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# Guidelines for developing a risk-based plan to mitigate virus transmission from imported feed ingredients

## A PILOT CASE FOR PORCINE EPIDEMIC DIARRHEA VIRUS

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## SUMMARY

There is increasing concern regarding the risk of swine disease transmission via feed ingredients, whether imported or domestically produced. This risk may be reduced in the feed ingredient supply chain by identifying and implementing preventive controls (supply chain, sanitation, transportation, and process) at different steps of the chain. The objective of this study was to develop a practical guide to help feed ingredient suppliers and buyers to safely manufacture, package, transport, and use feed ingredients in swine feeding programs. The Food Safety Modernization Act (FSMA) provides the basis of this study because these regulations require proactive risk-based preventive control processes that are applied in the food supply chain to prevent or reduce the risk of hazards from being present in the final product. Using this conceptual framework, implementation of preventive controls in the feed production chain can control or decrease the potential introduction of foreign animal viruses through feed ingredients into the U.S. A decision tree was developed as a first step in identifying preventive controls and potential high-risk feed ingredient sourcing scenarios. A case-study using Porcine Epidemic Diarrhea virus (PEDV) and the corresponding decision tree was developed as an illustration on how to use this new approach. Although this approach is based on swine viral diseases, it can serve as a template for other pathogenic viruses and species.

## GLOSARY OF TERMS AND DEFINITIONS

**Critical Limit:** Maximum and/or minimum process parameter values (e.g. temperature) of a process preventive control to prevent, eliminate, or reduce to an acceptable level the occurrence of a virus

**Endemic:** Constant presence and/or usual prevalence of a disease or infectious agent in an animal population within a geographic area

**FSMA:** Food Safety Modernization Act

**HARPC:** Hazard Analysis and Risk-based Preventive Controls

**HACCP:** Hazard Analysis and Critical Control Points

**Minimum Infectious Dose (MID):** Lowest virus concentration that can cause infection in at least one pig in a group

**Origin Facility:** First facility or farm in a supply chain that grows, manufactures, or processes an ingredient or raw material for distribution to receiving facilities

**Preventive Controls:** Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal feed would employ to significantly minimize or prevent the hazards identified under the hazard analysis, that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis

**Process Preventive Controls:** Procedures, practices, and processes to ensure the control of parameters during operations such as thermal processing, acidification, irradiation, and refrigeration of ingredients to control the virus identified in the hazard analysis

**Receiving Facility:** Facility that receives a raw material or ingredient from a supplier for further manufacturing and processing in the U.S. or feeding to animals

**Risk mitigation:** Procedures, practices, and processes that when implemented, decrease the survival of viruses in feed and feed ingredients. Risk mitigation differs from preventive controls

because there may not be scientific validation of the procedure, or because implementation varies greatly among facilities

**Sanitation Preventive Controls:** Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate for significantly minimizing or preventing the recontamination of the ingredient or finished product with a pathogen

**Supplier:** Facility or farm that grows, manufactures, or processes an ingredient for distribution to receiving facilities. A supplier may be the origin facility or it may be a facility for further manufacturing, processing, distribution, or warehousing of ingredients.

**Supply Chain Preventive Controls:** Procedures, practices, and processes in the raw material or ingredient distribution chain, involving multiple suppliers and receiving facilities, to prevent virus contamination and re-contamination

**Transportation Preventive Controls:** Procedures, practices, and processes to ensure the sanitary transportation of ingredients or finished products to minimize the risk of recontamination of the product with the virus

**Validation:** Obtaining and evaluating scientific and technical evidence that a process preventive control or combination of them, when properly implemented, is/are capable of effectively preventing virus presence

**Verification:** Application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a process preventive control or combination of them is or has been functioning as intended

## 1. INTRODUCTION

Pork product exports represent 25.5% of total U.S. pork production and provide a significant source of nourishment to other countries that rely on imported U.S. products [1]. A 2015 University of Minnesota report developed for the National Pork Producers Council (NPPC) highlighted the significant trade volume and number of swine feed ingredients (animal-based, plant-based, and other synthetic and naturally occurring feed additives) being imported into the U.S. [2]. This frequent and high-volume trade of ingredients carries an inherent risk for transmission of foreign animal viruses [3]. The most recent example was the introduction of Porcine Epidemic Diarrhea virus (PEDV) to the U.S. in 2012-14, with evidence that feed and feed ingredients can serve as potential routes of transmission. Additional experimental evidence confirmed that the survival of PEDV and other coronaviruses (Transmissible Gastroenteritis Virus and Porcine Delta Coronavirus) in multiple feed ingredients [4]. The risk of foreign animal viruses entering and spreading within the U.S. via feed increases with factors such as: 1) sourcing ingredients from countries or geographic areas known to be endemic or with history of previous outbreaks, 2) the likelihood of virus introduction into the feed ingredient supply chain, 3) the ability of viruses to survive in the ingredients for extended periods of time, and 4) the quantity of the ingredients imported or transported.

The Food Safety Modernization Act (FSMA) aims to ensure that the U.S. food supply is safe by shifting the focus of FDA regulation of human and animal food safety from responding to contamination to preventing it [5]. To do this, the agriculture industry and producers must identify preventive controls to avoid reasonable or foreseeable food safety hazards being introduced or present in the food supply chain (human or animal food) either from a domestic or an international source. The FSMA obligates human and animal food producers (FDA-regulated products) to use a Hazard Analysis and Risk-Based Preventive Controls (HARPC) system. The HARPC system is broader in scope than the traditional Hazard Analysis and Critical Control Points (HACCP) system. The HARPC system not only focuses on process preventive controls (like critical control points in a HACCP system), but it also includes other preventive controls such as supply chain preventive

controls, allergen preventive controls, and sanitation preventive controls. Furthermore, the FSMA rule to "Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" (Animal Food PC Rule), outlines how to develop a HARPC plan for food animal producers. The plan is focused on preventing physical, chemical, and biological food safety hazards. However, the Animal Food PC Rule does not specifically require consideration of viral contamination in feed. Regardless, most of the FSMA principles and preventive controls can be effectively applied to control and prevent viral contamination in feed ingredients. This document provides guidelines to develop and implement a generic risk-based preventive control plan in the animal feed supply chain focused on preventing foreign viruses from being introduced into the U.S. via imported feed ingredients. These guidelines can also be used for domestic sourcing and transportation of animals during disease outbreaks. A pilot case for PEDV risk-based preventive control was used to provide an example of the application of the current methodology. However, this methodology is also applicable to any foreign animal disease (FAD) using specific data and supply chain information for any virus of concern.

## 2. RISK-BASED PREVENTIVE CONTROL PLAN FOR VIRUSES IN FEED

### Hazard identification

The Swine Health Information Center (Ames, IA) has created a list of endemic and foreign swine diseases that are a high priority for preventing entry into the U.S. These high priority FAD were classified based on 1) likelihood of entry, 2) economic impact on pork production, and 3) impact on access to domestic and international markets. The outcome of this disease priority matrix ranks Food and Mouth Disease Virus (FMDV), African Swine Fever Virus (ASFV), and Classical Swine Fever Virus (CSFV) as the three most important viruses (Table 1). These three viruses have been demonstrated to survive in multiple feed ingredients for a period of 37 days at a temperature of about 10°C and relative humidity of about 70%.

**Table 1.** Virus of interest to the U.S. swine industry for hazards analysis and risk mitigation

| Virus | Family | Genome, sense | Enveloped | Impact[1] | Survival[2] | Heat resistance[3] |
|---|---|---|---|---|---|---|
| FMDV | *Picornaviridae* | ssRNA, + | No | 9.0 | 12/14 | $D_{50}$ = 732-1,275 s<br>$D_{80}$ = 2 - 6 s |
| ASFV | *Asfaviridae* | dsDNA, + | Yes | 8.3 | 10/14 | N/A |
| CSFV | *Flaviviridae* | ssRNA, + | Yes | 7.7 | 0/14 | N/A |
| PEDV | *Alphacoronaviridae* | ssRNA, + | Yes | 5.7 | 5/7 | $D_{25}$ = 0.7 – 4.9 |

[1]Ranked from 1-9 with 9 representing the highest rank (https://www.swinehealth.org/swine-disease-matrix/).
[2]Demonstrated survival in various feed ingredients and severity when known[6].
[3]Data from [7] and [8], [9]. D value is the time at certain temperature to reduce 90% the virus concentration.

During active outbreaks of African Swine Fever in Eastern Europe, various samples of complete feed on farms were found to test PCR positive for the virus [10]. Similarly, in the recent ASFV outbreak in China, feed mills near active outbreaks were been found to be positive for this virus, which poses a risk for disease transmission [11].

