

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-2008-0098.

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: 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. To obtain copies of the draft audit standard, contact Ms. Cindy Eck at (301) 734-0667, e-mail: cynthia.a.eck@aphis.usda.gov. The draft audit standard is also available on the Internet at http://www.aphis.usda.gov/biotechnology/news_bqms.shtml.

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. Such GE organisms and products are considered “regulated articles.” Applicants that are issued permits or received acknowledgment of notifications to introduce GE organisms are required to comply with all APHIS regulations.

To enhance improvements in compliance, APHIS initiated development of a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS). On September 20, 2007, APHIS issued a press release announcing plans to establish a BQMS Pilot Development Project.

APHIS selected five volunteer participants for the pilot program after soliciting letters of interest through a notice published in the **Federal Register** on September 2, 2008 (73 FR 51266–

51267, Docket No. APHIS-2008-0098). The main component of the BQMS pilot project is the draft audit standard, which provides criteria used for the objective evaluation of quality management systems to determine if a system will be certified as an APHIS Biotechnology Quality Management System during the audit portion of the pilot program. The regulatory requirements of 7 CFR part 340 for performance standards and permit conditions are the foundation for the draft audit standard.

The draft audit standard is used by pilot participants to develop sound management practices to enhance compliance with the regulatory requirements of 7 CFR part 340 for environmental releases, importations, and interstate movements of regulated articles. Participants have applied the draft audit standard to their organization's regulated biotechnology program to plan, implement, document, and examine the efficacy of quality assurance and quality control measures related to introductions of regulated articles.

APHIS is soliciting comments for a period of 60 days on the draft audit standard currently used in the BQMS pilot project. Within the draft audit standard, Requirement 7 specifies that participants address critical control points for the introduction of regulated articles by developing containment procedures for regulated articles; developing measures for the identification of regulated articles in storage, being moved, imported, or transferred, and in field locations; developing procedures for planning and monitoring environmental releases of regulated articles; developing methods for post-harvest handling activities and methods to maintain the identity of regulated material; developing procedures for the devitalization and disposition of regulated articles; as well as developing procedures for the submission of regulatory compliance incidents to the appropriate regulatory authorities. APHIS is soliciting comments on the draft audit standard as a whole, and Requirement 7 in particular.

1. Do the critical control points in Requirement 7 of the draft audit standard identify all areas and elements that organizations should focus on in order to maintain compliance with the regulatory requirements under 7 CFR part 340?

2. Is the draft audit standard consistent with current best practices used by the regulated community?

3. Can the public identify incentives USDA might employ to encourage

participation in the voluntary program by commercial industry as well as academic institutions?

4. The BQMS is designed to be flexible according to the size of the participating organization. Is this flexibility apparent in the draft audit standard?

Upon conclusion of the BQMS pilot project, APHIS will consider all comments received during the comment period to revise the draft audit standard to improve the efficacy of this project. This feedback, as well as comments from the participants on the pilot BQMS project, will be used to inform the development of a BQMS audit standard and any future BQMS initiative. The BQMS draft audit standard is available for public review as indicated under the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Done in Washington, DC, this 29th day of May 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9-13053 Filed 6-3-09; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2007-0016]

Syngenta Seeds, Inc.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered To Produce an Enzyme That Facilitates Ethanol Production

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice; reopening of comment period.

SUMMARY: We are reopening the comment period for a petition submitted by Syngenta Seeds, Inc., seeking a determination of nonregulated status for corn designated as transformation event 3272 and its associated environmental assessment prepared by the Animal and Plant Health Inspection Service under our regulations found at 7 CFR part 340. This action will allow interested persons additional time to prepare and submit comments on the petition, environmental assessment, and the revised plant pest risk assessment.

DATES: We will consider all comments that we receive on or before July 6, 2009.

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-2007-0016> 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-2007-0016, Regulatory Analysis and Development, PPD, APHIS, Station 3A03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2007-0016.

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: Dr. Andrea Huberty, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; (301) 734-0485, e-mail: andrea.f.huberty@aphis.usda.gov. To obtain copies of the petition, the draft environmental assessment, or the plant pest risk assessment, contact Ms. Cindy Eck at (301) 734-0667, e-mail: cynthia.a.eck@aphis.usda.gov. The petition, draft environmental assessment, and plant pest risk assessment are also available on the Internet at http://www.aphis.usda.gov/brs/aphisdocs/05_28001p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/05_28001p_ea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/05_28001p_ra.pdf.

SUPPLEMENTARY INFORMATION: 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 may be plant pests. Such genetically engineered (GE)

organisms and products are considered "regulated articles."

