



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0018]

Draft Environmental Impact Statement and Preliminary Pest Risk Assessment for Permit for Release of Genetically Engineered *Citrus tristeza virus*

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 draft environmental impact statement (EIS) and preliminary pest risk assessment (PRA) that evaluate the potential environmental impacts and plant pest risk associated with the proposed environmental release of genetically engineered *Citrus tristeza virus*. We are making the draft EIS and preliminary PRA available for public review and comment.

DATES: We will consider all comments that we receive on or before June 25, 2018.

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0018>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0018, 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-2017-0018> 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) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Alan Pearson, Chief, Plant Pests, and Protectants Branch, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3944, email: Alan.Pearson@aphis.usda.gov. To obtain copies of the documents, contact Ms. Cindy Eck at (301) 851-851-3882, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA), as amended (7 U.S.C. 7701 *et seq.*), 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." The regulations in § 340.2 contain a list of organisms considered to be regulated articles, including all members of groups containing plant viruses, and all insect viruses.

The regulations in § 340.4(a) provide that any person may submit an application for a permit for the introduction of a regulated article to the Animal and Plant Health Inspection Service (APHIS). Paragraph (b) of § 340.4 describes the form that an application for a permit for the environmental release of a regulated article must take and the information that must be included in the application. In addition, paragraph (b) states that applications must be submitted at least 120 days in advance of the proposed release into the environment in order to allow for APHIS review. However, the 120-day review period would be extended if preparation of an environmental impact statement (EIS) is necessary.

Under the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), Federal agencies must examine the potential environmental impacts of proposed Federal actions that may significantly affect the quality of the human environment before those actions can be taken. In accordance with NEPA, regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), U.S. Department of Agriculture regulations implementing NEPA (7 CFR part 1b), and APHIS' NEPA Implementing Procedures (7 CFR part 372), APHIS has considered how to properly examine the potential environmental impacts of issuing permits for the introduction of genetically engineered regulated articles into the United States.

In a notice¹ published in the *Federal Register* on April 10, 2017 (82 FR 17179-17180, Docket No. APHIS-2017-0018), APHIS announced its intention to prepare an EIS in connection with the potential approval of an application from Southern Gardens Citrus Nursery, LLC, seeking a permit for the environmental release of genetically engineered *Citrus tristeza virus* (CTV) throughout Florida. The virus has been genetically engineered to express defensin

¹ To view the notice and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0018>.

proteins from spinach as a biological control approach to managing citrus greening disease in the State of Florida. Citrus greening disease, also called huanglongbing, was first detected in the United States in 2005 in Florida, and has since become a devastating disease of citrus in Florida.

This approach for controlling citrus greening disease does not involve a genetically engineered tree. Instead, the gene from spinach that codes for the defensin protein will be delivered to the tree's circulatory system by the genetically engineered CTV. APHIS decided to prepare an EIS because of the scope of the proposed releases and to better understand the potential environmental impacts and the associated uncertainty related to permit issuance.

APHIS solicited public comment for a period of 30 days ending May 10, 2017, as part of its scoping process to identify issues to address in the draft EIS. We received a total of 94 public comments. Issues most frequently cited in public comments on the notice included:

- The potential for the genetically engineered CTV to change over time and the potential for recombination with other viruses;
- Impacts to non-target species;
- The potential for defensin proteins to be found in areas other than the phloem of the plant;
- The potential for the genetically engineered CTV to become more transmissible;
- The impacts to organic citrus growers; and
- Health and safety concerns.

The issues discussed in the draft EIS were developed by considering the public input from the *Federal Register* notice announcing the intention to draft an EIS. APHIS evaluated these issues to analyze the potential environmental impacts of CTV and included a discussion of these issues in the draft EIS.

Therefore, in accordance with NEPA, APHIS' NEPA Implementing Procedures (7 CFR part 372), and 7 CFR part 340, APHIS is making available the draft EIS, as well as a preliminary pest risk assessment (PRA), for a 45 day public review and comment period. The draft EIS and preliminary PRA are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

A notice of availability regarding the draft EIS was also published by the Environmental Protection Agency in the *Federal Register* on May 11, 2018 (82 FR 22060, Docket No. ER-FRL-9039-3).

Done in Washington, DC, this 11th day of May 2018 .

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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