Although, the U.S. pork industry is currently focusing on the risk of foreign virus transmission, pathogenic bacteria transmission via complete feed and feed ingredients is also a hazard to the health of pigs (https://www.swinehealth.org/swine-bacterial-disease-matrix/). While the focus of this document is on foreign viruses, multiple steps described for virus mitigation strategies may also be useful for bacterial pathogen risk mitigation.

## Risk mitigation and preventive controls

A risk-based preventive control plan for viruses in feed, including foreign animal viruses, should include *Process Preventive Controls, Supply Chain Preventive Controls, Sanitation Preventive Controls, and Sanitary Transportation Preventive Controls*

### 2.1 Process Preventive Controls

Process preventive controls include procedures, practices, and processes during ingredient manufacturing (thermal processing, acidification, irradiation, and refrigeration) to ensure

inactivation and control of pathogens, including viral pathogens. Process controls must include, as appropriate to the nature of the control and its role in the facility:

i. *Process parameters* known to control, reduce, and/or inactivate pathogens. There are several heating processes (dry and wet) used in the feed industry that may serve as process parameters including, but not limited to, pelleting, extruding, cooking, roasting, toasting, and long-term conditioning. For example, grains can be processed or treated by both dry or wet mechanical, thermal, or thermo-mechanical methods [12]. In addition, a combination of factors such as temperature, moisture, and holding time are important in processes like drying, pelleting, extruding, and other thermal processes [13][14]. Examples of feed ingredient treatment processes can be found in **Appendix 1**.

ii. The maximum or minimum value of the process parameter (e.g. temperature, pH, radiation energy, moisture), also known as the *critical limit*, represent the extent that a process needs to reach to significantly control, reduce, or inactivate the virus. Examples of critical values can be found during spray-drying of porcine plasma where the inlet air temperature reaches about 204±5°C and achieves an air outlet temperature of 79±1.9°C, and a final moisture content of 7.3±0.7% [15]. Rendering provides another example where the minimum product temperature needs to reach 115°C to ensure adequate inactivation of pathogens [16].

iii. Records of data showing that values within the critical limits have been achieved must be maintained to show that the process control is working as intended, and must provide the capability of detecting any failure immediately after its occurrence.

For each viral pathogen and process preventive control, the critical values for the process parameters should be identified and then shown to be achieved within the facility to verify the ingredient or finished product is free of the active virus. The activity performed to identify the critical values is called *validation*, while the activities performed to ensure that the values are consistently achieved are called *verification*.

*2.1.1 Validation and verification activities*

Any process preventive control identified in the facility requires that the effect of the control measure, or combination of control measures, be scientifically validated to ensure that it controls, reduces, or inactivates the virus in the feed ingredient to an acceptable level [14]. The validation activity must include two steps:

i. *Theoretical validation*: Theoretical validation encompasses activities focused on collecting and evaluating scientific and technical information about the effect of the control measure on the virus inactivation. The level of inactivation required by the control measure to ensure that the virus is completely inactivated depends on the initial virus concentration in the feed ingredient. For example, an ingredient that is contaminated with PEDV with a concentration of $10^3$ viral particles/g, will need at least 3 log reduction ($10^3$ or 99.9%) or more to assure the ingredient is free of the virus (or at least below the detection level). When evaluating the effect of a process preventive control measure on virus inactivation, log reduction is used (1 log equal 90% reduction or $10^1$, 2 log represents a 99% reduction or $10^2$, and 3 log reduction equals to 99.9% or $10^3$). To calculate the virus inactivation achieved during thermal processing, the concentration of the virus must be measured before and after the control measure as a function of temperature and time [16]. Inactivation potential of a process preventive control is determined through an inoculation study designed to apply different inactivation processes to create an inactivation curve. **Figure 1** provides an example of an inactivation curve at certain temperature over time. More information can be found in **Appendix 2**.

ii.

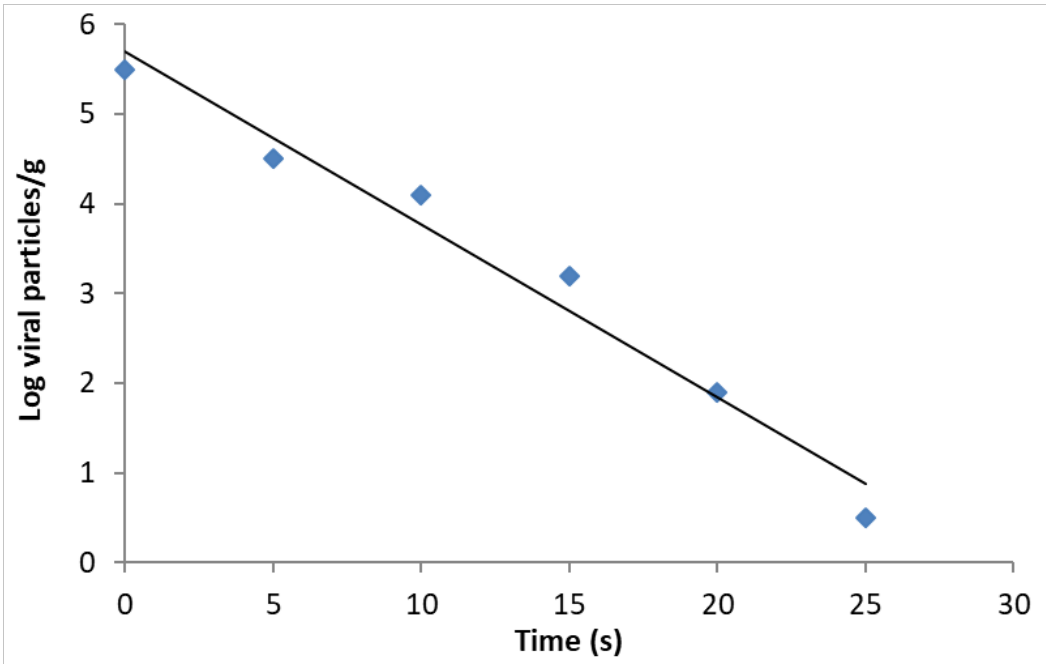



**Figure 1**: Example of a virus inactivation curve at a specific temperature.

An adequate inactivation level based on available studies on viral contamination of feed ingredients would be between a 3 and 5 log reduction ($10^3$ to $10^5$or 99.9% to 99.999%) [17]. However, this would depend on the initial concentration of virus found in the raw material or diet. Currently, there are no known studies that have estimated the concentration of pathogens, including PEDV, in feed ingredients and complete feed in the feed and pork industry.

iii. *In-plant validation*: In-plant validation encompasses activities focused on collecting data on processing parameters (e.g. temperature, pH, moisture) and recording it in the facility to demonstrate that the process at the facility can reproduce the same conditions found in the theoretical validation. The FSMA requires facilities to collect and record process parameter data for a minimum of 90 days [18]. For example, a feed manufacturer will gather time and temperature data during pelleting for 90 production days and use these data as the basis of the in-plant validation [19]. The importance of in-plant validation was highlighted in the study conducted by Maier

and Gardecki (1992). These researchers investigated 88 feed mills in the U.S.A. and found that only 23%of the feed mills had a properly functioning steam system for pelleting that could achieve the correct temperatures. The study also described the importance of equipment maintenance and immediate corrective actions as soon as a problem was identified [20].

Verification activities are performed by monitoring the application of methods, procedures, tests, and other evaluations to determine whether a control measure, or combination of them, are operating as intended [14] [21]. Examples of verification activities may include:

i. Calibration of monitoring and verification instruments (e.g. pH meter, thermocouples)
ii. Finished product testing for the virus (or appropriate indicator organism or surrogate)
iii. Monitoring of process parameters (e.g. temperature, pH)
iv. Review of the verification and/or monitoring records

These validation and verification activities are needed for each process preventive control implemented within the facility. For example, they may be needed not only in production of raw ingredients like soybeans, but also in production of ready-to-use products like pelleted animal feed [22]. **Table 2** provides an example of how a supplier or manufacturer can document a process preventive control within a facility.

