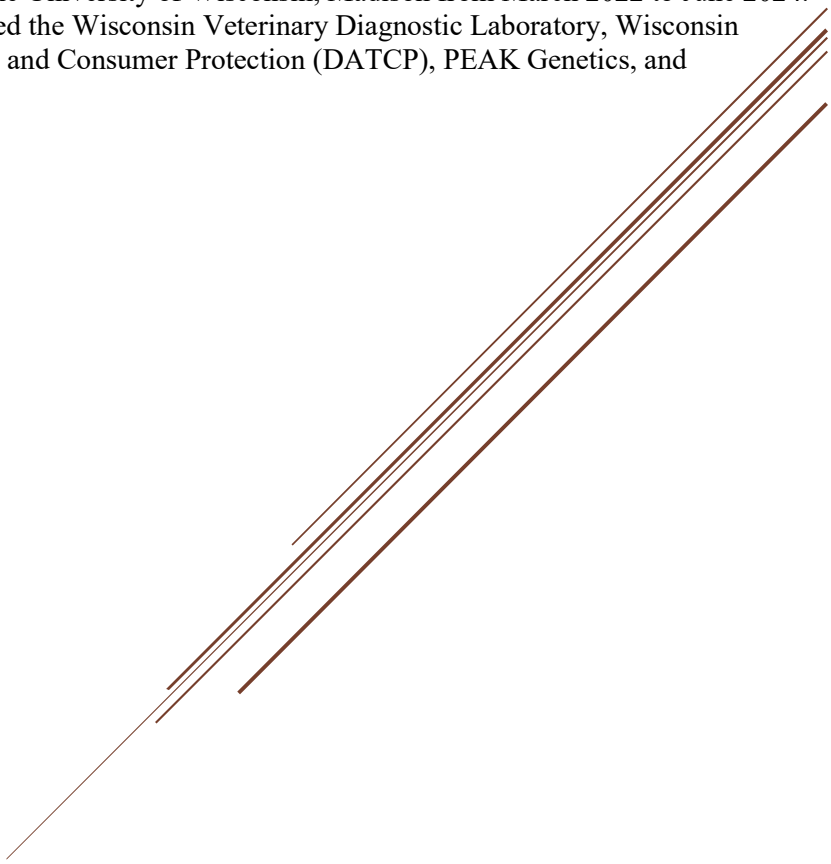
Bovine Germplasm Movement Plan

May 2024

The Bovine Germplasm Movement Plan (BGMP) provides movement guidance criteria to allow domestic movement of bovine semen, embryos, and high genomic merit cattle that have no evidence of infection and are in a foot-and-mouth disease (FMD) Control Area. It is guidance only. The BGMP is the result of a collaborative effort by industry, state, federal, and veterinary diagnostic laboratory representatives. The BGMP was made possible, in part, through funding from the USDA NADPRP grant #AP22VSSP0000C024 to the University of Wisconsin, Madison from March 2022 to June 2024. The project planning team included the Wisconsin Veterinary Diagnostic Laboratory, Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP), PEAK Genetics, and Preventalytics.



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Introduction

Foot and mouth disease (FMD) is a highly contagious foreign animal disease that affects cattle and other cloven-hooved animals, such as swine, sheep, goats, and deer. FMD is not a public health or food safety concern. The United States eradicated FMD in 1929 yet it is present in over two-thirds of the countries in the world and causes severe animal production losses. Industry, state, and federal officials have worked collaboratively with disease experts to develop response plans should FMD virus infect susceptible animals in the United States. Response strategies for controlling and containing the spread of this animal disease include stopping movement of susceptible animals and their products, rapid identification of infected animals, strategic depopulation with proper disposal, and vaccination. Regulatory Officials (local, state, tribal and federal officials, as appropriate) have the authority and responsibility to establish regulatory Control Areas around FMD infected premises. They can also regulate live animals and their germplasm[1] (semen, embryos, oocytes), animal products, and other movements that pose a risk to virus spread within, into, and out of these Control Areas. (See Appendices A and B for additional definitions and acronyms).

In an FMD outbreak, production of germplasm for global export will cease, negatively impacting the economic viability of semen and embryo centers. Maintaining the safe domestic movement of germplasm in an FMD outbreak will be essential for dairy and beef cattle production. Long delays to breeding cattle through stop movement of bulls, semen, or embryos combined with a nine-month gestation period could lead to gaps in production cycles. This could, in turn, negatively impact food availability. If animal depopulation is chosen as an FMD control strategy, that will further negatively impact the size of the U.S. cattle herd.

Purpose of the Bovine Germplasm Movement Plan

The **purpose of the Bovine Germplasm Movement Plan (BGMP)** is to provide guidance criteria to allow domestic movement of bovine germplasm and high genomic merit animals[2] located in a regulatory Control Area during an FMD outbreak in the United States. The Secure Beef (SBS) and Secure Milk Supply (SMS) Plans for Continuity of Business provide basic movement and surveillance guidance criteria for cattle, semen, and embryos. The BGMP guidance describes specific surveillance and movement options for domestic bovine germplasm from animals with no evidence of infection as well as high genomic merit cattle to maintain dairy and beef production and business continuity in the event of an FMD outbreak. Officials must balance the risks of allowing movement of animals and germplasm against the impact of not allowing movement.

The BGMP is the result of a collaborative effort by industry, state, federal, and veterinary diagnostic laboratory representatives who served on working groups from May 2022 to June 2024. Funding for its development was provided by USDA National Animal Disease Preparedness and Response Program (NADPRP). The BGMP provides **guidance only**. In an actual outbreak, decisions will be made by the Responsible Regulatory Officials based on the unique characteristics of the outbreak.

[1] For the purposes of this guidance, germplasm facilities are defined as those housing male or female donor animals that need to move one or more live animal(s), semen, or embryo(s) into or out of their facility. This includes semen production centers, embryo production centers, satellite collection centers, veterinary clinics, breeding facilities, and other livestock operations that are involved in the creation of bovine germplasm.

[2] These animals have unique genetic traits or genomic results that rank them in the top 1-2% of their breed. This could be determined by their breed specific indices like Net Merit (NM$) or Total Performance Index (TPI) for Holsteins; Jersey Production Index (JPI) for Jerseys and Expected Progeny Differences (EPD) for beef breeds.

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FMD Response Guidance Documents

There are several guidance documents for Responsible Regulatory Officials to use in an FMD Outbreak. The goals of the BGMP align with these guidance documents. Some are listed here, others throughout the document where appropriate.

- **Strategic guidance** for responding to FMD in the United States can be found in the following *Foreign Animal Disease Preparedness and Response Plan (FAD PReP)* documents:
  - *Foot-and-Mouth Disease Response Plan: The Red Book*
  - *Ready Reference Guides*, which accompany many of the detailed documents and materials below, offer quick summaries of the information for training and educational purposes.
- **Surveillance, epidemiology, and tracing** techniques will be utilized by Responsible Regulatory Officials during the outbreak to detect new cases, understand and adapt to the outbreak situation, and provide information for decision making and disease control procedures. The USDA has developed the *FAD PReP/National Animal Health Emergency Management System (NAHEMS) Guidelines: Surveillance, Epidemiology, and Tracing*. These activities likely will lead to additional regulatory activities such as quarantine and movement controls.
  - **Proposed animal surveillance** methods to demonstrate a lack of evidence of FMD infection may allow animal and/or product movement to support business continuity without increasing the risk of spreading infection are described in *Surveillance Guidance to Support the Secure Beef Supply (SBS) Continuity of Business Plan during an FMD Outbreak*, June 2017.
  - *Active Observational Surveillance (AOS) for Foot and Mouth Disease (FMD): An Overview*, June 2018.
- **Permits issued in an FAD outbreak serve to document movements** of animals and animal products into, within, and out of a regulatory Control Area. There are two types of permits in an FMD outbreak: specific and Continuity of Business (COB), both of which are based on risk and meeting certain criteria. The Secure Beef Supply Plan has developed permit guidance for the movement of cattle, semen, and embryos (see Table 1). For more information about permits, refer to the USDA documents:
  - *Ready Reference Guide – Defining Permitted Movement, February 2017 at:.*
  - *Ready Reference Guide – Permitting Process, February 2017.*
  - *Foreign Animal Disease Preparedness and Response Plan (FAD PReP) Permitted Movement (Manual 6-0)*.

Scope of the Germplasm Industry

The bovine germplasm industry consists of semen production, oocyte harvest, and embryo production. Most of the new genetic stock in both dairy and beef industries is produced by artificial insemination (AI) and embryo transfer (ET). It is estimated that 70-75% of dairy cattle and 10% of beef cattle in the U.S. are bred by artificial insemination (source: National Association of Animal Breeders (NAAB), Certified Semen Services (CSS)). Frozen semen and embryos are shipped to cattle operations in all 50 states (source: NAAB and the American Embryo Transfer Association). International movement of semen and embryos must meet strict biosecurity and testing criteria from the importing countries. The World Organization for Animal Health (WOAH), Terrestrial Animal Health Code (TAHC) provides guidance for hygiene, collection and processing of semen and embryos for international movement (see Appendix C for links and excerpts of specific TAHC sections). Germplasm companies involved in export have protocols in place to meet these standards. Production facilities that export semen or embryos:

- Have a thorough understanding of biosecurity and currently implement protocols to ensure disease-free animals for global export of semen and embryos.

- Have established relationships with industry, state, and federal animal health officials to conduct on-site inspections and National Animal Health Laboratory Network (NAHLN) veterinary diagnostic laboratories for sample testing for domestic diseases.
- Have detailed records for animal and product movement, visitor logs, and other critical inputs and outputs to facilitate trace forward/back should it be needed.
- Keep extensive health histories of animals in production.
- May maintain historical inventory of germplasm and other diagnostic specimens that allow for retrospective diagnostic analysis to establish freedom from disease.

It is widely recognized that an FMD diagnosis in the U.S. will cease semen and embryo export. Maintaining the domestic movement of germplasm and high genomic merit animals from their birth location into the genetic system is the focus of this guidance. This provides business continuity opportunities for the entire cattle industry. While there are extensive export requirements involving inspections of facilities, testing of bulls, and documentation, there are only a few U.S. states with interstate movement requirements for semen and embryos (Georgia, Montana, South Dakota). Therefore, the guidance described for outbreak movement would largely be new to the germplasm industry as well as dairy and beef producers.

To better understand the movements of germplasm that result in the creation of animal protein (meat and milk), one example of this segment of the cattle industry is provided for context:

- Female donor has her oocytes collected either on farm or at an embryo transfer facility by veterinarians using specialized equipment. The oocytes are aspirated, inspected, packaged, then shipped overnight to a laboratory, which may be in another state.
- Semen is collected at a semen production center. The semen has an initial quality check, is extended, frozen, and shipped to another location (laboratory, storage facility, typically no livestock on site), which may be in another state.
- Frozen semen meeting quality standards is shipped intra and interstate to the:
    - Oocyte laboratory to create *in vitro* fertilized (IVF) embryo(s),
    - Embryo transfer (ET) practitioners or centers to inseminate female donors for *in vivo* embryos,
    - Semen company field staff who purchase it then store it until sold to a dairy or beef customer, and
    - Dairy and beef producers for use on their farms.
- IVF fresh or frozen embryo(s) are shipped to a dairy or beef operation or ET facility, which may be in another state, for implant into recipients.
    - American Embryo Transfer Association (AETA) reported in 2022 that upwards of 512,000 embryos (in vivo and in vitro combined) were transferred to U.S. dairy and beef cattle in 43 states (Source: AETA 2023 Annual Report of the Statistical Information Committee).
    - The recipients that were moved to the ET facility are then moved back to their origin or bred heifer facility until 30-45 days pre-calving.
- Calf is born and is either raised on the dairy or beef operation or moved to a calf grower (days old until weaning).
- Bull calves from embryos have their DNA tested via an ear punch sample collected into a sealed container and sent to a genomic testing lab. Those that meet or exceed genomic testing expectations may move into the semen production system calf grower unit as early as approximately 30-40 days of age.
- Heifer calves from embryos have their DNA tested as described above. Those that meet or exceed genomic testing expectations may move through the growing system and then to a donor site once oocytes can be harvested and the cycle repeats.

Another example is an estimated 30,000 implanted embryos will result in approximately 10,000 calves from which nearly 220 bulls enter semen production for artificial insemination. Additional details are provided below for each segment of the industry to further explain production practices, including diagnostic sample collection, and movements.

Semen Production, Movement

There are approximately 50 semen collection/production centers in 17 states in the U.S. that house anywhere from 50 to 2000 bulls. Ohio and Wisconsin produce more than 75% of all bovine semen in the U.S. These two states also export more than 90% of the semen produced in the U.S. Bulls may be collected once or twice a week, and 2-3 times each collection day. The semen produced in one day is pooled and processed under one collection 'code', 'lot', or 'batch'. Semen is processed, frozen and packaged as individual straws (on average, one collection lot can yield 500 straws, or semen units) which are then shipped in containers[3] (either with liquid nitrogen or LN2 vapor) across the U.S. via commercial shipping companies to embryo production centers, sales staff, dairies, ranches, and local and regional distribution centers. The U.S. market for semen in 2023 was nearly 15.5 million units for dairy and 9.4 million units for beef. (Source: National Association of Animal Breeders Certified Semen Services, 2023 accessed March 19, 2024.)

Once semen is collected, it undergoes an initial quality check. Then extenders are added. Extenders are cryoprotectants used to freeze sperm cells so they can be thawed at time of use and remain viable and fertile. Extenders may be egg yolk, cow's milk, or plant based. For the purposes of this guidance, only products originating from FMD-susceptible animals and how they are processed and treated to inactivate FMD virus are described. Milk based extender is made from high temperature short time pasteurized cow's milk that is additionally heat treated to 203ºF (95ºC) to inactivate some enzymes that have a negative effect on sperm cell function. Powdered milk (human food grade, undergoes high temperature short time pasteurization plus desiccation) can be used to make extenders as well. Based on the guidelines for the inactivation of FMD virus in cow's milk in World Organization for Animal Health (WOAH) Terrestrial Animal Health Code (TAHC) Chapter 8.8 Infection with FMD Virus, Articles 8.8.35 and 8.8.36, milk-based extenders would be considered a negligible risk.

