Risk Assessment for the Transmission of Foot and Mouth Disease via Movement of Swine and Cattle Carcasses from FMD-infected Premises to a Disposal Site

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UNIVERSITY OF MINNESOTA

CENTER FOR ANIMAL HEALTH AND FOOD SAFETY

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
CFR	Code of Federal Regulations
DOT	Department of Transportation
EMRS	Emergency Management Response System
FAD	Foreign Animal Disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
FMD	Foot and Mouth Disease
FMDv	Foot and Mouth Disease virus
FMCSA	Federal Motor Carriers Safety Administration
FSIS	Food Safety Inspection Service
NASS	National Agricultural Statistics Service
NAHEMS	National Animal Health Emergency Management System
OIE	World Organization for Animal Health, Office International des Epizooties
US	United States of America
USDA	United States Department of Agriculture
USDA FAD PReP	United States Department of Agriculture Foreign Animal Disease Preparedness and Response Plan
VS	Veterinary Services

Definitions

Bio-Zip™ Liner

Bio-containment bags which are constructed of a thermally-bonded layering of polypropylene and featuring an industrial zippering system, The Bio-Zip™ Sealable Liners fit securely inside industrial roll-off containers, trailers or truck racks from 10 to 40 cubic yards in total volume. They are used to manage large volume biological and organic waste streams and the associated odor, leakage, disease and environmental contamination issues. **Disclaimer: The document is not endorsing the product of a specific vendor, but merely used the data on this product as an example**.

Carcass — The body of an animal that has died or been killed, and is not being slaughtered for human or animal consumption.

Collecting station

An establishment where carcasses may be placed for temporary holding until loaded on trucks.

Confirmed positive case (of FMD)

An animal with clinical signs consistent with FMD and from which FMDv is isolated and identified in a USDA laboratory or other laboratory designated by the Secretary of Agriculture.

Control Area — Consists of an infected zone and a buffer zone. Initially, the entire State, Commonwealth, Tribal Nation, or territory may be declared a control area and subject to movement restrictions until appropriate surveillance and epidemiological evidence has been evaluated and the extent of the outbreak is known.

Decomposition

The process by which organic substances are broken down into simpler forms of matter

Dump Truck — A standard dump truck is equipped with an open-box bed, which is hinged at the rear and equipped with hydraulic pistons to lift the front, allowing the material in the bed to be deposited on the ground behind the truck at the site of delivery. The truck does not have a sealed tailgate.

Fomites Inanimate objects that, when contaminated with a viable disease agent, can serve as a source of infection for a susceptible host.

Grapple A hydro-mechanical device able to rotate on an axis with a clamshell or bucket attached at the end of the boom, which is intended for the collection of large items, in this case carcasses

Hazardous Material

A substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C. 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table of 49 CFR 172.101), and materials that meet the defining criteria for hazard classes and divisions in part 173 of subchapter C of this chapter.

Herd The population of animals at defined premises.

Incubation period

The known or assumed period between the introduction of a pathogen into a susceptible animal and the occurrence of the first clinical signs of the disease; the OIE standard for FMD is 14 days.

ID_{50} Infectious Dose 50; amount of pathogen measured as number of colony forming units (CFU) for bacteria or number of virus particles required to infect 50% of exposed individuals.

Index premises

The first premises known to have a case of FMD during the outbreak under investigation. The true index premises are the premises with the first actual case in an outbreak; it is often not definitively determined.

Infected premises

Premises where a presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, case definition, and international standards

Leakage — The body fluids that have the potential to leak from the intact carcass post-mortem. These include feces, urine, stomach/rumen contents, blood, saliva, and milk spillage

Leachate — Liquid that is produced by the decomposition of livestock carcasses and seeps from the carcasses.

Leak-Proof Liner

A temporary durable sheet lining (made of plastic, vinyl, etc.) placed in the container of the truck and used to protect the bed and sidewalls of the cargo space of truck trailers

PFU — Plaque-forming unit; used in virology studies to estimate the quantity of viral particles present in a sample based on the number of plaques formed per unit volume.

Premises — A location where livestock are raised, housed, or pass through during commerce.

Rendering truck

Tractor-trailer truck with detachable trailer box and a leak-proof tailgate specifically designed for rendering. Trailer specifications can vary in length from 26 to 40 feet (most common are 28, 32 and 40 feet) with standard width of 8 feet and height of 12 feet.

Roll-Off Truck

Tractor-trailer truck with detachable box trailer which is able to be removed from the trailer component. They are characterized by a rectangular footprint, utilizing wheels to facilitate rolling the trailer in place. The open top container is designed to be transported by special roll-off trucks. As the roll-off truck raises its hydraulically operated bed, the roll-off container rolls off of the bed. A cable is used to slowly lower the container. These can operate on a winch system or a hook-lift system.

Saprophytic decomposition/putrefaction

One of the stages of decomposition, produced mainly by the action of bacterial enzymes, mostly anaerobic organisms derived from the gastrointestinal tract, causing hemolysis, disintegration of tissue, and gas formation in blood vessels and tissue spaces.

Stamping out

Depopulation of clinically affected and all presumed exposed susceptible animals.

Spillage — Seeping of carcass fluids from the carcass to the truck and then to the environment.

Tarp — A sheet of material, such as waterproofed canvas, vinyl coated polyester mesh, etc. which is used to cover the open trailer to protect contents from visibility or ejection of material.

$TCID_{50}$ — Tissue Culture Infective Dose 50; amount of a pathogen measured as number of virus particles required to produce pathological change in 50% of cell cultures inoculated, expressed as $TCID_{50}$/mL.

Truck — A vehicle or conveyance used for the transportation of carcasses.

Stages of disease:

Infected — Includes all stages of disease (L+I+C): latent (L), pre-clinically infected (I) and clinically infected (C).

Viremic — Active virus circulating in the bloodstream. Susceptible species can be viremic and shedding virus before they develop clinical signs. Includes the pre-clinical (I) and clinical (C) stages of disease in this risk assessment.

Incubation period

Time from exposure to the development of clinical signs.

Pre-clinically infected stage (I)

Animal is viremic, is shedding virus, but does not have clinical signs. These animals represent the highest risk for spread of virus.

Clinically infected stage (C)

Animal is viremic, shedding virus and is exhibiting clinical signs of disease.

Latent (L) Susceptible animal that has been exposed and is incubating the virus, but is not viremic.

Recovered (R)

No longer infected with the virus.

Susceptible (S)

Healthy animal likely to be exposed to the virus.

Executive Summary

The present risk assessment proactively evaluated the risk of infecting susceptible livestock by the movement of Foot and Mouth Disease (FMD) infected carcasses (swine and cattle) from FMD infected premises. The risk assessment evaluated the most up to date available science and solicited opinion from experts when data was lacking. This risk assessment is proactive in nature and the scenarios, pathways and depopulation practices assessed were based on the current practices and regulations applicable during an animal disease outbreak in the US. The characteristics, types of conveyance methods, and equipment used to transport the infected carcasses were provided from expert opinion and verified through site visits. Different modeling techniques were used to estimate the number of infected animals during a FMD outbreak at various time intervals, the total time estimated from infection to depopulation and the total amount of FMD virus (FMDv) contained in a disposal truck. The main outcomes of the risk assessment should be reviewed if needed as new data becomes available in the future.

Risk estimation: The risk of FMD infection of susceptible livestock associated with the movement of swine and cattle carcasses from FMD infected premises to a disposal site during a FMD outbreak in the United States is **negligible** when using a standard rendering truck (tailgate sealed and tarp cover) and a Bio-Zip™ bag, and between **negligible and low** when using a standard rendering truck or a roll-off /dump truck with a Bio-Zip™ bag. The risk level in other scenarios (uncovered standard rendering trucks, uncovered roll-off/dump trucks, covered roll-off/dump trucks and a liner) is between **moderate and high**.

Main results: Time for FMD detection was estimated by a disease spread model to be between 4-10 days for swine and beef cattle and 3-9 days for dairy cattle premises of different sizes. Total time from infection to depopulation (including detection and confirmation) for the first FMD infected case was estimated to be between 10-15 days for swine, 8-12 days for dairy and 10-14 days for beef cattle premises. Total time estimated for subsequent FMD cases was between 7-12 days for swine, 6-9 for dairy and 8-11 days for beef cattle premises. Most of the animals (>65% for the first case and >81% for subsequent cases) were viremic at the time of depopulation. The average concentration of FMDv in a carcass in experimental inoculation studies was 10^3 Plaque-Forming Unit per gram (PFU/g) for a pig carcass and 10^6 PFU/g for a cattle carcass. The total amount of infected carcasses moved to the disposal site (relative to the size of the animal carcass and the capacity of the truck trailer) was between 23-390 cattle carcasses and 117-780 pig carcasses per truck. Any small amount of body fluids (1 mL) would contain virus that is equal and greatly exceeds the infective dose by oral and inhalation route for pigs and cattle. The likelihood that swine and cattle carcasses moved from FMD positive premises will contain an infective dose was high. The use of a Bio-Zip™ bag in a standard rendering truck (tailgate sealed and tarp cover) reduces the likelihood of leakage, spillage and aerosolization to negligible.

1. Background

This risk assessment was performed by the University of Minnesota's Center for Animal Health and Food Safety to proactively evaluate the risk of moving swine and cattle carcasses to an offsite disposal location, from a Foot and Mouth Disease (FMD) confirmed positive premises during a FMD outbreak in the United States (US), as it relates to potential spread to susceptible livestock.

In the event of a FMD outbreak in the US, Local, State and Federal authorities will implement a foreign animal disease emergency response as described in the USDA Animal and Plant Health Inspection Service (APHIS) Framework for Foreign Animal Disease Preparedness and Response Plan (USDA FAD PReP). This response includes a control and eradication strategy that will utilize depopulation, quarantine, vaccination, and movement control measures applied throughout the swine and cattle industry. If depopulation is utilized, due to the large amount of biomass from carcasses and potential limitations on the premises of origin for disposal, there may be a need to transport carcasses offsite for disposal. This movement has the potential to result in virus spread to other uninfected premises and susceptible livestock.

Risk assessment in the animal health context comprises a framework that uses a tool set and available scientific information to assess the situational level of risk to the health of an animal population and the potential consequences. Completing this type of risk assessment in a timely manner during an outbreak is typically impractical. Risk assessment conducted proactively, before an outbreak occurs, provides the framework necessary for decision makers to identify the risk pathways for disease transmission. They are thus equipped to quickly assess the effectiveness of the current practices, preventive measures and additional mitigation measures, if needed, as they pertain to the risk associated with the movement of an agricultural commodity.

2. Scope

The purpose of this risk assessment is to determine the risk of FMDv infection of susceptible livestock associated with the movement of swine and cattle carcasses from a FMD-infected premise to an off-site disposal facility during a FMD outbreak in the United States. The risk evaluation is based on the likelihood of FMDv being present in the carcasses at the time of transportation and the likelihood their movement could serve as a source of infection for susceptible livestock. The risk assessment evaluates the likelihood that: 1) the swine and cattle carcasses from a FMD-infected premises will contain an infective FMDv dose after completion of euthanasia; 2) FMDv could be released into the environment from the carcasses through post-mortem leakage of infected body fluids and/or aerosolization of infectious particles from the body fluids; and 3) susceptible livestock will be infected by FMDv during the transportation of carcasses from the infected premises to the disposal site.

The primary mode of transportation evaluated for carcass movement from the FMD-infected premises of origin directly to a disposal site is a <u>rendering truck</u>. This is defined as a tractor-trailer truck equipped with a box trailer (lengths of 28 ft, 32 ft, or 40 ft) that has a sealed, leak-proof tailgate and is open on the top. The second type of truck that will be considered in this risk assessment is the <u>roll-off truck</u>. This truck has a removable open-top, box trailer that is fitted onto a rectangular footprint and utilizes wheels to facilitate rolling the trailer into place. The third type of truck that will be considered is the <u>dump truck</u>. A standard dump truck is equipped with an open-box bed, which is hinged at the rear and equipped with hydraulic pistons to lift the front, allowing the material in the bed to be deposited on the ground behind the truck at the site of delivery. The standard rendering truck, roll-off and dump truck will be considered with and without the following mitigations (one or in combination) that can be used in conjunction with the standard trailer:

1) Tarp covering
2) Bio-Zip™, leak-proof carcass bags
3) Leak-proof liner (only for roll-off and dump trucks)

For each of the transportation modes, the following release and exposure pathways were addressed:

- Cross-contamination of trucks, personnel and equipment from carcass fluids contaminated with FMDv escaping from the conveyance.
- Aerosol transmission of FMDv particles escaping from the conveyance.

3. Assumptions

A conservative approach using the "worst-case" scenario was used in this risk assessment. Literature data on FMDv concentration in swine and cattle carcass tissues consider animals artificially inoculated with FMDv at high concentrations, which may not represent the reality of a naturally occurring outbreak.

This risk assessment takes into consideration all applicable regulations, including preventive measures already in place, as well as additional preventive measures that could be implemented during an outbreak. This assessment is proactive in nature and cannot address the specific circumstances surrounding an outbreak in detail. Therefore, we are making some assumptions to establish context and applicability. These assumptions are:

- A FMD outbreak in the United States in the commercial pig and/or cattle (beef or dairy) population has occurred.
- A swine or cattle farm has been confirmed as a FMD-infected premises and a specific euthanasia protocol has been established as the depopulation method.
- All animals in the infected premises will be euthanized and moved to disposal offsite as intact carcasses.
- All disposal options have been predetermined so that the time to locate is not part of the delay of the disposal.
- Time to complete indemnity was not included in the estimation of total time from infection to depopulation due to the assumption that this is not a time limiting step.
- The movement considered will be from one infected premises directly to the disposal site, without any subsequent stops along the route.
- The same trucks, personnel and/or equipment will not be shared among multiple infected premises without complete cleaning and disinfection.
- Carcasses will be moved immediately after euthanasia, so environmental factors (temperature, pH) will not have an effect on FMDv concentration in the carcass.
- Post-mortem autolysis will occur, and there will be some leakage of fluids from the intact carcasses. As fresh carcasses will be moved immediately after euthanasia, there will be little saprophytic decomposition/putrefaction. We assume minimal rigor mortis at the onset of loading due to the short time between euthanasia and carcass loading.
- The tarp (roll-off or drawn down) will be appropriately cleaned and disinfected prior to each load and following each unloading or there will be a new tarp utilized for each trip.
- Options and mitigations evaluated were provided to the risk assessment team and were evaluated for their impact on the risk pathways. They were not evaluated for their functionality. We assume all mitigations considered (e.g. Bio-Zip™ bag, liner, tarp,

equipment, cleaning and disinfection procedures) will function appropriately and/or be performed according to their specifications.

- The exterior surfaces of trucks and tires will be cleaned and disinfected prior to leaving the infected premises, as well as at disposal area following drop off, and will follow accepted procedures outlined in the USDA APHIS FAD Prep Guidance (USDA FAD PReP)
- Wildlife population pathways will not be considered in this risk assessment.
- Roads taken by the disposal trucks will be shared with the open traffic.
- All vehicles will be in compliance with federal and applicable state Department of Transportation (DOT) regulations and APHIS carcass transportation regulations, including that all vehicles used in transportation of carcasses will be leak-proof.
- The driver of the carcass truck will not come into contact with any carcasses or infected equipment while on the infected premises, the carcass loading area or the carcass unloading areas at the disposal site.

4. Overview of data analysis approaches

Risk Assessment Overview

This risk assessment is based on the OIE guidelines and methodology for import risk analysis with some modifications (OIE, 2004). The OIE model is comprised of hazard identification and three steps within a risk assessment: 1) entry assessment (release of virus to the environment through the carcasses); 2) exposure assessment (exposure of susceptible animals); and 3) risk evaluation (considers the entry and exposure assessments to provide the overall risk estimation). The emphasis of this risk assessment is the release of FMDv associated with the movement of swine and cattle carcasses from a FMD positive premises and exposure of susceptible livestock. If the entry assessment demonstrates a negligible likelihood of the carcass being contaminated with FMDv, the risk assessment may be concluded. However, if the risk is estimated to be greater than negligible, the next step in the risk assessment is the exposure assessment, which would assess the likelihood that susceptible animals will be infected by FMDv through the movement of carcasses from FMD positive premises.

As recommended by the OIE, the risk analysis process is described as follows:

- Hazard identification is the process of identifying and understanding the biology and epidemiology of FMD and FMDv to determine whether the agent is a hazard under specified situations.
- Entry assessment determines the likelihood of an agricultural commodity (e.g. carcass) being infected or contaminated with a hazard (e.g. FMDv) and describes the biological pathways

necessary for that hazard to be introduced into a particular environment with susceptible livestock. It includes an estimation of the likelihood (i.e. qualitative or quantitative) of each of the pathways.

- Exposure assessment describes the biological pathway(s) necessary for exposure of animals to the identified hazard (e.g. FMDv) and estimates the likelihood of those exposures occurring.
- Risk estimation consists of integrating the results from the entry and exposure assessments to produce summary measures of the risk associated with the identified hazard.