**Table 2. Example of a risk mitigation or process preventive control plan**

| (1) Process preventive control | (2) Identify potential viruses and provide justification | (3) Validation | (4) Verification |
|---|---|---|---|
| Rendering | PEDV | *Theoretical*: Scientific study or technical report shows the time-temperature combination achieved in rendering can inactivate PEDV. | Monitoring of time-temperature combination during rendering. |

| | | | |
|---|---|---|---|
| | Ingredients can be contaminated with the virus | *In-plant*: 90 days of processing records showing time-temperature combination of the rendering equipment meets the values identified in the scientific study for viral inactivation. | Calibration of thermocouples within the rendering equipment.<br><br>Monitoring of the moisture of the finished product. |

Source: Adapted from FSMA (2018)

## 2.2. Supply Chain Preventive Controls

Supply-chain preventive controls are implemented to control the risk of viral contamination in feed ingredients destined for receiving facilities. They are applied at the origin facility or supplier in a foreign country, or domestically, and not at the receiving facility or buyer in the U.S. Supply-chain preventive controls are used to either avoid viral contamination of the raw material or ingredient, or to verify the hazard was controlled (e.g. inactivation of the virus) during processing at the supplier [17] [22] [23]. Supply chain preventive controls include controls for raw materials that do not undergo any process preventive controls, and controls to verify appropriate sanitation preventive controls at origin facilities and suppliers, to ensure that viral recontamination does not occur following process preventive controls at origin facilities and suppliers. Examples of supply chain preventive controls may include [22] [23]:

i. Conducting on-site third-party audits or review
ii. Sample raw materials or other ingredients for virus contamination or indicator organism
iii. Review the origin facility's or supplier's Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), and Good Warehousing Practices (GWP)
iv. Review the biosecurity measures (SOP's) of origin facilities and suppliers
v. Review the origin facility and supplier traceability and recall procedures
vi. Perform additional activities depending on the origin facility, supplier, and raw material inherent risk

More examples of supply chain preventive controls can be found in **Appendix 3**. **Table 3** provides an example of the supply chain preventive controls in soybeans.

**Table 3. Example of a Supply Chain Preventive Control Plan**

| (1)<br>Raw material | (2)<br>Supply Chain Preventive Control | (3)<br>Who performs the preventive control? | (4)<br>Verification frequency |
|---|---|---|---|
| Soybeans | GMP audit | Buyer or third-party certified auditor* | Initially before using the ingredient and annually thereafter |
| | GAP audit | Buyer or third-party certified auditor* | Initially before using the ingredient and annually thereafter |
| | Testing for fecal contamination** | Supplier | Sampling plan for generic *E. coli* |

* Third-party or private schemes may include ISO series, Safe Quality Food (SQF), Safe Feed/Safe Food and Global Food Safety Initiative (GFSI). USDA has a "Foreign Animal Disease Preparedness and Response Plan (FAD PReP) Standard Operating Procedures (SOPs)" that can be used in combination.

** Fecal contamination of the irrigation water or raw material may be an indirect measure for potential virus contamination. Additional tests for virus contamination may be carried out especially in endemic countries/geographic areas or with recent history of outbreaks. The Fresh Produce Rule of FSMA has more information on designing a sampling plan for generic *E. coli*.

## 2.3 Sanitation Preventive Controls

Sanitation preventive controls are procedures, practices, and processes (mainly cleaning and disinfection) to ensure a facility is maintained in a sanitary condition to minimize or prevent cross-contamination of viruses. Avoiding viral re-contamination or cross-contamination is critical after achieving process preventive control in a facility. Equipment and personnel can cross-contaminate and re-contaminate the finished product due to poor sanitation protocols, movement of personnel from raw material to finished product areas, and wear contaminated clothing or boots [24]. Several studies have shown that cross-contamination can occur from contaminated boots tracking and

spreading PEDV virus throughout a feed mill (virus was detected on concrete floor surfaces) [25]. Cross-contamination can also occur at feed mills due to the use of contaminated trucks or equipment.

All operations in the facility including processing, packaging, and holding of feed (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles [26]. The U.S. FDA recommends developing and implementing written sanitation procedures to ensure that the area and equipment are cleaned and sanitized in a manner that reduces the risk of contamination and re-contamination. Written sanitation procedures must be established, implemented, and monitored including the frequency with which they are to be performed to ensure cleanliness of facilities and prevent cross-contamination [27]. Examples of sanitation preventive controls are:

i. Physical cleaning
ii. Removal of feedstuff residues and dust
iii. Employee hygiene and livestock ownership
iv. Effective pest management

These sanitation controls have been developed based primarily on eliminating *Salmonella* spp. or other bacterial pathogens with little to no information documenting the elimination of viral contamination from feed production facilities [28][29]. It is recommended that such studies be conducted in the near future.

### 2.4 Sanitary Transportation Preventive Controls

Transportation occurs throughout the supply chain for feed ingredients and finished feeds, and must follow rigorous procedures to ensure the safety of the product by preventing viral contamination or re-contamination. Guidelines for safe transport of food products to avoid viral re-contamination include [30]:

i. Regular sanitation of all transport vehicles and containers
ii. Maintaining cleaning records of transport vehicles and containers

iii. Proper disposal of wastewater potentially contaminated with the virus

iv. Use of sanitized packaging and pallet materials

v. Use of proper loading practices and patterns that minimize crossing 'dirty' and 'clean' areas

vi. Minimize transport of mixed loads that may increase the risk for cross-contamination

vii. Adequate pest control (insects, birds, rodents) and prohibit access to pets (cats and dogs) in transportation units or storage facilities

viii. Adequate product holding to avoid unattended product, delayed holding, shipping of product while in quarantine, and poor rotation and throughput

**Table 4** provides examples of transportation of feed ingredients and relative risk situations for virus cross-contamination.

**Table 4. Transportation Risk Scenarios**

| Transportation type | Condition |
|---|---|
| Regular sanitation of transportation vehicles (truck, rail car, etc.) | Lower risk |
| Use of new or sanitized product containers (bags, bulk sacks, etc.) | Lower risk |
| Use of sealed product containers prior to shipping in impermeable packaging material | Lower risk |
| Shipment has multiple warehousing and delivery routes prior to receiving facility | Higher risk<br>Needs validation that cross-contamination will not occur |
| Shipment mixes batches from different suppliers (e.g. raw and ready to use ingredients) | Higher risk<br>Needs validation that cross-contamination will not occur |
| The ingredient is ready to use and is shipped in an unsealed container (e.g. finished feed shipped in bulk, soybean meal shipped in bulk) | Higher risk<br>Ingredient may be re-contaminated |

Buyers should review written transportation procedures to ensure adequate sanitary transportation conditions and records of monitoring or verification of sanitary transportation activities.

## 3. PORCINE EPIDEMIC DIARRHEA VIRUS (PEDV) AS THE PILOT CASE

Porcine Epidemic Diarrhea Virus (PEDV) was used in this project as the model virus due to the severe economic burden it caused for U.S. pork producers, potential evidence of feed transmission, and availability of data regarding inactivation and survival in feed ingredients. The virus belongs to the *Coronaviridae* family in the genus *Aphacoronavirus*. It has an enveloped, single-stranded, positive-sense RNA genome of ≈28 kb. It does not demonstrate cross-immunity with other porcine enteric coronaviruses such as the virus responsible for transmissible gastroenteritis (TGE) [31][32]. This disease appeared in the U.S. in 2013, and spread across over 25 states resulting in more than 6,500 confirmed cases in one epidemic year [33][13]. The virus causes an acute, highly contagious severe diarrhea and vomiting in pigs, with a high mortality rate in suckling pigs. The prevention and management controls have focused on strict biosecurity measures and early detection. There is no specific treatment for the disease. The PEDV is not zoonotic (does not present a human health risk) nor transmissible to other animal species. Thus, it is not a food safety risk for humans, or a risk to any species other than swine [34][32][13][35].

Transmission of PEDV occurs mainly via the fecal-oral route. Other sources of contamination have been observed such as sow's milk, aerosol droplets from infected pigs, contaminated feed, feed mills, and transport vehicles [31][33][36][37][32][36]. Viral infectious dose is age-dependent with a significantly lower minimum infectious dose (MID) for neonatal pigs compared to weaned pigs. Thomas et al. (2015) found that the MID in 5-day-old pigs was between 0.056 $TCID_{50}$ whereas the MID in 3-week-old pigs was 56 $TCID_{50}$ under study conditions. This suggests that the MID for neonatal pigs was at least 1000-fold less than in weaned pigs [38]. In another study, PEDV in feed containing 56 $TCID_{50}$/g was the minimum infective dose in 10-day-old pigs [39].

Results from studies evaluating PEDV thermal resistance in feed matrices is summarized in **Table 5.** When evaluating the effect of a process control measure on virus inactivation, log reduction is used (1 log equals to 90% reduction or $10^1$, 2 log equals to 99% or $10^2$, and 3 log reduction equals to

99.9% or $10^3$). This information is important to show adequate scientific validation of the control measure against PEDV.

