

Secure Food Supply Business Continuity Plans: Federal, State, Industry, and Academic Partnerships

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Secure Food Supply Business Continuity Plans During an FAD Outbreak

Overall goals include:

- Detect, control, and contain FAD as quickly as possible;
 - Avoid interruptions in animal/animal product movement to commercial processing from farms with no evidence of infection during a foreign animal disease outbreak;
 - Provide a continuous supply of safe and wholesome food to consumers; and
 - Maintain business continuity for producers, transporters, and food processors through response planning.
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- <http://www.cfsph.iastate.edu/Secure-Food-Supply/index.php>
 - <https://fadprep.lmi.org> (username and password can be requested)

Secure Food Supply Plans

Movement from Premises with No Evidence of Infection

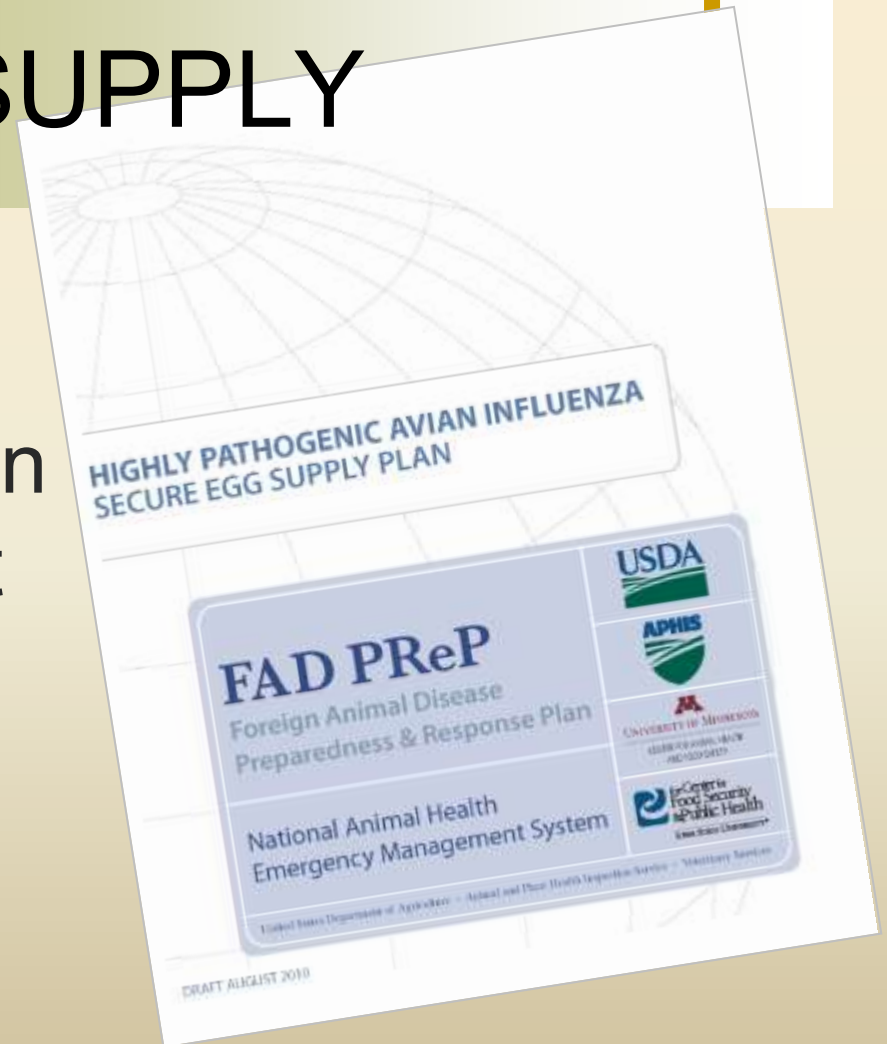
- Secure Egg Supply
 - High Pathogenic Avian Influenza
 - movement of eggs and egg products
- Secure Turkey Supply
 - High Pathogenic Avian Influenza
 - Movement of birds
- Secure Milk Supply
 - Foot and Mouth Disease (FMD)
 - Movement of milk
- Secure Pork Supply
 - FMD, Classical Swine Fever, African Swine Fever, and Swine Vesicular Disease
 - Movement of animals

Common Components of Secure Food Supply Business Continuity Plans

- Voluntary pre-outbreak preparedness components
- Biosecurity, surveillance, epidemiology questionnaires, movement permits
- Risk assessments (completed and in process)
- Plans must be based on current capabilities and will evolve with science, risk assessments and new capabilities
- Guidelines only: Final decisions made by responsible officials during outbreak
- Outreach and training pre and post outbreak

SECURE EGG SUPPLY

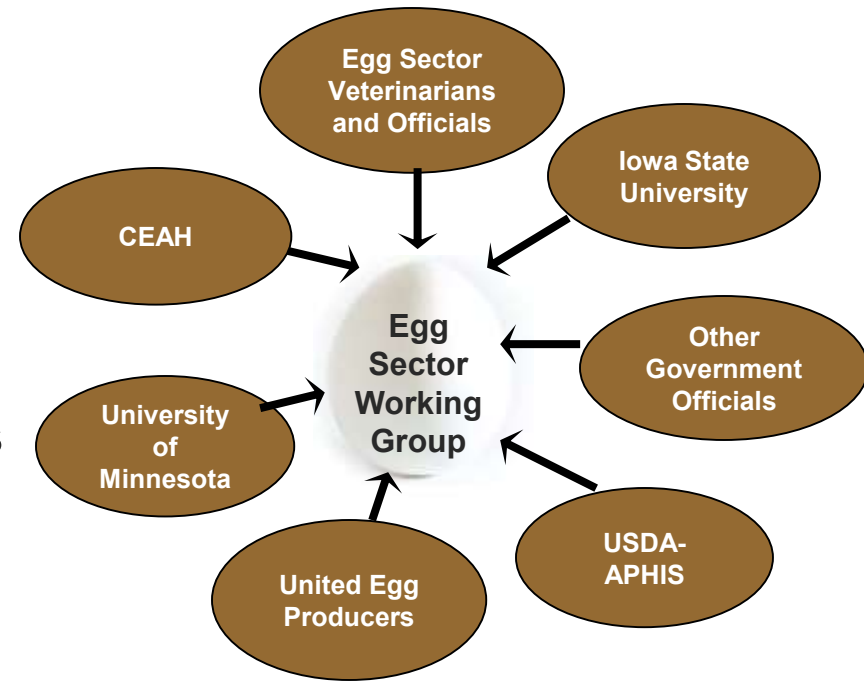
A collaboration between
Industry, Government
and Academia



[Egg Sector Working Group]

■ Public-private-academic partnership

- U of MN – Center for Animal Health and Food Safety (CAHFS)
- ISU – Center for Food Security and Public Health (CFSPH)
- United Egg Producers (UEP)
- Egg sector veterinarians and officials
- USDA-APHIS Veterinary Services (USDA APHIS VS)
 - Centers for Epidemiology and Animal Health (CEAH)
 - National Center for Animal Health Emergency Management (NCAHEM)



Components of the Secure Egg Supply Plan

- The SES Plan includes:
 - Proactive risk assessments
 - Voluntary preparedness biosecurity checklist and audits
 - SES Data portal (production data, PCR results)
 - Cleaning and disinfection guidelines
 - Permit guidance
 - Sample permits
 - Epidemiological questionnaire
 - Surveillance guidelines
- For further information:
 - www.secureeggsupply.com
 - <https://fadprep.lmi.org> (username and password can be requested)

Proactive Risk Assessments

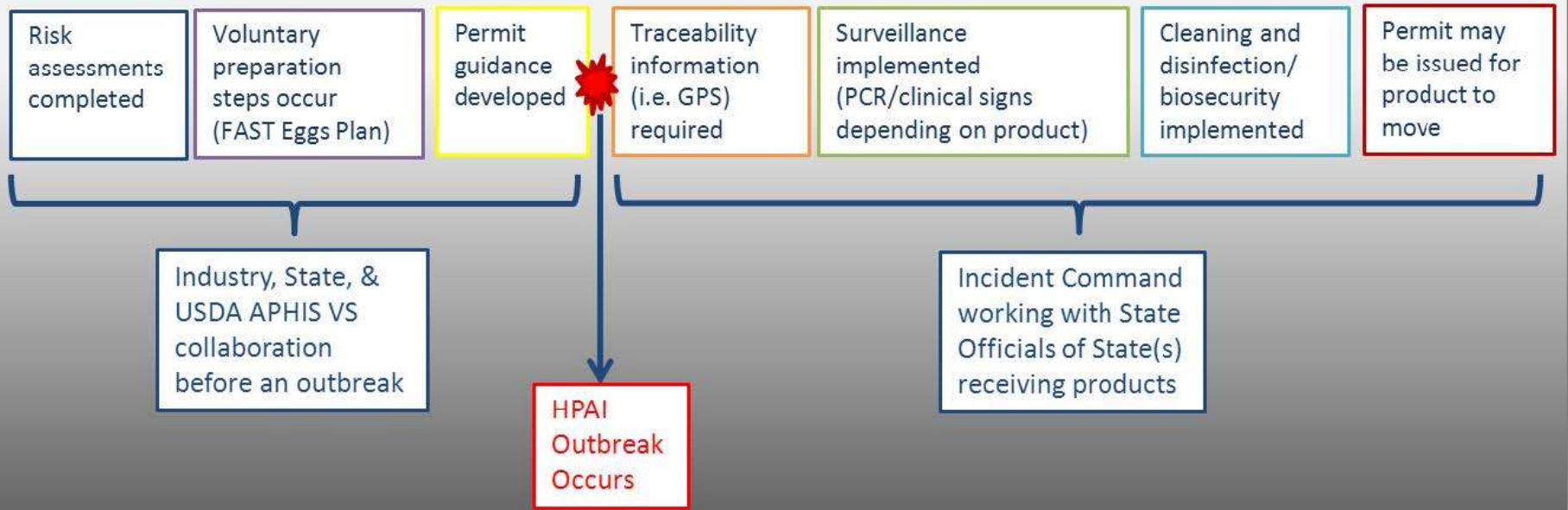
- *Pasteurized Liquid Eggs*
- *Non-pasteurized Liquid Eggs*
- *Washed and Sanitized Shell Egg*
- *Nest Run (unwashed) Eggs*
- *Egg-type Hatching Eggs*

