NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

SYNGENTA SEEDS, INC.
ALPHA-AMYLASE MAIZE
EVENT 3272

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS number 05-280-01p) by Syngenta Seeds, Inc. for Event 3272 Maize. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from the deregulation of Event 3272 corn (proposed action). The EA assesses alternatives to the granting of nonregulated status to Event 3272 corn and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Event 3272 Corn
Event 3272 corn is a genetically engineered (GE) *Zea mays* (corn) variety that was genetically engineered to produce thermostable alpha-amylase (AMY797E) and phosphomannose isomerase (PMI) proteins. AMY797E is an enzyme that facilitates the production of ethanol from corn. The intended use of Event 3272 corn is be grown as a specialty corn variety, to be exclusively directed to and utilized in facilities equipped to process corn for ethanol production. The PMI protein is used solely to assist in the isolation of successfully engineered Event 3272 plants by allowing them to utilize the sugar mannose as a sole carbon source. PMI has been used previously in genetically engineered plants that are approved for market use.

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with the environment" (40 CFR § 1508.14).

PURPOSE AND NEED FOR APHIS ACTION

Under the authority of 7 CFR part 340, APHIS has the responsibility for the safe development and use of genetically engineered organisms under the provisions of the Plant Protection Act. APHIS must respond to petitioners that request a determination of the nonregulated status of genetically engineered organisms, including genetically engineered crop plants such as Event 3272 corn. If a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk.

On October 7, 2005, Syngenta Seeds, Inc. filed a petition for a determination of nonregulated status for a corn variety (Event 3272) genetically engineered to produce a microbial enzyme that facilitates ethanol production. Syngenta requests that APHIS make a determination that these corn plants do not pose a plant pest risk, and, therefore, shall no longer be considered regulated articles under 7 CFR part 340.

DECISIONS TO BE MADE

APHIS will use the information from this EA, and the comments it received, to make a determination of whether to grant nonregulated status to Event 3272 corn and also whether to prepare an Environmental Impact Statement in connection with its determination of whether to grant nonregulated status to Event 3272 corn.

Regulatory Authority

Since 1986, the United States government has regulated genetically engineered organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of genetically engineered organisms only when there is evidence of "unreasonable" risk.

The Coordinated Framework explained the regulatory roles and authorities for the three major agencies involved in regulating genetically engineered organisms: USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from genetically engineered crops comply with their obligations under federal food

safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from genetically engineered crops currently on the market in the United States have successfully completed this consultation process.

APHIS is responsible for regulating genetically engineered organisms and plants under the plant pest authorities in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq*.) to ensure that they do not pose a plant pest risk to the environment. Under the Plant Protection Act (PPA), the term "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; any article similar to or allied with any of the articles specified in the preceding paragraphs." (7 USC § 7702 (14). The PPA gives the Secretary broad discretion to regulate plant pests and prohibits persons from importing, exporting or moving in interstate commerce plant pests, except as authorized under general or specific permits and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States. (7 USC § 7711). In enacting the PPA, Congress found that it is the responsibility of the Secretary of Agriculture to facilitate commerce in agricultural products and other commodities that pose a risk of harboring plant pests in a manner that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests and that decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science. (7 USC § 7701 (3), (4)).

APHIS' biotechnology regulations at 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 the importation, interstate movement, or release into the environment (use of a regulated article outside the constraints of a physical confinement that are found in a laboratory, contained greenhouse, a fermenter, or other contained structure) of genetically engineered organisms[2]. A genetically engineered organism is regulated by APHIS if it is a plant pest or if it or a gene donor or vector used in its construction are plant pests listed in 7 CFR 340.2. In addition, a genetically engineered organism can be considered a regulated article if APHIS has reason to believe it presents a plant pest risk.

APHIS' regulations provide for developers of genetically engineered plants to file a petition for nonregulated status (7 CFR 340.6). The developer is required to submit scientific data and other information to demonstrate that the plant does not come within the statutory definition of a plant pest, and, therefore, is no longer subject to APHIS jurisdiction and regulatory oversight.

SCOPE OF THE ENVIRONMENTAL ANALYSIS

[2] A regulated article is any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions. § 340.1

Event 3272 corn is genetically engineered to produce a microbial enzyme that facilitates ethanol production and, based upon information provided by Syngenta, ethanol production is the sole intended use of Event 3272 corn. Therefore, APHIS primarily focused the environmental analysis on those geographic areas that produce corn and are near corn ethanol plants either currently in production or under construction.

