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. 04–022–1]

Availability of an Environmental Assessment for Field Testing Feline Immunodeficiency Virus-Rhinotracheitis Vaccine, Live Feline Herpesvirus Vector

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

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 Feline Immunodeficiency Virus-Rhinotracheitis Vaccine for use in cats. 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 April 21, 2004.

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

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–022–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–022–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–022–1'' on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read the environmental assessment, the risk analysis (with confidential business information removed), and any comments that we receive in our reading room. The reading room 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.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, 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. Eleanor V. Eagly, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010; (515) 232–5785. Please refer to the docket number, date, and complete title of this notice when requesting copies.

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: Pfizer Animal Health.

Product: Feline Immunodeficiency Virus-Rhinotracheitis Vaccine, Live Feline Herpesvirus Vector, Code 16B1.R0.

Field Test Locations: California, Connecticut, Florida, Indiana, Iowa, Kansas, Louisiana, Maine, Michigan, Missouri, New York, Ohio, Pennsylvania, South Carolina, Tennessee, and Texas.

The above-mentioned product is composed of two attenuated, gene deleted feline herpes viruses that express rhinotracheitis antigens with genetic modifications to also express feline immunodeficiency virus antigens. The vaccine is for use in cats as an aid

in the prevention of disease caused by feline immunodeficiency virus and feline rhinotracheitis 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 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.

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC this 17th day of March, 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–6328 Filed 3–19–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–012–1]

Availability of Environmental Assessment for Field Test of Genetically Engineered Organism

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 for a confined release into the environment of genetically engineered nonpathogenic (avirulent) strains of a bacterium, *Erwinia amylovora,* the causal agent of fire blight disease. The purpose of the release is to determine whether the avirulent strains are effective as disease suppression agents of pathogenic fire blight disease on apple and pear trees. This environmental assessment is available for public review and comment.

DATES: We will consider all comments we receive on or before April 21, 2004.

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

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–012–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–012–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–012–1'' on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read the environmental assessment and any comments that we receive in our reading room. The reading room 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.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Mr. John Cordts, BRS, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5531. To obtain a copy of the environmental assessment, contact Ms. Kay Peterson at (301) 734–4885; e-mail: *Kay.Peterson@aphis.usda.gov.* The environmental assessment is also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/03_27901r_ea.pdf.*

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered ''regulated articles.'' A permit must be obtained or a notification acknowledged before a regulated article may be introduced into the United States. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, and release into the environment of a regulated article.

On October 6, 2003, the Animal and Plant Health Inspection Service (APHIS) received a permit application (APHIS No. 03–279–01r) from Oregon State University, Corvalis, OR, for a permit to release into the environment avirulent strains 153 HrpS− and 153 HrpL− of the bacterial pathogen, *Erwinia amylovora,* the causal agent of fire blight disease, on apple and pear trees in Benton and Jackson Counties, OR. The avirulent strains of *E. amylovora* have been genetically engineered using the neomycin phosphotransferase (*nptII*) gene of transposon 10 from *Escherichia coli* strain DH5α and the *hrp* gene from *E. amylovora* strain Ea321. Insertion of the transposon within the coding region of the *E. amylovora hrp* gene results in inactivation of the gene and disruption of the disease-causing mechanism within the bacterium, thereby rendering the bacterium nonpathogenic or avirulent. Use of the *nptII* gene also confers resistance to the antibiotic kanamycin, which is used as a marker for the avirulent strains. The introduction of the avirulent strains, alone and in combination with other non-pathogenic bacteria, is expected to protect susceptible plants from infection