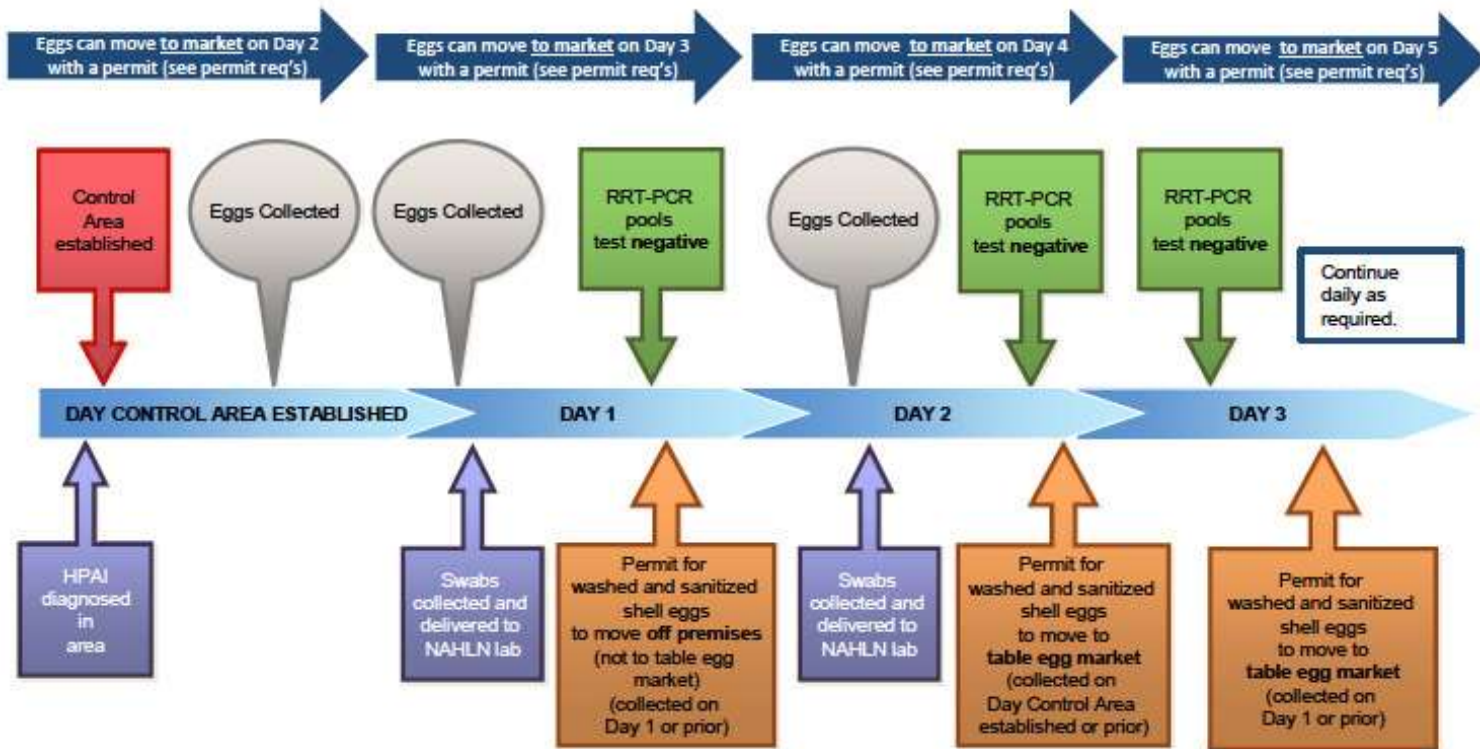
Permit Guidance

Product	(1) And the Proactive Risk Assessment is:	And Traceability Information (Premises ID, GPS Coordinates, other) is available:	(2) And Production Parameters are normal:	(3) And the following Biosecurity steps are in place:	(4) And the additional Product Specific Biosecurity steps are in place (see Section 2):	And the RRT-PCR result is negative*	Action	(5) Permit Guidance to move off farm (not to market):	And the Premises Biosecurity is acceptable:	And the Epi Assessment is acceptable:	And the second RRT-PCR result is negative**	Action	Permit Guidance (to move into market channel):
Pasteurized Liquid Egg	Negligible Risk	YES	YES	Truck & Driver Biosecurity									Issue PERMIT to Market
Non-pasteurized Liquid Egg	Negligible Risk	YES	YES	Truck & Driver Biosecurity		YES	Issue PERMIT to move to pasteurization						Non-pasteurized liquid eggs become pasteurized liquid eggs.
Washed & Sanitized Shell Egg (to premises without poultry)	Negligible Risk	YES	YES	Truck & Driver Biosecurity	1) Transport vehicle sealed by farm or company personnel under authorization of the Incident Commander.	YES	Issue PERMIT to move off farm to a storage or holding area	YES	YES	YES	YES		Issue PERMIT to market for eggs collected 2 days earlier
Washed & Sanitized Shell Egg (to premises with poultry)	Low Risk	YES	YES	Truck & Driver Biosecurity	1) Transport vehicle sealed by farm or company personnel under authorization of the Incident Commander. 2) Egg handling material used to transport eggs to breaking or further processing plants must be destroyed at the final destination or cleaned, sanitized and returned to the premises of origin without contacting materials going to other premises.	YES	Issue PERMIT to move off farm to a storage or holding area	YES	YES	YES	YES		Issue PERMIT to market for eggs collected 2 days earlier
Nest Run Shell Eggs	Low Risk	YES	YES	Truck & Driver Biosecurity	1) Eggs moved directly to a premises without poultry for washing & sanitizing, breaking, or for processing. 2) Transport vehicle sealed by farm or company personnel under authorization of the Incident Commander. 3) Egg handling material destroyed at the destination plant or cleaned and sanitized. 4) Egg handling materials can be returned to the premises of origin after at least 24 hours have elapsed since these materials were moved from the farm and without contacting materials going to other premises. 5) New paper or fiber flats must be used for hand gathered eggs.	YES	No permit issued until 2 negative RRT-PCR tests	YES	YES	YES	YES		Issue PERMIT to move for processing for eggs collected 2 days earlier (can move immediately to market after processing)



How the SES Plan Works...





Permit for moving washed and sanitized eggs off premises (not to table egg market) can be issued daily for eggs collected on that day or prior, as long as RRT-PCR results from that same day remain negative. Permit for moving washed and sanitized eggs to market can be issued after 2 negative RRT-PCRs and a 2-day hold, where at least one RRT-PCR result is from a pooled sample taken on the second day of holding or later.



Secure Turkey Supply Plan

- Iowa State University
 - Center for Food Security/Public Health
- University of Minnesota
 - Center for Animal Health/Food Safety
- National Turkey Federation
- Association of Veterinarians in Turkey Production
- USDA APHIS
 - VS, CEAH, NCAHEMS
 - Eastern and western region epidemiologists
- AVICs
- SAHOs



Secure Turkey Supply Plan Goals

- Market continuity for non-infected flocks
- Ensure HPAI infected turkeys don't move
 - Protect other flocks
 - Food safety
- Avoid trade restrictions
 - Interstate, international



Pre-movement Requirements

- Biosecurity (Level 2) In-place
- Epidemiology No contact
- rRT-PCR Surveillance Negative
- Mortality Normal
- Clinical signs Absent
- Pre-loading inspection Normal
- Farm traffic restriction 5 days

Secure Food Supply Plans

Movement from Premises with No Evidence of Infection

- Secure Milk Supply
 - Foot and Mouth Disease (FMD)
 - Movement of milk
- Secure Pork Supply
 - FMD, Classical Swine Fever, African Swine Fever, and Swine Vesicular Disease
 - Movement of animals

FMD: THE MOST Contagious Disease of Animals

FMD is the major animal disease preventing world trade of animals and animal products

Mortality is low but morbidity is high

High mortality associated with some strains and some control methods

Results in persistent infections in cattle

UK



Korea



Japan



Egypt



Prevalence of FMD 2011

World Organization for Animal Health (OIE) has 178 member countries:

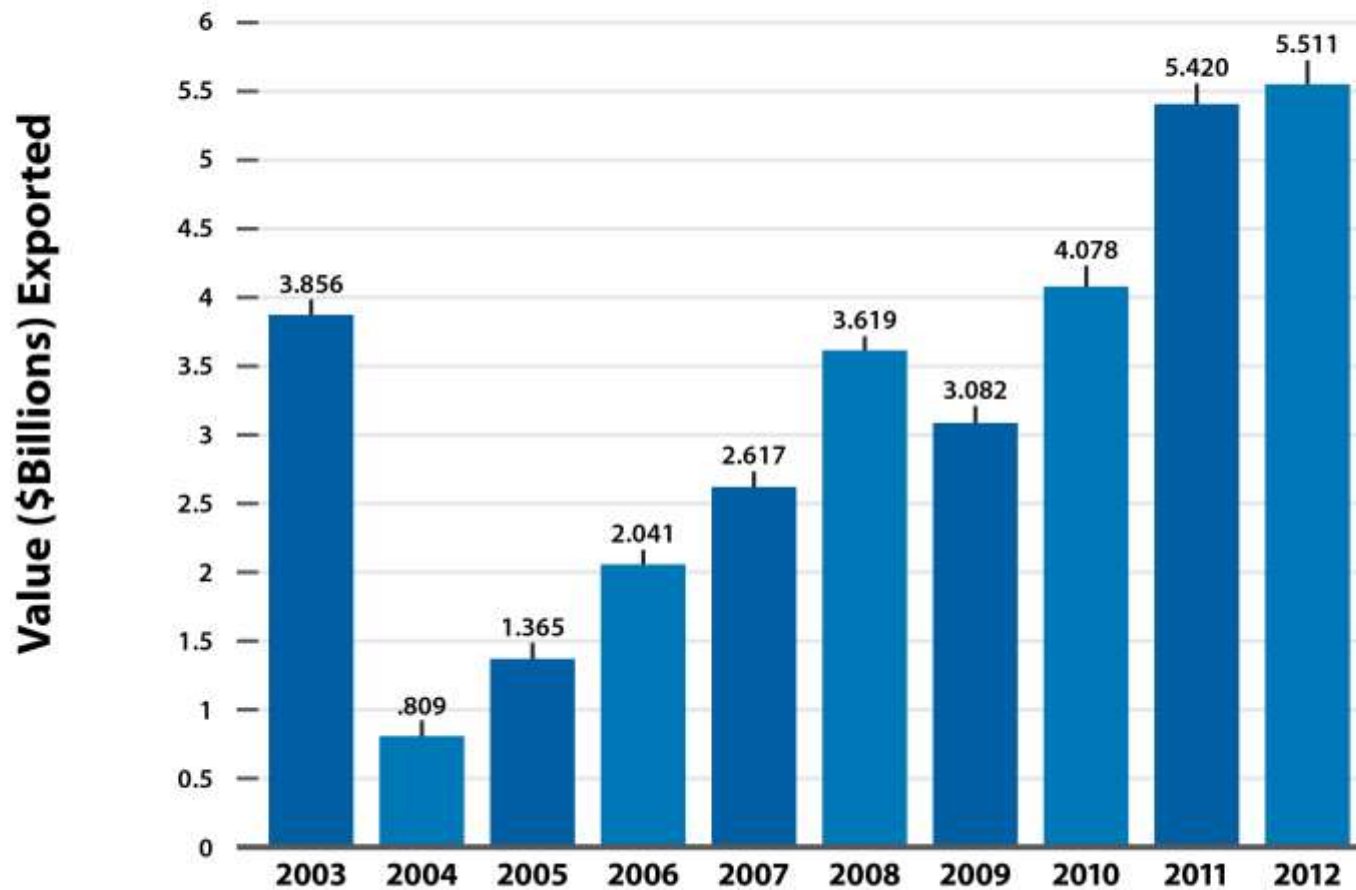
- 66 are recognized as free of FMD
- 11 countries have free zones either with or without vaccination
- 96 countries are endemic and have never been free of FMD
- 5 countries were free and recently suffered from a re-emergence of FMD



