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Subject: FW: Partial draft of swine virus import pathways analysis
Date: Friday, February 14, 2014 12:00:00 PM
Attachments: [Swine virus pathways entry assessment 2-14.docx](#)

From our friends at APHIS. Risk of importation of PEDV in animal feed components is negligible.
(But, it's still the feed, dammit!)

There was an abstract in today's AVMA update on a new swine virus just found in the US. Tom Burkgren didn't immediately say "it's the feed" so perhaps some perspective has been gained. I'll paste it in:

New porcine virus discovered in Ohio

Fecal samples collected from four Ohio farms carried swine deltacoronavirus, only seen once before and never in the U.S. Clinical signs of the disease are similar to those of porcine epidemic diarrhea virus, but mortality is apparently lower. Samples from three of the farms also were positive for PEDv, with the fourth positive only for the new virus, dubbed SDCV. "The discovery creates a whole new line of research to be done. It also raises questions about how did it get into the United States, as it has not been seen here before," said veterinarian Tom Burkgren, executive director of the American Association of Swine Veterinarians. [Reuters](#) (2/12)

Terry

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Sent: Friday, February 14, 2014 11:40 AM

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Subject: Partial draft of swine virus import pathways analysis

Hi all,

As promised a couple of weeks ago, here is a partial draft of our swine virus pathways entry assessment. As you will see , there are still lots of blank spaces for many of the potential pathway groups we discussed in December. However, we know there is a lot of interest in the feed aspects of this analysis, and this draft contains all of the feed information. We'd like your review of this draft – please let us know if there are pieces of information you think we've missed, or if you have other concerns. We view this as a collaborative process, and need your input into that process.

I'd encourage you to copy your comments to the entire group (sorry, everyone), so we can all see the discussion and/or issues raised. However, if that won't work for whatever reason, please send your comments to Julie Gauthier and myself. If possible, comments back to us by March 7 at the latest would be helpful – but let me know if you think that's too short.

Regards - Lisa

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United States Department of Agriculture

Pathways Assessment: Entry Assessment for Exotic Viral Pathogens of Swine

February 2014

1. Executive Summary

This document was prepared by United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) at the request of the United States Animal Health Association. The purpose of the project was to conduct an entry assessment as the first step towards determining whether significant gaps exist in import regulations that may result in infections of U.S. domestic swine with exotic viral pathogens of swine. The scope of the analysis was set as the risk of entry of any exotic viral pathogen of domestic swine (*Sus scrofa domesticus*) into the United States as a result of any type of import activity.

This analysis includes the first two components of an import risk analysis as defined by the World Organization for Animal Health (OIE), which are a hazard identification and an entry assessment. Further steps of the complete risk analysis will be completed later.

For the purpose of this analysis, we define a hazard as a viral pathogen of swine not known to be present in the United States, or present but not widely distributed and under official control. We excluded viruses that are not associated with clinical illness in infected swine. Viral pathogens of swine that are known to occur in the United States were also excluded from our list of hazards.

We defined pathways based on categories of traffic movement to which animal health import risk mitigations are typically applied. For each entry pathway, we based our likelihood estimation on:

1. the quantity of the commodity imported via the pathway,
2. the likelihood that a hazard is associated with the pathway, considering
 - a. the likelihood that an animal or article carrying a hazard is selected for export
 - b. the likelihood that a hazard survives processing, transport, and other pre-export events,
3. the likelihood that a hazard is not removed by and survives any import mitigation procedures.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients:

- derived from rendered animal proteins, rendered animal fats, and marine by-products is negligible,
- containing milk and milk derivatives is negligible,
- derived from animal manure is negligible,
- derived from plants or plant products is low if the material is unprocessed, and negligible if the material is processed by pelletizing or another process that effectively inactivates hazards,
- derived from microbial culture is negligible, and
- produced by chemical synthesis or mining is negligible.

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5. Abbreviations

APHIS	Animal and Plant Health Inspection Service
ASF	African swine fever
BSE	bovine spongiform encephalopathy
CBP	Customs and Border Protection
CVM	Center for Veterinary Medicine
CFR	<i>Code of Federal Regulations</i>
FDA	Food and Drug Administration
FMD	foot and mouth disease
DNA	deoxyribonucleic acid
HACCP	hazard analysis and critical control points
HTS	harmonized tariff schedule
NAHMS	National Animal Health Monitoring System
NESOI	not elsewhere specified or indicated
NIES	National Import Export Services
NVSL	National Veterinary Services Laboratories
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
PPQ	Plant Protection and Quarantine
PRRS	porcine reproductive and respiratory syndrome
RNA	ribonucleic acid
SRM	specified risk materials
SVD	swine vesicular disease
USDA	United States Department of Agriculture
VS	Veterinary Services

6. Key Terms

Animal: Any member of the taxonomic kingdom Animalia, including humans.

Article: Any inanimate object.

Commodity: An animal or article selected for import.

Contaminated: Describes an article carrying an exotic viral pathogen of swine.

Continental United States: The 48 United States that have common land borders with each other, plus Alaska and the District of Columbia.

Endemic: Known to be present in the continental United States.

Exotic: Not known to be present, or present but not widely distributed and under official control in the continental United States.

Germplasm: Semen, ova, and embryos of livestock.

Hazard: A viral pathogen of swine not known to be present in the United States, or present but not widely distributed and under official control.

Import: Introduction into the United States, regardless of whether legal or illegal, or for commercial or noncommercial purposes. The term “import” includes natural introduction such as through airborne spread or wild bird migration.

Infected: Describes an animal, including an arthropod carrying an exotic viral pathogen of swine.

Livestock: Domesticated equids, ruminants, and swine.

Pathway: A means of entry of a hazard to the United States.

Susceptible: At risk of becoming infected with an exotic viral pathogen of swine.

United States: The United States of America, including the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, and any territories or possessions of the United States.

7. Introduction

This document was prepared by USDA APHIS VS at the request of the United States Animal Health Association. The purpose of the project was to conduct an entry assessment as the first step towards determining whether significant gaps exist in import regulations that may result in infections of U.S. domestic swine with exotic viral pathogens of swine. The scope of the analysis was set as the risk of entry of any exotic viral pathogen of domestic swine (*Sus scrofa domesticus*) into the United States as a result of any type of import activity. The specific objectives of the entry assessment are:

- Identifying and describing the pathways by which exotic viral pathogens of swine may enter the United States.
- Estimating the likelihood that each identified pathway may introduce exotic viral pathogens of swine into the United States.

A complete import animal health risk analysis, according to international standards established by the OIE, includes not only an identification of hazards and an assessment of the hazards' likelihood of entry but also an exposure assessment, a consequence assessment, and an evaluation of risk management options. The ultimate goal of this work is to conduct a complete animal health risk analysis for the purpose of determining whether significant gaps exist in import regulations that may result in infections of U.S. domestic swine with exotic viral pathogens of swine. The following additional objectives are beyond the scope of this project, but they are necessary further steps toward the ultimate goal:

- For pathways with non-negligible likelihood of introducing exotic viral pathogens of swine into the United States, estimate the likelihood that domestic swine in the United States may be exposed to an introduced viral pathogen of swine.
- For pathways with non-negligible likelihood of exposing domestic swine in the United States to an introduced viral pathogen of swine, evaluate the consequences of domestic swine becoming infected.
- For pathways in which the consequences of infection, overall risk of introduction, and overall risk of exposure are non-negligible, identify potential measures to mitigate the risk.

8. Methods

The methods we use in this risk analysis follow the guidelines outlined in the OIE Terrestrial Animal Health Code for import risk analysis [1, 2]. An import risk analysis, as defined by the OIE, includes a hazard identification step, followed by a risk assessment. The components of a risk assessment are entry, exposure, and consequence assessments, followed by risk estimation. This scope of this document includes the first two steps, hazard identification and entry assessment. Further steps of the complete risk analysis will be completed later.

Below, we briefly summarize the methods we used for the analysis presented in this document. Because of data gaps and lack of information about some import pathways, we chose a qualitative approach, rather than attempting a quantitative analysis.

8.1 Animal health data sources

The information evaluated for this analysis includes data gathered from relevant scientific literature and other public sources, and information provided to USDA APHIS VS by other Federal agencies and agricultural industry representatives.

8.2 Hazard identification methods

For the purpose of this analysis, we define a hazard as a viral pathogen of swine not known to be present in the United States, or present but not widely distributed and under official control. We excluded viruses that are not associated with clinical illness in infected swine. Viral pathogens of swine that are known to occur, but are not under official control in the United States, were also excluded from our list of hazards.

8.3 Entry assessment methods

First, we identified and characterized pathways by which a hazard could enter the United States, using peer-reviewed publications and expert opinion gathered from U.S. border control officials and representatives of animal feed, veterinary biologics, and swine industries. Then, for each pathway for hazard entry that we identified, we qualitatively assessed the likelihood that a hazard might enter the United States through that pathway. The quantity of the commodity imported via a pathway is an important factor contributing to the likelihood of hazard entry. In addition, hazard entry requires the presence of the hazard in the country of origin; the presence and survival of the hazard in the pathway; and passage and survival of the hazard through any mitigation procedures, such as inspection or quarantine. Therefore, for each entry pathway, we based our likelihood estimation on:

4. the quantity of the commodity imported via the pathway,
5. the likelihood that a hazard is associated with the pathway, considering
 - a. the likelihood that an animal or article carrying a hazard is selected for export
 - b. the likelihood that a hazard survives processing, transport, and other pre-export events,
6. the likelihood that a hazard is not removed by and survives any import mitigation procedures.

See Figure 1 for a graphic representation of a generic entry pathway for a hazard.

We expressed our likelihood estimates for entry qualitatively, as negligible, low, medium, or high. These categories are intended to indicate relative likelihoods among the pathways. The levels are described in Table 1.

Table 1: Risk assessment estimation terms defined

Term	Definition
Negligible	So rare that it does not merit consideration
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often

8.4 Assumptions and limitations

Ideally, the likelihood that an animal or article carrying a hazard is selected for export would be estimated as part of the assessment. However, due to the broad nature of this entry assessment, it was not feasible to collect information on the current status of all of the viral pathogens considered in all of the countries from which the United States imports all of the relevant animals or articles. It was also not feasible to assess the current regulatory activities in all of these countries regarding all of these viral pathogens.

To substitute for the lack of current information on the status of hazards in various countries and the status of current regulatory activities in these countries for these hazards, a number of assumptions were required for purposes of this assessment:

1. We assume that one or more exotic viral pathogens of swine are present within any country or region that is exporting relevant animals or articles to the United States.
2. We assume that infected animals are selected for slaughter and rendering in the production of any relevant articles that are exported to the United States.

Steps 1 and 2 of Figure 1 are assumed to occur in each pathway.

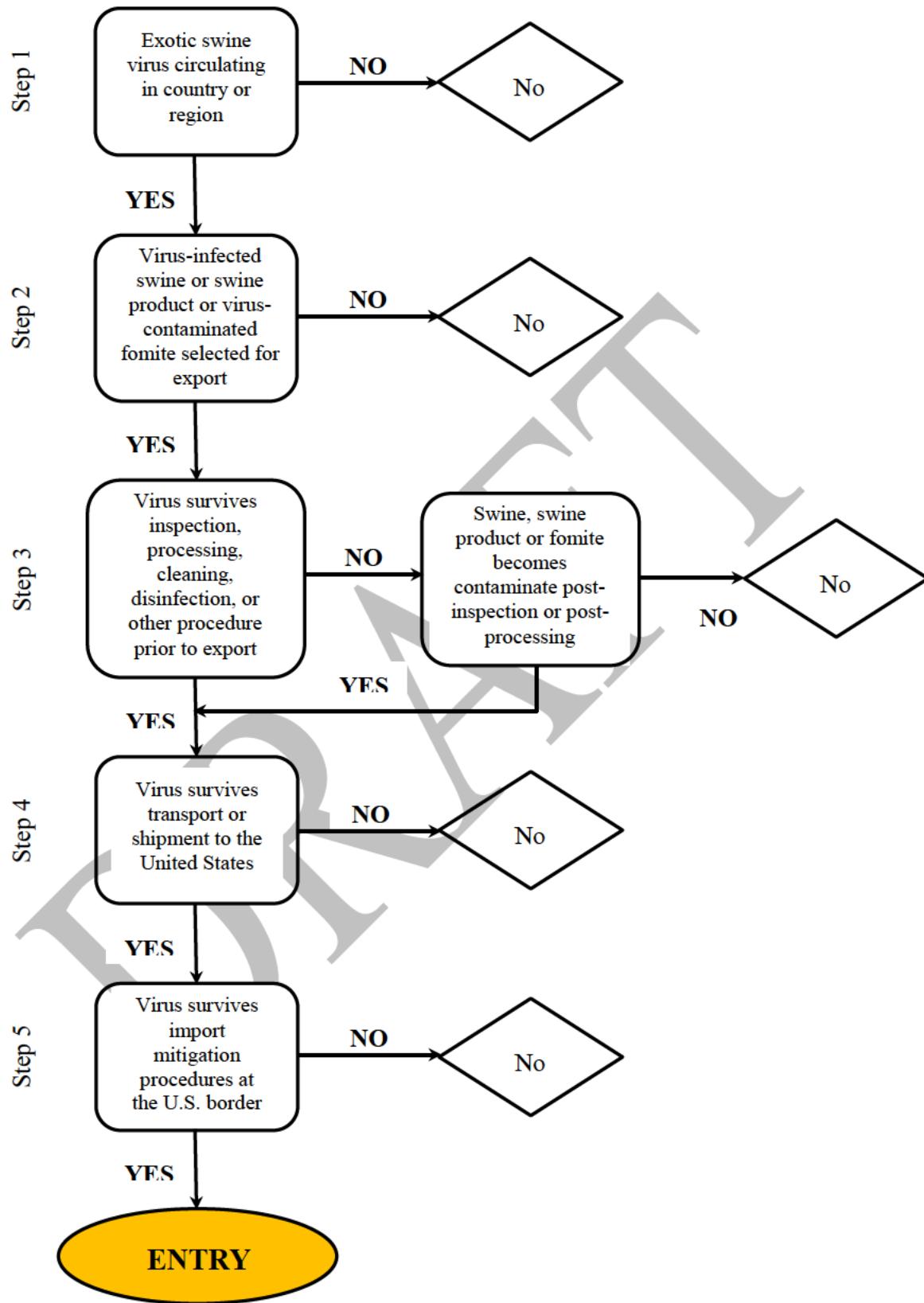
We assume that current regulations and inspection and quarantine procedures designed to mitigate hazard entry are effectively enforced, unless we found information to the contrary in the course of our research.

The risk assessment estimation terms defined in Table 1, and the associated risk estimates presented throughout this document, are by definition based on known occurrences of disease agent entry via the various pathways described. However, the concern prompting the request for this document by the United States Animal Health Association is regarding disease agent entry through unknown pathways that have resulted in disease outbreaks of concern to the swine and pork industries.

This entry assessment provides a comprehensive review of known potential entry pathways, the quantity of items that could potentially carry exotic viral swine pathogens along these pathways, the existing mitigations being applied to these pathways, and the known effectiveness of these mitigations in reducing the entry risk of these pathogens. In order to specifically identify the risks of exotic viral swine pathogens entering the United States via the unknown pathways mentioned above requires detailed

information and epidemiology regarding the index cases of the related outbreaks. This information was not available to the authors of this assessment at the time of writing.

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**Figure 1: Generic entry pathway for viral pathogens of swine**

9. Hazard Identification

A list of virus families and genera, according to their current taxonomic classification by the International Committee on Taxonomy of Viruses, that are known to cause clinical illness in swine is presented in Table 2 [3]. We grouped the virus families by type of genome in the manner described by Baltimore [4], provided a common name for a representative type of virus for each genus, and indicated whether the virus is exotic or endemic to the United States, according to published scientific literature.

In the past few decades, a number of viruses have been discovered in the global swine population, and we expect this trend to continue and cause the list in Table 2 to grow in the future [5]. Some of these emerging viruses, such as porcine reproductive and respiratory syndrome (PRRS) virus and porcine circovirus type 2, cause economically important diseases in pigs. The swine health impact of some newfound viruses, such as hepatitis E virus and porcine sapovirus, is unknown, but they do pose human health concerns due to the potential for transmission from pigs to people. Other emerging viruses, like torque teno sus virus and porcine bocavirus, are thought to infect pigs without causing noticeable signs of illness. Because the scope of this project is limited to viruses that cause illness in swine, we excluded from further consideration those emerging swine viruses that are not known to cause clinical signs of infection in pigs.

Not only do newly discovered viruses make our hazard identification a moving target, but also emerging strains of viral pathogens of swine complicate the scope of this evaluation. For example, since 2006, a serious epidemic of swine illness and death has swept through China and parts of Asia; the outbreak is attributed to a highly pathogenic strain of PRRS virus, which has not yet been found in North America [6]. At any time, strains of influenza virus are circulating in the U.S. swine population, while that population is simultaneously vulnerable to invasion and infection with novel or re-emerging strains of influenza virus [7, 8].

Disregarding exotic strains of endemic viruses or emerging swine viruses thought to have subclinical effects on pigs, we generated a list of hazards, identified by the common names of the pathogens, shown in the first column of Table 3. Along with the names of the hazards, Table 3 shows general structural and environmental survival characteristics of each virus.

Viruses are shed from their hosts into the environment where they have the potential to survive and be transported to another susceptible host by various routes. Numerous physical and chemical factors, mostly importantly temperature, humidity, and virus type, are involved in a viral particle's success at surviving in the environment until it reaches a susceptible host. Generalizations can be made about the survival characteristics of viruses based upon their structural properties. Viruses with genomes consisting of DNA are generally more stable than those with an RNA genome, and viruses which possess a lipoprotein envelope are generally more readily inactivated by disinfectants, heat, and changes in pH than non-enveloped viruses [9-11].