Due to the properties of Event 3272 corn, and the contractual obligations between growers and ethanol facilities, ethanol plant managers must make a manufacturing decision to use Event 3272 corn in their facility. Event 3272 corn cannot be used routinely in any and all ethanol plants. The inputs used for ethanol production are specific to each ethanol plant and margins of efficiency and efficacy are tied directly to characteristics of the locally grown corn (e.g., moisture content) and the specific parameters of other inputs used in a particular facility. Although the environmental analysis includes areas of corn production surrounding any corn ethanol plant, the true scope of the environmental consequences is substantially smaller and limited to only those corn production areas that surround an Event 3272-specific ethanol plant. The number of ethanol plants prepared to accept Event 3272 corn is currently limited to one functional ethanol plant and two facilities likely for use in 2011, if nonregulated status is granted, out of a total of 194 corn ethanol plants.

To determine areas of corn production, APHIS used data from the National Agricultural Statistics Service (NASS) 2002 Census of Agriculture to determine where corn is produced in the United States (www.nass.usda.gov, accessed 6/5/2008). NASS has since published the 2007 Census of Agriculture (www.nass.usda.gov, accessed 2/16/2010) but this information has not changed the findings that were determined with the 2002 data.

The list of 49 states that produce corn grain is found in Table 1, according to the 2002 and 2007 Censuses of Agriculture. As of February 2011, there are at least 194 operational corn ethanol plants with 7 plants under construction (www.ethanolrfa.org). The states that have operational ethanol plants or have plants that are under construction that use corn as the input are also listed in Table 1.

Table 1. States that grow corn according to the 2002 and 2007 Censuses of Agriculture, and whether the state also has an active corn ethanol facility or one under construction (according to February 2011 data from www.ethanolrfa.org). The states that grow corn and have an existing corn ethanol facility or one under construction will be included in the analysis for the environmental effects for Event 3272 corn.

Corn Growing State	Corn Ethanol Facility?	Corn Growing State	Corn Ethanol Facility?
Alabama	No	Nebraska	Yes
Arizona	Yes	Nevada	No
Arkansas	No	New Hampshire	No
California	Yes	New Jersey	No
Colorado	Yes	New Mexico	Yes
Connecticut	No	New York	Yes
Delaware	No	North Carolina	Yes
Florida	No	North Dakota	Yes

Corn Growing State	Corn Ethanol Facility?	Corn Growing State	Corn Ethanol Facility?
Georgia	Yes	Ohio	Yes
Hawaii	No	Oklahoma	No
Idaho	Yes	Oregon	Yes
Illinois	Yes	Pennsylvania	Yes
Indiana	Yes	Rhode Island	No
Iowa	Yes	South Carolina	No
Kansas	Yes	South Dakota	Yes
Kentucky	Yes	Tennessee	Yes
Louisiana	No	Texas	Yes
Maine	No	Utah	No
Maryland	No	Vermont	No
Massachusetts	No	Virginia	Yes
Michigan	Yes	Washington	No
Minnesota	Yes	West Virginia	No
Mississippi	Yes	Wisconsin	Yes
Missouri	Yes	Wyoming	Yes
Montana	No		

The corn-growing counties within the 28 states that have a corn ethanol plant or one under construction are listed in Appendix B of the EA. These 2360 counties in 28 states are included in the environmental effects analysis for the alternatives, even though the entirety of this area will not include Event 3272 corn or Event 3272 corn-specific ethanol facilities.

Document History and Public Involvement

On October 7, 2005 APHIS BRS received a petition from Syngenta Seeds, Inc. seeking a determination of nonregulated status for Event 3272 corn. A revised version of the petition was received on September 10, 2006. BRS reviewed the information submitted and deemed the petition complete on January 11, 2007. Based upon information provided in the petition, BRS prepared a draft EA and Plant Pest Risk Assessment (PPRA). The petition, draft EA, and PPRA were made available to the public for a 60-day public comment period in the Federal Register on November 19, 2008 (73 FR 69602-69604). APHIS received numerous comments questioning the conclusion of the PPRA that event 3272 corn does not pose a plant pest risk. In response to these comments, APHIS revised the environmental assessment and PPRA to better explain the PPA's statutory definition of a plant pest and why event 3272 corn is not a plant pest under that authority. Subsequently, in the Federal Register (74 FR 26832-26835), APHIS reopened the public comment period for an additional 30 days, to allow interested persons additional time to prepare and submit comments on the revised documents. In total, over 13,000 comments were received from the public during the two comment periods. All comments were carefully evaluated to identify new information and any new issues raised by the comments as well as additional regulatory alternatives that should be evaluated in this assessment. Responses to the comments are attached to this FONSI.