The PEDV can survive for variable periods of time in different matrices depending on the temperature, pH, and relative humidity. **Table 6** shows that the survivability of PEDV ranges from few days to up to 28 days depending on the matrix and storage conditions. The survivability of PEDV has been shown to be similar to ASFV in some ingredients such as conventional and organic soybean meal, soy oil cake, and choline stored at room temperature (20°C) [6]. Therefore, a guide developed for decreasing PEDV transmission via animal feed and ingredients can be used as a model for other viruses. **Table 7** shows the effect of acidification on PEDV survival. The addition of inorganic acids and other additives may reduce the survival of the virus in different feed ingredients.

**Table 5: Inactivation of PEDV after Thermal Processing**

| Matrix | Process Conditions | Detection Method | Initial Concentration | Viral Reduction | Reference |
|---|---|---|---|---|---|
| Porcine Plasma | Lab-scale spray-drying<br>Inlet air T: 166°C<br>Outlet T: 80°C<br>Drying time: <1 s | RT-PCR Sequencing<br><br>Bioassay | $10^{4.2}$ $TCID_{50}$/mL | 4.2 log viral reduction after spray-drying and storage for 7 d at 4°C | Gerber et al., 2014 [40] |
| Porcine Plasma | Lab-scale spray-drying<br>Inlet air T: 200°C<br>Outlet T: 80°C<br>Drying time: <1 s | Microtiter assay procedure in VERO cell monolayers | $10^{4.2}$ $TCID_{50}$/mL<br>$10^{5.1}$ $TCID_{50}$/g | 4.2 log viral reduction after spray-drying and heating in water bath | Pujols and Segalés, 2014 [41] |

| | | | | | |
|---|---|---|---|---|---|
| | Post-Drying (water bath): 70°C for 30 s 80°C for 60 s | | | | |
| Eagle's Minimum Essential Media | Water bath 50°C for 5 to 180 min And, 50-80°C for 30 min | Plaque test | $10^{5.5}$ pfu/mL | 5.5 log viral inactivation 60°C for 30 min 0.4 log viral reduction 50°C for 30 min | Hofmann & Wyler, 1989 [42] |
| Complete Feed | Water bath 120 to 145°C | Virus isolation in VERO cell monolayers | $6.8 \times 10^5$ $TCID_{50}$ mL | D-value (time to reduce 1 log) 145°C=2.7 min D-value 120°C=7.9 min | Verma and Goyal, 2013 [43] |
| Feed with 23.8% of moisture | Oven incubation 120-145°C | Microtiter assay procedure in VERO cell monolayers | 6.8 x $10^3$ $TCID_{50}$/mL | 3.0 log viral reduction after 30 min in each temperature (from 120 to 145°C) | Trudeau et al., 2016 [13] |

*Verma and Goyal (unpublished data).

Table 6: PEDV Survivability During Storage Conditions.

| Matrix | Survivability, days/weeks | Conditions | Source |
|---|---|---|---|
| Eagle's Minimum Essential Media | PEDV lost infectivity when heated | 37°C at pH 9.0 | Hofmann and Wyler, 1989 [42] |
| Slurry | 28 days | 4°C | OIE, 2014 [32] |
| Dry Feed Contaminated with Feces | 7 days | 25°C | OIE, 2014 [32] |
| Wet Feed | 14 days | 25°C | OIE, 2014 [32] |
| Fresh Feces | 7 days | 40 to 70°C in a range of 30% to 70% of humidity | Goyal, 2014 [44] |
| Complete Feed | 28 days | 22°C | Goyal, 2014 [44] |
| Recycled water (truck washes) | RNA of PEDV detected more than 7 weeks, and infectious in bioassay for 1 week | 25°C | Goyal, 2014 [44] |

Table 7: Effect of Acidification on PEDV Survivability

| Matrix | Survivability | Conditions | Source |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Pens/Barns surfaces | N/A | Virkon (potassium peroxymonosulfate) | Jung & Saif, 2015 [45] |
| | | Bleach (Sodium hypochlorite 5.25%) | |
| | | Phenolic compounds 2% sodium hydroxide | |
| | | Formaldehyde and glutaldehyde | |
| | | Sodium carbonate (4% anhydrous or 10% crystalline, with 0.1% detergent) | |
| | | Ionic and non-ionic detergents | |
| | | 1% strong iodophors in phosphoric acid | |
| | | Lipid solvents such as chloroform | |
| Feed treated with aqueous formaldehyde solution 37% and propionic acid (Sal Curb®) | Ct= 35.79, showing a reduction of PEDV, because the Ct value for a negative control was 40.0., and the positive control had a Ct value of 25.15 | Aqueous formaldehyde solution 37% and propionic acid | Dee et al., 2014 [46] |
| Pig Feed and Spray-dried Porcine Plasma | EO and BA resulted in a reduction of quantifiable RNA on d 21 and 42 at a greater rate in feed than in the SDPP matrix ($p$<0.001) | 0.5% Benzoic acid (BA) and/or 0.02% of an essential oil (EO) | Gebhardt et al., 2018 [47] |
| Pig feed | 3 log viral reduction after 21 days at 25°C | 0.2% of KEM-GEST® (blend of organic and inorganic acids), salt and sugar Additives containing phosphoric acid were the most effective at reducing virus concentration | Trudeau et al., 2016 [13] |

| | | | |
|---|---|---|---|
| Eagle's Minimum Essential Media and Vero cells | Stable | Stable in a pH range of 6.5-7.5 at 37°C and pH 5.0-9.0 at 4°C | Hofmann & Wyler, 1999 [42] |

There are some steps in the ingredient manufacturing that can be used as process preventive controls for PEDV (**Table 8).** For example, technical validation studies exist for storage, spray-drying, pelleting, and rendering processes that show substantial PEDV inactivation. Suppliers or manufacturers that use these processes must collect in-plant validation data to show that they can apply and maintain the processing conditions suitable for PEDV inactivation, as well as have adequate verification and monitoring activities (See **Table 1**). For the other processes, the industry should conduct a technical scientific validation study to show that the conditions used are suitable for PEDV inactivation.

