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SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.1 of the regulations lists regions of the world that are considered free of rinderpest or free of both rinderpest and FMD. The Animal and Plant Health Inspection Service (APHIS) considers rinderpest or FMD to exist in all regions of the world not listed.

On February 10, 2003, we published in the **Federal Register** a proposed rule (68 FR 6673-6677, Docket No. 02-109-1) to amend the regulations by allowing the importation of fresh (chilled or frozen) beef from Uruguay provided certain conditions were met. In that proposed rule, we notified the public of the availability of a risk assessment entitled, "Risk Assessment—Importation of Fresh (chilled or frozen) Beef from Uruguay" (November 2002).

We solicited comments concerning the proposed rule and the risk assessment for 60 days ending April 11, 2003. On April 14, 2003, we published in the **Federal Register** a notice (68 FR 17886, Docket No. 02-109-2) in which we reopened and extended the comment period for a period of 2 weeks ending April 25, 2003. We received a total of 28 comments by that date. The comments were submitted by domestic cattle producers, domestic cattle and livestock associations, a food company, a trade association, a State department of agriculture, a State public lands council, State veterinarians, foreign livestock associations, a representative of a foreign government, and other members of the public. Five commenters were supportive of the proposed rule, and three additional commenters generally supported the proposed rule provided APHIS continues to evaluate the validity and efficacy of the mitigation measures. The other commenters expressed concern about the effects of the proposed rule and about some of the specific provisions of the proposal. These comments are discussed by subject below.

Trade Issues

Several commenters expressed concern that there would be negative economic effects on the domestic cattle industry if fresh beef is allowed to be imported from Uruguay. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article in order to prevent the introduction or dissemination of a pest or disease of livestock. APHIS does not, however, have authority to restrict trade based on its potential economic effects. It should be noted, however, that past importations of fresh beef from Uruguay have comprised 0.2 percent or less of the total U.S. beef supply.

Equivalency and Verification Issues

Several commenters expressed concerns that Uruguay's health environment, level of management of disease control, and epidemiology are not equivalent to those of the United States. Based on our evaluation of information obtained from Uruguay, from APHIS site visits to that country, and from periodic visits conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), we have concluded that Uruguay's health standards, demonstrated ability to implement effective disease control methods in the event of an outbreak, and familiarity with modern epidemiology are effective.

One commenter stated that APHIS "needs to verify that the Uruguay FMD surveillance program is valid and that Uruguay is indeed free of the virus" and that "if APHIS confirms that FMD has been eliminated it must verify that the mitigating measures of de-boning, no blood clots, lymphatic tissue, and a pH of 5.8 or less is achieved in Uruguay." The commenter also stated that "[i]f these steps are verified, a wealth of scientific data indicates beef from Uruguay will not pose an FMD threat to the United States." Three commenters asked if APHIS had evaluated Uruguay's FMD surveillance program, processing system, and mitigation measures. One commenter stated that "APHIS must also verify that these mitigating measures are being conducted in an adequate manner in Uruguay.* * *" Three commenters suggested that evaluation teams include State laboratory officials, representatives of APHIS, the U.S. Food and Drug Administration (FDA), State animal health officials, and industry representatives. One commenter stated that more stringent inspections by non-Uruguayan officials are needed. Some of these commenters asked whether we would develop a verification plan.

We evaluate each request for initiation or resumption of trade in animals or animal products with foreign countries individually. The complete review process involves a thorough evaluation of the relevant infrastructure of the individual country by technical experts with experience in country disease evaluation and risk assessment. The risk assessment process, which is detailed below, is implemented specifically to evaluate and verify the efficacy of the surveillance programs, border controls, processing systems, and other disease control measures of the country in question.

The information is evaluated by personnel from APHIS's National Center for Import and Export (NCIE); Centers for Epidemiology and Animal Health (CEAH), which is an Office International des Epizooties (OIE) collaborating center for risk assessment and surveillance;¹ other Veterinary Services (VS) personnel, as appropriate; personnel from the National Veterinary Services Laboratories (NVSL); and personnel from APHIS's International Services who have first-hand knowledge of the animal health conditions in the region under evaluation. APHIS reviews the information provided by foreign government officials for completeness and acceptability with regard to all of the factors for evaluation listed in 9 CFR 92.2, "Application for recognition of the animal health status of a region." Topics covered in this review include, but are not limited to, border controls, surveillance, slaughter/processing plant controls, and security of sample integrity. In addition, the evaluation addresses effectiveness of veterinary infrastructure, disease status of the region, status of adjacent regions, disease control programs, vaccination status, separation of the region from adjacent higher risk regions, animal movement controls, livestock demographics and marketing practices, laboratory capabilities, and emergency response capabilities. APHIS requests additional information, if necessary, and seeks relevant information from other sources such as published literature.

Once the information provided by foreign officials is considered sufficient to conclude that the risks are low enough that the evaluation may proceed, a site visit to the region is

¹ In 1998, the OIE designated CEAH as a Collaborating Center for Risk Analysis and Animal Disease Surveillance Systems. The OIE is the international animal health standard-setting organization recognized by the World Trade Organization. The role of the collaborating center is to provide member countries of the OIE with scientific and technical assistance and expert advice on topics linked to animal health risk analysis and disease surveillance and control.