Table 2: Viral pathogens of swine

Baltimore classification group	Virus family	Genera known to affect swine	Common name of virus affecting swine	Exotic or endemic
Group I: Double-stranded DNA viruses	<i>Herpesviridae</i>	Varicellovirus unassigned	pseudorabies virus porcine cytomegalovirus	Exotic ¹ Endemic
	<i>Adenoviridae</i>	Mastadenovirus	swine adenovirus	Endemic
	<i>Asfarviridae</i>	Asfivirus	African swine fever virus	Exotic
	<i>Papillomaviridae</i>	Alphapapillomavirus	swine papillomavirus	Endemic
	<i>Poxviridae</i>	Suipoxvirus	swine pox	Endemic
Group II: Single-stranded DNA viruses	<i>Circoviridae</i>	Circovirus	porcine circovirus	Endemic
	<i>Parvoviridae</i>	Parvovirus	porcine parvovirus	Endemic
Group III: Double-stranded RNA viruses	<i>Reoviridae</i>	Rotavirus	porcine rotavirus	Endemic
Group IV: Positive-sense single-stranded RNA viruses	<i>Arteriviridae</i>	Arterivirus	porcine reproductive and respiratory syndrome virus	Endemic
	<i>Astroviridae</i>	Mamastrovirus	swine astrovirus	Endemic
	<i>Caliciviridae</i>	Sapovirus	porcine sapovirus	Endemic
		Vesivirus	vesicular exanthema of swine virus	Exotic
	<i>Coronaviridae</i>	Alphacoronavirus	porcine epidemic diarrhea virus	Endemic
		Torovirus	porcine torovirus	Endemic
	<i>Picornaviridae</i>	Aphthovirus	foot and mouth disease virus	Exotic
		Cardiovirus	encephalomyocarditis virus	Endemic
		Enterovirus	swine vesicular disease virus	Exotic
		Kobuvirus	porcine kobuvirus	Endemic
		Sapelovirus	porcine sapelovirus	Endemic
		Senecavirus	Seneca valley virus	Endemic
		Teschovirus	porcine teschovirus	Exotic
	<i>Flaviviridae</i>	Pestivirus	classical swine fever	Exotic
		Flavivirus	Japanese encephalitis	Exotic
	<i>Togaviridae</i>	Alphavirus	Getah virus	Exotic
Group V: Negative sense single-stranded RNA viruses	<i>Paramyxoviridae</i>	Henipavirus	Nipah virus	Exotic
		Respirovirus	Sendai virus	Endemic
		Rubulavirus	porcine rubulavirus Menangle virus	Exotic Exotic
	<i>Rhabdoviridae</i>	Vesiculovirus	vesicular stomatitis virus	Exotic
		Lyssavirus	rabies	Endemic
	<i>Orthomyxoviridae</i>	Influenzavirus A	Influenza A virus	Endemic
		Influenzavirus C	Influenza C virus	Endemic

References: [3-5, 12-17]

¹ Pseudorabies virus is not present in the commercial swine population in the United States, and it is subject to an official control program.

Table 3: Structural and resistance to inactivation characteristics of exotic viral pathogens of swine

Exotic viral pathogen of swine	Genome	Enveloped or non-enveloped	Resistance to physicochemical treatments
foot and mouth disease virus	Single-stranded RNA	Non-enveloped	High
porcine teschovirus	Single-stranded RNA	Non-enveloped	High
swine vesicular disease virus	Single-stranded RNA	Non-enveloped	High
vesicular exanthema of swine virus	Single-stranded RNA	Non-enveloped	High
African swine fever virus	Double-stranded DNA	Enveloped	Medium
pseudorabies virus	Double-stranded DNA	Enveloped	Medium
classical swine fever virus	Single-stranded RNA	Enveloped	Low
Getah virus	Single-stranded RNA	Enveloped	Low
Japanese encephalitis virus	Single-stranded RNA	Enveloped	Low
Menangle virus	Single-stranded RNA	Enveloped	Low
Nipah virus	Single-stranded RNA	Enveloped	Low
porcine rubulavirus	Single-stranded RNA	Enveloped	Low
vesicular stomatitis virus	Single-stranded RNA	Enveloped	Low

References: [3, 10]

Because the identity of the hazards is dynamic and the number of hazards is likely to grow, we selected three viruses, foot and mouth disease (FMD) virus, pseudorabies virus, and classical swine fever (CSF) virus, to represent the entire list presented in Table 3. These viruses were chosen to stand in for both single- and double-stranded RNA and DNA viruses and to encompass a range of resistance to inactivation. Also, the properties of the three representative viruses are relatively well-understood and adequate data about inactivation and effective mitigations for these viruses are available. The survival and inactivation characteristics of the three model viruses will be the focus of discussion throughout this analysis. See Table 4 for survival and inactivation data for CSF virus, FMD virus, and pseudorabies virus.

Table 4: Survival and inactivation characteristics of three exotic viral pathogens of swine

Hazard	Heat inactivation	pH inactivation	Pig slurry	Environmental survivability
Classical swine fever virus	65.5° C for 30 minutes or 71° C for one minute	Inactivated in pH <3.0 and >11.0	Survives at 5° C for >6 weeks and 20° C for > 2 weeks; inactivated in 3 minutes at 60° C	Survives in pens in winter up to 4 weeks; survives 3 days at 50° C and 7-15 days at 37° C; survives months in refrigerated meat, years in frozen meat
Foot and mouth disease virus	70° C for 30 minutes	Inactivated in pH <6.0 and >9.0	Survives at 5° C for >14 weeks and 20° C for 14 days; inactivated in 3 minutes at 67° C	Survives in fodder for up to a month; contaminated hay 5 month at 22° C; days to weeks in moist, cool, organic matter; 2 months on wool at 4° C
Pseudorabies virus	60° C for 30 minutes	Inactivated in pH <4.0 and >9.0	Inactivated 3 minutes at 62° C	Survives 7 days in non-chlorinated well water, 3 days in nasal washings on plastic and pelleted hog feed, and 4 days in straw bedding

References: [18-30]

10. Major Pathway Groups

Hazards can move into the United States through any of numerous pathways, including movement of infected live animals or contaminated cargo. Types of movement can be categorized in terms of whether the movement is initiated by people (intentional movement), proceeding through either legal or illegal means, or not initiated by people (accidental movement), such as through airborne spread or rodents stowing away on conveyances. For the purpose of this analysis, stowaways are animals, including arthropods, which are carried by, but are not biologically associated with, a conveyance.

We defined pathways based on categories of traffic movement to which animal health import risk mitigations are typically applied [31]. Table 5 lists the pathways that we considered feasible for transporting hazards, based upon information gathered from public sources, published literature, and expert opinion.

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Table 5: Pathways for entry of exotic viral pathogens of swine**Pathway groups and sub-categories**

Airborne
Entry of inanimate articles that may serve as fomites
Animal tissues or fluids and their products
Animal manure
Animal tissue extracts not intended for feed, food, or pharmaceuticals
Animal blood and blood products
Bones and teeth
Diagnostic samples
Hides, hair, and bristles
Pharmaceuticals containing animal-derived material, including traditional medicines
Transplant tissues
Vaccines or therapeutic serum products
Conveyances and containers for cargo
Equipment
Agricultural
Construction
Military
Veterinary
Food and feed
Animal feed ingredients derived from animals and animal products
Animal feed ingredients derived from raw materials other than animals and animal products
Food for human consumption
Garbage
Entry of live animals that may serve as vectors or fomites
Livestock and their germplasm
Humans
Microorganisms or arthropod vectors
Other live animals

10.1 Airborne**10.2 Articles****10.2.1 Animal tissues or fluids and their products****10.2.1.1 Animal manure****10.2.1.2 Animal tissue extracts not intended for feed, food, or pharmaceuticals****10.2.1.3 Blood and blood products****10.2.1.4 Bones and teeth****10.2.1.5 Diagnostic samples****10.2.1.6 Hides, hair, and bristles****10.2.1.7 Pharmaceuticals containing animal-derived material, including traditional medicines****10.2.1.8 Transplant tissues****10.2.1.9 Trophies****10.2.1.10 Vaccines or therapeutic serum products****10.2.2 Conveyances and containers for cargo****10.2.3 Equipment****10.2.4 Food and feed**

The animal feed industry is a complex industry with numerous companies, manufacturers, and individual producers, both domestic and abroad, contributing to the production, mixing, and distribution of animal feed ingredients and complete feed products [32]. Large-scale, vertically integrated, and high-throughput livestock operations that dominate U.S. agriculture need animal feeds that are specifically formulated to maximize animal growth rates and feed-conversion efficiencies. Animal feeds contain a mixture of plant-based products, proteins and fats from rendered animals as well as a wide range of other ingredients including micronutrients, livestock manure, and pharmaceuticals. The vast diversity of ingredients can affect the biological and chemical composition of the feed as well as determine its quality and safety.

We provide a brief review of the major animal feed ingredients used in the United States and qualitatively describe the likelihood that exotic viral pathogens of swine might be incorporated into feed ingredients and be imported into the United States. Table 6 contains a list of feed ingredients commonly used in U.S. animal feeds.

Table 6: Feed ingredients used in U.S. animal feed

Origin of raw material	Examples
Animal	
Rendered animal protein	Meat meal, meat and bone meal, poultry meal, dried blood products
Rendered animal fats	Tallow, grease, poultry fat
Marine by-products	Fish meal, fish oils
Dairy products	Dried milk, whey
Manure	Cattle manure, pig manure, poultry litter
Plant	
Forage	Hay, haylage, and silage
Grain	Corn, oats, sorghum, and wheat
Plant by-products	Distiller's products, molasses, and soybean meal
Fats, oils, and fatty acids	Vegetable oil, linoleic acid
Flavors	Capsicum and essential oils
Pelletizing aids	Lignin sulfonate
Vitamins	Betaine and Vitamin E
Microbial culture	
Amino acids	L-carnitine, lysine, threonine, and tryptophan
Direct-fed microbials	<i>Bacillus subtilis</i>
Minerals	Selenium yeast
Vitamins	Vitamins B2 and B12
Emulsifiers	Xanthan gum
Preservatives	Organic acids
Mined material	
Anticaking agents	Diatomaceous earth
Colorants	Iron oxide
Minerals	Salt and limestone
Synthetic	
Amino acids	Methionine
Anticaking agents	Calcium stearate and silicon dioxide
Antioxidants	Butylhydroxyanisol (BHA) and dibutylhydroxytoluene (BHT)
Chelating agents	Disodium ethylenediaminetetraacetate (EDTA)
Emulsifiers	Polyethylene glycol and synthetic wax
Flavors	Artificial flavors
Pelleting aids	Mineral oil and petrolatum
Minerals	Chromium, cobalt, and magnesium
Vitamins	Choline, Vitamin A, Vitamin B1

References: [32-34]

10.2.4.1 Animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products

The following section describes the imported quantities, the biological factors for entry, and the import mitigations for animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products. Among the exotic viral pathogens of swine listed in Table 3, several viruses are known to persist in animal tissues, including FMD, swine vesicular disease (SVD), African swine fever (ASF), and CSF viruses [28-30, 35-43]. Other viruses can be incorporated into raw animal by-products during slaughter via body fluids (e.g. feces, urine, and blood) and contaminated fomites (e.g. people and equipment). Viruses that are primarily dependent on vector transmission, such as Getah virus and Japanese encephalitis virus, are unlikely to be transmitted via animal feed ingredients.

Quantity imported

Table 7 provides a broad overview of the quantities and countries of origin of animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products. Commodities that may be diverted into livestock feed (i.e. pet food) are included. We discuss commodities labeled as “edible” and intended for human foods (e.g. edible gelatin) in Section 10.2.4.7. More detailed data about quantities of animal-derived feed imports are provided in Section 12.1.1.

It is difficult to accurately quantify amounts of imported animal-derived feed ingredients for swine feed because international harmonized tariff schedule (HTS) code categories are neither intended nor well suited for that purpose. The HTS code describes the finished product and not its components. Thus, specific subsets of data to identify individual product categories of interest are not available. For example, the HTS code 2301.10.00.00 for flours, meals, and pellets of meat or meat offal, and greaves (cracklings) is used to describe shipments that could contain a variety of imported feed ingredients including meat and bone meal, fishmeal, and/or poultry meal.

The volume of the imported commodity may include feed ingredients for many species, including livestock, poultry, and pets. Some of the categories include animal feed ingredients that are predominately plant-based or contain little, if any, animal origin material.

Table 7: Summary of imported animal-derived feed ingredients (rendered) and countries of origin, (in metric tons)

Commodity	Quantity in metric tons			Countries of Origin ¹
	2010	2011	2012	
Animal feed preparations excluding dog and cat pet food, mixed swine feeds or mixed swine feed ingredients, and animal feeds with milk derivatives	287,099	308,059	308,627	Canada, Nigeria, China, Malaysia, Germany, Mexico
Animal products used for animal feed, NESOI ² ; unfit for human consumption	86,907	87,887	100,502	Canada, New Zealand, China, Australia
Bones and horn cores; powder and waste of products	7,942	10,323	10,138	Canada, Australia, New Zealand, Brazil
Dried blood of animals	0	0	0	---
Edible and inedible fats of ruminants	46,207	49,093	0	Canada ³
Flours, meals, and pellets of meat or meat offal; and greaves (cracklings)	62,801	77,027	70,369	Australia, New Zealand, Canada
Mixed swine feeds or mixed swine feed ingredients	43,891	286,601	275,078	Ireland
Other animal fats and inedible mixtures or preparations of animal fats	8,883	19,807	15,940	Canada, Brazil, Panama, Mexico, China, India, Ecuador
Other animal products (other than semen, embryos, or dried blood) not intended for animal feed, NESOI, unfit for human consumption	3,038	2,780	3,547	Canada, China, Mexico
Pet food, dog and cat	142,003	161,030	183,343	Canada, Thailand, China

Reference: [44]

¹The countries of origin include the countries that export 90% or more of the total volume to the United States for each given commodity. The countries are listed in descending order. Unless otherwise specified, the calculations are based on 2012 trade volumes.

²NESOI means “not elsewhere specified or included”.

³The country of origin calculations are based on 2011 trade volumes.

Biological factors for entry

For the purpose of this assessment, we assume that one or more exotic viral pathogens of swine are present within any exporting country or region and that infected animals are selected for slaughter and rendering, although data are not available that would allow us to estimate the number or frequency.

Slaughterhouse by-products and animals that are deemed to be inedible for human consumption are converted into animal feed products via the rendering process. In general, the rendering process involves the application of heat, the extraction of moisture, and the separation of fat to physically and chemically transform the raw materials into a variety of useful products for industrial and agricultural uses [45, 46]. Rendering systems vary worldwide; they may include wet or dry processes, batch or continuous-flow cooking systems, and may or may not include an initial pressurization step. The basic production steps include:

1. Raw materials are ground to a uniform particle size, typically one inch or less.
2. Cooking, either in batch or continuous-flow configuration is done with steam at 115° to 145° C for 40 to 90 minutes. Time and temperature depends on the rendering system and the animal origin of the materials.
3. The cooked material is pressed to separate the fat from the cracklings (or crax) which includes protein, minerals, and some residual fat. The separated fat is stored and transported in tanks.
4. The cracklings undergo further processing for moisture removal and grinding. Rendered protein is stored in either feed bin structures or enclosed buildings.

Modern, large-scale renderers are concentrated primarily in North America, the European Union, and major livestock producing countries such as Argentina, Australia, Brazil, Uruguay, and New Zealand [46, 47]. Dry rendering with continuous-flow cooking is the most commonly employed system. The pressurization step is typically limited to hair and feather materials to improve protein digestibility. Heating and grinding processes are automated and monitored via computer technology to ensure that cooking reaches the appropriate time and temperature to kill specific microorganisms.

For swine feed, the major categories of animal-derived feed ingredients include meat meal, meat and bone meal, fish meal, dried blood products, steamed bone meal, and rendered animal fats [46]. To a lesser extent, poultry by-product meal and hydrolyzed feather meal are used, although these feed products are typically returned back into poultry feeds. The majority of these animal-derived ingredients for swine feed are sourced from the rendering industry.

Dried blood products, including spray dried blood, spray dried plasma, and dried blood meal products, are categorized in this section [33]. These products are considered rendered products as they undergo heat treatment processes similar to pasteurization that effectively inactivate viruses. Several studies have confirmed that viral pathogens of swine, including SVD virus, PRRS virus, pseudorabies virus, and porcine circovirus type 2, are effectively inactivated by spray drying treatments [46, 48-51].

The three representative viruses are effectively killed by the rendering process (see Table 4). Foot and mouth disease virus is inactivated at a minimum core temperature of 70° C for 30 minutes [18]. Pseudorabies virus is inactivated at 60° C for 30 minutes [22, 24]. Classical swine fever virus is inactivated at 65.5° C for 30 minutes or 71° C for one minute [18]. Typically, the heating step in the rendering process is 115° to 145° C for 40 to 90 minutes; this far exceeds the survival threshold for viruses [9, 46]. Thus, assuming exotic viral pathogens of swine are circulating in the country or region, and infected animals are chosen for slaughter and rendering, the rendering process would effectively inactivate hazards present in the raw materials.

Recontamination of rendered materials with microorganisms can occur within a rendering facility during processing, storage, and transport phases through contact with contaminated machinery, plant

environment, and people [52]. Post-rendering recontamination of animal feed has been documented, particularly for bacterial microorganisms such as *Salmonella* spp. [52-57]. Post-processing recontamination of rendered materials with viruses is plausible, although we could not find documentation that this has occurred.

The rendering industry is an organized, closely regulated industry that has a vested interest in preventing, identifying, and correcting processing errors and problems that might lead to recontamination of rendered products [46, 58]. In addition to government oversight in the regions where they operate, renderers voluntarily abide by industry-accepted standard operating procedures and quality assurance programs that govern raw material sourcing, traceability, product sampling, and pathogen analyses. To avoid microbial contamination of rendered products, current industry standards include programs that employ good manufacturing practices, hazard analysis and critical control points (HACCP) programs, biosecurity plans, Animal Protein Producers Industry (APPI) codes of practice, and third-party certification. However, we are unable to determine the proportion of renderers worldwide that participate in and comply with voluntary quality assurance programs, although FDA may soon require all renderers supplying products for U.S. animal feeds to adopt HACCP programs [59].

