

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 WOAHA 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 Premises¹. 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.

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.

INTERIM RESPONSE:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

VS does not anticipate significant progress on this resolution in fiscal year 2024. VS policy development staff are currently engaged in highly pathogenic avian influenza and African swine fever response and preparedness efforts, respectively. Once VS resources are available to focus on FMD planning, one of the first policies that VS implements will be a 72-hour standstill policy. At that time, we will also consider the additional recommendations included in this and resolution 11, including the potential consequences of such policy to interstate commerce and international trade.

In the interim, VS encourages the committee to communicate the FMD planning interest to their National Animal Disease Preparedness and Response Program (NADPRP) Consultation Board representative for consideration in the NADPRP fiscal year 2025 funding priorities.