Day 1 of a Foreign Animal Disease Outbreak

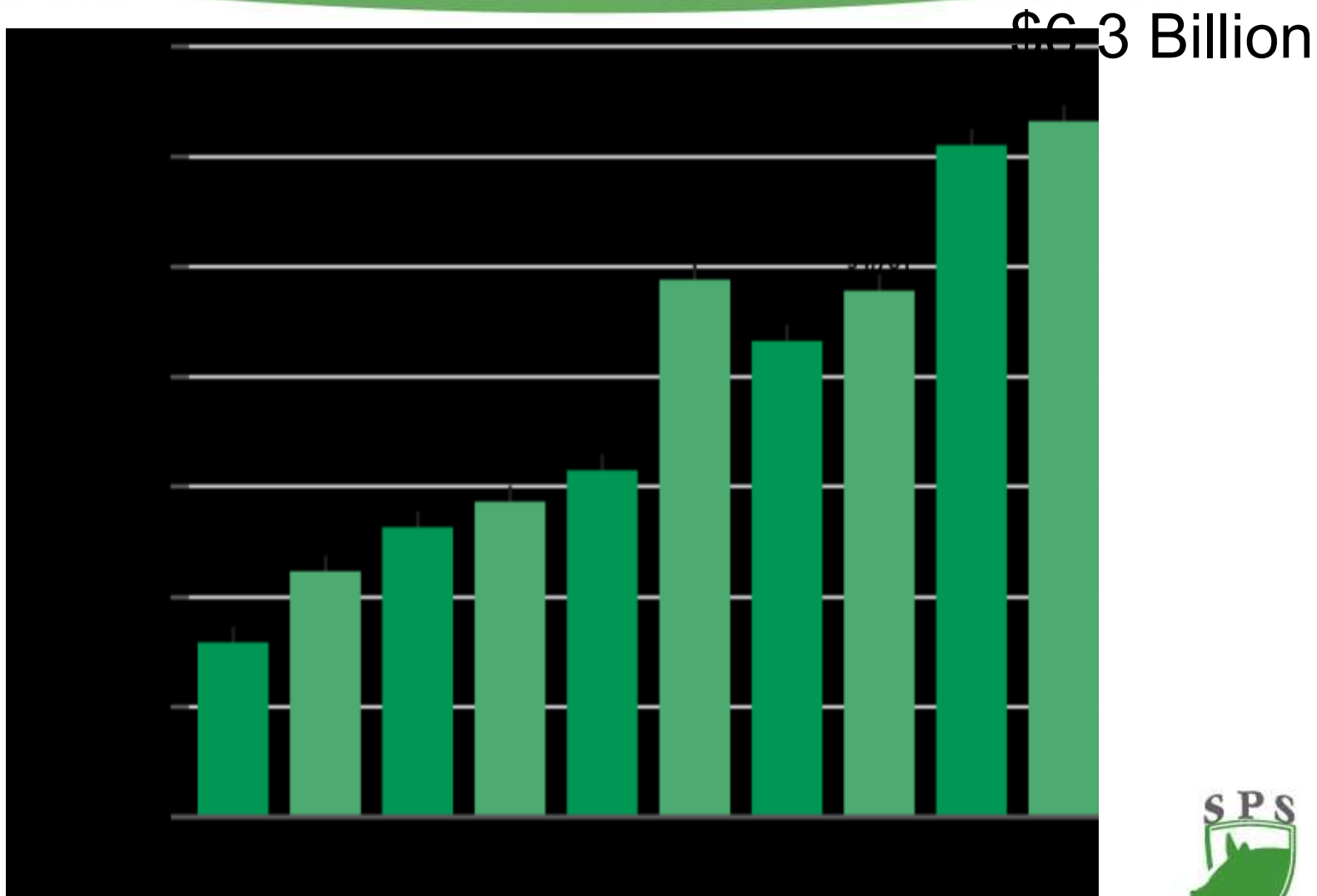
- All exports of cattle, swine, sheep, goats and their uncooked products will be stopped
- Prices will plummet
- Stop movement or controlled movement orders will be issued for the affected area in the U.S.

Total U.S. beef exports, (\$Billions) (2003-2012)



Data compiled by the U.S. Meat Export Federation and available at <http://www.usmef.org/news-statistics/statistics>

Total U.S. Pork Exports, Value (2003 - 2012)



The United States has had Nine Outbreaks of FMD

- 1870, 1880 and 1884: Due to importation of infected animals. Since the development of a Federal system of inspection and quarantine of imported livestock, no outbreak has been attributed to admission of live animals.
- 1902, 1908, 1914, 1924 (two separate outbreaks) and 1929
- All outbreaks were controlled by stop movement and stamping out

North American Animal Agriculture Industry is Unique

The size, structure, efficiency, and extensive movement inherent in the North American livestock industries will present unprecedented challenges in the event of a Foot and Mouth Disease (FMD) outbreak



North American Animal Agriculture Industry is Unique

Herd size:

- >50,000 cattle feedlots
- >5,000 cow dairies
- >70,000 calf ranches
- >20,000 sows



OIE Stamping-Out Policy

- ...the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises should be killed and their carcasses destroyed ...
- This policy should be accompanied by the cleansing and disinfection procedures defined in the Terrestrial Code.

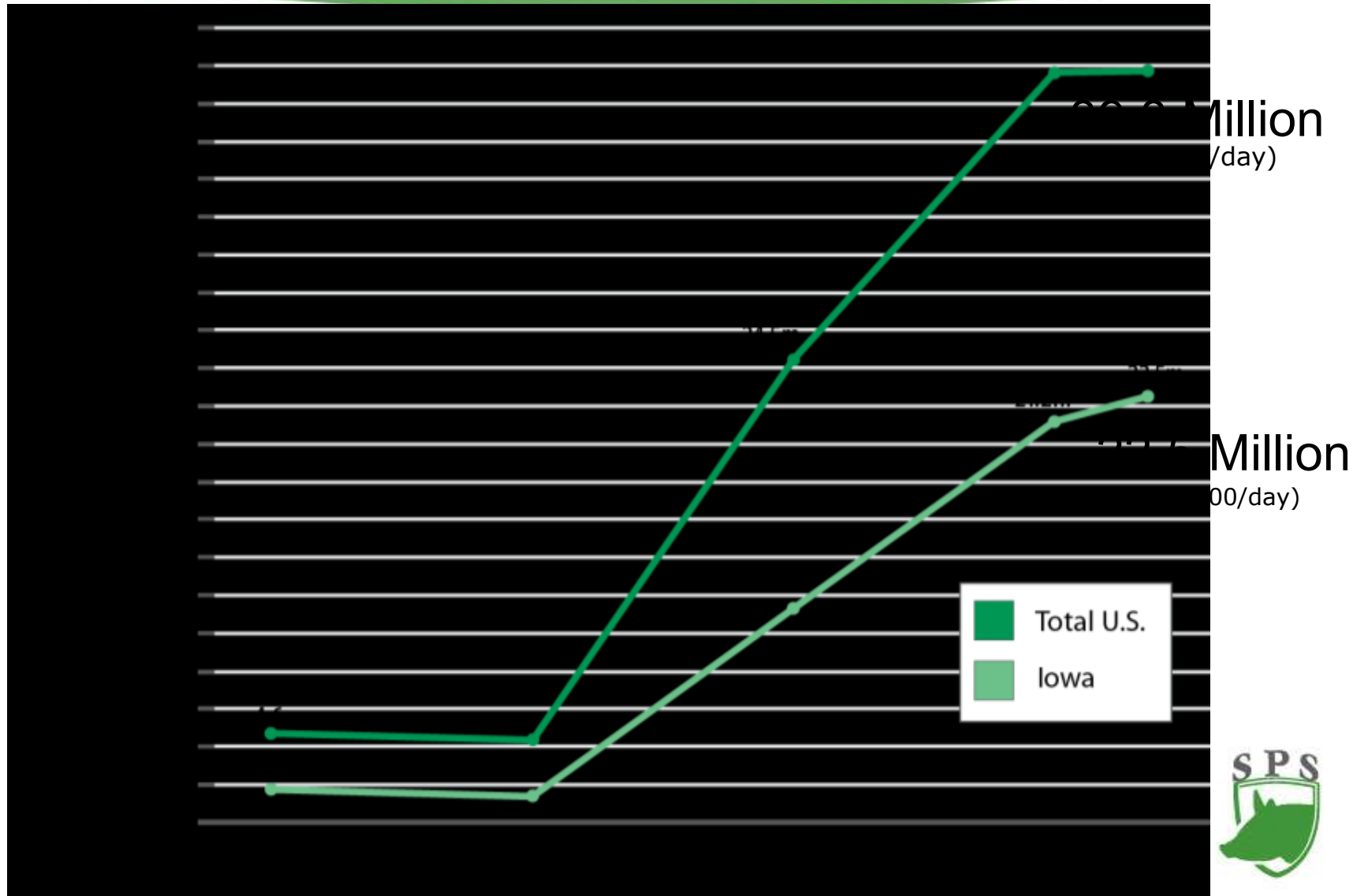
North American Animal Agriculture Industry is Unique

Extensive mobility of animals, products, feed

- ~625,000 swine in transit daily
- ~50,000 to 83,000 feedlot placements per day
- ~94,000 commercial cattle slaughter per day
- Dairy calves and replacement heifers?
- Auction markets, fairs, exhibitions?
- Sheep, goats, others?



Inshipments of Hogs to to All US States and to Iowa for Selected Years



Goals of an FMD Response

The goals of an FMD response are to

- (1) detect, control, and contain FMD in animals as quickly as possible;
- (2) eradicate FMD using strategies that seek to stabilize animal agriculture, the food supply, the economy, and protect public health; and
- (3) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products.

Achieving these three goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. They will also allow the United States to regain FMD-free status without the response effort causing more disruption and damage than the disease outbreak itself.

