

# FMD Vaccine Surge Capacity for Emergency Use in the United States

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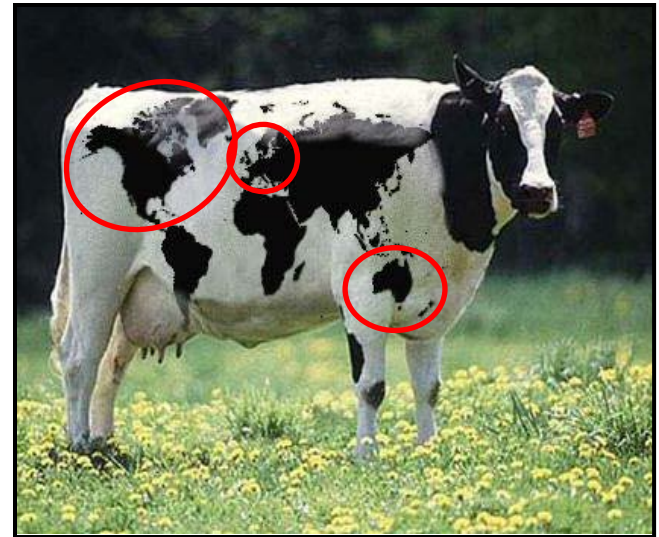
# Topics to Cover

- Need for FMD vaccine
- Important considerations regarding FMD vaccine and vaccination
- Approaches to meeting the surge capacity need for FMD vaccine in an outbreak

# Global Prevalence of FMDv

World Organization for Animal Health (OIE) has

- 178 member countries:
  - 96 countries are endemic (“have it”) and have never been free of FMD
  - 66 countries free of FMD
  - 11 countries have free zones either with or without vaccination
  - 5 countries were free and recently suffered from a re-emergence of FMD



# United States has had 9 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

# World Organization for Animal Health (OIE) Definition of Stamping-Out

- ...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 by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the animals killed.

# Factors Requiring a Change in the Planned Response to FMD

- Very large herd sizes
- Extensive movement of animals
- Public resistance to stamping out
- Environmental concerns with carcass disposal
- Changes in OIE policies related to FMD free with vaccination status

# United States Animal Agriculture Industry is Unique

## Herd size:

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



# United States Animal Agriculture Industry is Unique

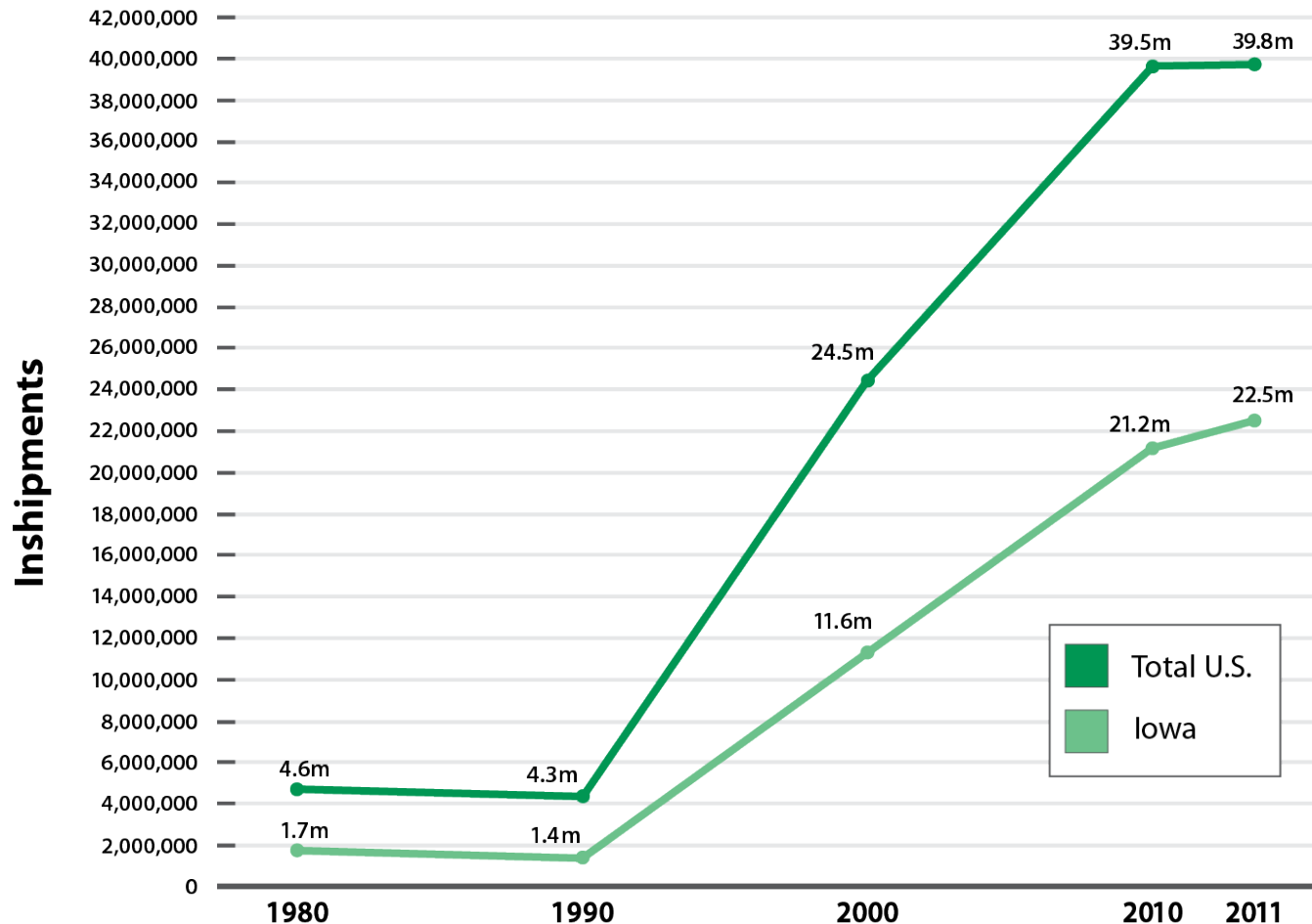
Extensive mobility of animals, products, feed

- ~1,000,000 swine in transit daily
  - 400,000 to 500,000 to slaughter
- ~400,000 cattle in transit per day
- Auction markets, fairs, exhibitions?
- Sheep, goats, others?





# In Shipments of Hogs to All U.S. States, Iowa



From Haley (2004) and NASS (2012b).

# Role of Wildlife in FMD Outbreak?

- ~5 million feral swine
- ~30 million deer

**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.*

2010

2004

1982

■ Feral Swine Identified  
■ No Feral Swine

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

**Feral Swine:  
Damage and  
Disease Threats**

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This publication supersedes Agricultural Information Bulletin No. 799, "Feral Wild Pigs: Potential Problems for Farmers and Hunters," which was published in October 2005.  
Issued August 2011

USDA

# Day 1 of a Foot and Mouth Disease Outbreak

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

# Annual Value of U.S. Exports

Total value of U.S. dairy exports (2013)*	\$6.7 billion
Total value of U.S. pork exports (2013)**	\$6.0 billion
Total value of U.S. beef exports (2013)**	\$6.2 billion
Total	\$18.9 billion

