

authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in "Subpart—Fruits and Vegetables" (7 CFR 319.56–1 through 319.56–47).

Under these regulations, peppers from Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua are subject to certain conditions before entering the United States to prevent the introduction of plant pests into the United States. The regulations require the use of information collection activities including inspections by Central American national plant protection organization officials, fruit fly trapping, monitoring, and recordkeeping, box labeling, and a phytosanitary certificate.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.0037936 hours per response.

Respondents: National plant protection organization officials and growers and shippers of peppers in Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua.

Estimated annual number of respondents: 245.

Estimated annual number of responses per respondent: 3,226.653.

Estimated annual number of responses: 790,530.

Estimated total annual burden on respondents: 2,999 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual

number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 26th day of August 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–2008–0098]

Solicitation of Letters of Interest To Participate in Biotechnology Quality Management System Pilot Project

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is soliciting letters of interest to participate in a voluntary pilot project for its Biotechnology Quality Management System (BQMS). The BQMS is a voluntary compliance assistance program designed to help stakeholders develop sound management practices, thus enhancing compliance with the regulatory requirements for field trials and movement of genetically engineered organisms in 7 CFR part 340. The Pilot Development Project will test the applicability of a biotechnology quality management audit standard and accompanying guidelines and assist APHIS in further development of BQMS. APHIS' goal for the pilot project is to obtain feedback from participants on the strengths and areas for improvement to the audit standard and guidelines prior to full implementation of the system.

DATES: Letters of interest will be accepted from September 2, 2008, to October 1, 2008.

FOR FURTHER INFORMATION CONTACT: Dr. Edward Jhee, Biotechnology Quality Management System Program Manager, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 91, Riverdale, MD 20737–1236; (301) 734–6356, edward.m.jhee@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Department of Agriculture's (USDA) Animal and Plant Health

Inspection Service (APHIS), regulates the introduction—meaning the importation, interstate movement, and environmental release—of genetically engineered (GE) organisms that are, or may be, plant pests. It is essential that applicants approved to introduce regulated GE organisms comply with all APHIS regulations and permit conditions. To improve compliance, APHIS is developing a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS). BQMS will help universities, small businesses, and large companies develop sound management practices to enhance compliance with the regulatory requirements for field trials and movements of GE organisms in 7 CFR part 340.

APHIS is seeking voluntary participants for a BQMS pilot project who will serve as a broad representation of the regulated community. APHIS will select participants who are:

(1) Currently conducting regulated environmental field release and movements under notification or permit, and who

(2) Intend to apply for a renewal or new notification or permit, annually, for the next 3 years.

APHIS will select one applicant from each of the following three categories to participate in the pilot project: One applicant from a large corporate business (greater than 50 employees), 1 applicant from a small business (less than 15 employees), and 1 applicant from an academic institution.

Participants in the BQMS Pilot Development Project will review the BQMS process and provide feedback. Specifically, participants will test the feasibility of the BQMS standards and guidelines by developing and implementing a quality management system for their organization that proactively manages regulated movement and field releases. Participating in the quality management system will demonstrate an organization's commitment to regulatory accountability, increased transparency, and identification and implementation of measures to minimize the occurrence of compliance infractions.

A draft audit standard for the BQMS program and a series of guidelines to assist participants in using this compliance assistance program to proactively comply with APHIS regulations are presently undergoing a technical review with audit industry experts. This review will be completed before the pilot project begins.

Organizations that wish to participate in the BQMS Pilot Development Project

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.

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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. 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. The petition and the environmental assessment are also available on the Internet at http://www.aphis.usda.gov/brs/aphisdocs/04_33701p.pdf and 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.