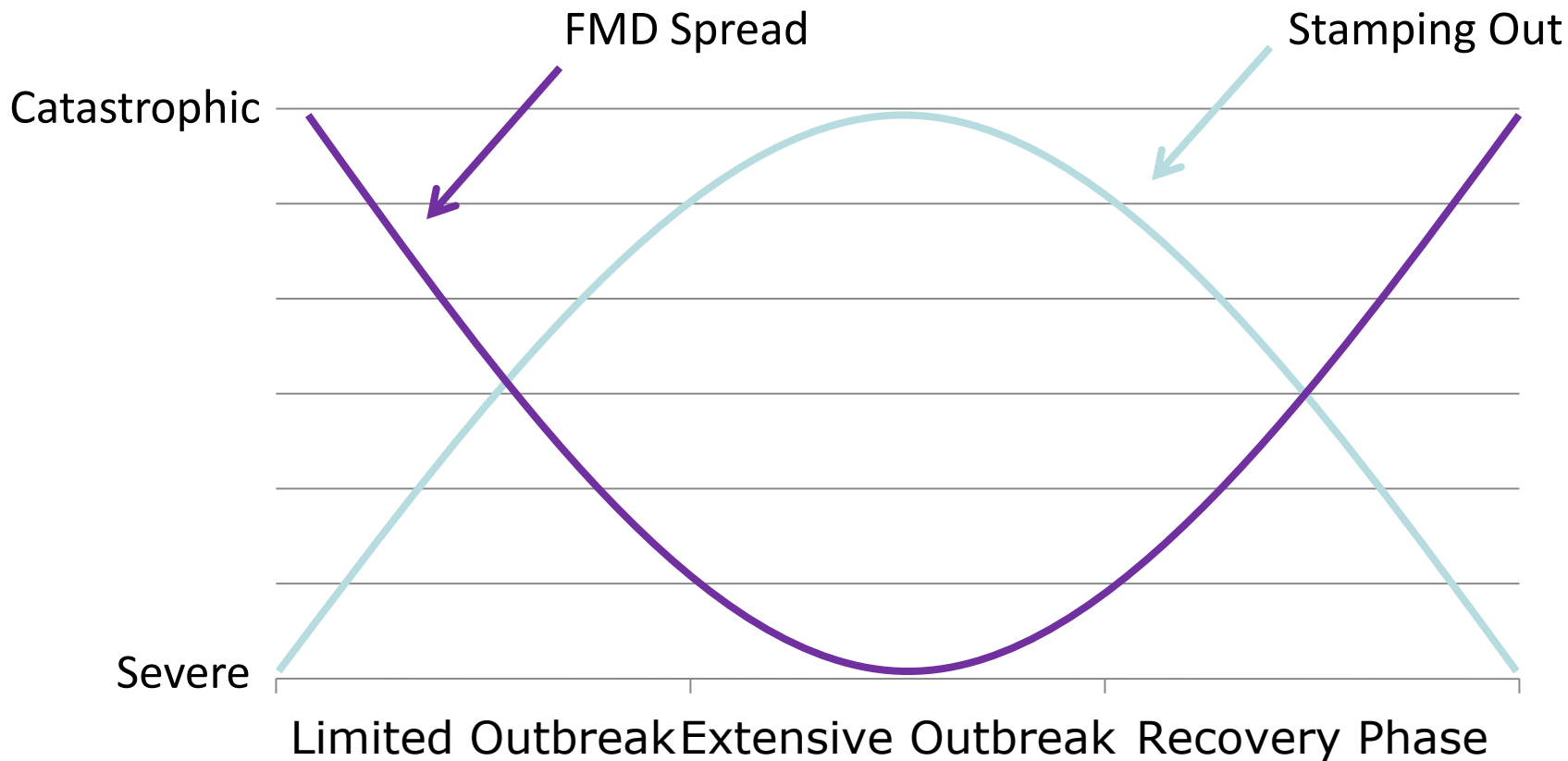


North American Animal Agriculture Industry is Unique

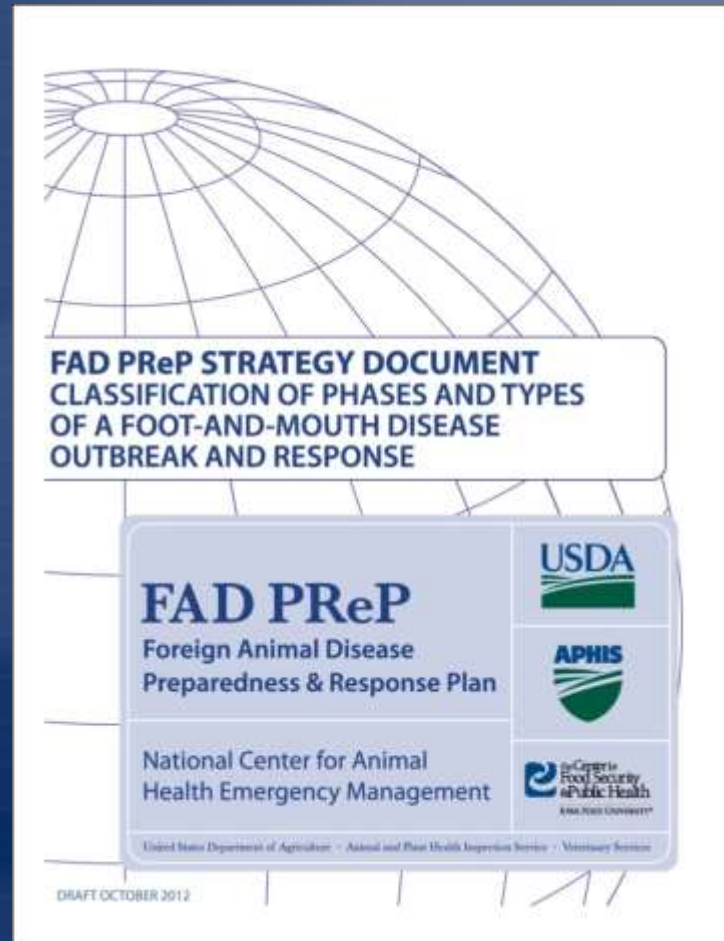
Strategies for the response to, and management of, an FMD outbreak will change as the outbreak progresses and will depend upon the magnitude, location and other characteristics of the outbreak



Consequences of FMD Spread vs. Stamping Out Depend on the Phase and Type of an FMD Outbreak



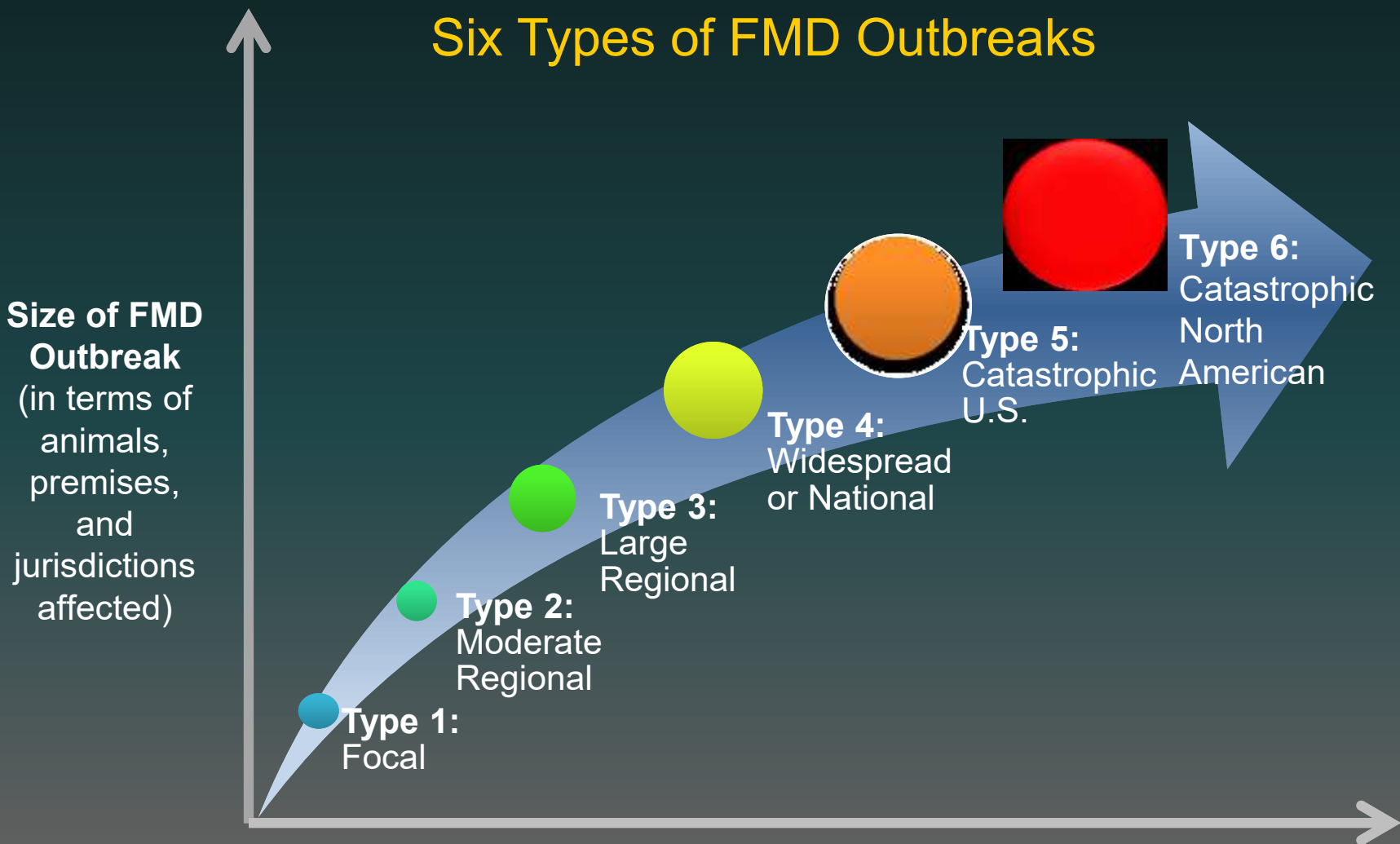
Phases and Types of FMD Response



<http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak>

FMD Detection in the United States: Types of an FMD Outbreak

Six Types of FMD Outbreaks



Response Shifts from Emphasis on Stamping-Out to Emphasis on Alternate Strategies (duration of FMD response)



Differentiating between Types of FMD Outbreaks

	Geographic Size of Outbreak	Animal Movement	Number of Premises	Size of Premises	Vaccine Assumptions	Appropriate Strategies	Minimum Time Required to Achieve FMD Free Status*
Type 1-Focal FMD outbreak	One state or small region	No extensive animal movement	Small number	Relatively small	Not applicable	Stamping-out	3 months after the last case
Type 2-Moderate regional FMD outbreak	Few focal areas in one region	No extensive animal movement out of the Control Area	Small to moderate number	Small to medium	Sufficient vaccine is available to vaccinate designated animals	Stamping-out Vaccinate-to-kill Vaccinate-to-slaughter Discontinue vaccination after the last case	3 months after the last case and slaughter of all vaccinated animals, or 6 months after last case or last vaccination if all vaccinated animals are not slaughtered
Type 3-Large regional FMD outbreak	Multiple areas in a region	No extensive animal movement outside of the region	Moderate number	Medium to large	Sufficient vaccine is available to vaccinate designated animals	Vaccinate-to-live Vaccinate-to-slaughter Discontinue vaccination after the last case	12 months after the last evidence of FMD infection and the last FMD vaccine was administered
Type 4-Widespread or national FMD outbreak	Widespread areas of infection	Extensive animal movement	Moderate to large number	Medium to large	Sufficient vaccine is available to vaccinate designated animals	Vaccinate-to-live Vaccinate-to-slaughter Continue vaccination after the last case	FMD Free with Vaccination : 18 months after the last case
Type 5-Catastrophic FMD outbreak	Widespread areas of infection	Extensive animal movement	Large number	Large	Sufficient vaccine is NOT available to vaccinate designated animals	Endemic FMD control program Vaccinate-to-live Continue vaccination after the last case	FMD Free with Vaccination : 2 years after the last outbreak
Type 6-North American FMD outbreak	Widespread infection in Mexico / Canada/ US	Extensive animal movement	Large number	Large	Sufficient vaccine is NOT available to vaccinate designated animals	Endemic FMD control program Vaccinate-to-live Continue vaccination after the last case	FMD Free with Vaccination : 2 years after the last outbreak

The North American FMD Vaccine Bank

- Recommends which topotypes to stock, in the form of vaccine antigen concentrate, to produce emergency vaccines of high potency
- Supplies are based on the old model of selective and restricted use of vaccine
- Emergency vaccine stocks are far below what would be required to address a livestock dense state or multi-state outbreak



Problems to Address

- Rapid availability of adequate supplies of FMD vaccine will be essential to mitigate the disastrous consequences of a large FMD outbreak in the U.S.



Tools for Control of FMD

- Stop Movement
- Biosecurity
- Stamping Out
 - Slaughter of all clinically affected and in-contact susceptible animals (within 24 hours or as soon as possible)
- Trace back/Trace forward
 - 2 incubation periods prior to outbreak (OIE incubation period for FMD is 14 days)
- Rapid Diagnostics
- Vaccination
 - Vaccinate to kill/Vaccinate to live



Tools for Control of FMD in a Large Outbreak

- Stop Movement
- **Biosecurity**
- Stamping Out
 - Slaughter of all clinically affected and in-contact susceptible animals (within 24 hours or as soon as possible)
- Trace back/Trace forward
 - 2 incubation periods prior to outbreak (OIE incubation)
- Rapid Diagnostics
- Vaccination
 - Vaccinate to kill/Vaccinate to live



Secure Pork Supply Partners

- SPS Planning Committee
 - Federal and State officials
 - Representatives of all phases of the swine industry
 - NPB, NPPC, AASV
 - Academia
 - Iowa State University
 - University of Minnesota

