

# **Risk Assessment for the Transmission of Foot-and-Mouth Disease via the Transport of Raw Milk Into, Within, and Outside of a Control Area during an Outbreak with Implementation of the Biosecurity Performance Standards (RA-BPS Analysis)**

## **Executive Summary**

In the event of a foot-and-mouth disease outbreak in the United States (U.S.) livestock industry, local, state, and federal authorities will implement a foreign animal disease (FAD) emergency response.

The response will consist of quarantines, movement controls and continuity of business (managed movement) which all have the ultimate goal to prevent transmission of the FAD to non-infected premises. Quarantines and movement controls are applied to premises in the regulatory Control Area to ensure infected animals, fomites and products do not leave premises. COB is intended to manage movement for the non-infected premises (At-Risk and Monitored Premises) in the Control Area. Managed movement involves the development and implementation of science and risk-based systems and protocols to help agriculture and food industries maintain essential business functions or return to business during an FAD response while the risk of disease spread is effectively managed (USDA, 2013).

“Proactive risk assessments are one component of the COB process and are used to develop the requirements for movement of commodities outside of a regulatory Control Area. These requirements can include biosecurity measures, C&D procedures and surveillance sampling prior to movement” (USDA, 2013). Performing the risk assessments prior to an FMD outbreak can enhance emergency response and facilitate timely movement permitting decisions during an outbreak. This report, the RA-BPS Analysis, evaluated the biosecurity performance standards developed for dairy premises, milk hauler, and processing plant during an FMD outbreak. This document assessed the risk that the transport of raw milk into, within, and outside of a Control Area to processing during an FMD outbreak will result in disease spread to susceptible premises when mitigations are in place following the BPS guidance. Based on this analysis, the BPS were revised and additional BPS were developed to address all identified risk pathways. The July 2015 BPS guidelines contain the revised risk-based outbreak measures based on the RA-BPS Analysis and risk assessment working group (RAWG) input.

This risk assessment is a joint effort between the Secure Milk Supply (SMS) industry working groups, University of Minnesota’s Center for Animal Health and Food Safety (CAHFS), and United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) Center for Epidemiology and Animal Health (CEAH) to support permits for the movement of raw milk to processing during an FMD outbreak in the U.S. This assessment is applicable to dairy production sites producing Grade “A” milk following the U.S. Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO)(FDA, 2009), applicable state regulations, and the proposed SMS Biosecurity Performance Standards (BPS) in the event of an FMD outbreak. The BPS evaluated within this report were developed and agreed upon by the dairy industry, state and federal animal health officials, and academic partners with the goal of preventing FMDv spread during milk movement in an outbreak. The BPS guidelines establish overarching goals for preventing disease spread, but require states and regions to develop their own specific protocols or procedures based on their local regulations, available

resources, climate, capabilities and scope of the outbreak. Prior to this document, a “Risk Assessment for the Transmission of Foot-and-Mouth Disease via the Transport of Raw Milk Into, Within, and Outside of a Control Area during an FMD Outbreak” (May 2013) was conducted and is hereafter referred to as the Baseline RA. The Baseline RA identified the pathways that could result in further spread of the FMDv from an infected but undetected dairy premises through the transport of raw milk to processing using current industry practices without additional mitigations in place. It is assumed that if sufficient concentrations of virus can be transported from an infected but undetected farm and gain entry onto other premises with susceptible species, there will be a high likelihood of exposure and infection of those animals. The baseline RA indicated that the movement of raw milk to processing during an FMD outbreak has a *moderate to high* likelihood of resulting in transport of virus to susceptible farms and exposure of susceptible livestock through infectious raw milk and contaminated environmental media (mud, manure, and soils containing virus) on the hauler, tanker, and associated equipment.

The RA-BPS report evaluated the BPS assuming that an integrated, collective approach is used to ensure that all potential means for viral transport are addressed and mitigated. The risk evaluation employed: a review of the scientific literature; historical outbreak information; current industry practices; input from the RAWG and other industry stakeholders; solicitation of expert opinion from the dairy industry, FMD researchers, and other scientific disciplines; and observations by the risk analysts. All of these sources of information were used to evaluate and determine the reduction in risk for each pathway with implementation of the applicable BPS.

The RA-BPS Analysis will ultimately provide the framework necessary for decision makers to:

- Quickly assess the effectiveness of current preventive measures and outbreak-specific risk mitigation measures as they pertain specifically to the movement of raw milk.
- Implement a permit system to allow premises not known to be infected with FMDv to move raw milk into, within, and out of the Control Area during an outbreak.

Seven risk pathways were evaluated to address the likelihood that movement of raw milk to processing will result in FMDv introduction to a susceptible farm. Condensed versions of the likelihood statements are used in the table below. This table highlights the change in risk for each pathway under current industry standards (no additional mitigations in place) and with application of BPS (additional mitigations in place). It is important to understand that the risk evaluation for each pathway is based on implementing the BPS in an integrated or collective approach, meaning that all applicable BPS must be applied together to decrease the risk of disease spread. The BPS should not be considered a “menu” in which one can pick and choose selections independently as this approach may not result in a reduction in risk.

**Table 1. Risk Results of Pathway Analysis for Baseline RA and RA-BPS Analysis**

	<b>Pathway Number and Description (Contaminant sources include infectious spilled milk and contaminated environmental media)</b>	<b>Risk Range: results without additional mitigations in place (Baseline RA)</b>	<b>Risk Range: results with BPS integrated approach (all milk collection options combined) (RA-BPS Analysis)</b>
1	Likelihood that <b>contamination of the hauler and tanker cab</b> will result in FMDv introduction onto a susceptible farm	Moderate to High	Negligible to Moderate
2	Likelihood that <b>external contamination of the tanker</b> will result in FMDv introduction onto a susceptible farm	Moderate to High	Very Low to Moderate
3	Likelihood that milk containing FMDv emanating from a milk tanker via <b>aerosolization</b> will result in FMDv introduction onto a susceptible farm	Very Low to Low	Negligible to Low
4	Likelihood that FMDv present in milk residues left within tankers that have been unloaded and <b>undergone CIP</b> will result in FMDv contamination of a processing plant or introduction onto a susceptible farm	Negligible	Negligible
5	Likelihood that FMDv present in milk residues left within tankers that have been unloaded but have <b>not undergone CIP</b> will result in FMDv contamination of a processing plant or introduction onto a susceptible farm	Low	Negligible to Low
6	Likelihood that contamination of the <b>transfer hose and storage compartment</b> will result in FMDv introduction onto a susceptible farm	Moderate to High	Negligible to Low
7	Likelihood that cross contamination of another <b>vehicle, person, or equipment</b> at the processing plant or during transport and stops will result in FMDv introduction onto a susceptible farm	Moderate to High	Very Low to Low
8	Likelihood of introduction of FMDv onto a susceptible farm through <b>contaminated milk and environmental media</b> via the transport of raw milk	Moderate to High	Negligible to Moderate

This document is an evolving, product-specific risk assessment that will be reviewed and updated as necessary before and during an FMD outbreak to incorporate the latest scientific information and preventive measures. If the Incident Command System (ICS) is activated in response to an FMD outbreak, APHIS (and Incident Command Staff) and State Animal Health Authorities will review this risk assessment with respect to the situation in order to assess industry requests for movement of raw milk to processing.

### **Overall Finding and Conclusion**

**The risk of FMDv contamination of a susceptible farm by contaminated milk and environmental media through the transport of raw milk into, within, and outside of a Control Area to processing is *negligible to moderate* provided the PMO guidance, state regulations, and the proposed BPS are strictly followed.**

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