Unlike bacterial microorganisms, viruses are obligate intracellular microorganisms and cannot reproduce independently outside their host's cells [9]. Thus, if viral recontamination of rendered materials occurs, propagation of the virus during the post-rendering, storage and transport phases will not occur, due to the absence of living cells.

Virus survival in the post-rendered material will depend upon the physicochemical make-up of the animal-derived material as well as environmental conditions including the moisture content, pH, and temperature. The physical characteristics of rendered materials vary [46, 47]. Similarly, temperature during storage and transport will also vary. Rendered animal protein meal, for example, typically has a moisture content ranging from 4-7% and a pH just below or at neutrality [46]. In a study by Garcia et al., the moisture content of sampled meat and bone meal from North American renderers ranged from 1.9 to 5.7 % (median 3.1%) and the pH ranged from 5.89 to 7.19 (median 6.30) [47]. Typical temperature, moisture, and pH conditions during storage and transport are not conducive to long-term survival of viruses [46, 60]. For example, pseudorabies virus remained infective for no more than five days in experimentally contaminated meat and bone meal maintained at 25° C [9]. Therefore, rendered materials are not regarded as a major vehicle for virus transmission to animals [46, 60].

Similarly, virus survival during shipment until entry into the United States will depend upon the physicochemical conditions of the transport environment as well as the time in which it takes to transport the feed material to the United States. Depending on the country or region of origin, the time for shipment will vary. Product storage times prior to export and modes of transport (i.e. air, land, or sea) will also affect the time from production to arrival at the U.S. ports of entry. Sea or land transportation of bulk or bagged feed shipments is less expensive, but longer, than air transportation. Thus, the typical time for transport is likely in the range of weeks to months rather than hours to days. Virus survival over long transport times in a low moisture environment stored at ambient temperature is unlikely.

Import mitigations

The Food and Drug Administration (FDA) is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act, a part of FDA's responsibility is to ensure that human and animal foods are safe and properly labeled. Within FDA, the Center for Veterinary Medicine (CVM) is

responsible for the regulation of animal drugs, medicated feeds, food additives and feed ingredients, including pet foods. The regulations based, in part, on this law are found in 21 CFR 500.

Due to concerns about bovine spongiform encephalopathy (BSE), APHIS prohibits the import of most rendered protein products from countries listed in 9 CFR 94.18. Import restrictions exist for countries or regions affected with BSE, undue risk for BSE, and minimal-risk for BSE. Rendered ruminant products (including bone meal) from countries affected by or at undue risk for BSE are prohibited from entering the United States. Restrictions for the importation of ruminant meat and bone meal, Specified Risk Materials (SRMs), and tallow from BSE minimal risk regions (Canada) are stated in 9 CFR 94.19 and 9 CFR 95.4. APHIS is in the process of aligning BSE-related import regulations with OIE guidelines by adopting the categories and criteria for classification of the BSE risk status of exporting countries (negligible, controlled, and undetermined BSE risk) and using those categories to determine appropriate import policies [61].

Importation of non-ruminant rendered animal products requires a VS permit. Similarly, regulations allow entry of single species non-ruminant protein, such as fishmeal or spray dried porcine plasma, under VS permit [31]. Additional restrictions on imported animal-derived products are listed in 9 CFR 95.4 and 9 CFR 94.27

The United States does not have a process for authorizing foreign rendering plants. However, regulations and procedures are in place governing the importation of products manufactured by foreign rendering plants. Renderers in foreign countries must meet domestic rendering regulatory standards set by FDA in order to be eligible to export animal-derived feed ingredients to the United States. Foreign rendering establishments must be in compliance with 21 CFR 589.2000 and 589.2001 which prohibit the use of mammalian proteins in feeds for ruminants.

For animal-derived feed products, treatments with heat or chemicals at U.S. border entry points are not required. Several agencies monitor and control the entry of animals and animal products, including processed animal products for animal feed. U.S. Customs and Border Protection (CBP) agents conduct the initial review of declarations and shipping documents. Depending on the country or region of origin, a VS permit or import certificate may be required for entry. If the product contains or may contain animal origin products, CBP refers it to APHIS for review and clearance. Additionally, FDA has issued Import Alert 99-25 to enhance the review of processed animal protein products arriving at U.S. ports from BSE-restricted countries. This alert restricts imports of animal feeds, animal feed ingredients, and other products for animal use consisting or containing ingredients of animal origin. Under this alert, CBP detains such products and can refuse them entry unless the products are the subject of a valid USDA import permit. More information is available at http://www.accessdata.fda.gov/cms_ia/importalert_381.html.

Entry assessment for animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products

The United States imports large quantities of animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products. The exception to this is dried blood products of animals (e.g. spray-dried plasma); no imports to the United States have been recorded for at least a decade. APHIS regulations related to bovine spongiform encephalopathy limit the countries or regions that may export rendered animal feed ingredients to the United States.

The rendering process effectively inactivates viruses. Post-processing recontamination of rendered materials with viral pathogens of swine has not been documented, and standard procedures used in the rendering industry are intended to prevent post-processing contamination. The long transport times and the physicochemical conditions of imported rendered materials are not conducive for long-term virus survival.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products is negligible.

10.2.4.2 Animal feed ingredients derived from milk and milk derivatives

The following section describes the imported quantities, the biological factors for entry, and the import mitigations for animal feed containing milk derivatives. Milk derivatives are processed from ruminant milk, primarily milk from cattle. Dry milk products, including dry milk proteins, dried buttermilk, casein, caseinate, and dried whey and its by-products are commonly incorporated into U.S. animal feed [31, 33].

Drying of milk products is done primarily to decrease the volume and increase the amount of time the product will keep [62]. A number of processes are used to remove water from fluid milk and create dried milk. These include spray-drying (the most commonly utilized drying technique), freeze drying, drum or roller drying, and foam drying [62]. Specific techniques and processing steps vary based on a number of factors such as the desired characteristics of the final product, end use of the product, volume to be processed, and individual operator.

Among the exotic swine viruses listed in Table 3, FMD, pseudorabies, Japanese encephalitis, and vesicular stomatitis viruses are known to infect ruminants. However, of those, only FMD virus is known to shed and persist in milk. Transmission to susceptible livestock via FMD virus-contaminated milk and milk products is known to occur [28-30, 35-43]. Therefore, this section will focus on the likelihood of entry of FMD virus via animal feed containing milk derivatives.

Quantity imported

The countries of origin and quantities of imported animal feeds that contain milk derivatives are presented in Table 8. Other milk or milk products (e.g. cultured milk products, fresh milk products and

canned or shelf-stable milk products) that are intended for human consumption are discussed in Section 10.2.4.7.

Table 8: Animal feeds containing milk or milk derivatives (in metric tons)

Country	2010	2011	2012 ¹
Spain	0	46	42
France	51	14	19
United Kingdom	14	15	11
Germany	11	11	2
TOTAL²	75	86	74

Reference: [44]

Harmonized trade code: 2309.90.24.10, 2309.90.28.10, 2309.90.28.90, 2309.90.42.90, 2309.90.48.90

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Biological factors for entry

Certain steps in the processing of dried milk products are necessary for the creation of the desired product. The majority of dried products will undergo multiple heat treatments as part of the drying process. These include the pasteurization or heat treatment step, an evaporation step, and the drying itself. Although not required, it is important to note that pasteurization of at least 72° C for 15 seconds is usually performed for product quality [62-65]. For spray drying, temperatures in excess of 150° C are often cited; however, it is important to note that due to evaporative cooling, the milk itself reaches a temperature closer to 80-100° C [65-67]. In general, while exceptions exist for certain specialty products, in most cases the temperature of the dried milk product itself will not exceed approximately 100° C during any of these steps.

Low heat processes for concentration of fluid product and for drying exist, including microfiltration processes and foam and freeze drying. These processes are used for a minority of products, but the use of microfiltration is increasing, and it is commonly used as a first step in the manufacture of whey powder [66, 68, 69].

Various acid pH treatments are used in the manufacture of some whey and casein products, but these products can also be made without an acid process. A number of processes are also used to manufacture whey by-products such as lactose and dried lactalbumin [70].

Overall, a wide variety of processes are used to produce dried products. While we can identify the frequently used processes and general trends, we are unable to assume that all products of a certain type must be manufactured the same way, or that all products of a certain type reach a specific temperature or pH during the manufacturing process.

For pasteurization, several studies have been performed on FMD virus inactivation in milk. In the 1970s, a series of studies examined the effects of pasteurization on FMD virus in milk from infected cows [71, 72]. In general, the studies showed that pasteurization of whole milk at 72° C, even with holding times as long as 5 minutes, did not eliminate FMD virus infectivity when inoculated into steers. Tomasula (2004) estimated the inactivation time at 72° C to be 230 minutes [73]. However, a 4-6 log₁₀ reduction

in virus concentration was noted, and virus was frequently undetectable in cell culture (limit of detection was 0.4 pfu/ml). Pasteurization at 80 or 85° C did not eliminate virus infectivity, nor did evaporation to 50% of original volume following pasteurization [71, 72].

Walker (1984) constructed a thermal death time curve for FMD virus in milk using milk from intramammarily infected cows [74]. Using Walker's curve, at 100° C heating times of over 20 minutes are required to inactivate the virus, while 2.5 seconds at 148° C is adequate for inactivation. The inactivation time of 2.5 seconds at 148° C is in agreement with another study on the effects of ultra-high temperature (UHT) pasteurization [75].

The studies discussed above show that pasteurization alone may be insufficient to eliminate all FMDV infectivity. In general, higher temperature and longer time increased viral inactivation. The time and temperature at which the virus is inactivated is 148° C for 3 seconds. Though inactivation was incomplete, all the studies showed that pasteurization decreased FMDV titer substantially, much of the time to a level that was undetectable in cell culture. Most samples showed a reduction of at least $4 \log_{10}$ pfu/ml, which corresponds to inactivation of at least 99.99% of the virus and results in a very low concentration of infectious virus in the pasteurized product.

In addition to pasteurization, dried milk products undergo additional processing treatments as described above. While most products receive multiple heat treatments, none of the individual time/temperature combinations is likely to cause the milk to reach the cited inactivation parameters of 148° C for 3 seconds [74, 75]. In most cases, the temperature reached by the milk product itself during the common drying processes will be near 100° C, with variation depending on the product. Based on Walker's thermal inactivation curve, holding times of more than 20 minutes would be needed to achieve complete virus inactivation at this temperature [74]. Milk particles that are spray dried only will be at this temperature for approximately 1 second. If a two stage process is used, drying times may be up to a few minutes. As discussed above, heating at 72° C for 15 seconds likely causes deactivation of approximately 99.99% of the virus [71, 72, 76]. In summary, each heat treatment applied as part of the drying process can be expected to reduce viral load in the product, but none of the treatment steps will achieve temperatures necessary for complete FMDV inactivation.

In addition to pasteurization and other dry milk processes, the low moisture achieved during the drying process and in the final product is also likely to have a detrimental effect on FMDV. Dried milk products have very low moisture content, usually less than 5% by weight [62, 65]. Donaldson (1973) [77] studied the effect of relative humidity on FMDV survival in aerosolized milk. (Milk for spray drying is essentially aerosolized). After 5 minutes in an aerosolized cloud of milk at ambient temperature (18-23° C) and relative humidity of 30%, less than 0.1% of virus remained viable. The relative humidity of inlet and outlet air during spray drying will vary; however the relative humidity of the outlet air is likely to be in the range of 10% [78]. While the exact impact of drying cannot be determined from this study, the study does indicate that the conditions during the drying processes would decrease virus survival. In fact, the OIE standards for FMDV inactivation in milk for animal consumption include HTST, followed by heating to at least 72° C combined with desiccation [79]. In summary, it is reasonable to conclude that the conditions during the drying process would be detrimental to FMDV survival, but there is no clear evidence that all FMDV infectivity in all dried milk products would be eliminated by the drying process.

Viral recontamination at any stage of production or storage is plausible but has not been documented for animal feed containing milk derivatives. The discussion on recontamination, industry standards, and

virus survival in Section 10.2.4.1 can be applied to animal feed with milk derivatives as well. Although the physicochemical make-up of animal feed containing milk derivatives will vary, the low moisture content of dried milk products (usually < 5%) is not conducive to long-term microbial survival [62, 65].

Similarly, virus survival during shipment until entry into the United States will depend upon the physicochemical conditions of the transport environment as well as the time in which it takes to transport the feed material to the United States. Depending on the country or region of origin, the time for shipment will vary. Product storage times prior to export and modes of transport (i.e. air, land, or sea) will also affect the time from production to arrival at the U.S. ports of entry. Sea or land transportation of bulk or bagged feed shipments is less expensive, but longer, than air transportation. Thus, the typical time for transport is likely in the range of weeks to months rather than hours to days. Virus survival over long transport times in a low moisture environment stored at ambient temperature is unlikely.

Import mitigations

The FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act, a part of FDA's responsibility is to ensure that human and animal foods are safe and properly labeled. Within FDA, the CVM is responsible for the regulation of animal drugs, medicated feeds, food additives and feed ingredients, including pet foods. The regulations based, in part, on this law are found in 21 CFR 500.

Animal feed with milk derivatives may contain animal-based and plant-based components. For the rendered animal-derived components, import mitigations discussed in Section 10.2.4.1 are applied. For import mitigations applied to plant-based components, refer to Section 10.2.4.4 . For the dried milk derivatives, FDA regulations do not require pasteurization of dried milk used in products for animal consumption. However, due to concerns about FMD and rinderpest, APHIS requires an import certificate or a VS permit for animal feeds containing milk or milk derivatives.

Countries or regions listed in 9 CFR 94.1 as free from FMD and rinderpest need an import certificate stating the milk product originated and was processed in a FMD-free and rinderpest-free region [31]. If the product containing dried milk is from a region USDA APHIS considers affected with FMD or rinderpest, a permit is required and one of the following treatments must be applied in the country or region of origin [31, 80]:

- Product heated to 148° C for 3 seconds
- Product heated to 138° C for 5 seconds
- Double HTST (72° C for 15 seconds, twice), or
- Product heated to 72° C for 15 seconds, followed by reduction to a pH less than 6 for 1 hour.

Several agencies monitor and control the entry of animals and animal products, including processed animal products for animal feed. CBP agents conduct the initial review of declarations and shipping documents. Depending on the country or region of origin, a VS permit or import certificate may be required for entry. If the product contains or may contain animal origin products, CBP refers it to APHIS for review and clearance. Additionally, FDA has issued Import Alert 99-25 to enhance the review of processed animal protein products arriving at U.S. ports from BSE-restricted countries. This alert restricts imports of animal feeds, animal feed ingredients, and other products for animal use consisting or containing ingredients of animal origin. Under this alert, CBP detains such products and

can refuse them entry unless the products are the subject of a valid USDA import permit. More information is available at http://www.accessdata.fda.gov/cms_ia/importalert_381.html.

Entry assessment animal feed ingredients containing milk or milk derivatives

The United States imports relatively small amounts of animal feed containing milk or milk derivatives. For 2010-2012, the United States imported animal feed containing milk or milk derivatives from only four countries (Spain, France, United Kingdom, and Germany), all of which are officially recognized by USDA APHIS as free from FMD. For countries or regions affected with FMD, a VS permit is required that states that one of the APHIS-approved treatments has been applied. These treatments are sufficient to inactivate FMD virus.

Post-processing recontamination of animal feed containing milk or milk derivatives with viral pathogens of swine has not been documented. Typical transport times and the physicochemical conditions of dry milk products are not conducive for long-term virus survival.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients containing milk and milk derivatives is negligible.

10.2.4.3 Animal feed ingredients derived from animal manure

Historically, livestock in the United States have been fed material containing animal feces, including poultry litter, pig manure, and cattle manure; however, no data are available to quantify the amount of animal manure that is currently fed to livestock. One expert estimates that in major broiler chicken producing states, 20-25% of poultry litter generated is fed to cattle [81].

Quantity imported

Animal manure is not imported into the United States for the purpose of feeding livestock [82, 83]. Animal manure is bulky and decomposes quickly, making it logically and economically infeasible to store or transport long distances, and therefore the practice of feeding manure to livestock is generally a local activity [81]. For this reason, we assume that illegal importation of manure intended for feeding livestock occurs rarely or not at all.

Biological factors for entry

With the exception of Japanese encephalitis virus which does not persist outside a host, any of the hazards might be found in the excretions of infected animals, and therefore, be present in untreated animal manure and bedding [28-30, 35-43, 84]. Depending upon the temperature and moisture of the environment, hazards might survive for prolonged periods in animal manure. Data on survival times of the three representative viruses in swine feces are presented in Table 9.

Table 9: Survival times of representative viruses in swine feces maintained at various temperatures

Hazard	Time to inactivation in contaminated swine feces			
	5° C	20° C	25° C	35° C
Foot and mouth disease virus	>14 weeks	14 days	No data	24 hours
Classical swine fever virus	>6 weeks	2 weeks	No data	4 hours
Pseudorabies virus	No data	No data	2 days	No data

References: [9, 21, 85]

Import mitigations

Importation of animal manure into the United States for the purpose of feeding livestock is not permitted by USDA APHIS VS NIES [82, 83]. Requests to import manure derived from poultry are reviewed individually by USDA APHIS VS NIES to determine whether and under what conditions the material may be imported safely with regard to protection of animal health. Ruminant manure originating from Canada or from a country that APHIS considers free from bovine spongiform encephalopathy is eligible for entry if the material meets the import conditions and is accompanied by an import permit issued by USDA APHIS VS NIES. Importation of ruminant manure originating from countries, other than Canada, that APHIS considers affected with bovine spongiform encephalopathy is prohibited. Manure derived from swine is eligible for entry into the United States if the material satisfies the import conditions of an accompanying import permit issued by USDA APHIS VS NIES.

Entry assessment for animal feed ingredients derived from animal manure

The hazards are likely to be present in animal manure from affected premises, and infectivity of most of the hazards can persist in the material for hours to weeks, depending on environmental temperature and other factors. However, the United States does not permit the importation of animal manure for the purpose of feeding animals.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients derived from animal manure is negligible.