\*US Dairy Export Council

\*\*US Meat Export Council



# Tools for Control of FMD

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

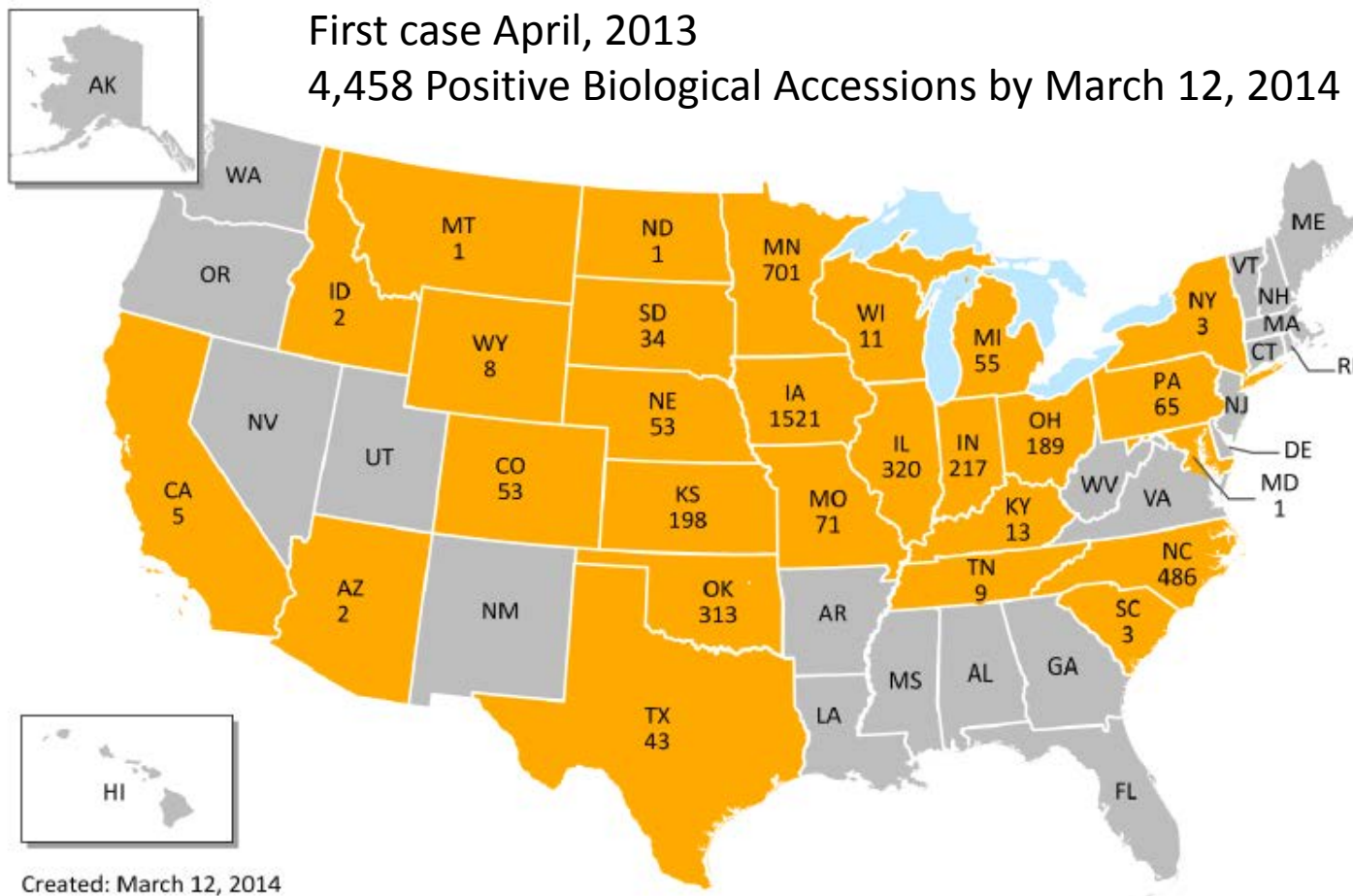
# Tools for Control of FMD in a Large Outbreak

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

# Porcine Epidemic Diarrhea Virus (PEDV) Positive Biological Accessions

First case April, 2013

4,458 Positive Biological Accessions by March 12, 2014



Created: March 12, 2014

Source: AASV website [www.aasv.org](http://www.aasv.org)



# FMD in UK and Uruguay, 2001

## UK

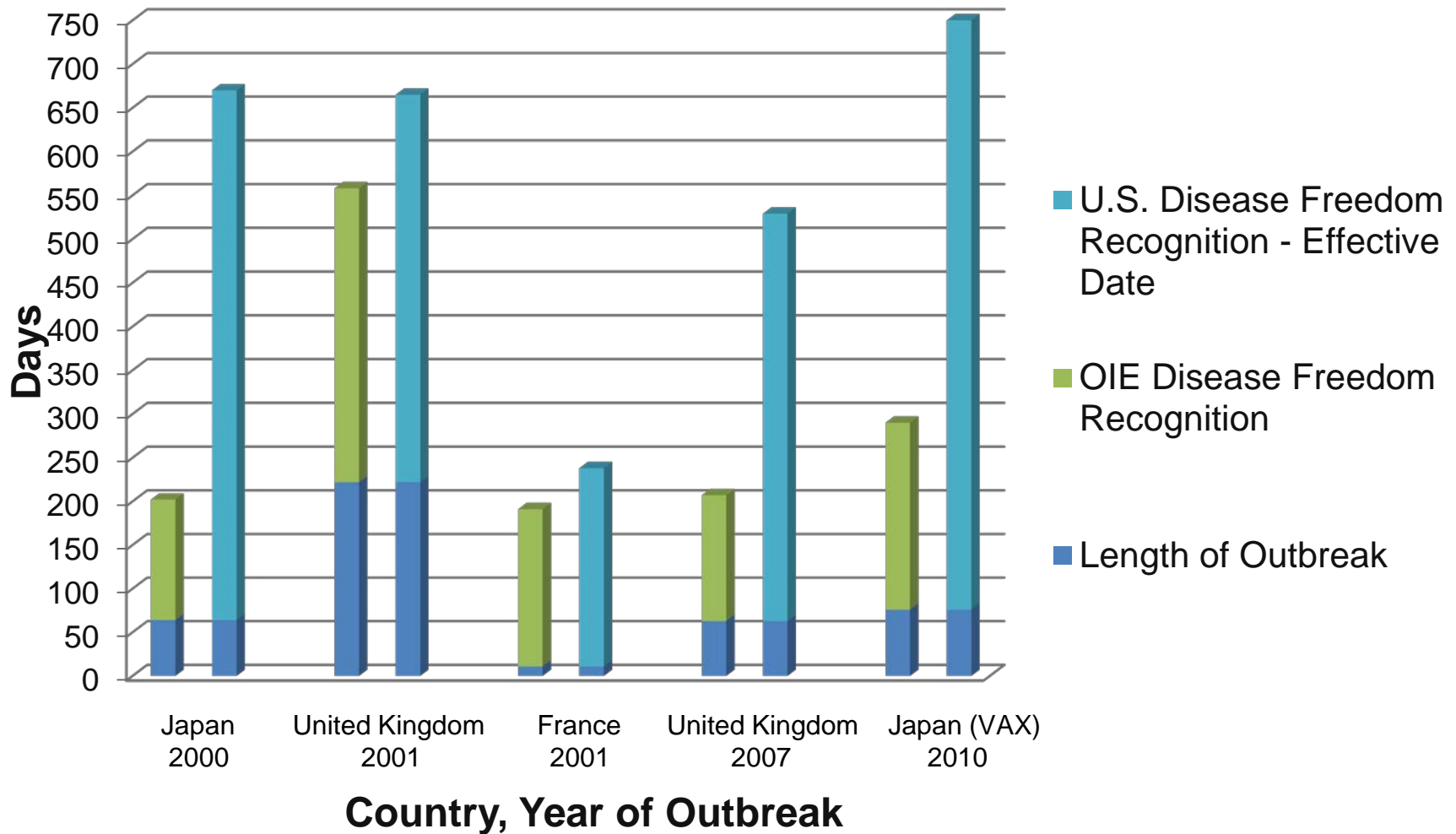
## Uruguay

- Type O FMD
  - 1.7 million cattle
  - No vaccination
  - 6,000,000 head killed
  - Cost ~ \$10 billion US dollars
  - FMD free
- Type A FMD
  - 10.6 million cattle
  - 24 million doses
  - 6,900 head killed
  - Cost - \$243.6 million US dollars
  - FMD free with vaccination