Likelihood and risk evaluation

The likelihood for each pathway was assessed and categorized using the descriptive scale in Table 1 below:

Table 1: Descriptive scale to estimate the likelihood for an event to occur

Likelihood	Descriptive Definition
High	The event is very likely to occur
Moderate	The event is unlikely but does occur with a certain probability
Low	The event is unlikely to occur
Negligible	The likelihood that the event will occur is insignificant, not worth considering

The risk estimation was based on the summarization of the likelihoods for each pathway in the entry and exposure assessments.

Uncertainty estimation

The uncertainty of the likelihood/risk estimation was assessed by using a range within the descriptive definitions in Table 1. When uncertainty about the estimation was low (the estimation was somewhat certain), only one descriptive definition was used to estimate the likelihood/risk (e.g., low, high). When the uncertainty on the estimation was moderate or high the descriptive definition used to estimate the likelihood/risk was within a range (e.g., between moderate and high), the range being broader as the uncertainty about the estimation was higher.

Modeling Overview

A within herd stochastic disease spread model was applied to simulate the transmission of FMDv within a group and estimate the number of pigs, dairy cattle and beef cattle in various disease states at each time period. The disease states include: susceptible (S), latent (L), pre-clinically infectious (PI), clinically infectious (CI) and recovered (R) (Carpenter TE, 2004).

Estimates of animal level disease stage durations (latent, preclinical, clinical, and recovered) were obtained from recently developed parameters used in the NAADSM (North American Animal Disease Spread Model) (USDA, 2012).The main outputs of the model were time for detection at different farm size scenarios and to simulate the number of viremic (pre-clinically and clinically infectious) and recovered animals that would be moved to the disposal site.

The model updates the number of animals in each disease state every 6 hours, which increases the accuracy of detection. The uncertainties in input variables, as well as the inherent variability associated with the course of infection in individual populations and the spread within the group, are considered in the model. Appendix A: Model Disease Spread presents the assumptions, definitions and background information used in the disease transmission model.

The detection module of the disease spread model estimates the time to detect FMD infection in the group based on heightened active observational surveillance for clinical signs, one of the mitigation measures that may be applied in an outbreak at the herd level. The model "checks" or applies specific detection mechanisms at user specified time steps (e.g., every day or twice per day). FMDv infection may be detected in a time period based on the specific detection mechanism and the number of clinically infectious animals.

Inputs for the disease spread model in the form of probability distributions for each disease state (latent, pre-clinical and clinical) for the transmission of FMDv within swine, dairy and beef cattle populations were obtained from an APHIS study where data from different FMD studies were analyzed by meta-analysis to estimate the probability distributions ((USDA 2012); (USDA, APHIS, NAHMS, 2012)).

5. FMD Depopulation Procedures and Carcass Movement

5.1. Standard Operating Procedures for FMD Depopulation

In infected premises that are being depopulated, the goals are to prevent contact between FMDv and susceptible animals, as well as to stop the production of FMDv in exposed or infected animals. The response strategy of stamping out infected premises is being considered in this risk assessment. This would be the case for an outbreak that is contained in jurisdictional areas in which FMD can be readily contained and further spread is unlikely. Stamping out is the preferred depopulation method for clinically infected and in-contact susceptible animals as a means to reduce the potential of disease spread. For purposes of this risk assessment, we assume the depopulation procedures will follow the USDA FAD PreP Guidance (USDA FAD PReP).

The standard operating procedures during depopulation are that the driver arrives at the site with the vehicle and makes contact with the officials/on-site command at the infected site. Many rendering industries utilize rendering trucks that are equipped with their own carcass lift arms and clam buckets (grapple systems) (Figure 1). These can be operated by the driver and although may need to leave the truck cabin to operate the lift, the driver will not step foot on the ground, nor have any contact with the carcasses.

Figure 1: Standard Rendering Truck with Grapple System

Image courtesy of Redwood Metal Works (http://redwoodmetalworks.com/)

Figure 2: Grapple truck with dump trailer.

Image courtesy of Mid-Atlantic Waste Systems (http://www.mawaste.com/mobile.html)

In cases where a forklift or front-end loader is used to lift an entire dump container and empty its contents into the trailer, an on-site operator (not the truck driver) would operate that machinery. If applicable, the driver would then cover the trailer using the roller tarp, operated from the front of the trailer (Figure 2).

During an outbreak, it is assumed that the driver never leaves the vehicle while on the infected premises (loading area). If duties cannot be performed by the driver from the cabin or platforms of the vehicle and would require the driver to be on the ground, personnel on the ground will load the vehicle and pull the tarp over the container. This tarp would be drawn tight in order to reduce air flow (although it still would not be 100% air-tight). In the US, it is required for trucks to be leak-proof while hauling animal carcasses (see 9 CFR 325.21 - Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported (Code of Federal Regulations and Federal Register).

For purposes of this risk assessment, the assumption is that euthanasia would take place only when there is a dedicated destination for the carcass disposal. This means that euthanasia will take place within a matter of minutes to hours prior to the carcasses being transported to the destination. The time limiting factor in a depopulation scheme is disposal rate, especially for large operations where burial on site is not an option. Storage of carcasses creates another set of problems for landfills, rendering, and hauling (more liquids) unless chilled. Therefore, simultaneous euthanasia and disposal will be the operational plan considered for this risk assessment.

Estimates for depopulation rates and timing for depopulation procedures are not available in the literature. Expert opinion was thus solicited for euthanasia and depopulation times. Experts in the field were contacted to provide their input on starting times for euthanasia for: 1) FMD Index premises, 2) subsequent FMD-infected premises, and 3) most likely depopulations rates for both swine and cattle (head/hour). A range (minimum, most likely, and maximum) was requested for each of the times and rates. See Appendix E: Expert Opinion – Depopulation for more information. These data are summarized in the table below.

Table 2: Expert opinion on time to euthanasia and euthanasia time*

Expert	Time to start depopulation (h)**	Depopulation time (head/hour)***
1	Min: 24 Most likely: 48-96 Max: 72-168	Min: 30 Most likely: 50 Max: 75
2	Min: 12 Most likely: 48 Max: 72	Min: 4*3 crews=12 (cattle) 20*3 crews=60 (swine) Most likely: 8*3 crews=24 (cattle) 160*3 crews=480 (swine)

		Max: 300*3 crews=900 (swine)
3	Min: 12 Most likely: 24 Max: 48	Min: 6*3 crews=18 Most likely: 12*3 crews=36 Max: 20*3 crews=60
4	Min: 24 Most likely: Max: 48	-
5	Min: 36 Max: 60	Cash pistol-grip captive bolt: 30 CO_2 gassing roll-off trailers: 140 Mobile electrocution trailer: 600 Maximum rendering capacity: 167

**: Assuming the outbreak is localized, and all the resources are available.*
***: Using the longest time when a range was provided.*
****: Using 3 eight men crews (20 h +4 h cleaning), 2 ten cow side discharge alleys and 2 loaders*

Time to transport the depopulation equipment and to set-up for the depopulation is a likely range of 24 to 48 hours. The time required to move animals into position for depopulation should also be taken into consideration. Once equipment and animals are in position and the depopulation procedures are ready to begin, the next time-limiting factor is the speed of the depopulation technology chosen. Table 3 below shows several of these technologies and their estimated speed.

Table 3: Expert opinion on depopulation technology time efficiency

Depopulation Technology	Time Efficiency
On farm mobile electrocution trailer (construction in progress)	Limit is estimated to be 600 feeder pigs/h (more time for sows and boars; not practical for iso-weans)
On farm cash pistol-grip captive bolt	Estimate is 30 head/h depending on the experience of the operator and their tolerance
On farm CO_2 gassing of swine in roll-off trailers or constructed chambers	Dependent upon the size of the chamber or trailer, and size of animal, to determine batch size. It usually will take about 15 minutes for the euthanasia process for each batch.
Transport to slaughter plant but divert line to disposal rather than processing	Estimate is the line speed of the plant whether using CO_2/bolt or electric paddles*

** This option is not likely applicable to the situation being evaluated in this assessment, unless the premise is a slaughter facility.*

Assuming the outbreak is localized and all resources for depopulation are available, in larger premises and feeder premises the process to completely depopulate the premises may be slowed due to disposal and indemnity issues. Depopulation efforts must be directly linked to the rate of disposal. The speed of euthanasia should not exceed the disposal rate. The disposal rate may be increased either through contracting multiple disposal options.

5.2. Types of Transportation

This risk assessment addresses mass depopulation at the infected premises site, with subsequent removal of carcasses from the infected premises using a standard rendering truck as conveyance. As defined for this risk assessment, the standard rendering truck is a tractor-trailer that is used to haul carcasses. This is a tractor-trailer truck (semi-truck) with an attached box trailer. The box trailers are constructed of aluminum, smooth wall panels or stakes and sheets of aluminum or steel. The trailers have a one-piece lift-off hinged doors or side swing tailgates, both of which are sealed and leak-proof, as required by federal law (9 CFR 325.21, Code of Federal Regulations and Federal Register). Standard trailers are 96 inches wide, with side heights of 5 ft or 6 ft smooth wall, double panel. The trailer lengths vary from 26 ft to 40 ft. and may be double- or triple axel. The most commonly used lengths in rendering industry practices are the 28, 32 and 40 ft trailers, which can haul 40000, 45000, and 50000 lbs., respectively.

Figure 3: Standard Rendering Truck and Trailer

Image courtesy of Walinga (http://www.walinga.com/index.php?id=223)

Figure 4: Example of a tarp drawn tight over a trailer.

Image courtesy of SolHuTech (http://www.solhutec.com/trucktarps.html)

Another option to the open-top trailer of the standard rendering truck is a trailer that is equipped with tarps systems. Tarps can be built in sizes that can accommodate dump trucks, roll off containers, dumpsters, and open top containers. Tarp cover systems can be constructed from range of materials including mesh, PVC or vinyl. In addition, tarp systems can come in a variety of formats including a sliding cable system, flip tarp system, rolling system, and solid waste tarps (tie-down system). Utilization of a tarp system is standard practice in states where law mandates that the top of the trailer be covered during carcass transportation to prevent leakage. Although the tarp reduces airflow, it is not airtight, and air will still flow over the carcasses. The tarp also helps to control scavengers. Other options are to have the trailer built with manual, air or hydraulic cylinder control lids, which tend to be less common.

For the purpose of lifting the carcasses into the trailer, trucks can be equipped with heavy duty hydraulic lift arms and buckets. Many farms will have a 'dump container' that is used to hold routine mortalities until the render haul truck arrives. The dump container could be used in the case of small premises depopulation. A forklift or front-end loader can also be used to lift the entire container in order to dump the carcasses into the truck's container.

There are other secondary types of trucks that can be used to transport carcasses, such as a roll-off truck. A roll-off truck is a tractor-trailer truck with detachable open-top box container, which is characterized by a rectangular footprint and wheels that facilitate rolling the container into position. As the roll-off truck raises its hydraulically operated bed, the container rolls off, and a cable is used to slowly lower it. These operate on a winch or hook-lift system.

Figure 5: Example of a roll-off truck trailer.

Image courtesy of Redwood Metal Works (http://redwoodmetalworks.com/)

The third type of truck trailer that will be considered in this risk assessment is the dump truck. A standard dump truck is equipped with an open-box bed, which is hinged at the rear and equipped with hydraulic pistons to lift the front, allowing the material in the bed to be deposited on the ground behind the truck at the site of delivery. By definition, this truck does not necessarily come equipped with a sealed tailgate. The roll-off and dump trucks will also be considered with and without a leak-proof liner, as some may not contain a sealed leak-proof tailgate.

Figure 6: Example of a dump truck trailer.

Image courtesy of Walinga (http://walinga.com/index.php?id=1741)

Each of these types of trucks has certain advantages and disadvantages. The decision to utilize the standard rendering truck as the primary form of conveyance is based on industry standard practices and the availability of equipment in the event of a FMD outbreak with mass animal depopulation. The standard rendering truck, roll-off and dump truck will be considered both with and without the following mitigations that can be used in conjunction with the trailer: 1) Tarp covering, and 2) Bio-Zip™, leak-proof carcass bags (Appendix B: Bio-Zip™ Bags product information). Bio-Zip™ liners can be used to manage large volume biological waste streams, leakage and environmental contamination issues. The bags are constructed of coated layers of polypropylene-based material fitted with an industrial grade zippered sealing system. The Bio-Zip™ material is 100% solids and contains no hazardous air pollutants. It has a zero rating for health, fire and reactivity and is zero class flammability. The Bio-Zip™ sealable liners fit securely inside industrial roll-off containers, trailers or truck racks from 10 to 40 cubic yards in total volume. Bags are placed in the trailer and filled on premises with infected carcasses. The entire bag is then removed from the trailer at the disposal site and disposed of. Bio-Zip™ bags meet US regulations for land fillable materials.

By determining the likelihood of leakage with the standard rendering truck and various mitigations, the assessment can be extrapolated to the other types of trucks with and without mitigations as well.

5.3. Transportation Regulations

Transportation of carcasses is well-regulated in federal, state and local jurisdictions. Although it can be inferred from rules and known standards for carcass transport, there are no specific governing regulations for movement of high numbers of carcasses, such as in a disease outbreak situation. For purposes of this risk assessment, the assumption is that all conveyance of carcasses during the depopulation procedure of a FMD infected premises will follow federal regulations for carcass movement (9 CFR 325.21, Code of Federal Regulations and Federal Register). This section states that "All vehicles and other means of conveyance used by persons subject to 9 CFR 325.20 for transporting in commerce or importing, any dead, dying, disabled, and diseased livestock or parts of carcasses of livestock that died otherwise than by slaughter shall be leak-proof and so constructed and equipped as to permit thorough cleaning and sanitizing."

Table 4: Federal Regulations Addressing Transportation of Carcass

Federal Regulation	Addresses
9 CFR 325.21	Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.
9 CFR 325.20	Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.

For the case of a mass depopulation, we assume that the federal transportation regulations are followed as the minimum standard for all states. It is assumed that all rendering vehicles used in depopulation transportation efforts will be leak-proof. Rendering vehicles are required to be leak-proof but not airtight. States have additional regulations for carcass transportation that vary somewhat from state to state. Most states require that the carcass transportation trucks be licensed and permitted, and pass annual vehicle inspections. Some states also have specific requirements as to the timing of cleaning and disinfection of vehicles. This risk assessment assumes the state of origin of carcasses and state of disposal site carcass transportation and disposal statutes will be followed (Appendix C: Federal and State Regulations for Carcass Movement).

5.4.Pathway analysis for Carcass Movement

Figures 7 and 8 show the series of events and pathways by which susceptible species may be infected via the movement of FMD infected carcasses from an infected farm. Two main release and exposure pathways are assessed in the current risk assessment: 1) leakage of contaminated body fluids from the rendering truck and cross-contamination with other trucks, personnel or equipment that will be in contact with susceptible livestock in other uninfected farms (Figure 7 and Figure 8 A); 2) aerosolization of FMDv particles from the carcasses during movement and subsequent air transportation of those particles to uninfected farms with susceptible species (Figure 7 and Figure 8 B).

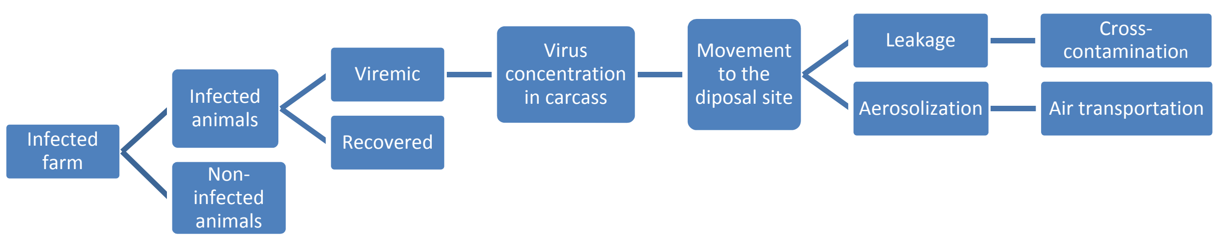
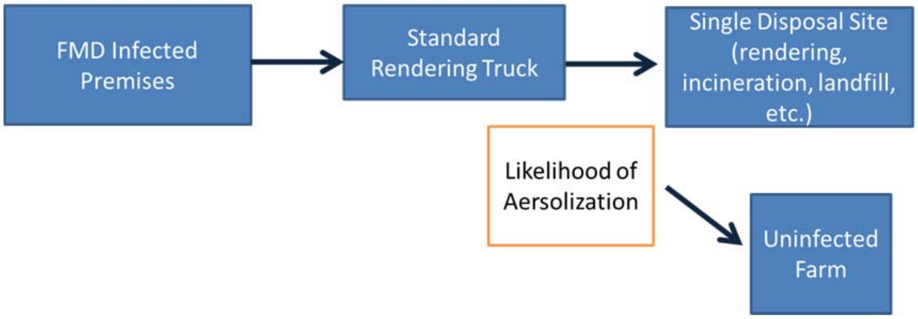


Figure 7: Series of events to expose susceptible species to FMDv through the movement of infected carcasses.