**Table 8: Ingredient Manufacturing Steps Used as Process Preventive Controls for PEDV**

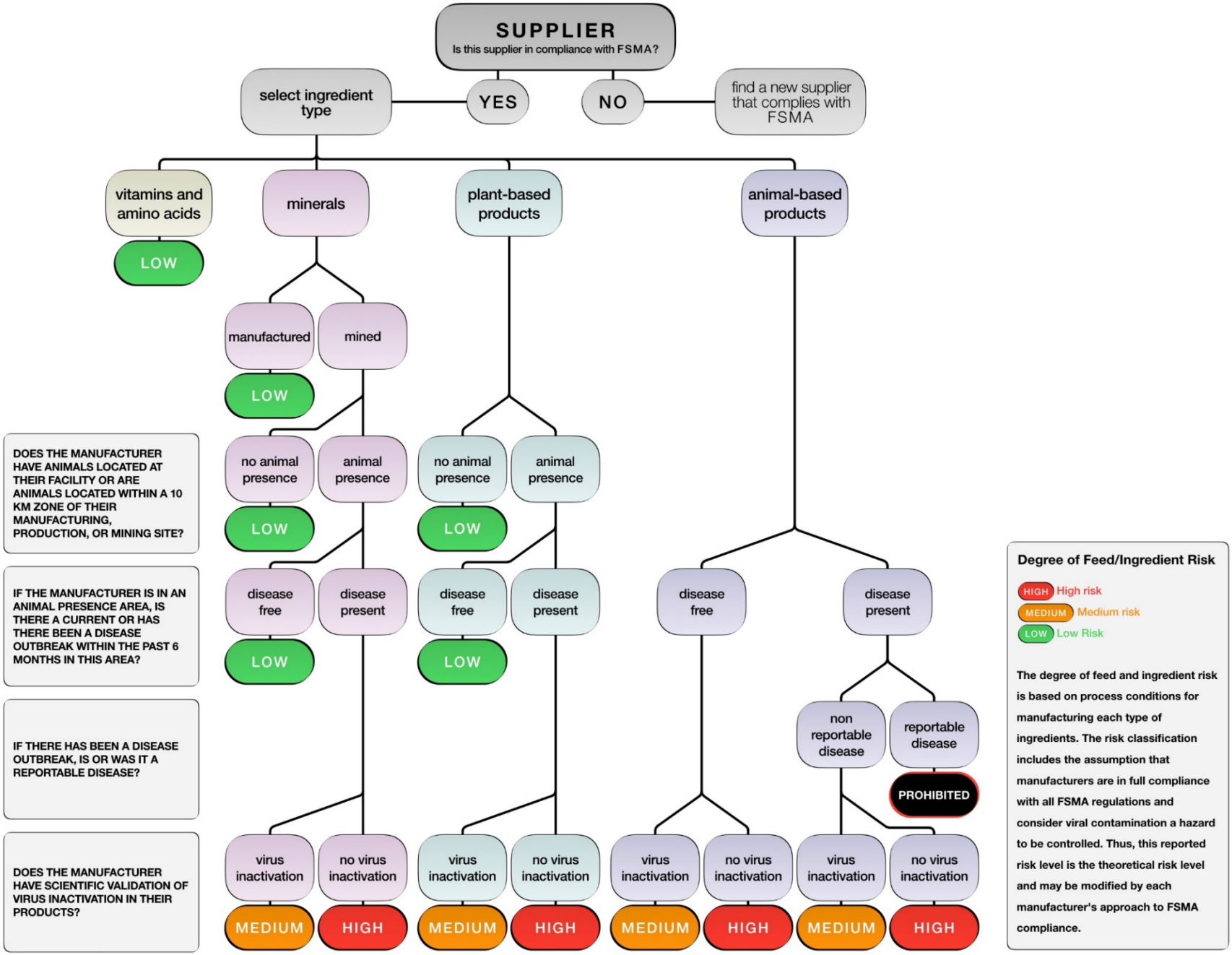
| Type of Process | Range | Scientific Validation of Viral Inactivation |
|---|---|---|
| Pelleting* | 68-95°C for 9-240 s and 14-18% final moisture (Industry source) | 2 log viral reduction in feed at 54°C or higher temperature<br>Cochrane et al., 2017 [48] |
| Extrusion | 80-200°C for 5-10 s and 20-30% final moisture (Industry source) | The time and temperature conditions are likely to reduce virus concentration. A validation study is needed to quantify the virus reduction. |
| Expansion | 90-150°C for 1-4 s and 10-80 bar (Source: Expander Andritz) | The time and temperature conditions are likely to reduce virus concentration. A validation study is needed to quantify the virus reduction. |
| Desolventizing and Toasting | Up to 120°C release temperature for 10-20 minutes (Gurbuz, 2017) [12] | The time and temperature conditions are likely to reduce virus concentration. A validation study is needed to quantify the virus reduction. |
| Storage | Ambient temperature storage | 3-5 log viral reduction in feed at 20°C for 2 weeks<br>Pujols and Segalés, 2014 [41]; Verma & Goyal, 2013 [43] |
| Spray drying | Inlet air T: 150 -200°C, outlet air T: 80°C for 20-90 s (Industry source) | 4.2 log viral reduction at 80°C<br>Gerber et al., 2014 [40] |

| | | |
|---|---|---|
| Rendering | 115–145°C for 40-90 min | 3.7 to 21.9 log viral reduction<br>Sampedro et al., 2015 [16] |
| Steam Flaking | 15°C incoming temperature at 14% moisture increasing to 100°C<br>(CPM Roskamp champion, 1999) | The time and temperature conditions are likely to reduce virus concentration. A validation study is needed to quantify the virus reduction. |
| Irradiation | Gamma rays, X-rays and electron beams are the permitted by FDA.<br>15 kGy per side (betaGRO, 2014) | 3 and 5 log reduction after 50 and 86.25 kGy, respectively<br>Trudeau et al.,2016 [13] |

*Pelleting may serve as a risk mitigation procedure, but it is not validated as a risk preventive control.

## 4. DECISION TREE FOR ASSISTING IN SELECTION OF LOW-RISK FEED INGREDIENTS

Decision trees are common decision-making tools used by regulatory bodies and industry for conducting a rapid assessment of a specific situation or risk by ranking the different combinations of foods/feeds and hazards. A decision tree incorporating viral contamination as a hazard is typically not recognized in current FSMA food safety planning and sanitary transportation decision making, but was developed as a method to select low risk feed ingredients. Each node of the decision tree denotes a type of ingredient, each branch within the node represents different ways those feed ingredients may reach animal producers, and each leaf node (terminal node) represents the relative risk that this type of feed ingredient poses to animal health from viral contamination (**Figure 2**). The decision tree is generic enough that it can be used for any viral contamination situation whether from imported or domestically produced feed ingredients.


SUPPLIER
Is this supplier in compliance with FSMA?
select ingredient type
YES
NO
find a new supplier that complies with FSMA
vitamins and amino acids
minerals
plant-based products
animal-based products
LOW
manufactured
mined
LOW
DOES THE MANUFACTURER HAVE ANIMALS LOCATED AT THEIR FACILITY OR ARE ANIMALS LOCATED WITHIN A 10 KM ZONE OF THEIR MANUFACTURING, PRODUCTION, OR MINING SITE?
no animal presence
animal presence
no animal presence
animal presence
LOW
LOW
IF THE MANUFACTURER IS IN AN ANIMAL PRESENCE AREA, IS THERE A CURRENT OR HAS THERE BEEN A DISEASE OUTBREAK WITHIN THE PAST 6 MONTHS IN THIS AREA?
disease free
disease present
disease free
disease present
disease free
disease present
LOW
LOW
IF THERE HAS BEEN A DISEASE OUTBREAK, IS OR WAS IT A REPORTABLE DISEASE?
non reportable disease
reportable disease
PROHIBITED
DOES THE MANUFACTURER HAVE SCIENTIFIC VALIDATION OF VIRUS INACTIVATION IN THEIR PRODUCTS?
virus inactivation
no virus inactivation
virus inactivation
no virus inactivation
virus inactivation
no virus inactivation
virus inactivation
no virus inactivation
MEDIUM
HIGH
MEDIUM
HIGH
MEDIUM
HIGH
MEDIUM
HIGH
Degree of Feed/Ingredient Risk
HIGH High risk
MEDIUM Medium risk
LOW Low Risk
The degree of feed and ingredient risk is based on process conditions for manufacturing each type of ingredients. The risk classification includes the assumption that manufacturers are in full compliance with all FSMA regulations and consider viral contamination a hazard to be controlled. Thus, this reported risk level is the theoretical risk level and may be modified by each manufacturer's approach to FSMA compliance.