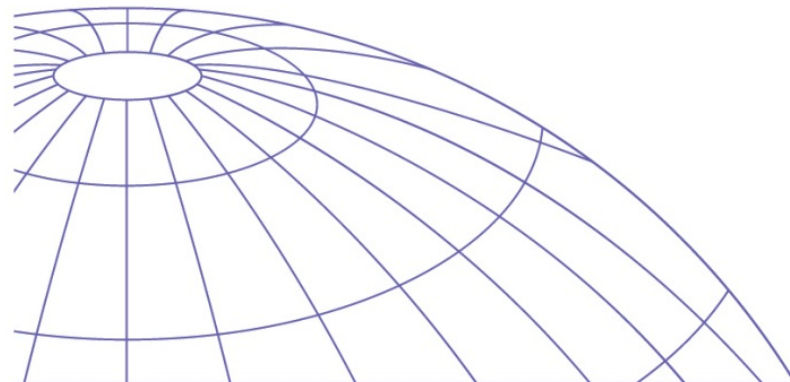




# Time to Regain FMD-Freedom



# Phases and Types of FMD Response



## FAD PReP STRATEGY DOCUMENT CLASSIFICATION OF PHASES AND TYPES OF A FOOT-AND-MOUTH DISEASE OUTBREAK AND RESPONSE

**FAD PReP**

Foreign Animal Disease  
Preparedness & Response Plan

National Center for Animal  
Health Emergency Management

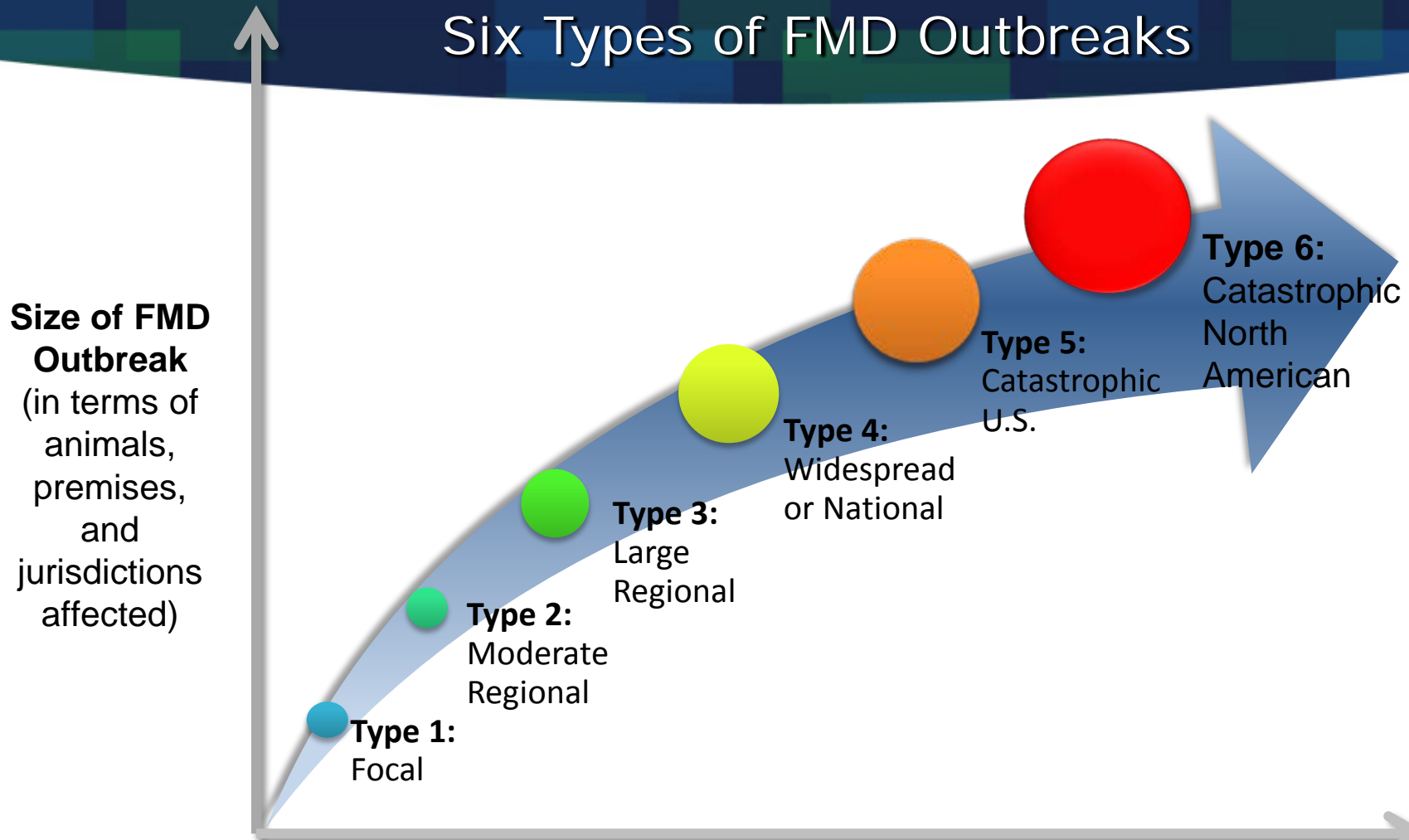


United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

DRAFT OCTOBER 2012

# 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)**

# USDA FMD Vaccination Policy in the U.S. September 2014

*Table 2: Current Capability of the United States to Effectively Implement Vaccination Strategy or Strategies<sup>4</sup>*

<b>Type of Outbreak</b>	<b>Vaccinate-to-Kill</b>	<b>Vaccinate-to-Slaughter and Vaccinate-to-Live</b>
<i>Type 1: Focal FMD Outbreak</i>	+	+/- (depends on regulatory infrastructure)
<i>Type 2: Moderate Regional FMD Outbreak</i>	+/- (depends on animal density)	+/- (depends on regulatory infrastructure and animal density)
<i>Type 3: Large Regional FMD Outbreak</i>	--	--
<i>Type 4: Widespread or National FMD Outbreak</i>	--	--
<i>Type 5: Catastrophic U.S. FMD Outbreak</i>	--	--
<i>Type 6: Catastrophic North American FMD Outbreak</i>	--	--

<sup>4</sup> Includes, but is not limited to, vaccine quantities, time to delivery, and regulatory infrastructure (regulatory issues such as procurement, licensing, permitting, distribution, use, and traceability).

# 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 or continue stamping out
- Sufficient vaccine and resources are not available to effectively use vaccine to control the outbreak

# Type 5 – Catastrophic FMD Outbreak

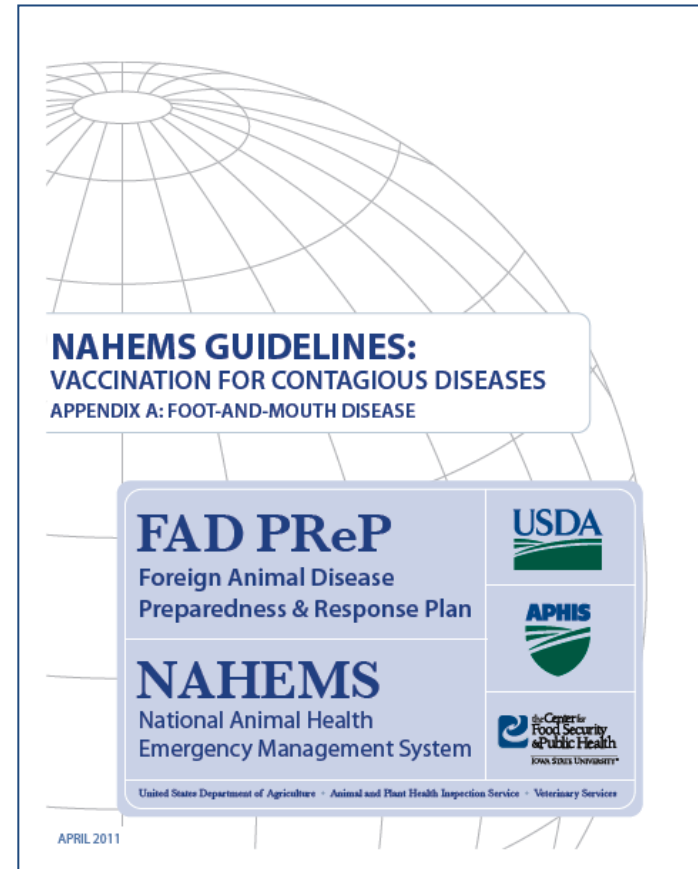
- It becomes apparent that FMD is widespread, and will not be eradicated within a year
- Transition from an emergency eradication response to a long term control program eventually leading to eradication, perhaps including vaccinate-to-live

# 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>



# FMD Vaccination

- Killed virus vaccine
- 7 distinct serotypes
  - Not cross protective
  - Approximately 65 Subtypes
    - Cross-protection varies between strains within a serotype
    - 23 strains are recommended for FMD vaccine banks
  - It is essential to isolate virus and identify the serotype to select the correct vaccine



# Vaccine Strains Recommended for National Antigen Banks

World Reference Laboratory for Foot and Mouth Disease at the Pirbright Institute in Pirbright, UK

## 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

# FMD Vaccination Considerations

- Vaccination protects from clinical signs of disease
- Vaccination does not prevent infection and establishment of persistent infection in cattle
- Vaccination reduces virus shedding and increases the dose of virus needed to cause infection

# FMD Vaccination Considerations

- There is no evidence that persistently infected cattle can transmit infection under natural conditions
- Reliable detection of persistently infected animals delays return to FMD free status

# Detecting Infection in Vaccinated Animals (DIVA)

- FMD vaccines to be used in the US can be used as marker vaccines (DIVA vaccines)
  - DIVA = Detect Infection in Vaccinated Animals
  - Do not induce antibody to virus Non-Structural Proteins (NSPs)
  - Infection after vaccination induces antibody to NSPs
  - Test for antibody to NSPs to detect infected herds for eradication and to eventually prove disease freedom

# World Organization for Animal Health (OIE) Terrestrial Animal Health Code 2014

- Chapter 8.7 Foot and Mouth Disease
  - Article 8.7.9 Recovery of free status
    - 2.b. 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Articles 8.7.42. to 8.7.47. and Article 8.7.49. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

# North American FMD Vaccine Bank

- Shared by U.S., Canada, and Mexico
- Vaccine antigen concentrate to be formulated into vaccine
- Stored in U.S.
  - Must be sent back to manufacturer for formulation into vaccine
- Expires after several years and must be discarded and replaced