APHIS received a letter from Syngenta dated December 7, 2010 containing additional information generated as a result of discussions between Syngenta and other commercial

entities[3]. The letter discusses both additional technical data related to the risk of the misdirection of Event 3272 corn and additional specificity about Syngenta's closed-loop system. In support of the information and analysis presented in the EA, the letter focused primarily on providing additional evidence that the deregulation of Event 3272 will not have an effect on other corn milling processes. The letter emphasized that, given the constraints of Syngenta's contract-based closed-loop system and the properties of Event 3272 corn, the risks of misdirection of Event 3272 corn are limited to a very few food processing systems that have specific combination of moisture, pH, time, and temperature. Specifically, the letter provided:

- additional data related to both the probability and risks of the potential misdirection of Event 3272 corn.
- further details regarding Syngenta's contract-based closed-loop system in place for all users of Event 3272 corn,
- an update to the current commercial mechanisms available to rapidly test for the presence of Event 3272, and
- results of product-quality tests looking at the possible influence of Event 3272 corn on dry milling processes and milled product applications.

In addition to the Syngenta letter referenced above, APHIS also received during the initial 60-day public comment period, a comment from Corn Refiners Association (CRA) that expressed concerns about the potential impacts of Event 3272 corn on corn-derived food processing, particularly corn starch processing. In March 2009, APHIS met with officials from the North American Millers' Association (NAMA), the National Grain and Feed Association (NGFA), and the North American Grain Export Association (NAGEA) to discuss topics of interest and concern. Based in part on these discussions, APHIS decided to re-open the public comment period for an additional 30 days and allow the public to comment on the issues and concerns raised. In the Federal Register notice re-opening the comment period (74 Fed. Reg. 26832-26835 (June 4 2009)), APHIS sought to better explain the application of the statutory definition of the term "plant pest" as set forth in the PPA and solicited additional public comments on the issues and concerns.

After the closing of the second comment period, APHIS drafted a response to all comments received including those regarding concerns of misdirected Event 3272 corn (see Response to Comments). Prior to the publication of the Final EA, but after the closing of the comment period, APHIS received additional information from both Syngenta and members of the corn processing community. Additional information was received as a result of meetings of the USDA with representatives from Syngenta (December 2009, January 2010, May 2010), and from the grain trader and milling organizations (November 2009, May 2010) to discuss concerns and to explore potential solutions. Additionally APHIS has encouraged and facilitated other meetings and discussions between Syngenta and the organizations representing grain traders and millers, including meetings between USDA and industry participants on both August 5, 2010 and December 15, 2010.

[3] Syngenta's December 7, 2010 letter has been included as part of the Docket (APHIS-2007-0016-287)

In a letter dated December 7, 2010, Syngenta submitted to APHIS additional information to support its position that there is minimal and negligible risk that misdirected Event 3272 corn would impact downstream users and also that the likelihood of misdirection will be quite small, and providing updates to the proposed "closed-loop" Event 3272 corn production management system. Included in this letter, and as a response to concerns presented by NAMA and other corn processors, were dozens of experimental test results provided by Syngenta, with findings demonstrating that, except under specific pH, moisture, and temperature conditions, the presence of the thermostable amylase enzyme present in Event 3272 corn would not impact most corn processing procedures, even at unlikely concentrations levels of Event 3272 corn comingled with other corn. Syngenta claims that the findings of these studies demonstrate that only a small segment of dry milled products (specifically table grits due to the ranges of pH, moisture, and temperature ranges used for production) could be impacted, and that even this impact could be effectively managed through the other commercial measures in place for Event 3272 corn production and distribution. These other commercial measures include the availability of tools for testing corn and corn products for the presence of amylase and the application of Syngenta's "closed-loop" production system.

In addition to the information that was included in the Draft EA (Appendix G) on this "closed-loop" system for Event 3272, in letters dated December 7, 2010, December 20, 2010, and February 1, 2011 Syngenta provided further assurances, including an expressed commitment to not license or approve grower contracts to produce Event 3272 within 40 miles (to avoid the "draw area") of wet or dry mills, and the development of an "Advisory Council" comprised of industry parties to monitor the "closed-loop" production system, to mitigate any potential economic and market impacts. The letter also discusses the influences of the U.S. grain handling system to dilute the concentrations of misdirected corn.