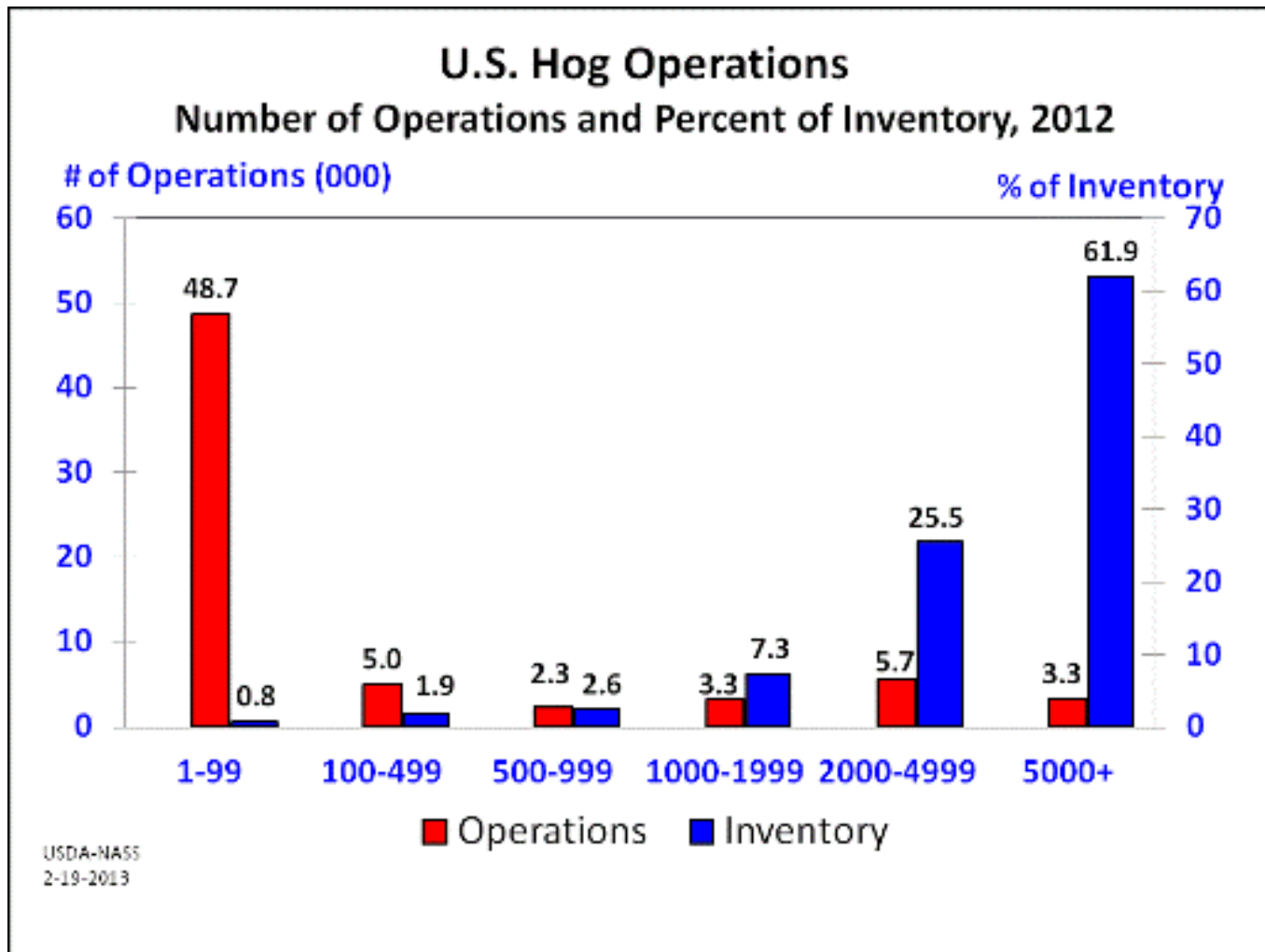


Secure Pork Supply Planning Committee

- First meeting October 11-12, 2011
 - Working Groups formed:
 - Biosecurity (pre and post outbreak)
 - Surveillance (pre and post outbreak)
 - Compartmentalization/Monitored Premises
 - Data Collection, Management, and Sharing
 - Risk Assessments
 - Communications
 - Plan for response to an FAD Outbreak
- Tomorrow



SPS Plan Must Consider All Hog Operations



Role of Wildlife in FMD Outbreak?

Distribution of Feral Swine Over Time

Feral swine are quickly spreading across the United States due to natural population growth, illegal movement by sports hunters, and escapes from domestic swine operations. Experts estimate their numbers at over 5 million animals nationwide.



■ ■ ■ Feral Swine Identified
■ No Feral Swine



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This publication represents Agricultural Information Bulletin No. 700, "Feral/Wild Pigs: Potential Problems for Farmers and Hunters," which was published in October 2005.

Issued August 2011



United States Department of Agriculture
 Animal and Plant Health Inspection Service
 Program Aid No. 2086

Feral Swine: Damage and Disease Threats



Foreign Animal Disease (FAD) Outbreak

“No one is free until everyone is free”

Jackie Robinson



Foreign Animal Disease (FAD) Outbreak

- Modern swine production in the US is very efficient, produces a high quality product, and depends on extensive movement of swine.
- A stop movement order for swine will quickly lead to overcrowding conditions with serious animal welfare and health issues.



Figure 4. Concept of Pig Flow



First 72 Hours of FMD Outbreak

Figure 5-9. Critical Activities in First 72 Hours of U.S. FMD Outbreak

Critical Activities

- Initiate controlled movement orders and 24-hour standstill orders for relevant zones and regions
- Notify States, industry, trading partners, media
- Initiate biosecurity measures
- Initiate tracing activities
- Initiate virus identification for vaccine

- Ongoing surveillance and tracing activities
- Initiate public awareness campaign
- Increased biosecurity measures
- Initiate continuity of business plans
- Continue virus identification for vaccine

- Continue ramping up ICS and Operations Center
- Ongoing surveillance and tracing activities
- Ongoing biosecurity activities
- Ongoing public awareness campaign
- Continue virus identification for vaccine

0-24 HOURS

24-48 HOURS

48-72 HOURS

FMD Detected
in the
United States

Controlled Movement of Swine in an FMD Outbreak

- At the beginning of an outbreak
 - No new movements initiated from the FMD control area
 - 625,000 pigs on the road each day
 - Some will have come from the control area
 - ~400,000 to 500,000 hogs and sows slaughtered daily
- Restarting movement
 - Depends on the type of outbreak



Controlled Swine Movement To and Through a Packing Facility

- Swine may be infected with FMD virus before showing any clinical signs or testing positive by PCR
- It is not possible to prove freedom from FMD infection in a herd, or in an individual animal. It is only possible to establish that there is lack of evidence of infection
- Therefore, all pork from a processing facility that has received swine from the FMD Control Area will be considered to potentially contain the FMD virus



Controlled Swine Movement To and Through a Packing Facility

- **FMD is not a public health or food safety problem**
- Animals which pass ante-mortem and post-mortem inspection by USDA FSIS are safe for human consumption, even if they may be in the pre-clinical stage of FMD infection
- Regulations regarding feeding garbage to swine must be strictly enforced.



Controlled Swine Movement To and Through a Packing Facility

- At the beginning of an FMD outbreak (Phase 1)
 - Packing plants should continue to process all swine in the plant and in transit to the plant which cannot be turned back or euthanized while in transit
 - State Animal Health Officials should not stop animals from crossing state lines
- During a large FMD outbreak (Phase 2, Type 3 or greater)
 - Market ready hogs and sows, from herds in the Control Area with no evidence of infection should be sent to slaughter as quickly as possible



Controlled Swine Movement To and Through a Packing Facility

- Processing of swine should continue, even if it is known that FMD infected animals have been in the plant
 - Federal and State Officials (Incident Command Post) would need to agree to this
 - Packing facility owners/managers would also need to agree to this



Controlled Swine Movement To and Through a Packing Facility

- Modern packing facilities process thousands of swine daily. At any point in time, there may be thousands of live animals in lairage awaiting slaughter.
- If any animals are incubating the virus, and the processing of swine is stopped, the virus will rapidly multiply in the swine in lairage.
- The thousands of animals that are in transit to slaughter facilities will not be able to be unloaded if the processing of swine at the plant is not continued.



Controlled Swine Movement To and Through a Packing Facility

- Processing of all healthy animals in the slaughter facility and in transit to the facility is the fastest way to dispose of those animals and presents the lowest risk of spreading FMD infection
- It also reduces the need for carcass disposal and preserves high quality protein for human consumption



Controlled Swine Movement To and Through a Packing Facility

- Packing plant employees, service personnel, and truck drivers must observe proper biosecurity protocols to avoid transmitting the FMD virus when they leave the plant
- All potential fomites leaving the plant must be cleaned and disinfected
- This will be very difficult to implement on an emergency basis. Ideally, an emergency plan for implementing biosecurity will be in place before an outbreak
- Biosecurity measures will be needed whether the plant receiving FMD infected animals continues or halts processing of healthy animals



Controlled Movement of Swine in an FMD Outbreak

Restarting movement

- Level 2 biosecurity
 - Producers, haulers, packers
- Surveillance, Traceability, Validated Prem ID
 - No evidence of infection on day of movement
- Movement permits
 - Electronic CVIs, Data management



Problems to Address

- Will the pork consuming public accept the product?
- Will Packers be willing to continue to process animals from an FMD control area in a large outbreak?
- Will State Animal Health Officials allow animals to cross state lines?
- Disposition of herds that have recovered from infection?
- Economics of production for uninfected herds and for infected herds?



Secure Milk Supply (SMS) Plan



SMS Partners

National Partners

Industry

- Working groups, topic experts

Academia

- Iowa State University
- University of California, Davis
- University of Minnesota

USDA-APHIS-VS

- Centers for Epidemiology and Animal Health (CEAH)
- National Center for Animal Health Emergency Management (NCAHEM)

Regional Partners

- California
- Colorado
- New England States Animal Agricultural Security Alliance (NESAAASA)
 - CT, MA, ME, NH, RI, VT
- Mid-Atlantic States
 - VA, MD, TN, NC, SC, DE, WV
- NY, NJ, PA
- Pacific Northwest
 - WA, OR, ID
- Wisconsin





SMS SECURE MILK SUPPLY

Foot-and-Mouth Disease

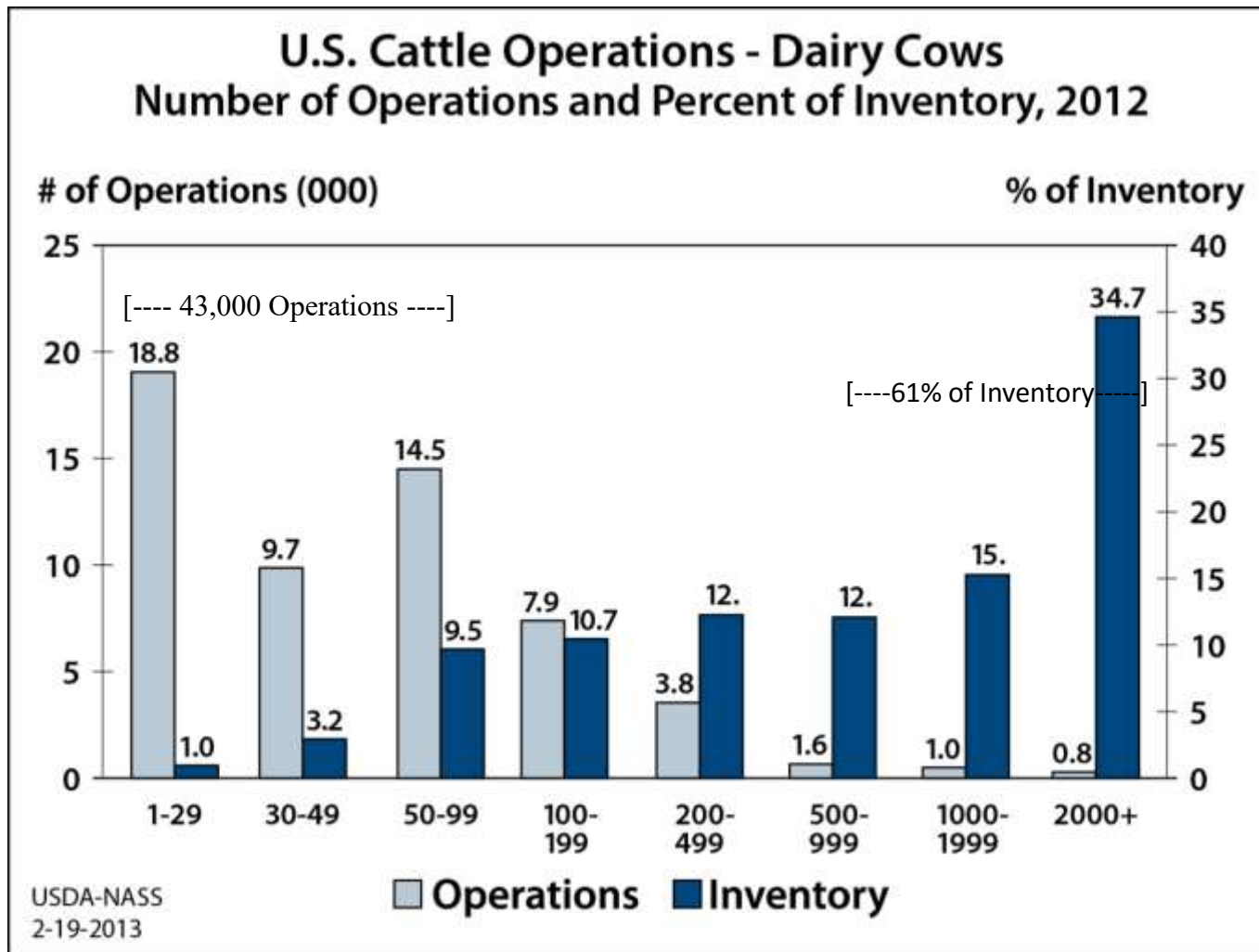
Foot-and-mouth disease (FMD), sometimes referred to as "hoof and mouth", is a highly contagious viral disease of cattle and other cloven-hooved animals such as pigs, sheep, and goats. FMD is not a public health concern. Signs of illness in affected animals include fever, blisters that become ulcers on the mouth, tongue, feet or teats, increased salivation or slobbering in cattle, decreased feed consumption, and lameness.

