Secure Milk Supply (SMS) Plan November 9, 2012

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Overview

- Foot-and-mouth disease (FMD)
- FMD Response Plan
 - Continuity of business planning
- Secure Milk Supply (SMS) Plan
 - Partners
 - Project components
 - Documents
- Next steps



FMD Virus in Dairy Products

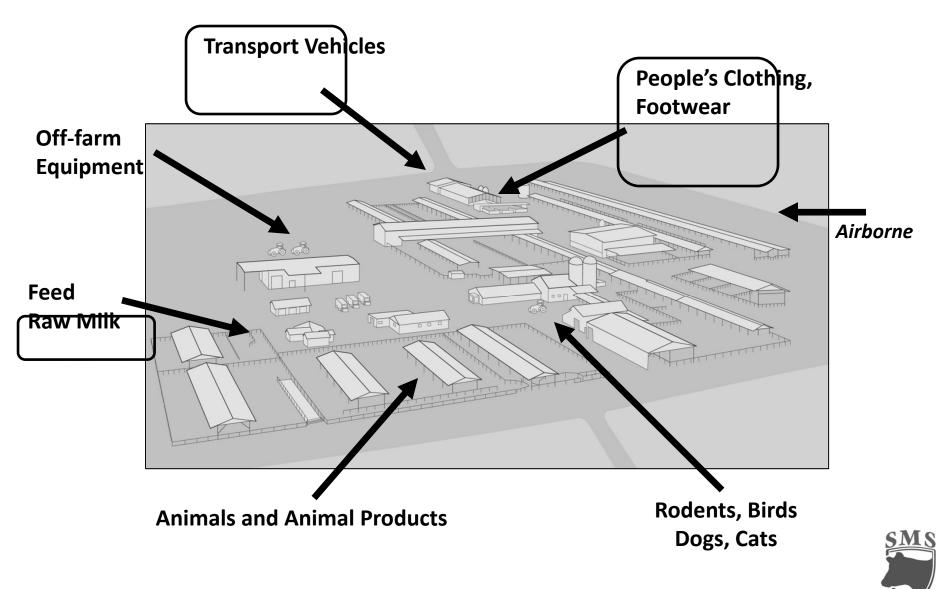
- Shed in milk
- Single HTST pasteurization does not completely inactivate it



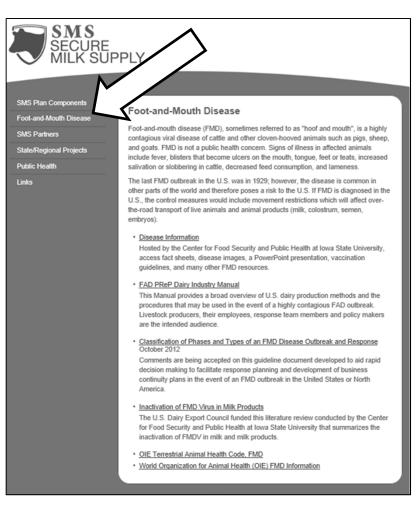
- Low levels of virus if milk pH above 7.0
- Traditionally zero tolerance despite no public health risk
- Trade partners (OIE), other industry lack of acceptance



FMD Entering/Leaving a Dairy



www.securemilksupply.org



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



National FMD Response Planning and Preparedness

Continuity of Business (COB) Planning



FOOT-AND-MOUTH DISEASE RESPONSE PLAN

FAD PReP
Foreign Animal Disease

USDA FMD Response Plan

- Response Goals (4.1)
 - Detect, control, contain FMD in animals as quickly as possible
 - Eradicate FMD using strategies
 that stabilize animal agriculture,
 food supply, economy, protect public health
 - Provide science- and risk-based approaches and systems that facilitate continuity of business for non-infected animals and non-contaminated animal products (MILK)

www.aphis.usda.gov/animal_health/emergency_management/dow nloads/fmd_responseplan.pdf



First 72 Hours of FMD Outbreak

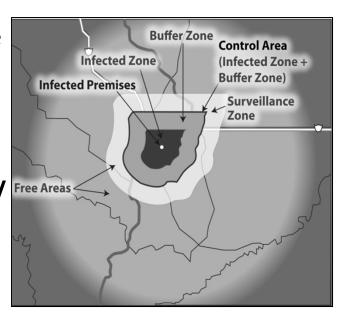
Figure 4-1. Critical Activities in the First 72 Hours of a U.S. FMD Outbreak

