

table 2). The 101 total positive sera from the UBI kit were distributed among 49 different holdings that were scattered all over the country with no geographical or epidemiological relationship. We used the higher prevalence estimates based on 101 positive animals in our quantitative risk assessment in order to maximize the risk estimate.

One commenter asked what the future follow-up procedures for serosamples found to be positive using the 3ABC ELISA test will be and how we will ensure that 3ABC positive serology cases trigger follow-up testing for virus isolation by OIE approved methods.

In bovine sampling, Uruguay has been using the UBI ELISA test kit to identify 3B FMD non-structural antibodies. According to the manufacturer's recommendation, the ELISA test for the detection of 3A FMD non-structural antibodies is used as a confirmatory test. As stated in the site visit report, this testing and retesting strategy has been followed in Uruguay. In cases in which positive animals persist after the two rounds of tests, Uruguayan officials proceed with clinical investigation of the susceptible species in order to confirm or reject any suspected presence of the disease.

One commenter asked what the scientific basis was for the statement in the risk assessment that fully protected animals are unlikely to become viremic. According to the commenter, a 2002 Pirbright Laboratory study showed that vaccinated swine will become viremic and shed virus despite their lack of clinical signs.

First, we note that our risk assessment was conducted specifically to determine the risk level associated with beef from Uruguay. The word "animal" throughout the risk assessment refers exclusively to the bovine species from which beef is derived.

Second, based on several different transmission studies,⁶ a case can be made for the lack of significant viremia in vaccinated cattle. The findings of these studies suggest that higher immunity levels due to multiple

applications of FMD vaccine or increased duration between vaccination and virus challenge result in reduced virus production or none at all.

We also note that swine respond differently than cattle do to the FMD virus. The study cited by the commenter relates to vaccinated swine, which were not largely affected by the strain of the virus that was present in Uruguay, and is not pertinent to this rule. However, we welcome any additional information or data that the commenter can provide, and we will review all such information as appropriate.

One commenter asked whether we had reviewed Uruguay's surveillance data to determine if Uruguay satisfies the OIE's "FMD-free with vaccination" status requirements. Although we do take international standards into consideration, we conduct independent risk assessments using our own stringent criteria as detailed previously. This rule relates to determining what mitigation measures would be effective in protecting the United States from the introduction of FMD in light of the fact that Uruguay does vaccinate, and this rule does not address whether Uruguay can be considered FMD-free with vaccination according to OIE standards.

One commenter expressed concern that FMD is often carried in animals that show no signs of disease until they are under stress. The commenter wanted to know how we would protect against this. We note that animals that show signs of FMD when under stress will do so as a consequence of viremia. All of our mitigation measures specifically target viremic animals.

General Questions

Several commenters expressed concern that the last outbreak of FMD was too recent for Uruguay to be considered a safe source of imported beef. Two of these commenters stated that we should require a longer disease-free waiting period, ranging from 3 to 5 years, and one commenter suggested that we conduct periodic, independent verification of the disease-free status of Uruguay during that waiting period. One commenter stated that we need to evaluate and take into consideration both the FMD status of Uruguay and the longevity of its disease-free status.

Our risk assessment process is thorough and rigorous. All of the evidence in our risk assessment and site visit report indicates that Uruguay is effectively controlling FMD and has established adequate precautions, including border and movement controls and surveillance and vaccination programs, to ensure the safety of the commodity it wishes to

export. Further, the mitigation measures that we require offer additional protection against the introduction of FMD into the United States from the importation of fresh (chilled or frozen) beef from Uruguay. We do not consider a 3 to 5 year disease-free waiting period to be either necessary or required by international requirements or standards.

One commenter noted that vampire bats are common in South America and asked if we had taken into account the fact that they could spread disease among cattle and how we planned to protect against this possibility. The commenter did not provide data to support the hypothesis that vampire bats are a transmission issue for FMD in Uruguay, and we are unaware of any such evidence.

One commenter noted that some of the supporting documents that accompanied the proposed rule were made available only in Spanish. The commenter stated that expenses to the reader are incurred when countries do not supply us with translated documents.

Although we were unable to identify the supporting documentation to which the commenter referred, the regulations in 9 CFR 92.2, which relate to applications by regions for recognition of the animal health status of that region, require that countries supply supporting documents in English. While we occasionally post supporting documents in a foreign language, these are usually documents obtained and discussed during site visits. In these instances, oral translation was provided to the site visit team, but no English language version of the document was made available. We have not always required written translations of such documents since the information in them, which was presented orally during the site visit, is included in the site visit report.

Two commenters stated that Uruguay should establish agreements with its neighboring countries and trading partners to ensure that they receive timely information about the presence of FMD in those countries. We agree that FMD in South America presents a regional challenge and that an effective regional approach is necessary to reduce the risk of disease spread from the region. Such a regional approach does exist. As noted in our site visit report, Uruguay, Argentina, and Brazil participate in the Cuenca del Plata FMD program under the auspices of PANAFTOSA. The main objective of the Cuenca del Plata program is to eradicate FMD with a regional, harmonized approach. Shortly after FMD outbreaks in 2001 in Argentina, Uruguay, and

⁶ Barnett, P.V. and Carabin, H., A review of emergency foot-and-mouth disease (FMD) vaccines. *Vaccine*, (2002), 20:1505-1514.

Doel, T.R., Natural and vaccine-induced immunity to foot-and-mouth disease: the prospect for improved vaccines. *Revue Scientifique et Technique, OIE*, (1996), 15(3):883-911.

Donaldson, A.I. and Kitching, R.P., Transmission of foot-and-mouth disease by vaccinated cattle following natural challenge. *Research in Veterinary Science*, (1989), 46:9-14.

Sellers, R.F., Herniman, K.A.J., and Gumm, I.D., The airborne dispersal of foot-and-mouth virus from vaccinated and recovered pigs, cattle and sheep after exposure to infection. *Research in Veterinary Science*, (1977), 23:70-75.