On October 7, 2005, APHIS received a petition seeking a determination of nonregulated status (APHIS Petition No. 05-280-01p) from Syngenta Seeds, Inc., of Research Triangle Park, NC (Syngenta), for corn (*Zea mays* L.) designated as transformation event 3272, which has been genetically engineered to produce a microbial enzyme that facilitates ethanol production. The petition stated that Event 3272 corn is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice¹ published in the **Federal Register** on November 19, 2008 (73 FR 69602-69604, Docket No. APHIS-2007-0016), APHIS announced the availability of the Syngenta petition and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject corn is likely to pose a plant pest risk, and on the draft EA. APHIS received over 13,000 comments on the petition, the draft EA, and the plant pest risk assessment by the close of the 60-day comment period, which ended on January 20, 2009.

There were 40 comments from organizations or individuals that supported the deregulation of the Event 3272 corn. Over 13,000 comments opposed to the deregulation were submitted. The vast majority of the approximately 13,000 comments opposing the deregulation were from letters conveying essentially identical points compiled by organizations generally opposed to any genetic engineering of plants. Several individuals and organizations also submitted documents, many popular press articles or documents published by those opposed to genetic engineering of plants in general, which they assert are relevant to this regulatory decision for Event 3272 corn.

Most of the comments supporting nonregulated status for Event 3272 corn came from organizations representing corn farmers and ethanol production interests. These comments include state-wide corn growers' and agribusiness associations from at least 12 different States where most of the nation's corn is grown. Several national organizations also voiced their support for the deregulation. The principal reasons given by these groups are the benefits anticipated for farmers and the ethanol

production industry, as well as the ability to meet biofuel production mandates and to promote international trading interests. While APHIS does not determine nonregulated status for GE organisms pursuant to its biotech regulations (Part 340) based on economic or marketing factors, the support from farmers of corn does suggest that individuals with a substantial interest in the health of the national corn crop do not perceive that either plant pest risks or economic/marketing risks will arise if Event 3272 corn is granted nonregulated status.

Several of the comments provided scientific support for the deregulation of Event 3272 corn. Many of these supportive statements were based on scientific studies included in the petition (such as evidence of decreased water use in ethanol production, reduced greenhouse gas emissions, other reduced inputs in ethanol production). There were several comments that also provided additional studies that would support deregulation of Event 3272 corn on the basis of diminished environmental impacts compared to current ethanol production practices. These studies supported the findings of lowered greenhouse gas emissions and reduced inputs, and also suggest that there will be no impacts on wet distilled grains and improved dried distilled grains, and that the Event 3272 corn is equivalent to currently grown corn lines in other agronomic and nutritional qualities, demonstrated through field and feed studies.

Many of the comments that opposed deregulation were based on general opposition to the development and use of GE plants, without citing or addressing any specific environmental issues in the EA or the pest risk assessment for the petition for Event 3272 corn. Many of these comments simply assert that APHIS should prepare an Environmental Impact Statement to fully address all the potential issues associated with a decision to grant nonregulated status to Event 3272 corn without specifically explaining what they perceive to be the inadequacies of the draft EA's environmental analysis. There were many general comments expressing generic, nonspecific concerns over possible gene flow, disruption to organic farming practices, and concerns of food and environmental safety.

Another common comment that APHIS received regarding the determination of nonregulated status for Event 3272 corn is the general "energy" concern related to the effectiveness and value of producing ethanol from corn. Many comments suggested that

¹ To view the notice, petition, draft EA, the plant pest risk assessment and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0016>.

producing ethanol from corn is not an efficient method for achieving energy needs or meeting any alternative energy mandates for the United States.

However, in determining the nonregulated status for a genetically engineered plant pursuant to its Part 340 biotechnology regulations, APHIS does not have authority to consider the economic, marketing, or commercial usefulness of the plant, or issues such as the feasibility of meeting energy needs through any particular crop and its related harvesting and processing aspects.

APHIS did receive some comments that raised specific issues of concern if Event 3272 corn was granted nonregulated status. These issues included specific food safety concerns such as the potential for Event 3272 corn to be allergenic, as well as concerns surrounding the potential economic and manufacturing issues if Event 3272 corn were to become present in corn wet-milling processes.

APHIS does believe it is appropriate to address in this notice certain comments submitted that questioned the conclusion that Event 3272 corn is not a plant pest, and that there is no basis for regulatory control of this GE plant under our statutory authorities and Part 340 biotechnology regulations. These comments argue that the alpha-amylase enzyme engineered into Event 3272 corn may cause damage (degradation of corn starch products) to manufactured or processed plant products if Event 3272 corn is included in the manufacturing and processing of corn starch products. The comments claim that this type of damage comes within the definition of a plant pest. One of these comments² claims that “a plant pest consists of any living stage of an article similar to or allied with a bacterium or any article similar to or allied with a bacterium that can cause direct damage to a processed plant product. The ‘article’ in this application [petition] is the thermo-stable alpha-amylase enzyme expressed in Event 3272, which has the potential for injury to plant products if misdirected to corn wet milling facilities.