10.2.4.4 Animal feed ingredients derived from plants and plant products

The following section describes the imported quantities, the biological factors for entry, and the import mitigations for animal feed ingredients derived from plant and plant products. A wide variety of plant-based products are incorporated into animal feed, including grain and grain by-products, oilseed meals and cakes, fruits and fruit by-products, alfalfa products, molasses and sugars, and nutrients chemically extracted from plant-based raw materials [32].

For swine feed, the major feed components are plant-based with corn and soybean meal representing 80 percent or more of the total diet [46]. On a global scale, the United States is a top producer and exporter of corn and soybean. The Heartland region including Iowa, Indiana, Illinois, South Dakota, Nebraska, Kentucky, Ohio, and Missouri produces the majority of corn and soybean in the United States with

approximately 60% of corn and 47% of soybeans used in domestic animal feed [86]. Because of robust domestic production, the vast majority of plant and plant products for animal feed are sourced within the United States.

Quantity imported

Table 10 provides an overview of imported plant and plant products that may be incorporated into animal feed. These commodities are imported for a variety of purposes including human consumption and industrial and agricultural uses. The volume of the imported commodity may include feed ingredients for livestock species other than swine. Thus, these quantities overestimate the volume of imported plant-derived feed ingredients that are used for animal feed, including swine feed.

Table 10: Summary of imported animal feed ingredients derived from plants and plant products and countries of origin, (in metric tons)

Commodity	Quantity in metric tons			Countries of Origin ¹
	2010	2011	2012	
Rutabagas (Swedes), Mangolds, Hay, Alfalfa (Lucerne), Clover, Forage Kale, Lupines And Similar Forage Products, Whether Or Not In The Form Of Pellets	115,604	256,421	357,939	Canada, Mexico
Wheat And Meslin	2,494,598	1,999,076	2,470,950	Canada
Oats	1,579,712	1,609,272	1,609,651	Canada
Corn (Maize)	380,583	640,500	1,805,005	Brazil, Canada, Argentina
Grain Sorghum	312	884	29,996	Argentina
Flours and meals of soybeans	23,691	4,243	20,365	Argentina, Canada, China
Fats, oils, and fatty acids	1,247	1,039	821	Malaysia, United Kingdom, China, Germany, Indonesia, Canada, France, Australia
Flavors	794,627	809,726	929,313	Mexico, Canada
Pelletizing aids	80,907	89,305	105,092	Norway, Canada, Mexico
Vitamin E	20,802	22,936	23,102	China, Switzerland, Germany

Reference: [87]

Harmonized trade code: 1214.00.00.00, 1001.00.00.00, 1004.00.00.00, 1005.00.00.00, 1007.00.00.00, 1208.10.00.00, 0709.60.00.00, 3301.00.00.00, 2916.15.00.00, 3804.00.10.00, 2936.28.00.00

¹The countries of origin include the countries that export 90% or more of the total volume to the United States for each given commodity. The countries are listed in descending order. Unless otherwise specified, the calculations are based on 2012 trade volumes.

Biological factors for entry

Viral pathogens of swine cannot propagate in plant cells [9]. Although plant-derived material does not support propagation of the hazards, theoretically the material could become contaminated with swine viruses if it has contact with infected animals, their excretions, or virus-contaminated fomites. With the exception of Japanese encephalitis virus which does not persist outside a host, any of the hazards in Table 3 might be found in the excretions of infected animals, and therefore, potentially contaminate

plants and plant products that are used for animal feed. [28-30, 35-43, 84]. We found little data regarding the survival of the three representative viruses on plant-derived fomites, which is presented in Table 11. Hazards might survive for prolonged periods on plant material stored in cool environments.

Table 11: Survival times of three hazards in experiments with contaminated plant material

Material	Time to inactivation of hazards in experiments		
	Classical swine fever virus	Foot and mouth disease virus	Pseudorabies virus
Hay	Between 7 -14 days at ambient temperature	Between 14 - 21 days at 16.7° C mean	<1 day at 25° C
		4 weeks in summer, 29 weeks in winter	
Green grass	No data	1 week in summer, 7 weeks in winter	2 days at 25° C
Shelled corn	No data	No data	36 days at 25° C
Straw	No data	Between 28 - 42 days at 16.7° C mean	4 days at 25° C

References: [9, 27, 88, 89]

Historically, sources for FMD outbreaks in Scotland, Japan, and Korea have been attributed to imported hay or straw, although animal feed is not considered one of the most likely vehicles for FMD virus introductions [90, 91]. Once hay and straw were recognized as potential vehicles for spreading FMD virus, countries began to restrict imports of plant-derived imports, including heat treatments intended to inactivate viruses.

Heat, chemical disinfection, and irradiation have been used by feed producers to reduce pathogens in plant-derived animal feed [92]. Pelletizing is probably the feed treatment most commonly used worldwide. Pellet mills apply heat and pressure to pulverized raw materials to produce a finished feed in the form of hard pellets. Raw materials are generally heated to 70-95° C during the pelletizing process; these temperatures inactivate hazards within a few minutes.

Viruses are relatively more resistant to ionizing radiation than most bacterial pathogens, and relatively high doses of radiation are required to destroy viruses contaminating plant-derived foods [92, 93]. For example, porcine circovirus is extremely resistant to gamma irradiation, and a very high dose of 40 kGy is recommended to eliminate FMD virus infectivity.

Post-processing contamination with hazards might occur if a plant-based product is mixed with animal-derived material or handled in a facility where animal-derived material, live animals, or livestock feces are present. The risks associated with commodities containing animal-derived material are discussed in Sections 10.2.4.1 and 10.2.4.2, with live animals in Section 10.3, and with animal manure in Section 10.2.1.1.

Import mitigations

Animal feed derived from pelletized straw, hay, or grass may be imported into the United States without restrictions based on animal health regulations [31]. The importation of straw, hay, or grass intended for

use as animal feed that is not pelletized is also unrestricted based on animal health regulations if the material originates from Canada, New Zealand, or Norway.

Straw, hay, or grass intended for use as animal feed that is not pelletized originating from the Mexican States of Chihuahua and Sonora and the Mexicali region of Baja California is eligible for entry if it is accompanied by a veterinary certificate issued by the Mexican government confirming the Mexican State/Region of origin for the imported materials [31]. Unpelletized straw, hay, or grass originating from other Mexican States may not enter the United States.

Requests to import unpelletized straw, hay, or grass intended for use as animal feed or bedding that originates from countries other than Canada, Mexico, New Zealand, or Norway are reviewed case-by-case by USDA APHIS Plant Protection and Quarantine, Veterinary Regulatory Support to determine whether the material may be allowed entry to the United States.

Importation of animal feed or feed ingredients containing only plant-derived materials (other than straw, hay, or grass) are not subject to U.S. animal health regulations. However, importation of these materials may be restricted by plant protection regulations.

Entry assessment for animal feed ingredients derived from plants or plant products

Hazards might persist for prolonged periods on unprocessed plant-derived animal feed, depending upon environmental conditions. Unprocessed straw or hay was suspected as a vehicle for introducing FMD virus to previously unaffected regions. Pelletizing and other processes applied to plant-derived animal feed can effectively inactivate hazards. Importation of animal feed containing only plant-derived materials (other than straw, hay, or grass) is not subject to animal health related mitigations.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients derived from plants or plant products is low if the material is unprocessed, and negligible if the material is processed by pelletizing or another process that effectively inactivates hazards.

10.2.4.5 Animal feed ingredients produced by microbial culture

Bacteria, fungi, and the products of their metabolic processes commonly supplement animal feed. Culture of whole, live organisms is the goal of large scale biomass production of probiotics, also known as direct-fed microbials, which are added to livestock diets to promote growth and gastrointestinal tract health. Bacteria and fungi are also exploited in industrial processes as catalysts in the biotransformation of many chemical reactions. The metabolic functions of a diverse array of microbes are harnessed to produce a variety of metabolites that are essential for animal nutrition, including amino acids, vitamins, organic acids, and enzymes. Table 12 shows animal feed ingredients derived from microbial culture.

Table 12: Feed ingredients derived from microbial culture

Purpose in feed	Ingredient
Amino acid	L-carnitine, lysine, threonine, tryptophan
Direct-fed microbials	<i>Bacillus</i> spp., <i>Bacteroides</i> spp., <i>Bifidobacterium</i> spp., <i>Enterococcus</i> spp., <i>Lactobacillus</i> spp., <i>Leuconostoc mesenteroides</i> , <i>Pediococcus</i> spp., <i>Propionibacterium</i> spp., <i>Saccharomyces</i> spp.
Emulsifier	Xanthan gum
Enzyme	α -amylase, cellulase, β -glucanase, phytase, zylanase
Mineral	Selenium yeast
Preservative	Organic acids (e.g. acetic acid, lactic acid, propionic acid)
Vitamin	Cyanocobalmin (Vitamin B12), riboflavin (Vitamin B2)

References: [32, 34, 94, 95]

Quantity imported

Substantial quantities of microbial culture products that might be used in animal feed are imported into the United States each year. Available data do not allow us to determine what proportions of the volumes of imported commodities in Table 13 were destined for incorporation into animal feed.

Table 13: Import quantities of selected feed ingredients derived from microbial culture

Commodity	Quantity in metric tons			Countries of Origin ¹
	2010	2011	2012	
Enzymes	74,135	73,672	65,631	China, Denmark, Finland, Mexico, Canada, France
Lysine	59,728	60,978	53,477	Brazil, China, Indonesia
Other amino acids	7,360	7,867	7,414	Japan, France, China
Vitamin B2	1,012	920	889	China, South Korea, Germany
Vitamin B12	328	296	286	China, Canada, Denmark

Reference: [87]

¹The countries of origin include the countries that export 90% or more of the total volume to the United States for each given commodity. The countries are listed in descending order. Unless otherwise specified, the calculations are based on 2012 trade volumes.

Biological factors for entry

The essential amino acids lysine, threonine, and tryptophan, which grain-fed livestock need to meet their nutritional requirements, are produced by microbial fermentation, as are vitamin B12, vitamin B2, and the vitamin-like compound carnitine [95-97]. Other feed additives are also harvested from industrial-scale microbial culture, including enzymes, such as phytase, which help pigs digest grain-based diets more efficiently. In these processes, a specialized strain of a microorganism is cultivated in a growth

medium containing a carbon source (e.g. sugar), a nitrogen source (e.g. ammonium sulfate), minerals, and vitamins. The desired nutrient produced by the microbes is recovered from the medium through either a chromatographic method or a concentration-crystallization method [96]. The latter method is most frequently used to harvest feed-grade nutrients. In the process of recovering the nutrient, the microbial cells, or biomass, are neutralized (killed) and separated from the product.

On the other hand, maintenance of live microbial cells is required for production of direct-fed microbials. Several different methods are used to immobilize, or trap, live microbes in a matrix that keeps them viable in a storable form [98].

Viral pathogens of swine are obligate intracellular parasites. Without living animal cells to serve as hosts, these viruses cannot reproduce [9]. Animal cells are not used in industrial microbial fermentation processes that produce nutrients incorporated in animal feed, and microbial cells are not hosts for viral pathogens of swine [96, 97, 99]. Therefore, industrial microbial cultures do not provide environments where it is possible for the hazards to propagate.

Although microbial cultures do not support propagation of the hazards, these processes could theoretically become contaminated with swine viruses, which plausibly could remain viable in culture media for hours to days. Fermentation process controls typically maintain the culture environment at temperatures from 30 to 35° C, conditions which support short-term survival of hazards [9, 21, 100]. For example, FMD virus remained viable for about 48 hours in cell culture medium maintained at 35° C, and under the same conditions, CSF virus remained viable for approximately four hours [21]. However, we found no documentation that contamination with a viral pathogen of swine has actually occurred in an industrial fermentation process.

Contamination of microbial cultures with undesirable bacteria, fungi, and viruses of bacteria (bacteriophages) is an ever-present risk in commercial fermentation processes [101-103]. Since contamination can result in increased manufacturing cost or poor product yield and quality, biotechnology businesses consider contamination events to be production failures. Current good manufacturing practices in microbial fermentation biotechnology focus on preventing contamination of fermentation processes with undesirable microbes, emphasizing sterility of raw ingredients and equipment, and carefully controlled operating conditions. Ideally, sites for manufacturing plants are selected away from agricultural areas because proximity to livestock farming is associated with bacteriophage contamination of facilities [102]. Because contamination is disruptive to production, conditions that favor contamination of a fermentation plant with undesirable microbes, such as inadequate sanitation or non-sterile feed stock, are unlikely to remain undetected or uncorrected long-term in a productive commercial facility.

After fermentation, downstream recovery of the product may involve sterilization, centrifugation, filtration, crystallization, drying, and other operations which are intended to purify and stabilize the product [99]. Many of these treatments are likely to create hostile conditions for virus survival. However, we were unable to find studies specifically documenting the effect of downstream processing on the viability of viral pathogens of swine.

Post-manufacturing contamination with hazards might occur if the product is mixed with animal-derived material or handled in a facility where animal-derived material, live animals, or animal manure are present. The risks associated with commodities containing animal-derived material are discussed in Sections 10.2.4.1 and 10.2.4.2, with live animals in Section 10.3, and with livestock manure in Section 10.2.1.1.

Import mitigations

Microbes that do not express material of an exotic livestock or poultry disease agent may enter the country without USDA restrictions [104]. A USDA import permit is not required for biochemicals produced by microbes, including enzymes, plasmids, proteins, antibiotics, hormones, extracts, phages, and DNA, provided that the material is produced by microbial fermentation and does not contain animal derived additives, such as albumin. If the material does contain animal derived additives, the intended use of the product must be *in vitro* only. A detailed and accurate description of the material and a declaration regarding absence of animal derived additives or intended use *in vitro* must accompany the product.

Entry assessment for animal feed ingredients produced by microbial culture

The United States imports substantial quantities of animal feed ingredients derived from microbial culture. Hazards are unlikely to enter or survive manufacturing processes. No introduction of an exotic viral pathogen of swine has been associated with these imported commodities, and contamination of the products with a hazard has not been documented. Current manufacturing practices are aimed at preventing contamination with undesirable microbes which are detrimental to efficient production. Present import mitigations related to these commodities do not detect or inactivate hazards if they are present in the commodities.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients derived from microbial culture is negligible.

10.2.4.6 Animal feed ingredients produced by chemical synthesis or mining

Industrially produced methionine, an essential amino acid, is made by complex chemical synthesis [95-97]. Several of the vitamins that fortify animal feed, such as Vitamin A, Vitamin B6, and Vitamin D, are also constructed synthetically from mineral and organic compounds [95]. Some feed components, such as diatomaceous earth, iron oxide, limestone, and salt are minimally processed materials mined from the earth [95]. Some common animal feed ingredients that are produced by chemical synthesis or that are mined from the earth are listed in Table 14.

Table 14: Animal feed ingredients produced by chemical synthesis or mining

Purpose in feed	Ingredient
Amino acid	Methionine
Anti-caking agents	calcium silicate, calcium stearate, iron ammonium citrate, sodium stearate, verxite, silicon dioxide, yellow prussiate of soda
Antioxidants	butylhydroxyanisol (BHA), dibutylhydroxytoluene (BHT), ethoxyquin
Chelating agent	disodium ethylenediaminetetraacetate (EDTA)
Emulsifiers	ethyl cellulose, polyethylene glycol, polysorbate 60, sorbitan monostearate
Minerals	calcium iodate, calcium selenite, chromium picolinate, chromium propionate, cobalt sulfate, cobalt carbonate, copper sulfate, copper oxide, copper carbonate, ethylenediamine dihydriodide (EDDI), ferrous sulfate monohydrate, dicalcium phosphate, magnesium oxide, magnesium chloride, manganous oxide, manganese sulfate monohydrate, potassium chloride, potassium iodide, sodium selenite, sodium selenate, tribasic copper chloride, zinc oxide, zinc sulfate
Pelletizing aid	mineral oil
Vitamin	Vitamins A, B1, B3 or B5, B6, B7, B9, D, K; choline

References: [32, 33, 94, 95]

Quantity imported

Substantial quantities of synthetic chemicals and mined materials that might be used in animal feed are imported into the United States each year [87]. Import quantities of selected synthetic and mined chemicals are presented in Table 15. Data about the intended use of these imported products are not available, so we cannot determine the proportion that is intended for incorporation in animal feed.

Table 15: Import quantities of selected synthetic chemicals or mined materials used in animal feed

Commodity	Quantity in metric tons			Countries of Origin ¹
	2010	2011	2012	
Diatomaceous earth	1,034	1,881	3,069	France, Mexico, China
Ethoxyquin	3,074	3,403	2,577	China, South Korea
Methionine	7,360	7,867	7,414	France, Japan, China
Vitamin A	2,157	2,304	1,999	China, Switzerland, France
Vitamin B6	1,196	1,260	1,278	China, Germany
Vitamin D	741	684	727	China, Denmark, India

Reference: [87]

¹The countries of origin include the countries that export 90% or more of the total volume to the United States for each given commodity. The countries are listed in descending order. Unless otherwise specified, the calculations are based on 2012 trade volumes.

Biological factors for entry

Without living animal cells to serve as hosts, viral pathogens of swine cannot reproduce [9]. Animal cells are not used in industrial chemical synthesis, and therefore, processes used to synthesize feed-grade chemicals do not provide environments where it is possible for viruses to propagate [95].

Although synthetic chemical processes do not support propagation of the hazards, precursors, intermediates, and other raw materials could theoretically become contaminated with swine viruses should the substances have contact with infected animals, their excretions, or virus-contaminated fomites. However, we found no documentation that contamination of a synthetic or mined chemical with a viral pathogen of swine has actually occurred during a manufacturing process.

Synthesis of complex chemical compounds usually involves a sequence of many individual reactions to break molecular bonds and form new ones [95]. Generally, the rate of chemical reactions increases with temperature, so chemical syntheses are often carried out at elevated temperatures that rapidly inactivate viruses. For example, one step in the production of methionine requires heating the solution to 160° C for 1.5 hours [105]. Reaction steps used to break or form chemical bonds commonly employ solvents, detergents, and pH extremes; these conditions are unfavorable for virus survival.