Semen that undergoes sex-sorting uses bovine serum albumin (BSA) in that process and then uses an egg-based extender for final processing and freezing. The origin of BSA, how it is processed and treated to inactivate FMD should be considered in an FMD mitigation plan.

Bulls for semen collection may enter a production center as a young calf (from a dairy or embryo recipient herd) or as an older bull purchased or leased from private seedstock producers. Most bulls are examined, tested for endemic diseases, and moved to isolation facilities for further testing before moving into the resident herd at a production center. Semen collected from these bulls is sold both internationally and domestically. Semen production centers test their resident herds twice a year for endemic diseases to remain Certified Semen Service (CSS) compliant and export eligible. Any bull with semen destined for international export are routinely tested post-collection. Some facilities routinely store serum samples (frozen) in case other testing is needed for a new or a different market to qualify semen for export. Those serum samples would be available in an outbreak for confirming the serology status of the bull and herd relative to FMD or some other FAD prior to the announced index case/herd of the outbreak. Some veterinary diagnostic laboratories archive/retain serum samples for 3-6 months after submission and these serum samples could be used to determine bull status prior to the outbreak.

[3] The containers used to ship semen vary based on the liquid nitrogen state and have slight differences in their ability to have the exterior cleaned and disinfected. Semen packed with liquid nitrogen as the cooling agent is placed in a steel container that is sealable. These are placed in a cardboard box for commercial movement to farms, field staff, embryo transfer clinics. Semen packed with vapor from liquid nitrogen, termed a vapor shipper, are smaller tanks placed inside a plastic shipment container. Both exterior surfaces are disinfectable.

Many bulls are moved to custom production centers for semen collection for the owner to use, trade, and sell domestically. These animals often do not undergo domestic disease testing and herd health records may not be available prior to or after movement. This semen may be stored, frozen, in dedicated tanks at the production center or given to the owner to store.

Some ranchers contract to have their bulls collected either at a production center or at their farm/ranch. Some production centers or individual technicians will collect, process, and freeze semen from bulls on a farm/ranch using a mobile laboratory. The semen may be stored at the farm/ranch in a smaller LN2 tank or at the main storage facility of the service provider.

Oocyte Collection, Embryo Production, Movement

The AETA certifies Embryo Transfer Businesses (ETB) and collects data yearly from them and embryo practitioners. Data has been collected by AETA since 2009. In 2022, there were 113 ETB that transferred bovine embryos and 36 that performed ovum pickup (OPU) procedures to harvest oocytes for embryo creation (Source: AETA 2023 Annual Report of the Statistical Information Committee). These ETB produce both fresh and frozen, *in vivo* and *in vitro* fertilized (IVF) embryos. The process to create them varies.

To create *in vivo* embryos, the process begins with a female donor receiving hormone injections on specific days over several weeks and then artificially inseminated with frozen semen. During this time, the female is or would be evaluated for signs of infectious disease (observational surveillance). Seven days later, embryos are recovered by flushing the uterus with a collection medium. The embryos are identified via microscope and transferred to another container with fresh medium. The International Embryo Transfer Society (IETS) Manual describes the process of evaluating and washing embryos to meet export requirements and these align with the WOAH TAHC guidance. The *in vivo* embryo can either be transferred fresh on site to a recipient or frozen in a straw which is stored in liquid nitrogen tanks for commercial shipping.

To create IVF embryos, a female donor may be given hormone injections on specific days over several weeks; it could also be done without hormone injection. During this time, the female (as young as three months of age) is or would be evaluated for signs of infectious disease (observational surveillance). Once ready, a licensed veterinarian examines the donor to confirm the absence of clinical signs. Serum samples may be collected for testing if the embryo is to be exported. This may happen on a farm or at a specific location where multiple females may be brought in for the day or housed for a longer period. In some instances, ovaries are harvested from cows at slaughter and oocytes retrieved. The ovum pick-up (OPU) procedure is performed by a licensed veterinarian, and the oocytes are searched, lavaged, and packaged in 2ml tubes that are stored in a temperature-controlled, clean and disinfected incubator. There may be oocytes from several donors pooled in one tube. The incubator is shipped overnight to an IVF laboratory or another location for maturation and fertilization. The oocytes mature for 20-24 hours in media. Then the oocytes are fertilized with semen (fresh or frozen) and allowed to sit in culture for six days. Multiple embryos can be fertilized with the same dose of semen.

IVF embryos that pass inspection on day six can be packaged in straws, overnight shipped fresh in cleaned/disinfected incubators via commercial shipping companies to a location where they are implanted into a recipient female the next day. Day seven embryos may be transferred fresh on site or frozen in a straw which is stored in liquid nitrogen tanks for commercial shipping.

Some of the media used for fertilization, embryo development, embryo washing, and freezing are products of animal origin that come from FMD-free countries, including bovine serum albumin, fetal bovine serum, porcine follicle stimulating hormone (FSH) and luteinizing hormone (LH). The origin of these items, how they are processed and treated to inactivate FMD (e.g., irradiated) should be considered in an FMD mitigation plan.

Destinations for IVF embryos include veterinary clinics, satellite centers where females are housed or brought to for implantation, commercial dairy and beef operations, and specialized operations that care for the recipient and raise the calf until 3-6 months of age when it is evaluated for genomic merit as a future female donor.

The U.S. dairy industry has dramatically increased the use of IVF produced embryos since 2016, reaching over 251,000 in 2022 according to the American Embryo Transfer Association (AETA). The beef industry was primarily implanting in vivo embryos until 2020 when IVF surpassed them and reached over 157,000 implanted in 2022 (Source: AETA 2023 Annual Report of the Statistical Information Committee).

Figure 1. AETA Summary of Bovine Embryo Transfers by Type, U.S. 2022

	In Vivo		In Vitro	
	Fresh	Frozen	Fresh	Frozen
Dairy	10,143	9,065	156,985	94,096
Beef	30,591	54,171	56,816	100,639

Embryo recipients may be located on a privately owned dairy or beef operation or may be moved to a location (private facility that is dedicated to embryo transfer, veterinary clinic) for implantation. The recipients may be on a single location for a few hours to several weeks.

High Genomic Merit Animal Movement

Young heifers and bulls (from 35 to 120 days of age) with high genomic merit are frequently moved intra- and interstate from their origin herds to semen production centers or donor facilities where they are raised. Bull calves that do not meet genomic specifications may be castrated and sold at a local auction market then enter the fed cattle market. Heifer calves that do not meet genomic specifications may be sold privately or at public auction.

Young female calves with high genomic merit may be moved once or twice from their origin recipient herds or private cattle operations to the oocyte collection facility. Adult female donors could be moved to a satellite center, usually within 2–3-hour drive of their origin, on the day of oocyte collection and return home the same day. She could also remain at that center and be collected a few times, every 14 days. Female donors on a long-term IVF program will usually move to a donor facility and stay for few months before returning to their herd of origin.

Bull movement was described above in the “Semen production, movement” section.

Safely moving high genomic merit animals out of an FMD Control Area under a movement permit will remove this population from potential higher risks of exposure. Their genetics are not easily replaceable. Often, the high genomic calves are not owned by the origin, complicating long term care responsibilities and indemnity should the livestock on that premises become infected. While beyond the scope of this guidance, if a vaccination strategy were used in the Control Area, this population of cattle may involve a different decision matrix.

FMD Survivability in Semen, Embryos, Oocytes

Semen

Semen from bulls infected with FMD can transmit the virus through natural breeding and via artificial insemination. Experimentally, bulls were exposed to six different FMD virus serotypes (only SAT-2 not tested) via tongue inoculation. FMD virus was detected in semen from 12 hours (pre-clinical stage) to 10 days (convalescent stage) post-inoculation. The first detection of FMD virus in blood was two hours post inoculation. Frozen, extended semen from infected bulls stored for 320 days did not lose virus titer. This

study also described five of 16 heifers artificially inseminated with semen collected from infected bulls developed clinical signs of FMD. (Source: Cottral GE, Gailiunas P, Cox BF. Foot-and-mouth disease virus in semen of bulls and its transmission by artificial insemination. *Archive fur die gesamte Virusforschung*, 23:362-377; 1968)

A quantitative risk assessment was published in 2023 by Meyer, Weiker, and Meyer that described mitigation steps for the release of FMD virus in frozen semen collected from infected, undetected bulls using data from five of the largest U.S. production centers. Probability and incidence data were modeled since the U.S. has been free of FMD since 1929. Several pathways were considered in their model including:

1. Semen collected during an outbreak at the facility
2. Failure to detect FMD in donor bulls through clinical surveillance
3. Failure to detect FMD in donor bulls while frozen semen stored either 14 or 30 days
4. Infected donor bull has semen collected and semen has viable FMD virus
5. Failure to detect FMD virus in semen via quality control and RT-PCR testing
6. Failure to detect FMD antibody or antigen on routine blood test

The mitigation step that was most effective at reducing the risk of FMD release was serum antibody testing performed every two weeks (model test sensitivity of 92-100%, specificity of 97%). That step combined with holding semen for 14 or 30 days had a median annual probability of release of at least one FMD contaminated batch of semen from the five facilities of less than one in 100 billion. (Source: Meyer A, Weiker J, Meyer R. Laboratory testing and on-site storage are successful at mitigating the risk of release of foot-and-mouth disease virus via production of bull semen in the USA. *PLoS ONE* 18(11): e0294036;2023.) While there is no validated test for semen, nor is it an approved sample type, the U.S. has a commercially available and validated antibody enzyme linked immunosorbent assay (ELISA) for FMD (more below under Disease Monitoring). Additionally, active observational surveillance (described below) would mitigate two of the pathways above. Enhanced biosecurity (described below) for FMD could mitigate the introduction of the virus.

The U.S. does not vaccinate for FMD virus, but emergency vaccination is a consideration as one strategy to control and contain an outbreak if it were to occur. Therefore, it is important to consider the impact of FMD vaccination on the ability to transmit virus through bull semen. This was evaluated in a field situation in France as published in a study by Parez and Jondet in 1971. The whole of France chose to vaccinate cattle, except for one area, Finistère. A report by Callis in 1996 that looked at that study and additional research concluded that "semen from bulls which have been multiply vaccinated with an efficacious product, and which are not carriers of the virus, has been shown to be safe for use in animals which have not been immunized." (Source: Callis JJ. Evaluation of the presence and risk of foot and mouth disease virus by commodity in international trade. *Rev sci tech OIE* 15; 3:1075-1085; 1996) Carrier status was determined through esophageal-pharyngeal samples (also known as pro-bang). This information should be considered in the decision to vaccinate bulls during an FMD outbreak. Other considerations regarding FMD vaccination of bulls include the acceptance of semen from vaccinated donor bulls by importing countries and the overall USDA strategy to achieve FMD free without vaccination (tracing all vaccinates through slaughter or death).

Based on survivability of FMD in bull semen, the WOAH TAHC Chapter 8.8 Infection with FMD provides recommendations for the safe movement of semen from vaccinated and unvaccinated bulls from endemic countries (see Appendix C for more information). The guidance on semen and embryo importation is based on FMD status of the country/zone. The TAHC does not account for animals with no evidence of infection located in a regulatory Control Area that meet specific movement criteria to achieve business continuity during an FMD outbreak, which is the focus of this document. Applicable WOAH TAHC guidance is included in this document.

Oocytes, Embryos

Bovine oocytes and early embryos are surrounded by the zona pellucida (ZP), a thick acellular membrane that serves as a barrier to pathogens. The ZP becomes progressively thinner around the embryo until it hatches, approximately nine days after fertilization. (Source: Escobar CJ. Embryo transfer, a potential risk in disease transmission. *MOJ Anat & Physiol*. 2018;5(4):259–262.)

In vivo embryos

The IETS and WOAH consider the risk of FMD virus transmission in *in vivo* derived cattle (*Bos indicus* and *Bos taurus)* embryos to be **negligible** if properly handled between collection and transfer according to the IETS Manual Chapter 6. Recommendations for the sanitary handling of in vivo-derived embryos. (Source: Appendix B. Conclusions of the Research Subcommittee of the IETS Health and Safety Advisory Committee, 4th Edition Manual 2018). This is based on research studies published in the 1980s and 1990s in *Theriogenology* and *Revista de Medicina Veterinaria* demonstrating the steps necessary to mitigate transmission. (Source: IETS Health and Safety Advisory Committee Research Update, 2020, pp. 41-43.)

FMD virus is loosely attached to the zona pellucida of in vivo derived embryos and is removed by the IETS recommended ten washing steps. (Source: Escobar CJ. Embryo transfer, a potential risk in disease transmission. MOJ Anat & Physiol. 2018;5(4):259–262.) This is documented in the IETS Form ABC – Certificate of Embryo Recovery, Transfer, and Freezing, which must accompany any frozen embryo shipped domestically or internationally. This form must also be signed by a veterinarian certifying the embryo processing procedures have been completed.

A quantitative risk assessment was published in 1997 by Sutmoller and Wrathall that looked at the risk of FMD transmission due to *in vivo* derived embryo transfer in cattle using data from a country where the annual FMD incidence was 1/1000 herds. Several pathways were considered in their model including:

1. At least one infected donor animal
2. Failure to detect disease in donor herd through animal surveillance or embryo collection team
3. Contamination of embryos in genital tract of infected donor
4. Failure to remove contamination during processing (which align with the IETS handling protocols)
5. Failure to observe disease in donor herds while embryos are stored, frozen
6. Failure of diagnostic tests to detect FMD in collection fluids, other samples

Their conclusion was that using the risk reduction measures, the probability that one or more *in vivo* derived embryos out of 300 are contaminated with FMD virus is less than one in 100 billion. The authors state that the extremely low risk is mainly due to how easily FMD is recognized in cattle. (Source: Sutmoller P, Wrathall AE. A quantitative assessment of risk of transmission of foot-and-mouth disease, bluetongue, and vesicular stomatitis by embryo transfer in cattle; *Preventive Veterinary Medicine*, 32 (1997): 111-132.) The U.S. does not test collection fluids for FMD; there is no validated test nor is it an approved sample type. However, active observational surveillance (described below) would mitigate three of the pathways above. The IETS embryo handling methods are the internationally accepted standard and followed in the U.S. and mitigate two pathways.