The last FMD outbreak in the U.S. was in 1929; however, the disease is common in other parts of the world and therefore poses a risk to the U.S. If FMD is diagnosed in the U.S., the control measures would include movement restrictions which will affect over-the-road transport of live animals and animal products (milk, colostrum, semen, embryos).

- [Disease Information](#)
Hosted by the Center for Food Security and Public Health at Iowa State University, access fact sheets, disease images, a PowerPoint presentation, vaccination guidelines, and many other FMD resources.
- [FAD PRP: Dairy Industry Manual](#)
This Manual provides a broad overview of U.S. dairy production methods and the procedures that may be used in the event of a highly contagious FAD outbreak. Livestock producers, their employees, response team members and policy makers are the intended audience.
- [Classification of Phases and Types of an FMD Disease Outbreak and Response](#)
March 2013
Comments are being accepted on this guideline document developed to aid rapid decision making to facilitate response planning and development of business continuity plans in the event of an FMD outbreak in the United States or North America.
- [Inactivation of FMD Virus in Milk Products](#)
The U.S. Dairy Export Council funded this literature review conducted by the Center for Food Security and Public Health at Iowa State University that summarizes the inactivation of FMDV in milk and milk products.
- [FAD PRP: FMD Guidelines - Appendix A: Vaccination for Foot-and-Mouth Disease \(2011\)](#)
Appendix A: Vaccination for Foot-and-Mouth Disease covers the disease-specific strategies and general considerations related to the use of vaccine as an aid to control an outbreak of foot and mouth disease (FMD) in the U.S.
- [USDA FAD PRP: FMD Response Plan "The Red Book"](#)
- [OIE Terrestrial Animal Health Code: FMD](#)

- FMD Info
- Dairy Industry Manual
- Phases and Types
- Inactivation of FMDV in dairy products
- Vaccination info
- FMD Response Plan
- OIE resources

SMS Plan Must Consider All Dairy Producers



Secure Milk Supply

- **Initial Goal**

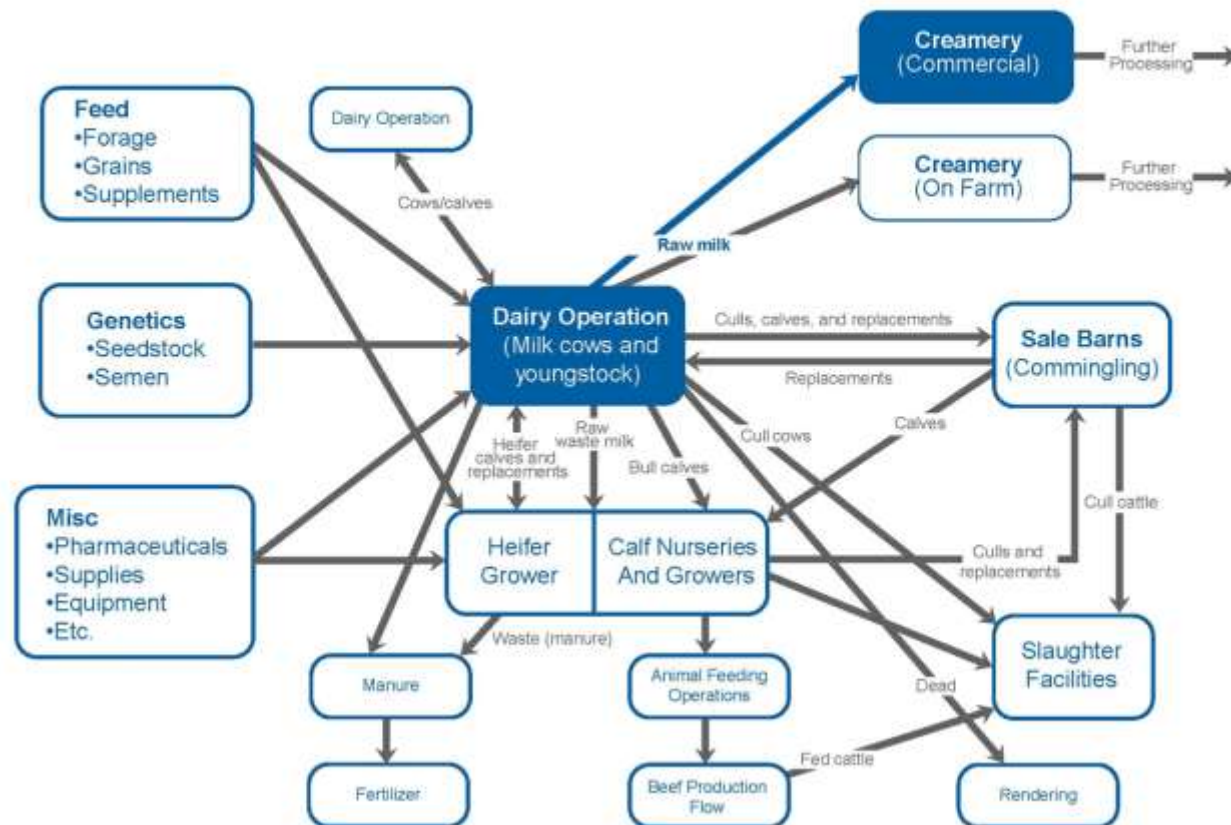
- To maintain milk movement from dairy farms with no evidence of infection in an FMD outbreak and to provide a continuous supply of wholesome milk and milk products for consumers

- Provide clear recommendations for emergency response leaders to facilitate safe movement of dairy products to processing



SMS Initial Focus: Raw Milk Movement from Farm to Processing

The dairy industry (producer and processor) business flow is complex



SMS Plan Components

- Biosecurity performance standards
 - Dairy premises, milk haulers, processing plants
- Milk movement decision support tools
 - Guidance documents for those in decision making roles
 - Active observational surveillance
- Pre-event risk assessment
 - Identify mitigation steps to minimize FMD virus spread



Executive Summary 2012

SMS Plan Executive Summary 2012 

Introduction
In the event FMD is diagnosed in the United States, a national animal health emergency will be declared and livestock and allied industries will feel the immediate impact of animal and animal product quarantine and movement restrictions. Quarantine, managed movement and mandatory biosecurity protocols are designed to contain and control the disease and minimize virus spread. In the dairy industry, the just-in-time supply practices of milk movement in the U.S. could be significantly impacted by managed movement and the need for additional biosecurity at farms and processing facilities. This could lead to a disruption of the provision of milk and milk products to consumers. Additionally, there could be significant milk disposal and animal welfare issues on dairies. Most dairy operations and processing plants do not have the capacity to store milk for more than 48 hours, some have less than 24 hours storage capacity. Hence, pre-planning for safe, timely, risk-based, permitted movement of animals and animal products will be critical to maintaining the business continuity of the dairy industry while controlling and containing the outbreak.

Goals
The overall goals of the national Secure Milk Supply (SMS) Plan are to maintain business continuity for dairy producers and processors during an FMD outbreak, to minimize disease spread, and to ensure a continuous supply of milk and milk products to consumers. The specific aims of the SMS Plan are to:

- Engage stakeholders in the planning process for an FMD response,
- Develop and socialize tools and guidance documents that support business continuity within the dairy industry, and
- Ensure that producers, processors, federal and state agency personnel agree the proposed guidelines are feasible, implementable, and effectively enable critical movements of animals and animal products with minimal risk of further FMDs spread during an outbreak response.

Initial Project Focus – Raw milk movement from farm to commercial processing (Figure 1)

- Develop pre-event, agreed upon national biosecurity performance standards (for dairy premises, milk haulers, and processing plants) that support raw milk movement from farms not known to be infected with FMD virus to commercial processing without risk of disease spread. These enhanced biosecurity measures should be rapidly implementable during an FMD outbreak response.
- Develop consensus decision support guidance and tools to facilitate timely permitting and movement of raw milk from farms not known to be infected in the FMD Control Area. Encourage the development of a robust, scalable information management infrastructure to support the permitting needs of an incident. This includes the timely availability (ideally pre-event) of livestock and premises data to populate the permitting system.
- Conduct a proactive risk assessment for the transport of raw milk from the dairy farm to the processing plant that considers existing production practices with subsequent evaluation of proposed biosecurity mitigation procedures.

1

Draft Recommendations
A set of recommendations (and supporting scientific justification and rationale) pertaining to raw milk handling and processing has been drafted for pre-event review, discussion, and ideally

2

Secure Milk Supply

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- 4 page doc overview
- 80 page doc
 - Biosecurity Performance Standards
 - Factors to consider
 - Phases and Types
 - Decision matrix
 - Draft recommendations



FMD Virus in Dairy Products

- Cows may shed FMD virus in the milk before they show clinical signs
- Standard milk pasteurization (HTST) and some cheese processing times and temperatures used in the US are not sufficient to completely eliminate FMDV from dairy products
- **FMD is not a public health or food safety problem**



Biosecurity Practices during FMD Outbreak

- Goal is to reduce the risk of FMD:
 - Entering a dairy operation,
 - Being transmitted off infected, undetected farms, and
 - Contaminating processing prior to pasteurization



Assurance that Milk from an FMD Control Area is Safe and Wholesome

- Biosecurity performance standards are implemented:
 - Premises
 - Haulers
 - Processors
- Active observational surveillance for FMD is implemented
 - Active daily observational surveillance
 - Periodic testing of animals and/or milk



Assurance that Milk from an FMD Control Area is Safe and Wholesome

- Milk is processed to meet OIE standards for human or animal consumption
 - World Organization for Animal Health (OIE) Terrestrial Animal Health Code
 - “...assures the sanitary safety of international trade in terrestrial animals and their products”



OIE Article 8.5.38: Milk/Cream for Human Consumption

- One of the following procedures should be used to inactivate FMDv:
 1. Sterilization process applying a minimum temperature of 132°C (270°F) for at least 1 second (UHT), -OR-
 2. Milk with pH less than 7.0, sterilization process applying a minimum temperature of 72°C (162°F) for at least 15 seconds (HTST), -OR-
 3. Milk with pH of 7.0 or over, the HTST process applied twice



OIE Article 8.5.39: Milk for **Animal Consumption**

- One of the following procedures should be used to inactivate FMDv:
 1. HTST process applied twice;
 2. HTST combined with another physical treatment
 - Maintaining a pH 6 for at least 1hour or
 - Additional heating to at least 72°C (162°F) combined with desiccation;
 3. UHT combined with another physical treatment referred to in point 2 above

Risk Assessment of Foot-and-Mouth Disease Virus Spread via Pasteurized Dairy Products from Cattle in the United States after an FMD Incursion

Aaron Scott DVM PhD, Diplomate ACVPM
Center Director, National Surveillance Unit
Centers for Epidemiology and Animal Health
May 2003



Executive Summary

- A threshold number of FMDV particles must be present to cause FMD in animals:
 - $\sim 10^5$ virus units for hogs (oral)
 - $\sim 10^6$ virus units for cattle (oral)
 - The amounts of virus present in dairy products after pasteurization is typically in the range of 0 to 10 virus particles per milliliter



Executive Summary

- The results indicate that risk of infection for either cattle or hogs is very low if not impossible from pasteurized milk or cheese



Draft Recommendation 1

- At the beginning of an FMD outbreak, it is **not necessary to recall** from commerce for human consumption pasteurized milk or milk products that originated in the Control Area.
- Milk products for animal consumption that have been treated to OIE standards do not need to be recalled.
- Milk products for animal consumption which may have originated from an infected herd and which were not treated to OIE standards should be recalled and destroyed.



Draft Recommendation 2

- Milk originating from farms with no evidence of infection within a FMD Control Area which has been treated to OIE standards for either human or animal consumption **may enter commerce** for either human or animal consumption.



