

techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Emergency Management Response System (EMRS).

OMB Control Number: 0579-0071.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. Through the Foreign Animal Disease Surveillance Program, the Animal and Plant Health Inspection Service (APHIS) compiles essential epidemiological and diagnostic data that are used to define foreign animal diseases (FAD) and their risk factors. The data is compiled through the Veterinary Services Emergency Management Response System, a web-based database for reporting investigations of suspected FAD occurrences.

Need and Use of the Information: APHIS collects information such as the purpose of the diagnostician's visit to the site, the name and address of the owner/manager, the type of operation being investigated, the number of and type of animals on the premises, whether any animals have been moved to or from the premises and when this movement occurred, number of sick or dead animals, the results of physical examinations of the affected animals,

the results of postmortem examinations, and the number and kinds of samples taken, and the name of the suspected disease. APHIS uses the collected information to effectively prevent FAD occurrences and protect the health of the United States.

Without the information, APHIS has no way to detect and monitor foreign animal disease outbreaks in the United States.

Description of Respondents: Business or other for-profit State, Local or Tribal Government.

Number of Respondents: 471.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,884.

Animal and Plant Health Inspection Service

Title: Importation of Fruits and Vegetables.

OMB Control Number: 0579-0264.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701-7772), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests. Regulations contained in Title 7 of the Code of Federal Regulations, Part 319 (Subpart-Fruit and Vegetables), Sections 319.56 *et seq.* implement the intent of this Act by prohibiting or restricting the importation of certain fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of fruit flies and other injurious plant pests that are new to the United States or not widely distributed within the United States. These regulations are enforced by the Plant Protection and Quarantine, a program with USDA's Animal and Plant Health Inspection Service (APHIS).

Need and Use of the Information: The use of certain information collection activities including phytosanitary certificates, fruit fly monitoring records, and cooperative agreements will be used to allow the entry of certain fruits and vegetables into the United States. Without the information all shipment would need to be inspected very thoroughly, thereby requiring considerably more time and would slow the clearance of international shipments.

Description of Respondents: Business or other for-profit; Federal Government.

Number of Respondents: 15.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 123.

Ruth Brown,

Departmental Information Collection Clearance Officer.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2011-0129]

Biotechnology Regulatory Services; Changes Regarding the Solicitation of Public Comment for Petitions for Determinations of Nonregulated Status for Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for genetically engineered organisms to allow for early public involvement in the process. Under the updated process, APHIS will publish two separate notices in the **Federal Register** for petitions for which APHIS prepares an environmental assessment. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decisionmaking documents. This change will provide two opportunities for public involvement in the decisionmaking process.

FOR FURTHER INFORMATION CONTACT: Dr. T. Clint Nesbitt, Chief of Staff, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3917, email: Thomas.C.Nesbitt@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (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 (GE) 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. Paragraph (d) provides that, for petitions that meet the submission procedures, format, required data, and information requirements in paragraphs (b) and (c), APHIS will publish a notice in the **Federal Register** to inform the public that APHIS will accept written comments regarding the petition for a period of 60 days from the date of the notice.

As part of the USDA Customer Service Plan,¹ which seeks to improve the Agency’s customer service processes, APHIS analyzed the current petition process using Lean Six Sigma business process techniques. Based on this analysis, APHIS is implementing changes to improve our process for evaluating and responding to petitions for determinations of nonregulated status. Changes include earlier publication of the notice announcing the petition’s availability in the **Federal Register**, which will allow early public involvement in the process, and changes to the way we currently solicit and use public comment.²

Current Comment Process for Petitions for Determinations of Nonregulated Status

Once APHIS deems a petition to be complete (i.e., the petition meets all the submission procedures, format, required data, and information requirements in § 340.6(b) and (c)), APHIS, in most instances, prepares a plant pest risk assessment (PPRA) and a draft environmental assessment (EA). APHIS prepares a PPRA to assess the plant pest risk of the article and an EA, in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. After the completion of these documents, APHIS typically publishes a notice in the **Federal Register**

announcing the availability of the petition, PPRA, and draft EA for public comment.

After the comment period closes, APHIS reviews all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the petition, draft EA, PPRA, and other data, APHIS prepares a final EA, PPRA, and NEPA decision document, which can be either a Finding of No Significant Impact (FONSI) or notice of intent (NOI) to prepare an environmental impact statement (EIS).³

If APHIS determines, based on the PPRA, that the regulated article is unlikely to pose a plant pest risk and a FONSI is reached, APHIS subsequently furnishes a response to the petitioner approving the petition. APHIS also publishes a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS’ final EA, PPRA, FONSI, and regulatory determination. Copies of these documents are made available as indicated in the **Federal Register** notice.

Changes to the Comment Process for Petitions for Determinations of Nonregulated Status

Under our updated process, APHIS intends to decide whether a petition is complete within 3 months of its receipt. If APHIS deems that a petition is not complete, APHIS will so inform the petitioner. For petitions APHIS deems complete, APHIS will follow the process for public involvement described below.