The WOAH TAHC Chapter 4.8 provides guidance for collection and processing of *in vivo* derived embryos from livestock and equids (updated 2015) for international movement describes the embryo collection team should be supervised by a veterinarian, record keeping expectations, USDA inspection frequency (annually), processing lab conditions, and conditions the donor animals must meet (which were the basis for the BGMP recommendations). WOAH does not recommend donor testing (females or males). WOAH also refers to the Manual of the IETS for internationally accepted risk mitigation procedures for the embryos (washed at least ten times with at least 100-fold dilutions between each wash

using a fresh pipette for transfer, examine the zona pellucida after washing to ensure intact, no adherent material, a statement signed by a veterinarian certifying the above were completed).

The WOAH TAHC Chapter 4.10 provides guidance for collection and processing of micromanipulated oocytes or embryos from livestock and horses (updated 2009) for international export. This guidance assumes the same sanitary conditions described in Chapter 4.8 are met for *in vivo* derived embryos prior to micromanipulation.

The WOAH TAHC Chapter 8.8 Infection with FMD provides guidance on embryo importation based on FMD status of the country/zone.

WOAH TAHC Article 8.8.17: Recommendations for the importation of *in vivo* derived embryos of cattle

> *"Irrespective of the FMD status of the exporting country, zone or compartment, Veterinary Authorities should authorize without restriction on account of FMD the import or transit through their territory of in vivo derived embryos of cattle subject to the presentation of an international veterinary certificate attesting that the embryos were collected, processed and stored in accordance with Chapters 4.8.and 4.10., as relevant."*

In vitro embryos

A study by Marquant-le Guienne published in 1998 looked at the risk of *in vitro* produced (IVP) bovine embryos and their ability to retain FMD virus. Both developed and degenerated embryos were incubated with FMD virus type 01 for various lengths of time. Then embryos were washed according to IETS protocols. The embryo-suspension was evaluated in cell culture for cytopathic effects and the wash fluid was tested by PCR. The results demonstrated most of the IVP embryos retained FMD virus irrespective of being developed (morulae and blastocysts) or degenerated.

To date, there is no approved treatment that removes FMD virus from *in vitro* produced embryos and other risk mitigations should be considered in an outbreak. (Source: Escobar CJ. Embryo transfer, a potential risk in disease transmission, MOJ Anat & Physiol. 2018;5(4):259–262.) There is no conclusive evidence documenting the risk of FMD transmission from IVF embryos.

For the purposes of this guidance document, mitigation strategies for embryos are based on the last date of exposure to the donor animal, not the embryo age in days.

Disease Monitoring (Surveillance)

Disease monitoring (surveillance) in an FMD outbreak aims to find infected animals as early as possible after exposure through observation and testing. There are well-established protocols, sample types, diagnostic tests, and policies for decision making based on test results for animals with clinical signs of FMD. Diagnostic tests for FMD can only be conducted at approved National Animal Health Laboratory Network (NAHLN) labs. Samples can only be submitted from Control Areas and Surveillance Zones for testing. Labs are not authorized to test samples from "Free Areas".

This document describes available sample types and proposes diagnostic tests that could be used for cattle that have no evidence of infection that need to move within or outside of a Control Area. There are no established protocols or policies for decision making based on test results for animals with no clinical signs of FMD. Surveillance testing should provide the highest degree of confidence possible that cattle and germplasm movement can occur to support business continuity without spreading infection. These proposed surveillance methods cannot prove freedom from infection, they can only establish lack of evidence of infection.

This document expands on the guidance provided in the *Surveillance Guidance to Support the Secure Beef Supply (SBS) Continuity of Business Plan during an FMD Outbreak* by describing specific surveillance protocols for domestic bovine germplasm and high genomic merit cattle movement. This

guidance does not describe sample sizes or frequencies which are dependent upon outbreak or virus strain related factors and the surveillance plan factors.

Surveillance for Designation as a Monitored Premises

Premises seeking a movement permit for outside of the Control Area must be designated as a Monitored Premises. Surveillance could include:

- Completing or updating an epidemiology questionnaire,
- Conducting Active Observational Surveillance (AOS) daily by trained Cattle Health Monitors employed by the premises,
- Periodic inspection of animals and daily AOS records by Regulatory Officials or their designees,
- Follow-up laboratory testing for animals with any suspicious clinical signs, and
- Diagnostic testing, as available, for specific populations and sample types.

Epidemiology Questionnaire

Germplasm facilities with livestock quarantined in a Control Area will need to provide some information about possible exposure risks. The SBS and SMS Plan websites each have a "Practice questionnaire for FMD exposure" that includes some of the information premises owners/managers may need to provide in an outbreak. Details related to the movement of animals, feed, supplies, equipment, personnel, and wildlife interactions are included. The USDA FMD Response Plan, October 2020 includes an FMD Investigation Form for Beef Cattle that serves as a template for the types of information needed for tracing.

Active Observational Surveillance (AOS)

To determine the presence or absence of clinical signs, close observation of animals is needed. Active Observational Surveillance (AOS) can be used as an initial screening test. The following is an excerpt from the USDA FMD Response Plan, October 2020 that defines AOS and its use in surveillance:

> "4.3.1 Surveillance Planning for FMD Outbreak
>
> 4.3.1.2 Definitions
>
> *Active observational surveillance (AOS)* is a purposeful effort to detect evidence of disease through observation of clinical signs following these criteria:
>
> - Observations are ongoing, frequent (e.g., once or twice a day in confinement facilities or once every 2 to 3 days in large grazing operations), and follow a pre-planned schedule.
> - Observer is specifically tasked with monitoring for evidence of disease, toxicity, or other causes of morbidity, mortality and decreased production.
> - The group of animals undergoing AOS is clearly defined.
> - A set of guidelines exist describing expected production parameters and corresponding investigation triggers.
> - A communication plan is created for a response to the investigation triggers, including when to contact regulatory animal health officials or their designees.
> - Observer is aware of and understands the production parameters, investigation triggers, and communication plan.
> - Observation of clinical signs or other change consistent with the disease of interest during AOS serves as the screening "test." Confirmatory testing is laboratory-based.
>
> Utility of AOS is highest for diseases that show overt clinical signs such as HPAI or FMD. Vesicular diseases such as FMD in a naïve population are particularly amenable for AOS in many U.S. animal populations. Most confinement livestock operations have standard management practices with the above criteria and, in fact, already conduct AOS."

AOS Resources

The SBS Plan website includes resources to accomplish the above tasks. There are materials that visually depict FMD lesions in cattle, record-keeping forms to track health observations, and reporting guides for operations who do not already have a system.

- **Daily visual observation** of cattle by trained farm-based observers (referred to as Cattle Health Monitors) who are familiar with the health status of the livestock and able to recognize abnormal findings (clinical signs and/or changes in production parameters) that may be an early indicator of FMD virus infection.
    - Examination Checklist: English
    - See Something, Say Something Sign: English
    - FMD Pocket Guide: English | Spanish
    - FMD Poster: English | Spanish
- **Recording** normal or abnormal findings (referred to as AOS records) by Cattle Health Monitors **for at least 14 days prior** to the proposed animal movement demonstrating no evidence of FMD virus infection of animals on the premises. Data may include clinical signs or the lack of (e.g., fever, nasal discharge, lameness), health events (e.g., death loss), or performance data (e.g., no changes, decreased feed consumption).
    - Daily Observation Form: English
    - Abnormal Findings Explanation Form: English
- **Prompt reporting** of abnormal findings to Regulatory Officials with a follow up examination of animals by them or their designee (USDA Accredited Veterinarian). The Regulatory Officials may decide to conduct laboratory testing on any suspicious cases.
    - Expected Parameters and Investigation Triggers: English
    - Communication Plan: English

Diagnostic testing could increase the confidence of the SAHO reviewing business continuity permit requests that the movement will not spread FMD virus.

Diagnostic Testing

There are two options for FMD testing, each with advantages and additional considerations to be determined, described below. Using these tests for continuity of business (COB) purposes means the target population are animals that have no clinical signs of FMD located within a Control Area. A negative test result aims to add additional evidence of no detectable infection. This is NOT the same as proving a negative. Test interpretation should consider this aspect. COB sample testing priority will be based on laboratory capacity, available reagents, and will impact the test result timeline for movement decisions. Sample testing from outside a Control Area will be dependent on guidance from SAHO, NAHLN, and USDA.

Quoted sections are from the *Surveillance Guidance to Support the SBS Plan*, June 2017 document.

> **Serological surveillance** "measures antibodies against FMD virus. Serum antibodies are not detectable until several days after infection and typically after cattle develop clinical signs. Therefore, serological surveillance is not useful for providing a high degree of confidence that cattle are not in an early stage of infection at the time of movement. Serologic surveillance can provide a high degree of confidence that the animal or herd were/was not infected 14 days previously. This can be useful for issuing movement permits for animal products that can be stored for 14 days (e.g., frozen semen and embryos)."
>
> **Virological Surveillance** "analyzes specimens for the presence of FMD virus. NAHLN laboratories are approved to conduct real-time reverse transcription polymerase chain reaction (rRT-PCR) assays for FMDV."

Serum Antibody ELISA Test for FMD (Validated at FADDL)

The USDA Foreign Animal Disease and Diagnostic Laboratory (FADDL) has a commercially available and validated antibody enzyme linked immunosorbent assay (ELISA) test[4] for FMD. The 2023 U.S. Animal Health Association (USAHA) Resolution 1[5] urges USDA FADDL to deploy this test to NAHLN labs. There are six NAHLN laboratories that conduct the majority of antibody ELISA testing for domestic diseases as part of semen and embryo export protocols (California, Cornell, Iowa, Ohio, South Dakota, and Wisconsin). Once exports cease due to FMD, these labs should have the capacity to conduct outbreak serology testing. Each lab would need to undergo non-outbreak proficiency testing for FMD. This is NOT the same as passive serology testing for FMD as that is not permitted in non-outbreak situations. SAHOs would need to support sample movement to one of the labs that has been proficiency tested.

Target Population:

- Bulls with no clinical signs whose semen was collected between the start of the outbreak (day 0) and 28 days prior. The semen is stored frozen and distributed domestically beyond the point of origin.
- Donor females with no clinical signs whose oocytes or *in vivo* embryos were collected between the start of the outbreak (day 0) and 28 days prior. The embryo is stored frozen and distributed domestically beyond the point of origin.
- Bulls with no clinical signs at the time of semen collection as documented through AOS records after the first diagnosis of FMD in the U.S.
- Donor females with no clinical signs at the time of oocyte or embryo collection as documented through AOS records after the first diagnosis of FMD in the U.S.

Samples:

- Collecting and storing serum at the start of an FMD outbreak from bulls and donor females actively having semen/oocytes/embryos collected could be part of a business contingency plan for germplasm facilities. These banked serum samples would be available to test, as needed, for permitted movements into, within, or out of a Control Area.
- Some AI studs collect and retain serum samples for bulls with semen destined for international export. These serum samples are collected by or under the guidance of a USDA Category II Accredited Veterinarians approximately every 28 days when the bull semen is being collected and archived, in some cases, for up to three years. Those facilities would have serum available in an outbreak for confirming the serology status of the bull and semen stored frozen and distributed beyond the point of origin.
- Some veterinary diagnostic laboratories that test serum for semen export purposes archive/retain samples for a few weeks up to six months after submission. These serum samples could be an option for bulls that have had semen exported before the first diagnosis of FMD in the U.S. and used to determine the status of that bull before domestic semen movement.
- The cost of testing serum for business continuity will be the responsibility of the submitter (owner, business, etc.) not the state and federal agencies managing the response.

Test Results Interpretation and Reporting:

- A negative serology test from the semen/embryo collection date would determine that bull or donor female was not FMD exposed more than 14 days prior to the day of collection. The semen/embryos that were held frozen for 14 days from that collection date would be eligible for movement so long as other criteria set by the SAHO are met.

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[4] The test is called VMRD 3B ELISA and is used for FMDV serology. Through studies conducted at FADDL on bovine sera, the diagnostic sensitivity is 99.8% and the diagnostic specificity is 96.6%. Source: Personal communication with USDA APHIS FADDL, February 1, 2024

[5] United States Animal Health Association (USAHA) Resolution 1, 2023, Foot-and-Mouth Disease Diagnostics – Serology Assay Deployment to National Animal Health Laboratory Network Laboratories.

- A non-negative or inconclusive result makes the animal ineligible for a movement permit until more information is available on the animal's status. The non-negative/inconclusive sample will be forwarded to FADDL for further testing.
- All results would be reported and managed following a protocol established by NVSL and USDA working through the SAHO.
- NOTE: Antibody ELISA testing has limited value for movement of high genomic merit animals.

Testing Frequency:

- Propose a rolling 28-day serum ELISA testing (with AOS) to allow for continuous frozen semen movement from that collection lot (after a 14-day frozen semen hold).
- Propose a rolling 14-day serum ELISA testing (with AOS) to allow for movement of frozen embryos from that collection date (after a 14-day frozen embryo hold).

Remaining Gaps (in addition to those listed above):

- Development of a NAHLN Standard Operating Procedure, a training and proficiency testing program, and a procurement and distribution plan of a commercially available and validated antibody ELISA test for FMD to a cohort of high-volume serum testing NAHLN labs.
- Policy describing test result interpretation and reporting protocols should be developed under the guidance of the National Preparedness and Incident Coordination Center.
- Testing frequency guidance should be developed with input from the USDA Center for Epidemiology and Animal Health (CEAH) Surveillance Design and Analysis Group.

Oral Swab rRT-PCR Test for FMD (Deviation Request for a New Population of Animals)

The oral swab real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test is a validated sample type for use in animals with clinical signs of FMD and a validated test with known specificity (99%) and sensitivity (94%). A positive test indicates the animal has FMD. NAHLN labs are proficiency tested for the rRT-PCR FMD assay but are not approved to test oral swabs on non-clinical animals.

Oral swab rRT-PCR can be used sooner than a serology assay to detect FMD infection but may still produce false negative results during an early stage of pre-clinical infection. This testing coupled with Active Observational Surveillance (AOS) records could increase the confidence of the SAHO reviewing business continuity permit requests that the live animal movement within or out of a Control Area will not spread FMD virus.

