Qualitative Assessment of the likelihood of African swine fever virus entry to the United States: Entry Assessment

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Key Results: Illegal entry of swine products and byproducts presents the largest potential pathway for the entry of African swine fever virus (Table 1). Port inspection and interception data indicates that 1) air passenger baggage and foreign mail are two of the largest illegal pathways and 2) pork, ham, and sausage are the products with the highest interception rates. The interception data agrees with other studies that demonstrate potential entry of African swine fever virus other swine diseases through the air passenger pathway. While there are no studies that look at foreign mail as a pathway for entry of animal disease, our interception data, estimate of annual volume of packages entering the U.S., and estimate of product concealment in mailed packages indicates that foreign mail is an entry pathway that warrants greater analytical scrutiny similar to the air passenger pathway.

TABLE 1. SUMMARY OF EVALUATED LIKELIHOOD RATINGS BY PATHWAY

Pathway	Legal	Illegal
Live Pigs	Negligible, with low uncertainty	Negligible to low, with moderate uncertainty
Semen	Negligible, with low uncertainty	Low, with moderate uncertainty
Swine products and by-products	Negligible to low, with moderate uncertainty	High, with low uncertainty
Wildlife: Meat and Trophies	<Not reviewed>	Low to moderate, with high uncertainty
Feed (animal origin)	Low to moderate, with high uncertainty	Negligible to low, with high uncertainty
Feed (plant origin)	Negligible to moderate, with high uncertainty	Low, with high uncertainty
Feed (supplements)	Negligible to low, with high uncertainty	<No data to evaluate>
Fomites	<Not reviewed>	Negligible to moderate, with high uncertainty
Regulated Garbage	Low, with moderate uncertainty	<Not applicable>

Executive Summary

The likelihood of African swine fever virus (ASFv) entering the United States (U.S.) is variable depending on the pathway assessed. Illegal entry of swine products and byproducts presents the largest potential pathway for the entry of ASFv. We qualitatively evaluated the likelihood of human-assisted entry of ASFv to the U.S. via legal[1] and illegal[2] movements of potentially infected animals and contaminated products from African swine fever (ASF)-affected countries/regions. We evaluated imports of live animal, animal products, and animal feed ingredients occurring through commercial cargo, air passenger baggage, cruise ships, international mail, border crossings, regulated garbage from ship and airliners coming from outside the U.S., and fomites. The purpose of this analysis was to determine the transboundary pathways representing the greatest likelihood of entry for ASFv into the U.S., and to identify pathways where limited data or high uncertainty occur to highlight areas for future investigation. We did not evaluate exposure pathways (how the virus may reach susceptible pigs) or probability of infection following potential exposure: therefore, we cannot make any definitive statements about how likely the transboundary pathways evaluated would result in an ASF outbreak in U.S. pig populations.

Animal feed ingredients and fomites have the potential to be pathways associated with a moderate likelihood of ASFv entry, but there is high uncertainty because of the lack of data on transmission from these sources. Most of the available evidence is based on virus survival in fecal matter and a single feed ingredient study. The likelihood of transmission from these pathways relies on the assumption that a large enough infectious dose continues to survive unadulterated through various processing and shipping steps, none of which are adequately described or quantified. While fomite transmission via footwear may have small approach rates, the volume of air passenger traffic combined with potential underreporting of declared visits to farms elevates the likelihood of fomites entering the U.S. undetected. More research and/or data collection on these transmission pathways would reduce the uncertainty of these preliminary estimates.

We considered the following factors when rating the likelihood of ASFv entry:

1. The overall volume of imports in terms of passengers, animals, shipments, etc. that could potentially be contaminated
2. Inspection effort and detection efficiency
3. The number and effectiveness of various regulatory and mitigation actions to reduce disease prevalence/transmission along the pathway such as diagnostic testing, treatment, disinfection, certificates of animal health, compliance agreements, product labeling/traceability, quarantine, regionalization, etc.
4. Available research to quantify viral prevalence, survival, and/or transmission probabilities by pathway

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[1]The formal entry of shipped goods which has filed appropriate entry documents (entry manifest, permits, veterinary certificates, etc), has passed inspection and compliance checklists, is authorized for entry by CBP according to various CFRs, and has paid duties to enter the country. https://www.cbp.gov/sites/default/files/documents/Importing%20into%20the%20U.S.pdf

[2]The informal entry of items under "personal use" that would be rejected entry due to exceeding personal allowances for consumption or animal health concerns via various CFRs.