Post-manufacturing contamination with hazards might occur if a synthetic or mined product is mixed with animal-derived material or handled in a facility where animal-derived material, live animals or livestock feces are present. The risks associated with commodities containing animal-derived material are discussed in Sections 10.2.4.1 and 10.2.4.2, with live animals in Section 10.3, and with animal manure in Section 10.2.1.1.

Import mitigations

Animal health regulations of the United States do not restrict the importation of commodities derived from synthetic materials or manufactured solely by chemical synthetic processing [106]. USDA APHIS recommends that materials derived from chemical synthesis be accompanied by producer's or shipper's written statement that identifies the material and confirms that the material is chemically synthesized,

does not contain animal or cell culture derived products, and was not derived from any animal or cell culture derived products.

Similarly, feed ingredients derived from mined materials, such as diatomaceous earth, iron oxide, salt, and limestone, may be imported into the United States without restrictions related to animal health regulations [31].

Entry assessment for animal feed ingredients produced by chemical synthesis or mining

The United States imports substantial quantities of synthetic chemicals and mined materials of which a fraction is incorporated into animal feed. Hazards are unlikely to enter or survive manufacturing processes. No introduction of an exotic viral pathogen of swine has been associated with these imported commodities, and contamination of the products with a hazard has not been documented. Present import mitigations related to these commodities do not detect or inactivate hazards if they are present in the commodities.

The risk of entry of exotic viral pathogens of swine into the United States through the importation of animal feed ingredients produced by chemical synthesis or mining is negligible.

10.2.4.7 Food for human consumption

10.2.5 Garbage

Imported garbage includes refuse generated during a voyage, rejected cargo, and prohibited items removed from passenger baggage at ports of entry.

10.3 Live Animals

10.3.1 Livestock and their germplasm

Intentional movement of livestock and their germplasm into the United States by both legal and illegal means occurs, as does accidental movement of stray livestock wandering across a border. Livestock can play three roles in the transport of hazards: they can be infected hosts, they can be contaminated with disease agents and serve as fomites, or they can serve as hosts to tick vectors of disease agents. Table X lists hazards that are associated with livestock and their germplasm through these three roles, including hazards for which livestock may play a minor or theoretical role in transmission.

10.3.2 Humans

In this pathway, we consider the risk of hazard entry through the movement of people into the United States. People can transport hazards in three roles: they can be infected hosts, they can be contaminated with disease agents and serve as fomites, or they can serve as hosts to tick vectors of disease agents. Baggage, clothing, or other personal belongings accompanying travelers can be contaminated with disease agents or transport tick vectors. Animal products can also be carried in baggage, clothing, or personal belongings; this possibility is covered in the inanimate article entry pathway. Table X lists

hazards that are associated with people or their accompanying baggage, including hazards for which humans may serve as dead-end hosts or play a minor or theoretical role in transmission.

10.3.3 Microorganisms and arthropod vectors

10.3.4 Other animals

DRAFT

11. Conclusions and Next Steps

Table 16: Risk of entry of exotic viral pathogens of swine by pathway

Pathway groups and subcategories		Risk of entry		
Airborne				
Animal tissues or fluids that may serve as fomites	Animal manure (not intended for feed)			
	Animal tissue extracts (not intended for feed, food, or pharmaceuticals)			
	Animal blood and blood products (not intended for feed)			
	Bones and teeth (not intended for feed)			
	Diagnostic samples			
	Hides, hair, and bristles			
	Pharmaceuticals containing animal-derived material, including traditional medicines			
	Tissues intended for medical transplantation			
	Vaccines or therapeutic serum products			
Conveyances and containers for cargo				
Equipment (agricultural, construction, military, veterinary)				
Live animals that may serve as vectors or fomites	Food and feed	Animal feed ingredients derived from rendered animal proteins, rendered animal fats, and marine by-products	Negligible	
		Animal feed ingredients containing milk and milk derivatives	Negligible	
		Animal feed ingredients derived from animal waste	Negligible	
		Animal feed ingredients derived from plants or plant products	Processed Unprocessed	Negligible Low
		Animal feed ingredients produced by microbial culture	Negligible	
		Animal feed ingredients produced by chemical synthesis or mining	Negligible	
		Food for human consumption		
	Garbage			
	Livestock and their germplasm			
	Humans			
	Microorganisms or arthropod vectors			
	Other live animals			

12. Appendices

12.1.1 Import Trade Data

Entries reported in under the tariff codes in Table 17 include bone meal, bone ash or charcoal, degreased bone chips, and various pet food products.

Table 17: Bones and horn cores, unworked, defatted, prepared, treated with acid or degelatinized; powder and waste of the products (in metric tons)

Country	2010	2011	2012 ¹
Canada	5,052	5,494	6,586
Australia	725	2,052	1,334
New Zealand	1,457	2,013	1,130
Brazil	207	199	336
Paraguay	337	285	198
Germany	0	0	183
China	41	57	149
Chile	0	49	105
Nigeria	40	95	61
India	21	8	25
Indonesia	34	32	21
Mexico	3	12	9
Colombia	14	5	1
Hong Kong	0	0	1
South Africa	0	0	0
Zimbabwe	0	0	0
Argentina	12	20	0
Italy	0	0	0
Netherlands	0	0	0
Switzerland	0	2	0
TOTAL²	7,942	10,323	10,138

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade codes: 0506.10.00.00, 0506.90.00.20, 0506.90.00.40.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Entries under the tariff code in Table 18 include a variety of products, ranging from specialty protein products to meat and bone meal derived from various species.

Table 18: Flours, meals, and pellets of meat or meat offal; and greaves (cracklings) (in metric tons)

Country	2010	2011	2012 ¹
Australia	20,386	29,261	28,880
New Zealand	25,974	31,201	25,630
Canada	15,862	11,132	9,493
France	413	5,174	5,948
Italy	0	20	287
Germany	0	0	39
Denmark	0	0	38
India	0	15	34
Ecuador	33	0	20
Colombia	0	95	0
Malaysia	0	57	0
Netherlands	19	54	0
Norway	22	0	0
Peru	92	0	0
Spain	0	18	0
TOTAL²	62,801	77,027	70,369

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 2301.10.00.00.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Table 19 includes a variety of animal products, from pig ears intended as pet treats to tankage and offal intended for use in pet food production.

Table 19: Animal products used for animal feed, NESOI; unfit for human consumption (in metric tons)

Country	2010	2011	2012 ¹
Canada	36,351	35,921	43,281
New Zealand	30,969	35,141	35,985
China	6,146	6,996	8,734
Australia	472	2,095	4,787
France	623	1,055	2,573
Brazil	7,244	2,147	1,623
Colombia	2,806	2,379	1,488
Italy	146	197	445
Ecuador	468	139	338
Paraguay	0	98	262
Argentina	137	245	235
Panama	3	99	144
Germany	172	153	116
India	830	806	109
Peru	25	35	98
Taiwan	170	78	75
Netherlands	24	48	48
Costa Rica	110	36	46
Japan	15	12	31
Thailand	0	14	25
Korea South	35	27	18
Mexico	2	2	12
Turkey	0	0	11
Indonesia	14	9	10
Nicaragua	39	82	6
Hong Kong	16	12	2
Iceland	0	4	1
United Kingdom	11	1	0
Uruguay	47	0	0
Venezuela	0	17	0
Vietnam	6	0	0
Spain	2	0	0
Norway	0	11	0
Chile	1	16	0
Denmark	11	11	0
Belgium	13	0	0
TOTAL²	86,907	87,887	100,502

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 0511.99.30.60.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. import from the world and may not represent the sum of the countries listed due to rounding.

Table 20 includes any animal product not specifically identified elsewhere. Some of the more common entries under this HTS code are denatured ground poultry parts, various fish items, and pig ears.

Table 20: Other animal products (other than semen, embryos, or dried blood) not intended for animal feed, NESOI, unfit for human consumption (in metric tons)

Country	2010	2011	2012 ¹
Canada	1,446	1,737	2,613
China	574	476	396
Mexico	430	333	383
Peru	41	3	87
France	6	15	15
Colombia	22	16	10
Germany	16	13	9
Australia	9	19	8
Malaysia	2	2	6
Japan	5	6	4
New Zealand	54	21	3
South Africa	2	1	3
Indonesia	0	0	2
Sweden	0	0	2
Argentina	0	0	1
United Kingdom	0	0	1
Hong Kong	0	0	0
Zimbabwe	0	0	0
Italy	0	0	0
Chile	0	0	0
Hungary	0	0	0
Switzerland	2	1	0
Namibia	0	0	0
Mongolia	0	0	0
India	6	0	0
Bulgaria	0	0	0
Barbados	0	0	0
Norway	0	0	0
Paraguay	198	44	0
Nicaragua	14	1	0
Netherlands	0	6	0
Korea South	0	0	0

Iceland	0	0	0
Israel	0	0	0
Belgium	0	0	0
Brazil	190	77	0
Greece	0	0	0
Guatemala	1	0	0
Honduras	3	2	0
Costa Rica	10	2	0
El Salvador	2	0	0
Thailand	0	2	0
Vietnam	2	0	0
Spain	1	3	0
Russia	0	0	0
Singapore	0	1	0
Zambia	0	0	0
TOTAL²	3,038	2,780	3,547

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 0511.99.40.70.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Entries in Table 21 include edible and inedible fats (tallow) from bovines, sheep, and goats that may be incorporated into swine feed.

Table 21: Edible and inedible fats of ruminants (in metric tons)

Country	2010	2011 ¹	2012
Canada	46,106	49,051	0
Mexico	11	25	0
Brazil	0	14	0
Australia	20	2	0
Portugal	0	1	0
New Zealand	70	0	0
TOTAL²	46,207	49,093	0

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade codes: 1502.00.00.20, 1502.00.00.40, 1502.00.00.60.

¹Rank of countries based on 2011 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

The entries in Table 22 describe other imports of animal fats and inedible mixtures other than tallow that may be incorporated into swine feed.

Table 22: Other animal fats and inedible mixtures or preparations of animal fats (in metric tons)

Country	2010	2011	2012¹
Canada	1,228	11,151	7,068
Brazil	4,270	3,914	3,434
Panama	0	0	1,146
Mexico	43	1,823	872
China	221	117	787
India	1,588	368	623
Ecuador	8	634	592
France	637	672	560
Norway	142	206	365
Colombia	0	269	270
Aruba	0	237	47
Germany	258	82	38
Australia	0	4	22
Dominican Republic	0	0	21
New Zealand	19	12	19
United Arab Emirates	0	0	19
Korea South	45	0	17
Spain	34	30	10
Netherlands	2	0	8
Taiwan	0	0	6
Belgium	0	0	6
Japan	3	2	4
Honduras	0	0	3
Malaysia	0	0	2
Suriname	0	0	0
Chile	0	0	0
Czech Republic	0	0	0
United Kingdom	375	275	0
South Africa	0	0	0
Peru	10	0	0
Trinidad & Tobago	0	6	0
Ukraine	0	0	0
Israel	0	2	0
Italy	0	2	0
Costa Rica	0	1	0
Bangladesh	0	1	0
TOTAL²	8,883	19,807	15,940

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade codes: 1506.00.00.00, 1516.10.00.00, 1518.00.40.00.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Entries in Table 23 include swine feed components, supplements, and additives containing no animal-origin products when imported from countries affected by or at undue risk for BSE. Swine feed and feed ingredients from the countries listed above may consist of a wide variety of components, supplements, and premixes. Swine feed could contain animal-origin products including poultry meal, feather meals, milk or milk products, and Vitamin D derived from sheep wool, or hide-derived gelatin. A high proportion of these feeds and feed ingredients typically include plant-based products. The swine feeds may also include medicated swine feeds. Because of the strict requirements for medicated feeds, such feeds are generally not salvaged for use in species other than those for which they were manufactured.

Table 23: Mixed swine feeds or mixed swine feed ingredients (in metric tons)

Country	2010	2011	2012 ¹
Ireland	40,824	284,187	271,107
Israel	0	0	2,134
Canada	1,952	2,206	1,680
United Kingdom	1,110	204	118
Australia	0	0	34
India	1	2	3
China	4	0	1
Italy	0	0	1
Korea South	0	2	0
TOTAL²	43,891	286,601	275,078

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 2309.90.10.35.

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Entries in Table 24 include a wide variety of animal feed ingredients and treats for poultry, cattle, equine, fish, and other animals such as pet birds, small mammals, and rodents. The majority of these feeds do not contain ingredients of animal origin.

Table 24: Animal feed preparations other than dog and cat pet food, mixed swine feeds or mixed swine feed ingredients, and animal feeds with milk derivatives (in metric tons)

Country	2010	2011	2012 ¹
Canada	129,553	161,216	157,770
Nigeria	38,211	30,320	49,350
China	40,684	49,322	34,504
Malaysia	29,349	33,345	29,355
Germany	2,827	4,810	5,922
Mexico	6,823	5,913	5,850
Belgium	4,999	3,187	4,662
Ireland	1,904	2,240	4,621
Bulgaria	692	1,089	1,975
Austria	2,805	989	1,938
France	2,931	3,165	1,882
United Kingdom	3,295	718	1,870
Italy	1,144	795	1,730
New Zealand	800	938	1,456
Taiwan	510	1,001	950
Japan	599	662	690
Czech Republic	5,022	711	663
Peru	286	304	652
Spain	76	161	398
Netherlands	434	459	385
Switzerland	94	152	345
Singapore	0	0	284
Finland	472	779	218
Thailand	177	140	191
Denmark	388	373	138
India	585	4410	124
Argentina	539	0	122
Korea South	11,012	93	118
Indonesia	28	172	99
South Africa	0	12	79
Brazil	82	24	77
Australia	427	356	49
Dominican Republic	9	38	41
Pakistan	4	10	31
Macau	21	29	30

Israel	0	1	20
Norway	12	36	12
Colombia	13	10	9
Vietnam	1	6	7
Hong Kong	0	4	3
Chile	27	5	3
Luxembourg	0	0	2
Uruguay	0	1	1
Portugal	0	0	1
Greece	0	0	0
Poland	208	44	0
Ghana	0	19	0
Kyrgyzstan	3	0	0
Sweden	4	0	0
Ecuador	49	0	0
TOTAL²	287,099	308,059	308,627

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 2309.90.10.05, 2309.90.10.15, 2309.90.10.20, 2309.90.10.30, 2309.90.10.32, 2309.90.10.45, 2309.90.10.50, 2309.90.60.00, 2309.90.70.00, 2309.90.95.00

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

Entries in Table 25 include canned and dry dog or cat food as well as a variety of treats and chews.

Table 25: Pet food, dog and cat (in metric tons)

Country	2010	2011	2012¹
Canada	63,925	76,320	80,905
Thailand	31,957	35,494	44,388
China	36,051	38,907	43,102
Australia	4,339	3,787	4,081
Mexico	709	1,326	3,527
Costa Rica	875	1,755	2,596
Ireland	1,366	1,110	1,114
New Zealand	350	590	769
Brazil	614	157	626
Uruguay	523	327	531
Colombia	1	0	412
Cambodia	573	617	289
Netherlands	90	200	276
Paraguay	0	0	142
Taiwan	107	87	123
Germany	199	98	113
Nepal	26	64	112
India	9	20	73
Iceland	0	0	28
Argentina	21	12	28
Chile	0	0	20
Vietnam	0	23	19
Italy	11	64	15
Cook Islands	0	0	12
Korea South	0	2	10
Hong Kong	0	11	8
Slovenia	65	21	6
Denmark	35	0	5
United Kingdom	5	19	5
Peru	2	2	2
France	3	1	2
Turkey	0	0	2
Ecuador	0	16	1
Pakistan	0	0	1
Malaysia	35	0	0
Spain	23	0	0
Tunisia	2	0	0
Belgium	87	0	0
TOTAL²	142,003	161,030	183,343

Reference: U.S. Department of Commerce Census Bureau Foreign Trade Statistics.

Harmonized trade code: 2309.10.00.10, 2309.10.00.90

¹Rank of countries based on 2012 trade volumes.

²Total is based on total U.S. imports from the world and may not represent the sum of the countries listed due to rounding.

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From: [Proescholdt, Terry](#)
To: [Schell, Timothy](#)
Subject: FW: PEDV meeting next week?
Date: Tuesday, December 03, 2013 9:02:00 AM
Attachments: [draft Swine viral diseases PA project plan.doc](#)
 [draft agenda - import pathways mtg.docx](#)

Hi, Tim.

I promised to fill you in on this and haven't yet. Bottom line seems to be a consensus by most of the parties that the virus was imported on/in feed from China (although there is no evidence of that, the virus is very environmentally fragile, and NVSL showed that there was no infectivity in the suspect feed supplement), and what the hell is FDA going to do about it?

But, here's the info on the meeting next week.

Such fun.

Terry

From: Jordre, Shannon
Sent: Tuesday, December 03, 2013 8:59 AM
To: Nelson, Eric; Proescholdt, Terry
Subject: Fw: PEDV meeting next week?

Here is some updated info on the PEDV meeting next week.

Shannon

Shannon Jordre
From my Blackberry

From: Ferguson, Lisa A - APHIS [<mailto:Lisa.A.Ferguson@aphis.usda.gov>]
Sent: Tuesday, December 03, 2013 07:41 AM Eastern Standard Time
To: Jordre, Shannon; Zack, Jonathan T - APHIS <Jonathan.T.Zack@aphis.usda.gov>
Subject: RE: PEDV meeting next week?

Hi Shannon – I'll try to call you a little later this morning. In the meantime, the location is NPPC's offices – 122 C Street NW, Suite 875 – in Washington. We'll go from 8:30 – 5 on Thursday, and 8:30 to noon on Friday. I'll explain more about the agenda when we talk – but here's a rough draft, and also the project plan that lists the possible pathway groups that will be the focus of the discussion.

Cheers - Lisa

From: Jordre, Shannon [<mailto:Shannon.Jordre@fda.hhs.gov>]
Sent: Tuesday, December 03, 2013 7:18 AM
To: Ferguson, Lisa A - APHIS; Zack, Jonathan T - APHIS
Subject: PEDV meeting next week?

Have you guys worked out the details for the meeting next week – location, time & agenda? If so, please let me know so we can make plans. Thanks!

