

BIOSECURITY

DEVELOPING BIOSECURITY PRACTICES FOR FEED & INGREDIENT MANUFACTURING



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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, both foreign and domestic.

Comments and suggestions are welcome. Correspondence should be sent to the **American Feed Industry Association**, 2101 Wilson Blvd., Suite 810, Arlington, VA 22201, afia@afia.org.

INTRODUCTION

Controlling diseases associated with animal production is important for protecting animal and human health, preventing economic hardship and protecting the livelihoods of our animal agriculture customers.

In addition to the more common endemic disease threats to livestock production, numerous foreign animal diseases have been identified at the global level. Little evidence is currently available to demonstrate feed is commonly associated with transmission of foreign animal diseases into the United States, but preventing the entry and transmission of these diseases should be a goal for any biosecurity program ([FAO, 2010](#), [APHIS Animal Diseases, 2018](#)). The U.S. Department of Agriculture (USDA) maintains information about animal diseases on [its website for animal disease](#). The National Animal Health Reporting System (NAHRS) provides data from chief state animal health officials on the presence of confirmed World Organization for Animal Health (OIE) reportable diseases in the U.S. If a reportable disease is found in the U.S., there are specific requirements for the facility impacted. Contacts, processes and procedures may be found within the [NAHRS Operational Manual](#).

Today, due to ever-increasing global travel and international trade of feed ingredients, the concerns for biosecurity and the spread of animal diseases, particularly those of foreign origin, are high within animal agriculture. Biosecurity programs are an important tool for reducing the likelihood that pathogens will be introduced into the feed chain. Guidelines for developing a biosecurity plan for foreign animal diseases are available from the USDA's Animal and Plant Health Inspection Service ([APHIS 2016](#)).

In order for a biosecurity plan to be successful, facilities must control the spread of animal disease through feed or feed ingredients. Important steps include:

- 1) Identify reasonably foreseeable animal disease hazards;
- 2) Assess the risks of those potential hazards and develop a biosecurity plan according to the risk assessment process outlined below;

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- 3) Communicate the biosecurity plan to facility personnel, including encouraging management commitment as well as education and training of personnel to implement the plan; and
- 4) Verify the plan's implementation through effective corrective actions for deviations to ensure the degree of biosecurity desired.

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HAZARD IDENTIFICATION AND RISK ASSESSMENT

The Food Safety Modernization Act (FSMA) 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 as appropriate.

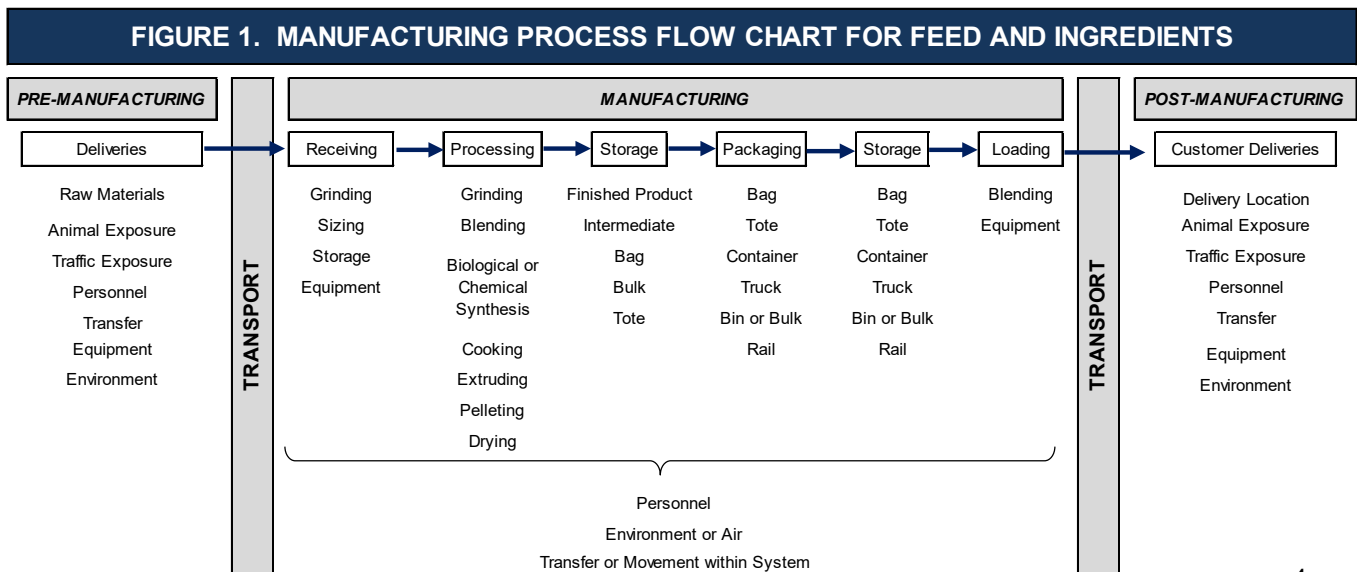
Every facility is different and a biosecurity plan to control the spread of animal disease must be specific for the location. A team should be created to ensure the appropriate procedures and processes are implemented. Responsibilities of the team include the following:

- Identifying areas of reasonably foreseeable hazards for the spread of animal diseases;
- Developing a site-specific biosecurity plan for preventing animal diseases;
- 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, and by delivery vehicles (both incoming and outgoing) and delivery personnel. Potential hazards should be identified, evaluated and prioritized. Appropriate risk mitigation steps should be implemented. A well-designed and maintained animal food safety plan, when adhered to, will help mitigate disease risks and increase biosecurity.