Background

ASF is a highly contagious and deadly viral disease affecting both domestic and feral (wild) pigs in all age groups. ASF has been detected in multiple countries on the Asian, European, and African continents. Since September 2018, the World Organization for Animal Health (OIE) reported the following countries as having new ASF outbreaks in swine or wild boar populations: Belgium, Bulgaria, China, Hungary, Latvia, Lithuania, Moldova, Mongolia, Poland, Romania, Russia, Ukraine, Vietnam, and Zimbabwe[3]. The United States is currently free of ASF.

According to the OIE technical disease card[4], ASFv is extremely stable in the environment (Table 2). Some research has documented viral survivability according to different environmental conditions. However, this varies according to temperature, humidity, pH, presence of organic matter, and exposure to various chemicals.

TABLE 2. ASF RESISTANCE TO PHYSICAL AND CHEMICAL ACTION, FROM THE OIE ASF TECHNICAL DISEASE CARD.

Temperature	**Highly resistant to low temperatures. Heat inactivated by 56°C/70 minutes; 60°C/20 minutes**
pH	Inactivated by pH <3.9 or >11.5 in serum-free medium. Serum increases the resistance of the virus, e.g. at pH 13.4 – resistance lasts up to 21 hours without serum, and 7 days with serum.
Chemicals/Disinfectants	Susceptible to ether and chloroform. Inactivated by 8/1000 sodium hydroxide (30 minutes), hypochlorites – 2.3% chlorine (30 minutes), 3/1000 formalin (30 minutes), 3% ortho-phenylphenol (30 minutes) and iodine compounds.
Survival	Remains viable for long periods in blood, faeces and tissues; especially infected, uncooked or undercooked pork products. Can multiply in vectors (Ornithodoros sp.)

Results

The likelihood that ASFv will enter the U.S. through the legal importation of live pigs is *negligible* with *low uncertainty*. These estimates are based on:

- All live animal imports are from countries that are currently free of ASF (primarily Canada)
- Various regulatory and import requirements relating to animal health mitigate the likelihood of ASFv transmission, if properly implemented
- High quality and availability of live animal import data reduces uncertainty of likelihood rating

The likelihood that ASFv will enter the U.S. through the illegal importation of live pigs is *negligible to low* with *moderate uncertainty*. These estimates are based on:

- Available data across three databases report zero interceptions of smuggled live pigs in recent years

[3] *http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/ASF/Report_12_Current_situation_ASF.pdf*

[4] *http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/AFRICAN_SWINE_FEVER.pdf*

- Increasing U.S. demand for imported wildlife/wildlife products increases the likelihood of illegal importation, despite no reports of interceptions
- Imports likely underreported as there may be a bias of inspection toward CITES wildlife and wildlife products, increasing likelihood estimate
- Uncertainty with regard to accuracy of data reporting increases uncertainty to moderate

The likelihood that ASFv will enter the U.S. through the <u>legal importation of semen</u> is *negligible* with *low uncertainty*. These estimates are based on:

- All semen imports are from countries that are currently free of ASF
- Various regulatory requirements and import requirements relating to animal health mitigate the likelihood of ASFv transmission, if properly implemented
- High quality and availability of semen import data reduces uncertainty of the likelihood rating

The likelihood that ASFv will enter the U.S. through the <u>illegal importation of semen</u> is *low* with *moderate uncertainty.* These estimates are based on:

- Few occurrences of Customs and Border Protection (CBP) - Emergency Action Notification-related semen interceptions, with none from ASF-affected countries suggests a low volume approach rate along this pathway
- No mechanism for querying semen-only data in the CBP Agricultural Quarantine Inspection Monitoring (AQIM) or Work Accomplishment Activity Data System (WADS) which increases uncertainty of actual volume of interception
- The relatively low volume of illegal semen interceptions occurring via international mail with uncertainty of whether the semen is swine-origin
- The relative ease of such shipments evading import restrictions compared to live animals due to low mail inspection rates and high mass volume

The likelihood that ASFv will enter the U.S. through the <u>legal importation of swine products and by-products</u> is *negligible to low* with *moderate uncertainty*. These estimates are based on:

- Zero import volume for pork products from ASF-affected countries. Imports are limited to swine by-products
- Various regulations in place that either prohibit entry or subject these products to various additional processing measures to inactivate disease-causing agents reduces the likelihood of entry
- Conflicting or insufficient evidence on OIE treatment recommendations to inactive ASF virus increases uncertainty and likelihood estimates
- Uncertainty with regard to detailed processing/handling of hog casings imported or re-imported from ASF-affected countries

The likelihood that ASFv will enter the U.S. via the <u>illegal entry of swine products and by-products</u> is *high* with *low uncertainty*. These estimates are based on:

- High volume of arrivals and the variety of human-assisted movement pathways increase likelihood even with very low prevalence of infectivity
- Low inspection rates at ports of entry increase likelihood that products enter the U.S. undetected
- Available interception and inspection databases are either complete or have been supplemented to reduce uncertainty

- Certain pathways were discontinued from the AQIM surveillance program, so unbiased approach rates are no longer available for cruise ships, express couriers, etc. However, WADS continues to report high volumes of swine products interception on these pathways, reducing uncertainty
- Imperfect detection efficiency of X-ray scanners compared to manual inspection increases likelihood
- Evidence of ASFv contamination in swine products intercepted at other foreign airports, though there is uncertainty in the prevalence of infectivity for U.S. imports

The likelihood that ASFv will enter the U.S. via the illegal entry of swine bush meat or wild animal parts is *low to moderate* with *high uncertainty*. These estimates are based on:

- Low volume of bushmeat/trophies reported as being intercepted compared to other pathways
- Increased uncertainty in import volume as there may be bias of inspection toward CITES wildlife and wildlife products
- Increasing U.S. demand for imported wildlife/wildlife products might increase likelihood of illegal import
- The U.S. and other countries report illegal entry of bush meat from countries affected by ASF
- Uncertainty of whether intercepted bush meat or animal parts were of swine origin
- No data available on the detection rate of wildlife import violations, particularly undeclared imports

The likelihood that ASFv will enter the U.S. via legal importation of animal-origin feed ingredients from ASF countries is *low to moderate* with *high uncertainty*. These estimates are based on:

- Large percentage of slaughtered animal by-products imported to the U.S. originate from ASF-affected countries increases likelihood of entry
- Uncertainty in the reporting of volume as shipments lines instead of weight makes it difficult to estimate entry likelihood relative to other pathway import volumes.
- Survivability of ASFv in raw pork products and high ASFv titers in blood from infected animals suggest similar survivability in slaughtered animal by-products if insufficiently treated
- Persistence of ASFv in blood (a relatively high protein matrix) for extended periods in the environment
- Rendering and other manufacturing processes may inactivate ASFv (lowering the likelihood rating), but there is insufficient information available to evaluate the sufficiency of these practices
- Uncertainty associated with data for slaughtered mammal by-product imports which do not indicate a processing step that could inactive ASFv (such as heat treatment)
- Uncertainty introduced by the inclusion of mixed or prepared feeds to the analysis which have unknown processing standards (such as during pelletization)

The overall likelihood that ASFv will enter the U.S. via illegal entry of animal-origin feed ingredients is *negligible to low* with *high uncertainty*. The overall rating is due to:

- Extremely low approach rates for prepared animal feeds and no interception volume for slaughtered animal by-products from AQIM.

- Uncertainty introduced by non-specific reporting of slaughtered animal by-products/feed ingredients in WADS. Closest category of interest may be inedible swine products which includes many non-target commodities.
- Uncertainty introduced by AQIM database reporting issues that required supplemental datasets for negative data
- Certain pathways were discontinued from the AQIM surveillance program and are no longer available for analysis
- Uncertainty introduced by the assumption that personally transported/smuggled animal blood, parts, skins, or carcasses could be treated as food scraps for backyard feeding or as ingredient for making a mixed feed
- Uncertainty of the level of ASFv infectivity of prepared animal feeds, if any

The likelihood that ASFv will enter the U.S. via the <u>legal importation of plant-origin feed ingredients</u> from ASF countries is *negligible to moderate* with *high uncertainty*. These estimates are based on:

- Moderate to high percentage of soybean imported to the U.S. originate from ASF-affected countries increases likelihood
- Low percentage of mixed/prepared animal feeds imported to the U.S. originate from ASF-affected countries reduces likelihood
- Uncertainty in the reporting of volume as shipments lines instead of weight makes it difficult to estimate entry likelihood relative to other pathway import volumes
- Likelihood estimates rely on assumption of plant contamination from viral shedding in the fields:
  - Variability in the degree of shedding of ASF viruses in feces depending on the virus strain, where higher titers in feces could be reached for some virus strains in a small proportion of infected pigs
  - Uncertainty in the rate of inactivation of ASF viruses in moist or dry feces at different temperatures over time
  - The relatively higher dose required for oral transmission of ASF viruses and outcomes from oral feeding trials from several studies
- A single study indicates potential for ASFv (Georgia 2007 isolate) to persist post-inoculation in various feed ingredients under a 30-day simulated shipping model.
- Uncertainty due to unknown processing and manufacturing processes at feed mills that would affect ASFv survivability in prepared feeds