8A



8B

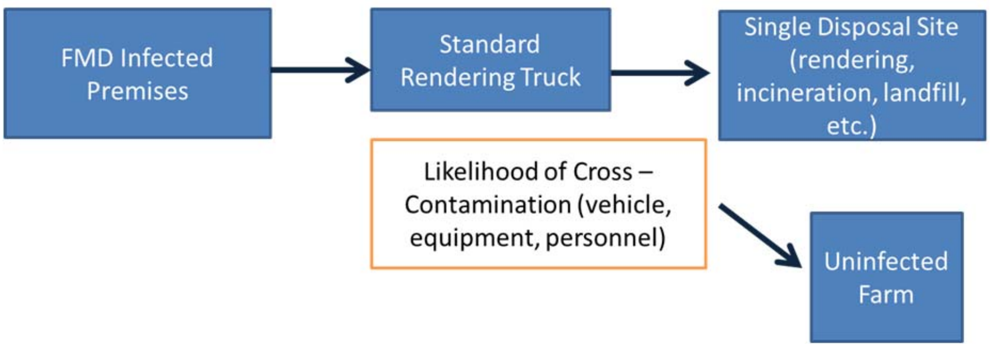


Figure 8: Aerosol (A) and cross-contamination (B) pathways for the exposure of susceptible species to FMDv through the transportation of infected carcasses.

6. Hazard identification

6.1.Background

Foot and mouth disease (FMD) is a highly contagious viral disease affecting primarily cloven-hoofed animals. The disease is characterized by the development of vesicles in and around the mouth and on the feet. Although natural FMD infection rarely causes the death of mature animals, the disease results in decreases in livestock productivity and causes serious economic impact on international trade of animals and animal products (OIE Technical Disease Cards)

FMD was last reported in the U.S. in 1929 and in North America in 1952 (Canada) and 1954 (Mexico). As of May 2012, of the OIE's 178 Member Countries, 102 do not have FMD-free status, 66 are recognized as officially free (65 without vaccination and one with vaccination), and ten have officially free zones (6 without vaccination and 4 having zones with or without vaccination). Out of the 102 countries without FMD-free status, 6 had an official status that is currently suspended (current FMD status can be found at www.oie.int.gov). There is substantial concern about incursions of this disease into the U.S., because of the unexpected occurrence of FMD outbreaks in previously FMD-free countries, including Taiwan (1997, 2000); Japan (2010, 2000); South Korea (2010, 2000, 2002); North Korea (2007); South Africa (2000, 2006, 2007); Argentina (2001, 2006); Russia (2006, 2007) and Europe (2001). The potential risks and impacts that FMD may pose were demonstrated by the severe economic and livestock losses experienced in the United Kingdom in 2001. The historical consequences of these FMD outbreaks has reinforced the need for FMD awareness and evaluation of the possible pathways by which FMDv can spread and infect livestock and contaminate food sources, and how these can serve as a further route for spread of the virus (USDA FAD PReP, 2013).

6.2. Virus Characteristics

There are seven FMDv serotypes: A, O, C, SAT 1, SAT 2, SAT 3 and Asia 1. Each serotype can be divided further into subtypes. Serotypes A, O, C, SAT1, SAT2, SAT3, and Asia1 contain 32, 11, 5, 3, 6, 3, and 4 subtypes, respectively. All serotypes produce disease that is clinically indistinguishable, but immunologically distinct. No cross-immunity is conferred between serotypes. Serotype O is the most prevalent and occurs in many parts of the world. Within each serotype is a spectrum of antigenic variation, resulting in strains having close or distant relationships to each other. Serotype A has the greatest antigenic variation ((Kitching RP, 1989); (Kitching RP, 1998); (Alexandersen S, 2005)).

6.3. Host range of FMD

Cloven-hoofed animals (ungulates) are the natural domestic and wild hosts of FMDv. They are susceptible to all 7 serotypes and many of the subtypes of FMDv. The severity of illness may differ depending on the specific serotype and the species that is affected. Susceptible species include cattle, pigs, sheep, goats, water buffalo, impala, bison, African buffalo, American Bison antelope, reindeer, moose, elk (although low), hedgehogs, porcupines, giraffes, elephants and Bactrian camels. Horses are resistant to FMD infection. New World camelids (llamas, alpacas, vicunas and guanacos) have low susceptibility to FMD infection. FMDv may also be transmitted to mice, rats, guinea-pigs, rabbits, hamsters, embryonating chicken eggs, chickens and various wild species, including European hedgehogs, chinchillas, muskrats, armadillos and peccaries. However, these latter species are not generally capable of spreading FMD (Alexandersen S, 2005).

Humans can become infected with FMD through (1) handling of diseased livestock with virus entry through skin wounds and mucous membranes, (2) exposure through laboratory situations, or (3) by drinking infected milk. The virus is not readily transmissible to humans and thus should not be considered a zoonotic disease. (OIE, 2008) Cases of human disease are rare and have resulted in temporary and mild signs of disease (fever, vesicles on the hands, feet or in the mouth) (Alexandersen S, 2005). In contrast, Hand, Foot, and Mouth disease (HFMD) in humans is an unrelated viral disease that primarily affects infants and children. The human disease is often confused with FMD of livestock.

6.4. Transmission

FMDv is highly contagious, and can be transmitted by a variety of mechanisms. When infected and susceptible animals are in close proximity, the airborne transfer of droplets is the most common mode of transmission. Other common mechanisms by which FMDv is spread are summarized below ((Alexandersen S, 2003b); (Alexandersen S, 2005)).

- Direct contact with infected animals and movement of animals between premises.
- Contact with secretions from shedding animals— exposure to secretions or mechanical transfer between groups by fomites (hands, footwear, clothing, vehicles, and equipment) and subsequent virus entry through cuts or abrasions in the skin or mucosa.
- Ingestion of FMDv contaminated animal products (meat) by pigs through swill feeding.
- Spread by wind, an uncommon event that requires the simultaneous occurrence of particular epidemiological and climatic conditions.

6.5. Incubation Period

The incubation period of an infectious disease is the time interval between exposure to an infective dose and development of clinical signs. The incubation period for FMD is known to be variable and dependent on the strain and dose of the virus, the route of transmission, the husbandry situation, and the species (Alexandersen S, 2003a). It is well known that FMD infected animals can shed virus during the incubation period, before the first detectable clinical signs are noted ((Orsel K, 2009); (Alexandersen S, 2001)). The peak of viremia can occur just before the animal breaks with clinical signs.

For control purposes, the OIE uses 14 days as the incubation period of FMD ((OIE, 2008); (Alexandersen S, 2003b)) summarized the variability observed in the incubation period of the disease, which is presented below:

- There is a strong inverse relationship between the dose of virus and the length of the incubation period, i.e., the higher the dose, the shorter the incubation period.
- The incubation period is usually 2-14 days, but can be as short as 24 hours.
- The latent period (animal exposed, infected and shedding the virus) is 1-2 days (Eble P, 2006).

6.6. Clinical Signs

Primary replication of FMDv takes place in the nasal and pharyngeal mucosa. Spread from these primary sites occurs to lymph nodes and the bloodstream, and resultant viremia distributes the virus to all organs and tissues. Viremia can commence a few hours after infection, and usually within 36 hours post-infection. Further replication of virus occurs in permissive cells and particularly at sites where characteristic lesions of FMD develop (Alexandersen S, 2001). The appearance of vesicles usually coincides with the peak of viremia and the highest concentration of virus is in tissues where the vesicles develop.

FMD in pigs is clinically indistinguishable from other viral vesicular diseases of swine (swine vesicular disease, vesicular stomatitis, vesicular exanthema) (Alexandersen S, 2001). It is usually severe and is characterized by lameness, reduced feed intake, lowered production, and the development of vesicles in and around the mouth and feet. Affected pigs become lethargic, remain huddled together and develop vesicles on the coronary band and heel of the feet, snout, lower jaw and tongue (Kitching RP, 2002). Body temperatures in pigs usually range from 39°C to 40°C, but can reach 42°C. The morbidity rate varies by the species affected, virus serotype and/or strain, and other factors. In regions where FMD is not endemic, the morbidity rate can be as high as 100 percent. The mortality rate is generally very low in adult animals, but may be high in young animals due to acute myocarditis (Alexandersen S, 2003b).

6.7. Concentration of virus in tissues, secretions, excretions

FMDv is present in multiple tissues, secretions and excretions of infected animals during pre-clinical, clinical, and post-clinical stages. Urine and feces contain virus but in low concentrations. Fresh feces collected from the floor have been found to contain small concentrations of the virus up to 10 days post infection in pigs (Parker J, 1971). The amount of aerosolized virus from infected animals can vary considerably. In contrast to other animals affected by FMD, infected pigs are recognized as the largest producers of aerosolized virus, excreting virus concentrations in the range of $10^{5.6}$ to $10^{8.6}$ $TCID_{50}$ per pig/day (Alexandersen S, 2005). Although pigs are large aerosol producers, they are very resistant to infection by this route. If a large group of pigs becomes infected with an appropriate viral serotype, the group can excrete large volumes of aerosolized virus, which can be transported to farms downwind and constitute a risk to sheep and cattle. Ruminants excrete less virus in their breath (10^4 to 10^5 $TCID_{50}$/day) compared to pigs, but are highly susceptible to infection via the inhalation route (Alexandersen S, 2005)

In comparison with other livestock species, cattle are the largest overall producers of FMDv from all secretions/body fluids combined and are probably the main source for environmental contamination. They produce large volumes of FMDv in the epithelium of the tongue, which often sloughs off during clinical disease, as well as in saliva, urine, feces and milk, in comparison to other species. Cattle are extremely susceptible to infection by aerosol exposure to virus due to their large respiratory volume and may become infected at concentrations of FMDv as low as 0.06 $TCID_{50}$ per cubic meter of air (Donaldson AI, 2001). Survival time of FMDv post-mortem depends on the stage of disease at the time of slaughter, the organs affected, and the strain of virus.

6.8. Environmental Persistence

FMDv retains infectivity for considerable periods of time in the environment, provided it is protected from desiccation, heat and adverse pH conditions. For example, the virus may survive for 14 days in dry fecal material; six months in slurry in winter; 39 days in urine; 28 days on the surface of soil in autumn; and three days on the surface of soil in summer. Such observations have generally been made in countries with a temperate climate, and these survival times can be expected to be much the same in hotter climates (Geering WA, 2002). FMDv is sensitive to desiccation. Relative humidity and temperature are the primary factors that affect survival of the virus in the environment. The virus survives best when the relative humidity exceeds 70%, and has poor survival when the relative humidity is below 50-60 (Sellers R, 1971). Sunlight and ultraviolet radiation have little effect on virus persistence (Donaldson AI, 1975).

7. Entry Assessment

The entry assessment comprises the risk associated with the release of FMDv during the movement of swine and cattle carcasses from FMD positive premises to the disposal site. The release could occur by cross-contamination via contaminated body fluids escaping from the disposal vehicle or by transmission of FMDv by aerosolization. Each of these events was characterized by a pathway and, for each of the pathways, the likelihood of occurrence was evaluated based on available scientific information, logical assumptions and input from experts.

The pathways considered in the entry assessment that would result in the release of FMDv through swine and cattle carcasses movement were the following:

- Likelihood that carcasses moved from FMD positive premises will contain an infective dose. In this pathway, a disease spread model for FMD in swine, dairy and beef cattle and expert opinion were used to estimate the total time from infection to depopulation, the number of viremic and recovered animals, and the FMDv concentration in carcasses to be moved after depopulation.
- Likelihood that transportation of carcasses will produce leakage and spillage of fluids contaminated with FMDv. In this pathway, body fluid capacity of swine, dairy and beef cattle was estimated. Characteristics of the disposal trucks were analyzed for the potential for leakage of body fluids.
- Likelihood that transportation of carcasses will produce aerosolization of FMDv. In this pathway, the potential for aerosolization of FMDv particles during movement of carcasses was evaluated by using expert opinion.

7.1. Likelihood that swine and cattle carcasses moved from a FMD positive premise will contain an infective dose

Summary: Time for FMD detection was estimated by a disease spread model to be between 4-10 days for swine and beef cattle and 3-9 days for dairy cattle premises at different sizes. Total time from infection to depopulation (including detection and confirmation) for the first FMD infected case was estimated to be between 10-15 days for swine, 8-12 days for dairy and 10-14 days for beef cattle premises. Total time estimated for subsequent FMD cases was between 7-12 days for swine, 6-9 for dairy and 8-11 days for beef cattle premises. Most of the animals (>65% for the first case and >81% for subsequent cases) will be viremic at the time of depopulation. The average concentration of FMDv in a carcass in experimental inoculation studies was 10^3 PFU/g for a pig carcass and 10^6 PFU/g for a cattle carcass. The total amount of infected carcasses moved to the disposal site was between 23-390 cattle carcasses and 117-780 pig carcasses per truck. This range was based on the weight of the animal carcass as well as the capacity of the truck trailer, taking into account the number of carcasses that could fit in the trailer. Any small amount of body fluids from the carcasses would contain virus that greatly exceeds the infective dose. 1 mL of body fluids could contain same amount and 10-100,000 times higher virus quantity (10^3-10^6 PFU) than the minimum infectious dose by oral ($1.4x10^4$-$1.4x10^6$ PFU) and inhalation route (7-357 PFU) for pigs and cattle. **Likelihood estimation: The likelihood that the disposal truck with swine and cattle carcasses moved from FMD positive premises will contain an infective dose is high.**

7.1.1. Time for FMD detection

The time for FMD detection was estimated by a stochastic disease spread model. The parameters used in the model for the simulation of disease spread within a group are presented in Table 5: Input parameters used in the FMD spread model in a swine farm.. Estimates of animal level disease stage duration (latent, pre-clinical, clinical and recovery) were obtained from a recent study completed by USDA-APHIS-CEAH (USDA, 2012) by evaluating animal level data from published studies involving experimental infection with FMDv. The farm sizes selection was based on a compilation of statistics published by the National Agricultural Statistics Service (NASS) of the USDA for 2007-2012.

The surveillance component used in the model was based on observation of clinical signs and, using a conservative approach, was set at one time per day. The threshold for considering detection of the disease was set at 5% of the herd showing clinical signs. These values were based on expert opinion of subject matter experts regarding the average percentage of naturally occurring lameness on swine and cattle farms in the period of 2007 and 2009 ((USDA 2007); (USDA 2009)). The following components of the NAHMS survey were considered: the percentage of pig deaths from lameness (i.e. 5.4% for all group sizes); unusually high number of pigs unwilling to eat or stand up (i.e. 7.3% for all group sizes); and lame pigs with reddened areas above the hooves (i.e. 2.4% for all group sizes). Naturally occurring lameness is hard to predict, since it will be different from one producer to another, depending on the farm characteristics. Endemic lameness could mask the clinical signs of a FMD outbreak and has been reported to be less than 5% for cases of mild lameness and less than 0.5% for severe lameness (Dr. Peter Davies, personal communication).

Table 5: Input parameters used in the FMD spread model in a swine farm.

Variable [a]	Input Distribution/Value
Latent Period	Gamma (α=1.896, θ=0.869)
Pre-clinical Period	Gamma (α=1.770, θ=0.690)
Clinical Period	Gaussian (μ=4.330, σ=1.944)
Group Size	500, 1000, 5,000 and 10,000 head
Adequate Contact Rate	6.14 (3.75, 10.06)[b]
Detection Threshold	5% of group

[a]*: Distributions refer to swine groups of more than 200 head*
[b]*: Contact rate value from Eble et al.,* (Eble P 2006)

Table 6: Input parameters used in the FMD spread model in a dairy and beef cattle herd.

Variable	Input Distribution/Value
Latent Period	Exponential 0.709 (mean of 33.72 h, SD of 34.17 h)
Pre-clinical Period	Lognormal (μ=0.862, σ=0.774)
Clinical Period	Gamma (α=4.752, θ= 0.736)
Farm Size	100, 500, 1,000 and 2,000 head (dairy) 5,000, 15,000, 30,000 and 50,000 head (beef)
Adequate Contact Rate	52 to 216 contacts/day
Detection Method	5% of herd

The assumptions applied to the model included the following:

- The spread model does not include the aerosol route of infection or cross-contamination within groups (personnel and equipment), only direct contact between animals.
- The disease spread model assumes direct contact between all the animals in a herd, which may overestimate the number of infectious animals in large feedlots.
- The on-farm surveillance is based on daily visual observation for clinically suspicious animals. Clinically suspicious animals include animals with signs from any disease that is similar to FMD.
- Inputs for the analysis are based on published literature and the best current knowledge of the disease biology.

Appendix A: Model Disease Spread, contains the detailed information on the inputs and analysis of the model.

