

should submit a letter of interest (1–2 pages) that includes the following:

(1) A short description of current active notifications and permits; and  
(2) A statement of the organization's commitment to:

- Develop and implement a BQMS program within their organization;
- Attend all required training sessions on the development and implementation of a BQMS to be held by APHIS-BRS-Regulatory Operations Programs (ROP);
- Establish methods and procedures for monitoring critical processes and procedures for the movement and field testing of regulated GE agriculture;
- Provide required data and provide feedback to APHIS-BRS-ROP on how to improve the BQMS program standard and guidelines;
- Participate in surveys after completing training modules; and
- Submit to a third-party external verification audit.

APHIS will accept letters of interest through October 1, 2008. APHIS will evaluate letters and notify all applicants of its final selections. You may submit participation letters of interest by mail or e-mail to the person listed under **FOR FURTHER INFORMATION CONTACT** at the beginning of this notice.

Done in Washington, DC, this 26th day of August 2008.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E8–20285 Filed 8–29–08; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0054]

#### University of Florida; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Papaya Genetically Engineered for Resistance to the Papaya Ringspot Virus

**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 received a petition from the University of Florida seeking a determination of nonregulated status for papaya genetically engineered for resistance to the papaya ringspot virus derived from a transformation event designated as X17–2. The petition has been submitted in accordance with

our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting comments on whether this genetically engineered papaya is or could be a plant pest. We are also making available for public comment a draft environmental assessment for the proposed determination of nonregulated status.

**DATES:** We will consider all comments we receive on or before November 3, 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=0054> 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–2008–0054, 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–2008–0054.

**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:** Mr. John Cordts, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5531, e-mail:

[john.m.cordts@aphis.usda.gov](mailto:john.m.cordts@aphis.usda.gov). To obtain copies of the petition or the environmental assessment, contact Ms. Cindy Eck at (301) 734–0667, e-mail: [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov). The petition and the environmental assessment are also available on the Internet at [http://www.aphis.usda.gov/brs/aphisdocs/04\\_33701p.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_33701p.pdf) and [http://www.aphis.usda.gov/brs/aphisdocs/04\\_33701p\\_ea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/04_33701p_ea.pdf).

**SUPPLEMENTARY INFORMATION:**

## Background

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 § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On December 2, 2004, APHIS received a petition seeking a determination of nonregulated status (APHIS No. 04–337–01p) from the University of Florida, Institute of Food and Agricultural Sciences (UFL–IFAS) of Homestead, FL, for papaya (*Carica papaya* L.) designated as transformation event X17–2, which has been genetically engineered for resistance to the papaya ringspot virus (PRSV), stating that papaya line X17–2 does not present a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340. UFL–IFAS responded to APHIS’ subsequent requests for additional information and clarification and submitted revisions to their petition on January 12, 2007, and June 14, 2007. The petition is available for public review and comment.

## Analysis

As described in the petition, papaya transformation event X17–2 has been genetically engineered with a sequence from the PRSV. This sequence was derived from the PRSV coat protein (*cp*) gene and introduced into X17–2 papaya along with one plant-expressed selectable marker gene, *nptII*, via *Agrobacterium*-mediated transformation. The marker gene is commonly used and enables researchers to select those plant tissues that have been successfully transformed with the gene of interest. The resistance to PRSV appears to be conferred through post transcriptional gene silencing.

Transformation event X17-2 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. X17-2 papaya has been field tested in the United States since 1999 under notifications authorized by the U.S. Department of Agriculture (USDA). APHIS has presented two alternatives in the draft environmental assessment (EA) based on its analyses of data submitted by UFL-IFAS, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS may: (1) Take no action (X17-2 papaya remains a regulated article); or (2) deregulate X17-2 papaya in whole (the preferred alternative).

In section 403 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS views this definition broadly to cover direct or indirect injury, disease, or damage not just to agricultural crops, but also to other plant parts and plant products whether natural, manufactured, or processed.

X17-2 papaya is subject to regulation by other Federal agencies. Under the Coordinated Framework for the Regulation of Biotechnology, the U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In order to be registered as a pesticide under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment. Because the use of Plant Incorporated Protectants (PIP), such as viral coat proteins, is considered pesticidal, the University of Florida has submitted a registration package to EPA for X17-2 papaya.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the U.S. Food and Drug Administration (FDA) enforces the

tolerances set by EPA. EPA has previously granted a tolerance exemption for PRSV coat protein in papaya.

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the **Federal Register** on May 29, 1992, and appears at 57 FR 22984-23005. Under this policy, FDA ensures that human food and animal feed, including those derived from bioengineered sources, are safe and wholesome. The University of Florida has submitted a food and feed safety and nutritional assessment summary to FDA for X17-2 papaya in 2007 that is currently under agency review.

A draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status for X17-2 papaya. The draft EA was 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).

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested or affected persons on the draft EA prepared to examine any environmental impacts of the proposed determination for the deregulation of the subject papaya event. The petition, the draft EA, and any comments received are available for public review, and copies of the petitions and the draft EA are available as indicated under

**ADDRESSES and FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the petition and the EA and other data and information, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of

UFL-IFAS PRSV-resistant papaya event X17-2 and the availability of APHIS' written regulatory and environmental decision.

**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 26th day of August 2008.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E8-20289 Filed 8-29-08; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Grain Inspection, Packers and Stockyards Administration

#### Designation for the Aberdeen, (SD), Decatur (IL), Hastings (NE), Fulton (IL), Missouri, and South Carolina Areas

**AGENCY:** Grain Inspection, Packers and Stockyards Administration, USDA.

**ACTION:** Notice.

**SUMMARY:** We are announcing designation of the following organizations to provide official services under the United States Grain Standards Act, as amended (USGSA): Aberdeen Grain Inspection, Inc. (Aberdeen); Decatur Grain Inspection, Inc. (Decatur); Hastings Grain Inspection, Inc. (Hastings); John R. McCrea Agency, Inc. (McCrea); Missouri Department of Agriculture (Missouri); and South Carolina Department of Agriculture (South Carolina).

**DATES:** Effective October 1, 2008.

**ADDRESSES:** USDA, GIPSA, Karen Guagliardo, Chief, Review Branch, Compliance Division, STOP 3604, Room 1647-S, 1400 Independence Avenue, SW., Washington, DC 20250-3604.

**FOR FURTHER INFORMATION CONTACT:** Karen Guagliardo at 202-720-7312, e-mail [Karen.W.Guagliardo@usda.gov](mailto:Karen.W.Guagliardo@usda.gov).

**Read Applications:** All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(b)).

**SUPPLEMENTARY INFORMATION:** In the March 3, 2008, **Federal Register** (73 FR 11387), we requested applications for designation to provide official services in the geographic areas assigned to the official agencies named above. Applications were due by April 2, 2008.

Aberdeen, Decatur, Hastings, McCrea, Missouri, and South Carolina were the sole applicants for designation to provide official services in the entire area currently assigned to them, so