# North American FMD Vaccine Bank

- Supplies are based on the old model of selective and restricted use of vaccine to accompany stamping out\*
- Emergency vaccine stocks are far below what would be required to address a single livestock dense state or multi-state outbreak\*

\*JR Diez and DK Styles, Dev in Biologicals 135:15-22, 2013

# National Veterinary Stockpile

- National repository of critical veterinary supplies, equipment, and services
- Homeland Security Presidential Directive 9 (2004)
  - Directed Secretary of Agriculture to establish the NVS
  - Required the NVS to deploy within 24 hours “sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy”



# High-Consequence Foreign Animal Diseases and Pests

## Tier 1:

- African swine fever\*
- Classical swine fever\*
- Foot-and-mouth disease\*
- Avian influenza (any strain that is highly pathogenic or has zoonotic significance)\*
- Virulent Newcastle disease\*

## Tier 2:

- Heartwater
- New World screwworm
- Rift Valley fever\*
- Venezuelan equine encephalitis\*

## Tier 3:

- African horse sickness
- Contagious bovine pleuropneumonia and contagious caprine pleuropneumonia
- Glanders and melioidosis
- Henipaviruses (Hendra and Nipah)\*
- Rinderpest\* and peste des petits ruminants\*
- Tropical bont tick

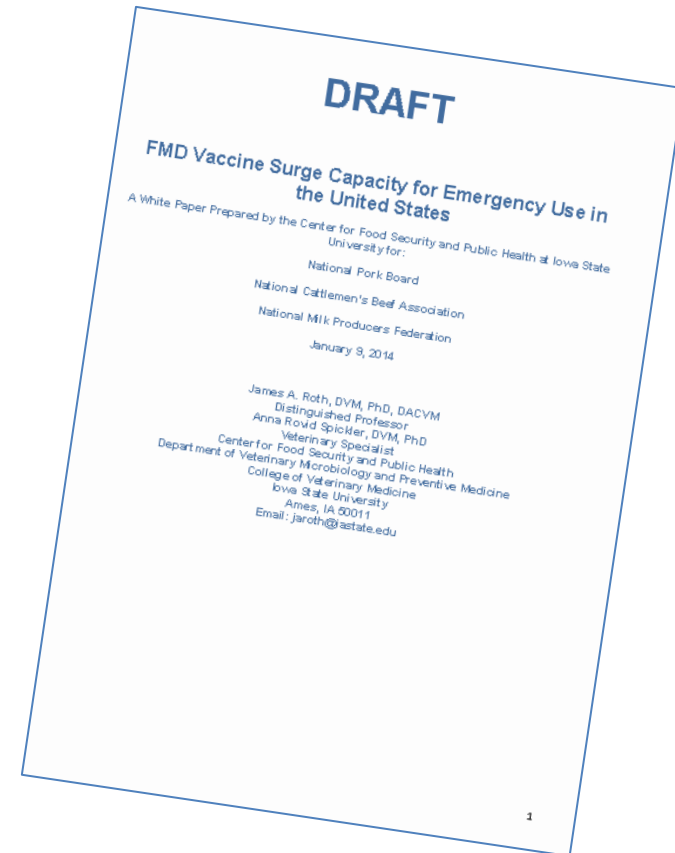
\*Biological threats that need to be considered in program priorities and countermeasure stockpile requirements.



# FMD Vaccine Surge Capacity for Emergency Use in the United States

January 9, 2014

- A White Paper (134 pages) Prepared by the Center for Food Security and Public Health at ISU for:
  - National Pork Board (NPB)
  - National Cattlemen's Beef Association (NCBA)
  - National Milk Producers Federation (NMPF)



# FMD Vaccine Surge Capacity for Emergency Use in the United States

January 9, 2014

- Acknowledgements
  - Reviewed in draft form by persons chosen for their scientific expertise, expertise in emergency response, familiarity with regulatory requirements, and/or experience in production animal agriculture (including APHIS, DHS, and biologics company representatives).
  - All reviewer comments were carefully considered. Responsibility for the final content of the report rests with the authors.

# Sources of FMD Vaccine

- International commercial manufacturers of killed FMD vaccine (none in US)
- New technology FMD vaccines that could be safely manufactured in the U.S. and which are based on a platform that allows various capsid serotypes/topotypes to be inserted into the vaccine

# Internationally Manufactured FMD Vaccine

- More doses of FMD vaccine are used in livestock worldwide than for any other disease (estimated at more than 2 billion doses per year)
- Very little excess production capacity worldwide
- Most existing inventory is committed to current customers

# Internationally Manufactured FMD Vaccine

- USDA APHIS VS Center for Veterinary Biologics Permit for importation and sale
  - Meets same safety and efficacy requirements as other USDA licensed veterinary vaccines
- Emergency exemption from licensure
  - Allows importation for emergency use
  - Unproven safety and efficacy for use in the U.S.

# Concerns with Emergency Exemption from Licensure

- Potential for extraneous agents in vaccine due to use of non-irradiated adult bovine serum to grow cell cultures
- Failure to kill FMD virus in the vaccine
- Inadequate potency
- Sourcing of bovine serum from countries that are not low risk for BSE
- Failure to remove non-structural proteins from the vaccine. Could not be used as DIVA vaccines for surveillance and eradication purposes

# Internationally Manufactured FMD Vaccine

- USDA CVB tested and permitted for importation
  - Transboundary Animal Biologics, Inc. (not for profit, funded by DHS)
    - Biogenesis Bago quadrivalent FMD vaccine, Argentina
      - Permit issued Feb 2013
      - Essentially all vaccine in inventory is already committed to current customers



# Internationally Manufactured FMD Vaccine

- Recommendation: Consider that all FMD vaccines approved for use in original EU member states be pre-approved for emergency use in the U.S.

# New Technology FMD Vaccines

- Have great potential
- All require further research and development
  - HAd5 vectored FMD vaccines (one strain conditionally licensed) (Merial)
  - Leaderless killed FMD-LL3B3D vaccines (Zoetis)
  - Alphavirus vectored FMD vaccines (Harrisvaccines, Inc)
  - Plasmid DNA FMD vaccines (VGX Animal Health/Inovio Pharmaceuticals)

# Approaches to Assure Surge Capacity for FMD Vaccines

- Immediate Availability:
  - Finished vaccine held in vendor-managed-inventory and ready for shipment within 24 hours
  - Enough doses for the first two weeks of the outbreak
    - ~10 million doses of multivalent vaccines
    - Must be vaccine that is currently being sold

# Approaches to Assure Surge Capacity for FMD Vaccines

- Short-Term Availability:
  - Vaccine antigen concentrate (VAC) held in vendor managed-inventory ready to be formulated into finished vaccine and shipped to the U.S.
    - ~40 million doses for 23 strains of FMD
    - Rotate the VAC before it expires if possible. Only an option for strains of vaccines currently produced by approved companies

# Approaches to Assure Surge Capacity for FMD Vaccines

- Long-Term Availability
  - Vaccine production initiated at the beginning of the outbreak for the specific outbreak strain(s) of FMD virus
    - Estimated to require 14 weeks to produce
    - Enter into contracts with international manufacturers of FMD vaccines for surge capacity production of commercially available FMD vaccines

# Approaches to Assure Surge Capacity for FMD Vaccines

- Long-Term Availability
  - Seek USDA licensure of new technology FMD vaccines that could be safely manufactured in the U.S. and which are based on a platform that allows various capsid serotypes/topotypes to be inserted into the vaccine

# Approaches to Assure Surge Capacity for FMD Vaccines

- Convene a stakeholder community working group of experts capable of evaluating existing and new technology FMD vaccines under development to determine the technologies which can best meet the needs for emergency response vaccination in the US.

# Approaches to Assure Surge Capacity for FMD Vaccines

- Form a standing advisory committee with expertise in FMD vaccines, production agriculture, economics, and emergency response to make recommendations on optimal use of vaccine as the outbreak unfolds.



# Approaches to Assure Surge Capacity for FMD Vaccines

- Secure funds to enable the surge capacity need for FMD vaccines mandated in HSPD 9 to be met
  - Estimated at \$150 million/year for 5 years
  - At the end of 5 years, perhaps new technology FMD vaccines manufactured in the U.S. could be part of the solution

Questions, Comments: [jaroth@iastate.edu](mailto:jaroth@iastate.edu)



# Estimated FMD vaccinations by country

Region	Vaccinations	
	Doses (millions)	%
China	1600	68.1
India	150	6.4
Rest of Asia	50	2.1
Africa	15	0.6
Europe and Turkey	15	0.6
Middle East	20	0.9
South America	500	21.3
Total	2350	100.0

The majority of those doses are used, and likely produced, in China, India, and the rest of Asia. As you pointed out, there are very good reasons to be concerned about importing vaccines from this region without first having the USDA Center for Veterinary Biologics certify that they are pure, safe, potent, and efficacious. Some of the more serious concerns are:

- Potential for extraneous agents in the vaccine. It is common for manufacturers in some countries to use non-irradiated adult bovine serum to grow the cell cultures for virus production.
- Failure to kill the FMD virus in the vaccine (which has been documented in the past)
- Inadequate potency
- Sourcing of bovine serum from countries that are not low risk for BSE
- Failure to remove the non-structural proteins from the vaccine. They could not be used as marker vaccines for surveillance and eradication purposes.