Percentages of farm sizes (100-50,000 head) for swine, dairy and beef cattle premises based on USDA NASS data for 2007-2012 was used to predict the most likely farm size where the occurrence of an FMD outbreak could happen. For example, for the swine industry the percentages of different farm sizes were as follows: 1-99 head (71.3%), 100-499 head (7.3%), 500-999 head (3.4%), 1,000-1,999 head (4.8%), 2,000-4,999 head (8.3%), and ≥5,000 head (4.8%). These data were included in a discrete distribution function to characterize the distribution of the swine farm sizes in the US by using @Risk software (Palisade Corp., Ithaca, NY, US) by the following distribution:

RiskDiscrete({100,500,1000,2000,5000,10000},{0.713,0.073,0.034,0.048,0.083,0.048}) Eq. 1

In any given outbreak situation, there is a 95% chance that the outbreak occurs in a pig farm with 5,000 head or less, in a dairy farm with 500 head or less, and in a feedlot beef farm with 1,000 head or less. Time for disease detection will depend on the farm size and clinical observation and was estimated to be between 4-10 days for swine and 3-9 days for dairy and beef cattle premises.

7.1.2. Time from detection to depopulation

Time from detection to depopulation was estimated by adding the time for detection and the time for starting the depopulation with the following equation:

$$\text{Total time} = t_{det} + t_{conf} + t_{sdep} \qquad \text{Eq. 2}$$

where t_{det} is the time for FMD detection depending on the farm size, t_{conf} is the time to the official laboratory confirmation of the disease and t_{sdep} is the time to start the depopulation procedure.

Time values for disease confirmation, starting the depopulation and depopulation rates were obtained from experts from Texas A&M Transportation Institute, West Texas A&M, Department of Homeland Security and APHIS. Time values were characterized by a Pert distribution, and @Risk software was used to estimate the total time by using Monte Carlo simulation with 10,000 iterations. Input values for swine, dairy cattle and beef cattle premises are shown in Tables 9, 10 and 11, respectively. Total time from infection to depopulation for the first FMD infected case was estimated to be between 10-15 days for swine, 8-12 days for dairy and 10-14 days for beef cattle premises. Total time estimated for subsequent FMD cases was between 7-12 days for swine, 6-9 for dairy and 8-11 days for beef cattle premises (Table 7).

Table 7: Total time from infection to starting the depopulation procedure

Type of farm	Total time (days)*	
	First index case	Subsequent cases
Swine	11.7 (9.6-15.2)	8.7 (6.9-12.0)
Dairy cattle	9.4 (7.5-11.6)	7.4 (5.7-9.4)
Feedlot cattle	12.6 (10.5-14.4)	9.6 (7.8-11.1)

**: After 10,000 iterations (mean, 5th, and 95th percentile values)*

Depopulation times were estimated by the following equation:

$$\text{Time for depopulation} = D_R \times \text{farm size} \qquad \text{Eq. 3}$$

where D_R is the depopulation rate in heads/h and farm size is the amount of heads in a farm.

Table 8: Time to depopulate a farm for each of the species

Type of farm	Depopulation time (h)*
Swine	7.59 (0.27-43.12)
Dairy cattle	4.33 (0.66-19.67)
Feedlot cattle	35.85 (19.90-43.93)

**: After 10,000 iterations (mean, 5th, and 95th percentile values)*

Table 9: Input values to estimate timings for depopulation procedure in case of FMD outbreak in a dairy cattle farm.

Herd size	Time to detect disease post infection (5th, mean, 95th) (h)*	Time from disease detection to lab confirmation (min., most likely, max. values) (h)	Time from confirmation to starting depopulation (min., most likely, max. values) (h)	Depopulation rate (min., most likely, max. values) (heads/h)**
0-100	Pert (72, 115, 192)	Pert (24, 48, 72)	Pert (24, 48, 72)	Pert (18, 36, 60)
100-500	Pert (96, 125, 192)			
500-1,000	Pert (96, 130, 192)			
1,000-2,000	Pert (96, 137, 216)			

*: 5% detection level. **: Using three crews (8 men each) during 3 working shifts (20 h + 4 h cleaning) and two cow side discharge alleys (10 cows each) with two loaders.

Table 10: Input values to estimate timings for depopulation procedure in case of FMD outbreak in a swine farm

Herd size	Time to detect disease post infection (5th, mean, 95th) (h)*	Time from disease detection to lab confirmation (min., most likely, max. values) (h)	Time from confirmation to starting depopulation (min., most likely, max. values) (h)	Depopulation rate (min., most likely, max. values) (heads/h)**
0-500	Pert (96, 144, 192)	Pert (24, 48, 72)	Pert (24, 48, 72)	Pert (30, 140, 600)
500-2,000	Pert (120, 168, 216)			
2,000-5,000	Pert (144, 168, 240)			
5,000-10,000	Pert (144, 190, 240)			

*: 5% detection level. **: Using three crews (8 men each) during 3 working shifts (20 h + 4 h cleaning) and two side discharge alleys with two loaders.

Table 11: Input values to estimate timings for depopulation procedure in case of FMD outbreak in a feedlot beef cattle farm

Herd size	Time to detect disease post infection (5th, mean, 95th) (h)*	Time from disease detection to lab confirmation (min., most likely, max. values) (h)	Time from confirmation to starting depopulation (min., most likely, max. values) (h)	Depopulation rate (min., most likely, max. values) (heads/h)**
0-5,000	Pert (96, 142, 216)	Pert (24, 48, 72)	Pert (24, 48, 72)	Pert (18, 36, 60)
5,000-15,000	Pert (120, 151, 216)			
15,000-30,000	Pert (120, 154, 216)			
30,000-50,000	Pert (120, 159, 240)			

*: 5% detection level. **: Using three crews (8 men each) during 3 working shifts (20 h + 4 h cleaning) and two cow side discharge alleys (10 cows each) with two loaders.

7.1.3. Number of viremic livestock after depopulation

The stochastic disease spread model was used to estimate the number of viremic (pre-clinical and clinical) and recovered animals at the time of depopulation for specific farm sizes (3,000 head for swine, 2,000 head for dairy and 5,000 head for feedlot cattle). Two different scenarios were evaluated: 1) First FMD case (Table 12); 2) Subsequent FMD cases (Table 13). The subsequent cases scenario was set at the minimum values obtained from experts for laboratory confirmation of the disease (24 h) and starting the depopulation procedure (24 h), due to the higher awareness of the disease. As shown in the table, most of the animals will be viremic (containing active FMDv) at the time of depopulation.

Table 12: Results from the simulation for the first FMD case

Type of farm	Time elapsed before depopulation (days)*	Percentage of viremic animals (pre-clinical + clinical) (%)	Percentage of recovered animals (%)
Swine (3,000 head)	11.2 (9.3-14)	82 (72-88)	16 (7-27)
Dairy cattle (2,000 head)	9.7 (7.7-12.8)	78 (65-88)	21 (9-34)
Feedlot cattle (5,000 head)	9.9 (8-12.9)	78 (65-88)	21 (9-34)

**: After 10,000 iterations (5th and 95th percentile values). Times are adjusted for each of the farm sizes.*

Table 13: Results from the simulation for the subsequent FMD cases

Type of farm	Time elapsed before depopulation (days)*	Percentage of viremic animals (pre-clinical + clinical) (%)	Percentage of recovered animals (%)
Swine (3,000 head)	9.2 (8-12)	85 (81-89)	3 (2-5)
Dairy cattle (2,000 head)	7.7 (6-11)	91 (90-92)	3 (1-5)
Feedlot cattle (5,000 head)	7.9 (6-11)	91 (90-92)	3 (1-5)

**: After 10,000 iterations (5th and 95th percentile values). Times are adjusted for each of the farm sizes. The time from detection to laboratory confirmation and from confirmation to starting the depopulation procedure was set at a total time of 48 h.*

Figures 9, 10 and 11 show the disease spread curve within a swine, dairy and beef cattle population for the first index case. As shown in the figures below at the time of depopulation there will be 2,300 viremic pigs, 1,400 viremic dairy cows and 3,500 viremic beef cattle.

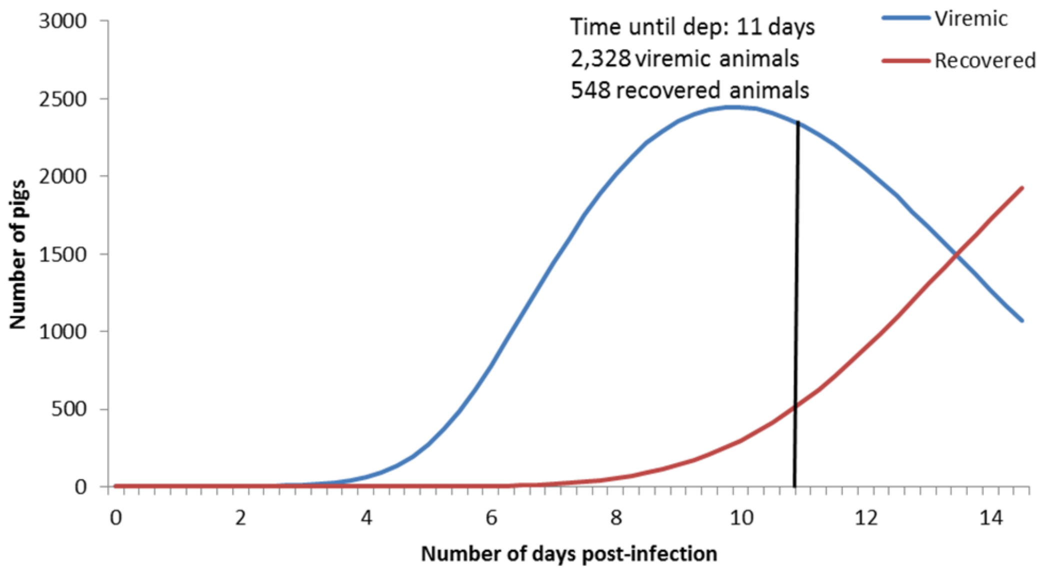


Figure 9: FMD curve in a 3,000 head swine farm during the first index case

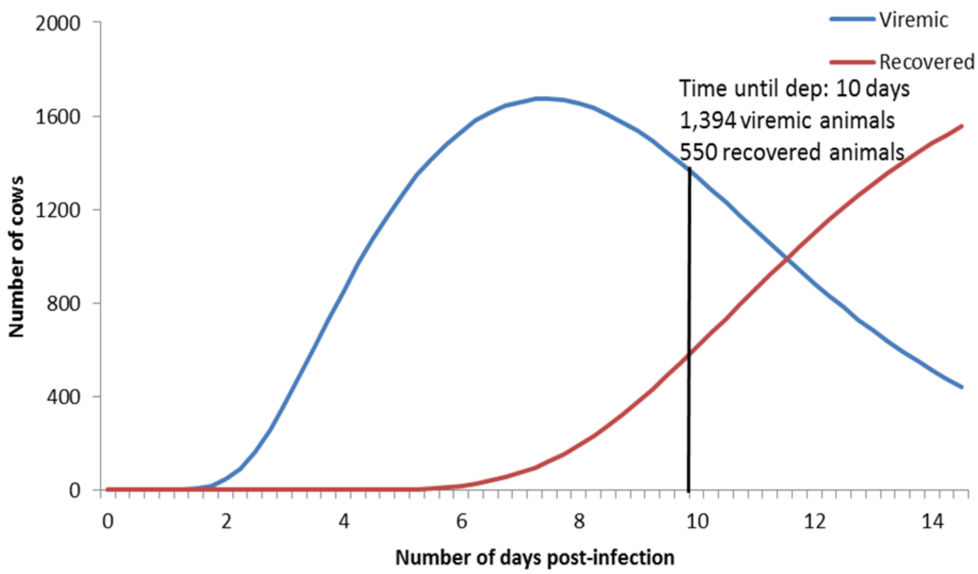


Figure 10: FMD curve in a 2,000 head dairy cattle farm during the first index case

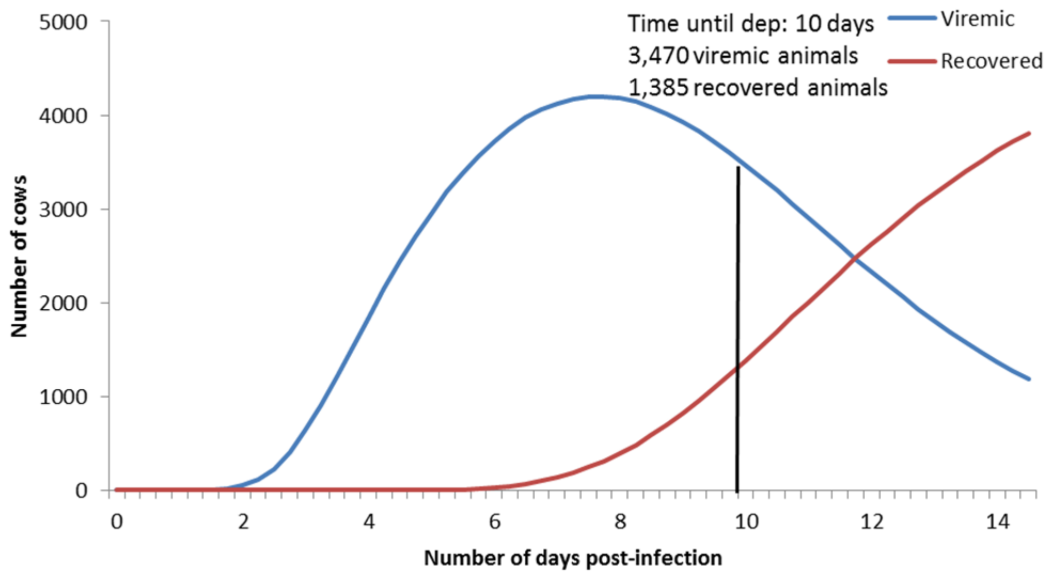


Figure 11: FMD curve in a 5,000 head feedlot beef cattle farm during the first index case

7.1.4. FMDv concentration in swine and cattle viremic carcasses

The concentration of FMDv observed in fresh tissues of pig skeletal muscle, fat, blood, lymph nodes and bone marrow in literature studies was from 6.31 PFU/g to $10^{9.6}$ ID_{50}/g for pigs (Table 14). It is worth noting the majority of reports were based on the 'worst-case scenario', where pigs were inoculated with high virus titers (Mebus C, 1997). The studies suggest that the greater quantities of virus were detected in pig blood, bone marrow or lymph nodes ((Alexandersen S, 2001); (Sellers R, 1971); (Chou CC, 2004); (Mebus CA ,1993); (Savi P, 1962)). The lowest quantities of virus were found in fat and muscle ((Mebus CA 1993); (Chou CC, 2004)). Given the high viral titers found in the various tissues, it is highly likely that FMDv would be present in the pig carcass tissues.

Table 14: Titers of FMDv present in select tissues, excretions and secretions of pigs after slaughter

Source of tissue, secretion, or excretion	Initial virus inoculation	Virus concentration at slaughter	Reference
Skin	10^7 $TCID_{50}$ (0.5 mL inoculum)	10^9 $TCID_{50}$/g	(Alexandersen S, 2001)
Pharynx		10^5-10^6 $TCID_{50}$/g	
Blood	$10^{7.5}$ $TCID_{50}$/mL	$10^{2.5}$-$10^{3.75}$ DCP_{50}/mL	(Savi P, 1962)

Source of tissue, secretion, or excretion	**Initial virus inoculation**	**Virus concentration at slaughter**	**Reference**
Blood clot	10^6 $TCID_{50}$ (0.5 mL inoculum)	$10^{4.8}$ $TCID_{50}/g$	(Chou CC, 2004)
Lymph node		$10^{3.8}$ $TCID_{50}/g$	
Muscle		ND	
Foot epithelium	NP	$10^{9.6}$ ID_{50}/g	(Sellers R, 1971)
Blood		$10^{7.2}$ ID_{50}/mL	
Bone marrow		$10^{6.1}$ ID_{50}/g	
Liver		$10^{5.6}$ ID_{50}/g	
Feces		$10^{2.9}$ ID_{50}/g	
Lymph node	$10^{8.9}$ $TCID_{50}/mL$	$10^{4.1}$ PFU/g (black pigs) $10^{2.7}$ PFU/g (white pigs)	(Mebus CA, 1993)
Blood		$10^{4.3}$ PFU/mL (black pigs) $10^{2.8}$ PFU/mL (white pigs)	
Bone marrow		$10^{2.7}$ PFU/g (black pigs) 10 PFU/g (white pigs)	
Fat		~6.31 PFU/g (black pigs) 1.58 PFU/g (white pigs)	
Muscle		ND*	
Blood	$10^{8.9}$ $TCID_{50}/mL$	$10^{3.6}$ PFU/mL	(Mebus C, 1997)
Lymph node		$10^{3.4}$ PFU/mL	
Bone marrow		$10^{1.9}$ PFU/mL	
Fat		~3.16 PFU/mL	
Muscle		~1.1 PFU/mL	
Muscle	$10^{7.5}$ PFU/mL	$>10^5$PFU/mL	(Panina, GF 1989)
Fat		$>10^5$PFU/mL	
Muscle psoas	NP	$10^{1.4}$-$10^{2.6}$**	(Dhenin L, 1980)

Source of tissue, secretion, or excretion	Initial virus inoculation	Virus concentration at slaughter	Reference
Shoulder muscle		$10^{0.3}$-$10^{4.0}$	
Tenderloin muscle		$10^{1.0}$-$10^{1.4}$	
Lymph node		$10^{2.5}$-$10^{4.0}$	
Fat		$10^{1.0}$-$10^{2.6}$	
Tonsils		$10^{2.0}$-$10^{4.0}$	

NP: None reported

ND*: None detected - The average titer of the sampled pigs was slightly greater than 0 PFU/g, with two samples with titers 10 PFU/g

**: Units not reported

$TCID_{50}$ (Median Tissue culture infectious dose) = The amount or quantity of a pathogenic agent (e.g. FMDv) required to produce a damaging effect to 50% of cells in the tissue inoculated.

