

# 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.

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0010]

#### Availability of an Environmental Assessment for Field Testing of a *Clostridium Perfringens* Type A Vaccine, Live Salmonella Vector

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**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 *Clostridium Perfringens* Type A Vaccine, Live Salmonella Vector. 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, 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 May 15, 2020.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0010>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0010, 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-2020-0010> 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 information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment or the risk analysis with confidential business information removed, Dr. Barbara J. Sheppard, Senior Staff Veterinary Medical Officer, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, Ames, IA; phone (515) 337–6100, fax (301) 337–6120.

The alternative contact is Dr. Matthew Erdman, Senior Staff Veterinary Medical Officer, 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 conducted a risk analysis to assess the potential effects of this product on the safety of animals, public health, and the environment. Based on the risk analysis, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

*Requester:* Huvepharma, Inc.  
*Product:* Clostridium Perfringens Type A Vaccine, Live Salmonella Vector.

*Possible Field Test Locations:* Alabama, Arkansas, Georgia, Mississippi, and North Carolina, among others.

The above-mentioned product consists of a live, recombinant, attenuated *Salmonella enterica* vector containing genes from *C. perfringens* type A. So that the vaccine will be effective against necrotic enteritis associated with *C. perfringens* type A, the chickens will be vaccinated twice, once at the hatchery by spray route and 11 days later in a grow-out house by drinking water application.

APHIS' review and analysis of the potential environmental impacts associated with the proposed field tests are documented in detail in an EA entitled "Environmental Assessment for Field Testing of a Clostridium Perfringens Type A Vaccine, Live Salmonella Vector." We are making this EA available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the **DATES** section at the beginning of this notice.

The EA may be viewed on the *Regulations.gov* website 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 EA by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the EA when requesting copies.

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; 7 CFR 2.22, 2.80, and 371.4)

Done in Washington, DC, this 8th day of April 2020.

**Michael Watson,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2020-07914 Filed 4-14-20; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0005]

#### Decision To Authorize the Importation of Fresh Citrus From China Into the Continental United States

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our decision to authorize the importation of five species of commercially produced fresh citrus fruit (pummelo, Nanfeng honey mandarin,

ponkan, sweet orange, and Satsuma mandarin) from China into the continental United States. Based on the findings of the pest risk analysis, which we made available to the public to review and comment through a previous notice, we have concluded that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of these five species of citrus fruit from China.

**DATES:** The articles covered by this notification may be authorized for importation after April 15, 2020.

**FOR FURTHER INFORMATION CONTACT:** Ms. Claudia Ferguson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2352.

**SUPPLEMENTARY INFORMATION:** Under the regulations in “Subpart L—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a notice-based process based on established performance standards for authorizing the importation of fruits and vegetables. The performance standards, known as designated phytosanitary measures, are listed in paragraph (b) of that section. Under the process, APHIS proposes to authorize the importation of a fruit or vegetable into the United States if, based on the findings of a pest risk analysis, we determine that the measures can mitigate the plant pest risk associated with the importation of that fruit or vegetable. APHIS then publishes a notice in the **Federal Register** announcing the availability of the pest risk analysis that evaluates the risks associated with the importation of that fruit or vegetable.

In accordance with that process, we published a notice<sup>1</sup> in the **Federal Register** on May 1, 2019 (84 FR 18474–18475, Docket No. APHIS–2014–0005), in which we announced the availability, for review and comment, of a pest risk assessment (PRA) that evaluated the

risks associated with the importation into the continental United States of five species of commercially produced citrus fruit from China into the continental United States. These citrus fruits were: *Citrus grandis* (L.) Osbeck cv. Guanximiyou, referred to in this document as pummelo; *Citrus kinokuni* Hort. ex Tanaka, referred to in this document as Nanfeng honey mandarin; *Citrus poonensis* Hort. ex Tanaka, referred to in this document as ponkan; *Citrus sinensis* (L.) Osbeck, referred to in this document as sweet orange; and *Citrus unshiu* Marcov., referred to in this document as Satsuma mandarin.

In the notice, PRA, and RMD published previously, we referred to *Citrus grandis* (L.) Osbeck cv. Guanximiyou, as pomelo; however, the preferred spelling of the common name for this fruit is pummelo. We have corrected the spelling in this document and in our revised RMD.

The PRA identified the following 15 quarantine pests as potentially following the pathway on the importation of these citrus species from China into the continental United States: The mites *Brevipalpus junicus* and *Tuckerella knorri*; the fruit flies *Bactrocera correcta*, *B. cucurbitae*, *B. dorsalis*, *B. minax*, *B. occipitalis*, *B. pedestris*, *B. tau*, and *B. tsuneonis*; and the moths *Carposina niponensis*, *C. sasakii*, *Ostrinia furnacalis*, *Cryptoblabes gnidiella*, and *Rosseliella citrifrugis*.

The PRA also identified *Xanthomonas citri*, the causal agent of citrus canker, and *Phyllosticta citricarpa*, the causal agent of citrus black spot, as existing in China. These pathogens, present in the United States, are considered quarantine pests since they have limited distribution and are under official control in the United States.

Based on the conclusions of the PRA, APHIS prepared a risk management document (RMD) recommending mitigations for the 15 quarantine pests and 2 pathogens the PRA had identified as potentially following the pathway on the importation of citrus from China into the continental United States.

We solicited comments on the PRA and RMD for 60 days ending on July 1, 2019. We received 11 comments by that date. They were from the national plant protection organization (NPPO) of China, the NPPO of Ghana, two State departments of agriculture, four organizations representing domestic citrus producers, a domestic citrus producer, and private citizens.

The issues raised by the commenters are addressed below, by topic.

<sup>1</sup>To view the notice, PRA, RMD, supporting documents, and the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0005>.