APHIS’ statutory authority to regulate genetically engineered organisms under the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*) and its Part 340 biotechnology regulations is limited to those GE organisms that are plant pests as defined in Section 403, Subsection 14 of the PPA:

Plant Pest—The term “plant pest” means 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) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.
- (G) An infectious agent or other pathogen.
- (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

Thus, in regulating GE organisms under 7 CFR part 340, APHIS takes a “safeguarding” approach and examines the plant pest risk for genetically engineered plants by looking at all regulated genetically engineered plants for their potential to be plant pests (See plant pest risk assessment, pg. 1). However, under its PPA statutory authorities APHIS cannot regulate GE plants that are outside the PPA’s plant pest definition in 7 U.S.C. 7702(14). This statutory definition provides specifically that only a parasitic plant can be a plant pest.

One of the central purposes of the PPA is to prevent the introduction into or dissemination of plant pests within the United States. The PPA at 7 U.S.C. 7702(14) provides that a plant pest must be a living stage of one of a specific list of organisms (“articles”) that cause injury, damage, or disease in plants or plant products, or an article similar to or allied with such an organism (article). An “article” is defined in the PPA (7 U.S.C. 7702(1)) as follows:

Article—The term ‘article’ means any material or tangible object that could harbor plant pests or noxious weeds.

As mentioned above, there were some comments that questioned the conclusion that Event 3272 corn is not a plant pest. These comments argue that the alpha-amylase enzyme in Event 3272 corn is a plant pest because it may interfere with corn starch processing and thus directly or indirectly damage plants or plant products. The developer of Event 3272 corn submitted a document after the close of the document³ period that argues that Event 3272 corn does not meet the PPA statutory definition of a plant pest. In this document, the commenter provided its analysis of APHIS’ regulatory authority under the PPA, and among other things, suggests that separate constituent parts of an organism (in this case, an enzyme expressed by Event

3272 corn) are excluded from the definition of plant pest in the PPA because the enzyme “cannot be regarded as ‘living’.”

APHIS agrees that enzymes such as alpha-amylase are proteins that catalyze chemical reactions. Enzymes are not “living.” Thus, enzymes cannot be plant pests because they are not living and cannot be a “living stage” of any of the organisms (“articles”) listed in the PPA’s definition of a plant pest in subparagraphs (A) through (G) of 7 U.S.C. 7702(14). Likewise, the Event 3272 corn alpha-amylase enzyme also cannot be a living stage of any article similar to or allied with any of the articles specified in subparagraphs (A) through (G), and thus does not fall within the statutory definition of a plant pest as listed in subparagraph (H) of the PPA’s plant pest definition (*i.e.*, “Any article similar to or allied with any of the articles specified in the preceding subparagraphs”). APHIS has determined that the alpha-amylase enzyme engineered into Event 3272 corn is not a plant pest because the alpha-amylase enzyme in Event 3272 corn is not living and thus cannot itself be a living stage of any organism listed in the PPA’s plant pest definition.

Moreover, Event 3272 corn itself is not a plant pest since it is clearly not a living stage of any of the organisms (articles) listed in subparagraphs (A) through (G) of 7 U.S.C. 7702(14). Nor is Event 3272 corn itself the living stage of any article (organism) similar to or allied with any of the articles specified in subparagraphs (A) through (G) as required by subparagraph (H) of 7 U.S.C. 7702(14). Thus, APHIS has likewise determined that Event 3272 corn itself is not a plant pest as defined by the PPA. Nevertheless, APHIS evaluated the ability of Event 3272 corn to harbor plant pests in the Plant Pest Risk Assessment and determined that Event 3272 corn does not harbor any living stage of any of the organisms (articles) that are defined as potential plant pests in subparagraphs (A) through (G). First, APHIS described the genetic material that was inserted into Event 3272 corn, which included sequences from plant pests, and included an assessment analyzing the plant disease risk posed by the genetic sequences. Second, APHIS also analyzed the risk that Event 3272 corn would disseminate plant pests (*i.e.* act as an ‘article’). APHIS concluded that the inserted genetic material in Event 3272 corn does not cause plant disease and Event 3272 corn does not increase susceptibility to plant disease or insect pests, and therefore does not harbor plant pests. (The comments received on the docket

² See <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=APHIS-2007-0016-0175.1>.

³ See <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=APHIS-2007-0016-0222.1>.

during the initial comment period did not dispute or comment on these particular issues related to APHIS' plant pest risk assessment.)