# For More Information

[www.cfsph.iastate.edu/Secure-Food-Supply/index.php](http://www.cfsph.iastate.edu/Secure-Food-Supply/index.php)

- Secure Food Supply Plans
- USDA Foot-and-Mouth Disease Response Plan "The Red Book"
- Phases & Types of an FMD Outbreak
- NAHEMS Guidelines: Continuity of Business
- NAHEMS guidelines: Vaccination for contagious diseases; Appendix A: Vaccination for Foot-and-Mouth Disease
- FMD Vaccine Surge Capacity for Emergency Use in the United States
- Inactivation of Foot-and-Mouth Disease Virus in Milk Products
- Foot and Mouth Disease in Pigs - Progression of Lesions



*Table 2: Current Capability of the United States to Effectively Implement Vaccination Strategy or Strategies<sup>4</sup>*

<b>Type of Outbreak</b>	<b>Vaccinate-to-Kill</b>	<b>Vaccinate-to-Slaughter and Vaccinate-to-Live</b>
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<sup>4</sup> Includes, but is not limited to, vaccine quantities, time to delivery, and regulatory infrastructure (regulatory issues such as procurement, licensing, permitting, distribution, use, and traceability).

# Foot-and-Mouth Disease Vaccination Policy in the United States, September 2014

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Appendix A North American Foot-and-Mouth Disease Vaccine Bank Vaccine Antigen Concentrate (not available in public version of document)

Appendix B Key Regulatory Authorities

Appendix C Selected References and Literature

Appendix D Potential Economic Impact of FMD

Appendix E World Reference Laboratory for Foot-and-Mouth Disease Strain Recommendations

# Leaderless killed FMD-LL3B3D vaccines (Zoetis)

- Developed by ARS scientists at PIADC
- Master seed virus does not transmit, therefore it is safe to manufacture in US
- DIVA marker is built in, no need to purify
- FMD topotypes can be inserted
- Killed virus vaccine potentially produced using common technology
- APHIS could produce pre-approved master seed virus and outline of production for US manufacturers to use in an outbreak



# FMD: The MOST Contagious Disease of Animals

Affects cloven hooved animals

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

Mortality may be low but morbidity is high

**High mortality associated with some strains and some control methods**

**Not a public health or food safety concern**

UK



Korea



Japan



Egypt



# FMD Lesions



# United States Animal Agriculture Industry is Unique

- US animal agriculture is highly efficient and produces high quality products
- The size, structure, efficiency, and extensive movement inherent in the U.S. and North American livestock industries will present unprecedented challenges in the event of an FMD outbreak

# Phases of FMD Response

Heightened Alert Phase: FMD Outbreak in either Canada or Mexico, but not U.S.

Phase 1: From confirmation of the first case of FMD in the U.S. until reasonable evidence to estimate outbreak extent.

Phase 2: Surveillance and epidemiology provides timely evidence of outbreak extent to support decisions by Incident Command.

Phase 3: Recovery: surveillance and epidemiology indicates FMD is under control; plan implemented to recover disease-free status.

Phase 4: U.S. declared free of FMD, possibly with vaccination.

# Approaches to Assure Surge Capacity for FMD Vaccines

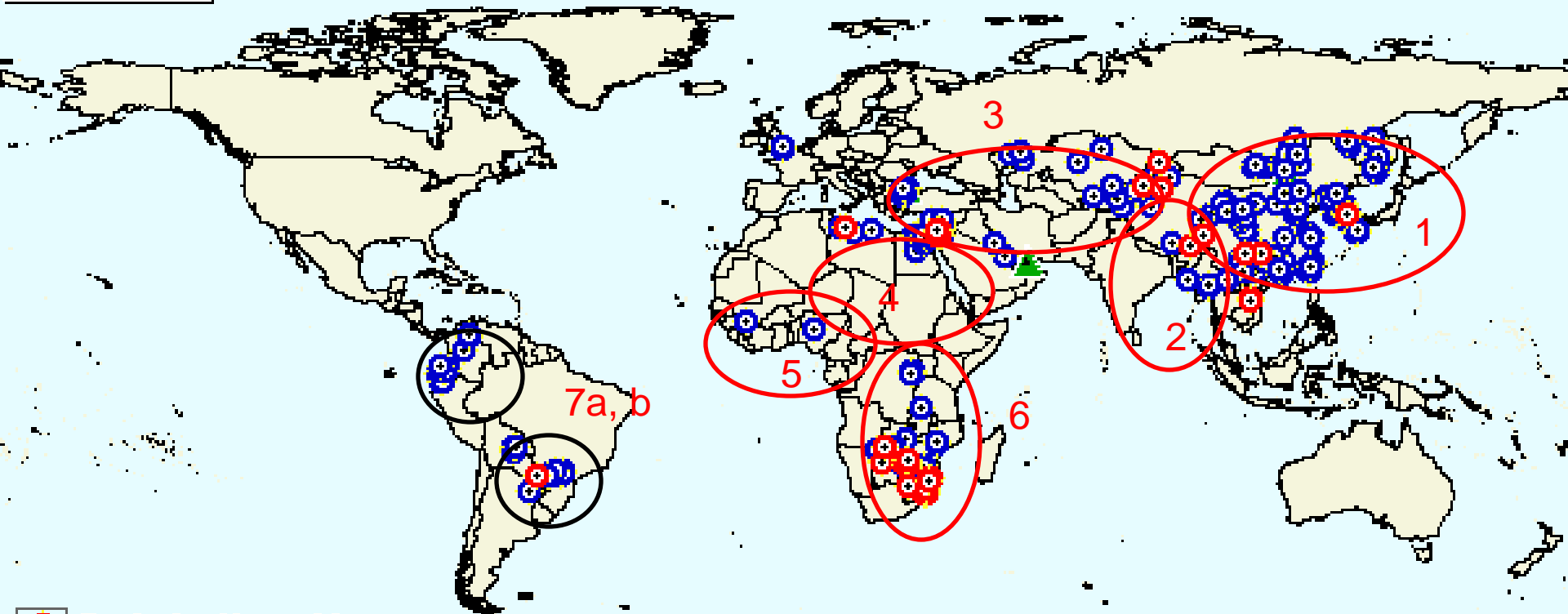
- Secure funds to enable the surge capacity need for FMD vaccines mandated in HSPD 9 to be met
  - Estimated at \$150 million/year for 5 years
  - DHS S&T should conduct a classified Biological Threat Risk Assessment (BTRA) in collaboration with the USDA (APHIS and ARS), the Department of Commerce, and the Office of National Intelligence.

