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–2013–0102]

Availability of an Environmental Assessment for Field Testing a Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the field testing of this vaccine, examines the potential effects that field testing this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis and other relevant data, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine for field testing following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before March 6, 2014.

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

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0102-0001.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2013–0102, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0102* or in our reading room, which 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 851–3426, fax (301) 734–4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337–6100, fax (515) 337–6120.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS), as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS considers the potential effects of this product on the safety of animals, public health, and the environment. Using the risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: ProtaTek International, Inc.

Product: Porcine Reproductive and Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus.

Possible Field Test Locations: Iowa, North Carolina, and Texas.

The above-mentioned product is a live chimeric virus constructed from an infectious clone and a field isolate of porcine reproductive and respiratory syndrome virus to produce an attenuated vaccine. The vaccine is intended for use in swine, 3 weeks of age or older, as an aid in the reduction of lung lesions caused by porcine reproductive and respiratory syndrome virus.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the

issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following completion of the field test provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 29th day of January 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–02273 Filed 2–3–14; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0100]

International Sanitary and Phytosanitary Standard-Setting Activities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with legislation implementing the results of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade, we are informing the public of the international standard-setting activities of the World Organization for Animal Health, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization, and we are soliciting public comment on the standards to be considered.

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

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0082-0001.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2012–0082, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0082* or in our reading room, which 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general information on the topics covered in this notice, contact Mrs. Jessica Mahalingappa, Acting Associate Deputy Administrator for SPS Management, International Services, APHIS, room 1132, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC 20250; (202) 799–7121.

For specific information regarding standard-setting activities of the World Organization for Animal Health, contact Dr. Michael David, Director, International Animal Health Standards Team, National Center for Import/Export, VS, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737–1231; (301) 851–3302.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Ms. Julie E. Aliaga, Program Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 851–2032.

For specific information on the North American Plant Protection Organization, contact Dr. Christina Devorshak, PPQ Technical Director for NAPPO, PPQ, APHIS, 1730 Varsity Drive, Suite 300, Raleigh, NC 27606; (919) 855–7547.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established as the common international institutional framework for governing trade relations among its members in matters related to the Uruguay Round Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act (Pub. L. 103–465), which was signed into law on December 8, 1994. The WTO Agreements, which established the WTO, entered into force with respect to the United States on January 1, 1995. The Uruguay Round Agreements Act amended Title IV of the Trade Agreements Act of 1979 (19 U.S.C. 2531 *et seq.*). Section 491 of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization. The designated agency must inform the public by publishing an annual notice in the **Federal Register** that provides the following information: (1) The SPS standards under consideration or planned for consideration by the international standard-setting organization; and (2) for each SPS standard specified, a description of the consideration or planned consideration of that standard, a statement of whether the United States is participating or plans to participate in the consideration of that standard, the agenda for U.S. participation, if any, and the agency responsible for representing the United States with respect to that standard.

''International standard'' is defined in 19 U.S.C. 2578b as any standard, guideline, or recommendation: (1) Adopted by the Codex Alimentarius Commission (Codex) regarding food safety; (2) developed under the auspices of the World Organization for Animal Health (OIE, formerly known as the Office International des Epizooties) regarding animal health and welfare, and zoonoses; (3) developed under the auspices of the Secretariat of the International Plant Protection Convention (IPPC) in cooperation with the North American Plant Protection Organization (NAPPO) regarding plant health; or (4) established by or developed under any other international organization agreed to by the member countries of the North American Free Trade Agreement (NAFTA) or the member countries of the WTO.

The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the Secretary of Agriculture as the official responsible for informing the public of the SPS standard-setting activities of Codex, OIE, IPPC, and NAPPO. The United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) informs the public of Codex standard-setting activities, and USDA's Animal and Plant Health Inspection Service (APHIS) informs the public of OIE, IPPC, and NAPPO standard-setting activities.

FSIS publishes an annual notice in the **Federal Register** to inform the public of SPS standard-setting activities for Codex. Codex was created in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization. It is the major international organization for encouraging international trade in food and protecting the health and economic interests of consumers.