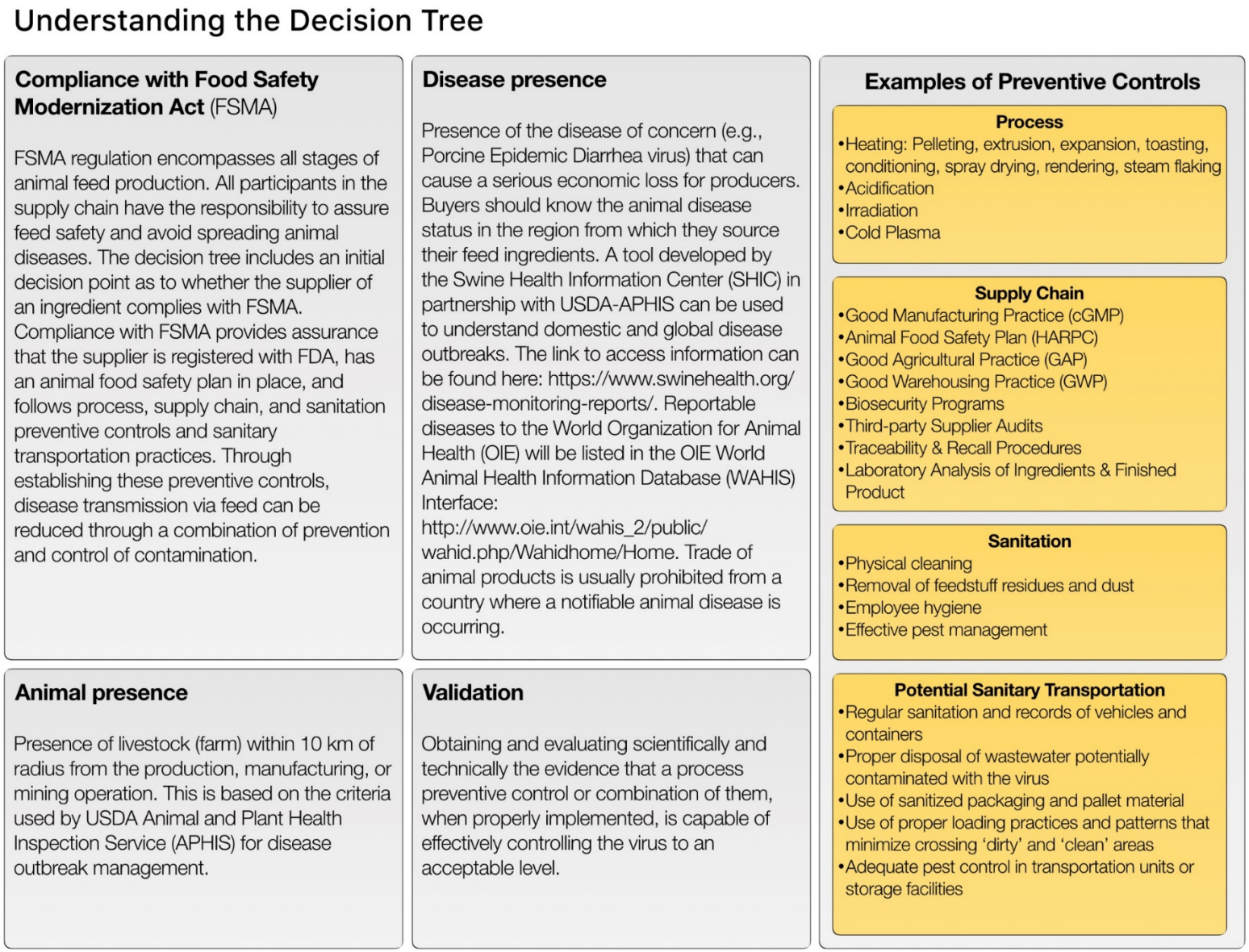



Figure 2. Generic decision tree to identify lower risk feed ingredients

### 4.1 How should the decision tree be used?

The decision tree includes an initial decision point regarding whether the supplier complies with FSMA or not. Compliance with FSMA provides assurance that the supplier is registered with FDA, has an animal food safety plan in place (Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals), and follows sanitary transportation practices (Sanitary Transportation of Human and Animal Food Rule). The FSMA compliance may also be met through Foreign Supplier Verification. In the context of the decision tree, in order to identify feed ingredients at low risk of viral contamination, the buyer should choose a feed ingredient from a supplier in compliance with FSMA to ensure that the supplier has basic process, supply chain, sanitation preventive controls, and sanitary transportation practices in place.

Following selection of supplier status, the decision tree user then selects the type of ingredient to be assessed. In a multi-component ingredient or feed mixture, the user should select the most conservative (higher risk) feed ingredient in the mixture. For example, in a mixture plant-based and animal-based ingredients, the combination should be assessed by the animal-based ingredient node.

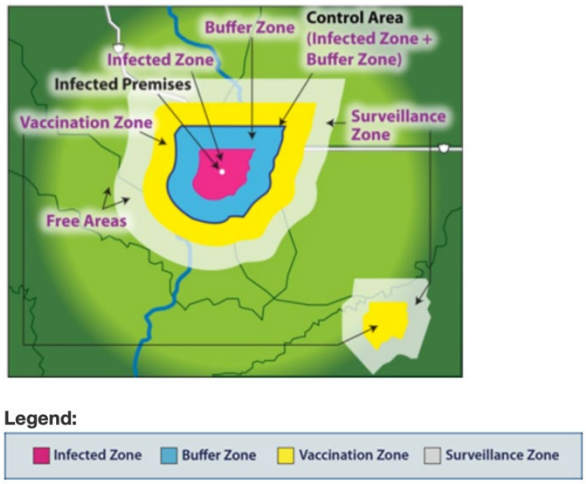
For vitamins and amino acids, the processing conditions of these products inherently contain process preventive controls that make viral contamination and survival unlikely. Therefore, when this type of ingredient is sourced from a supplier that is in compliance with FSMA (i.e. following the preventive process, supply chain, sanitation, and sanitary transportation control procedures), it should represent a low risk of viral transmission via feed. However, it is necessary to mention that the risk of post-processing contamination can occur if the sanitation and sanitary transportation (part of FSMA regulation) preventive controls are not followed or they fail. For example, if we consider a situation where fecal contamination (within certain limits) is monitored in a ready-to–use ingredient as a potential source for viruses, the presence of virus in the final product is certainly foreseeable to be a post-processing contamination (failure in the application of sanitation or sanitary

transport preventive controls) failure and not a failure in the processing stage involving the process of vitamin and amino acid production.

Although many manufactured minerals are may be considered to be similar to vitamins and amino acids, many minerals are mined from the earth. In this case, the presence of animals near the mining location should be assessed. The presence of animals near mining operations increases the likelihood of viral contamination of the mineral through fecal contamination of soil and/or irrigation water in the area.

If no animals are present in a 10 km zone surrounding the mining location, the mineral sourced from a supplier in FSMA compliance should present a low risk of viral transmission via feed. The 10 km zone was selected based on USDA-APHIS recommendations for an outbreak scenario where the smallest infected zone (3 km ) and buffer zone (7 km beyond the infected zone) yield a recommended 10 km control zone (**Figure 3** [49]).

**Figure 3. Disease control area and zone boundaries in an outbreak situation**




Source: USDA-APHIS [49]

If animals are present within the 10 km control zone surrounding the mine, then the presence of animal disease in the area should be assessed. If viral disease is not present in the area, then the mineral sourced from a supplier in FSMA compliance should present a low risk of viral transmission

via feed. However, if disease is present in the area, then additional precautions need to be taken. In the case of viral pathogens, the mineral ingredient would need to undergo a process preventive control that is scientifically validated to inactivate the virus of concern. If the origin of the mineral is not known, scientific validation of viral inactivation should also be considered. In both of these cases, when viral inactivation is scientifically validated, the mineral sourced from a supplier in FSMA compliance would present a medium risk of viral transmission via feed. If scientific validation of viral reduction or inactivation is not available, then mineral sourced from an area where animal disease is present or from an unknown origin would present a high risk of viral transmission via feed. Under these circumstances, alternate suppliers should be considered.

When ingredients are sourced from areas where animals are present, especially in areas with animal disease presence, emphasis should be placed on the scientific validation of process preventive controls to reduce or inactivate the potential viral pathogen. This requires that a technical study be conducted to demonstrate that the processing conditions (e.g. combination of temperature and time) is capable of substantially inactivating the virus (e.g. a 3 log reduction), showing that the process conditions can be replicated at the manufacturing plant, and that FSMA compliance controls are in place to prevent re-contamination.

Disease presence can be determined by evaluating current outbreaks or endemic areas for reportable diseases to the World Organization for Animal Health (OIE). In addition, sources such as the Minnesota Board of Animal Health and Swine Health Information Center (SHIC) may be referenced to understand the presence of non-reportable diseases to OIE, which may be reportable diseases to USDA.

Plant-based feed ingredients are those that are derived from plants ranging from being minimally processed to highly purified plant-based compounds. These types of feed ingredients may be similarly assessed based on the presence of animals followed by the presence of a disease.

Animal-based feed ingredients present a higher risk profile for viruses due to their animal origin. The key risk factor in animal-based products is the presence of virus and demonstrated scientific validation of viral inactivation. In addition, if animal-based products originate from an area with a reportable disease outbreak, importation and use of these ingredients may be banned through domestic and international trade regulations. Any animal-based product that has not undergone scientific validation for virus inactivation should be considered at high risk for viral transmission and alternate suppliers should be identified.

Finally, biosecurity measures at the feed mills and animal production units receiving the feed should be applied. An updated biosecurity manual and "Options" for Handling Imported Feed Ingredients are both available from the American Feed Industry Association (AFIA). Furthermore, and a check-list from Kansas State University (**Appendix 4)** is available to help maintain biosecurity at feed mills and animal production sites to prevent viral re-contamination or cross-contamination before providing feed to pigs on farms. These documents provide suggested actions that can be taken by facilities or buyers that are in line with FSMA rules.

## 5. CONCLUSION

This report is intended to provide suggested guidelines and a decision tree to minimize the potential transmission of animal viruses in feed ingredients imported into the U.S. The decision tree was based upon current FSMA animal feed regulations requiring preventive controls for foreseeable hazards and a case study with PEDV. The case study examples showed that the virus can be inactivated by several manufacturing processes, and when combined with supply chain sanitation preventive controls and sanitary transportation practices, risk of viral transmission can be reduced. Therefore, the decision tree may be used as a method for helping buyers import feed and feed ingredients with a negligible risk to pig farms.