The overall likelihood that ASFv will enter the U.S. via an <u>illegal plant-origin feed pathway</u> to be *low* with *high uncertainty.* The overall rating is due to:

- Extremely low approach rates for pathways with available data in AQIM
- Uncertainty introduced by AQIM database reporting issues which required supplemental datasets for negative data
- Certain pathways were discontinued from the AQIM surveillance program and are no longer available for analysis
- Uncertainty as to whether the intent of the intercepted plant products was for animal feed
- Uncertainty of rate of ASF contamination of intercepted feed ingredients, if any

The likelihood that ASFv will enter the U.S. via the <u>legal import of animal feed supplements</u> is *negligible* to *moderate* with *high uncertainty*. These estimates are based on:

- Low import volume relative to other feed ingredients but high variety of supplement types increases likelihood
- Uncertainty in the reporting of volume as shipments lines instead of weight makes it difficult to estimate entry likelihood relative to other pathway import volumes
- Uncertainty associated with a single study of ASFv persistence in animal feed ingredients which indicated potential persistence in choline inoculated with ASFv, but not lysine or Vitamin D
- Uncertainty due to lack of ASFv persistence studies in other types of feed supplements
- Uncertainty due to unknown processing and manufacturing processes at feed mills that would affect ASFv survivability in prepared feeds
- Uncertainty due to lack of data on infectious dose via contaminated feed supplements

The likelihood that ASFv will enter the U.S. via <u>fomites</u> is *negligible to moderate* with *high uncertainty*. These estimates are based on:

- An extremely low approach rate for air passengers with shoes or clothing contaminated with soil or other substances that requires cleaning/disinfection from all countries of origin decreases likelihood
- Approach rate for air passengers with contaminated shoes or possessions is zero from ASF-affected countries of origin decreases likelihood
- Targeting efficiency of intercepting passengers with soiled footwear appears to be declining in recent years, which may also underreport the approach rate, potentially increasing the likelihood
- Potential underreporting of contaminated footwear based on bias toward passenger declaration of farm visitation, which would underestimate the approach rate.
- Lack of available data for other fomite vectors (cloth, contact surfaces, etc), which would underreport the likelihood for this pathway
- Variability in the degree of shedding of ASF viruses in feces depending on the virus strain, where higher titers in feces could be reached for some virus strains in a small proportion of infected pigs
- ASFv remains infectious in pig faeces for up to 5 days at 70°F or 14 days at 40°F, indicating potential for temporal windows of transport via shoes/clothing, increasing the likelihood. However, there is a lack of data on ASFv persistence in soil contaminated with excreta and on various media (clothing, shoes, tires, etc)

The likelihood that ASFv will enter the U.S. via <u>regulated garbage</u> from countries where ASF is present is *low* with *moderate uncertainty*. These estimates are based on:

- Stringent regulations from the Code of Federal Regulations and the Swine Health Protection Act mitigates the likelihood of entry
- The low rate of inspection on vessels and aircraft for regulatory garbage compliance increases likelihood that contaminated garbage could enter the U.S. undetected
- The combination of the high volume of ship arrivals and a low violation rate on aircraft/vessels combined with a high compliance rate of garbage handling facilities that handle removal, transport, and treatment suggests a low likelihood of ASFv entry
- Uncertainty introduced via unknown process for targeting spot inspections for ships and aircraft most likely to be in violation of regulations
- Uncertainty introduced due to unknown false negative detection rate of inspectors

Definitions of Categories

For the purposes of this qualitative assessment, we assigned a qualitative likelihood rating. Tables 3 and 4 define the terminology that were applied for expressing likelihoods.

TABLE 3. DEFINITION OF LIKELIHOOD CATEGORIES FOR THIS QUALITATIVE ASSESSMENT

Term	Definition
Negligible	This event would almost certainly never occur
Low	This event would be unlikely to occur
Moderate	This event would be nearly as likely to occur as not to occur
High	This event would be likely to occur
Very High	This event is almost certain to occur

TABLE 4. DEFINITION OF LEVELS OF UNCERTAINTY

Term	Definition
Low	Available data is well supported, reliable, complete, accessible from multiple sources or published references, and are in general agreement.
Moderate	Data is available, and has few issues with interpretability, potential biases, reliability, insufficient attribute resolution, and/or underreporting.
High	A complete lack of available data *OR* some data is available but may be incomplete, unreliable, from a small number of published sources, and/or demonstrates conflicting evidence. Includes the combination of anecdotal evidence, personal communications, and expert opinion with available published data.

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