Shannon

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Project plan: Entry assessment for exotic viral pathogens of swine pathways analysis

Prepared by: Tim Clouse, Lisa Ferguson, Kenneth Forsythe, Julie Gauthier, Rebecca Gordon, Columb Rigney, Steve Weber

Updated: November 22, 2013

Purpose:

Conduct an entry assessment as the first step towards determining whether significant gaps exist in import regulations that may result in infections of U.S. domestic swine with exotic viral pathogens of swine.

Scope:

Analyze the risk of entry of any exotic viral pathogen of domestic swine (*Sus scrofa domesticus*) into the United States as a result of any type of import activity.

Objectives:

1. Identify and describe the pathways by which exotic viral pathogens of swine may enter the United States.
2. Estimate the likelihood that each identified pathway may introduce exotic viral pathogens of swine into the United States.

For future consideration:

A complete import animal health risk analysis, according to international standards established by the OIE, includes not only an identification of hazards and an assessment of the hazards' likelihood of entry (proposed in Objectives 1 and 2 listed above) but also an exposure assessment, a consequence assessment, and an evaluation of risk management options. The ultimate goal of this work is to conduct a complete animal health risk analysis for the purpose of determining whether significant gaps exist in import regulations that may result in infections of U.S. domestic swine with exotic viral pathogens of swine. The following additional objectives are beyond the scope of this project, but they are necessary further steps toward the ultimate goal:

3. For pathways with non-negligible likelihood of introducing exotic viral pathogens of swine into the United States, estimate the likelihood that domestic swine in the United States may be exposed to an introduced viral pathogen of swine.
4. For pathways with non-negligible likelihood of exposing domestic swine in the United States to an introduced viral pathogen of swine, evaluate the consequences of domestic swine becoming infected.

5. For pathways in which the consequences of infection, overall risk of introduction, and overall risk of exposure are non-negligible, identify potential measures to mitigate the risk.

Possible pathway groups to be evaluated:

(Consider *intentional legal*, *intentional illegal*, and *unintentional* motives for each pathway)

- Airborne
- Importation of live animals that may serve as vectors or fomites
 - Live swine
 - Swine germplasm
 - Humans
 - Microorganisms or arthropod vectors
 - Other live animals
 - Rodents
- Importation of inanimate objects that may serve as fomites
 - Animal tissues or fluids
 - Animal tissues or fluids for manufacturing or further processing
 - Animal waste
 - Blood
 - Bones and teeth
 - Hides and bristles
 - Trophies
 - Animal tissues or fluids for human or veterinary medicine
 - Pharmaceuticals, including traditional medicines
 - Vaccines
 - Reagents
 - Transplant tissues
 - Blood products
 - Nucleic acids
 - Animal tissues or fluids for diagnostic or research purposes
 - Conveyances and containers for cargo
 - Equipment
 - Agricultural
 - Military
 - Veterinary
 - International garbage from vehicles, ships, or aircraft
 - Food and feed
 - Animal feed containing animal-derived ingredients
 - Other animal feed ingredients
 - Foods for human consumption

Key data inputs:

1. Support for biological plausibility that a hazard is associated with a pathway.
2. Prevalence of hazards associated with import activity.

3. Volume of travelers, animals, or commodities entering the U.S.
4. Geographic origins of travelers, animals, or commodities.

Expected Deliverables/Products:

The primary document produced from the team will be the entry assessment document, with accompanying executive summary.

Tentative schedule:

December 4, 2013	Drafting and acceptance of project plan
December 6, 2013	Hazard identification draft prepared
December 12, 2013	Brainstorm pathways and begin data collection
January 31, 2013	Draft entry assessment prepared and distributed for review
February 28, 2013	Finalize entry assessment

Import pathways for exotic viral pathogens of swine

December 12-13, 2013

NPPC offices, 122 C Street NW, Suite 875, Washington, DC

Dec 12: (will work in breaks and lunch when appropriate)

8:30 am – Welcome and introductions

9:00 am – Intro to pathways analysis

9:15 am – Update from University of Minnesota – PED survivability

10:00 am – 5 pm – discuss list of possible pathways, with relevant group providing data as appropriate when the pathway is discussed (for example, the feed industry can provide info about production practices in China when we get to that item on the list)

Dec 13 –

8:30 am – continue discussion of possible pathways

11 am – summarize discussions and next steps

12 noon - adjourn

From: [DeLancey, Siobhan](#)
To: [Jordre, Shannon](#); [Nelson, Eric](#); [Benz, Sharon A](#); [Proescholdt, Terry](#); [Forfa, Tracey](#); [McChesney, Daniel G](#)
Subject: Fw: Readout on WSJ and AP calls
Date: Tuesday, March 25, 2014 5:08:13 PM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)

Here's the readout on the interview that APHIS did with Kelsey Gee today.

From: Curlett, Ed C - APHIS [mailto:Ed.C.Curlett@aphis.usda.gov]
Sent: Tuesday, March 25, 2014 05:04 PM Eastern Standard Time
To: DeLancey, Siobhan
Subject: Fw: Readout on WSJ and AP calls

Fyi

From: Cole, Lyndsay M - APHIS
Sent: Tuesday, March 25, 2014 04:28 PM
To: Mabry, Brian -OSEC
Cc: Jones, Bethany - APHIS; Ivy, James C - APHIS; Curlett, Ed C - APHIS; Bond, Suzanne M - APHIS; Schwarz, Cullen - OC; Rowe, Courtney - OC
Subject: Readout on WSJ and AP calls

Hi Brian,

I wanted to provide a summary of the two media calls Dr. Lisa Ferguson completed on PED. Both calls went very well, and Lisa did a great job of providing information about the virus and APHIS' role.

The first, with Kelsey Gee of the Wall Street Journal, was specific to the pathways assessment. Lisa answered questions on the assessment, including exactly what these assessments look at in terms of the possible paths of transmission. Lisa also agreed to share the draft of the assessment, as it has already been shared with several industry groups, and is therefore publically available (and would be provided in its entirety with a FOIA request). I'll send you a copy of that draft as soon as I receive it. (She told Kelsey she would send it tomorrow, so that's probably when I'll get it as well.) The only question that came up that was unforeseen was about regulatory diseases – why we regulate some and not others. In this case, Lisa explained the OIE's guidelines for reportable diseases, and maintained that even though we were not currently taking regulatory action on this particular disease, we are still taking it very seriously and working with our partners to respond and gather information about the virus.

The second call, with Michelle Johnson of the AP in Milwaukee, was shorter. The reporter explained that this is the first time she has written about an animal virus, so Lisa provided some very general information about how we respond to different types of viruses and diseases. Lisa also quickly explained "reportable diseases" and provided information on the different things APHIS has done to address PED (both in the lead and in a supporting role). After the general information, the reporter

did ask about the request for disaster funding, and Lisa explained that she'd need to go back to the Office of Communications with that question, as it was outside the scope of her role.

Thanks!

Lyndsay Cole
Assistant Director of Public Affairs
Legislative and Public Affairs
USDA Animal and Plant Health Inspection Service
Office: (970) 494-7410
Mobile [b] (b)(6) USDA, APHIS redaction
Lyndsay.M.Cole@aphis.usda.gov

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From: [Hughes, George](#)
Subject: FW: Role of Transportation in Spread of Porcine Epidemic Diarrhea Virus Infection, United States
Date: Thursday, March 13, 2014 3:03:53 PM

Ladies and Gentlemen,

FYI and thanks Marianne...

George

George F. Hughes
Senior Advisor, Counterterrorism and Intelligence
Food and Drug Administration
Office of Criminal Investigations
7500 Standish Place, Room 250N
Rockville, MD 20855

240 276-9456 (Direct)

(b) (6) (Cell 24/7)

FDA redaction

240 276-8368 (Fax)

(b) (6) (Secure)

FDA redaction

571 280-5421 (NCTC)

Email: george.hughes@oci.fda.gov

ICE mail: hughesg@fda.csp.ic.gov

NCTC ICE mail: gfhughes@fbi.ic.gov

From: Elbertson, Marianne - FSIS [mailto:Marianne.Elbertson@fsis.usda.gov]

Sent: Thursday, March 13, 2014 2:38 PM

To: Hughes, George

Subject: Role of Transportation in Spread of Porcine Epidemic Diarrhea Virus Infection, United States

Please send to the AGINT group.

This has more to do with biosecurity, but may be of interest ...

http://wwwnc.cdc.gov/eid/article/20/5/13-1628_article.htm

Marianne Elbertson
Senior Food Defense Analyst
USDA-FSIS-ODIFP
Mail Stop 3793, PP3, Room 9-171A
1400 Independence Avenue, SW
Washington, DC 20250
Email: Marianne.Elbertson@fsis.usda.gov
Ph.: 202-690-6514
Cell: (b) (6) FDA redaction

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Laboratory Test Report

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005959****Animal Location****Date Collected:** 02/21/2014**Date Received:** 02/21/2014**Submitter - 4239****Date Completed:** 03/28/2014**Collected By:** J. Lambert, et al

Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229

Purpose: General Diagnostic**Referral Number:****Country Origin/Destination:****This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.****Sample: 848752 Specimen Type: Feed Ingredient Animal ID: d332614008 Species: N/A**

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.

The plasma sample was evaluated in a bioassay.

No evidence of PEDV infection was detected based on PCR and serologic assays.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

(This new section will be updated periodically with tips for submitters.)

Quality samples yield the most accurate results. Please call if you have questions.

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005960****Animal Location****Date Collected:** 02/21/2014**Date Received:** 02/21/2014**Submitter - 4239****Date Completed:** 03/28/2014**Collected By:** J. Lambert, et al

Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229

Purpose: General Diagnostic**Referral Number:****Country Origin/Destination:****This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 848753 Specimen Type: Feed Ingredient Animal ID: d332614009 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005961****Animal Location****Date Collected:** 02/21/2014
Date Received: 02/21/2014**Submitter - 4239**Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229**Date Completed:** 03/28/2014
Collected By: J. Lambert, et al**Purpose:** General Diagnostic
Referral Number:
Country Origin/Destination:**This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 848754 Specimen Type: Feed Ingredient Animal ID: d332614010 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.

The plasma sample was evaluated in a bioassay.

No evidence of PEDV infection was detected based on PCR and serologic assays.**Results authorized by:**Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

(This new section will be updated periodically with tips for submitters.)

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005962****Animal Location****Date Collected:** 02/21/2014**Date Received:** 02/21/2014**Submitter - 4239****Date Completed:** 03/28/2014**Collected By:** J. Lambert, et al

Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229

Purpose: General Diagnostic**Referral Number:****Country Origin/Destination:****This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 848748 Specimen Type: Feed Ingredient Animal ID: d332614002 Species: N/A

Polymerase chain reaction (PCR)	Positive
Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test	Positive
Polymerase chain reaction (Sequencing)	PEDV

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.

The RNA was amplified using nested PCR and the PCR product was sequenced. The sequence showed closest homology to 2012 Asian PED virus sequences in Genbank.

Results authorized by: Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551

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Quality samples yield the most accurate results. Please call if you have questions.



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Owner

American Protein Company
Arion, IA

Accession Number: **14-005963**

Animal Location

Date Collected: 02/21/2014
Date Received: 02/21/2014

Submitter - 4239

Date Completed: 03/28/2014
Collected By: J. Lambert, et al

Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229

Purpose: General Diagnostic
Referral Number:
Country Origin/Destination:

This is not a billable case.

NOTE: Condition of the sample(s) was adequate unless otherwise noted.

Sample: 848749 Specimen Type: Feed Ingredient Animal ID: d332614003 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.

Results authorized by: Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005964****Animal Location****Date Collected:** 02/21/2014
Date Received: 02/21/2014**Submitter - 4239****Date Completed:** 03/28/2014
Collected By: J. Lambert, et alShannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229**Purpose:** General Diagnostic
Referral Number:
Country Origin/Destination:**This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 848750 Specimen Type: Feed Ingredient Animal ID: d332614004 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.

The plasma sample was evaluated in a bioassay.

No evidence of PEDV infection was detected based on PCR and serologic assays.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005965****Animal Location****Date Collected:** 02/21/2014
Date Received: 02/21/2014**Submitter - 4239**Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229**Date Completed:** 03/28/2014
Collected By: J. Lambert, et al
Purpose: General Diagnostic
Referral Number:
Country Origin/Destination:**This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 848751 Specimen Type: Feed Ingredient Animal ID: d332614007 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005966****Animal Location****Date Collected:** 02/21/2014
Date Received: 02/21/2014**Submitter - 4239**Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229**Date Completed:** 03/28/2014
Collected By: J Lambert, et al
Purpose: General Diagnostic
Referral Number:
Country Origin/Destination:**This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: inv834814 Specimen Type: Feed Ingredient Animal ID: d334814018 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

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OwnerAmerican Protein Company
Arion, IA**Accession Number:** **14-005967****Animal Location****Date Collected:** 02/21/2014
Date Received: 02/21/2014**Submitter - 4239**Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229**Date Completed:** 03/28/2014
Collected By: J Lambert, et al
Purpose: General Diagnostic
Referral Number:
Country Origin/Destination:**This is not a billable case.****NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: inv834813 Specimen Type: Feed Ingredient Animal ID: d404924038 Species: N/A

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test Positive

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. RNA was extracted from the sample and the RNA was tested by real-time reverse transcription PCR (rRT-PCR) assay for the presence of PEDV RNA. This assay has not been validated.

PEDV RNA was detected in the sample.**Results authorized by:** Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551**Help Us Help You**

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Owner

Arion, IA

Accession Number: **14-007358****Animal Location****Date Collected:** 03/04/2014
Date Received: 03/06/2014**Submitter - 4239****Date Completed:** 04/01/2014
Collected By: Krepel, D

Shannon Jordre
Food & Drug Administration Center for Veterinary
Medicine
Division of Compliance HFV-232
7519 Stadish Place
Rockville, MD 20855
FAX #: 240-276-9241
Phone #: 240-276-9229

Purpose: General Diagnostic
Referral Number: FDA Sample #
Country Origin/Destination: 834816

This is not a billable case.**NOTE: Condition of the sample(s) was adequate unless otherwise noted.**

Sample: 834816 Specimen Type: Plasma Animal ID: "834816 02/04/2014 DKK" Lot#D327414007, SKU# 10455 Species: Pig, Domestic (No breed s)

Porcine Epidemic Diarrhea - Polymerase Chain Reaction (PCR) Test

Suspicious

A dried plasma sample was submitted for porcine epidemic diarrhea virus (PEDV) testing. A 10% suspension was made and RNA was extracted from the sample. The RNA was tested by realtime reverse transcription PCR (rtt-PCR) assay for the presence of PEDV RNA. This assay has not been validated for use with plasma.

PEDV RNA was detected in the suspect range for this assay. **The sample status is suspect.**

Results authorized by: Dr Sabrina Swenson, Head, Bovine, Porcine, and Aquaculture Section,
Diagnostic Virology Laboratory (515) 337-7551

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From: [Dunham, Bernadette M](#)
To: [Jordre, Shannon](#)
Cc: [Nelson, Eric](#)
Subject: RE: Diagnostics
Date: Friday, May 31, 2013 9:42:00 AM

Thanks very much Shannon. ☺

Cheers,
Bernadette

From: Jordre, Shannon
Sent: Friday, May 31, 2013 9:39 AM
To: Dunham, Bernadette M
Cc: Nelson, Eric
Subject: FW: Diagnostics

Bernadette, I saw that you asked a question about our FDA feed samples, but you were not in the address list where I supplied that info to APHIS – so see below for my response to APHIS. Let me know if further questions.

Shannon

Shannon Jordre
Division of Compliance, HFV-232
FDA Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855

Phone: 240-276-9229
Fax: 240-276-9241
E-mail: shannon.jordre@fda.hhs.gov

From: Jordre, Shannon
Sent: Friday, May 31, 2013 8:42 AM
To: Nelson, Eric; Zack, Jonathan T - APHIS; Ferguson, Lisa A - APHIS
Cc: Fisher, Sharon S - APHIS; Myers, Thomas J - APHIS; Woody, Dillard
Subject: RE: Diagnostics

I was in touch with our lab yesterday. Our PCR analysis (for the presence of prohibited animal proteins) should take only a few days, but will be even less definitive than the NVSL PCR because we're looking for animal protein (which could be a fomite), and is not at all indicative of the presence of virus.

The microscopic filth analysis will likely take 2-3 weeks, it is very labor intensive – the analysts are looking at feed under a microscope, and looking for things that don't belong, such as undeclared ingredients, insects, insect parts, fecal matter.

We will let you know how it's progressing, though. Thanks!

Shannon

Shannon Jordre
Division of Compliance, HFV-232
FDA Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855

Phone: 240-276-9229
Fax: 240-276-9241
E-mail: shannon.jordre@fda.hhs.gov

From: Nelson, Eric
Sent: Friday, May 31, 2013 8:28 AM
To: Zack, Jonathan T - APHIS; Jordre, Shannon; Ferguson, Lisa A - APHIS
Cc: Fisher, Sharon S - APHIS; Myers, Thomas J - APHIS; Woody, Dillard
Subject: RE: Diagnostics

Jon, Please have the NDSL forward the results to Shannon, Dillard Woody and myself. We will likely share with other as needed. When the FDA results start arriving, I will forward those to you. It is likely to take weeks to complete all of the analysis we have undertaken, as the results are reported to us, we will forward them to you. Hopefully we will be able to determine a trend early.

Eric

From: Zack, Jonathan T - APHIS [<mailto:Jonathan.T.Zack@aphis.usda.gov>]
Sent: Thursday, May 30, 2013 5:21 PM
To: Jordre, Shannon; Ferguson, Lisa A - APHIS
Cc: Nelson, Eric; Fisher, Sharon S - APHIS; Myers, Thomas J - APHIS
Subject: RE: Diagnostics

Hi Shannon and Eric,

- Who (all) from FDA do you want to get the official results directly from NVSL?
- NVSL is going to send out the official preliminary results (PCR only) when the CO samples are all completed, as early as tomorrow.
- Virus isolation will take longer, may take couple weeks to call PED negative on virus isolation.
- Bio assay tests are not expected to be completed for several weeks.

CO PCR testing update:

- The vitamin premix samples collected at Yuma feed mill are negative (pcr)
- The mixed sow rations – retained – held at the “new” feedmill facility are negative.
- The mixed sow rations from the individual farrowing units (55, 56) will be completed tomorrow, most likely.