Draft Recommendation 3

- Milk processors should be asked to provide evidence that their processing procedures meet the World Organization for Animal Health (OIE) Terrestrial Animal Health Code 2011 requirements for the inactivation of the FMD virus in milk and milk products for human consumption and for the inactivation of the FMD virus in milk and milk products for animal consumption.
- Audits (next slide)



Draft Recommendation 3 (cont'd)

- The procedures should be subject to audit by appropriate authorities
 - Those processors whose procedures meet OIE standards would be issued a certificate by the SAHO indicating that they may continue to process milk from farms within a Control Area which have no evidence of FMDV infection during an FMD outbreak (with appropriate biosecurity at the processing plant).
 - If processor standard procedures do not meet OIE requirements, they may propose to implement new procedures which meet OIE standards in the event of an FMD outbreak.
 - These processors could be issued a certificate which would allow them to continue to process milk if they immediately implement the new OIE compliant procedures in the event of an FMD outbreak.



Proactive Risk Assessments

- Evaluate the risk raw milk transport from an FMD infected, but undetected, dairy farm to further processing poses to spread of FMD
 1. Current Grade A milk production practices
 - **Baseline** Risk Assessment
 2. Effect of proposed mitigations (Biosecurity Performance Standards) on risk of virus spread through identified pathways
 - **Biosecurity Performance Standards (BPS)** Risk Assessment



Acceptable Level of Risk?

- ICS officials must decide the acceptable level of risk:
 - Risk associated with moving milk to processing
 - Disease spread
 - Risk associated with dumping milk
 - Environmental impact
 - Economic impact on dairy industry
 - Food security- availability of milk and milk products
 - Public perception (as outbreak progresses)
 - Disease spread
- Acceptable level of risk will change with the phase and type of outbreak



Type 3, 4, 5, or 6 FMD Outbreak: Infected herds will be allowed to recover from FMD

- what to do with milk from healthy cows from large herds that are FMD positive?
- If the individual cow is healthy (not yet infected, or has recovered, or been vaccinated) the pasteurized milk is safe for human consumption.
 - Should it be dumped?
 - Should it be put into commerce as liquid milk?
 - Should it go to special processing (powdered milk, condensed milk, certain types of cheese, other)?



Comments and Questions:
jaroth@iastate.edu 515-294-8459



Serotypes and Strains

- 7 Serotypes
 - O, A, C, Asia-1, SAT-1, SAT-2, SAT-3
 - > 65 strains are recognized within these serotypes
- Stability
 - New strains can develop spontaneously as the virus spreads to new areas
 - SAT strains are highly variable
 - Asia-1 strains tend to remain relatively stable
- Cross protection
 - There is **no** cross-protection between serotypes!
 - Cross-protection varies between strains within a serotype

Vaccine Strains Recommended for National Antigen Banks

High Priority:

- O Manisa
- O PanAsia-2
- O BFS or Campos
- A-Iran-05
- A24 Cruzeiro
- A22 Iraq
- Asia 1 Shamir
- SAT 2 Saudi Arabia (or equivalent)

Medium Priority:

- A Argentina 2001
- A Iran 96
- A Iran 99
- A Eritrea
- A Iran 87 or A Saudi Arabia 23/86
- A Malaysia 97 (or Thai equivalent)
- O Taiwan 97 (pig-adapted strain)
- SAT 1 South Africa
- SAT 2 Zimbabwe

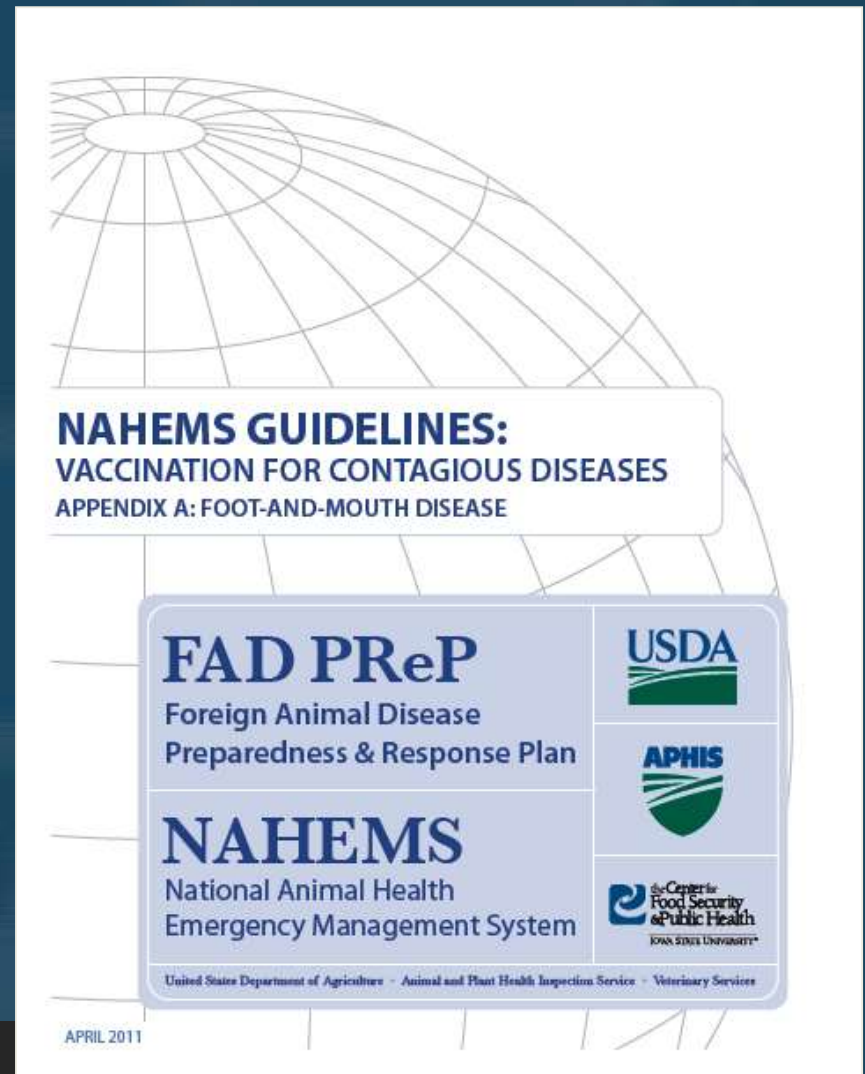
Low Priority:

- A 15 Bangkok related strain
- A Kenya
- A87 Argentina related strain
- SAT 1 Kenya
- SAT 2 Kenya
- SAT 3 Zimbabwe
- C Noville

Foreign Animal Disease Preparedness & Response Plan

- FAD PReP/NAHEMS Guidelines: Vaccination for Contagious Diseases
- APPENDIX A: Foot-and-Mouth Disease (April 2011, 93 pages)

<http://cfsph.iastate.edu/emergency-response/fad-prep.php>



For More Information

- For more information on the Secure Food Supply plans, access the following website:
<http://www.cfsph.iastate.edu/Secure-Food-Supply/index.php>
- The phases and types of an FMD outbreak document is available at:
<http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak>
- NAHEMS guidelines: Vaccination for contagious diseases; Appendix A: foot-and-mouth disease:
<http://www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease>
- USDA APHIS FMD Response Plan: The Red Book:
http://www.aphis.usda.gov/animal_health/emergency_management/



Disease Transmission

(FMD, CSF, ASF, SVD)

- **Not public health concerns**
- Direct contact and oral exposure are the most important routes of infection for swine (Pigs are relatively resistant to airborne infection by all 4 FADs)
- Indirect contact (fomites) also can play an important role for transmission
- Pigs exhale large concentrations of FMDV, cattle are highly susceptible to aerosolized virus



Type 5 – Catastrophic FMD Outbreak

- Widespread areas of infection are detected involving a large portion of the United States
- Too many animals are affected to implement stamping out
- Sufficient vaccine and resources are not available to effectively use vaccine to control the outbreak



Type 5 – Catastrophic FMD Outbreak

- It becomes apparent that FMD is widespread, and will not be eradicated within a year
- Declare FMD to be an endemic disease and implement a program for long term eradication and control, including vaccinate-to-live



Active Observational Surveillance (AOS) to support Permitting Milk Movement as Part of the Secure Milk Supply (SMS) Business Continuity Plan During an FMD Outbreak

Jim Roth

Pam Hullinger

June 6, 2012



Secure Milk Supply

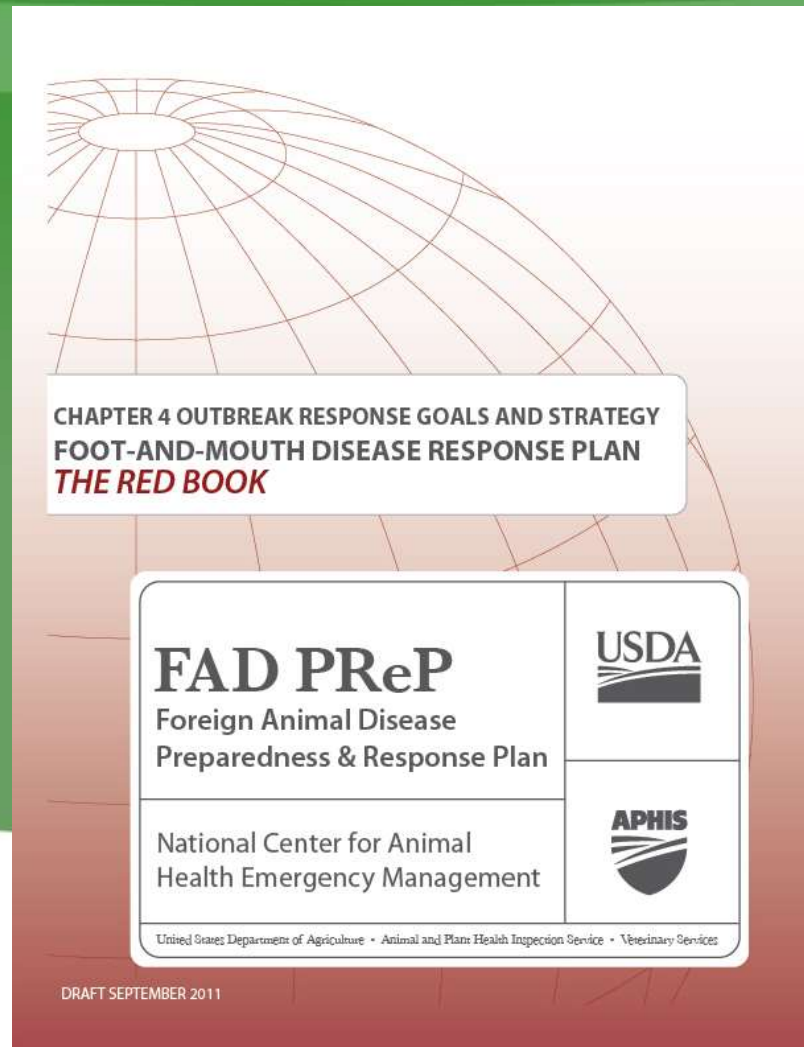
- **Initial Goal**

- To maintain milk movement from dairy farms with no evidence of infection in an FMD outbreak and to provide a continuous supply of wholesome milk and milk products for consumers



- Provide clear recommendations for emergency response leaders to facilitate safe movement of dairy products to processing



USDA APHIS Foreign Animal Disease Preparedness and Response Plan



CHAPTER 4 OUTBREAK RESPONSE GOALS AND STRATEGY
FOOT-AND-MOUTH DISEASE RESPONSE PLAN
THE RED BOOK

FAD PReP Foreign Animal Disease Preparedness & Response Plan	
National Center for Animal Health Emergency Management	

United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

DRAFT SEPTEMBER 2011



USDA FAD PReP FMD Response Plan

Figure 5-9. Critical Activities in First 72 Hours of U.S. FMD Outbreak

Critical Activities

- Initiate controlled movement orders and 24-hour standstill orders for relevant zones and regions
- Notify States, industry, trading partners, media
- Initiate biosecurity measures
- Initiate tracing activities
- Initiate virus identification for vaccine

- Ongoing surveillance and tracing activities
- Initiate public awareness campaign
- Increased biosecurity measures
- Initiate continuity of business plans
- Continue virus identification for vaccine

- Continue ramping up ICS and Operations Center
- Ongoing surveillance and tracing activities
- Ongoing biosecurity activities
- Ongoing public awareness campaign
- Continue virus identification for vaccine