Figure 4. Concept of Pig Flow



# FMD Outbreak Reports 2005- 2011: Endemic Pools

WAHID OIE © 2011



- Continuing (domestic)
- Resolved (domestic)
- Resolved (wild)
- No information

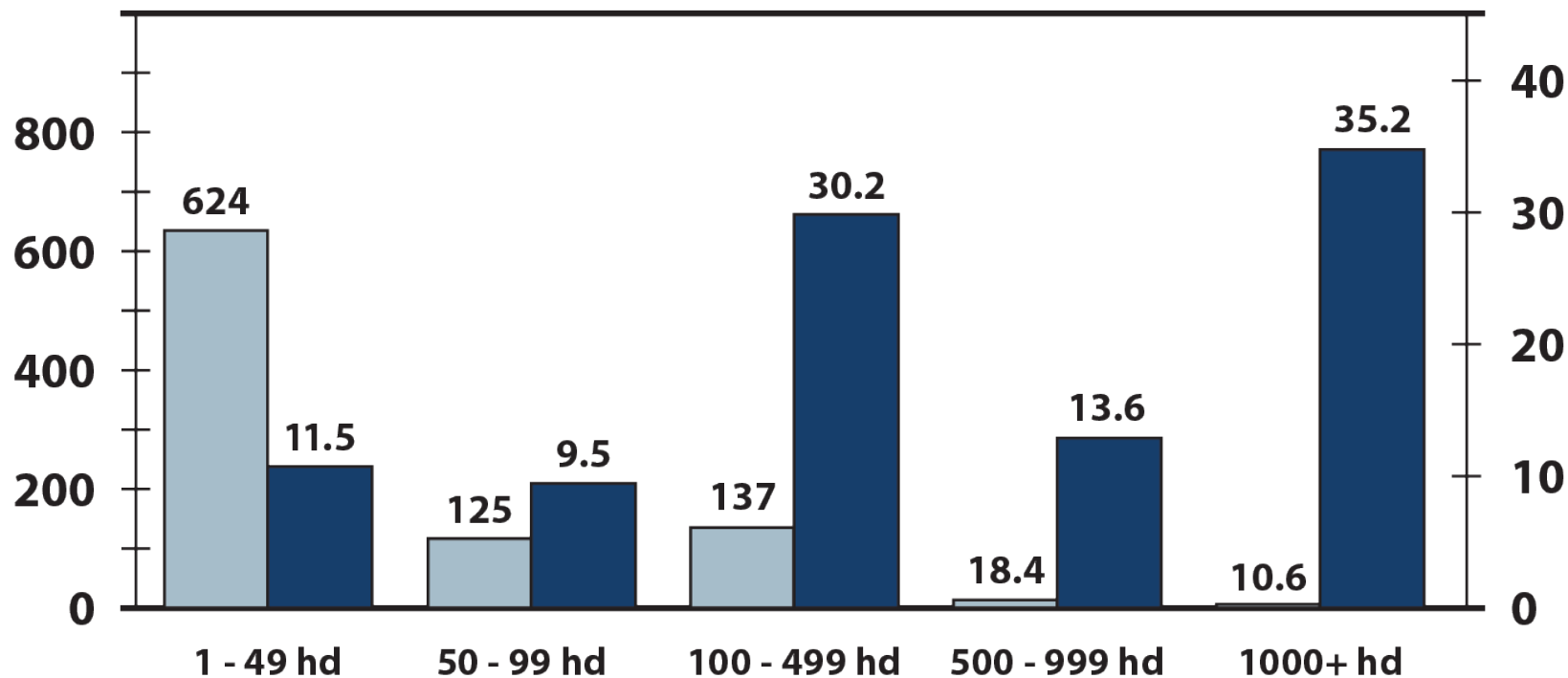
Pool 1 East Asia	Pool 2 South Asia	Pool 3 Eur Asia	Pool 4 East Africa	Pool 5 West Africa	Pool 6 South Africa	Pool 7 South America
A, O, Asia 1	A, O, Asia 1	A, O, Asia 1	A,O, Sat 1-3	A,O, Sat1-2	Sat 1,2,3	A, O

# U.S. Cattle Operations and Inventory

## Total Operations during 2012 - 915,000

# of Operations (000)

% of Inventory



Operations Inventory



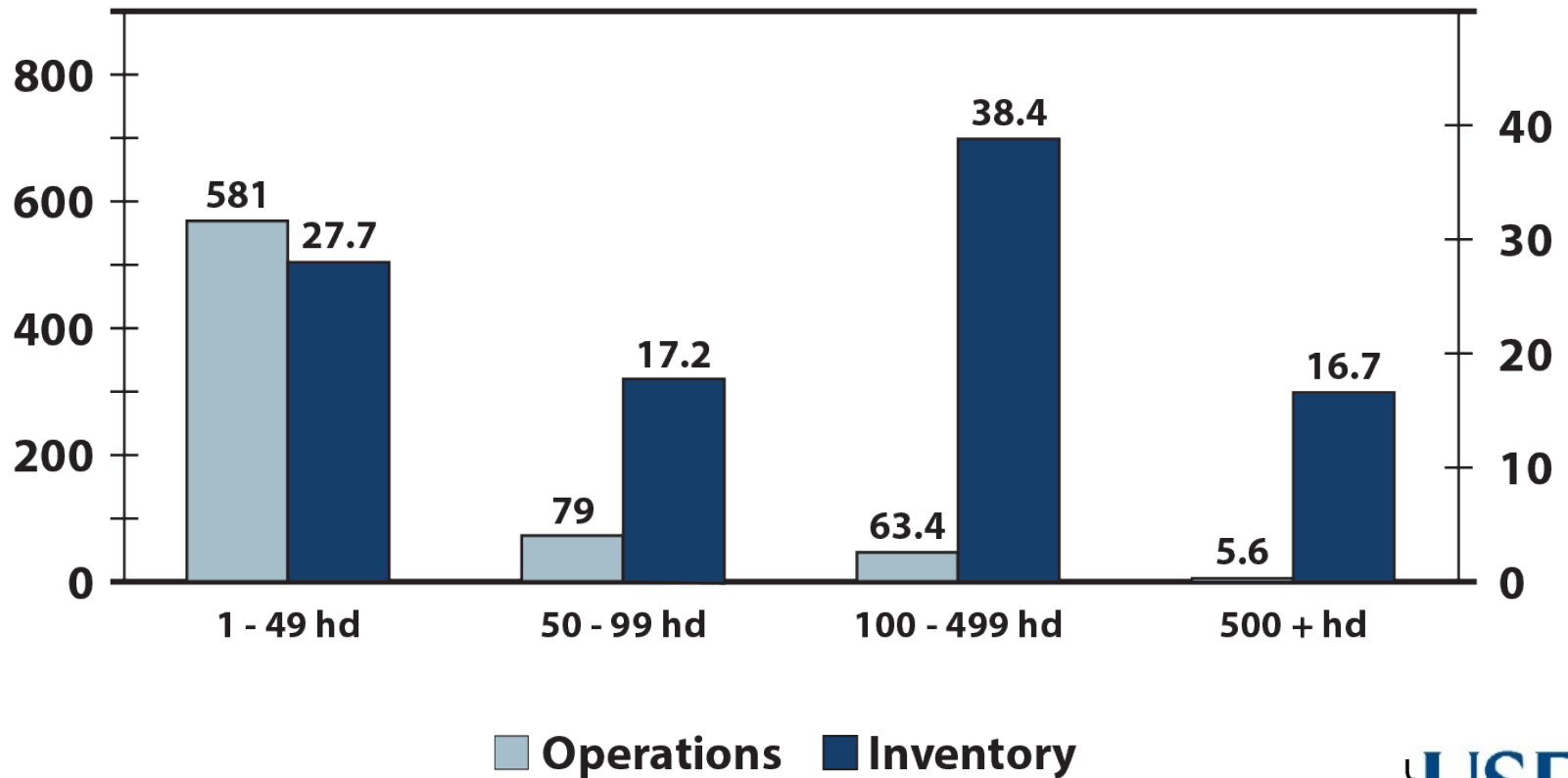


# U.S. Beef Cow Operations and Inventory

## Total Operations during 2012 - 729,000

# of Operations (000)

% of Inventory



# Foot-and-Mouth Disease Vaccination Policy in the United States, September 2014

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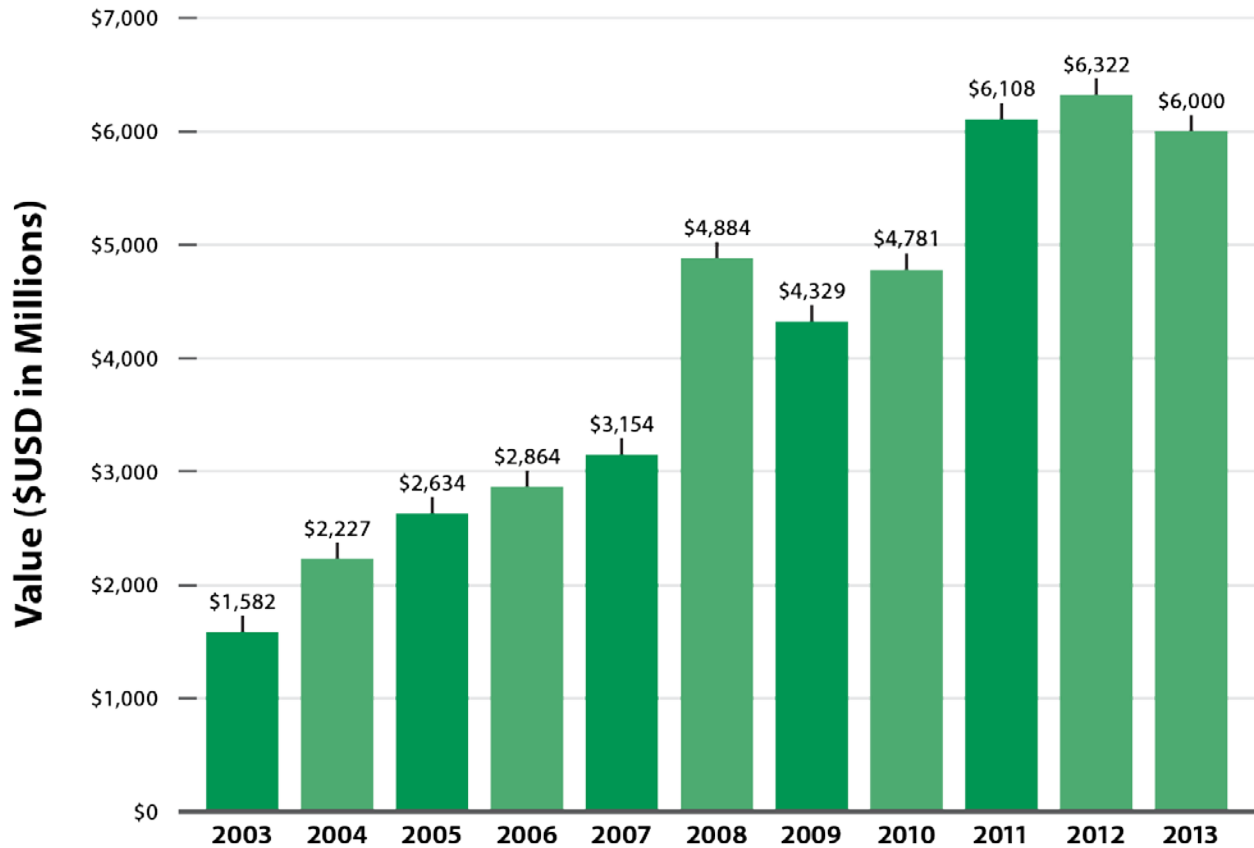
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Appendix C Selected References and Literature