Do you have an estimated time of completion for the FDA testing (rough estimate, week, weeks, month, etc)

From: Jordre, Shannon [<mailto:Shannon.Jordre@fda.hhs.gov>]

Sent: Thursday, May 30, 2013 4:46 PM

To: Ferguson, Lisa A - APHIS; Zack, Jonathan T - APHIS

Cc: Nelson, Eric; Fisher, Sharon S - APHIS

Subject: RE: Update on Porcine Epidemic Diarrhea (PED)

Lisa/Jon, Are you going to communicate those results to Seaboard, and/or what is the plan for passing that info back to them? Maybe you did that already, but I know our Denver office will want to know that.

Thanks!

Shannon

Shannon Jordre
Division of Compliance, HFV-232
FDA Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855

Phone: 240-276-9229

Fax: 240-276-9241

E-mail: shannon.jordre@fda.hhs.gov

From: Ferguson, Lisa A - APHIS [<mailto:Lisa.A.Ferguson@aphis.usda.gov>]

Sent: Thursday, May 30, 2013 4:38 PM

To: Jordre, Shannon

Cc: Zack, Jonathan T - APHIS; Nelson, Eric; Dunham, Bernadette M; Fisher, Sharon S - APHIS

Subject: Re: Update on Porcine Epidemic Diarrhea (PED)

I know that the CO samples were negative at NVSL - don't have all the details on exactly what we received and tested.

Sent from my iPad

On May 30, 2013, at 3:33 PM, "Jordre, Shannon" <Shannon.Jordre@fda.hhs.gov> wrote:

Zack & Lisa, Thanks for getting the statement out re the feed investigation – the information release helps us out, too.

We have no direct communication from NVSL, so if they're still testing feed, we haven't heard anything. If you've got results (from the Seaboard location in Colorado), please let us know about them.

Shannon

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From: Zack, Jonathan T - APHIS [<mailto:Jonathan.T.Zack@aphis.usda.gov>]
Sent: Thursday, May 30, 2013 2:14 PM
To: Nelson, Eric; Jordre, Shannon; Dunham, Bernadette M
Cc: Ferguson, Lisa A - APHIS; Fisher, Sharon S - APHIS
Subject: FW: Update on Porcine Epidemic Diarrhea (PED)

Hi all,
John Clifford just sent update o industry groups.
Thank you for your patience.
And of course now I have a request...
Can someone from the FDA provide an FDA update on the State Veterinarian (not industry) conference call Dr. Clifford is hosting tomorrow, 3:00 pm east? I will forward call details,
Thank you,
Jon

Jon Zack, DVM
Director Preparedness and Incident Coordination
Emergency Management and Diagnostics
USDA APHIS Veterinary Services
4700 River Road Unit 41
Riverdale MD 20737
(301) 851-3595 office phone
(301) 851-3460 desk phone
(301) 734-7817 fax

From: Christensen, Laura C - APHIS **On Behalf Of** Clifford, John R - APHIS
Sent: Thursday, May 30, 2013 2:07 PM
To: [REDACTED]

(b)(6) - USDA APHIS redaction

Cc: APHIS-VS Leadership Team; Zimmers, Hallie - APHIS
Subject: Update on Porcine Epidemic Diarrhea (PED)

Porcine Epidemic Diarrhea (PED)

Update

USDA's Animal and Plant Health Inspection Service (APHIS) is working closely with stakeholders to monitor the situation around porcine epidemic diarrhea (PED) in the United States. We received reports that animal feed may be a possible factor in transmitting this disease, so we partnered with the Food and Drug Administration (FDA) to investigate this possibility. At this time, here is what we know - we tested samples of feed and feed ingredients associated with one case of PED at the National Veterinary Services Laboratories (NVSL), with no positive results for PED antigen by polymerase chain reaction (PCR). However, our investigation with FDA is ongoing. We are also collaborating closely with American Association of Swine Veterinarians (AASV), National Pork Board (NPB) and the National Pork Producers Council (NPPC) on a broad epidemiological investigation to help identify any risk factors in the transmission of this disease.

Background

On May 16, the National Veterinary Services Laboratories (NVSL) confirmed a detection of PED virus in Iowa. PED virus is associated with outbreaks of diarrhea and vomiting in swine. PED virus is not zoonotic, does not affect people, and is not a food safety concern.

PED exists in many parts of the world. PED is not a listed disease of the World Organization for Animal Health (OIE); is not on the National Animal Health Reporting System (NAHRS) Reportable Disease List; is not considered a Foreign Animal Disease in the United States; and there are no interstate trade restrictions pertaining to PED in U.S. swine.

This is the first time PED virus has been found in the U.S. USDA is working with veterinary diagnostic laboratories, veterinarians, swine producers, State animal health officials and related swine industries to manage PED and determine, to the extent possible, how long the virus has been here, the first location of the virus, and where the virus came from.

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From: [Proescholdt, Terry](#)
To: [Jordre, Shannon](#)
Subject: RE: Meeting with National Pork Board to discuss feed ingredients & PEDV
Date: Tuesday, September 24, 2013 1:18:00 PM

Hi Shannon.

I see no mention of discussion on the diagnostic results from NVSL and OR. I hope they will be included, since they are rather important.

Terry

From: Jordre, Shannon
Sent: Tuesday, September 24, 2013 1:14 PM
To: Nelson, Eric; Proescholdt, Terry; Woody, Dillard
Subject: FW: Meeting with National Pork Board to discuss feed ingredients & PEDV
Importance: High

While I was out (more or less the last two weeks), APHIS agreed to meet w/ the National Pork Board at 9 AM on Oct. 9, in downtown DC at the NPPC office (not too far off the mall or from Union Station, if you haven't been there before). The agenda is below. I think they expect me to make the invitation to NGFA & AFIA, and I plan to do so today or tomorrow.

Let me know ASAP if you have any feedback.

Shannon

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From: Paul Sundberg [<mailto:PSundberg@pork.org>]
Sent: Friday, September 20, 2013 3:57 PM
To: Myers, Thomas J - APHIS; (b) (6) FDA redaction
Cc: Ferguson, Lisa A - APHIS; Zack, Jonathan T - APHIS; burkgren@aasv.org
Subject: RE: Meeting to discuss feed ingredients

TJ and Lisa,

With meetings that involve different agencies and departments there's always a question of location. There is a FAZD facilitated meeting on continuing the FAD research discussion and priorities that concludes on the 8th so I plan to stay over for this one. Tom B may be doing the same.

Is it possible to have this meeting in the morning so we can fly back out of town relatively early that afternoon? And is it also possible to hold this somewhere downtown? If the Whitten Building isn't available, we can see if NPPC's meeting room is.

We see this as an extremely important question that is brought about by it but much bigger than PED and we're looking forward to putting heads together to see if/how it can be enhanced.

Thanks for the help

Paul

Paul Sundberg, DVM, PhD, Dipl ACVPM
Vice President, Science and Technology
National Pork Board
1776 NW 114th Street
Des Moines, IA 50325
office (515) 223-2764
fax (515) 223-2646
email psundberg@pork.org

From: Myers, Thomas J - APHIS [<mailto:Thomas.J.Myers@aphis.usda.gov>]

Sent: Thursday, September 19, 2013 5:28 PM

To: Paul Sundberg; Bob Acord

Cc: Ferguson, Lisa A - APHIS; Zack, Jonathan T - APHIS

Subject: Meeting to discuss feed ingredients

Dear Paul and Bobby –

I have asked Lisa Ferguson to spearhead this meeting. She is currently my Team Leader for all of NCIE and has more extensive contacts in FDA than I do. Also, as my role in trade and import/export issues decreases with the reorganization beginning October 1, she will be able to provide you with a consistent point of contact.

Lisa has been in contact with Shannon (sorry, I don't recall Shannon's last name) at FDA, and they have developed the following meeting outline:

- **Purpose:** Discuss/identify potential gaps/vulnerabilities from imported feed ingredients.
- **Attendees:** APHIS (Lisa Ferguson, lead), FDA (Shannon, lead), Swine industry (Paul Sundberg, lead), feed industry representatives TBD (FDA will contact AFIA and NGFA).
- **Date/Time/Location:** Tentatively set for some time Oct 9 – face to face or conference call?
?

Agenda:

- (1) Introductions
- (2) Summary of APHIS import regulations/requirements pertaining to feed ingredients
- (3) Summary of FDA import regulations/requirements pertaining to feed ingredients
- (4) Feed industry – outline of feed ingredients and sources
- (5) Swine industry – questions, comments, identified gaps
- (6) Open discussion

Please let me know if this works for you, and if your preference for this initial discussion is a face-to-face meeting or a conference call. Also, please recall from our previous emails that from this initial meeting, together we can determine the type of discussion we will need to have with CBP and any need to broaden the discussion to other commodity industries.

Thanks,
TJ

Dr. T.J. Myers
Associate Deputy Administrator
APHIS Veterinary Services
Riverdale, MD

Desk: 301-851-3576

Cell: [REDACTED] (b) (6)

FDA redaction

From: [Swenson, Sabrina L - APHIS](#)
To: [Jordre, Shannon](#)
Cc: [Hauer, Paul - APHIS](#); [Schmitt, Beverly J - APHIS](#)
Subject: RE: mising sample result?
Date: Tuesday, April 01, 2014 2:42:14 PM

The results are reported as positive, suspect, or negative based on the CT value for the assay we are using. Remember assay is not validated for use with feed products. This particular sample CT was in the "suspect" range. If we were testing animals, that type of result with compatible clinical signs would lead me to suggest collection of additional samples to determine if the animal were just becoming infected or if it is a false reaction. Basically we are right at the level of detection. So it is testing suspiciously. We aren't saying positive or negative.

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Tuesday, April 01, 2014 12:59 PM
To: Swenson, Sabrina L - APHIS
Cc: Hauer, Paul - APHIS; Schmitt, Beverly J - APHIS
Subject: RE: mising sample result?

Sabrina, Paul or Beverly, I just got the report for that last sample, and had a question that I hope is simple.

On this report (14-007358) the bolded result is: "The sample status is suspect." But it also says "PEDV RNA was detected in the suspect range for this assay". This is a little different terminology than used on the rest of the samples – the rest say "PEDV RNA was detected in the sample".

Does that mean this sample is positive, probably positive, or something else? (CVM reports this sample as negative, which is why I ask.)

Shannon

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From: Swenson, Sabrina L - APHIS [<mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Monday, March 31, 2014 5:34 PM
To: Jordre, Shannon
Cc: Hauer, Paul - APHIS; Schmitt, Beverly J - APHIS
Subject: RE: mising sample result?

Shannon,

To avoid any concerns about the potential for cross contamination, we tested the first round of plasma samples, then moved to testing bioassay samples. Since this sample came in during bioassay testing, we put it on hold. Testing has just finished on the sample. We should have a report to you tomorrow.

Sabrina

From: Jordre, Shannon [<mailto:Shannon.Jordre@fda.hhs.gov>]

Sent: Monday, March 31, 2014 2:45 PM

To: Swenson, Sabrina L - APHIS

Subject: mising sample result?

Sabrina, I'm trying to reconcile the 10 samples that Haile reported, with the 9 samples you reported. It appears that you did not report on your sample number 14-007358, which I believe is the sample represented by this form. So I'm wondering if that is still pending, or if you simply logged it in and then sent a split to Haile? Thanks!

Shannon

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From: Swenson, Sabrina L - APHIS [<mailto:Sabrina.L.Swenson@aphis.usda.gov>]

Sent: Wednesday, March 05, 2014 11:12 AM

To: Krepel, Diana

Cc: Jordre, Shannon

Subject: Plasma sample for NVSL

Diana,

Thanks for the call. I've attached the submission form that needs to come with the plasma sample. Please also send chain of custody form. We will sign and return to you via e-mail. I need you to complete the following on the form (can be electronic or handwritten).

#3-Owner, city, state-I wasn't sure if this was the same as the last submissions.

#15-Referral number-I didn't know if you has investigation names/numbers that you refer to on these types of things. If so, that is where you would put the information.

#16-Preservation-I didn't know if you were sending on ice packs.

#18-I assumed 1 based on e-mails I received.

#21-ID's-Last time we had lot numbers, sku numbers, and a FDA assigned number.

#23-Sign and date as the submitter.

Let me know if you have any questions. Please also send me the UPS tracking number so we can track package and make sure it shows up tomorrow.

Sabrina

Sabrina L. Swenson, DVM, PhD

Head, Bovine, Porcine, and Aquaculture Viruses Section

Diagnostic Virology Laboratory

National Veterinary Services Laboratories

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From: [Myers, Michael J](#)
To: [Jordre, Shannon](#); [Yancy, Haile](#)
Subject: RE: NVSL Bioassay results (APC)
Date: Thursday, March 20, 2014 3:47:59 PM

The link worked this time.

Never heard of swiffering before. I view it as GIGO (garbage-in, garbage out) literally and figuratively.

No mention of the extraction method in the file. Will have to get the papers.

mike

-----Original Message-----

From: Jordre, Shannon
Sent: Thursday, March 20, 2014 3:31 PM
To: Myers, Michael J; Yancy, Haile
Subject: RE: NVSL Bioassay results (APC)

Thanks, Mike -- very helpful!

Have you heard of "swiffering" before? People are talking like they're doing dozens or even hundreds of these samples. I could try to find out more, if this is not a common technique.

Appreciate the Ct value explanation.

You mention that a PDF document did not come through. I tried to send you a link (but hadn't tested it myself) -- did it not work?

Shannon

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-----Original Message-----

From: Myers, Michael J
Sent: Thursday, March 20, 2014 3:25 PM
To: Jordre, Shannon; Yancy, Haile
Subject: RE: NVSL Bioassay results (APC)

Swiffering (as opposed to swift-boating) is going to be a nightmare with respect to getting DNA extracted away from all possible PCR inhibitors. You are basically talking about extracting DNA from dirt, and if there is any "sand" present, the DNA is going to be absorbed onto the silica and be difficult to extract.

If they are going to go this route for environmental samples, then they are going to need something akin to our original DNA extraction method (attached) from our very first PCR-based method. Haile may have some additional thoughts, but basically the method in this SOP is still considered the gold-standard for DNA extraction.

The Ct, or cycle threshold, values, are a measure of the relative amount of starting DNA in the test sample. All things being equal, the more DNA you have in your test sample, the sooner you will begin to see a positive reaction occurring in your PCR run. Earlier translates into a lower Ct value

What Ct means is the amplification cycle (the C) at which you first see a response above the baseline/background values (the threshold). In well-defined systems, you can translate changes in Ct values to relative amounts of DNA.

But in systems such as swiffering (and especially our method for ruminant material in feed), these assumptions break down and are no longer valid. But most folks who are dilatants in these areas are unaware of the assay short-comings.

The PDF file did not come through.

Mike

-----Original Message-----

From: Jordre, Shannon
Sent: Thursday, March 20, 2014 2:44 PM
To: Yancy, Haile; Myers, Michael J
Subject: FW: NVSL Bioassay results (APC)

Haile & Mike, The plasma manufacturer shared the results of some bioassaying they had done on their own product, and I shared that information with NVSL. They responded with the info below. They like the feed extraction that Canada uses. See below.

While we're at it, I went to a meeting yesterday re PEDV and a lot of people talked about environmental sampling -- they called it "swiffering". I should have asked someone for clarification, but I expect they simply cut up swiffers (you know those floor dusting things?) and then do an extraction of that for PCR. Do you suppose the extraction from a Swiffer would be any different than from feed? I'm thinking it quite likely could be easier, but maybe you use the same method (that's easy) and the response is that you get a greater recovery in your extraction?

Also, people were talking about Ct values, and that analyzing some things they'd get a "strong" Ct of 18-20 range, or a "weak" Ct in the upper 30's. I'm not sure what to relate Ct to -- it is not quantitation of amount, but could it have something to do with signal strength or matching of base pairs, or something on that line?

Thanks!

Shannon

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-----Original Message-----

From: Swenson, Sabrina L - APHIS [<mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Monday, March 17, 2014 12:43 PM
To: Jordre, Shannon; Zack, Jonathan T - APHIS
Cc: Ferguson, Lisa A - APHIS; Hauer, Paul - APHIS; McCluskey, Brian J - APHIS; Scott, Aaron E - APHIS; Nelson, Eric; Krieger, Darlene; Schmitt, Beverly J - APHIS; Schiltz, John J - APHIS
Subject: RE: NVSL Bioassay results (APC)

Shannon,

Because we were having to reproduce what Canada did in order to be able to compare results, we attempted their extraction procedure. We also tried the procedure your lab provided to us so we could compare with your results. In both instances we used the same PCR method for testing. We found the Canadian sample dilution and extraction method did a better job of detecting nucleic acid.

We are happy to share with you what we did. Keep in mind this was only looking at plasma. We don't know about other feed/feed ingredients and impacts dilution/extraction may have on those types of materials. Our PCR is based on the U of MN assay and can be found at the link below. We are running the S and N gene PCRs.

http://www.cvm.umn.edu/cahfs/prod/groups/cvm/@pub/@cvm/@cahfs/documents/content/cvm_content_446868.pdf

Sabrina

From: [Krieger, Darlene](#)
To: [Jordre, Shannon](#)
Subject: RE: NVSL Report - reporting to APC
Date: Friday, April 04, 2014 4:08:09 PM

Shannon~

You should not have said anything about the results and let the district provide. We generally just relay the results to do not give reports unless requested. These is information that should only come from the district.

Thanks,
Darlene

-----Original Message-----

From: Jordre, Shannon
Sent: Friday, April 04, 2014 4:06 PM
To: Krieger, Darlene
Subject: RE: NVSL Report - reporting to APC

Darlene, He called, and the sample reports are sitting on my desk -- I'm not going to withhold the info. I summarized the results and told him he'd be getting the actual reports via KAN-DO in a few days.

I don't know why he didn't call the district, but he knows this is not a routine situation, and enough time has lapsed that he called around and figured out who to talk to. Plus, he met me in Des Moines a couple weeks ago, and has called 2-3 times since then.

Sending the lab reports in a minute.

