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–2011–0094]

Availability of an Environmental Assessment for Field Testing Avian Influenza-Marek's Disease Vaccine, H5 Subtype, Serotype 3, Live Marek's Disease 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 Avian Influenza-Marek's Disease Vaccine, H5 Subtype, Serotype 3, Live Marek's Disease 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 November 25, 2011.

ADDRESS: You may submit comments by either of the following methods:
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2011–0094, 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–2011–0094 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) 690–2817 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 50016; 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, a risk analysis has been prepared 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: Biomune Company.


Field Test Locations: Delaware and Kansas.

The above-mentioned product consists of a live recombinant Marek’s disease virus vector expressing an avian influenza virus protein. The vaccine is for in ovo vaccination of 18-day-old chick embryos or for the subcutaneous vaccination of healthy day-of-age chicks as an aid in the prevention of Marek’s Disease and avian influenza.

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 provision 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.


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

Kevin Shea.
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–27555 Filed 10–24–11; 8:45 am]
BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0072]

Plants for Planting Whose Importation Is Not Authorized Pending Pest Risk Analysis; Notice of Availability of Data Sheets for Taxa of Plants for Planting That Are Quarantine Pests or Hosts of Quarantine Pests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice; reopening of comment period.

SUMMARY: We are reopening the comment period for a notice that advised the public that we have determined that 41 taxa of plants for planting are quarantine pests and 107 taxa of plants for planting are hosts of 13 quarantine pests and therefore should be added to our lists of taxa of plants for planting whose importation is not authorized pending pest risk analysis. The notice also made available to the public for review and comment data sheets that detail the scientific evidence we evaluated in making the determination that the taxa are quarantine pests or hosts of quarantine pests. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before November 25, 2011.

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

• Federal eRulemaking Portal: Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0072-0001
• Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2011–0072, 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-2011-0072 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) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Tschanz, Senior Plant Pathologist/Senior Risk Manager, Plants for Planting Policy, RPM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–0627.

SUPPLEMENTARY INFORMATION:

On July 26, 2011, we published in the Federal Register (76 FR 44572–44573, Docket No. APHIS–2011–0072) a notice advising the public that we have determined that 41 taxa of plants for planting are quarantine pests and 107 taxa of plants for planting are hosts of 13 quarantine pests and therefore should be added to our lists of taxa of plants for planting whose importation is not authorized pending pest risk analysis. The notice also made available to the public for review and comment data sheets that detail the scientific evidence we evaluated in making the determination that the taxa are quarantine pests or hosts of quarantine pests.

Comments on the notice were required to be received on or before September 26, 2011. We are reopening the comment period on Docket No. APHIS–2011–0072 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between September 27, 2011, and the date of this notice.


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

Kevin Shea.
Acting Administrator, Animal and Plant Health Inspection Service.