Appendix D Potential Economic Impact of FMD

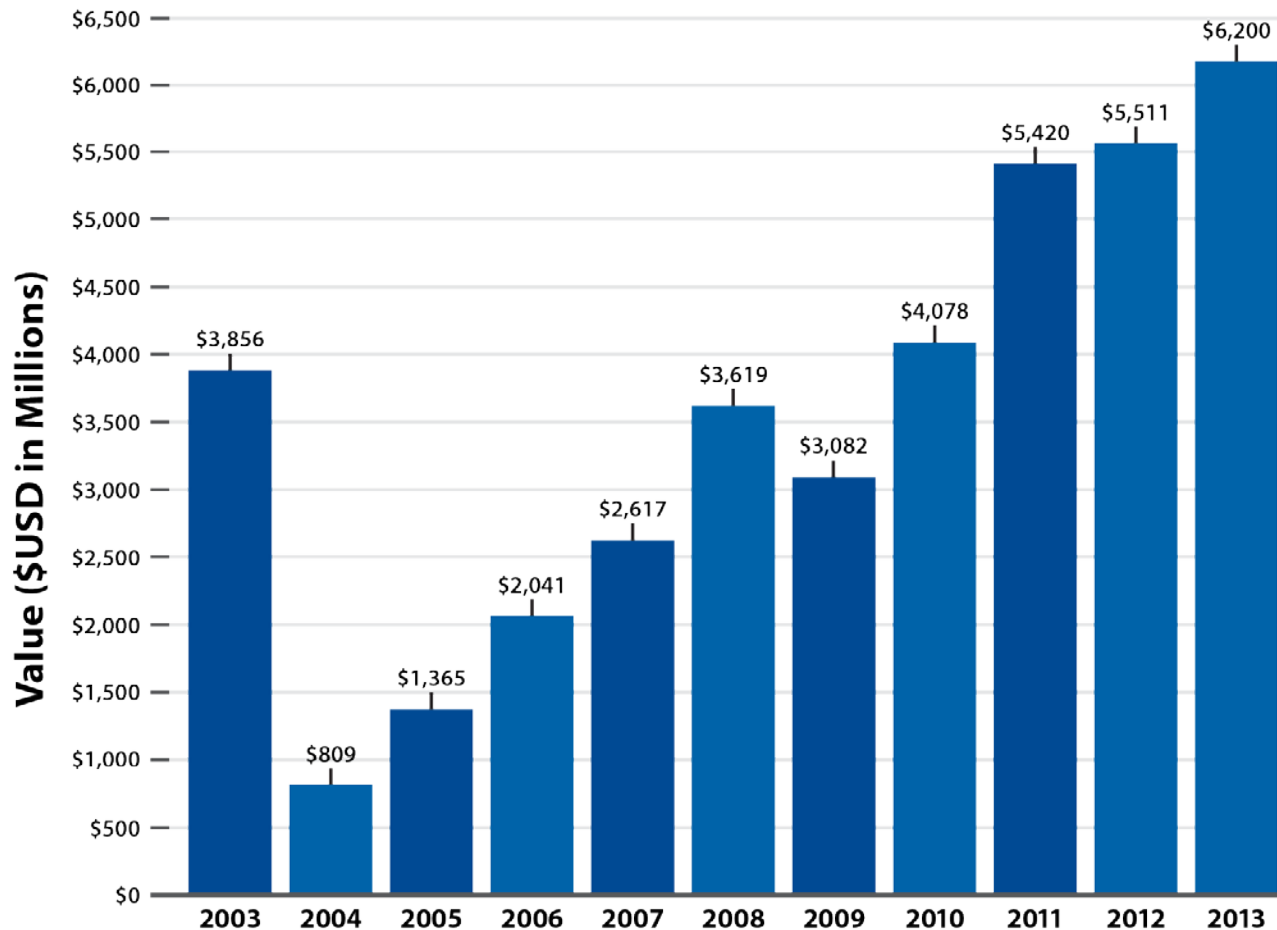
Appendix E World Reference Laboratory for Foot-and-Mouth Disease Strain Recommendations

# Total U.S. Pork Exports, 2003 to 2013



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

# Total U.S. Beef Exports, 2003 to 2013

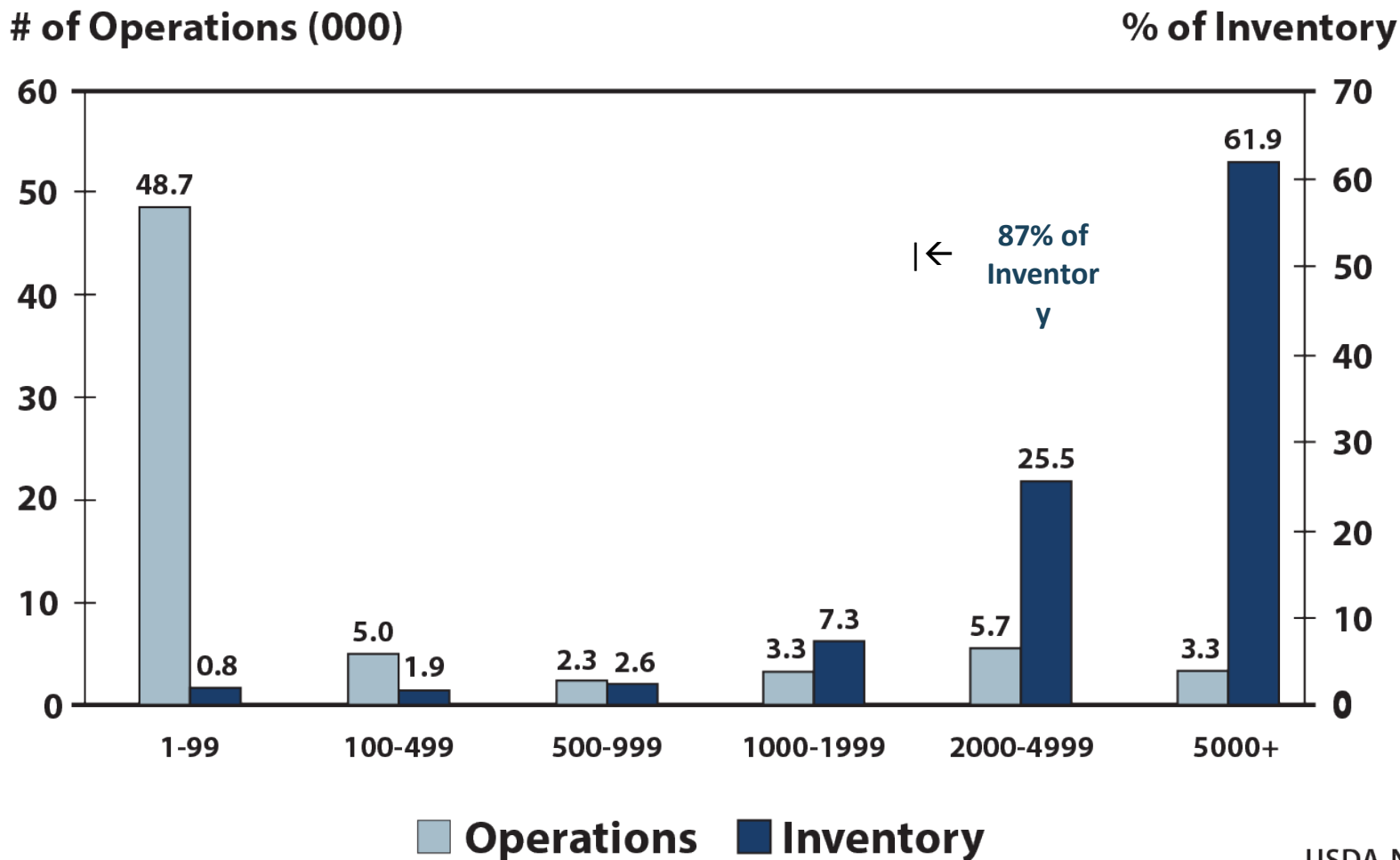


Data compiled by the U.S. Meat Export Federation and available at <http://www.usmef.org/news-statistics/statistics>