After APHIS made the December 2010 letter from Syngenta publicly available, response letters from NAMA (January 26 and February 1, 2011) and CRA (January 31, 2011) were received and also made publicly available. The letters restated these industry parties' position that deregulation of Event 3272 is still not supported and additionally criticized the December letter from Syngenta, requesting more details, studies, and time to interpret the results. Specific criticisms were as follows: 1) studies on milling were looking at milling yield results but should have also included milling processes; 2) common milling processes do include high moisture levels and/or temperatures, along with a wide pH ranges, that were not sufficiently analyzed; 3) the studies presented in the letter had unclear or insufficient statistical power; 4) the study did not sufficiently analyze the impacts that Event 3272 might have on the consistency of extruded corn products and provided results raise concern regarding bulk density; 5) important parameters related to viscosity measurements were not provided and the provided results raised concerns related to unacceptable variations of viscosity; 6) the impact to 'table grits' as specified in the letter from Syngenta is significant because of the wide range of products and applications that depend on the production of grits, and the data presented regarding grits production are not sufficient to make an accurate assessment; 7) Syngenta's model for risk mitigation by containment and dilution is not adequate to control the distribution of Event 3272 corn or to prevent economic losses that are likely to arise from product displacement; 8) the costs and other requirements for testing (and disposal of products mixed with Event 3272 corn) are considerable and would be borne by those at risk not Syngenta; 9) impacts to USAID blended foods were not

sufficiently analyzed; 10) changes to starch viscosity that could result from misdirected Event 3272 corn could adversely affect downstream commercial processing; 11) an analysis of the potential effects of Event 3272 corn on corn gluten meal is still needed; 12) testing viscosity using the suggested method is impractical, could incur significant costs, and may even be impossible, for certain commodity streams that could be affected; 13) the commercial effect of misdirected corn could have significant repercussions to material supply chains; and 14) several concerns were raised about the "closed loop" management system, including an unclear mandate on whether Syngenta is obligated to purchase all excess Event 3272 corn produced, insufficient financial incentives to growers of Event 3272 corn to assure delivery of 100% of corn to approved locations, and the insufficiency of the "draw area" restrictions due to the varied sources of corn to milling operations. The letter from CRA also encourages the USDA Agricultural Marketing Service to be an active participant in reviewing and monitoring the stewardship program for Event 3272 corn (or similar traits), which would allow the USDA to better understand the issues associated with adding new output traits that require special handling to the corn market. The letter also expressed concerns about a potential regulatory "gap" that would allow significant disruptions in food and other industries. The position taken by CRA is that no action should be taken to deregulate Event 3272 corn until sufficient and satisfactory studies are completed and potential economic impacts thoroughly considered and resolved.

Major Issues Addressed in the EA

The EA describes the alternatives considered and evaluated using the identified issues. Issues considered in the EA were developed based APHIS' authority pursuant to the PPA, the regulations at 7 CFR part 340, the requirements of the National Environmental Policy Act (NEPA), comments and information received from the public in response to scoping and publication of two draft EAs, and the petition for deregulation and supporting materials submitted by Syngenta Seeds, Inc. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Management Considerations:

- Corn Production
- Cropping Practices
- Tillage Practices
- Pesticide Use
- Specialty Corn and Processing
- Ethanol Production

Public Health Considerations

- Human Health
- Worker Safety
- Animal Feed and DDGS

Environmental Considerations

- Gene Movement (Pollen flow)
- Water Use in Ethanol Production
- Animals
- Plants

- Biodiversity
- Soil
- Conservation Reserve Program

Alternatives that were fully analyzed
The EA analyzes the potential environmental consequences of granting nonregulated status to Event 3272 corn. In order for Event 3272 corn to be granted nonregulated status, it must be found to be unlikely to pose a plant pest risk. Based on the analysis provided in the plant pest risk assessment (USDA-APHIS 2009), APHIS has determined that Event 3272 corn does not pose a plant pest risk.

The EA thus analyzed two alternatives: (1) no action and (2) to grant nonregulated status to Event 3272 corn.