This test has not been validated for use in animals with NO clinical signs of FMD (new target population). Therefore, a NAHLN laboratory would need to request a Deviation from NAHLN Program Office for Emergency Use Approval (EUA) of this test on non-clinical animals (see Appendix D: Oral Swab Deviation Process). Drafting a Deviation Process with the support of NAHLN and SAHOs pre-outbreak that could be put in place in an outbreak would facilitate getting this test implemented quickly in the NAHLN labs in the event of an FMD outbreak. The 2023 USAHA Resolution 2[6] urges USDA FADDL to determine the sensitivity of an oral swab rRT-PCR test for FMD in a new population of animals.

Target Population:

- High genomic merit animals (bulls, heifers, cows) that have no evidence of FMD infection based on Active Observational Surveillance (AOS) data for at least 14 days needing to move from their origin premises in a Control Area to enter the semen/embryo system (maintaining genetic supply chain) – within or outside of a Control Area (additional criteria for the source herd and destination premises explained under Movement Recommendation #1 and in Appendix D: Oral Swab Deviation Process).

[6] USAHA Resolution 2, 2023, Foot-and-Mouth Disease Diagnostics – Oral Swab Deviation for a New Population of Animals.

Samples:

- A protocol describing supplies, techniques, and packaging will need to be developed by/with guidance from FADDL.
- Ideally, oral swabs could be collected on-farm, across age, sex, and species groups by USDA Category II Accredited Veterinarians and, with training as is being done for FMD as part of the Certified Swine Sample Collector (CSSC) Training/Secure Pork Supply (SPS) Plan, producers, and caretakers.
- The cost of testing oral swab for business continuity will be the responsibility of the submitter (owner, business, etc.) not the state and federal agencies managing the response.

Test Results Interpretation and Reporting:

- Policy describing test result interpretation and reporting protocols should be developed under the guidance of the National Preparedness and Incident Coordination Center.
- Pairing the diagnostic test results with AOS data for at least 14 days for the source herd should be considered.
- All results would be reported and managed following a protocol established by NVSL and USDA working through the SAHO.

Testing Frequency:

- Determine the testing frequency and interval through input from the USDA Center for Epidemiology and Animal Health (CEAH) Surveillance Design and Analysis Group (single vs. serial test, how soon before movement, individual animal vs. pooled sample).
- FMD virus may be undetectable in oral swabs during early stages of pre-clinical infection and serial testing (24-48 hours prior movement) may be needed.

Remaining Gaps (in addition to those listed above):

- USDA FADDL to determine the sensitivity of an oral swab rRT-PCR test for non-clinical animals.
- NAHLN program office should define guidelines for a pre-outbreak deviation process that can be initiated by a NAHLN laboratory interested in requesting this Emergency Use Approval.

Semen PCR Test for FMD (Emergency Use Approval and/or Validation)

Semen PCR testing is done by NAHLN laboratories for a variety of endemic viruses as part of export testing for the industry. NAHLN laboratories are currently proficiency tested for the rRT-PCR FMD assay but are not approved to test semen. Semen is a new sample type which would require validation by FADDL or through Emergency Use Approval (EUA) process prior to deployment to the NAHLN labs. Typically, an EUA is for a new sample type in clinical animals.

Target Population:

- Semen collected from bulls with no evidence of infection.
    - Bulls collected between the start of the outbreak (day 0) and 28 days prior without a suitable serum sample (less than 14 days post-collection) with Active Observational Surveillance (AOS) data for at least 14 days.
    - Bulls collected between the start of the outbreak (day 0) and 28 days prior that are deceased (from causes other than FMD infection), do not have serum available for testing, and the semen in inventory has high genomic value.

Sample:

- One or more frozen, extended semen samples from a collection lot.
- The cost of testing semen for business continuity will be the responsibility of the submitter (owner, business, etc.) not the state and federal agencies managing the response.

Challenges of Semen Sample Validation and EUA Pre-outbreak

A positive cohort would be needed to validate this new sample type. Laboratory validation using FMD virus-spiked semen samples has merit in the initial discovery process. There are no labs outside of FADDL authorized to study FMD virus (select agent). FADDL is the only U.S. laboratory authorized to study live animals with FMD infection. Their facilities are not set up for safely handling bulls for challenge studies. The cost to conduct these types of studies is beyond the scope of this project. The National Bio and Agro-Defense Facility (NBAF) will not be commissioned for live animal research in their Biosafety Level 4 (BSL-4) unit until after 2024.

Validation and EUA – Outbreak Scenario

Early in an FMD outbreak it may be difficult to find enough infected bulls for a positive cohort for sample validation and the EUA process. Later in an outbreak when working towards disease freedom and re-opening trade for international export of semen, it may be more feasible.

Next Steps

Based on the following factors, pre-outbreak semen sample PCR validation and EUA will not be part of the recommended bovine germplasm diagnostic testing options at this time:

- Semen can be frozen and held for extended periods of time (it is not a "just-in-time" product).
- Current inventories of frozen semen can meet the initial outbreak needs to maintain cattle reproduction in the U.S.
- Serum ELISA is closer to being available for deployment at NAHLN labs and the serology status of the bull can determine the status of the semen collected at that time.
- The focus of this guidance is on maintaining domestic movement of high genomic merit animals and germplasm; while the international export of semen is vital to the world's cattle industry, it is beyond the scope of this project.
- Oral swab rRT-PCR, pending a deviation approval for non-clinical animals, provides a diagnostic testing opportunity across all ages and sexes of cattle, for domestic live animal movement of high genomic merit animals that provides a business continuity opportunity for the germplasm industry.

Other Sample Types

Other sample types available from the germplasm industry includes embryo wash fluid, vaginal swabs, and nasal swabs. Each would require validation or EUA and are limited to certain age groups and sex. Pursuit of the serum ELISA and oral swab rRT-PCR will allow resources to be focused on the sample types with the greatest applicability.

Requesting a Movement Permit

Requesting and receiving a COB permit for cattle and germplasm can take time given the documentation needed, review process, and obtaining diagnostic test results. Planning is critical, especially for germplasm like oocytes and fresh embryos that require special handling to maintain viability. Industry should review the movement recommendations in this guidance document and plan adequate time to meet all the steps before resuming germplasm collection. All interstate movements must meet existing movement/state entry requirements in addition to outbreak-specific conditions. The details below are an excerpt from SBS Plan, April 2024.

The person or entity requesting the movement permit should be the responsible party with physical or legal control of the animals/germplasm and have access to the required documentation and information. It could vary depending on what "item" needs to move. For high genomic merit animals born on operations and owned by a semen or embryo production company, it may involve both the owner/manager of the operation of birth and the company representative. For germplasm, it could be the semen production company, a field representative who possesses the semen straw, the IVF lab if sending embryos to a farm, or a combination.

Before requesting a Secure Food Supply movement permit for cattle or cattle products (semen or embryos), both the premises of origin and the premises of destination need to have a National Premises Identification Number (PIN), and the destination premises and State need to be willing to accept the risk of receiving the animals or their products. Each premises requesting a movement permit must be registered through the office of their SAHO and/or established as a premises in the USDA's Emergency Management Response System (EMRS) before requesting a permit. EMRS is the USDA APHIS official system of record for all animal health incidents. If a State elects to use their own information management system to handle permitting, the information must, in near real-time, be linked into EMRS, especially for interstate movements where approval of both origin and destination State must be granted and Unified Incident Command be informed.

Provide the following information (it will be recorded in EMRS):

- Permit class—where you want to move animals or animal products in relation to the Control Area (such as out of Control Area).
- Permit reason—why you want to move animals or animal products (e.g., semen to a farm for breeding).
- Origin premises—location (physical latitude/longitude) including validated National PIN.
- Destination premises—location (physical latitude/longitude) including validated National PIN.
- Item(s) permitted—category of what you want to move (groups of animals, germplasm, etc.).
- Item class—specifically what is moving (such as donor cows for oocyte retrieval).
- Duration/span of permit—first movement date, how long the permit is valid, frequency of movements, and over what time period movements are expected to occur.

For any permitted movement, the Origin State can request documentation from the premises making the request. This documentation may include:

- Trace back/forward information. Evidence that the premises is NOT Infected, NOT Suspect, and NOT a Contact Premises.
- A completed copy of the Biosecurity Checklist and the operation-specific enhanced biosecurity plan.
- Written assurance by the producer of compliance with the Biosecurity Checklist.
- A biosecurity audit of premises depending on the item being moved.
- Information demonstrating normal health status for the animals on the production premises involved (such as cattle health monitoring documents and/or Certificate of Veterinary Inspection signed by an Accredited Veterinarian that inspected the animals destined for load out).
- Diagnostic testing results from samples tested. When submitting samples for testing, it is imperative that the National PIN for the location sampled is always included with the diagnostic submission.
- For animal movements to another operation, the destination premises must indicate that they understand and accept the risks associated with receiving the animals. States may require a signed form be submitted with the permit request.

Completed movement permit requests will be reviewed first by the Origin State. The permit can be recommended for approval to Destination State, not recommended for approval by Destination State, or rejected. If approved by the Origin State, then the Destination State reviews and approves or rejects the permit. The destination premises may also reject a permit. If the permit request is not approved, an explanation for denial will be provided. If approved, the producer will receive the approved permit (likely as an electronic PDF) from the appropriate official working to inform Unified Incident Command; it is also available for download directly from the EMRS Gateway. The permitted movement must comply with all requirements on the permit; all subsequent permitted movements associated with that permit must be submitted to and recorded in EMRS through the permit Gateway or other State-approved data information system for permits.

Recommendations for Managed Movement of Cattle, Germplasm in an FMD Response

National Movement Standstill

The recommendations in the Bovine Germplasm Movement Plan guidance to exempt the following bovine germplasm products from a national movement standstill issued due to FMD in the U.S. are based on available science, published risk assessments, national, and international guidelines:

- Frozen bovine semen and frozen *in vivo*-derived and *in vitro*-produced bovine embryos collected/created more than 28 days prior to the first U.S. FMD diagnosis as long as there are records to document the collection date and the origin is not an Infected, Suspect or Contact Premises.
- Fresh and frozen *in vivo*-derived bovine embryos handled according to IETS sanitary standards with documentation signed by an accredited veterinarian.
- Semen, in vitro embryos, and oocytes collected from live donor animals during the standstill can move to a laboratory or storage facility without livestock as long as the movement is recorded and the origin is not an Infected, Suspect or Contact Premises.

Prior to leaving livestock facilities, semen and embryo storage tanks must have their exterior cleaned and disinfected with an Environmental Protection Agency-registered product labeled effective against FMD virus. These exemptions were supported by the 2023 USAHA Resolution 11: Foot-and-Mouth Disease National Movement Standstill Exemptions: Bovine Germplasm and Resolution 12: Movements of in vivo-derived Bovine Embryos in a Foot-and-Mouth Disease Outbreak. The USDA interim response in March 2024 described that the recommendations will be considered, along with potential consequences to interstate commerce and international trade, when Veterinary Services resources are available to focus on FMD planning.

Control Area

Into a Control Area

In general, non-terminal animal movements into a Control Area are strongly discouraged as they will expand the population of susceptible animals, thus increasing the potential for outbreak spread. Moving germplasm (oocytes, semen, embryos) into a Control Area poses a lesser risk than live animal movement. All movements will need to meet the criteria set by the state managing the Control Area. This may include, among other things, a biosecurity audit for the destination premises. Also, the destination may not be eligible for indemnity should livestock on it become infected after the move into a Control Area.

Within and Out of a Control Area

The recommendations from the Bovine Germplasm Movement Plan Working Groups for movement within and out of an FMD Control Area are based on available science, published risk assessments, national, international guidelines, and the following assumptions:

1. The 72-hour national movement standstill for cattle, semen, embryos has been lifted for areas outside of Control Areas.
2. The FMD incubation period for cattle is up to 14 days.
3. Cattle may shed FMD virus in bodily fluids up to four days before clinical signs appear.
4. Active observational surveillance (AOS) is a screening tool, not a diagnostic test.
5. *In vivo* derived cattle embryos are negligible risk for FMD virus transmission if properly handled between collection and transfer according to the IETS Manual Chapter 6. Recommendations for the sanitary handling of *in vivo*-derived embryos.
6. Semen collection centers and embryo transfer centers do not receive live animals for at least 14 days prior to collection of semen, oocytes, and in vivo embryos.

7. Premises seeking a movement permit meet the FMD Response Plan (October 2020) criteria for an At-Risk or Monitored Premises which is: no susceptible animals have clinical signs compatible with FMD. Premises objectively demonstrates that it is not an Infected, Contact, or Suspect Premises. At-Risk Premises (ARP) seek to move susceptible animals or products within the Control Area by permit. Monitored Premises (MP) meet a set of defined criteria in seeking to move susceptible animals or products out of the Control Area by permit. Only ARP are eligible to become MP.
8. Surveillance criteria (sample size, testing frequency) on a premises level have been developed by USDA Center for Epidemiology and Animal Health (CEAH).
9. Diagnostic testing capability and capacity for business continuity movement permit requests exists at NAHLN laboratories.
10. Policies for test result interpretation have been developed by USDA APHIS VS National Preparedness and Incident Coordination (NPIC) Center.
11. NAHLN laboratories would use existing result reporting methods to share business continuity testing results with clients while using electronic messaging to share testing results with the SAHO via Emergency Management Response System (EMRS).

Unless otherwise described, recommendations align with the guidance in the USDA FMD Response Plan (October 2020) and the Secure Beef Supply (SBS) Plan (April 2024). The movement permit guidance described in SBS Plan Table 1 (below) applies. More information about each item is provided under the section, "Business Continuity Components".

Secure Beef Supply Plan Table 1. Summary of Movement Permit Guidance for Cattle, Semen and Embryos located within a Control Area during an FMD Response

Permitting Guidance for Movement of Cattle/Semen/Embryos	Condition Met?
Traceability information is available (PIN, GPS Coordinates, and information on type and number of animals/quantity of semen/embryos moved)	Yes
Biosecurity measures listed in the Biosecurity Checklist are in place and acceptable to Responsible Regulatory Officials	Yes
Trace back/forward information is acceptable; premises is not Infected, Suspect or Contact	Yes
Destination premises and State are willing to accept the cattle/semen/embryos	Yes
No evidence of infection based on disease monitoring (surveillance)	Yes
Permit guidance to move cattle/semen/embryos if all above responses are "Yes"	Consider Issuing MOVEMENT PERMIT

The BGMP guidance describes additional considerations below to meet the "**No evidence of infection based on disease monitoring (surveillance)**" criteria for the movement within or out of a Control Area of high genomic merit animals entering the germplasm segment of the industry, as well as semen and embryos. The target population are animals with no clinical signs of FMD located within a Control Area. A negative test result aims to add additional evidence of no detectable infection. Recommended diagnostic tests are considered continuity of business (COB) testing. COB sample testing priority will be based on laboratory capacity, available reagents, and will impact the test result timeline for movement decisions. See Appendix E for the Movement Permit Guidance Table.

