calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the risk analysis when requesting copies.

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 11th day of February 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–2912 Filed 2–14–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0024]

Draft Guideline: Target Animal Safety for Veterinary Live and Inactivated Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) has developed a draft guideline titled ''Target Animal Safety for Veterinary Live and Inactivated Vaccines.'' This draft guideline provides guidance for designing and executing studies to evaluate the safety of the final formulation of veterinary live and inactivated vaccines in animals. Because the draft guideline may have an effect on the requirements for vaccines that are regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on the scope of the guideline and its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

DATES: We will consider all comments that we receive on or before April 15, 2008.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0024* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0024, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0024.

Reading Room: You may read any comments that we receive on this docket 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: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Center for Veterinary Biologics-Policy Evaluation and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise on veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based, harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

The draft guideline ''Target Animal Safety for Veterinary Live and Inactivated Vaccines'' (VICH Topic GL44) has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to provide guidance for designing and executing studies to evaluate the safety of the final formulation of veterinary live and inactivated vaccines prior to approval for licensing/registration. Because the draft guideline applies to some veterinary vaccines regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to the safety of the dose of the vaccine on the health and welfare of the target animal—we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft guideline reflects current APHIS thinking regarding designing and executing studies to assess the safety of the final formulation of live and inactivated veterinary vaccines in target animals. In accordance with the VICH process, once a final draft of the document has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, each final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy applicable regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee's final guideline for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, we may consider using the final guideline as the basis for proposed amendments to the regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final versions of ''Target Animal Safety for Veterinary Live and Inactivated Vaccines'' may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft guideline.

The draft guideline may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the draft guideline by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 21 U.S.C. 151 *et seq.*

Done in Washington, DC, this 11th day of February 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–2913 Filed 2–14–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2007–0018]

Oregon State University; Availability of an Environmental Assessment and Finding of No Significant Impact for a Controlled Release of Genetically Engineered Populus Species and Hybrids

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment has been prepared for a proposed controlled field release of genetically engineered (transgenic) clones of *Populus* species and hybrids. The purpose of this controlled field release is to examine the effects of the genetic constructs on the intended traits of reproductive sterility, reduced stature, reduced light response, and modified lignin content. After assessing the application, reviewing pertinent scientific information, and considering public comments, we have concluded that this field release will not present a plant pest risk, nor will it have a significant impact on the quality of the human environment. Based on the environmental analysis that there are no significant impacts associated with this controlled field release, the Animal and Plant Health Inspection Service has determined that a finding of no significant impact is appropriate and therefore an environmental impact statement need not be prepared for this field release.

EFFECTIVE DATE: February 15, 2008.

ADDRESSES: You may read the environmental assessment (EA), finding of no significant impact (FONSI) and decision notice, and our response to the comments we received on the EA 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. The EA, FONSI and decision notice, and our response to public comments are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/06_25001r_ea.pdf*.

FOR FURTHER INFORMATION CONTACT: Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–7324. To obtain copies of the environmental assessment, contact Ms. Cynthia Eck, Document Control Officer, at (301) 734–0667; e-mail: *cynthia.a.eck@aphis.usda.gov*.

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. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, or release in the environment of a regulated article.

On September 7, 2006, the Animal and Plant Health Inspection Service (APHIS) received a permit application (APHIS No. 06–250–01r) from Oregon State University, in Corvallis, OR, for a controlled field release of genetically engineered *Populus alba* and *Populus* hybrids. A previous environmental assessment (EA) was prepared for a subset of trees in this release under Permit 95–031–01R. Under that permit, trees engineered with sterility constructs were allowed to flower. Since the researcher intends to add more trees to the permit and allow these additional trees to flower, this new EA has been prepared which updates the previous EA.

Permit application 06–250–01r describes 95 genetic constructs that can be categorized into reproductive sterility genes, genes affecting stature or light response, genes aimed to modify tree chemistry, and activation tagging mutants aimed at the development of ''experimental domesticates.'' These DNA sequences were introduced into *Populus* plants using disarmed *Agrobacterium tumefaciens* and also contain regulatory sequences from the plant pests cauliflower mosaic virus, tobacco mosaic virus, *Aspergillus nidulans*, and *Agrobacterium tumefaciens*. The subject *Populus* plants are considered regulated articles under the regulations in 7 CFR part 340 because they were created using donor sequences from plant pests.

On July 18, 2007, APHIS published a notice [1] in the **Federal Register** (72 FR 39378–39379, Docket No. APHIS–2007–0018) announcing the availability of an EA for controlled release of genetically engineered *Populus* species and hybrids. During the 30-day comment period, which ended on August 17, 2007, APHIS received five comments. Comments opposing the granting of the permit were submitted by two individuals and a public interest group. Comments supporting the granting of the permit were submitted by the permit applicant and a limited liability company. APHIS has addressed the issues raised during the comment period and has provided responses as an attachment to the finding of no significant impact (FONSI).

Pursuant to the regulations in 7 CFR part 340 promulgated under the Plant Protection Act, APHIS has determined that this field release will not pose a risk of introducing or disseminating a plant pest. Additionally, based upon analysis described in the EA, APHIS has determined that the action proposed in Alternative C of the EA, to issue the permit with supplemental permit conditions, will not have a significant impact on the quality of the human environment. You may read the FONSI and decision notice on the Internet or in the APHIS reading room (see **ADDRESSES** above). Copies may also be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

The EA and FONSI were 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

[1] To view the notice, the EA, and the comments we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2007–0018*.