

# Notices

Federal Register

Vol. 82, No. 11

Wednesday, January 18, 2017

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–2016–0069]

#### Availability of a Final Environmental Assessment and Finding of No Significant Impact for a Biological Control Agent for Giant Reed

**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 a final environmental assessment and finding of no significant impact relative to the release of *Lasioptera donacis* for the biological control of giant reed, *Arundo donax*, in the continental United States. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

**FOR FURTHER INFORMATION CONTACT:** Dr. Colin D. Stewart, Assistant Director, Pests, Pathogens, and Biocontrol Permits, Permitting and Compliance Coordination, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2327, email: [Colin.D.Stewart@aphis.usda.gov](mailto:Colin.D.Stewart@aphis.usda.gov).

**SUPPLEMENTARY INFORMATION:** Giant reed (*Arundo donax*), a native of the Mediterranean and Middle East, has become one of the most pervasive non-native plants to invade the riparian areas of the Southwest United States, especially in California and the Rio Grande area of Texas. Giant reed infestations in riparian habitats lead to loss of biodiversity, stream bank erosion, altered channel morphology, enhanced survival of cattle fever ticks, damage to bridges, increased costs for chemical and mechanical control along transportation corridors, and impede

law enforcement activities on the international border. Many Federal and State agencies, as well as private entities, conduct programs to manage giant reed, as well as other -invasive weeds.

The Animal and Plant Health Inspection Service (APHIS) is proposing to issue permits for the field release of a gall-forming fly, *Lasioptera donacis*, into the continental United States to reduce the severity of giant reed infestations.

On November 8, 2016, we published in the **Federal Register** (81 FR 78567–78568, Docket No. APHIS–2016–0069) a notice<sup>1</sup> in which we announced the availability, for public review and comment, of an environmental assessment (EA) that examined the potential environmental impacts associated with the proposed release of this biological control agent into the continental United States.

We solicited comments on the EA for 30 days ending December 8, 2016. We received 14 comments by that date. A written response to all comments received on the EA can be found in appendix 5 of the final EA (see footnote 1).

In this document, we are advising the public of our finding of no significant impact (FONSI) regarding the release of *L. donacis* into the continental United States for use as a biological control agent to reduce the severity of giant reed infestations. The finding, which is based on the EA, reflects our determination that release of this biological control agent will not have a significant impact on the quality of the human environment.

The EA and FONSI may be viewed on the *Regulations.gov* Web site (see footnote 1). Copies of the EA and FONSI are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

<sup>1</sup>To view the notice, environmental assessment, finding of no significant impact, and the comments we received, go to <https://www.regulations.gov/docket?D=APHIS-2016-0069>.

The EA and FONSI have 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).

Done in Washington, DC, this 11th day of January 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2017–01018 Filed 1–17–17; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0070]

#### Availability of an Environmental Assessment for Field Testing a Vaccine for Use Against Infectious Bursal Disease, Marek's Disease, and Newcastle Disease

**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 Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector. Based on the environmental assessment, 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. We are making the documents available to the public for review and comment.

**DATES:** We will consider all comments that we receive on or before February 17, 2017.

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

• *Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0070>.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2016-0070, 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-2016-0070> 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) 7997039 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 redacted), 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.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious before a veterinary biological product license may be issued. Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning

veterinary biological products are contained in 9 CFR parts 101 to 124.

A field test is generally necessary to satisfy preclicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from 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. Based upon a 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:* Biomune Company.

*Product:* Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

*Possible Field Test Locations:* Alabama, Delaware, Georgia, Maryland, North Carolina, Pennsylvania, and Virginia.

The above-mentioned product is a live Marek's Disease serotype 3 vaccine virus containing a gene from the Newcastle disease virus and a gene from the infectious bursal disease virus. This vaccine would be the recombinant fraction used in combination with a conventional live Marek's disease vaccine virus, either a serotype 1 or serotype 2 strain, during the field safety tests. The attenuated vaccine is intended for use in healthy 18-day-old or older embryonated eggs or day-old chickens, as an aid in the prevention of infectious bursal disease, Marek's disease, and Newcastle disease.

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).

We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. 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 and the two products with a conventional live Marek's disease vaccine virus, either a serotype 1 or serotype 2 strain, that incorporate it as a recombinant fraction, 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 associated product licenses, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine and the two associated products containing it following satisfactory 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 11th day of January 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2017-01010 Filed 1-17-17; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0079]

#### Updates to the Biotechnology Regulatory Services BQMS Program

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public that Biotechnology Regulatory Services of the Animal and Plant Health Inspection Service (APHIS) is updating its Biotechnology Quality Management System Program and renaming it the Biotechnology Quality Management Support Program to offer a more flexible, more customizable, and less costly program that is easily accessible to a wider universe of researchers and developers conducting biotechnology activities under APHIS' regulations. These updates represent the next step in