Figure 2: An example outbreak timeline illustrating the 72-hour national movement standstill after an FMD outbreak is declared in the U.S. Movements of susceptible animals and their products from and within a Control Area will be based on risk. Negligible risk items may be able to move upon issuance of

an electronic Certificate of Veterinary Inspection (eCVI); others will require a permit issued by regulatory officials. The timeline is indefinite right and left.

Figure 2. Example Timeline

1. High Genomic Merit Animals (young bulls, young heifers, donor bulls, donor females)

These animals have unique genetic traits or genomic test results that rank them in the top 1-2% of their breed. This could be determined by their breed specific indices like Net Merit (NM$) or Total Performance Index (TPI) for Holsteins; Jersey Production Index (JPI); or Expected Progeny Differences (EPD) for beef breeds. Permit requestors should be prepared to provide documentation if requested.

Permitted to move out of or within a Control Area if the following surveillance criteria are met:

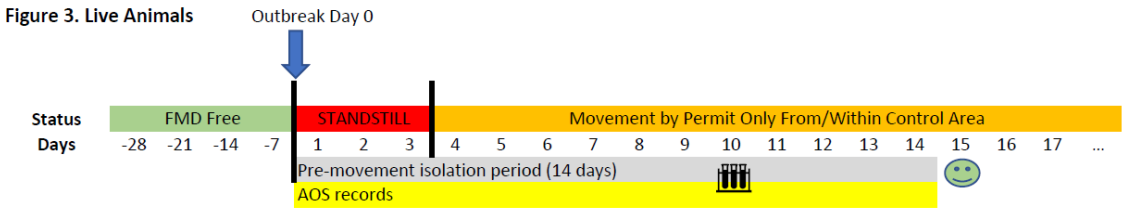
- Animal(s) met the pre-movement isolation period (PMIP) criteria as described in the SBS Plan for at least 14 days^ (see Appendix F).
- AOS conducted daily for those 14 days, with records of observations noting no abnormal findings suggestive of FMD.
- Negative diagnostic test results* for the live animal needing to move:
    - Oral swab sample(s) collected no sooner than 10 days from start of PMIP.
- Destination premises can quarantine animals upon arrival and conduct AOS for 14 days. This may involve an on-site audit pending resource availability.
- See "diagnostic testing" section for more details.

^The SBS Plan PMIP suggests a minimum of seven days for cattle in a control area. The seven-days was derived from expert opinion using disease spread models, the increased likelihood of disease being identified clinically in cattle in a control area, and business continuity needs of feedlots receiving cattle after taking animals to harvest. The 14-day period suggested here is the result of the SAHO Working Group initial request of 14 days of AOS on a static population.

*If diagnostic tests are NOT available, recommend PMIP for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

Figure 3. The animal(s) were part of a static herd (pre-movement isolation period – gray shading) for at least 14 days starting on day 0 (outbreak announced) and AOS records were kept during this time (yellow shading). An oral swab sample was submitted to the lab on day 10. If there is no evidence of disease based on AOS and negative test results, and other movement criteria met, the animal(s) are permit eligible on day 15.

Figure 3. Live Animals

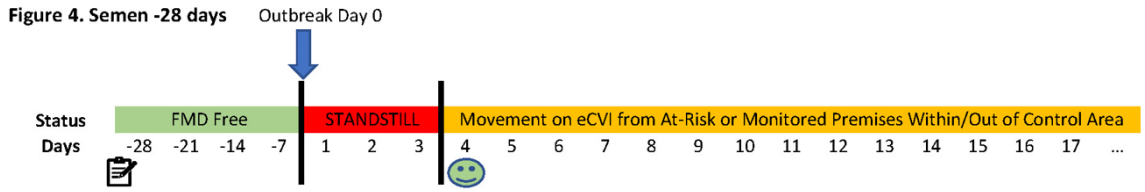


2. Frozen semen collected at least 28 days prior to first U.S. FMD diagnosis

Allowed to move from a Monitored or At-Risk Premises on an eCVI out of or within a Control Area **without** diagnostic testing if the following criteria are met:

- Records demonstrate semen collection date was at least 28 days prior to the first FMD diagnosis in the U.S.
- Bull had no clinical signs on collection day with records to demonstrate the observation.
- If the origin premises has livestock, biosecurity for the semen storage tank should include exterior cleaning and disinfection with a product labeled effective against FMD virus.

Figure 4: Semen was collected at least 28 days prior to the first FMD diagnosis in the U.S. based on records. The semen would be movement eligible on day four, after the standstill is lifted.



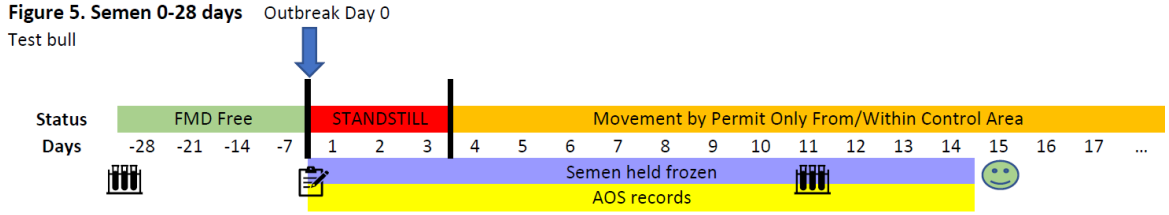
3. Frozen semen collected on day of outbreak (day 0) and prior 28 days

Permitted to move out of or within a Control Area if the following surveillance criteria are met:

- Records demonstrate semen collection date.
- Bull has no clinical signs on collection day with records to demonstrate the observation.
- AOS conducted daily for 14 days past collection date, with records of observations noting no abnormal findings suggestive of FMD.
- Frozen semen has been held for at least 14 days from date of collection.
- Negative diagnostic test results* for the donor male via:
    - Oral swab sample(s) collected no sooner than seven days post-semen collection from donor bulls and at least three days prior to permit request, OR
    - Banked serum sample(s) from donor bull collected not more than 28 days prior and not less than 14 days prior to semen collection date.
- See “diagnostic testing” section for more details.

*If diagnostic tests are NOT available, recommend holding frozen semen for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

Figure 5: Semen was collected on day 0 (outbreak announced) and held frozen for 14 days (purple shading). The donor bull has had AOS conducted daily for 14 days with records kept (yellow shading). A banked serum sample was collected not more than 28 days prior and submitted to the lab on day 11. If there is no evidence of disease based on AOS and negative test results, and other movement criteria met, the semen is permit eligible on day 15.

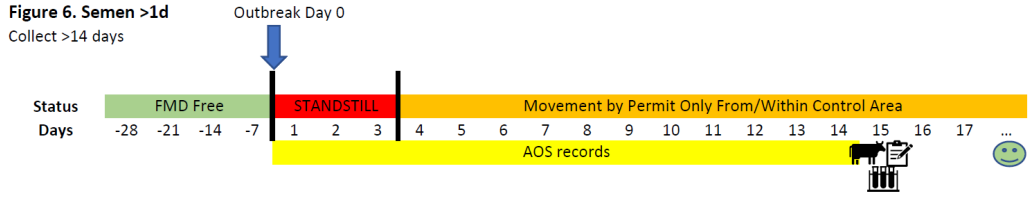


4. Frozen semen collected after outbreak

Permitted to move out of or within a Control Area if the following surveillance criteria are met:

- **Option 1: Do not collect bulls for at least 14 days**
  - AOS conducted daily for at least 14 days, with records of observations noting no abnormal findings suggestive of FMD.
  - Semen collected after 14th day of AOS and date recorded.
  - Negative diagnostic test results* for the donor male via:
    - Oral swab sample(s) collected on semen collection date, OR
    - Serum sample(s) collected from donor bull on initial post-outbreak semen collection date and repeated every at least every 28 days as semen collection continues.
  - See "diagnostic testing" section for more details.

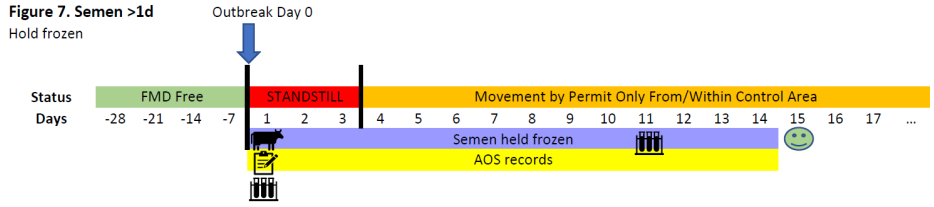
Figure 6: The donor bull has had AOS conducted daily for 14 days with records kept (yellow shading). Semen was collected on day 15 and date recorded. A diagnostic sample was collected and submitted to the lab on day 15. If there is no evidence of disease based on AOS, negative test results, and other movement criteria met, the semen is permit eligible once lab results are available.



- **Option 2: Hold frozen semen for at least 14 days after collection**
  - Frozen semen has been held for at least 14 days from date of collection.
  - Records demonstrate semen collection date.
    - Bull has no clinical signs on collection day.
  - AOS conducted daily for 14 days past collection date, with records of observations noting no abnormal findings suggestive of FMD.
  - Negative diagnostic test results* for the donor male via:
    - Oral swab sample(s) collected no sooner than seven days post-semen collection from donor bulls and at least three days prior to permit request, OR
    - Serum sample(s) collected from donor bull on initial post-outbreak semen collection date and repeated every at least every 28 days as semen collection continues.
  - See "diagnostic testing" section for more details.

*If diagnostic tests are NOT available, recommend holding frozen semen for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

Figure 7: Semen was collected on day 1 after outbreak and held frozen for 14 days (purple shading). The donor bull has had AOS conducted daily for 14 days with records kept (yellow shading). There are two possible diagnostic sample options: 1) An oral swab sample was collected on day 11, or 2) Collect serum on semen collection date (day 1). If there is no evidence of disease based on AOS and negative test results, and other movement criteria met, the semen is permit eligible on day 15.

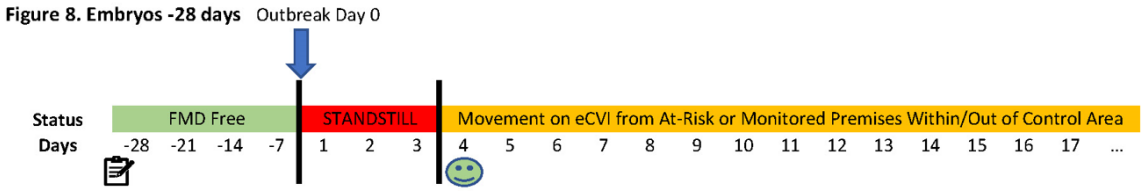


5. Frozen in vivo-derived and in vitro-produced embryos collected/created at least 28 days prior to first U.S. FMD diagnosis

Allowed to move from a Monitored or At-Risk Premises on an (eCVI) out of or within a Control Area **without** diagnostic testing if the following criteria are met:

- Records demonstrate embryo collection/creation date was at least 28 days prior to the first FMD diagnosis in the U.S.
- Donor female and bull had no clinical signs on collection day with records to demonstrate the observation.
- If the origin premises has livestock, biosecurity for the embryo storage tank should include exterior cleaning and disinfection with a product labeled effective against FMD virus.

Figure 8: Embryo was collected/created at least 28 days prior to the first FMD diagnosis in the U.S. based on records. The embryo would be movement eligible on day four, after the standstill is lifted.

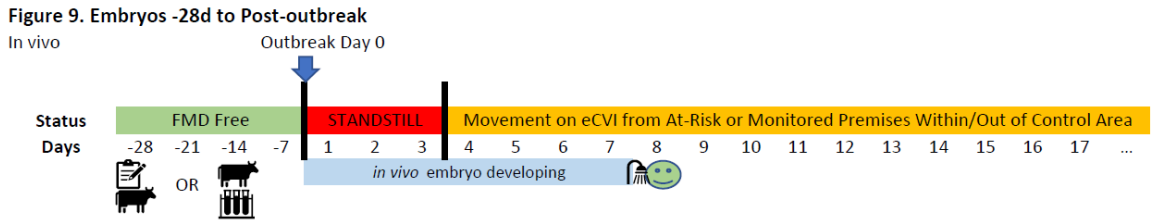


6. Fresh and frozen in vivo-derived embryos collected from 28 days prior to outbreak (day 0) and after

Allowed to move from a Monitored or At-Risk Premises on an eCVI out of or within a Control Area if the following criteria are met:

- Donor female bred with frozen semen that meets criteria described above under recommendations 2, 3 or 4
- The embryos were handled according to IETS sanitary standards. Labs and/or veterinarians may be asked to provide documentation of these practices using IETS Form ABC – Certificate of Embryo Recovery, Transfer, and Freezing or an equivalent for the embryo type. For all embryos, include a statement about 10 washes of the fresh embryo prior to implantation or freezing, and the form must be signed by a USDA Accredited Veterinarian.