PFU (Plaque forming units) = Provides an estimation of the number of infectious viral particles present by measuring the number of clear areas (areas of cell lysis) that are formed for a given culture plate area. One PFU equals about 1.4 $TCID_{50}$ for FMDv based on the equation by Horzinek (Horzinek MC, 1985).

Detectable viral titers in different cattle tissues ranged from $10^{2.5}$ PFU/g to $10^{10.6}$ PFU/g (Table 15). As was the case with swine, the majority of reports in cattle were based on the 'worst-case scenario', where cattle were inoculated with high virus titers. The studies suggest that the greater quantities of virus were detected in heart muscle, adrenal glands, pharynx and lymph nodes (Burrows R, 1966). The lowest quantities of virus were found in nervous tissue and spleen ((Scott FW, 1965); (Cottral GE, 1969)). Given the high viral titers found in these tissues, it is highly likely that FMDv would be present in cattle carcass tissues.

Table 15: Titers of FMDv present in select tissues, excretions and secretions of cattle after slaughter.

Source of tissue, secretion, or excretion	Initial virus inoculation	Virus concentration at slaughter	Reference
Pharynx	-	10^{7}	(Burrows R. 1966)

Source of tissue, secretion, or excretion	Initial virus inoculation	Virus concentration at slaughter	Reference
Blood	$10^{5.0}$ bovine ID_{50} U virus	$10^{5.6}$ PFU/g	(Cottral GE, 1969)
Semen	-	$10^{6.2}$ $TCID_{50}$/mL	(Sellers RF, 1968)
Milk	-	$10^{6.6}$ $TCID_{50}$/mL	(Donaldson AI, 1987)
Bone marrow	$10^{5.0}$ bovine ID_{50} U virus	$10^{5.9}$ PFU/g	(Cottral GE, 1969)
Lymph nodes	-	$10^{8.2}$ PFU/g	(Burrows R, 1981)
Heart muscle		10^{10} PFU/g	
Adrenal gland		$10^{10.6}$ PFU/g	
Thyroid gland	$10^{5.0}$ bovine ID_{50} U virus	$10^{6.0}$ PFU/g	(Cottral GE, 1969)
Pancreas		$10^{6.4}$ PFU/g	
Liver		$10^{3.6}$ PFU/g	
Rumen		$10^{6.4}$ PFU/g	
Spleen		$10^{3.1}$ PFU/g	
Kidney		$10^{4.0}$ PFU/g	
Cerebrum	-	$10^{2.5}$ PFU/g	(Scott FW, 1965)
Spinal cord		$10^{3.2}$ PFU/g	
Pineal body		$10^{4.3}$ PFU/g	
Pituitary		$10^{6.8}$ PFU/g	
Skin/Hides	-	$10^{6.0}$ PFU/g	(Gailiunas P, 1966)

7.1.5 FMDv concentration in the disposal truck

Tables 16 and 17 show the weight ranges of different production phases and animal capacity at different size options for the standard rendering truck trailer. The concentration of the FMDv in the disposal truck will depend on the number of viremic carcasses and the virus concentration per carcass. Table 17 shows that the total amount of FMDv contained in a 50000 lbs disposal truck is between $2x10^{11}$ and $2x10^{14}$ Plaque Forming Units. This FMDv concentration is 6-12 times higher than the minimum infectious dose for cattle, pig and sheep for the inhalation route. Any small amount of body fluids escaping the truck would contain enough quantity of virus to potentially infect susceptible population.

Table 16: Weight ranges of different species, depending on the production phase.

Dairy	**Weight Ranges (lbs.)**
Calf (birth)	55-100
Yearling (12 months)	520-1100
Adult Cows/Bulls	800-1700
Beef	
Calf (birth)	60-100
Weaning (6-10 mo.)	450-700
Market wt. (18-22 mo.)	1200-1400
Swine	
Nursery pig	up to 55
Grower pig	55-154
Finisher pig	154-330

Table 17: Number of carcasses in a disposal truck, depending on the capacity

Animal weight (lbs)	**Disposal Vehicle Weight Capacity**		
	Trailer Weight Capacity (40,000 lbs) Trailer Length (ft) 28'	**Trailer Weight Capacity (45,000 lbs) Trailer Length (ft) 32'**	**Trailer Weight Capacity (50,000 lbs) Trailer Length (ft) 40'**
	Number of carcasses per X lbs		
10	4000	4500	5000
25	1600	1800	2000
50	800	900	1000
100	400	450	500
200	200	225	250
300	133	150	167
400	100	113	125
500	80	90	100
600	67	75	83
700	57	64	71

800	50	56	63
900	44	50	56
1000	40	45	50
1100	36	41	45
1200	33	38	42
1300	31	35	38
1400	29	32	36
1500	27	30	33

Table 18: Total amount of FMDv per disposal truck and growth phase

Type of farm	Number of carcasses per truck (40')	% of viremic carcasses	Number of viremic carcasses	Total amount of FMDv per truck (40') (PFU)*
Calf Dairy cows	500	78%	390	$2x10^{14}$
Yearling Dairy cows	45		35	
Adult Dairy cows	29		23	
Calf beef cow	500		390	
Weaning beef cow	71		55	
Market beef cow	36		28	
Nursery pig	1000	82%	780	$2x10^{11}$
Grower pig	350		273	
Finisher pig	150		117	

*: Average FMDv concentration per carcass is 10^6 PFU/g for cattle carcasses and 10^3 PFU/g for swine carcasses.

Table 19: Selected estimated Minimum Infectious Doses (TCID50) for cattle, sheep and pigs by route of exposure [1, 2, 3]

Species	Inhalation	Nasal inoculation	Oral
Cattle	10	10^4-10^5	10^5-10^6
Sheep	10	10^4-10^5	10^5-10^6
Pigs	>800	Unknown	10^4-10^5

[1]: Doses are given as $TCID_{50}$ (50% bovine thyroid tissue culture dose endpoint estimates).
[2]: One PFU equals about 1.4 TCID50 for FMDv.
[3]: Source: Alexandersen S. Q., 2003; Donaldson AI, 1987.

7.2. Likelihood that transportation of carcasses will produce leakage and spillage of fluids contaminated with FMDv

Summary: The volume of body fluids of carcasses will vary depending on the growth phase, body weight and species. The time from depopulation to movement of carcasses to the disposal site will be very short (as a matter of hours), so the potential for body fluids to escape from carcasses (leachate) will be minimized. Mitigation measures such as sealed tailgate, tarp cover and the use of Bio-Zip™ bags will minimize the likelihood of leakage and spillage of carcass fluids from the disposal truck. Likelihood estimation: **The likelihood of leakage and spillage of carcass fluids from a standard rendering truck (sealed tailgate and tarp cover) will be low. Adding a Bio-Zip™ bag will reduce the likelihood to between low and negligible for any type of truck. The rest of the scenarios (roll-off/dump trucks with/without tarp covering and liner) will have risk levels higher than low.**

7.2.1. Carcass fluids

7.2.1.1. Leachate, Leakage and Spillage

Leachate is the liquid that is produced by the decomposition of livestock carcasses when water travels through a burial site and picks up products from decomposing carcasses and carries them through the soil. This is a process that follows euthanasia as the carcass starts to decompose. Through literature search and expert opinion, ranges of leachate production for livestock were quantified. Mammals are approximately 70% water and, as they decompose, they turn into a compost-like material capable of holding onto about 50% of that water (e.g., in a 50 lb. carcass, 17.5 lb. of body weight will be lost during the leachate process). Due to the short time elapsed between euthanasia and disposal, post-mortem autolysis will be minimal. Leachate as a potential contributor to spillage will, thus, not be considered further in this risk assessment. If time to disposal following euthanasia is extended, leachate may become more significant and warrant further consideration.

Leakage is the volume of liquid matter (including feces, urine, blood, ingesta, serum, saliva, etc.) that could be released from the carcass upon euthanasia, but is not part of the decomposition process. This can happen post-mortem through various means, such as loss of sphincter tone, through maneuvering of carcasses, and through the site of euthanasia (e.g. captive bolt entry point). Leakage is a factor that could facilitate the release of FMDv from the truck during movement. Spillage is when carcass fluid from leachate or leakage spills out from the conveyance source into the environment and could potentially contribute to the spread of FMDv.

7.2.1.2. Amount of Carcass Fluids

The table below summarizes the estimated body fluid volumes for cattle (both dairy and beef), as well as swine at different life stages. This is based on fluid volume comprising about 70% of total weight for most mammals. About two-thirds of these fluids are intracellular. So for example, based on total body fluids on a per weight basis, the volume range for potential leakage under worst case scenario for a calf (beef or dairy) would range from 6 to 20 liters. The volume of potential leakage from a nursery pig would range from 2 to 6 liters. These fluid quantities provide a reference for the total potential volume of leakage by weight and species. They are not considered an estimate of expected leakage.

Table 20: Volume of Body Fluids found in Cattle and Swine

Cattle	**Calf (birth)** Min	- Max	**Weaning (6-10 mo.)** Min	- max	**Market wt. (18-22 mo.)** Min	- max
Weight, kg (lbs)	27 (59)	45 (99)	204 (449)	318 (700)	544 (1197)	810 (1782)
Total Body Fluid Volume (L)	19	32	143	223	381	567
Total Free Fluid Volume (that which is not intracellular) (L)	**6**	**10**	**48**	**74**	**127**	**189**
Swine	**Nursery pig** Min	- Max	**Grower pig** Min	- max	**Finisher pig** Min	- max
Weight, kg (lbs)	10 (22)	25 (55)	26 (57)	70 (154)	70 (154)	150 (330)
Total Body Fluid Volume (L)	7	18	18	49	49	105
Total Free Fluid Volume (that which is not intracellular) (L)	**2**	**6**	**6**	**16**	**16**	**35**

7.2.2. Potential for Leakage and Spillage of Carcass Fluids during Movement

In consulting with rendering industry experts on the typical amounts of leakage from fresh, intact carcasses under normal conditions, the body fluids normally remain in the carcass. In a full load of a standard rendering truck (29–1000 carcasses), the amount of leakage that was estimated by expert opinion was around 20 liters per load. The table below summarizes the likelihood of leakage and spillage of carcass fluids from intact carcasses during transport, with or without further mitigation measures. The tarp covering will provide protection against aerosolization and spillage of carcass fluids, and the Bio-Zip™ bag will provide full protection for any of the possible pathways. The liner would provide a leak-proof barrier for fluids with a full-containment of carcasses and may aid in preventing spillage. It is not, however, sealed containment, such as with the sealed leak-proof tailgate or the Bio-Zip™ bag.

Table 21: Leakage and Spillage of carcass fluids during conveyance

Comparison of Conveyance Methods and Mitigations	Likelihood
Standard Rendering Truck (sealed tailgate)*	
With tarp covering, and Bio-Zip™ bag	Negligible
With tarp covering	Low
With Bio-Zip™ bag (uncovered)	Negligible
Uncovered	Moderate
Roll-off Truck/Dump Truck (no seal properties)*	
With tarp covering, liner and Bio-Zip™ bag	Negligible
With tarp covering and liner	Low to Moderate
With tarp covering and Bio-Zip™ bag	Negligible
With liner only (uncovered)	Moderate to High
With Bio-Zip™ only (uncovered)	Low

*: Capacity: 28', 32', 40'

From the table, it can be concluded that the use of a Bio-Zip™ bag, with any of the vehicle types, will produce a negligible to low risk of leakage and spillage of fluids during conveyance. The scenario of the standard rendering truck or roll-off and dump truck without tarp covering would have a moderate to high likelihood of spillage, due to the proximity of carcasses to the top of the trailer in a full load. Without mitigations to prevent spillage from the truck (i.e. tarp), carcass fluids may have the potential to escape

7.3. Likelihood that transportation of carcasses will produce aerosolization of FMDv particles

Summary: Bioaerosol is a complex field of science where multiple parameters (e.g.., environmental, climatic) can affect the survival and air transmission of FMDv. Likelihood estimation: **The overall likelihood of bioaerosols emanating from a trailer and spreading infectious virus through carcass transportation activities is estimated as negligible to low if conveyance is in a standard rendering truck with tarp covering. If aerosols could be**

produced from the carcass leakage, there is a moderate likelihood they could then move into the airstream.

7.3.1. Bioaerosol Science

Aerosols refer to an assortment of liquid or solid particles suspended in a gaseous medium (Gilbert Y 2009). Bioaerosols are aerosols that contain microorganisms, such as bacteria, fungi, and viruses—or organic compounds (endotoxins, metabolites, toxins, proteins from animals and plants, and other microbial fragments) (Macher J, 1999). The science of bioaerosols is extremely complex and requires an understanding of microbiology, biology, chemistry, meteorology, and aerosol physics (Mohr A, 2005). The sections below focus on the key points for general bioaerosol behavior that may pertain to FMDv associated bioaerosols. The ability to generate bioaerosols depends on the source, aerosolization mechanisms, environmental conditions, and composition (Pillai SD, 2002). Bioaerosols vary in size from 20 nm to >100 µm in diameter. Almost any environmental reservoir for microorganisms, such as fresh and marine surface waters, soil, plants, wastes and animals, is susceptible to being a source of bioaerosols.

Bioaerosols generated from water sources are generally surrounded by a thin layer of liquid that rapidly evaporates to give droplet nuclei. Droplet nuclei are the dried residue of larger aerosols that can remain airborne indefinitely on air currents. Transport of bioaerosols, and survival of airborne microorganisms, are influenced by many physical and environmental factors. The size, shape, and density of bioaerosols are of particular significance to transport because they are related to the aerodynamic diameter, which controls the settling velocity ((Cox C, 1995) (Mohr A, 2007)). Bioaerosols between 1 and 5 µm normally follow the pathlines of surrounding air, making them less susceptible than larger particles to impact surfaces and deposition (Mohr A, 2007).

7.3.2. Bioaerosols and FMDv

The airborne transmission of FMDv aerosols is complex. Windborne transport of virus can occur under specific epidemiological, climatic, and meteorological conditions, but is very uncommon. Prevailing climatic conditions, particularly wind speed and the vertical temperature structure, are major determinants of physical decay of aerosols. This is also influenced by the roughness of the surface over which the air plume travels. The survival of FMDv in plumes is likely across seaways, as the surface turbulence is low and concentrations of airborne particles can be maintained for greater distances than over land (Gloster J, 2005). The stability of FMDv is affected by radiation, RH, temperature, and weather factors. RH is the major meteorological determinant affecting virus survival. It has been established that the virus is stable in aerosols at a RH above 60 percent and at temperatures below 33°C (91°F). Sunlight and a pollution complex termed "the outside air factor" have minimal direct effect on virus survival (Donaldson AI, 1975). The aerosols, once airborne, are subject to both physical and biological loss. Biologically, the virus may become inactivated if the RH of the air falls below 60 percent or the water vapor pH of the aerosol particle becomes acidic or alkaline (Gloster J, 2004). In the absence of turbulence, particles greater than 10 µm are likely to be removed from the atmosphere within minutes. Smaller particles may remain airborne for several hours and be carried many kilometers in the wind (Gloster J, 2007). Particles of 5 µm or less act as vapors and can move in and follow an airstream without impacting obstacles; this is the size of particle that represents the worst risk. It is unknown if bioaerosols from leakage of carcass fluids would require the same type of environmental conditions to remain viable and potentially lead to infection of susceptible livestock.

7.3.3. Expert Opinion on Bioaerosolization

There are no studies on carcass bioaerosols production in the literature. Bioaerosol science is a very complex field, and aerosol characteristics and behavior are measured quantitatively using sophisticated sampling methods and equipment. Questions on aerosol behavior cannot be accurately modeled mathematically, as it requires knowledge of the concentration of aerosols, the size distribution of aerosols, the media composition, and the environmental/atmospheric conditions under which they are generated. Due to the lack of information on carcass aerosols, the experts' opinions and rationale were based on extrapolation of their knowledge in aerosol science. All of the experts agreed that experimentation is required to accurately answer these questions and to validate their opinions.

