RESOLUTION NUMBER: 12 Combined with 26 and 31 Approved

SOURCE: **COMMITTEE ON ANIMAL EMERGENCY MANAGEMENT**
COMMITTEE ON CATTLE AND BISON
COMMITTEE ON FOREIGN AND EMERGING DISEASES

SUBJECT MATTER: **Movements of *in vivo*-derived Bovine Embryos in a Foot-and-Mouth Disease Outbreak**

BACKGROUND INFORMATION:

A group of stakeholders from the bovine germplasm industry, state and federal animal health officials and veterinary diagnostic laboratory representatives are collaborating to create guidance criteria to allow domestic movement of bovine germplasm and high genomic merit animals located in a regulatory control area during a foot-and-mouth disease (FMD) outbreak in the United States. The Bovine Germplasm Movement Plan is a guidance document being developed through funding provided by the United States Department of Agriculture (USDA) National Animal Disease Preparedness and Response Program (NADPRP). Maintaining safe domestic movement of bovine 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 and preservation of genetic material.

The International Embryo Transfer Society (IETS) considers 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). FMD virus is loosely attached to the zona pellucida of *in vivo* derived embryos and is removed by the recommended washing steps by the IETS. (Source: Escobar CJ. Embryo transfer, a potential risk in disease transmission. MOJ Anat & Physiol. 2018;5(4):259–262. DOI: 10.15406/mojap.2018.05.00205 available at: https://medcraveonline.com/MOJAP/embryo-transfer-a-potential-risk-in-disease-transmission.html)

A quantitative risk assessment was published in 1997 by Sutmoller and Wrathall that evaluated 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 or other samples

Their conclusion was that using the risk reduction measures, the probability that one or more *in vivo* derived embryos out of 300 is contaminated with FMD virus is less than 1 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 IETS embryo handling methods are the internationally accepted standard and followed in the United States (US) and mitigate two of the pathways above. The US does not test embryo collection fluids for FMD; there is no validated test nor is it an approved sample type. However, active observational surveillance (as described in the USDA FMD Response Plan, Secure Beef Supply and Secure Milk Supply Plans) would mitigate three of the pathways above.

The World Organization for Animal Health (WOAH), Terrestrial Animal Health Code (TAHC) Chapter 4.8 provides guidance for collection and processing of *in vivo* derived embryos from livestock and equids (updated 2015) for international movement: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_coll_embryo_equid.htm. 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: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_coll_embryo_micro.htm 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 embryo importation based on FMD status of the country/zone. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/index.php?id=169&L=1&htmfile=chapitre_fmd.htm.

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 authorise 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 non-outbreak situations, some state codes (e.g., Georgia) describe that a certificate of veterinary inspection (CVI) should accompany the embryo shipment, although it is not always enforced (as of October 2023).

In the event of an FMD outbreak in the US, *in vivo*-derived bovine embryos would be considered a negligible risk for transmitting FMD virus if they are collected, processed and stored in accordance with WOAH TAHC Chapters 4.8 and 4.10 and the IETS Manual Chapter 6. Recommendations for the sanitary handling of *in vivo*-derived embryos. Companies involved in international export have the capabilities, knowledge and record keeping capabilities to meet these criteria for domestic movements of *in vivo*-derived embryos during an FMD outbreak.

States managing infected premises and requests for business continuity permits may be quickly overwhelmed. Identifying negligible risk items to remove from outbreak movement permit requirements while preventing FMD spread will lessen the burden on states and provide business continuity opportunities for the safe movement of *in vivo*-derived bovine embryos. Tracking movements into, within and out of control areas is important for outbreak management and future trade discussions. Negligible risk items, like *in vivo*-derived bovine embryos, could be tracked through certificates of veterinary inspection. This would apply to At-Risk Premises and Monitored Premises[1]. Storage tank exteriors must be cleaned and disinfected prior to leaving livestock facilities.

It should be noted that there is no conclusive evidence documenting the risk of FMD transmission from *in vitro* fertilized (IVF) bovine embryos and should not be included in this resolution. This should not be applied to *in vivo*-derived sheep, goat or pig embryos given the species differences in the zona pellucida's permeability to FMD virus.

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[1] USDA Foreign Animal Disease Preparedness and Response Plan (FAD PReP) Foot-and-Mouth Disease Response Plan: The Red Book, October 2020 available at: www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_responseplan.pdf defines the following:
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.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services to exempt *in vivo*-derived bovine embryos from the 72-hour national movement standstill required during foot-and-mouth disease (FMD) outbreaks. Prior to leaving livestock facilities, embryo storage tanks must have their exterior cleaned and disinfected with an Environmental Protection Agency-registered product labeled effective against FMD virus. Once FMD control areas are defined, state animal health officials are urged to allow movement of *in vivo*-derived bovine embryos from At-Risk and Monitored Premises (defined in the USDA FMD Response Plan) on a certificate of veterinary inspection rather than an outbreak movement permit.