Figure 9: Donor female bred using frozen semen that was either produced more than 14 days prior to use based on collection date records and negative bull diagnostic test or it was produced more than 28 days prior to first U.S. FMD diagnosis with records. In vivo derived embryos were collected on day seven and handled according to IETS sanitary standards. The embryos can be implanted fresh or held frozen



7. Frozen in vitro-produced embryos created from 28 days prior to outbreak (day 0) and after

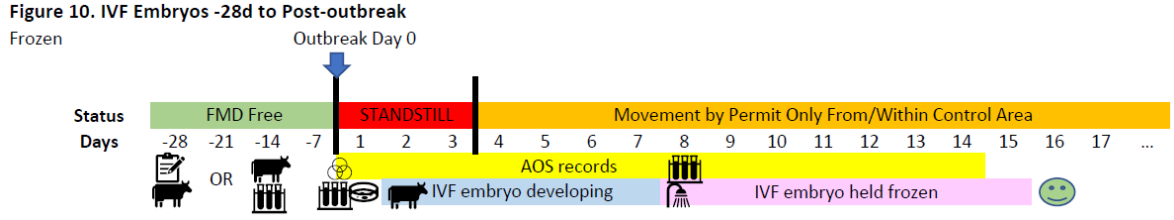
The creation of in vitro embryos will require fresh oocytes and frozen semen which may need to be moved into, out of, or within a Control Area. The donor animals will need to demonstrate "no evidence of infection" by meeting the following criteria:

- Ovum pick-up (OPU) from donor female with no clinical signs on collection day with records to demonstrate the observation.
- Donor female AOS conducted daily for 14 days from OPU date, with records of observations noting no abnormal findings suggestive of FMD.
- Negative diagnostic test results* for the donor female via:
    - Oral swab sample(s) collected no sooner than seven days after OPU and at least three days prior to permit request, or
    - Serum sample(s) collected from donor female on OPU collection date and repeated at least every 14 days as oocyte collection continues.
- Fertilization was done with frozen semen that meets criteria described above under recommendations 2, 3 or 4.
- Embryos held, frozen from day eight to 15 (which is 14 days since fertilization).
- The embryos were handled according to IETS sanitary standards. Labs may be asked to provide documentation of these practices using IETS Form C – Certificate of Freezing, and signed by a USDA Accredited Veterinarian.
- Products of animal origin used for fertilization, embryo development, embryo washing, and freezing come from FMD-free countries.
- See "diagnostic testing" section for more details.

*If diagnostic tests are NOT available, recommend holding frozen embryo for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

Figure 10: OPU conducted on day zero from donor female with no clinical signs and with records. Donor female AOS conducted daily for 14 days from OPU date with records kept (yellow shading). Serum sample collected on OPU date. Oocytes were fertilized on day two using frozen semen that was either produced more than 14 days prior to use based on collection date records and negative bull diagnostic test or it was produced more than 28 days prior to first U.S. FMD diagnosis with records. IVF embryos were collected on day eight, inspected, and handled according to IETS sanitary standards. The embryos were held, frozen until day 15. Oral swab sample was collected from donor female on day eight and submitted to the lab. The frozen embryo is permit eligible on day 16 if there is no evidence of disease based on AOS, negative test results, semen meets criteria, embryo meets criteria, and other movement criteria are met.

Figure 10. IVF Embryos -28d to Post-outbreak



8. Fresh in vitro-produced embryos created after outbreak

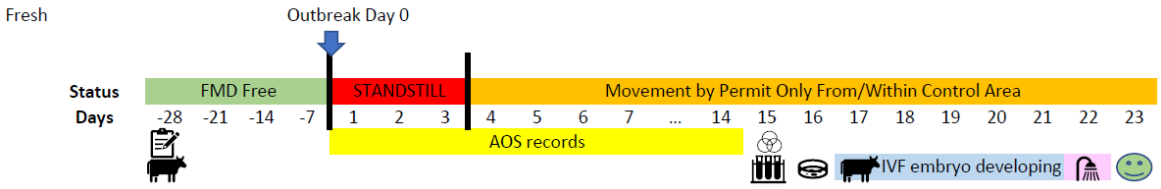
The creation of fresh in vitro embryos will require fresh oocytes and frozen semen which may need to be moved into, out of, or within a Control Area. The donor animals will need to demonstrate "no evidence of infection" by meeting the following criteria:

- AOS conducted daily on donor female for at least 14 days, with records of observations noting no abnormal findings suggestive of FMD.
- Ovum pick-up (OPU) after 14th day of AOS and date recorded.
- Negative diagnostic test results* for the donor female via:
    - Oral swab sample(s) collected on OPU date, or
    - Serum sample(s) collected from donor female on OPU collection date and repeated at least every 14 days as oocyte collection continues.
- Fertilization was done with frozen semen that meets criteria described above under recommendations 2, 3 or 4.
- Embryos inspected at day six post-fertilization and either implanted fresh on day seven
- The embryos were handled according to IETS sanitary standards. Labs may be asked to provide documentation of these practices using IETS Form C – Certificate of Freezing, and signed by a USDA Accredited Veterinarian.
- Products of animal origin used for fertilization, embryo development, embryo washing, and freezing come from FMD-free countries.
- See "diagnostic testing" section for more details.

*If diagnostic tests are NOT available, recommend holding frozen embryo for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

Figure 11: Donor female AOS conducted daily for 14 days with records kept (yellow shading). OPU conducted on day 15 from donor female with no clinical signs and with records. Oral swab and/or serum sample collected from donor female on day 15 and submitted to the lab. Oocytes were fertilized on day 16 using frozen semen that was produced more than 28 days prior to first U.S. FMD diagnosis with records. IVF embryos were inspected on day 22 and handled according to IETS sanitary standards. The embryo is permit eligible on day 23 to implant as a fresh embryo, or frozen, so long as there is no evidence of disease based on AOS, negative test results, semen meets criteria, embryo meets criteria, and other movement criteria are met.

Figure 11. IVF Embryos Post-outbreak



9. Oocytes recovered from an abattoir

- Not eligible for a movement permit.
- Cattle moved on an outbreak movement permit to an abattoir are considered a terminal movement and neither the cow nor their oocytes would be eligible for reshipment.

Business Continuity Components

In addition to disease monitoring (surveillance), premises seeking a movement permit for business continuity purposes must provide regulatory officials with information that demonstrates the animals or

animal products can be moved safely and not contribute to disease spread. The Secure Beef Supply (SBS) Plan for Continuity of Business, April 2024 components are included below.

National Premises Identification Number (PremID or PIN)

Having a PIN facilitates requesting movement permits during an outbreak. A PIN is linked to the geospatial location reflecting the actual location of the animals on the premises. This includes a valid 911 address and a set of matching coordinates (latitude and longitude). A PIN is required for both the premises of origin and the premises of destination. Obtain a 7-digit alphanumeric PIN from the office of the State Animal Health Official (SAHO). When animals on a premises become infected, all premises with the same PIN number will be considered infected. Generally, it is best to have separate PINs for premises with animals reared off-site and accessed via a public road even if managed or owned by the same individual or corporation.

Germplasm facilities that export semen or embryos may have one or more PINs for their different housing areas/buildings as required by the importing country. FMD is spread through direct contact with infected animals and indirect contact with contaminated fomites (vehicles, equipment hauling live or dead animals, feed, manure, tires, footwear, clothing, etc.) that may carry the virus from an infected location. FMD may also be spread via aerosol (distance dependent on wind, humidity, air temperature, and viral load of the infected species). These factors should be considered when determining whether each area/building with a PIN is a unique premises or if managerially, they would be epidemiologically linked.

Demonstrating not a Contact Premises – Traceability/Movement Records

Premises within an FMD Control Area will be part of the disease investigation to identify potential exposure to the virus. Accurate records speed up the traceability process and allow faster determination of the premises status – Contact, At-Risk, or Monitored. This information would help demonstrate that the premises has not had specific contact with Infected, Suspect, or Contact Premises in a Control Area. Find USDA definitions for traceability and premises designations in Appendix B. These designations guide additional surveillance and permitting decisions. Animal and germplasm movement permits are not issued to Infected, Suspect, or Contact Premises due to the risk of disease spread.

Enhanced Biosecurity Plan

Stringent biosecurity measures are essential to protect the herd from virus exposure. One of the movement permit guidance criteria in the Secure Beef Supply (SBS) Plan (2020) for the movement of cattle/semen/embryos includes the following statement: "*Biosecurity measures listed in the Biosecurity Checklist are in place and acceptable to Responsible Regulatory Officials*." To date, there is not a specific "biosecurity checklist" for FMD prevention for bovine germplasm facilities (e.g., bulls for semen collection, female donors (oocytes/embryos), or embryo recipients). The risk mitigation steps found in the SBS, Secure Milk Supply (SMS), and Secure Pork Supply (SPS) Plans are aimed at preventing FMD exposure and were evaluated for applicability by the BGMP State Animal Health Officials Working Group. See Appendix G: Bovine Germplasm Facility Enhanced Biosecurity Plan Guidance for more details.

Acknowledgements

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Appendix A: BGMP Definitions and Acronyms

AAVLD: American Association of Veterinary Laboratory Diagnosticians, the accrediting body of most state veterinary diagnostic laboratories.
AETA: American Embryo Transfer Association (https://www.aeta.org/)
BGMP: Bovine Germplasm Movement Plan
Control Area (CA): Perimeter should be at least 10 km (~6.21 miles) beyond the perimeter of the closest FMD Infected Premises.
CSS: Certified Semen Services
Donor Female: high genomic merit female
Donor Male: high genomic merit male (bull)
EBP: Enhanced Biosecurity Plan, generally developed following the guidance in the Secure Food Supply Plans
ETB: Embryo Transfer Businesses
EMRS: Emergency Management Response System. The USDA APHIS official system of record for all animal health incidents, including data needed to request movement permits.
EUA: Emergency Use Approval
FADDL: Foreign Animal Disease and Diagnostic Lab
FADI: Foreign Animal Disease Investigation
Female program: high genomic merit females used to produce the next generation of AI sires and female donors using IVF embryos and conventional embryos
FMD Red Book: The USDA APHIS FMD Response Plan
https://www.aphis.usda.gov/sites/default/files/fmd_responseplan.pdf)
FMD: Foot and mouth disease, caused by an aphthovirus
Germplasm facility: Those housing male or female donor animals that need to move one or more live animal(s), semen, or embryo(s) into or out of their facility. This includes semen production centers, embryo production centers, satellite collection centers, veterinary clinics, breeding facilities, and other livestock operations that are involved in the creation of bovine germplasm.
High Genomic Merit Animal: These animals have unique genetic traits or genomic test results that rank them in the top 1-2% of their breed. This could be determined by their breed specific indices like Net Merit (NM$) or Total Performance Index (TPI) for Holsteins; Jersey Production Index (JPI); or Expected Progeny Differences (EPD) for beef breeds.
HPAI: Highly pathogenic avian influenza
IETS: International Embryo Technology Society (https://www.iets.org/)
In vitro produced/fertilized embryo: Oocytes fertilized with frozen semen in a laboratory setting
In vivo derived embryos: Oocytes/ovum fertilized in a live female (conventionally produced)
IVF: In vitro fertilization
Jersey Production Index (JPI): Based on the ratio of lifetime combined fat and protein to lifetime dry matter intake, relative to other cows in the same herd born in the same year.
LIMS: Laboratory Information Management System
Movement Standstill: Controlled movement orders and 24-72-hour standstill of live susceptible animals (cattle, pigs, sheep, goats, captive cervids) and their products (semen, embryos) upon detection of FMD virus in the U.S. In the event of a movement standstill, the USDA will provide clear concise policy guidance on the implementation and provisions of, made easily accessible to all stakeholders. Additional national-level guidance will be provided when the national/regional movement standstill is lifted.
NAAB: National Association of Animal Breeders
NADPRP: National Animal Disease Preparedness and Response Program, USDA APHIS funding

NAHLN: National Animal Health Laboratory Network; 48 approved for FMD PCR in the U.S.
NBAF: National Bio- and Agro-Defense Facility, located in Manhattan, KS
Net Merit (NM$): Ranks dairy animals through a formula that factors a combination of traits that are genetically and economically important to dairy herds.
NVSL: National Veterinary Services Laboratories consisting of three in Ames Iowa (DVL: Diagnostic Virology Lab, DBPL: Diagnostic Bacteriology & Pathology Lab, and DBRL: Diagnostic Bioanalytical & Reagent Lab) and one in Plum Island NY (FADDL: Foreign Animal Disease and Diagnostic Lab)
OPU: Ovum pick up
PIADC: Plum Island Animal Disease Center, located off the coast of New York State
SAHO: State Animal Health Official
SBS: Secure Beef Supply Plan for Continuity of Business (http://securebeef.org/)
Semen Collection Center: A location with a bull population where semen is collected, extender added and frozen. The bulls are owned by the semen collection center management or private individuals and return to their home location the same or next day, with the frozen semen.
Semiannual Testing: Bulls are tested twice a year for domestic diseases to meet export requirements.
SMS: Secure Milk Supply Plan for Continuity of Business (http://www.securemilk.org/)
SPS: Secure Pork Supply Plan for Continuity of Business (http://www.securepork.org/)
TAHC: Terrestrial Animal Health Code
Total Performance Index (TPI): A method of ranking sires and cows according to a formula. It seeks to identify cattle who excel in three categories: production, health, and conformation.
USDA APHIS: Lead federal agency during an FMD outbreak for response and recovery
WOAH: World Organization for Animal Health (formerly Office International des Epizooties)

Appendix B: USDA Definitions

The following definition is from the USDA Animal Disease Traceability website, April 2024:

- Animal disease traceability: knowing where diseased and at-risk animals are, where they have been, and when is important to ensure a rapid response when animal disease events take place.

The definitions below are from the USDA Foreign Animal Disease Preparedness and Response Plan (FAD PReP) Foot-and-Mouth Disease Response Plan: The Red Book, October 2020:

- Infected Premises (IP): Premises where a presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, FMD case definition, and international standards.
- Contact Premises (CP): Premises with susceptible animals that may have been exposed to FMD, either directly or indirectly, including but not limited to exposure to animals, animal products, fomites, or people from IP.
- Suspect Premises (SP): Premises under investigation due to the presence of susceptible animals reported to have clinical signs compatible with FMD. This is intended to be a short-term premises designation.
- At-Risk Premises (ARP): Premises that have susceptible animals, but none of those susceptible animals have clinical signs compatible with FMD. Premises objectively demonstrates that it is not an IP, CP, or SP. ARP seek to move susceptible animals or products within the Control Area by permit. Only ARP are eligible to become MP.
- Monitored Premises (MP): Premises objectively demonstrates that it is not an Infected, Contact, or Suspect Premises. Only ARP are eligible to become MP. Monitored Premises meet a set of defined criteria in seeking to move susceptible animals or products out of the Control Area by permit.

Appendix C: World Organization for Animal Health (WOAH) Guidance

The World Organization for Animal Health (WOAH), Terrestrial Animal Health Code (TAHC) provides guidance for hygiene, collection and processing of semen and embryos for international movement. Germplasm companies involved in export have protocols in place to meet these standards. The WOAH TAHC Chapter 8.8 Infection with FMD provides guidance on semen and embryo importation based on FMD status of the country/zone. Excerpts and links are provided below.