We queried three bioaerosol experts on the potential for generation of bioaerosols during transport and the expected behavior of the aerosols. The experts have different professional backgrounds and expertise within the field of aerosol science. The list of experts interviewed, the questions asked and a summary table of their answers are presented in Appendix G: Expert Opinion – Aerosols. Responses were compiled and compared for consensus between experts. The explanation of aerosol behavior varied slightly among experts, but the overall conclusions of the probability of occurrence of bioaerosols did not vary significantly. Expert opinion consensus was that the likelihood of aerosolization in an uncovered rendering vehicle during transportation was negligible to moderate. When the rendering vehicle was covered during transportation, expert opinion consensus was that the likelihood of aerosolization was negligible to low.

Table 22: Summary of bioaerosol responses from experts.

Questions posed to the experts	Expert 1	Expert 2	Expert 3
Aerosolization in uncovered rendering vehicle during transportation			
What is the likelihood (see chart) of significant aerosolization of carcasses fluids during transportation?	**Moderate**	**Low**	**Negligible**
What is the likelihood that a significant portion of the aerosolized particles be less than 10 µm in size	**Moderate**	**Low**	**-**
If aerosols could be produced from the carcass leakage, what is the likelihood they could then move into the airstream at a farm?	**High**	**Moderate**	**-**
Aerosolization in covered rendering vehicle during transportation			
What is the likelihood (see chart) of significant aerosolization of carcasses fluids during transportation?	**Low**	**Negligible**	**Negligible**
What is the likelihood that a significant portion of the aerosolized particles be less than 10 µm in size	**Low**	**-**	**-**
If aerosols could be produced from the carcass leakage, what is the likelihood they could then move into the airstream at a farm?	**Moderate**	**-**	**-**

7.3.4. Potential for Aerosolization of Carcass Fluids during Movement

The likelihood estimate was based on the review of expert opinion, observation of truck design and operations, and current knowledge of FMDv epidemiology. The overall likelihood of bioaerosols emanating from a trailer with potential for spreading infectious virus through carcass transportation activities is estimated as low to moderate, if conveyance is in an uncovered standard rendering truck. When using a tarp covering, the likelihood was reduced to negligible-low, and with a Bio-Zip™ bag to negligible. In this case, if aerosols could be produced from the carcass leakage, there is a moderate to high likelihood they could then move into the airstream. Experts rated the likelihood of FMDv moving from the airstream into farms along the truck route as between moderate and high when trailer is uncovered, and between negligible to moderate when covered.

Table 23: Aerosolization of virus particles during conveyance

Comparison of Conveyance Methods and Mitigations	Likelihood
Standard Rendering Truck (sealed tailgate)*	
With tarp covering, and Bio-Zip™ bag	Negligible
With tarp covering	Negligible-Low
With Bio-Zip™ bag (uncovered)	Negligible
Uncovered	Low-Moderate
Roll-off Truck/Dump Truck (no seal properties)*	
With tarp covering, liner and Bio-Zip™ bag	Negligible
With tarp covering and liner	Negligible-Low
With tarp covering and Bio-Zip™ bag	Negligible
With liner only (uncovered)	Low to Moderate
With Bio-Zip™ only (uncovered)	Negligible

*: Capacity: 28', 32', 40'.

8. Exposure Assessment

The exposure assessment is an evaluation of the potential exposure pathways by which susceptible animals could be exposed to infectious amounts of FMDv. There are four major aspects of the exposure assessment: the exposed population, the pathway of exposure, the magnitude of exposure, and the likelihood of exposure. For the purpose of this assessment, the population of interest is primarily susceptible agriculture livestock species. The potential pathways for exposure are through the cross-contamination of trucks, personnel or equipment by FMDv contaminated carcass fluids, and exposure to aerosolized particles. These events and the factors associated with virus survival and infectiveness are uncertain.

For the exposure assessment of this risk assessment, the use of a standard rendering truck was assumed. In the entry assessment, the likelihood of the FMDv to be released during transportation was estimated to be between negligible to low (both for aerosolization and spillage). Based on the proposed mitigations in this assessment and the apparent effectiveness on the likelihood of virus to be released by the movement of carcasses, we conclude that the likelihood of exposure to FMDv by susceptible populations during the movement of infected carcasses will be **negligible**.

9. Risk Estimation

The risk of FMD infection of susceptible livestock associated with the movement of swine and cattle carcasses by leakage, spillage and aerosolization of carcass fluids will be **negligible** when using a standard rendering truck (tailgate sealed and tarp cover) and a Bio-Zip™ bag, between **negligible and low** when using a standard rendering truck or a roll-off /dump truck with a Bio-Zip™ bag. Other scenarios (uncovered standard rendering trucks, uncovered roll-off/dump trucks, covered roll-off/dump trucks and a liner) will have risk levels higher than low (**moderate to high**).

10. Conclusions

The following conclusions were drawn from this report:

- Conveyances evaluated will contain carcasses with a total FMDv amount that will exceed in several degrees of magnitude the minimum FMD infective dose for pigs and cattle.

- The use of Bio-Zip™ bags is an effective mitigation to reduce the risk of leakage and aerosolization to negligible in standard rendering trucks and to low in the other conveyance types.

11. Recommendations for further research

An important goal of the risk assessment process is to inform the risk managers about the data gaps encountered during the production of the document and research strategies to fulfill the data gaps, in order to decrease the uncertainty in the risk estimation.

A review of the literature on FMDv in cattle and swine indicated the following data gaps, research needs and uncertainties:

1. The amount of virus that would be present in naturally infected animals and their tissues. It may be significantly lower than the doses that have been used in scientific research. Some variables that could be studied include: strains of FMDv, post-exposure intervals, age/size of pig/cattle.
2. Data on infectivity of waste materials (i.e. aerosols, liquids, and solids) generated during 3D operations (i.e. Depopulation, Disposal, and Decontamination).
3. Confirmation on how FMD infected carcasses will be classified for transportation purposes, especially under the circumstances of mass depopulation, with the possibility that infected carcasses could be designated with a different classification. In the case of a FMD outbreak, it is possible that the Federal HazMat Transport Regulations could be used to cover transportation. However, the Code of Federal Regulations 49 CFR Part 175 addresses the movement of test samples and vials, but not intact infected carcasses.
4. New modeling approaches that contain the aerosol route of infection or cross-contamination within groups (personnel and equipment) need to be explored.
5. Research on the aerosolization of FMD is limited or lacking. Expert opinion was used in this assessment, but targeted research would add additional data and confidence to the issue.

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Contributors:

Jamie Slingluff, DVM, MS
    Veterinary Public Health and Preventive Medicine Resident
    Center for Animal Health and Food Safety
    University of Minnesota College of Veterinary Medicine

Fernando Sampedro, PhD
    Risk Analyst/Assistant Professor
    Center for Animal Health and Food Safety
    University of Minnesota College of Veterinary Medicine

Timothy J. Goldsmith DVM, MPH, DACVPM
    Assistant Clinical Professor
    Center for Animal Health and Food Safety
    University of Minnesota College of Veterinary Medicine

Reviewed by:

Robert E. De Otte Jr., Ph.D., P.E., P.G.
Professor of Civil & Environmental Engineering
School of Engineering & Computer Science
West Texas A&M University

Vanessa Spradlin
Research Assistant
School of Engineering & Computer Science
West Texas A&M University

Carie Alexander DVM
Graduate Research Assistant
Center for Animal Health and Food Safety
University of Minnesota

Curtis A. Morgan
Program Manager, Multimodal Freight Programs,
Texas A&M Transportation Institute (TTI)

Lori P. Miller, PE
3D/WARRP Program Manager,
Agricultural Defense Branch
Department of Homeland Security
Science and Technology Directorate

Michael Mays
North Carolina Department of Agriculture and Consumer Services

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Appendix A: Model Disease Spread

This appendix provide additional information on the disease spread model used to simulate the spread of FMDv within a swine and cattle group and estimate the number of pig and cows in various disease states at different time periods. The disease states included in the module are susceptible (S), latent (L), pre-clinically infected stage (I), clinically infected (C) and (R) (Carpenter, 2004). The module updates the number of pig/cows in the disease states at specific time steps (e.g., every 6 hours). The uncertainties in input variables as well as the inherent variability associated with FMD infection course in a pig/cow and spread within the group were considered in the model.

Assumptions and Notation

We have the following notation for this section:

N- The number of pig/cows in the group.
$\boldsymbol{i}$ - index of pig/cows in the farm i $\in 1, \dots, N$
$\boldsymbol{t}$ - index of time periods. i $\in 1, \dots, t$
$\boldsymbol{\widehat{S}(t)}$- Set of indices of pig/cows that are in a susceptible state in time period t
$\boldsymbol{\hat{L}}(\boldsymbol{t})$- Set of indices of pig/cows that are in a latent state in time period t
$\boldsymbol{\widehat{SI}}(\boldsymbol{t})$- Set of indices of pig/cows that are in a pre-clinically infectious state in time period t
$\boldsymbol{\widehat{CI}}(\boldsymbol{t})$- Set of indices of pig/cows that are in a clinically infectious state in time period t
$\boldsymbol{\widehat{R}}(\boldsymbol{t})$- Set of indices of pig/cows that are in an immune state in time period t.
$\boldsymbol{P_t}$- The probability that a pig/cow that is susceptible in period *t* becomes infected with FMD by period t+1.
$N_i(t)$-The number of infectious pig/cows/cows/cows in time period *t.*

K-The adequate contact rate is defined as the expected number of contacts that a pig/cow has with other pigs/cows in a time period that are adequate to transmit FMD infection.

$I_{t,t+1}^{new}$-The number of newly infected pig/cows between period t and t+1.

$N_s(t)$- The number of susceptible pig/cows in period t.
$\tau^L(i)$- A model variable denoting the length of the latently infected period for a pig/cow in a specific simulation iteration. This parameter was simulated using an exponential distribution as detailed in section 9.3
$\tau^{SI}(i)$- A model variable denoting the length of the pre-clinically infectious period for a pig/cow/cow in a specific simulation iteration. This parameter was simulated using a lognormal distribution as detailed in section 9.3

$\tau^{CI}(i)$- A model variable denoting the length of the clinically infectious period for a pig/cow/cow in a specific simulation iteration. This parameter was simulated using a gamma distribution as detailed in section 9.3
$T^{L}(i)$- A model variable denoting the simulation time at which a pig/cow/cow *i* entered into latently infected state.
$T^{SI}(i)$- A model variable denoting the simulation time at which a pig/cow/cow *i* entered into pre clinically infectious state.
$T^{CI}(i)$- A model variable denoting the simulation time at which a pig/cow *i* entered into clinically infectious state.
λ- The number of hours represented by each time period *t* of the simulation model. λ was set at 6 hours in our simulations.
The main assumptions associated with this model are listed below

- The pig/cows that are in susceptible state in a time period, all have an identical probability of becoming infected by the next period, (i.e., differences in transmission due to grouping of pig/cows in pens are not considered).
- Pre-clinically infectious or clinically infectious pig/cows are both equally infective with respect to transmitting FMD, if they have an adequate contact with a susceptible pig/cow.
- The number of adequate contacts per pig/cow in a period follows the Poisson distribution.
- The variability in adequate contact rate due to differences in density of pig/cows (number of pig or cows per unit area) among different swine or cattle operations is not considered (i.e., the transmission is modeled as being frequency dependent).
- The clinically immune state is not considered in the model

The Transmission Equation

The transmission equation estimates the number of susceptible pig/cows that become newly infected with FMD in each time period. The transmission equation is based on calculation of the probability that a susceptible pig/cow has an adequate contact with at least one infected pig/cow in a time period. The variables considered in the equation include the adequate contact rate, the number of infectious pig/cows, the number of susceptible pig/cows and the total number of pig/cows in the farm. In general, a higher adequate contact rate or higher proportion of infectious pig/cows will lead to increased transmission. We use the transmission equation derived in Dietz and Schenzle (Dietz K, 1985) as shown in Equation 1. This transmission equation assumes that the number of adequate contacts each pig/cow has in a period is Poisson distributed with a mean (k). A Poisson process indicates a continuous and constant opportunity for an event to occur.

$$P_t = 1 - e^{-\frac{k(N_i(t))}{N-1}}$$

$$I_{t,t+1}^{new} \sim Binomial(S, P_t)$$

Transition between Different Disease States

The transmission equation provides the basis for calculating the number of pigs/cows transitioning from susceptible to the latently infected state in one time period. In this section, we briefly describe the implementation details for transitions between other disease states. As stated earlier, the model updates the disease states of the pig/cows in unit time steps (e.g., 6 hours). The transitions from latently infected to pre-clinically infectious, pre-clinically infectious to clinically infectious and from clinically infectious to recovered are based on keeping track of each individual pig/cow's length of each disease state and timing of when a pig/cow transitioned into a disease state. For instance, in the case of transitioning between the latent to preclinical infected state for a pig/cow, the model first calculates the length of the latent period for the pig/cow (τ^L) based on the latent time distribution. The model also keeps tracks of the time period when a pig/cow transitioned into the latently infected state (T^L). The model transitions the pig/cow from the latently infected to sub-clinically infected state in the first time period t where $t*\lambda \geq \tau^L + T^L$. Other disease state transitions are performed in a similar manner. The main input parameters for this section of the model are the probability distributions of latent, sub clinically infectious and clinically infectious time periods. The model can be run for a specified number of time periods and provides the estimates of number of pig/cows in various disease states

WM®

Bio-Zip™ Rev. 2.0

Sealable Liner

Technical Data June 2007

Product Description

The **BIO-ZIP™** *SEALABLE LINER* is a cleaner way of managing large volume biological waste streams and potential odor, leakage, disease, and environmental contamination issues. Constructed using proprietary coated layers of polypropylene-based material also featuring an industrial grade zippered sealing system, the **BIO-ZIP™** *Sealable Liner* fits securely inside industrial roll-off containers, trailers or truck racks from 10 to 40 cubic yards in total volume. It's easy to install, capable of containing large, heavy loads and will slips right out when it's time. ONE SIZE FITS ALL.

Typical Physical Properties and Performance Characteristics

A. Dimensions:

Approximate Nominal Thickness	**96 mil-105 mil**
Physical Dimension	**See attached Engineering Drawing**
Standard Folded Size	**44"W X 48"L X16"H**
Weight per unit	**98 lbs**

B. Typical Physical Properties and Performance Characteristics

Nylon Coil Zipper

PROPERTY	TEST METHOD	UNITS US
Crosswise Strength of Chain	ASTM D-2061-93	254 lbs
Holding Strength of Separable Units	ASTM D-2061-93	70.1 lbs
Resistance to Pull Off of Slider Pull	ASTM D-2061-93	141.8 lbs
Salt Spray Exposure		Operational and Functional

Typical Physical Properties and Performance Characteristics *(Continued)*

6000 DENIER Thread

PROPERTY	TEST METHOD	UNITS US
Construction		1000 denier 6ply continuous filament
Elongation	ASTM D-882	17%
Tensile	ASTM D-882	105 lbs
Finish		Silicone 4%-6%

7.5 oz Inner Coated Water Proof Layer (proprietary coating)

PROPERTY	TEST METHOD	UNITS US
Weight		7.4oz
Thickness	ASTM D-5199	86.0 mils
Coating	ASTM D-5199	3mils
Grab Tensile	ASTM D-4632	290 lbs
Elongation	ASTM D-822	45%
Mullen Burst	ASTM D-3786	350 psi
Trapezoidal Tear Strength	ASTM D-4533	50 lbs
Puncture Strength	ASTM D-4833	120 lbs

3.0 oz Coated Polypropylene Outer Layer (proprietary coating)

PROPERTY	TEST METHOD	UNITS US
Weight	ASTM D-1910	3.7 oz/yd2
Thickness	ASTM D-5199	11mill min
Tensile Strength Warp	ASTM D-4623	140 lbs
Tensile Strength Weft	ASTM D-4632	132 lbs
Puncture	ASTM D-4355	69 lbs

C. Environmental Resistance

PROPERTY	TEST METHOD	UNITS US
7.5 oz Inner Water Proof Coated Layer UV Resistance (after 500 hrs)	ASTM D-4355	70% Strength
3.0 oz Water Proof Coated Outer Protective Layer UV Resistance (after 1200 hrs)	ASTM D-4355	>70% Strength

Safety and Regulatory

- **Material is 100% solids and contains no hazardous air pollutants**
- **Hazard rating: Zero rating for health, fire and reactivity and is zero class flammability**
- **Disposal: Meets US regulations for landfillable materials.**