 Initiate quarantine, hold orders, · Evaluate quarantine and · Evaluate quarantine and movement restrictions and movement controls movement controls standstill notices (e.g., 24-72 Continue ramping up Incident Ongoing surveillance and Use of hours) for relevant zones and Command and Operations tracing activities appropriate regions Center Initiate publicawareness critical Notify States, industry, trading Detection of Ongoing surveillance and activities and partners, media campaign FMD virus in tracing activities Initiate biosecurity measures tools will Ongoing biosecurity measures the United Ongoing biosecurity activities · Initiate tracing activities continue Initiate continuity of business States Ongoing public awareness throughout · Initiate virus identification for plans FMD vaccine campaign Continue virus identification · Initiate Incident Command response Continue virus identification for vaccine processes for vaccine 0 - 24 HOURS 24 - 48 HOURS 48 - 72 HOURS



USDA-APHIS FAD PReP FMD Movement Guidelines

- Establish FMD Control Area
 - Infected and Buffer Zone
 - Federal quarantine
 - Movement by permit and risk assessment only
 - Movement controls in place until FMD eradicated





Continuity of Business (COB) Planning

- Minimize unintended negative effects of disease and disease response, while achieving response goals
 - Control or eradicate disease without "destroying" the industry
- Provide risk-based solutions derived from scientific data, national and international standards
 - Mitigate unintended consequences of FAD response on agriculture, food industries, consumers, and communities

Secure Milk Supply (SMS) Plan – Partners

National SMS Partners

Academia

- Iowa State University, Center for Food Security and Public Health
 - Jim Roth, DVM, PhD, DACVM
 - Danelle Bickett-Weddle, DVM, MPH, PhD, DACVPM
- University of California, Davis
 - Pam Hullinger, DVM, MVPM, DACVPM
- University of Minnesota, Center for Animal Health and Food Safety
 - Tim Goldsmith, DVM, MPH, DACVPM
 - Sarah Easter-Strayer, DVM

USDA-APHIS-VS

- Centers for Epidemiology and Animal Health (CEAH)
 - Tim Clouse, MA
 - Kristen Johnson, DVM, MS
- National Center for Animal Health Emergency Management (NCAHEM)
 - Jon Zack, DVM
- Provides funding to Partners

Industry

- Working groups
- Topic experts



State/Regional SMS Partners

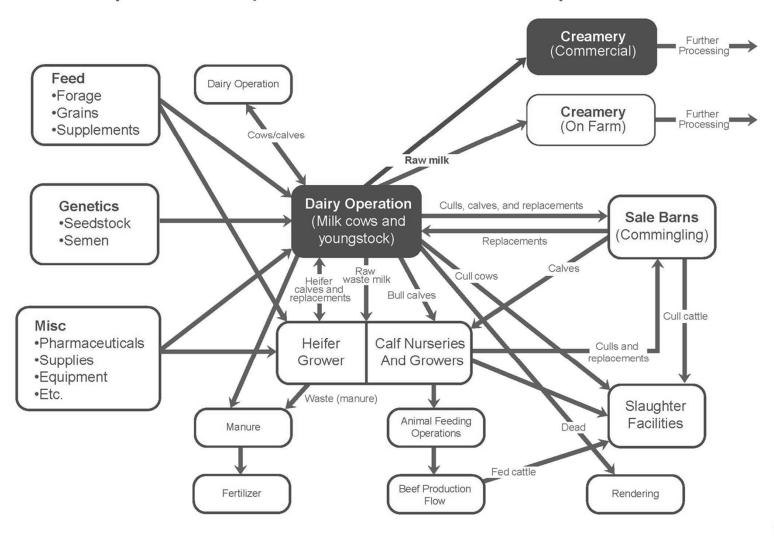
- North Carolina Dairy biosecurity workgroup
- New England States Animal Agricultural Security Alliance (NESAASA) – Six NE states
- SMS-Wisconsin
 - Coordinated by the Wisconsin Milk Marketing Board
- Mid-Atlantic states
 - VA, MD, TN, NC, SC, DE, WV
- California
- Colorado
- New York, New Jersey, PA
- Pacific Northwest
- Texas
- Quarterly coordination calls





Secure Milk Supply (SMS) Plan – Components

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





Secure Milk Supply Plan

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

Initial Focus

Milk trucks

Working Groups

- 1. Biosecurity (sunsetted)
 - Premises, Milk hauler (transport),
 Milk processing
 - Final 'drafts' January 2012
- 2. Milk movement
 - Proposed decision matrix for Incident Management Team, Draft recommendations
- 3. Cleaning & disinfection
- 4. Risk assessment

Biosecurity Performance Standards



Biosecurity Practices during FMD Outbreak

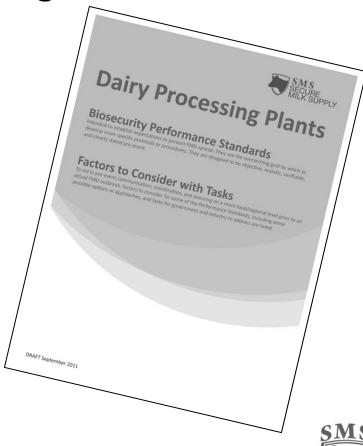
- Goal is to reduce the risk of FMD:
 - Entering a dairy operation,
 - Being transmitted off infected, undetected farms, and
 - Contaminating processing prior to pasteurization