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.



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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 (e.g., customer pick-up or third-party feed delivery).

Animal Feed Contamination:

As outlined by [APHIS \(2011\)](#), there are numerous routes of pathogen transmission, which may vary depending on the specific diseases. These include the following:

- Airborne transmission;
- Animal manure and soiled bedding.
- 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;
- Vehicles and other fomites;
- Vectors, including rodents, feral animals and insects; and
- Feed, including water.

The feed manufacturer is responsible for biosecurity of the feed chain, which includes selecting, receiving and processing ingredients into the compounded feed all the way through to the 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 the facility's 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.

The 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, appropriate 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

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features, such as the layout, traffic patterns, geography and staffing, can increase the risk of disease transmission.

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, 2018](#)).

RECOMMENDED BIOSECURITY PRACTICES

The potential risk of exposure to pathogenic agents can be managed through the use of biosecurity measures aimed at reducing 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 ensure 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. 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 is recommended.
 - Developing a testing and risk mitigation program if ingredients are sourced from a supplier that does not implement an adequate biosecurity program is another component.
- *Maintaining ingredient specification requirements for feed or ingredients,* including the requirements for biosecurity; and ensuring suppliers understand those ingredient specifications and biosecurity requirements.

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- *Establishing a verification program ensure suppliers maintain appropriate biosecurity programs*, which may include: supplier site visits, a review of the supplier's quality programs and/or procedures to control potential hazards (including the potential spread of animal diseases); and third-party certifications that may be used for verification, such as the Safe Feed/Safe Food certification program.

Ingredient Receiving:

Ingredients and their delivery represent a potential for introduction of a pathogen(s) into the animal food chain. It may become necessary to implement preventive controls for known and reasonably foreseeable hazards, at receiving or other areas of production, when analysis determines that such hazards cannot be adequately controlled with standard operating procedures, current good manufacturing practices (CGMP) or other prerequisite programs. Consider the following:

- *Establishing the relative risk associated with the ingredient delivery method*. For example, bulk ingredients received in an open-topped vessel may represent a greater risk of environmental contamination compared to bagged, palletized and/or shrink-wrapped ingredients delivered in a dedicated sealed truck.
 - Developing biosafety procedures to ensure each type of ingredient is delivered properly; and communicating these procedures/expectations to the freight company and auditors to ensure compliance with biosecurity procedures is recommended.
 - Discussing the potential hazards for ingredients with differing risk profiles and verifying the supplier has procedures in place to control reasonably foreseeable hazards is another important action.
 - Verifying that containers are properly cleaned before loading is essential, which will help assure that no hazardous ingredients are hauled prior to, or in combination with, feed or ingredients.
 - Verifying the ingredient is from an approved supplier from the facility's approved supplier list is critical.
- *Documenting that transportation vehicles and their conveyance equipment are clean and in good working order before allowing entry into the receiving area*, which includes removing debris from underneath the vehicle; documenting that vehicles are acceptable; and rejecting vehicles that do not meet the facility's clean criteria.
- *Developing procedures for the receiving area and/or unloading pit*, which includes the following:
 - Inspecting the unloading pit and cleaning (as appropriate) between use.

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- Protecting the unloading pit between uses to prevent contamination.
- 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.
 - Accumulation of ingredients on tracks or roadways during receiving.
- Preventing debris from accumulating in the unloading area. Measures should be considered (e.g., a pit cover to avoid debris from entering the receiving pit during the movement of transportation vehicles in or out of the receiving area).
- *Inspecting seals and ingredients on shipment vessels 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; and ensuring seals have not been tampered with or broken.
 - Inspecting all receiving shipments for potential contamination and assessing the potential risk for the spread of animal diseases. Any conditions that could result in rejection/quarantine of a shipment should be identified before receipt, but keep in mind that determining if a load is contaminated with an animal disease may be markedly difficult.
- *Assessing whether the ingredient or raw material was contaminated from the environment*, particularly when soft-topped trailers are used, during transit or by unauthorized persons.
- *Maintaining a receiving log for all receipts* with batch or lot number for traceability purposes, which includes rejected items on receiving records.
- *Developing processes and procedures to prevent contamination during unloading of bulk ingredients*, which includes pest control, housekeeping and other preventive control measures.
- *Inspecting bagged products for integrity of packaging and/or potential contamination including surface contamination.*

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- *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 programs for cleaning to address surface contamination.
 - Developing programs for the disposal of material determined to be contaminated, if determined it cannot be cleaned.
- *Monitoring personnel flow in the receiving area should include the following:*
 - 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.
 - Restricted driver movement and cleaning protocols for personnel when moving from the receiving area to other areas within the feed plant (e.g., foot baths, dedicated footwear, "danish entry," hand washing stations, etc.)

