) are housed or pass through.
  - Cleaning bagged product delivery trailer interiors, which should be cleaned and inspected for potential contamination prior to loading.
  - Inspecting the underside of the trucks where organic material can build up prior to returning to the feed manufacturing site and properly cleaned when necessary.
  - Prohibiting return of wood pallets; requiring all plastic pallets returning from customers on delivery trucks to be transported to a dedicated area at the manufacturing facility that has separation from manufacturing areas for appropriate cleaning and washing; placing clean pallets in a designated area for reuse.
  - Prohibiting bulk totes from being reused or should be thoroughly cleaned and sanitized prior to reuse.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

- Quarantine all products returned to the manufacturing facility and assessing the potential risks prior to reentry into the facility.

Education and Communication
In order for a biosecurity plan to be effectively implemented, the plan must be communicated to everyone involved in the operation. The owners, managers, operators and employees must all be informed of the plan and know how to implement biosecurity measures in their daily operations. A biosecurity plan’s effectiveness of preventing disease is only as good as the efforts of the people using it.

Management commitment: The management team of a facility establishes the “culture” or commitment to practices. Commitment to the biosecurity plan is necessary for the success of the program. Management personnel must support the development and implementation of the program. This includes participation in the process as well as providing resources to ensure the success of implementation and maintenance of any plan. Commitment may be demonstrated in policies or company communications to personnel, which should be clear and ongoing.

Education and training: Education about the biosecurity plan should be incorporated into the company’s training program. Procedures should be developed and records maintained to demonstrate their effectiveness. Such processes should be considered part of the facilities Current Good Manufacturing Practices (CGMPs) as required by FDA for the manufacturing of animal foods as described within the Food Safety Modernization Act (FSMA, 2015).

Continuous improvement: The biosecurity plan should be reviewed and updated on a scheduled basis, as defined within written procedures. The procedures should be updated based on feedback from personnel, changes of processes or ingredients and/or ingredient sources, after a review of records finds concerns, and changes in the assessment of potential hazards or risks from animal diseases. Quality and food safety certification programs help feed and ingredient manufacturers demonstrate their commitment to driving continuous improvement within their food safety processes (SQFI, 2014; Safe Feed/Safe Food, 2015).

Communication: The communication of the biosecurity program to suppliers, company personnel and customers is important to ensure its effectiveness. Suppliers must understand facilities’ requirements for incoming materials. Company personnel should have an understanding the importance of the biosecurity program and their role in its effectiveness, and this should be bolstered by a strong management commitment to the plan. Customers should know your practices to ensure the biosecurity of products provided.

Another resource of international importance is the principles of a biosecurity plan described within a publication by the United Nations’ Food and Agriculture Organization (FAO, 2007).

Summary
The concept for biosecurity to control the spread of animal diseases is not new. However, the societal and financial impact of spreading highly contagious animal diseases has increased due
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

to the intensity and the global nature of animal agriculture and transport of pathogens worldwide. Recommendations in this guidance document should greatly help feed and ingredient manufacturing facilities develop a biosecurity plan to assist in controlling the spread of animal diseases introduced by foreign sources or within the U.S.

The effectiveness of a biosecurity plan depends upon the culture of the facility to drive the program and the commitment of employees, and most importantly to the facility’s management to implement the plan. A facility must continuously assess the risks for spreading animal diseases to ensure the effectiveness of its biosecurity plan. Communication with employees, customers and industry associates is important to preventing and controlling the spread of animal diseases.
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

REFERENCE CITATIONS


FSMA, 2015. Food Safety Modernization Act and Animal Feed, Food and Drug Administration. http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm347941.htm


REFERENCES FOR MORE INFORMATION


Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing


http://www.fao.org/docrep/012/i1379e/i1379e01.pdf


PEDV Resources, National Pork Board.
http://www.pork.org/pork-checkoff-research/pedv/pedv-resources/

PEDV Update and Biosecurity Suggestions, American Association of Swine Veterinarians, 2014.

Porcine Epidemic Diarrhea Virus (PEDv), AASV.

http://www.pork.org/pedv-2014-research/pedv-feed/


Suggested outline of potential critical control points for biosecurity and biocontainment on
Guidance for Developing Biosecurity Practices for Feed and Ingredient Manufacturing

AFIA would like to thank the following individuals and industry associations for their contributions to this document:

<table>
<thead>
<tr>
<th>Company</th>
<th>Representative</th>
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<tbody>
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<tr>
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<td>Dan Kovich</td>
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<td>National Renderers Association</td>
<td>David Meeker</td>
</tr>
</tbody>
</table>