The TAHC does not account for animals with no evidence of infection located in a regulatory Control Area that meet specific movement criteria to achieve business continuity during an FMD outbreak, which is the focus of this document. Where WOAH TAHC guidance applies, it is included in the BGMP.

Chapter 4.6. General Hygiene in Semen Collection and Processing Centres, updated 2010, accessed March 2023.

Chapter 4.7. Collection and Processing of Bovine, Small Ruminant, and Porcine Semen, updated 2013, accessed March 2023.

Chapter 4.8. Collection and processing of *in vivo* derived embryos from livestock and equids, updated 2015, accessed March 2023.

Chapter 4.9. Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses, updated 2018, accessed March 2023.

Chapter 4.10. Collection and processing of micromanipulated oocytes or embryos from livestock and horses, updated 2009, accessed April 2023.

Chapter 8.8 Infection with FMD, updated 2015, accessed March 2023.

This guidance pertains to FMD free countries.

Article 8.8.13. Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

For fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor males:
    a. showed no clinical sign of FMD on the day of collection of the semen;
    b. were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is not practised or FMD free *compartments*;
    c. were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;
2. the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.8.14. Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor males:
    a. showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
    b. were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is not practised or FMD free *compartments*;
2. the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.8.15. Recommendations for importation from FMD free countries or zones where vaccination is practised

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor males:
    a. showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
    b. were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is practised;
    c. either
        i. have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months;

    or
        ii. were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
2. the semen:
    a. was collected, processed and stored in accordance with Chapters 4.6. and 4.7.;
    b. was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

This guidance is based on FMD infected countries or zones:

WOAH TAHC Article 8.8.16: For frozen semen of domestic ruminants and pigs

- Donor Males
    - No clinical signs on collection, next 30 days
    - No animals added to AI centre 30 days prior to collection, not in Control Area (10km radius) 30 days prior and after collection
    - Donor males vaccinated at least twice, 30-180 days prior
      OR
    - Antibody negative 21 days or more after collection
- Semen
    - Semen collected, processed, stored according to WOAH TAHC Chapters 4.6 and 4.7
    - Negative test results if donor male vaccinated within 12 months prior to collection
    - Stored in country of origin for 1 month following collection, no animal housed on the same premises with the donor males showed any signs of FMD

WOAH TAHC Article 8.8.17: Recommendations for the importation of in vivo derived embryos of cattle

- In vivo embryos
    - Irrespective of FMD status
    - Import or transit without restriction with an international veterinary certificate attesting embryos collected, embryos processed as Chapters 4.8 and 4.10

There is no guidance about in vitro produced embryos from WOAH TAHC for FMD positive countries.

This guidance pertains to FMD free countries.

WOAH TAHC CH. 8.8.18: Recommendations for importation from FMD free countries or zones where vaccination is not practiced or FMD free compartments

- In vitro embryos should be accompanied by an international veterinary certificate attesting that:
    - Donor females
        - No clinical signs of FMD at time of oocyte collection,
        - Kept at least 3 months prior to collection in free country/zone or where vaccination is not practiced
    - Fertilization with semen meets Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant
    - Oocytes collected, embryos processed as Chapter 4.9 and 4.10, as relevant

WOAH TAHC CH. 8.8.19: Recommendations for importation from FMD free countries or zones where vaccination is practiced

- In vitro embryos should be accompanied by an international veterinary certificate attesting that:
    - Donor females
        - No clinical signs of FMD at the time of oocytes collection
        - Kept for at least 3 months prior to collection in free country/zone or where vaccination is practiced
            - Vaccinated at least twice, between one month and 6 months, unless protective immunity demonstrated for more than 6 months
              OR
            - Antibody negative 21 days or more after collection
    - Fertilization was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;

Oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.9. and 4.10., as relevant.

Appendix D: Oral Swab Deviation Process

Introduction

The oral swab real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test is a validated sample type for use in animals with clinical signs of FMD and a validated test with known specificity (99%) and sensitivity (94%) for use by USDA FADDL. NAHLN labs are proficiency tested for the rRT-PCR FMD assay but are not approved to test oral swabs on non-clinical animals.

Oral swab rRT-PCR can be used sooner than a serology assay to detect the FMD infection but may still produce false negative results during an early stage of pre-clinical infection. This testing coupled with Active Observational Surveillance (AOS) records could increase the confidence of the SAHO reviewing business continuity permit requests that the live animal movement within or out of a Control Area will not spread FMD virus.

Purpose

This test has not been validated for use in animals with NO clinical signs of FMD (new target population). Therefore, a NAHLN laboratory would need to request a Deviation from NAHLN Program Office for Emergency Use Approval (EUA) of this test on non-clinical animals. This document describes the Deviation Process that could be put in place in an outbreak to facilitate getting this test implemented quickly in the NAHLN labs in the event of an FMD outbreak. During an outbreak, time and resources will be limited to request and secure the deviation. Defining this process pre-outbreak benefits all parties so sample collection and testing can be promptly implemented during an FMD outbreak.

Deviation Process – Outbreak Scenario

- NAHLN lab receives oral swab samples from a new target population (no clinical signs)
    - **Target population:** High genomic merit animals (bulls, heifers, cows) that have no evidence of FMD infection based on Active Observational Surveillance (AOS) data for at least 14 days needing to move from their origin premises in a Control Area to enter the semen/embryo system (maintaining genetic supply chain) – within or outside of a Control Area.
        - The number of animals tested would only be a portion of the high genomic population born each year (assuming the entire U.S. is not a Control Area). Average yearly data from four commercial semen production centers across the 48-contiguous states are 2,350 bull calves and 3,800 heifer calves.
    - Source herd (At Risk or Monitored Premises) requesting a movement permit for high genomic merit animals can meet the Secure Food Supply Plan criteria, and any set forth by the state of origin:
        - Traceability information is available (Premises Identification Number, Global Positioning System Coordinates, and information on type and number of animals moved).
        - Biosecurity measures listed in the Biosecurity Checklist are in place and acceptable to Responsible Regulatory Officials.
        - Trace back/forward information is acceptable; premises is not Infected, Suspect or Contact.
        - Destination premises and State are willing to accept the cattle.
        - No evidence of infection based on disease monitoring (surveillance).
    - Destination premises should have the ability to quarantine animals upon arrival, conduct AOS for 14 days.
- Lab submits a Deviation request to NAHLN Program Office.

- This triggers an immediate call with NAHLN Lab Director, NAHLN Coordinator, NVSL Director, SAHO, AVIC and other Regulatory Officials (NPIC, APHIS Emergency Coordinator for that State, etc.) to come up with a plan. Discussion topics:
    - Do the animals meet the target population description?
    - Does the source herd meet the movement permit criteria?
    - Are there adequate samples (quality, number) available to test?
        - Numbers will be established by the group
    - Does the SAHO support collecting and submitting additional samples?
    - How do we get the samples to FADDL for concordance testing?
- If in agreement with proceeding, samples will be tested in parallel at NAHLN lab and at FADDL.
    - Need at least 75% concordance in test results between labs for that sample "clinical situation" (i.e., animals with no clinical signs) to be consider for approval.
    - Additional samples may need to be collected for parallel testing before approval for EUA at the NAHLN lab.
    - Frequency of testing TBD; potential for serial testing to be considered by FADDL.
- States need to be on board with permitting using the oral swab diagnostic sample results; SAHOs will need to determine how much value to put on the results.

Deviation Process – Pre-outbreak Scenario

- NAHLN lab and SAHO determine the need to test oral swab samples from a new target population (no clinical signs).
    - **Same Target population** as described above.
- Lab submits a Deviation request to NAHLN Program Office.
- This triggers a call to discuss EUA testing criteria (same as above).
    - Are there adequate samples (quality, number) available to test?
        - Number of samples may be determined in study design.
- If in agreement with proceeding, samples will be collected and tested in parallel at NAHLN lab and at FADDL.
    - USDA APHIS VS program office may allow this sample type as 'outbreak only' sample type for NAHLN labs (similar to current approval of blood cards for African Swine Fever).

Other Discussion Topics

- Using this test as surveillance testing.
- Sample size based on herd size, prevalence, sensitivity, specificity, positive predictive value of test – guidance needed from FADDL and CEAH.
    - Testing the epidemiological unit, not necessarily individual animal.
- Frequency of testing TBD; potential for serial testing to be considered pending viral shedding data – guidance needed from FADDL and CEAH.
- NAHLN network needs to determine how to handle samples sent across state lines.

The 2023 USAHA Resolution 2, 2023, Foot-and-Mouth Disease Diagnostics – Oral Swab Deviation for a New Population of Animals urges USDA FADDL to determine the sensitivity of an oral swab rRT-PCR test for FMD in a new population of animals.

Appendix E: BGMP Movement Permit Guidance for High Genomic Merit Cattle, Semen, Embryos Located within an FMD Control Area

This table has the guidance criteria to be met to request a movement permit (it aligns with Secure Beef Supply Plan, April 2024, Table 1). In ALL cases below, the destination premises and State must be willing to accept the high genomic cattle/semen/embryos. In an actual outbreak, decisions will be made by the Responsible Regulatory Officials based on the unique characteristics of the outbreak.

Oocytes from an abattoir are NOT ELIGIBLE for a movement permit.

Item to Permit	Collected/ Created	Risk assessment for movement is:	Traceability (PIN, GPS coordinates) info is available:	And Premises Biosecurity is acceptable?	And product-specific biosecurity measures are in place?	And Premises is not Infected, Suspect, or Contact?	And production parameters normal (Active Observational Surveillance (AOS) records are acceptable)?	And Diagnostic Test results are negative[7]?		Hold at least:	Permit Guidance to Move Item:
								Oral Swab	Serum		
Frozen semen, Frozen in vivo-derived, or Frozen in vitro-produced embryo	At least 28 days prior to first FMD diagnosis	Negligible[8]	YES	N/A	Semen/ embryo tank exterior clean and disinfect if held at livestock facility	N/A	No clinical signs on collection date per records; no AOS needed	N/A	N/A	0 days	Traceability achieved with electronic Certificate of Veterinary Inspection (CVI)

[7] If diagnostic tests are NOT available, recommend holding frozen semen, embryo, high genomic merit animals for at least 28 days and AOS conducted daily for those 28 days with records of observations noting no abnormal findings suggestive of FMD.

[8] The incubation period for FMD in cattle is 14 days. Semen/embryos produced/collected at least two-times the incubation period (28 days) prior to the first FMD diagnosis in the United States have negligible risk of spreading FMD. Source: World Organization for Animal Health, Terrestrial Animal Health Code Chapter 8.8 Infection with FMD

Item to Permit	Collected/ Created	Risk assessment for movement is:	Traceability (PIN, GPS coordinates) info is available:	And Premises Biosecurity is acceptable?	And product-specific biosecurity measures are in place?	And Premises is not Infected, Suspect, or Contact?	And production parameters normal (Active Observational Surveillance (AOS) records are acceptable)?	And Diagnostic Test results are negative[7]?		Hold at least:	Permit Guidance to Move Item:
								Oral Swab	Serum		
Frozen semen	-28 days to day 0 of FMD outbreak	Negligible[9]	YES	N/A	Semen tank exterior C&D if held at livestock facility	YES	No clinical signs on collection date; AOS at least 14 days	No sooner than 7 days post-semen collection and at least 3 days prior to permit request	Sample collected not more than 28 days prior and not less than 14 days prior to semen collection date	14 days from collection	Issue PERMIT to move to any location
Frozen semen	After day 0 of FMD outbreak	Negligible[9]	YES	YES	Same as above	YES	Same as above	Collected on semen collection date -OR- No sooner than 7 days post-semen collection and at least 3 days prior to permit request	Collected on initial post-outbreak semen collection date, repeated every at least 28 days as collection continues	If bull not collected for at least 14 days, 0 day holding; If bull collected before 14 days of AOS, hold 14 days	Issue PERMIT to move to any location

[9] Meyer A, Weiker J, Meyer R. Laboratory testing and on-site storage are successful at mitigating the risk of release of foot-and-mouth disease virus via production of bull semen in the USA. *PLoS ONE* 18(11): e0294036 (2023). https://doi.org/10.1371/journal.pone.0294036

Item to Permit	Collected/ Created	Risk assessment for movement is:	Traceability (PIN, GPS coordinates) info is available:	And Premises Biosecurity is acceptable?	And product-specific biosecurity measures are in place?	And Premises is not Infected, Suspect, or Contact?	And production parameters normal (Active Observational Surveillance (AOS) records are acceptable)?	And Diagnostic Test results are negative[7]?		Hold at least:	Permit Guidance to Move Item:
								Oral Swab	Serum		
Fresh or frozen in vivo-derived embryos	28 days prior to first FMD outbreak and after	Negligible[10]	YES	YES	Embryos handled according to IETS sanitary standards; product of animal origin come from FMD-free countries	YES	AOS not applicable Fertilized with frozen semen that meets criteria described above based on collection date	N/A	N/A	0 days	Move on an electronic CVI

[10] Source: World Organization for Animal Health, Terrestrial Animal Health Code Chapter 8.8 Infection with FMD, Article 8.8.17 Recommendations for the importation of in vivo derived embryos of cattle.