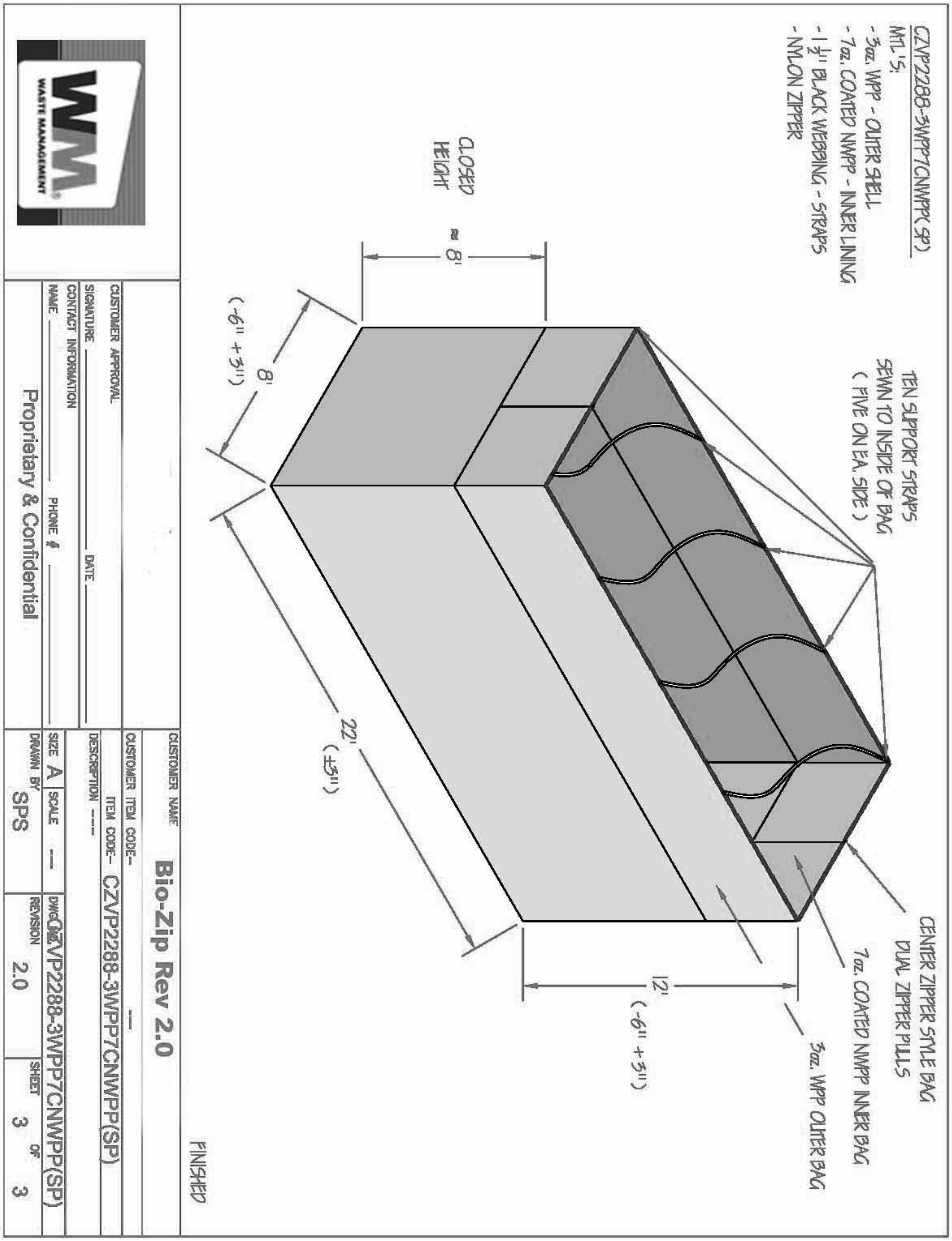
Manufacturing

- **Lead Time**
  - **Emergency Request: 24 hour lead-time, 25% expedite fee will apply with a 20-50 bag daily capacity.**
  - **Non-Emergency- Two week lead-time is required and a 20-50 bag daily capacity**
- **Capacity**
  - **Daily Maximum Capacity- 75-100 units per day**

Shipping and Storage

- **Shipping**
  - **Pallet Dimensions- 49"Wx52"L**
  - **Bio-Zip Dimension Folded- 44"WX48"LX16"H**
  - **Units Per Pallet-5**
  - **Weight Per unit-98 lbs**
  - **Weight Per Pallet-540 lbs (98 lbs x 5 +Pallet (50 lbs)**
- **Units per Semi-Trailer**
  - **48' Semi-trailer-22 pallets (110 Bio-Zip bags)**
  - **52' Semi-trailer-24 pallets (120 Bio-Zip bags)**
- **Storage**
  - **Optimal Storage: Climate control- shelf life 20 years**
  - **Covered, out of direct sunlight and out of elements: 5-10 years**

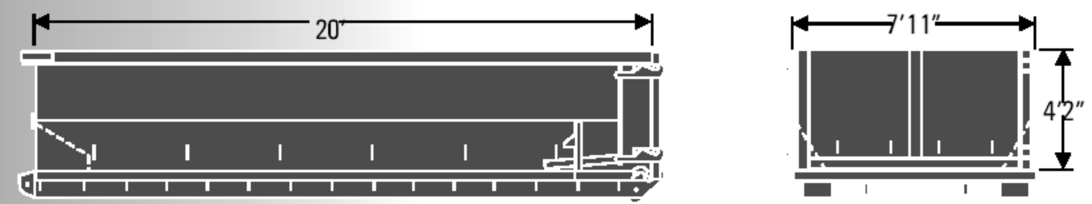
1001 Fannin, Suite 4000
Houston, TX 77002
www.wmupstream.com/biozip


CZVP2288-3WPP7CNWPP(SP)
MTL'S:
- 3oz. WPP - OUTER SHELL
- 7oz. COATED NWPP - INNER LINING
- 1 1/2" BLACK WEBBING - STRAPS
- NYLON ZIPPER
CLOSED HEIGHT
≈ 8'
8'
(-6" + 3")
22'
(±3")
12'
(-6" + 3")
TEN SUPPORT STRAPS SEWN TO INSIDE OF BAG (FIVE ON EA. SIDE)
CENTER ZIPPER STYLE BAG DUAL ZIPPER PULLS
7oz. COATED NWPP INNER BAG
3oz. WPP OUTER BAG
FINISHED
WM WASTE MANAGEMENT
CUSTOMER APPROVAL
SIGNATURE
DATE
CONTACT INFORMATION
NAME
PHONE #
Proprietary & Confidential
CUSTOMER NAME
Bio-Zip Rev 2.0
CUSTOMER ITEM CODE
ITEM CODE CZVP2288-3WPP7CNWPP(SP)
DESCRIPTION
SIZE A
SCALE
DWG NO. CZVP2288-3WPP7CNWPP(SP)
DRAWN BY SPS
REVISION 2.0
SHEET 3 OF 3

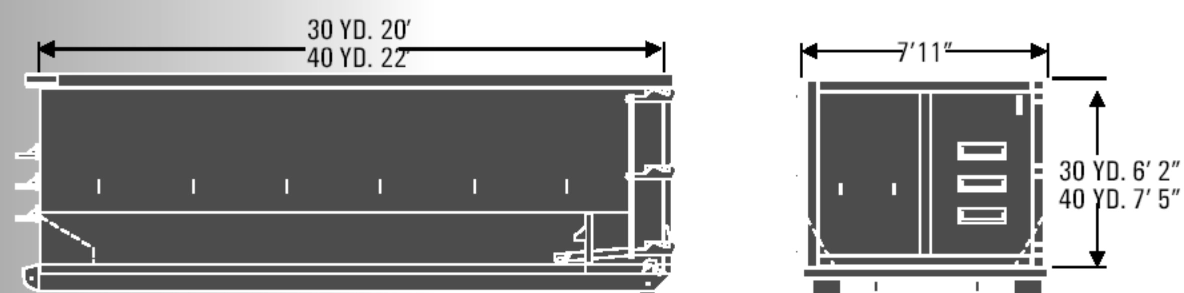
Bio-Zip Sealable Liner Compatible Containers
(10 yard container not shown)

NATIONAL ACCOUNTS SALES & SERVICE

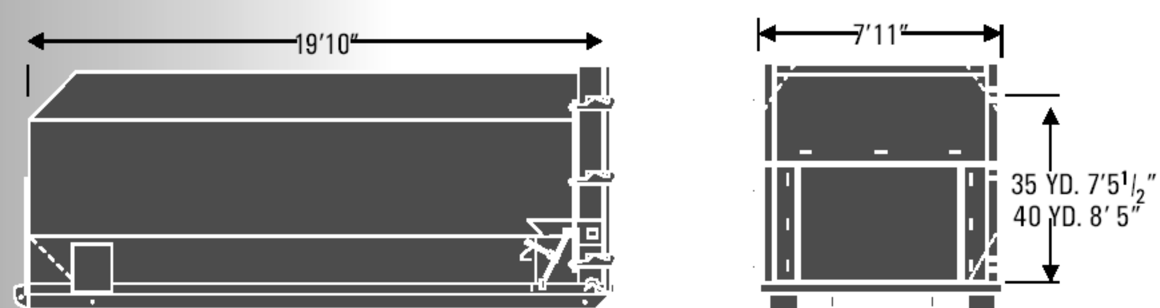
OPEN TOP CONTAINERS



20 YARD OPEN TOP



30 AND 40 YARD OPEN TOP



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Appendix C: Federal and State Regulations for Carcass Movement

Federal Regulations

Summary 1: Code of Federal Regulations, pertaining to carcass transportation

CFR	
APHIS	
Title 9 - Animals and Animal Products » CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE » SUBCHAPTER A--AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION» Part 325--TRANSPORTATION » § 325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter**.**	No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled or diseased animals or parts of the carcasses of any animals that died otherwise than by slaughter shall: (a) Buy, sell, transport, or offer for sale or transportation, in commerce, or import any dead livestock if its hide or skin has been removed; (b) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, unless such livestock and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 320 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of paragraph 301(c) of the Act;4 4 A list of such registrants, States, and amendments thereof, will be published in the Federal Register, and information concerning the registration status of particular animal food manufacturers, renderers, or collection stations, or the status of particular States or Territories may also be obtained from the Director, Administrative Management Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. (c) Buy in commerce or import any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 320 of this subchapter, or is the operator of an establishment inspected as required by paragraph (b) of this section and such livestock or parts of carcasses are to be delivered to establishments eligible to receive them under paragraph (b) of this section; (d) Unload en route to any establishment eligible to receive them under paragraph (b) of this section, any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, which are transported in commerce or imported by any such person: Provided, That any such dead, dying, disabled, or diseased livestock, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Compliance Staff, Meat and Poultry Inspection Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. (e) Load into any means of conveyance containing any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any livestock or parts of carcasses not within the foregoing description or any other products or other commodities.
Title 9 - Animals and Animal Products » CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE » SUBCHAPTER A--AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND	All vehicles and other means of conveyance used by persons subject to § 325.20 for transporting in commerce or importing, any dead, dying, disabled, and diseased livestock or parts of carcasses of livestock that died otherwise than by slaughter shall be leak-proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance so used in conveying such livestock, or parts thereof, shall be cleaned and disinfected prior to use in the transportation of any product intended for use as human food. The cleaning procedure shall include the complete removal from the means of conveyance of any fluid, parts, or product of such dead, dying, disabled, or diseased livestock and the thorough application of a disinfectant to the interior surfaces of the cargo space. Substances permitted for such use are: (a) “Liquified phenol” (U.S.P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to 1 gallon of water.

VOLUNTARY INSPECTION AND CERTIFICATION» Part 325--TRANSPORTATION » § 325.21 Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.	(b) “Cresylic disinfectant” in the proportion of not less than 4 fluid ounces to 1 gallon of water; and such other disinfectants as are approved by the Administrator in specific cases. The use of “cresylic disinfectant” is permitted subject to the conditions prescribed in § 71.10(b) of this title.
DOT	
Title 49 › Subtitle B › Chapter I › Subchapter A › Part 105 - Hazardous Materials Program Definitions And General Procedures	Infectious Substances, CFR 49, 173.134 Class 6, Division 6.2 (1) Division 6.2 (Infectious substance) means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN 3373, or UN 3291 as appropriate, and must be assigned to one of the following Category A An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging resulting in physical contact with humans or animals. Category B An infectious substance that is not in a form generally capable of causing generally capable of causing permanent disability or life threatening or fatal disease in healthy humans or animals when exposure occurs; incl. Cat B trans. for diagnostic or investigational purposes

Summary 2 - Examples of State Carcass Transportation Regulations

State	Regulations
Kansas	http://kansasstatutes.lesterama.org/Chapter_47/Article_12/ 47-1209: Transportation of carcasses of domestic animals and packing house refuse; conditions and limitations. All vehicles used in the transportation upon public highways of the carcasses of any domestic animals or packinghouse refuse, shall conform with the following conditions and limitations: (1) The carcasses of dead animals or packinghouse refuse, shall be placed in containers or vehicles which are constructed of, or lined with, impervious material, and which do not permit the escape of any liquid (2) after original loading, the carcasses of domestic animals shall not be moved from the transporting container or vehicle upon a public highway or in any other place except at the disposal plant, at an authorized substation, or at an authorized place for transfer of carcasses or refuse into line vehicles; (3) containers and vehicles shall be disinfected each time before leaving a disposal plant, or substation, and the exterior thereof shall be disinfected each time after loading and before entering the public highway, all in conformance with requirements and regulations prescribed by the commissioner; (4) containers and vehicles used for transporting of carcasses of animals or packinghouse refuse shall not be used for the transportation of live animals except to a licensed disposal plant or the transportation of food or feed for human or livestock consumption until properly cleaned and sterilized.
Wisconsin	http://docs.legis.wisconsin.gov/statutes/statutes/95/50 5.50 Transportation and disposal of animal carcasses. (2) Carcass transportation and disposal prohibitions. No person may do any of the following, either directly or through an employee or agent: (a) Transport or dispose of a carcass that the person knows or reasonably should know to be a diseased carcass in a manner that creates a significant and foreseeable risk of transmitting disease to humans or animals. (b) Dispose of a carcass in the waters of the state. This paragraph does not prohibit the use of farm-raised fish as bait. (4) Regulation of carcass transportation and disposal. The department may, by rule or order, regulate the transportation and disposal of carcasses to prevent and control contagious and infectious diseases.
Florida	https://www.flrules.org/gateway/ChapterHome.asp?Chapter=5C-23 5C-23.003 Transporting or Hauling Animal Carcasses or Refuse; Procedures; Records; Equipment; Quarantine.

(1) A copy of the official permit shall be kept in each vehicle used for transporting or hauling animal carcasses or refuse.

(2) Any person transporting or hauling animal carcasses or refuse shall keep records regarding the collection, transportation and distribution of animal carcasses or refuse. Such records must include the names and addresses of persons, firms and partnerships or corporations for which animal carcasses or refuse is being transported and cover the previous twelve months of operation.

(3) All vehicles and/or containers used to transport or haul animal carcasses or refuse shall be thoroughly cleaned and disinfected weekly or more often if deemed necessary by a representative of the Division. Each operator shall be responsible for the proper cleaning of his vehicles and/or containers.

(4) Vehicle and/or containers used to transport or haul animal carcasses or refuse which do not meet the requirement of this rule shall be placed under quarantine by the department until they are in compliance with this Chapter and proper cleaning and disinfection of the same has occurred

Texas

http://info.sos.state.tx.us/pls/pub/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=4&pt=2&ch=59&rl=12

(a) Purpose: Livestock in Texas are subject to a variety of highly contagious, foreign animal diseases (FAD). The infection or exposure of Texas livestock to a FAD would create an animal health emergency requiring the commission to respond as expediently as possible. A FAD may be very contagious; it may affect both farm/ranch animals and wildlife in Texas, and it may be extremely difficult to identify, isolate, control, and eradicate. It may spread to other areas in the state or other states and countries if the outbreak is not controlled in an expedient or effective manner. Any time delay in responding to such an emergency could cause a severe impact to, or even destroy, the agricultural economic stability and viability of the State and possibly the Nation. The purpose of this section is to authorize the executive director to be able to respond quickly and restrict the movement of livestock from specific areas or facilities in order to reduce any potential exposure of Texas livestock to a disease as provided in §58.2 of this title (relating to Disease Control).

(b) Emergency Response Movement Restrictions: As a control measure, the commission by rule may regulate the movement of livestock in this state. Movement restrictions contained in this section are to become effective upon a determination that there is exposure to a disease or an agent of transmission of one of the diseases as identified in §58.2 of this title (relating to Disease Control) and that these restrictions are necessary to protect livestock in this state.

(c) Executive Director Authority: The executive director may restrict movement of livestock in any part or all of the state, through this section, if the executive director determines that livestock are exposed or infected with a disease as identified in §58.2 of this title (relating to Disease Control) and believes that the disease presents a danger to the public health or livestock industry and that the executive director considers it necessary to protect livestock in this state, by restricting movement under this subchapter. The executive director may require testing, vaccination, or another epidemiologically sound procedure in order to authorize movement from restricted locations.

(d) Effect of Movement Restrictions: These movement restrictions will remain in effect until the executive director has determined that the exposure to the disease or infection from the disease has been eradicated or controlled.