SJ

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-----Original Message-----

From: Krieger, Darlene
Sent: Friday, April 04, 2014 3:49 PM
To: Jordre, Shannon; Nelson, Eric; Woody, Dillard; Proescholdt, Terry; Benz, Sharon A
Subject: RE: NVSL Report - reporting to APC

You are not planning on sharing the results are you? Can I ask why they called and did not call the district?

I will share with Kan-do

Thanks,
Darlene

-----Original Message-----

From: Jordre, Shannon
Sent: Friday, April 04, 2014 3:48 PM
To: Krieger, Darlene; Nelson, Eric; Woody, Dillard; Proescholdt, Terry; Benz, Sharon A
Subject: RE: NVSL Report - reporting to APC

Darlene, USDA gave permission to use their reports, and Eric said that was fine. I will scan them and send you a PDF file, and you can share them w/ KAN-DO. I will probably speak with APC before they get the results -- I just missed a phone call from them a few minutes ago. Thanks!

Shannon

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-----Original Message-----

From: Krieger, Darlene
Sent: Friday, April 04, 2014 3:44 PM
To: Jordre, Shannon; Nelson, Eric; Woody, Dillard; Proescholdt, Terry; Benz, Sharon A
Subject: RE: NVSL Report - reporting to APC

Shannon~

I thought we were waiting for USDA to decide on the results to share with APC. KAN-DO is ready when you let them know what they can say. If the information below is ok, I will forward on to KAN-DO and have them share.

Thanks,
Darlene

-----Original Message-----

From: Jordre, Shannon
Sent: Friday, April 04, 2014 3:21 PM
To: Nelson, Eric; Woody, Dillard; Proescholdt, Terry; Krieger, Darlene; Benz, Sharon A
Subject: RE: NVSL Report - reporting to APC

I had a call from Jon Zack at APHIS this afternoon -- a couple of questions re the call we had w/ KAN-DO the other day. It reminded me that as far as I know, we have still not reported the lab findings to APC -- I didn't get any feedback from anyone, and as a result forgot about it when other hot topics took over [REDACTED] (b) (5).

My original message (4:26 PM on Tuesday) contained an attached USDA lab report, if you want an example. Otherwise, the other option is something like this:

Sample Report:

NVSL received nine (9) porcine plasma samples collected by the FDA from the American Protein Company, Arion, IA, on February 21, 2014. These samples were tested by PCR for the presence of

FDA redaction [REDACTED]

PEDV RNA and all samples were positive. One additional sample (#10) is still pending.

Three of these samples (lot nos. D332614008, D332614010, and D332614004) were prepared and inoculated into 17-19 day old piglets (5 pigs/lot). Piglets were maintained separately by lot number. Positive and negative controls (5 pigs each) were also included in the study.

PCR results for the plasma-inoculated pigs were negative for PEDV RNA throughout the study (fecal swabs collected daily for 8 days). Serological results for the plasma pigs were negative for PED at Day 21 by IFA testing.

Positive control pigs were positive for PEDV RNA and antibodies.

Negative control pigs were negative for PEDV RNA and antibodies.

CVM Office of Research found 8 of the 10 samples to be positive for PEDV RNA by PCR.

This table summarizes the NVSL and CVM work on sample analysis

Sample Number	CVM PCR Result	NVSL PCR Result	NVSL Bioassay	Comments
14-007358	-	suspect		
14-005959	+	+	-	
14-005960	-	+		
14-005961	+	+	-	
14-005962	+	+		Homology closest to 2012 Asian PED virus sequence
14-005963	+	+		
14-005964	+	+	-	
14-005965	+	+		
14-005966	+	+		
14-005967	+	+		

What is your preference? I would like to use the actual USDA lab report.

Shannon

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-----Original Message-----

From: Jordre, Shannon
Sent: Tuesday, April 01, 2014 4:26 PM
To: Eric Nelson (eric.nelson@fda.hhs.gov); Woody, Dillard; Proescholdt, Terry; Krieger, Darlene; Benz, Sharon A
Subject: FW: NVSL Report - reporting to APC

Attached is the 10th sample report from NVSL as an example. Because they are dealing with animal diseases and there is confidentiality on many samples, they have that standard language on the top of the report "Sensitive But Unclassified....", and I wondered if they were okay if we shared these reports

as is -- they are. We collected the samples, and plan to notify the firm (APC), thus we can distribute these reports if we want to.

I like the idea of sharing the official report -- it is more transparent, and nothing is lost due to us paraphrasing, etc.... But let me know what you think re sharing the official lab reports.

Thanks!

Shannon

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-----Original Message-----

From: NVSL Case Coordinator [<mailto:NVSLCASECOORDINATOR@MGD.USDA.GOV>]
Sent: Tuesday, April 01, 2014 12:24 PM
To: Jordre, Shannon
Subject: NVSL Report - Accession#14-007358,Purpose:GEN_DIAG,Exam Req:PED sent to shannon.jordre@fda.hhs.gov

Submitter Name: Shannon Jordre

Submitter Company: Food & Drug Administration Center for Veterinary Medicine

Division of Compliance HFV-232

Referral Number: FDA Sample # 834816

FAD Number:

Accession: 14-007358

Date Received: 03/06/2014 09:45:30 AM

Purpose: General Diagnostic

Exam(s) Requested: PED

Submitter State: MD

Owner State: IA

Animal State:

From: [Swenson, Sabrina L - APHIS](#)
To: [Jordre, Shannon](#); [Yancy, Haile](#); [Myers, Michael J](#); [Hauer, Paul - APHIS](#)
Cc: [Schmitt, Beverly J - APHIS](#)
Subject: RE: PEDV assay results?
Date: Thursday, March 27, 2014 4:25:15 PM

Shannon,

The amount of data we have to go through is taking a little longer than expected. Reports should be to you next week.

Sabrina

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Wednesday, March 26, 2014 8:50 AM
To: Swenson, Sabrina L - APHIS; Yancy, Haile; Myers, Michael J; Hauer, Paul - APHIS
Cc: Schmitt, Beverly J - APHIS
Subject: RE: PEDV assay results?

Thanks, Sabrina! I heard from Haile yesterday, and he is hoping that they'll get our samples finished this week, too.

I would suggest that the two labs visit w/ each other directly on the finer points of the method(s) – you don't need to work through me – I haven't worked in a feed lab since 1990. That said, one of the outcomes of the meeting last week in Des Moines re PEDV was a list of prioritized research needs, and standardizing the bioassay, standardizing the PCR, and coming up with some type of surrogate for bioassay to determine viability were all high on the list.

Further, specific to PCR, there has been some discussion that the virus may be so virulent (I don't know if that's the right word or not) that even "PCR negative" feed could transmit the virus. Of course, there is always sampling error, or non-homogenous product, but the person who raised that question was talking about limit of detection, and is it possible to reduce the LOD by another order of magnitude or two.

Shannon

Shannon Jordre
Division of Compliance, HFV-232
FDA Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855

Phone: 240-276-9229
Fax: 240-276-9241
E-mail: shannon.jordre@fda.hhs.gov

From: Swenson, Sabrina L - APHIS [<mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Wednesday, March 26, 2014 9:08 AM
To: Jordre, Shannon; Yancy, Haile; Myers, Michael J; Hauer, Paul - APHIS
Cc: Schmitt, Beverly J - APHIS
Subject: RE: PEDV assay results?

Hi Shannon,

We are just wrapping up the bioassay for the 3 samples we tested. We plan to release the PCR results on the original submissions this week. The reports will come directly to you. We have not tested the last sample that came in after we started the bioassay. I wanted to keep diagnostic samples separate from the pigs samples so there would not be a question about any potential for cross contamination.

Have you completed your testing yet?

We did not have good luck trying to use the protocol provided by FDA for getting plasma into solution and extracted. We tried a side-by-side using the FDA technique and a technique provided by the Canadian lab [REDACTED] (b) (4) and found we did a better job of detecting positives with the Canadian method. Let us know if you would like us to provide you more details.

Sabrina

From: Jordre, Shannon [<mailto:Shannon.Jordre@fda.hhs.gov>]
Sent: Monday, March 24, 2014 3:24 PM
To: Yancy, Haile; Myers, Michael J; Swenson, Sabrina L - APHIS; Hauer, Paul - APHIS
Subject: PEDV assay results?

Good afternoon everyone! How is the PEDV analysis going? I'm getting pushed for lab results, and I have even heard some people suggest that they've heard unofficial results. But I have not heard anything, official or otherwise. Could you let me know where we stand?

Sabrina & Paul, I was in Des Moines last week for the PEDV meeting hosted by the National Pork Board. I know it has been very cold winter, and I was told fairly dry out there. Here in MD we've had some green grass all winter, but out there all I saw was gray sky and brown vegetation (the 2 days I was in town), albeit various shades of brown. Hopefully you start getting a little green-up of the grass soon!

Thanks!

Shannon

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From: [Swenson, Sabrina L - APHIS](#)
To: [Jordre, Shannon](#)
Cc: [Schiltz, John J - APHIS](#); [Hauer, Paul - APHIS](#); [Schmitt, Beverly J - APHIS](#)
Subject: RE: PEDv sample reports
Date: Monday, March 31, 2014 6:01:13 PM

Shannon,

There isn't a standardized protocol for doing bioassays for feed in pigs. We've heard a number of different ways that people have done assays. Our goal was to evaluate for infectivity using 2 methods-fecal shedding and seroconversion. This allowed us to have 2 measures to confirm our outcome. Therefore, all of our studies have gone out 3 weeks so we can get a blood sample and check for seroconversion. You may hear that some are doing much shorter time frames and focusing on shedding.

For the recent study, we attempted to mirror as closely as possible what Canada did since the purpose of the investigation was to confirm Canada's results. With the short time frame of notification and needing pigs (also getting them in the midst of a blizzard), and availability of rooms we opted to focus on the 3 samples that Canada ID'd as being in their study as that had the greatest chance of finding infectious material. Based on the number of pigs available and the need to confirm Canada's results, we divided the pigs up so as to allow the largest number of pigs per group for best opportunity of detection. In our instance we had 5 pigs. I believe Canada used 4 pigs. We made a 10% plasma homogenate. 25 mls provided via gastric tube and 25 mls provided orally via syringe following Canada's lead. Canada did use gas anesthesia for the gastric tube part, but we opted to tube awake. All pigs were housed by group (neg, pos, plasma 1, plasma 2, plasma 3). Our understanding is that all 3 plasma groups were housed together for the Canada study.

Regarding biosecurity, PED has become widespread in the U.S. so work in BSL-2 is probably sufficient. For our work, we did in BSL-3. Not due to the security needs, but because of room availability that would allow for each group of pigs to be housed individually and to allow for showers between animal rooms.

Sabrina

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Monday, March 31, 2014 10:54 AM
To: Swenson, Sabrina L - APHIS
Subject: RE: PEDv sample reports

Sabrina, A couple of follow-up questions:

What is the protocol for doing the bioassay? How many pigs does it take, what is the biosecurity requirement, etc...? We expect we're going to need to respond to questions about why only 3 samples were bioassayed.

Thanks!

Shannon

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Rockville, MD 20855

Phone: 240-276-9229
Fax: 240-276-9241
E-mail: shannon.jordre@fda.hhs.gov

From: Swenson, Sabrina L - APHIS [<mailto:mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Monday, March 31, 2014 9:19 AM
To: Jordre, Shannon
Subject: RE: PEDv sample reports

Correct.

From: Jordre, Shannon [<mailto:mailto:Shannon.Jordre@fda.hhs.gov>]
Sent: Monday, March 31, 2014 8:18 AM
To: Swenson, Sabrina L - APHIS
Subject: RE: PEDv sample reports

Thanks, Sabrina! Just to clarify, you only bioassayed the lots that Canada bioassayed?

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From: Swenson, Sabrina L - APHIS [<mailto:mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Monday, March 31, 2014 9:01 AM
To: Jordre, Shannon; Hauer, Paul - APHIS
Subject: RE: PEDv sample reports

That is correct, Shannon. Canada ID'd the lots that they had put into pigs so we put the same lots in pigs.

Sabrina

From: Jordre, Shannon [<mailto:Shannon.Jordre@fda.hhs.gov>]
Sent: Monday, March 31, 2014 6:58 AM
To: Swenson, Sabrina L - APHIS; Hauer, Paul - APHIS
Subject: PEDv sample reports

Good morning, Sabrina & Paul! Thanks for sending the lab reports Friday. I had received our PCR results from Haile late Thursday, and so put all the results into a simple spreadsheet for easier review – see the attachment. I only found results re bioassay on 3 samples, so wanted to check and see if more results will be forthcoming on the other samples, or if that is all you were able to do. Let me know. Thanks!

Shannon

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From: [Swenson, Sabrina L - APHIS](#)
To: [Jordre, Shannon](#); [Schiltz, John J - APHIS](#)
Subject: RE: Photos of plasma labels
Date: Monday, April 28, 2014 5:27:38 PM

Shannon,

I will have to double check on this for you. I recall having an extremely difficult time poking through the bag. I'm thinking possibly 2-3 layers with an internal plastic layer.

Sabrina

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Monday, April 28, 2014 3:06 PM
To: Schiltz, John J - APHIS; Swenson, Sabrina L - APHIS
Subject: RE: Photos of plasma labels

John, A copy of the CD would be nice – I can just put it in the case record, and delete the e-mail from my Outlook. If you send to the address below, that would work great.

What was the packaging? Paper only, paper w/ plastic lining, poly? Just curious. Thanks!

Shannon

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From: Schiltz, John J - APHIS [mailto:John.J.Schiltz@aphis.usda.gov]
Sent: Monday, April 28, 2014 3:57 PM
To: Jordre, Shannon; Swenson, Sabrina L - APHIS
Subject: RE: Photos of plasma labels

Here is about all I can find of the feed bag labels. Do you want me to copy the CD and send to you?

John

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Monday, April 28, 2014 2:41 PM
To: Schiltz, John J - APHIS; Swenson, Sabrina L - APHIS
Subject: RE: Photos of plasma labels

Thanks, John! What I was looking for was the last photo, showing the label of the finished feed product. I don't know if you have any others like that, showing feeding directions, storage directions, etc..., but if you do you could sent those to me.

Shannon

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Sent: Monday, April 28, 2014 1:09 PM
To: Swenson, Sabrina L - APHIS
Cc: Jordre, Shannon
Subject: RE: Photos of plasma labels

Don't know if these are what you are looking for or not. Maybe I should just have the CD copied and sent to you? Let me know.

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Ames, IA 50010
515-337-7551 (phone)
515-337-7348 (fax)
John.J.Schiltz@aphis.usda.gov

From: Swenson, Sabrina L - APHIS
Sent: Wednesday, April 23, 2014 3:07 PM
To: Schiltz, John J - APHIS
Cc: Shannon.Jordre@fda.hhs.gov
Subject: Photos of plasma labels

John,

Now that you have the CD from IES, please send a photo of each sample label to Shannon Jordre on

the cc line. This was raised on a call with FDA on 2/24/14, but hasn't been addressed yet.

Thanks!

Sabrina

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From: [Schiltz, John J - APHIS](#)
To: [Swenson, Sabrina L - APHIS](#)
Cc: [Jordre, Shannon](#)
Subject: RE: Photos of plasma labels
Date: Monday, April 28, 2014 1:13:52 PM
Attachments: [DSC_0008.JPG](#)
[DSC_0018.JPG](#)
[DSC_0017.JPG](#)
[DSC_0016.JPG](#)
[DSC_0015.JPG](#)
[DSC_0014.JPG](#)
[DSC_0013.JPG](#)
[DSC_0021.JPG](#)
[DSC_0020.JPG](#)
[DSC_0019.JPG](#)
[DSC_0037.JPG](#)
[DSC_0036.JPG](#)

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Crude Protein, min	78%
Crude Fat, min	0.3%
Crude Fiber, max	0.5%
Moisture, max	9%
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Sodium, max	3%

Export Only to Japan

This Product can be consumed by any species of animal
except for those listed below.

1. This feed must not be given to cattle, sheep, goats or deer.
(Caution: Giving this feed to cattle, sheep, goats, or deer is
subject to penalty.) 2. This feed must be stored in such a way
that it will not be mixed with feed (including raw materials)
used to manufacture the feed) for cattle, sheep, goats,
or deer.

Product of U.S.A.

Net Weight 25 kg (55.1 lb)
Manufactured by
APC, Inc Ankeny, IA 50021 SKU# 10301

商品名称
饲料の通称
製造業者の氏名
又は名称及び住所
輸入業者の氏名
又は名称及び住所
輸入先国名
粗たん白質の成分量の最小量
粗灰分の成分量の最大量
使用上及び保存上の注意

豚血しょうたん白(AP 920 Spray
Dried Porcine Plasma)
血しょうたん白
APC, Inc.
2425 SF Oak Tree Court Ankeny, IA
50021
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From: [Schiltz, John J - APHIS](#)
To: [Jordre, Shannon](#); [Swenson, Sabrina L - APHIS](#)
Subject: RE: Photos of plasma labels
Date: Tuesday, April 29, 2014 9:57:03 AM

I took pictures of the packaging this morning and have a small full-thickness piece of the bag. The bag is two outside layers of paper, a layer of plastic, and an inside layer of paper. The pictures will be included in the CD I am sending and the piece of the bag will be included as well.

John

From: Jordre, Shannon [mailto:Shannon.Jordre@fda.hhs.gov]
Sent: Monday, April 28, 2014 8:01 PM
To: Swenson, Sabrina L - APHIS; Schiltz, John J - APHIS
Subject: Re: Photos of plasma labels

Sabrina, no worries--just curious. It is an expensive, hygroscopic product, so when I saw the package I started wondering.

Shannon

From: Swenson, Sabrina L - APHIS [<mailto:Sabrina.L.Swenson@aphis.usda.gov>]
Sent: Monday, April 28, 2014 05:27 PM
To: Jordre, Shannon; Schiltz, John J - APHIS <John.J.Schiltz@aphis.usda.gov>
Subject: RE: Photos of plasma labels

Shannon,

I will have to double check on this for you. I recall having an extremely difficult time poking through the bag. I'm thinking possibly 2-3 layers with an internal plastic layer.

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