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# APPENDICES

## Appendix 1 – Examples of processing methods that may serve as preventive controls:

### Pelleting

Pelleting is a common thermal and mechanical treatment process used in feed mills. During the pelleting process, single ingredients, or combinations of ingredients, are conditioned with steam and pressed through openings in a pelleting die under considerable pressure followed by cutting of the pressed feed forms to the preferred length. Conditioning usually increases the temperature of the feed matrix to about 70°C- 90°C before flowing into the pelleting die. [12]

### Extrusion

Thermoplastic extrusion is considered a high-temperature, short-time process in the food industry. It is a process that is used in the production of a wide variety of food and feed products with little or no modification of the basic equipment and appropriate process control. Operational parameters that are used as important process preventive controls are: temperature, pressure, die diameter, and shear force. Shear force is influenced by the internal design of the extruder, and by its length and the screw geometry and rotation speed. Extrusion results in conditions where feed and food are exposed to high temperatures (up to 200°C) for 1 to 2 minutes with sudden increases to reach the optimal feed and food temperature during the last 15 to 20 seconds. [12] [50]

### Expansion

Extrusion and expansion methods are based on similar principles. Fundamentally, expanders are similar to extruders but vary in the method of forming the final product and force of treatment. [12]

### Desolventizer toaster

A desolventizer toaster (D-T) for soybean treatment has two sections, one for desolventizing and one for toasting and drying. Desolventizing is carried out by steam injection or indirect heating and results in a combination of solvent removal and meal toasting. Meal toasting is

continued on the lower trays of the D-T where meal moisture is reduced by indirect steam heating. After desolventizing, the soybean meal has a temperature of 100°C, and the moisture content is dependent on the amount of residual solvent in the spent flakes, the initial moisture content, and the heating surface in this section. Retention time of the soybean meal in the desolventizing section is about 5 minutes. After thermal exposure, mechanical pressure between two rollers can be used to form flakes, followed by subsequent cooling. This process can be used to treat several types of raw materials, but is most commonly used in edible oil production, where it is used to extract the solvent from the meal after oil extraction. [12] [51]

### Spray drying

Spray-drying consists of the evaporation of water as a function of the difference in the water activity (aw) of the wet particles and the humidity of the inlet air. The particle temperature is increased as it passes for 2 to 5 seconds through the dryer from an inlet air temperature (170 to 310°C) to dryer outlet temperature of about80 to 84°C. Total transit time of processing in spray driers are usually between 20 to 90 seconds. [16]

### Rendering

The rendering process transforms raw materials from the food animal supply chain into a range of animal by-products used across many industries, including animal feed. Rendering processes prevent serious challenges to public, animal, and environmental health that could result from the mismanagement of the potentially infective raw materials. The exit temperature of the rendered material from the thermal processor ranges from 115 to 143 °C, and the minimum time spent by the materials in the cooker stage is 30 minutes, with a possible range from 40 to 90 minutes. [16]

### Steam flaking

Steam flaking is the procedure in which the grain is exposed to steam under conditions of atmospheric or high pressure followed by rolling into thin sheets. Grain reaches about 100°C

and the retention time varies from 30 to 60 minutes during flaking, depending upon type of ingredient and equipment. [12]

### Acidification

Acidification is a process used to reduce the pH of feed, which may result in improved nutrient digestibility and inactivate some pathogens (e.g. *Salmonella* sp. and *Coliforms*) that can cause disease in pigs. Emerging evidence indicates that acidification may be helpful in inactivating some viruses in feed ingredients.[52]

### Irradiation

Irradiation is a process in which food or feed are exposed to ionizing radiation. The main use of this technology is in the food industry, to extend the shelf-life of products (mainly ground meat, chicken, fruits and vegetables, and spices), control insect infestation in stored products, and kill (or reduce the number of) pathogens that might be present in food products. [16]

## Appendix 2 – Theoretical Validation Process for Viral Inactivation

To determine the inactivation of a virus in a thermally-treated product, the D-value (time at a certain temperature to reduce 90% or 1 log the initial concentration of the virus) and z-value (temperature rise to reduce 90% or 1 log the D-value) of the virus must be known. It is important to note that D-values are temperature and matrix specific [11] [9]. If no studies have been conducted to determine the effect of the process control on the virus inactivation, a pathogen challenge or inoculation study must be conducted to prove the effectiveness of the process control. In this type of study, the feed ingredient or matrix is inoculated with a known concentration of a virus, control measures (e.g. different combinations of temperature and time) are applied, and the final concentration of active virus is measured. The difference in virus concentration is the reduction obtained with the control measure, and is usually expressed as a percentage of reduction or log reduction (D and z values can also be calculated from this). Surrogate viruses (alternative virus strains that are not virulent) may be used instead of the targeted virus. The important characteristic of the surrogate virus is that it must be equally or more resistant to the process control that the targeted virus itself. Depending on the virus in question, different surrogate viruses can be used. **Figure 4** provides a list of surrogate viruses. Other common surrogate viruses of importance to swine may be found at the SHIC Disease Matrix (https://www.swinehealth.org/swine-disease-matrix/).

### Figure 4. List of surrogate viruses

| FAD target virus | Surrogate virus | Viral Family | Genome | Outer membrane | Size |
|---|---|---|---|---|---|
| Foot and Mouth Disease Virus | Seneca Virus A | *Picornaviridae* | ss RNA | Non-Enveloped | 25–30 nm |
| Classical Swine Fever Virus | Bovine Virus Diarrhea Virus | *Flaviviridae* | ss RNA | Enveloped | 40–80 nm |
| Pseudorabies Virus | Bovine Herpesvirus-1 | *Herpesviridae* | ds DNA | Enveloped | 150–200 nm |
| Vesicular Exanthema of Swine Virus | Feline Calicivirus | *Caliciviridae* | ss RNA | Non-Enveloped | 35–40 nm |
| Nipah Virus | Canine Distemper Virus | *Paramyxoviridae* | ss RNA | Enveloped | 150–200 nm |
| Swine Vesicular Disease Virus | Porcine Sapelovirus | *Picornaviridae* | ss RNA | Non-Enveloped | 25–30 nm |
| Vesicular Stomatitis Virus | Not applicable* | *Rhabdoviridae* | ss RNA | Enveloped | 75 nm x 180 nm |
| Porcine Reproductive and Respiratory Syndrome Virus | Not applicable* | *Arteriviridae* | ss RNA | Enveloped | 45–60 nm |
| Porcine Circovirus type 2 | Not applicable* | *Circoviridae* | ss DNA | Non-Enveloped | 10–20 nm |
| African Swine Fever Virus | Not applicable* | *Asfarviridae* | ds DNA | Enveloped | 175–215 nm |
| Influenza A Virus | Not applicable* | *Orthomyxoviridae* | ss RNA | Enveloped | 80–120 |

* = No surrogate virus used. Actual pathogen was used in these cases.

Source: Dee et al. (2018) [6]

## Appendix 3 - Examples of supply chain preventive controls:

### Current Good Manufacturing Practice (cGMP)

During the manufacturing of animal feed and feed ingredients, manufacturers are required by GMP regulations to develop a quality approach to manufacturing that enables minimization or elimination of contamination and errors. The cGMP approach includes record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, and process validation. The cGMP requirements are very general and open-ended to provide manufacturers flexibility in how the requirements are implemented in their production processes and system. Compliance with cGMP has been required in animal feed and feed ingredient production under FSMA since September 2017. [24]

### Animal Food Safety Plan (HARPC)

Most animal food facilities must implement a written food safety plan that identifies hazards and defines preventive controls; supply chain programs; recall plans; and monitoring, corrective actions, verification, and validation to control the hazards. The requirement for the written food safety plan, also known as a Hazard Analysis Risk-based Preventive Control (HARPC) plan has been required for most animal-derived food manufacturers since September 2018. It includes aspects of but is more complete than Hazard Analysis Critical Control Points (HACCP). [22]

### Good Agricultural Practice (GAP)

The GAPs are a set of principles, regulations, and technical recommendations applicable to production, processing, and food transport, addressing human health care and environment protection. These procedures follow the same principles as GMP, but are focused on farm production. [53]

### Good Warehousing Practices (GWP)

The GWP defines storage and transportation of finished food practices and recommendations that will protect food against physical, chemical, and microbial contamination, as well as against deterioration of the food and the container [26].

### Biosecurity Programs

Biosecurity programs can be a part of cGMP whether in the facility or on a farm. Biosecurity measures are essential to prevent contamination of pathogens that can be a threat for animal health and production.