(e) Inspection of Shipment of Animals or Animal Products: An agent of the commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state in order to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or noncommunicable disease. An authorized agent of the commission may issue a hold under this chapter to detain a shipment of animals or animal products in order to determine if the shipment had been exposed to a disease as identified in §58.2 of this title (relating to Disease Control) or to determine if the shipment is being transported in violation of this chapter. The authorized agent of the commission may require that the shipment be unloaded at the nearest place designated as appropriate unloading/loading and boarding facility in order to assess health status or to protect against possible exposure from a disease provided by §58.2 of this title.

(f) Restricted Movement Locations: If the executive director has determined that there is an animal health emergency and that there is a need to restrict movement of livestock, then movement of livestock is restricted, until authorized by the commission through an agent of the commission, at the following locations:

(1) Livestock Market;

(2) Feedlots;

(3) Shows, Fairs and Exhibitions;

(4) Any premise where a caretaker for livestock has received written notice that movement restrictions are in place based on possible exposure to a disease as identified in §58.2 of this title (relating to Disease Control).

(g) Notice of Restrictions: Restricted movement from locations provided for in subsection (f) of this section are effective upon receipt of notice in accordance with §58.22 of this title (relating to Notice of Livestock Movement

	Restrictions). (h) Statewide application or part of state: The movement restrictions contained in this section can be made effective for all or part of the state in order to protect against exposure from a disease as identified in §58.2 of this title (relating to Disease Control).
Georgia	http://agr.georgia.gov/Data/Sites/1/media/ag_animalindustry/equine/files/laws/ocga4-5-1disposalofdeadanimals527031.pdf Dead animals or parts thereof, raw or unrendered, except green salted hides, shall not be allowed to enter the State of Georgia except by written permit issued by the Georgia Department of Agriculture; provided, however, that licensed research institutes, accredited colleges or state colleges and universities, and departments of municipal governments may transport and receive dead animals for research or investigational purposes only. (Ga. L. 1969, p. 1018, § 7.)3 4-5-9 Prohibition or restriction on transport of dead animals; permit issuance. The Commissioner of Agriculture may prohibit or restrict, at his or her discretion, and issue permits for the hauling or transportation of dead animals or types of dead animals and order the destruction thereof in accordance with this chapter.
Maine	www.maine.gov/sos/cec/rules/01/001/001c211.doc SECTION 15. TRANSPORTATION OF POULTRY AND LIVESTOCK CARCASSES 1. Secure Containers - Poultry or livestock carcasses transported over any public road shall be transported in secure containers. 2. Diseased Carcasses - Carcasses from animals that died or were slaughtered due to a disease outbreak may only be transported from the farm or other regulated facility where they originated with the permission of the Commissioner. A written biosecurity plan shall be required prior to transportation of diseased carcasses.
Minnesota	http://www.vetmed.state.mn.us/portals/22/BAH%20Rule%20Book.pdf Disposal of Dead Animals and Rendering Plants 1719.0200 Permits. Subpart 1. Generally. Permits from the board are required for all trucks used to transport carcasses or discarded animal parts over public roads. The permit authorizes the permittee to transport the carcasses or discarded animal parts over public roads to an establishment but does not authorize crossing state lines. Permits are valid for one year unless revoked in accordance with Minnesota Statutes, section 35.93. The permittee shall comply with rules of other state and federal agencies. No permit is required for a person to haul the carcass of an animal which was owned by that person before the animal died. 1719.0310 Trucks crossing state lines. Trucks crossing state lines must meet applicable conditions in any reciprocal agreement between the states involved. 1719.0400 Truck owned by person other than owner or operator of rendering plant. If a truck is owned by a person other than the owner or operator of the establishment, the owner or operator of the truck and the owner or operator of the establishment are responsible for compliance with all laws and rules pertaining to the transportation of carcasses. The application must indicate the name and address of the owner of the truck. 1719.0500 Inspection of plant facilities and trucks. Subpart 1. Generally. Before permits are issued, an inspection of the plant, collecting station, and trucks must be made by an agent of the board to determine if the facilities of the plant and the trucks comply with this chapter. A report of the inspection must be filed with the board. Subp. 2. Repealed by amendment, 20 SR 2033
Wyoming	http://legisweb.state.wy.us/statutes/titles/Title11/T11CH23AR3.htm ARTICLE 3 - TRANSPORTATION OF CARCASSES TO RENDERING PLANTS 11-23-301. Generally; exceptions. With the consent of the owner, unless removal is contrary to state, county or local sanitary regulations or in the opinion of the state veterinarian might result in spreading contagious or infectious disease or threaten the health of human beings, animals or poultry, carcasses of animals may be transported to any rendering plant legally operating without prior inspection for brands and ownership. The operator of a rendering plant within this state receiving the carcasses is a hide buyer and shall comply with W.S. 11-23-201 through 11-23-207.

Appendix D: Expert Opinion – Rendering

Expert opinion was sought on standard carcass transportation practices. Rendering companies have expertise in mass carcass removal and conveyance on a daily basis. Central Bi-Products, a full service rendering company that operates two complexes in Redwood Falls, MN and in Long Prairie, MN was contacted to provide expert opinion on carcass transportation in the rendering industry.

Expert opinion was sought on the means of conveyance (specifications, types of vehicles commonly utilized), standard procedures in carcass pick-up and transportation, and regulations regarding carcass conveyance.

The most commonly used trailers in the industry with the standard rendering truck (semi-truck with an open box container) are 28, 32 and 40 feet. Open containers are sealed with a tarp covering prior to transportations. These come in a variety of mechanisms. The majority of the industry in the Upper Midwest utilizes a roll-top system. Transportation regulations mandate that the rendering vehicles are leak-proof. In Minnesota, rendering vehicles are permitted and inspected. The driver can retrieve carcasses from locations without ever stepping foot on the premises using an automated grapple system on the standard rendering truck. Estimates on truck capacity for the maximum carcass weights of what each trailer can hold are below:

Trailer Length (ft)	**Trailer Weight Capacity lbs (kg)**
28'	40,000 lbs (18,182 kg)
32'	45,000 lbs (20,455 kg)
40'	50,000 lbs (22,727 kg)

According to the industry experts, in a full carcass load (cattle), the carcass fluid (manure, urine, blood, basically any liquid that can spill out of the carcasses and into the truck during transport process) depth that one typically would see in the bed of the rendering truck is very little if the animals are loaded fresh (within 24 hours). It was estimated that if one were to clean the bottom of the trailer with a broom and shovel you might get a 5 gallon pail full of carcass fluids, as there is very little leakage from fresh animals.

Appendix E: Expert Opinion – Depopulation

Sources and Generation

Expert opinion was sought for likely times for depopulation. Although official regulations state euthanasia and disposal will occur within 24hrs or as soon as possible after premises classification (Red Book, National Center for Animal Health Emergency Management, 2011), we know that these will be dependent on resources and scale of outbreak as well as interpretation. Experts in depopulation were contacted and requested to provide opinion on euthanasia time and depopulation rates.

Experts who agreed to provide opinions for euthanasia and depopulations times were:

- David Finch, Texas Animal Health Commission
- Lori Miller, Department of Homeland Security
- Donald Topliff, West Texas A&M University
- Jimmy Tickel, North Carolina Department of Agriculture and Consumer Services
- Darrel Styles, USDA APHIS

Euthanasia Time

The following questions were provided to experts. For each of these questions, experts were requested to provide their opinion on 1) minimum, 2) most likely, and 3) maximum timing.

1. What is the most likely time to start of euthanasia for FMD Index premises?
2. What is the most likely time to start of euthanasia for Subsequent FMD premises?
3. What are the most likely depopulation rates (Expert Opinion) for cattle and hogs. (animals /day or animals /hr)?

Appendix F: Aerosol Science

Sources and Generation

Generation of bioaerosols can occur under natural conditions as well as from human activities such as spreading of slurries, pressurized spray irrigation, and aeration basins at wastewater treatment plants. In general, airborne microorganisms (bacteria, fungi, and viruses), and their components, are generated as a mixture of droplets or particles, having different aerodynamic diameters ranging from 0.5 to 100 µm ((Cox C, 1995); (Lighthart B, 1994)).

Microorganisms associated with droplets evaporate to dryness or near-dryness before impacting the ground or vegetation and are transported by air currents (Dungan RS, 2010). The optimum aerodynamic particle range which represents a hazard to the human respiratory tract is between 1.0 and 10 µm ((Mohr A, 2005); (Mohr A, 2007)).

The dissemination and transport of bioaerosols depends on the method of bioaerosol generation and energy input into the system. Pressurized air, electricity, centrifugal forces, impaction, or heat can provide the energy needed to produce small particles. Many of these forces are so violent that inactivation of the microorganisms will occur. Fluids associated with newly aerosolized particles will instantaneously start to evaporate. The distribution and concentration of particle sizes are two important variables that directly affect the potential for dissemination and transport.

Transport

The transport, behavior, and deposition of bioaerosols are affected by their physical properties (i.e., size, shape, and density) and meteorological factors they encounter while airborne. Naturally occurring bioaerosols are ejected into the atmosphere by wind, rain and bursting bubbles, and other processes. The environmental conditions of wind velocity, RH, temperature, and precipitation significantly affect transport of bioaerosols with atmospheric stability being a major factor ((Jones AM, 2004); (Lighthart B, 2000)).

Bioaerosols are subject to inactivation and transport the moment they become airborne. Particle sizes of droplets are usually small (2 to 10 µm) and they tend to follow the streamlines of the local wind. Particles with sizes smaller than 5.0 µm act as vapors and follow the streamlines of the airstream. The aerodynamic diameter of particles determines whether it is small enough to follow the streamlines of the surrounding flows, or if it is large enough to cross streamline flow and impact upon a surface. Deposition of larger aerosols occurs through gravitational settling, impaction, diffusion, convection (due to temperature variations), and wash-out by raindrops (Muilenberg M, 1995).

Viability, Stability, and Infectivity

The viability of bioaerosols is dependent upon their chemical makeup and the environmental and meteorological factors they are exposed to, such as wind speed, temperature, and RH. These atmospheric conditions are strongly influenced by features such as large-scale flow fields, geographical locations, and local topography. The most significant environmental factors influencing viability are RH, solar irradiance, temperature, and oxygen concentration. Additional influences include air ions and open-air factors (OAF). Atmospheric turbulence is responsible for diffusion of particles during transport by the wind (mean wind speed) and is strongly influenced by local atmospheric conditions and the diurnal variation of solar irradiance reaching the ground.

Of all of the measurable meteorological parameters, RH is the most important with respect to aerosol stability, which is an important determinant of bioaerosol viability and infectiousness ((Mohr A, 2005); (Mohr A, 2007)). The majority of airborne microorganisms are immediately inactivated upon release because of environmental stresses (desiccation, temperature, and oxygen) which act upon and alter the surface of the microorganism. The fundamental factors that affect the viability of microorganisms are the state of the water and water content of the bioaerosol. As RH decreases, the water available to the exterior environment of the microorganism also decreases. Loss of water can cause dehydration, resulting in inactivation of many microorganisms. The RH of the system also directly affects the density of the bioaerosol unit. The size, shape, and density of the aerosolized particles are directly related to the aerodynamic diameter, which determines settling velocity and location of deposition in the respiratory tract ((Mohr A, 2005); (Mohr A, 2007)).

Studies to determine the effect of temperature on the fate of bioaerosols have generally shown that increasing temperatures tend to decrease the viability of airborne microorganisms (Dimmock NJ, 1967). It is difficult to separate the effects of temperature and RH, as the vapor pressure and RH of a system are dependent on temperature. The lipid content of the outer coat, or capsid of a virus, determines the stability at high or low RH values.

Appendix G: Expert Opinion – Aerosols

Bioaerosol Experts Interviewed and Questions

The three experts who responded to a request for expert opinion were interviewed about the probability of generating bioaerosols during pumping and transport of FMD-infected carcasses. Background information was provided to the experts on truck design, mitigations, and regulations. The following experts that agreed to an interview have varying backgrounds in aerosol /bioaerosols research including engineering and aerosol physics..

- Robert DeOtte, PhD, PE, PG, Professor of Civil & Environmental Engineering, West Texas A&M University
- Thomas Kuehn, MS, PhD , Professor, University of Minnesota, Department of Mechanical Engineering
- Peter Raynor, MS, PhD, Associate Professor, University of Minnesota, Division of Environmental Health Sciences

The questions below were posed to the experts in bioaerosol science. The table below summarizes their responses.

Expert opinion was sought as to whether or not infected fluids that may leak from the carcasses post-mortem (infectious fluids like feces, urine, stomach/rumen contents, blood, milk etc.) would generate aerosols while being transported from site of euthanasia to disposal. The conveyance assessed were a box trailer that is 1) open on the top and 2) one that is covered with a tarp.

Based on the likelihood definitions below, please provide expert opinion on aerosolization in 1) **uncovered** and 2) **covered** standard rendering vehicle during transportation

Likelihood	Descriptive Definition
High	The event would be very likely to occur
Moderate	The event is unlikely but does occur with a certain probability
Low	The event would be unlikely to occur
Negligible	The likelihood that the event will occur is insignificant, not worth considering

1. What is the likelihood (see chart) of significant aerosolization of carcasses fluids during transportation?
2. What is the likelihood that a significant portion of the aerosolized particles to be less than 10 µm in size?
3. If aerosols could be produced from the carcass leakage, what is the likelihood they could then move into the airstream at a subsequent farm?
4. Can you briefly describe your rationale for the selected likelihood levels?

Summary 3 - Expert Opinion on Bioaerosols

	Expert 1	Expert 2	Expert 3
UNCOVERED			
What is the likelihood of significant aerosolization of carcasses fluids during transportation?	**Moderate** There could be two potential mechanisms for particle formation: (1) the sloshing of fluids back and forth against walls and surfaces which could form particles as the fluids impact, and (2) wind eddies forming drops along the surface of the fluids. Although the carcasses will limit the sloshing of the fluids and the access of strong eddies against the surface of the fluids, thus reducing the risk of generation, I still think the likelihood is Moderate.	**Low** The only aerosolization process considered is direct generation by the air stream when the trailer is in motion. Generating aerosol particles from wet liquids or material that is moist is nearly impossible without extremely large shear forces caused by high air velocities. The liquid viscosity also plays a role, the more viscous the liquid the more shear force is required and the less likely that particles will be generated. Dried material that was liquid at one time is also quite resistant to particle production. Dry loose dust could be aerosolized in an open trailer but I think the materials you are working with should be very resistant to this. Another scenario is dripping from the trailer onto the roadway. This potentially could generate aerosols directly at elevated speeds and perhaps the material deposited on a roadway could be aerosolized by passing vehicles. I think the potential for this scenario to generate particles is higher than simply looking at the air forces generated in an open trailer because the fluid is being dripped in the form of small droplets into a fast moving air stream. Nonetheless, I think the likelihood of this causing any secondary infection is quite remote	**Negligible** Generating aerosols from the liquid collecting at the bottom of a trailer is unlikely. The carcasses above that pool will hinder air flow and limit the shear necessary to generate droplets. A more likely possibility for the uncovered trailer is matter on the hide of the upper layer or two of animals breaking loose by mechanical means and being carried by air currents away from the vehicle. These solid particles could be fairly large but if so, will settle quickly. The particles could impact solid surfaces and break into smaller particles. The particles of concern would be dust from dried, crushed manure on the hide. These can easily be smaller than 10 µm.
What is the likelihood that a significant portion of the aerosolized particles to be less than 10 µm in size	**Moderate** If some aerosol droplets are generated, a significant number could be smaller than 10 micrometers because the water portion of droplets will evaporate, potentially causing larger droplets to rapidly become smaller.	**Low**	-
If aerosols could be produced from the carcass leakage, what is the likelihood they could then move into the airstream at a subsequent farm?	**High** With the open top, I think there is a strong possibility for any aerosol droplets created to get into the air at a subsequent farm. Thus, I rate 1. c. High, although the overall likelihood of this outcome is only moderate because I think the risk of aerosols being produced in the first place is moderate.	**Moderate**	-
COVERED			

What is the likelihood of significant aerosolization of carcasses fluids during transportation?	**Low** Formation of droplets by wind eddies is negligible here, although droplet formation by sloshing fluid impacting on surfaces is still possible. Thus, I give 2. a. the Low rating.	**Negligible** Dripping could be an issue but direct aerosol production from under a covered load should be negligible	**Negligible** If the trailer is covered, that further reduces air flow at the bottom of the trailer, the likelihood for any aerosol generation and release is negligible for the covered trailer.
What is the likelihood that a significant portion of the aerosolized particles to be less than 10 µm in size	**Low** Because the trailer is covered, humidity inside the trailer is likely to be higher than if the trailer is uncovered, meaning that aerosol droplets are less able to evaporate than in 1. b. Thus, I have rated 2. b. as Low.	-	-
If aerosols could be produced from the carcass leakage, what is the likelihood they could then move into the airstream at a subsequent farm?	**Moderate** The trailer is not air tight, so there is still a significant possibility that any droplets formed will be able to escape the trailer at a subsequent farm. However, it is certainly less likely than if the trailer was uncovered, so I rate 2. c. as Moderate as opposed to the rating of High for 1. c.	-	-