

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 January 27, 2012.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0114-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2011-0114, 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-2011-0114> 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) 6902817 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) 734-8245, 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 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: Harrisvaccines, Inc.

Product: Swine Influenza Vaccine, RNA.

Field Test Locations: North Carolina, Illinois, and Nebraska.

The above-mentioned product consists of propagation-defective RNA particles that encode the hemagglutinin protein of swine influenza virus. The vaccine is for intramuscular use in healthy pigs, three weeks of age or older, as an aid in the prevention of disease caused by swine influenza virus, subtype H3.

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 19th day of December 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011-33205 Filed 12-27-11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2011-0078]

Notice of Decision to Authorize the Importation of Shredded Lettuce From Egypt 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 into the continental United States of fresh shredded lettuce from Egypt. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined 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 fresh shredded lettuce from Egypt.

DATES: *Effective Date:* December 28, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Marc Phillips, Import Specialist, RCC, RPM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 734-4394.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in "Subpart-Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-54, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture 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 performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis (PRA), can be safely imported subject to one or more of the designated phytosanitary

measures listed in paragraph (b) of that section. Under that process, APHIS publishes a notice in the **Federal Register** announcing the availability of the PRA that evaluates the risks associated with the importation of a particular fruit or vegetable. Following the close of the 60-day comment period, APHIS may begin issuing permits for importation of the fruit or vegetable subject to the identified designated measures if: (1) No comments were received on the PRA; (2) the comments on the PRA revealed that no changes to the PRA were necessary; or (3) changes to the PRA were made in response to public comments, but the changes did not affect the overall conclusions of the analysis and the Administrator's determination of risk.

In accordance with that process, we published a notice¹ in the **Federal Register** on August 17, 2011 (76 FR 50992–50993, Docket No. APHIS–2011–0078), in which we announced the availability, for review and comment, of a PRA that evaluated the risks associated with the importation into the continental United States of fresh shredded lettuce (*Lactuca sativa* L.) from Egypt. The PRA consisted of a risk assessment identifying pests of quarantine significance that could follow the pathway of importation of fresh shredded lettuce from Egypt into the United States and a risk management document identifying phytosanitary measures to be applied to that commodity to mitigate the pest risk. We solicited comments on the notice for 60 days ending on October 17, 2011. We received two comments by that date.

One comment from a private citizen who opposed the importation of shredded lettuce from Egypt into the United States did not address any specific aspect of the PRA.

The other comment, submitted by an agricultural official representing the State of Florida, questioned the efficacy of the post-harvest phytosanitary measures we included in the PRA. The commenter agreed with the PRA that lettuce from Egypt is potentially a host for several species of destructive leaf miners but stated that the phytosanitary measure of shredding lettuce does not remove the risk of their introduction into the United States. The commenter requested that shipments of shredded lettuce from Egypt not be permitted entry into Florida until the shipping protocol has had time to demonstrate the effectiveness of the mitigation measures listed in the PRA.

Only commercial consignments of shredded lettuce will be allowed to be imported from Egypt. Commercial consignments, as defined in § 319.56–2, are consignments that an inspector identifies as having been imported for sale and distribution. Produce grown commercially is less likely to be infested with plant pests than noncommercial consignments. Noncommercial consignments are more prone to infestations because the commodity is often ripe to overripe, could be of a variety with unknown susceptibility to pests, and is often grown with little or no pest control.

We identified in the PRA 12 pests of quarantine significance for lettuce from Egypt that are highly unlikely to follow the pathway due to the standard post-harvest processing practices applied to commercial consignments of shredded lettuce from Egypt. Although these 11 arthropods and 1 mollusk affect lettuce leaves, we took into account the standard commercial post-harvest procedures of: (1) Removing outer leaves; (2) visual inspection and culling, with cutting; (3) shredding; and (4) washing and centrifuging. We concluded that these procedures sufficiently mitigate the risk of introducing leaf miners or other plant pests through the importation of shredded lettuce from Egypt. The commenter provided no evidence to indicate that these measures would not effectively mitigate the pest risk.

Consignments of shredded lettuce from Egypt will also be required to be accompanied by a phytosanitary certificate of inspection and pest freedom issued by the national plant protection organization (NPPO) of Egypt, with an additional declaration stating that the shredded lettuce in the consignment had been inspected and found free from quarantine pests. This condition provides additional assurances that the commercial production process has removed quarantine pests from the commodity.

For these reasons, APHIS has concluded that the mitigations described will effectively mitigate the pest risk associated with shredded lettuce imported from Egypt. Accordingly, we have determined that no changes to the PRA are necessary based on the comment.

Therefore, in accordance with the regulations in § 319.56–4(c)(2)(ii), we are announcing our decision to authorize the importation into the continental United States of fresh shredded lettuce from Egypt subject to the following phytosanitary measures:

- The shredded lettuce must be imported in commercial consignments only.
- Each consignment of shredded lettuce leaves must be accompanied by a phytosanitary certificate issued by the national plant protection organization of Egypt with an additional declaration stating the following: “Shredded lettuce leaves in this consignment were inspected and found free from quarantine pests.”

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at <http://www.aphis.usda.gov/favir>). In addition to these specific measures, shredded lettuce from Egypt will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 19th day of December 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2010–0112]

Notice of Decision to Authorize Importation of Fresh Litchi From the Republic of South Africa 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 fresh litchi from the Republic of South Africa into the continental United States. Based on the findings in a pest risk analysis, which we made available to the public for review and comment through a previous notice, we believe 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 litchi from the Republic of South Africa.

DATES: *Effective Date:* December 28, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Marc Phillips, Import Specialist,

¹ To view the notice, the PRA, and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2011-0078>.