Employees, Visitors and Drivers:

Employees, visitors and drivers arriving to the feed mill from unsecured locations can carry pathogens into the feed mill on their person and through 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/change stations, including stations for hands and boots at entry points.*
- *Instilling a sense of biosecurity awareness in all employees, starting with top management; everyone must vigilantly monitor the activities of visitors, customers, service providers and fellow employees and restrict access to manufacturing areas, particularly for non-employees.*
- *Training employees to recognize and report suspicious individuals or abnormal activities,*

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security breaches, and suspicious ingredients or devices.

- *Establishing a personal hygiene policy* that reduces the likelihood of spreading animal diseases. As an example, employees who own or come in contact with livestock should shower prior to reporting to work and wear clean, laundered clothes and clean, dedicated footwear.
- *Checking-in all visitors and contractors with a designated company representative*; procedures should protect against unwanted visitors and account for all persons during an emergency.
- *Maintaining a record of individuals' names and companies, arrival and departure times, and purposes for the visit*; such activities signal that your company takes its 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 these personnel may represent a potential threat to the spread of animal disease.
- *Prohibiting livestock and livestock trailers on the premises* unless the trailers have been thoroughly cleaned prior to their 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* (i.e., ingredients, intermediate materials or finished products).
- *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.

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- *Ensuring that all employees have adhered to the company personal hygiene policy prior to entering the manufacturing area.*
- *Restricting access to key manufacturing areas to employees only.*

Shipment of Customer Deliveries:

Transporting finished products or ingredients from an unsecure facility can increase the risk for potential contamination and spread of animal diseases. The exposure of finished products to an uncontrolled environment (e.g., contaminated vehicles, storage bins and/or people exposed to animal diseases) 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 and cleaning and/or repairing equipment as needed.*
- *Securing truck trailers, both bag and bulk, once loaded.*
- *In the case of soft-topped 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 soiled.*
 - *Ensuring tarps (or covers) are in good repair, are not torn and are 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; the 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 with a commercial finishing location).*
 - *The disease that may be present at the location [i.e., porcine epidemic diarrhea 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)].*

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- 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 the previously established disease status hierarchy.
- Routing deliveries to avoid contact with any known "infected or controlled areas."
- *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 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; and developing a decision-making process for special biosecurity requests from customers to determine mutually agreeable protocols.
- *Establishing appropriate cleaning procedures for delivery trucks that come in contact with livestock waste 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 the disease risk hierarchy of the livestock production location.
 - Prohibiting drivers from entering a building where animals are housed or pass through.

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- 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 cleaning them when necessary.

- Prohibiting the 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 is separate from the manufacturing areas for appropriate cleaning and washing; and placing clean pallets in a designated area for reuse.

- Prohibiting bulk totes from being reused, or establishing protocols so that they will be thoroughly cleaned and sanitized prior to reuse.

- *Quarantining 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 in 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 biosecurity 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 successful implementation and maintenance of the 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 facility's CGMPs as required by the FDA for the manufacturing of animal foods, described within FSMA ([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,

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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 ([Safe Feed/Safe Food, 2017](#)).

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 of 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.

Biosecure Definition:

Many segments of industry are requesting to source products from facilities that are "biosecure," Since there is no regulatory definition for biosecure, AFIA developed a working definition in 2018 after consultation with its members and pork industry representatives. This working definition is provided for the animal food industry's consideration as firms work with their suppliers on biosecurity, verification activities and to communicate such practices to their customers.

A "biosecure facility" is a facility that has adopted procedures to reduce the risk of pathogenic microbes being transmitted into or contaminating the final animal food product. These procedures may vary depending on the animal food product produced, the disease status of the country or region where the facility is located, and where the facility's ingredients are sourced. A facility should consider appropriate procedures as part of its biosecurity plan, including:

- *Mechanisms for evaluating suppliers for quality, safety and biosecurity, including verification that such programs are followed;*
- *Designing and maintaining facilities to reduce and/or prevent the introduction of pathogenic microbes;*
- *Adequate, routine housekeeping procedures to reduce and/or prevent the introduction of pathogenic microbes;*
- *Standard Operating Procedures (SOPs) for biosecurity considerations in ingredient sourcing, receiving and storage;*
- *Protocols for visitors, employees and drivers to control access to the facility, including maintaining proper hygiene;*
- *Manufacturing practices that are effective/adequate in maintaining the facility's biosecurity objectives; and*
- *Secure transportation of finished goods, including disinfection as appropriate, and the use of sealed containers.*

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

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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 to the intensity and 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, the commitment of its employees, and most importantly, the commitment by a facility's management team to implement and assess 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.

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This guidance document is not intended to provide legal advice from AFIA. You are advised to consult your regulatory or legal advisors in developing specific policies or in responding to specific problems.

Comments and suggestions are welcome. Correspondence should be sent to the **American Feed Industry Association**, 2101 Wilson Blvd., Suite 810, Arlington, VA 22201, afia@afia.org.

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