For the reasons explained above, APHIS has determined that neither Event 3272 corn itself, nor the alpha-amylase enzyme in Event 3272 corn, is a plant pest. To make clear APHIS' above determination that neither Event 3272 corn, nor the alpha-amylase enzyme in Event 3272 corn, is a "living stage" of any of the organisms (articles) listed in subparagraphs (A) through (H) of the PPA's plant pest definition, APHIS has revised the plant pest risk assessment for Event 3272 corn to include the PPA's definition of a plant pest. The revised assessment also concludes that neither Event 3272 corn nor the alpha-amylase enzyme in Event 3272 corn is a plant pest because neither Event 3272 corn nor the alpha-amylase enzyme meets the PPA's definition of a plant pest. These revisions to the plant pest risk assessment are for clarity and further explanation, but do not change the overall conclusions made in the draft plant pest risk assessment that Event 3272 corn is unlikely to pose a plant pest risk.

APHIS welcomes additional comment on the issues raised during this process. APHIS is also requesting comment on the revised plant pest risk assessment, and APHIS' conclusion, as explained above, that Event 3272 corn and the alpha-amylase enzyme in Event 3272 corn are not plant pests. APHIS will carefully evaluate all additional comments received during this process, and any other relevant information. All comments received regarding the petition, draft EA, and plant pest risk assessment will be available for public review on the Regulations.gov Web site (see footnote 1 for a link). After reviewing and evaluating the comments on the petition, draft EA, plant pest risk assessment, and other relevant information, APHIS will make its determination, either approving or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Event 3272 corn and the availability of APHIS' written regulatory and environmental decision.

Accordingly, we are reopening the comment period on Docket No. APHIS-2007-0016 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between January 21, 2009 (the day after the close of the original comment period), and the date of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.13.

Done in Washington, DC, this 29th day of May 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9-13055 Filed 6-3-09; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

PowerSouth Energy Cooperative; Notice of Finding of No Significant Impact

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS), an agency delivering the United States Department of Agriculture (USDA) Rural Development Utilities Programs, has made a Finding of No Significant Impact (FONSI) with respect to a request from PowerSouth Electric Cooperative (PowerSouth) for assistance to finance the construction and operation of a new 360 megawatt peak-load natural gas-fired generation facility at PowerSouth's existing McIntosh Power Plant in Washington County, Alabama.

ADDRESSES: The FONSI is available for public review at USDA Rural Utilities Service, 1400 Independence Avenue, SW., Stop 1571, Washington, DC 20250-1571; and at PowerSouth's headquarters office located at 2027 East Three Notch Street, Andalusia, Alabama 36420. To obtain copies of the FONSI or for further information, contact Stephanie Strength, Environmental Protection Specialist, USDA, Rural Utilities Service, 1400 Independence Avenue, SW., Stop 1571, Washington, DC 20250-1571; Telephone: (202) 720-0468 or e-mail: stephanie.strength@wdc.usda.gov; or PowerSouth's headquarters office located at 2027 East Three Notch Street, Andalusia, Alabama 36420.

SUPPLEMENTARY INFORMATION:

PowerSouth is proposing to construct a new 360 megawatt peak-load natural gas-fired generation facility at PowerSouth's existing McIntosh Power Plant with an in-service date of late 2010. The proposed project would consist of two 180 megawatt combustion turbine units operated by natural gas. Burns and McDonnell Engineering Company, Inc., an environmental consulting firm, has prepared an

Environmental Analysis (EA) for RUS. Rural Utilities Service has conducted an independent evaluation of the EA and believes that it accurately assesses the impacts of the proposal and has determined that no significant impacts would result from the construction and operation of the proposal.

Any final action by RUS related to the proposed project will be subject to, and contingent upon, compliance with all relevant Federal environmental laws and regulations and completion of environmental review procedures as prescribed by the 7 CFR part 1794, Environmental Policies and Procedures.

Dated: May 29, 2009.

James R. Newby,

Acting Administrator, Electric Program, Rural Utilities Service.

[FR Doc. E9-13114 Filed 6-3-09; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Lewis & Clark County Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lewis & Clark County Resource Advisory Committee (RAC) will meet on Wednesday, June 10, 2009, from 6 p.m. until 8 p.m., in Helena, Montana. The purpose of the meeting is to conduct welcomes and introductions, review RAC charter, discuss the guidelines for Title II and Title III funding and proposals, discuss operating protocols, brief RAC members on available funding, capture and record preliminary project ideas, discuss outreach process for project proposals, set a next meeting date and receive public comment on the meeting subjects and proceedings.

DATES: Wednesday, June 10, 2009, from 6 p.m. until 8 p.m.

ADDRESSES: The meeting will be held at the USDA-Helena Ranger District office located at 2001 Poplar, Helena, Montana 59601 (MT 59601).

FOR FURTHER INFORMATION CONTACT:

Kathy Bushnell, Committee Coordinator, Helena National Forest, 2880 Skyway Drive, Helena, Montana 59602, 406-495-3747; e-mail: kbushnell@fs.fed.us.

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Welcome and Committee introductions; (2) Review and revise, if necessary, established RAC charter; (3) discussion of requirements related to Title II and