0-24 HOURS

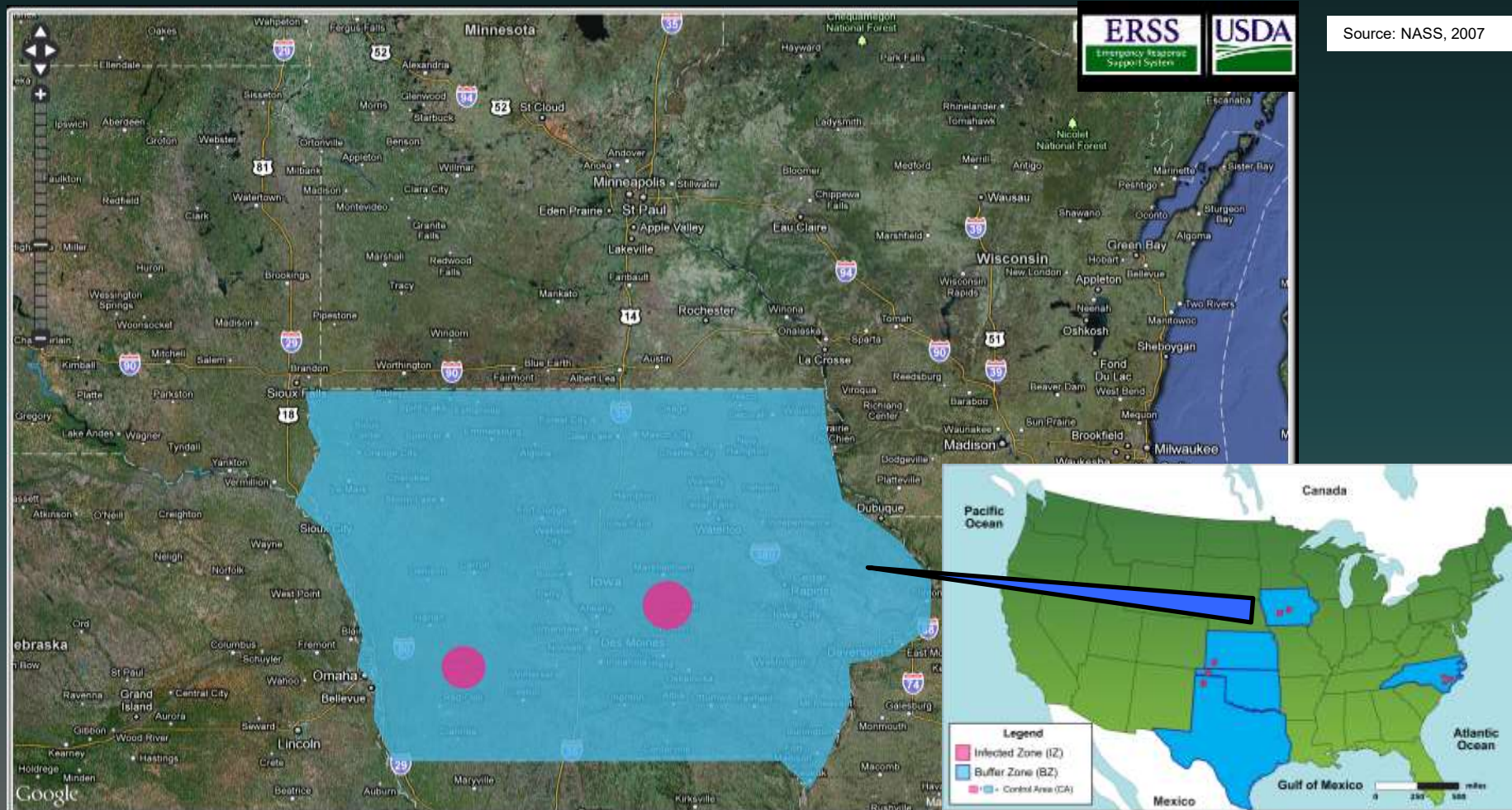
24-48 HOURS

48-72 HOURS

FMD Detected
in the
United States



FMD Outbreak in Iowa—Large Control Area



Number of Swine Affected: **19,883,988**
Number of Bovines Affected: **2,366,535**
Number of Operations Affected: **110,727**



World Organization for Animal Health (OIE) Terrestrial Animal Health Code

- Article 8.5.28 (2011)
 - Recommendations for importation from FMD infected countries or zones where an official control programme exists for milk, cream, milk powder and milk products.
 - Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
 - 1. These products
 - a. originate from herds or flocks **which were not infected or suspected of being infected with FMD** at the time of milk collection;
 - b. **have been processed to ensure the destruction of the FMD virus** in conformity with one of the procedures referred to in Article 8.5.38. and in Article 8.5.39.;
 - 2 The necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.



OIE Standards for Processing Milk to Inactivate the FMD Virus

Article 8.5.38: For the inactivation of viruses present in milk and cream **for human consumption**, one of the following procedures should be used:

1. a sterilization process applying a minimum temperature of 132°C (270°F) for at least one second (**ultra-high temperature [UHT]**), or
2. if the milk has a **pH less than 7.0**, a sterilization process applying a minimum temperature of 72°C (162°F) for at least 15 seconds (**high temperature - short time pasteurization [HTST]**), or
3. if the milk has a **pH of 7.0 or over**, the **HTST process applied twice.**



OIE Standards for Processing Milk to Inactivate the FMD Virus

Article 8.5.39: For the inactivation of viruses present in milk **for animal consumption**, one of the following procedures should be used:

1. the **HTST process applied twice**;
2. **HTST combined with another physical treatment**, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C (162°F) combined with desiccation;
3. **UHT combined with another physical treatment** referred to in point 2 above.

The USDA National Surveillance Unit (NSU) has provided guidance on Active Observational Surveillance

- Active observational surveillance (AOS) is an active effort to detect evidence of disease through observation of clinical signs meeting the following criteria:
 - The observations are ongoing and follows a pre-planned schedule
 - The observer is specifically tasked with monitoring for evidence of disease, toxicity, or other causes of mortality and decreased production
 - Observer is professionally trained or receives major portion of compensation for management and care of herd or flock
 - **The screening “test” is the observation of clinical signs. Confirmatory test is laboratory based.**
 - It allows “testing” of the animal, herd, or flock very frequently (e.g., in commercial dairies, feedlots, confinement swine and poultry active observation occurs once or twice a day)
 - Observation of clinical signs affecting one or more animals with overt rapidly spreading signs or mortality is a trigger for further investigation. Criteria are established for a response following evidence of an event (e.g., call flock or herd manager if mortality increases beyond a preset percent, call veterinarian if milk production drops below a preset level)
 - Utility is highest for diseases that show overt clinical signs such as HPAI or FMD



Who will be responsible for AOS?

- An individual (or individuals) must be designated as being responsible for overseeing AOS on the dairy premises
 - Official **Herd Health Monitor (HHM)** on-duty
 - Different individuals may be responsible for AOS for different sub-populations of animals
 - Qualified HHMs should have a history of daily involvement with the herd
 - HHM must be capable of deciding when the incidence of clinical signs has an unexplained higher incidence than “normal”
 - A check list will be completed and signed by the HHM each day for each group of animals.



How will the HHM perform and document AOS?

- The on duty HHM will be responsible for observing all animals under their responsibility at least once per day
- The HHM should observe for any abnormal behavior of the animals
- Any animals with abnormal behavior should be immediately reported to someone designated by the Incident Command
- HHMs will need to be trained and this training documented with state animal health officials in advance of an outbreak of FMD



How will the HHMs be trained?

- A packet of training materials for the HHMs will be developed in English and Spanish
 - Visual aids for recognizing clinical signs
 - Instructions on how to conduct AOS
 - Instructions on who to contact if unusual clinical signs are observed



Questions/Comments

- ...our state vets are considering the “surveillance” of control area non-infected farms to consist of periodic (perhaps every other day) visits by a state or federal animal health officials
 - a state official could still visit the farm to conduct surveillance periodically as manpower permits. Part of the surveillance visit could be to inspect the AOS records.



Questions/Comments

- “having the farm themselves do the surveillance seems a bit like having the fox watch the henhouse”
 - Farms are currently expected to withhold milk from cows treated with antibiotics. Testing at the plant will reveal if they are not following the rules. A validated milk PCR could be used to randomly test samples at the processing plant for FMD.
 - That combined with an education program that emphasizes that it will become obvious if a herd of lactating cows comes down with FMD will provide incentive to self-report evidence of FMD infection obtained through AOS.



Questions/Comments

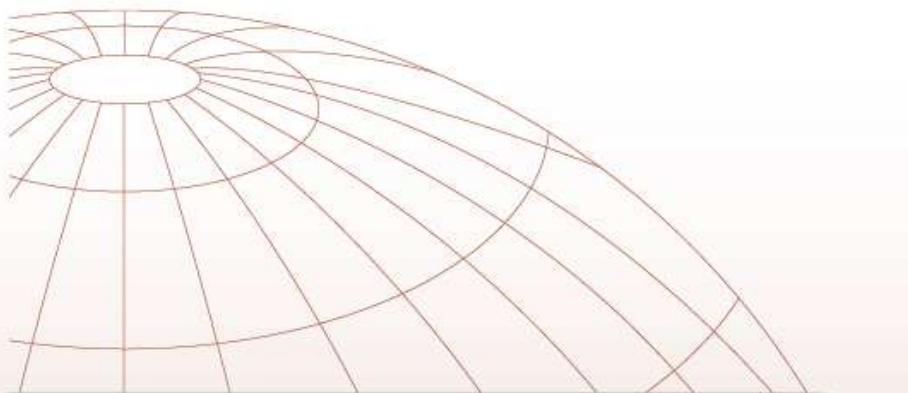
- “Even with AOS it is still possible that milk could be moved that is infected before clinical signs appear.”
 - AOS should minimize the amount of infected milk that moves and the titer of virus in the milk by catching infection quicker than without AOS
 - Moving milk that may contain some FMDv to commercial processing under procedures which meet the biosecurity performance standards should mitigate the risk of that load of milk spreading infection
 - Treating milk to OIE guidelines should greatly minimize risk of the milk spreading an FMD infection



Questions/Comments

- It may be that during a phase 1, or phase 2, type 1 or 2 FMD outbreak that the responsible officials may not allow milk to move based on biosecurity and AOS only
- During a large outbreak (phase 2, type 4 or higher), AOS may be the only type of surveillance that can be implemented. In that situation, it would be good to have an AOS program in place





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FAD PReP
Foreign Animal Disease
Preparedness & Response Plan



National Center for Animal
Health Emergency Management



United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

Participating in the Working Groups

1. Risk Assessment

- Sarah Easter-Strayer easte068@umn.edu

2. Milk Movement

- Jim Roth jaroath@iastate.edu or
- Pam Hullinger phullinger@ucdavis.edu

3. Cleaning & Disinfection

- Danelle dbw@iastate.edu

- Industry & Government partners essential
- Draft guidance shared with USDA-APHIS, States, informs risk assessments



Proactive Risk Assessments

- Evaluate the risk raw milk transport from an FMD infected, but undetected, dairy farm to further processing poses to spread of FMD
 1. Current Grade A milk production practices
 - **Baseline** Risk Assessment
 2. Effect of proposed mitigations (Biosecurity Performance Standards) on risk of virus spread through identified pathways
 - **Biosecurity Performance Standards (BPS)** Risk Assessment



Risk Estimation

Estimate	Description
Negligible	The likelihood that the event will occur is insignificant, not worth considering
Very Low	It is highly unlikely the event will occur, but it is not negligible
Low	It is very unlikely that the event will occur
Moderate	The event is unlikely but does occur
High	There is more than an even chance that the event will occur
Very High	The event is almost certain to occur
Certain	The likelihood that the event will occur is 100%



Negligible, Very Low, Low *Baseline RA*

- Risk of bioaerosols from milk tanker causing FMD in susceptible animals
 - Low to very low
- Risk from accidental loss of milk causing cross contamination that results in FMD in susceptible animals
 - Low
- FMD virus present in tanker following CIP is negligible
 - No CIP = low



Moderate to High *Baseline RA*

- Environmental contamination leaving infected, undetected farm
- Infectious milk leaving infected, undetected farm

