

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](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](mailto: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<sup>1</sup> 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

<sup>1</sup> 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>.

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).

**Authority:** 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

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

**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–2007–0023]

#### SemBioSys Genetics, Inc.; Availability of an Environmental Assessment and Finding of No Significant Impact for a Proposed Field Release of Genetically Engineered Safflower

**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 field release of a safflower line genetically engineered to express, within its seeds, human proinsulin fused to an *Arabidopsis* oleosin molecule. After our assessment of the application, review of pertinent scientific information, and consideration of comments provided by the public, we have concluded that this field release will not present a risk of introducing or disseminating a plant pest, nor will it have a significant impact on the quality of the human environment. 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 these field releases.

**EFFECTIVE DATE:** February 15, 2008.

**ADDRESSES:** You may read the environmental assessment (EA), finding of no significant impact (FONSI), and any comments we received 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. The EA, FONSI and decision notice, and responses to comments are available on the Internet at: [http://www.aphis.usda.gov/brs/aphisdocs/06\\_363103r\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/06_363103r_ea.pdf).

**FOR FURTHER INFORMATION CONTACT:** Dr. Patricia Beetham, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–0664. To obtain copies of the EA, FONSI and decision notice, and response to comments, contact Ms. Cynthia Eck at (301) 734–0667; e-mail: [cynthia.a.eck@aphis.usda.gov](mailto: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 December 18, 2006, the Animal and Plant Health Inspection Service (APHIS) received a permit application (APHIS No. 06–363–103r) from SemBioSys Genetics, Inc. of West Sacramento, CA, for a field trial using a line of transgenic safflower. Permit application 06–363–103r describes a transgenic safflower (*Carthamus tinctorius*) cultivar that has been genetically engineered to express a fusion protein consisting of oleosin from *Arabidopsis thaliana* and human proinsulin exclusively within its seeds. Expression of this fusion protein is controlled by the phaseolin promoter and terminator sequences from *Phaseolus vulgaris* L. (common bean). Constructs were inserted into the recipient organisms via a disarmed *Agrobacterium tumefaciens* vector system. The seeds from these safflower plants will be ground up and used for the development of proinsulin purification technology and are not for commercial production.

The subject safflower is considered a regulated article under the regulations

in 7 CFR part 340 because it has been genetically engineered utilizing a recombinant DNA technique that uses a vector derived from *Agrobacterium tumefaciens*.

On June 22, 2007, APHIS published a notice<sup>1</sup> in the **Federal Register** (72 FR 34426–34427, Docket No. APHIS–2007–0023) announcing the availability of an environmental assessment (EA) for the proposed field release. During the 30-day comment period, APHIS received seven comments. There was one individual who was opposed to the use of biotechnology in food crops in general, but did not cite specific plant pest risk issues associated with this EA. Another commenter raised specific issues regarding the EA that mirrored the concerns of one of the five public interest groups that also sent in comments on the EA. In total, five public interest groups wrote letters in opposition to allowing the planting of this GE safflower. APHIS has responded to these comments in 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 B of the EA (the preferred alternative), to issue the permit with supplemental permit conditions, will not have a significant impact on the quality of the human environment. Therefore, APHIS has determined that a FONSI is appropriate for this proposed action. You may read the FONSI and decision notice on the Internet or in the APHIS reading room (see **ADDRESSES** above). Copies of the EA are also available from the individual 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 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).

<sup>1</sup> To view the notice, the EA, and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2007–0023>.