Item to Permit	Collected/ Created	Risk assessment for movement is:	Traceability (PIN, GPS coordinates) info is available:	And Premises Biosecurity is acceptable?	And product-specific biosecurity measures are in place?	And Premises is not Infected, Suspect, or Contact?	And production parameters normal (Active Observational Surveillance (AOS) records are acceptable)?	And Diagnostic Test results are negative[7]?		Hold at least:	Permit Guidance to Move Item:
								Oral Swab	Serum		
Frozen in vitro-produced embryos	28 days prior to outbreak and after	Not determined	YES	YES	Embryos handled according to IETS sanitary standards; product of animal origin come from FMD-free countries		No clinical signs on OPU date; AOS at least 14 days on donor female; Fertilized with frozen semen that meets criteria described above based on collection date	No sooner than 7 days after breeding and at least 3 days prior to permit request	Collected on OPU date, repeated every at least 14 days as collection continues	14 days post-breeding	Issue PERMIT to move to any location
Fresh in vitro-produced embryos (oocytes from live donors)	After day 0	Not determined	YES	YES	Same as above	YES	Same as above plus: OPU after 14th day of AOS, date recorded;	Collected on OPU date	Collected on OPU date, repeated every at least 14 days as collection continues	0 days	Issue PERMIT to move to any location

Item to Permit	Collected/ Created	Risk assessment for movement is:	Traceability (PIN, GPS coordinates) info is available:	And Premises Biosecurity is acceptable?	And product-specific biosecurity measures are in place?	And Premises is not Infected, Suspect, or Contact?	And production parameters normal (Active Observational Surveillance (AOS) records are acceptable)?	And Diagnostic Test results are negative[7]?		Hold at least:	Permit Guidance to Move Item:
								Oral Swab	Serum		
High genomic merit animals (based on genomic test results)	N/A	Not determined	YES	YES	N/A	YES	AOS at least 14 days; Animal(s) met the pre-movement isolation period (PMIP) criteria as described in the SBS Plan for at least 14 days	Collected no sooner than day 10 of Pre-Movement Isolation Period	N/A	14 days	Issue PERMIT to move to destination; 14-day quarantine at destination with AOS for 14 days

Appendix F: Secure Beef Supply (SBS) Plan Pre-Movement Isolation Period Description

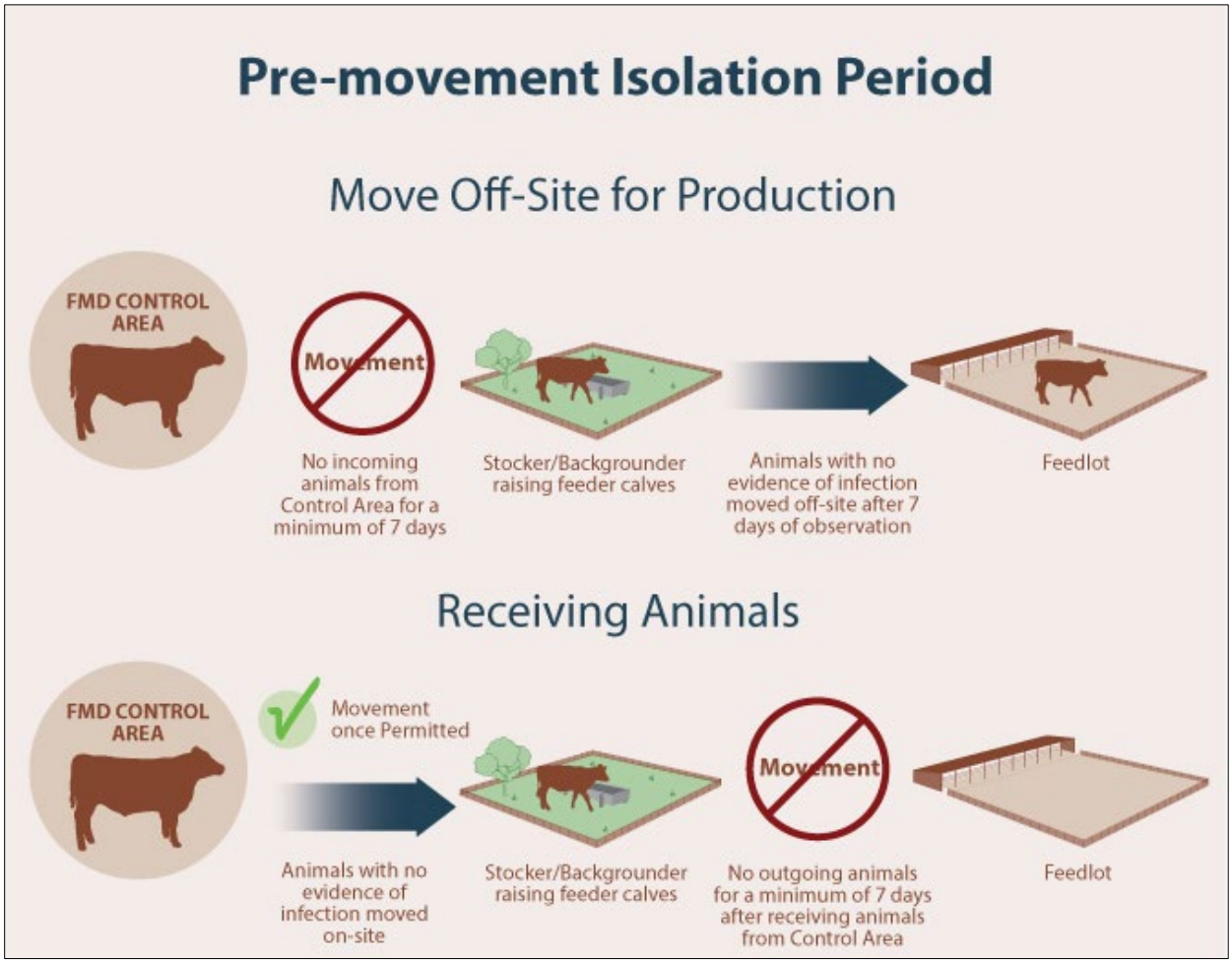
This content comes from the SBS Plan Information Manual for Enhanced Biosecurity for FMD Prevention: Cattle on Pasture, April 2024. Under section 6. Animal Movement, it states:

Pre-movement Isolation Period

> No animals from an FMD Control Area are introduced onto the operation for at least 7 days prior to moving animals to another production site with susceptible animals.

Animals from a Control Area are at a higher risk of being infected with FMD virus but may be undetected clinically if in early stages of infection. Because of the increased risk any introduction of cattle from within a Control Area should be carefully considered. Restricting animal introduction onto the entire operation for a minimum of seven days before any animals are moved off the operation to another production site will increase confidence that FMD virus was not introduced through animal movements. This does not apply if animals are being moved directly to slaughter, for instance in the case that slaughter plants begin accepting lighter weight cattle in the event of an outbreak.

For example, if a stocker/backgrounder accepts calves from a cow/calf operation that is within a Control Area on the first of the month, no shipments of feeder calves that are raised on the stocker/backgrounder to a feedlot should occur until the following week, on the 8th, at the earliest. This minimum of a one-week restricted entry provides added assurance to those receiving the animals that no clinical signs were found in the animals on the premises of origin. If the stocker/backgrounder does not wish to send any shipments of outgoing feeder calves other than direct to slaughter, there is no restricted entry time between incoming loads of calves. Feeder calves moving off of the stocker/backgrounder directly to slaughter may do so at any point in time once movement requirements have been met and a permit issued. This concept is described in the figure (below).



The pre-movement isolation period puts a seven-day period between different types of movements (incoming or outgoing), no matter which movement comes first. Shipments of incoming animals could occur more frequently than once per seven days (for example, several shipments of calves could arrive at the operation on the same day or loads of calves could arrive two days apart from one another), as long as there are then no outgoing shipments for seven days after the last incoming shipment. Likewise, if no animals have been brought in for the prior seven days, multiple loads of feeder calves could move off-site to a feedlot on the same or different days. In other words, movements of one type (incoming or outgoing) could occur frequently, but once the operation wants to switch the type of movement (from incoming to outgoing or vice versa), there is a seven -day isolation period.

Appendix G: Bovine Germplasm Facility Enhanced Biosecurity Plan Guidance

Introduction

One of the movement permit guidance criteria in the Secure Beef Supply (SBS) Plan (2020) for the movement of cattle/semen/embryos includes the following statement: "*Biosecurity measures listed in the Biosecurity Checklist are in place and acceptable to Responsible Regulatory Officials*." To date, there is not a specific "biosecurity checklist" for FMD prevention for bovine germplasm[11] facilities (e.g., bulls for semen collection, female donors (oocytes/embryos), or embryo recipients). The risk mitigation steps found in the SBS, Secure Milk Supply (SMS), and Secure Pork Supply (SPS) Plans are aimed at preventing FMD exposure and were evaluated for applicability.

Guidance

States have the authority to determine movement permit criteria in an FMD outbreak. The State Animal Health Officials that are part of the Bovine Germplasm Movement Plan (BGMP) Working Group provide the following **guidance** to germplasm facilities to develop their written, operation-specific Enhanced Biosecurity Plan (EBP) to describe the measures they will put in place prior to or during an FMD outbreak. Germplasm facilities should ensure the level of detail aligns with the biosecurity measures listed in the checklist that best represents your facility type (described below). The corresponding biosecurity templates provide the minimum level of detail to include in your written, operation-specific EBP. In an actual outbreak, decisions will be made by the Responsible Regulatory Officials based on the unique characteristics of the outbreak.

Biosecurity checklist, manual, and template resources by Cattle Facility Type

- **Cattle primarily raised outdoors in a dry-lot setting feeding forage-based diets that are delivered to the animals**, the SBS Plan Biosecurity Checklist for Beef Feedlots, corresponding Information Manual, and customizable Biosecurity Plan Template addresses the mitigations needed.
- **Cattle primarily raised on pasture**, the SBS Plan Biosecurity Checklist for Cattle on Pasture, corresponding Information Manual, and customizable Biosecurity Plan Template addresses the mitigations needed.
- **Cattle primarily raised indoors**, the SPS Plan includes an additional layer of "protection" for the area around the buildings, called the Perimeter Buffer Area (PBA) that could be included. Note that the SPS Plan Biosecurity Checklist for Animals Raised Indoors, corresponding Information Manual, and customizable Biosecurity Plan Template may have steps that are not applicable given the concepts are for pigs fed grain-based diets with automated delivery from bulk bins. Therefore, the concepts under "Protecting the Pigs" can be extracted and added into the SBS Plan Template.
- **Cattle located on a dairy that ships milk**, the SMS Plan Biosecurity Checklist for Dairy Operations, corresponding Information Manual, and customizable Biosecurity Plan Template addresses the mitigations needed.

Facilities that already have a written, enhanced biosecurity plan in place should compare it to the checklist that aligns with their facility type to make sure all items are included in their plan. If not, use the resources described to enhance the plan.

[11] For the purposes of this guidance, germplasm facilities are defined as those housing male or female donor animals that need to move one or more live animal(s), semen, or embryo(s) into or out of their facility. This includes semen production centers, embryo production centers, satellite collection centers, veterinary clinics, breeding facilities, and other livestock operations that are involved in the creation of bovine germplasm.

Risk Mitigation Topics from SBS, SMS, and SPS Biosecurity Checklists

The topic areas listed below are from the SBS, SMS, and SPS Plan Biosecurity Checklists. Where they align, they are **bolded** and where different, are (in parenthesis). The items that apply to your facility should be included in your Enhanced Biosecurity Plan in the order shown below. The "Scope of Biosecurity Plan" section of the EBP should describe the housing type for which the EBP applies. Below is an overview of the topics from SBS, SMS, and SPS. Follow the guidance in the corresponding template (linked above). For specific questions, please contact the office of your State Animal Health Official.

1. **Biosecurity Manager and Written Plan**
2. **Training**
3. **Protecting the Cattle/Pigs**
    i. Site entry (SPS indoor raised animals)
    ii. Line of Separation (LOS) and LOS Access Points
    iii. Perimeter buffer area (PBA) and PBA Access Points (SPS indoor raised animals)
    iv. Cleaning & Disinfection (C&D) Station
    v. Designated parking area
    vi. **Maximize Distance between Susceptible Livestock on Adjacent Premises** (SBS pasture)
    vii. Securing buildings (SPS indoor raised animals)
4. **Vehicles and Equipment**
    i. Vehicles and Equipment (non-animal transport)
    ii. Livestock Trucks/Trailers (animal transport)
5. **Personnel**
    i. Prior to arrival
    ii. Entry log
    iii. Biosecure entry/exit procedures
6. **Animal Movement**
    i. **Incoming animals** (SPS includes semen here)
    ii. Pre-movement isolation period
    iii. Contingency Plan for Interrupted Animal Movement
    iv. Loading/Unloading Animals
7. **Animal Product Movement** (SBS, SMS only)
    i. Milk Collection (SMS only)
    ii. Milk Disposal (SMS only)
    iii. ***Semen,** embryos (not in pigs)
    iv. Feeding dairy products
8. **Carcass Disposal**
9. **Manure Management**
10. **Wildlife, Rodent and Other Animal Control**
11. **Feed**

*The SBS/SMS Plan Enhanced Biosecurity Checklist item was written for facilities receiving semen and embryos: "*Semen and embryos collected after FMD has been diagnosed in the United States come from sources with documented, enhanced biosecurity practices and no current or previous evidence of FMD infection. Semen and embryos are transported in containers whose exteriors can be cleaned and effectively disinfected to minimize the risk of virus contamination*."

Germplasm facilities located in a Control Area that want to move semen and embryos "off" their premises will need to meet the same checklist requirements as facilities receiving them (described above in *italics*). To meet these criteria, the germplasm source herd should:

- Document their **enhanced biosecurity practices** using the Secure Food Supply Plan template that represents their facility type (Secure Beef, Pork, or Milk), and

- Document **Active Observational Surveillance (AOS) for at least 28 days** prior to requesting a movement permit to ship- a recipient animal, and
- Ship semen and/or embryos in containers whose exteriors can be cleaned and effectively disinfected.

The goal of **enhanced biosecurity** is to prevent exposure to livestock. Germplasm facilities may introduce items unique to their business such as liquid nitrogen, supplies for collecting semen, embryos or oocytes, media, and hormones of animal origin (bovine serum albumin, fetal bovine serum, porcine follicle stimulating hormone, porcine luteinizing hormone). However, the mitigations for anything crossing the Line of Separation (LOS) that may contact animals applies. Germplasm facilities should describe and put in place biosecurity measures that will prevent exposure.

The **28-day AOS recommendation** is longer than the 14-days of AOS described in the SBS/SMS EBP templates (April 2024/September 2017 versions, respectively) for herds receiving semen and/or embryos. The rationale for the 28-day AOS recommendation was based on:

- The potential risk of disease spread in the event the donor animal was infected with FMD but undetected through visual screening.
- The potential impact of disease spread due to the broad distribution from one male or female donor to multiple herds.
- AOS is the only screening test with no additional diagnostic testing on the source animal(s). Should diagnostic testing of the donor animal(s) become available as recommended in the Bovine Germplasm Movement Plan, the duration of AOS documentation may be decreased.