Biosecurity Documents

- Premises, hauler, processing
- Standardized language based on input
 - Purpose
 - Intended Audience
 - Scope
 - Info about FMD
 - Terminology
 - Cleaning and Disinfection
 - Approved Disinfectants



Biosecurity Performance Standards

- Establish expectations to prevent FMD spread
- Overarching goal by which to develop more specific protocols or procedures
- Developed by members of various SMS Plan Biosecurity Working Groups
- Designed to be objective, realistic, verifiable, and clearly stated pre-event

Example BPS: Processor Document (Jan 2012)

- 3.4.3 After off-loading milk, the performance standard is to ensure no residual raw milk in the tanker and hoses leaks upon leaving the receiving bay at the processing plant:
 - 3.4.3.1 The Pasteurized Milk Ordinance (PMO) requires CIP of milk tankers once every 24hr period when in use.
 - 3.4.3.2 In absence of full CIP or performing a sanitary rinse of the tanker after each off-load, all access points to raw milk on tanker should be completely sealed to prevent leaking.
 - Complete CIP of the tanker after each off-load may not be possible in many situations (lack of CIP equipment, lack of waste water permits, lack of off-loading capacity for in ming loads, etc.).
 - Sa tary rinse may not be possible due to lack of permit General Procedures – More Specific Guidance Needed

More Specific Guidance

- Dependent upon resources, climate, capabilities, scope of outbreak
- Establish expectations
 - State agencies, industry
- Verification, confidence in protocols

Next steps for states, industry,
 C&D working group...

Slowed Movement

Recognize implementation and verification of biosecurity performance standards (BPS) is going to impact the speed of product movement



Milk Movement Working Group

Decision Support Tools Permitting Resources

Movement Workgroup

- Developing tools to facilitate movement and permitting decisions
 - Decision matrix by phases of an outbreak
 - Biosecurity, surveillance, OIE standards
- Need a robust, scalable, fully functional permitting system in place
 - Without traceability in place, a permitting system will take more time



Phases and Types of FMD Outbreaks



Overview of Phases and Types of FMD Outbreaks

An FMD outbreak in the United States will be a complex event. Having pre-defined phases and potential types of an FMD outbreak may be useful to facilitate the development of adaptable emergency response plans and processes. This information is intended to be guidance, acknowledging that any FMD outbreak will be unique and responders will need to tailor the response accordingly. The phase and the type of the FMD outbreak will change over the course of the outbreak.

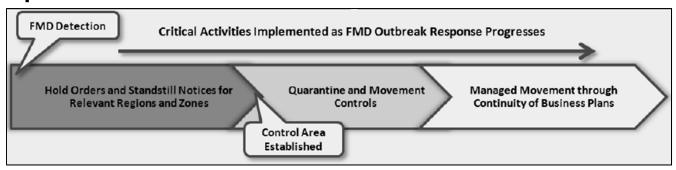
Phase: A temporal stage in FMD outbreak response.

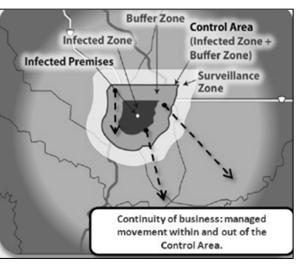
Type: A categorical measure of magnitude of an FMD outbreak.

Six Types of FMD Outbreaks Phases of FMD Response Even a focal FMD outbreak Heightened Alert Phase: FMD Outbreak would require significant in either Canada or Mexico, but not U.S. operational capabilities and have significant economic Phase 1: From confirmation of the first implications for the United States, including from lost case of FMD in the U.S. until reasonable Type 6: international trade and evidence to estimate outbreak extent. Catastrophi disruptions to interstate North American vpe 5: Size of FMD commerce. Catastrophic FMD Outbreak Outbreak Phase 2: Surveillance and epidemiology U.S. FMD (in terms of provides timely evidence of outbreak Type 4: Outbreak animals. Widespread or extent to support decisions by Incident premises. National FMD Command. Type 3 and Outbreak Large iurisdictions Regional Phase 3: Recovery: surveillance and affected) FMD epidemiology indicates FMD is under Type 2: Outbreak control; plan implemented to recover Moderate Regional FMD disease-free status. Outbreak Type 1: This proposed typology of an FMD outbreak was developed by Dr. Focal FMD Phase 4: U.S. declared free of FMD, Jim Roth, of the Center for Food Security and Public Health, lowa Outbreak possibly with vaccination. State University. It is one approach to describing a response to an FMD outbreak in the United States. Response Shifts from Emphasis on Stamping-Out to Emphasis on Alternate Strategies (duration of FMD response)

