Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0001]

Notice of Availability of a Risk Analysis for the Foot-and-Mouth Disease Status of the Republic of South Africa

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that a risk analysis has been prepared by the Animal and Plant Health Inspection Service concerning the foot-and-mouth disease status of the Republic of South Africa and the related disease risks associated with importing animals and animal products into the United States from the Republic of South Africa. This risk analysis will be used as a basis for determining whether to relieve certain prohibitions and restrictions on the importation of ruminants and swine and the fresh meat and other animal products of ruminants and swine into the United States from the Republic of South Africa. We are making this risk analysis available to the public for review and comment.

DATES: We will consider all comments we receive on or before April 15, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0001* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0001, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0001.

Reading Room: You may read any comments that we receive on the risk analysis in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Animal Scientist, Regionalization Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–0756.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, including rinderpest and foot-and-mouth disease (FMD). 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 and FMD. Section 94.11 lists regions of the world considered free of rinderpest and FMD but from which the importation of meat and other animal products into the United States is subject to additional restrictions because of those regions' proximity to or trading relationships with FMD-affected regions.

In an interim rule effective November 6, 2000, and published in the **Federal Register** on February 9, 2001 (66 FR 9641–9643, Docket No. 00–122–1), we amended the regulations by removing the Republic of South Africa from the list of regions considered to be free of rinderpest and FMD. We also removed the Republic of South Africa from the list of regions in § 94.11 that are considered to be free of these diseases, but are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions. These actions were necessary because FMD had been confirmed in two provinces in the Republic of South Africa. The effect of the interim rule was to prohibit or restrict the importation of ruminants and swine and the fresh meat and other animal products of ruminants and swine into the United States from the Republic of South Africa.

Although we removed the Republic of South Africa from the list of regions considered to be free of rinderpest and FMD, we recognized that the Republic of South Africa's National Department of Agriculture responded immediately to the detection of the disease by imposing restrictions on the movement of ruminants, swine, and ruminant and swine products from the affected areas and by initiating measures to eradicate the disease. We stated that we intended to reassess the situation in the region at a future date in accordance with Office International des Epizooties (OIE) standards. We solicited comments concerning our interim rule ending April 10, 2001; we received no comments by that date.

In this notice, we are announcing the availability for review and comment of a document entitled ''Evaluation of the Foot-and-Mouth Disease Status of the Republic of South Africa'' (October 2007). This risk analysis assesses the FMD status of the Republic of South Africa and the related disease risks associated with importing animals and animal products into the United States from the Republic of South Africa. This risk analysis will be considered as part of our decisionmaking process regarding whether to relieve certain prohibitions and restrictions on the importation of ruminants and swine and the fresh meat and other animal products of ruminants and swine into the United States from the Republic of South Africa. The importation of live swine and certain swine products would continue to be restricted because the Republic of South Africa has not been evaluated by APHIS for African swine fever, classical swine fever, and swine vesicular disease. We are making the risk analysis available for public comment for 60 days.

The risk analysis may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the risk analysis by

calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the risk analysis when requesting copies.

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 11th day of February 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–2912 Filed 2–14–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0024]

Draft Guideline: Target Animal Safety for Veterinary Live and Inactivated Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) has developed a draft guideline titled ''Target Animal Safety for Veterinary Live and Inactivated Vaccines.'' This draft guideline provides guidance for designing and executing studies to evaluate the safety of the final formulation of veterinary live and inactivated vaccines in animals. Because the draft guideline may have an effect on the requirements for vaccines that are regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on the scope of the guideline and its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

DATES: We will consider all comments that we receive on or before April 15, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0024* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0024, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0024.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Center for Veterinary Biologics-Policy Evaluation and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise on veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based, harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

The draft guideline ''Target Animal Safety for Veterinary Live and Inactivated Vaccines'' (VICH Topic GL44) has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to provide guidance for designing and executing studies to evaluate the safety of the final formulation of veterinary live and inactivated vaccines prior to approval for licensing/registration. Because the draft guideline applies to some veterinary vaccines regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to the safety of the dose of the vaccine on the health and welfare of the target animal—we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft guideline reflects current APHIS thinking regarding designing and executing studies to assess the safety of the final formulation of live and inactivated veterinary vaccines in target animals. In accordance with the VICH process, once a final draft of the document has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, each final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy applicable regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee's final guideline for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, we may consider using the final guideline as the basis for proposed amendments to the regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final versions of ''Target Animal Safety for Veterinary Live and Inactivated Vaccines'' may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft guideline.