### Third-party Supplier Audits

Third-party audits require that an independent organization reviews the manufacturing process of a product or facility to determine if the final product is produced according to accepted standards of food safety and quality. These audits are made by reviewing written plans and by conducting inspections of the facility. The accredited third-party certification regulation of FSMA provides for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered foreign food facilities), and food produced by such entities, to ensure meeting of applicable FDA requirements. [17]

### Traceability & Recall Procedures

Traceability and recall procedures are an integral part of the FSMA Animal Food Preventive Control rule and must be included in the written food safety plan. Traceability is used to identify the origin of a product in the event of contamination to control further public health consequences. For example, in case of an outbreak caused by FADs, verifying the origin of problem will allow localization of response to the facilities and farms where contaminated feed was delivered. This traceability may be potentially accomplished by many methods including blockchain technology.

### Laboratory Analysis of Ingredients & Finished Product

Laboratory analysis of ingredients and finished products may be used as part of a verification plan, where each facility implements controls and analysis to demonstrate the lack of contamination of their products.

Appendix 4 - Example of Check List for Biosecurity in Feed Mills (Source: Kansas State University)

KANSAS STATE UNIVERSITY

**Swine Feed Mill Biosecurity Audit**

*This audit has no pass/fail score. Instead, the intent is for producers to use this audit as a method of engaging in discussion with feed manufacturers about potential methods that may be employed to maximize feed safety from biological hazards.*

Feed Mill Name and Address: _____ Date: _____

**GENERAL**

- ☐ Distance of nearest pigs: ☐ < ½ mile ☐ ½ to 1 mile ☐ > 1 mile
- ☐ Is the mill in compliance with the Food Safety Modernization Act (FSMA)? ☐ Yes ☐ No
- ☐ Does the mill have any hazards requiring a preventive control? ☐ Yes ☐ No
  - o If Yes, describe: _____
  - o If Yes, are controls properly implemented? ☐ Yes ☐ No
- ☐ Does the facility document employee training on feed safety? ☐ Yes ☐ No
- ☐ Does mill have written biosecurity protocols in place? ☐ Yes ☐ No
  - o If Yes, is it followed? ☐Yes ☐No
- ☐ Does the mill have a biological hazard monitoring program? ☐ Yes ☐ No
  - o If Yes, what? ☐ Enterobacteriaceae ☐ Salmonella ☐ PEDV ☐Other: _____

**INGREDIENTS**

- ☐ Does the facility have forward and backward traceability? ☐ Yes ☐ No
- ☐ Are the vehicles that haul grain used for hauling livestock? ☐ Yes ☐ No
- ☐ How are microingredients added to the ration? ☐ Hand add ☐ Micro table ☐ Other: _____
- ☐ Are porcine-based ingredients used in the mill? ☐ Yes ☐ No
- ☐ What type of fats are utilized in rations in this mill? ☐ Bovine tallow ☐ Choice white grease ☐ Animal/Vegetable Blend ☐ Vegetable Oil ☐ Other: _____
  - o If non-porcine, is there a risk of cross-contamination of fats or oils with swine products? ☐ Yes ☐ No
- ☐ Does the facility utilize ingredients that were manufactured or packaged outside the United States? ☐ Yes ☐ No
  - o If Yes, was the ingredient imported following the FDA Foreign Supplier Verification Program? ☐ Yes ☐ No
  - o If Yes, did the hazard analysis specifically address swine viruses known to survive in feed ingredients, such as foot and mouth disease virus, classical swine fever virus, African swine fever virus, and pseudorabies virus? ☐ Yes ☐ No
  - o Describe mitigation strategies used for ingredients sourced from countries of heightened viral risk to prevent or minimize risk of transmission? _____

Adapted from, with appreciation to, PIC USA, Inc. September 2018

**MILL OPERATIONS**

**Ingredient Receiving**

- Is an ingredient reception protocol visible to inbound drivers? ☐ Yes ☐ No
- Is there an effective method to verify previous loads hauled by bulk containers to limit cross-contamination? ☐Yes ☐ No
- Is there separation of inbound and outbound trucks/equipment? ☐Yes ☐ No
- Who unloads inbound bulk ingredients? ☐ Inbound driver ☐ Mill personnel
- When exiting their truck cabs, do inbound drivers observe biosecurity protocols by putting on disposable booties prior to exiting the tractor cab?
  ☐ Yes ☐ No ☐ Not required
- Is there equipment in place to prevent overflow of the bulk ingredients to areas around the dump grate at the unloading pit? ☐ Yes ☐ No
- If bulk ingredients are allowed to unload on the floor around the inbound grate, how is material on the concrete deck handled?
  ☐ Swept into the unloading pit ☐ Swept up and discarded into dumpster
- Do inbound trucks and trailers drive over an uncovered receiving pit grate before unloading? ☐ Yes ☐ No
- Is there a plan in place that ensures usage of vitamin and trace minerals (VTMs) and other microingredients are used on a last in last out basis?
  ☐ Yes ☐ No

**Manufacturing**

- Does mill allow non-employees in the production area? ☐ Yes ☐No
- Does mill have defined clean/dirty lines to control foot traffic? ☐ Yes ☐ No
- Does mill have separate pathways for incoming ingredients and outgoing completed feed to minimize vehicle traffic crossover? ☐ Yes ☐ No
- Does mill supply boots/coverall to outside visitors while on site? ☐ Yes ☐ No
- Do any mill personnel work routinely with pigs? ☐ Yes ☐ No
- Does mill prepare feed for other pigs? ☐ Yes ☐ No
  - If Yes, are they commercial or multiplication units? ☐ Yes ☐ No
- Does mill prepare feed for other livestock? ☐ Yes ☐ No
  - If Yes, what species? ☐ Beef Cattle ☐ Dairy Cattle ☐ Poultry
    ☐ Sheep/Goat ☐ Fish ☐ Other: _____
- Does mill offer pelleting? ☐ Yes ☐ No
- Does mill have methods to protect the feed from becoming contaminated during manufacturing? ☐ Yes ☐ No
- Is pest control in place and effective? ☐ Yes ☐ No
- Does the mill have a dust collection system? ☐ Yes ☐ No
  - If Yes, how is the dust disposed: _____
- Does the mill effective housekeeping? ☐ Yes ☐ No
- How are feed spills at the mill handled? ☐ Spills removed immediately
  ☐ Spills removed at end of the day
  ☐ Spills removed at end of the week
  ☐ Spills not removed

**Delivery**

- Is feed delivery based on a dynamic biosecurity pyramid? ☐ Yes ☐ No
- Is feed delivered to multiplier pigs before non-multiplier units? ☐Yes ☐ No
- Does the mill have a disease management plan in case of a farm disease break to prevent farm-to-farm disease transmission? ☐Yes ☐ No
  - If Yes, explain: _____
- Does the mill deliver feed to high health risk populations, such as lairage or buying stations? ☐ Yes ☐ No
  - If Yes, explain: _____
- Are deliveries made in dedicated trucks? ☐ Yes ☐ No
- Is feed delivered in trucks used only for hauling feed? ☐ Yes ☐ No
- Do other, non-feed or ingredient-related vehicles, enter the mill? ☐ Yes ☐ No
- Is there an inbound driveway and outbound driveway? ☐ Yes ☐ No
- Are ingredient delivery vehicles (undercarriage/tires) cleaned? ☐ Yes ☐ No
  - If Yes, how?
    Water: ☐ Hot ☐ Cold
    Pressure: ☐ High ☐ Low
    Volume: ☐ High ☐ Low
  - Detergent used: ☐ Yes ☐ No If Yes, what kind: _____
- Are feed delivery trucks (undercarriage/tires) disinfected? ☐ Yes ☐ No
  - If Yes, how often: ☐ At completion of delivery ☐ Between farms ☐ At the end of the day ☐ As needed
- Are inside of feed delivery truck cabs cleaned? ☐ Yes ☐ No
  - If Yes, how? _____
  - If Yes, how often: ☐ Daily ☐ Weekly ☐ Monthly ☐ As needed
- Does cab have floor mats? ☐ Yes ☐ No
  - If Yes, how often are they washed, disinfected and dried?
    ☐ Daily ☐ Weekly ☐ Monthly ☐ As needed
- Does feed truck enter the compound fence of farms? ☐ Yes ☐ No
- Is there a plan in place to control feed spills at the farms? ☐ Yes ☐ No
- How are feed spills at the farm handled?
  ☐ Farm is notified and farm staff picks up ☐ Driver picks up the spill
- Where is the spilled feed disposed? ☐ In a trash ☐ Swept onto ground ☐ Placed back in feed bin ☐ Other: _____
- Is feed from a farm ever returned to the mill? ☐Yes ☐ No
  - If Yes, explain: _____