USDA-APHIS FAD PReP FMD Movement Guidelines

- Establish FMD Control Area
 - Infected and Buffer Zone
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 risk assessment only
 - Movement controls in place until FMD eradicated







Example Decision Matrix

Milk Movement Permit Decision Matrix in the Event of an FMD Outbreak								
(Example) Phase 2: Type 4 - Wid	espread or Nat	ional FM	D Outbre	ak				
		Increased Premises	Increased Milk	Increased Milk Plant	Active surveillance for absence of clinical	Multiple Farm Loads per Truck	Permit to Treat	to OIE Standards
Premises Designation		Biosecurity*	Biosecurity*	Biosecurity*	signs **	Allowed	in Control Area	Area
Control Area		Diosecunity	Diesesunity	Diesecunity	signs	,		7.1.00
Infected premises	No milk movement							
Contact premises		Yes	Yes	Yes	Yes	No	ОК	No
Suspect premises	No milk movement							
At risk premises		Yes	Yes	Yes	Yes	No	ОК	No
Monitored premises		Yes	Yes	Yes	Yes	Yes	ОК	ОК
Vaccinated premises (14 days post vac)		Yes	Yes	Yes	Yes	Yes	OK	OK
Free Area***								
Free Premises in surveillance zone		No	No	No	Yes	Yes	ОК	ОК
Free Premises not in surveillance zone		No	No	No	No	Yes	ОК	ОК

^{*} Milk truck biosecurity, premises biosecurity, and milk plant biosecurity will all be increased in the event of an FMD outbreak. The increased biosecurity needs to be defined.

- ISU working on computerized mock-up
- Above Yes/No are just <u>examples</u>



^{**} Active surveillance for absence of clinical signs needs to be defined.

^{***} Even though it may not be required for milk movement, all livestock operations in the U.S.should implement FMD specific biosecurity plans and continue until freedom from FMD is reestablished.

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

Draft Recommendation

 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.

Audit next...



Draft Recommendation (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 EMD 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.



Risk Assessment Working Group

Pro-active Risk Assessments

Scope:

- Assessment of the risk associated with the movement of raw Grade A milk into, within, and outside of a Control Area during a FMD outbreak prior to processing
- First step: Normal dairy operations and risk of FMD virus spread from infected, undetected farms
 - Bioaerosol risk from tankers

Risk Assessment Update

- Final draft of baseline risk assessment (RA) has been completed
 - Undergoing technical editing
- Working Group monthly conference calls, 3rd Tuesday
 - Address results of RA in conjunction with the applicable BPS
 - Dairy premises, hauler, processing plant
 - Industry, regional SMS groups,
 Federal/State officials, academic partners

RA Working Group Goals

- Determine if identified risk pathways from the RA are addressed by BPS
- Estimate risk reduction with implementation of BPS
- Identify potential gaps and provide sciencebased input into development of specific mitigations or SOPs
- Address other concerns raised by the group
- Develop document that provides additional information to consider in development of regional emergency response plans

Participating in the Working Groups

- 1. Cleaning & Disinfection
 - Danelle dbw@iastate.edu
- 2. Milk Movement
 - Jim Roth jaroth@iastate.edu or
 - Pam Hullinger phullinger@ucdavis.edu
- 3. Risk Assessment
 - Sarah Easter-Strayer easte068@umn.edu
- Industry & Government partners essential
- Draft guidance shared with USDA-APHIS, States, informs risk assessments



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, preplanning 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 assure 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 FMDv 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.

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d framework for nt) and type ing. As the cific aspects

4 page doc overview

- 80 page doc
 - BPS
 - Factors to consider
 - Phases and Types
 - Decision matrix
 - Draft recommendations

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



Next Steps



Next Steps

- Movement guidance
 - Active observational surveillance tools
 - "Phases and Types" out for comment
- Cleaning and disinfection
 - Help establish options for local SOPs
 - Citric acid exemption from EPA
 - Working with USDA-APHIS
- Risk assessment
 - Discuss mitigation steps with WG

Next Steps (cont'd)

- Support state/regional plan development
- Gain acceptance
 - Local, state, tribal, national government agencies
 - Agriculture, food sectors
 - International trading partners
 - Civil, consumer, environmental organizations
- Maintain, exercise and update plans so they remain current

www.securemilksupply.org



- Project updates
- Working group info
- Partner information
 - Contact information
- FMD info
- BPS documents are NOT posted due to 'draft' status