EA Comment Process for Petitions for Determinations of Nonregulated Status

For complete petitions, APHIS will make the petition available for public comment before preparing our EA and PPRA.⁴ APHIS will, therefore, publish two separate notices in the **Federal Register**—a notice announcing the availability of the petition, with an opportunity for public comment, followed by a notice announcing the availability of APHIS’ EA and PPRA and

an opportunity for public involvement on those documents. This will provide two separate and specific opportunities for public involvement in the decisionmaking process.

First Opportunity for Public Involvement

The first opportunity for public involvement will be a public comment period on the petition itself, once it is deemed complete by APHIS. APHIS will publish a notice in the **Federal Register** to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. The comment period will provide the public with an opportunity to raise any issues regarding the petition and will be used by APHIS as a scoping opportunity to identify potential issues and impacts that APHIS would then determine should be considered in our evaluation of the petition.

Second Opportunity for Public Involvement

The second opportunity for public involvement will come with the publication of a notice of availability for APHIS’ EA and PPRA in the **Federal Register**. This second notice will follow one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues.

Approach 1

This approach for public participation will be used when APHIS decides, based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that raises no substantive new issues. This would include instances, for example, where APHIS decides that the petition involves gene modifications that do not raise substantive new biological, cultural, or ecological issues due to the nature of the modification or APHIS’ familiarity with the recipient organism.

Under this approach, APHIS will publish a notice in the **Federal Register** announcing APHIS’ preliminary regulatory determination and the availability of APHIS’ EA, FONSI, and PPRA for a 30-day public review. Upon completion of the 30-day review period, APHIS will review and evaluate any information received. If APHIS determines that no substantive information has been received that

¹ For more information on the USDA Customer Service Plan, go to [http://www.usda.gov/open/Blog.nsf/dx/USDA-CSPlan.pdf/\\$file/USDA-CSPlan.pdf](http://www.usda.gov/open/Blog.nsf/dx/USDA-CSPlan.pdf/$file/USDA-CSPlan.pdf).

² For information regarding APHIS’ analysis and other internal process changes APHIS is making to our petition process, go to http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml.

³ If an EIS is determined to be necessary, APHIS completes the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS’ NEPA implementing regulations (7 CFR part 372) and prepares a record of decision prior to either approving or denying the petition.

⁴ This notice describes our process for handling most petitions for determinations of nonregulated status. APHIS may decide that an EIS is necessary, either when we deem the petition to be complete or at any time during the EA process, in which case APHIS would complete the NEPA EIS process in accordance with Council on Environmental Quality regulations and APHIS’ NEPA implementing regulations.

would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination.

Should APHIS determine that we have received substantive new information within 30 days of publication of the **Federal Register** notice that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, our preliminary determination will not become effective. In this case, APHIS intends to notify the public through an announcement on our Web site of our intent to conduct additional analysis. APHIS will also inform the petitioner of our intent.

Based on the information APHIS received and our further analysis, the Agency will prepare an amended EA, a new FONSI, and/or a revised PPRA, as necessary. APHIS will then publish a notice in the **Federal Register** announcing the availability of these documents for public review and APHIS' preliminary regulatory determination. After reviewing and evaluating any additional information received within 30 days of publication of this **Federal Register** notice, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further **Federal Register** notice will be published announcing the final regulatory determination.

Approach 2

A second approach for public participation will be used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues

not previously analyzed by APHIS. Substantive issues would be identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

Under this approach, APHIS will solicit written comments on a draft EA and PPRA for 30 days through the publication of a **Federal Register** notice. The draft EA and PPRA will be made available as indicated in the **Federal Register** notice. Upon completion of the 30-day comment period, APHIS will review and evaluate all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document—either a FONSI or NOI to prepare an EIS. If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will publish a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

These changes to the public participation process are effective March 6, 2012. All petitions for determinations of nonregulated status for GE organisms received by APHIS on or after this date will be handled using the new process for handling petitions described in this notice. For petitions received before this date and currently under consideration by APHIS, our ability to transition to the new process will depend upon the current status of the petition. For those petitions where APHIS has not completed a draft EA and PPRA, APHIS will follow the new process, i.e., the complete petition will be published for a 60-day comment period followed by later public involvement regarding the EA and PPRA. For those petitions where APHIS has completed or is nearing completion of a draft EA and PPRA, APHIS will follow our previous process, i.e., the petition, draft EA, and PPRA will be made available in a single **Federal Register** notice for a 60-day comment period. APHIS will notify petitioners which process their petition will follow and will make this information available at http://www.aphis.usda.gov/biotechnology/pet_proc_imp.shtml.

These public participation process changes are consistent with (1) 7 CFR part 340, (2) the National Environmental

Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), (3) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (4) USDA regulations implementing NEPA (7 CFR part 1b), and (5) 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 29th day of February 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–5364 Filed 3–5–12; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0005]

Notice of Availability of a Pest Risk Analysis for the Importation of Litchi, Longan, and Rambutan From the Philippines Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with the importation into the continental United States of fresh litchi, longan, and rambutan fruit from the Philippines. Based on that analysis, we believe that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh fruit of litchi, longan, and rambutan from the Philippines. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before May 7, 2012.

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

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0005-0001>.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS–2012–0005, Regulatory Analysis and Development, PPD, APHIS, Station