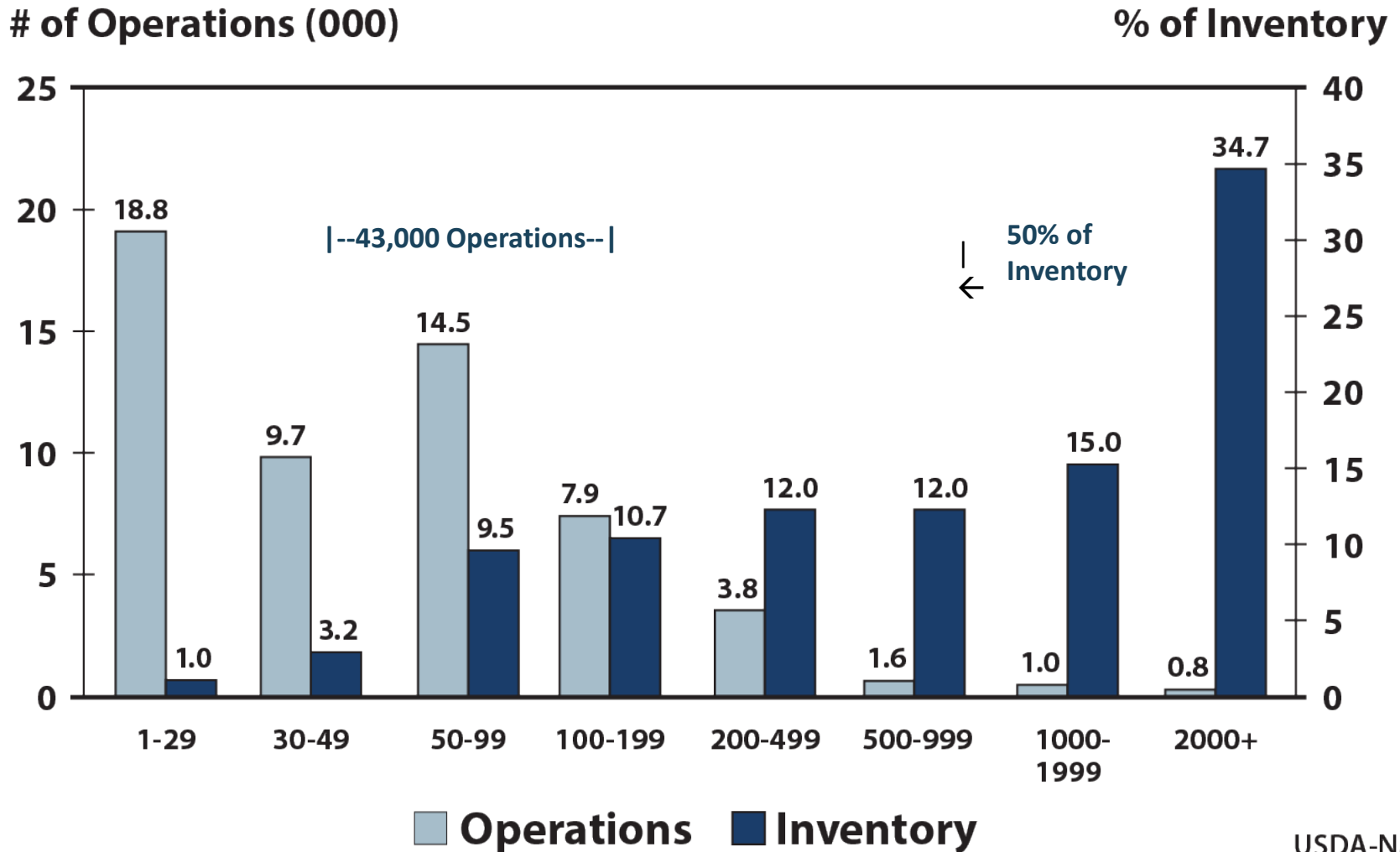
# U.S. Hog Operations

## Number of Operations and Percent of Inventory, 2012



# U.S. Cattle Operations - Dairy Cows

## Number of Operations and Percent of Inventory, 2012

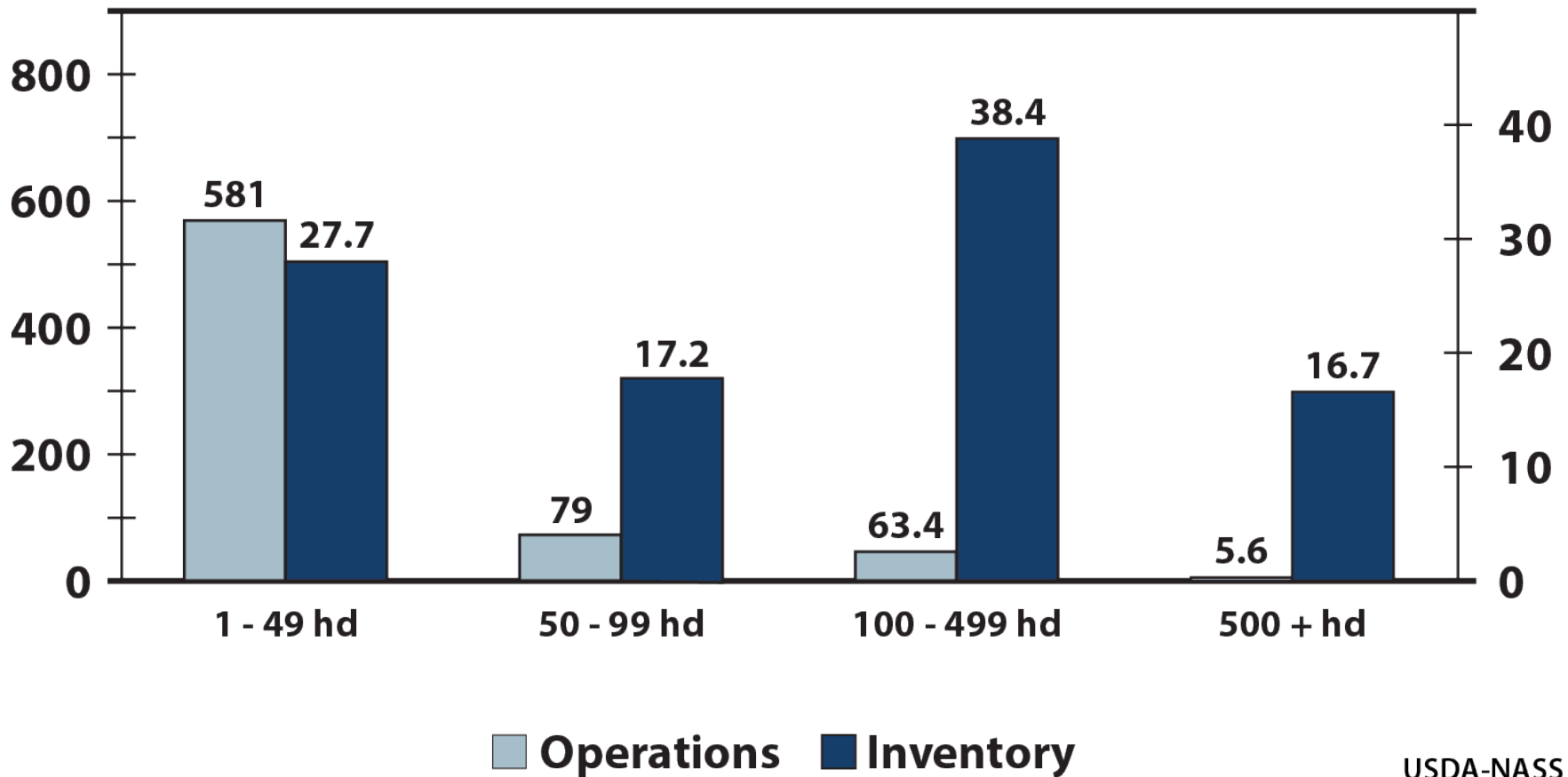


# U.S. Beef Cow Operations and Inventory

## Total Operations during 2012 - 729,000

# of Operations (000)

% of Inventory



Operations Inventory

# Business Continuity Challenges in a Type 5 FMD Outbreak

- Commodity prices will drop
- Productivity of infected animals will be low (feed efficiency, rate of gain, milk production)
- Some animals will be culled due to severe disease
  - Indemnity may not be available
- Producers may go out of business for economic reasons