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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.

[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.

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]

[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.

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.

[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.

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.

Approach1:

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 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 [Insert date of publication in the Federal Register]. 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.

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