Alternative A. No Action: Continuation as a Regulated Article
Under the "no action" alternative, APHIS would deny the petition to grant nonregulated status to Event 3272 corn. Event 3272 corn would continue to be subject to regulation pursuant to 7 CFR part 340. The company would have to continue to request permits and notifications for new introductions of Event 3272 corn plants. Permit conditions would be specified by APHIS. These conditions would be designed to confine Event 3272 corn. The size of planting would be limited to help maintain confinement. In addition, the number of permits granted would be limited by agency resources, both in terms of the number of permits which could be reviewed by APHIS, and in APHIS' ability to inspect the field trials and enforce compliance with regulations.

As such, it would be difficult for the company to commercialize Event 3272 corn under the permit or notification process. This alternative is not the preferred alternative because APHIS has concluded through a plant pest risk assessment (USDA-APHIS 2009) that Event 3272 corn does not pose a plant pest risk. Choosing this alternative would not be consistent with the purpose and need of APHIS to allow for the safe development and use of GE organisms given that Event 3272 corn does not pose a plant pest risk.

Alternative B. Preferred Alternative: Determination that Event 3272 Corn Plants are No Longer Regulated Articles, in Whole
Under this alternative, Event 3272 corn would no longer be a regulated article under the regulations at 7 CFR part 340. Event 3272 corn should be granted nonregulated status because APHIS has concluded that this GE organism does not pose a plant pest risk (USDA-APHIS 2009). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Event 3272 corn, or progeny derived from these events. This alternative best meets the purpose and need for agency action. The agency's need is to make a decision on the petition that is consistent with the regulatory requirements in 7 CFR part 340. Granting nonregulated status to Event 3272 corn is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a comprehensive list of alternatives that might be analyzed as part of the NEPA decision process for Event 3272 corn. The agency evaluated each alternative on the basis of consistency with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. At the same time, the agency also evaluated each alternative on the basis of environmental safety, efficacy, and practicality to identify which alternatives would be further considered during the NEPA decision process. Based on these dual evaluations, APHIS rejected several alternatives. In the interest of transparency, these alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any Event 3272 corn from being released.
In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of Event 3272 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate because it has concluded that Event 3272 corn does not pose a plant pest risk (USDA-APHIS 2009).

Isolation distance between Event 3272 corn and non-GE corn production and Geographic restrictions
In response to public concerns regarding possible gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance greater than 660 feet separating Event 3272 corn from non-GE corn production. However, because Event 3272 corn does not pose a plant pest risk (USDA-APHIS 2009), an alternative based on requiring isolation distances was viewed as inconsistent with the current regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of Event 3272 corn based on production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for Event 3272 corn, there are no geographic differences associated with any identifiable plant pest risks for Event 3272 corn (USDA-APHIS 2009). This alternative was rejected and not analyzed in detail because APHIS has concluded that Event 3272 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' regulatory authority and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to act on the petition in accordance with its regulatory authorities. APHIS is not expecting significant effects that would minimize with isolation distances or geographic restrictions. However, individuals might choose on their own to geographically isolate their non-GE corn production from Event 3272 corn, or to use isolation distances and other management practices to minimize gene movement between corn fields. Information to assist growers in making informed management decisions for Event 3272 corn is available from Association of Official Seed Certifying Agencies (AOSCA 2004) and Syngenta (*see* Appendix D and Appendix G in the EA).

Requirement of testing for Event 3272 corn
During the comment periods for other petitions for granting nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. However, there are no nationally-established regulations requiring testing or limits of GE material in non-GE systems. The imposition of any such testing requirements would be both novel and extremely difficult to implement and maintain. Additionally, because Event 3272 corn does not pose a plant pest risk (USDA-APHIS 2009), the imposition of testing requirements is inconsistent with APHIS' regulatory authority and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, the requirement of testing for Event 3272 corn would not meet APHIS' purpose and need to act on the petition in accordance with its regulatory authorities

Environmental Consequences of APHIS' Selected Action
The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	*Outcome if Alternative A No Action is Chose*	*Outcome if Alternative B Deregulation is Chosen*
Meets Purpose and Need and Objectives	No	Yes
Is there a plant pest risk?	No (USDA-APHIS 2009)	No (USDA-APHIS 2009)
Management Practices		
Corn Production	No change in U.S. corn acreage. No change in use of GE or non-GE corn varieties during corn production. No change in corn acreage for ethanol production.	No change in U.S. corn acreage. No change in use of GE or non-GE corn varieties during corn production. U.S. corn acreage for ethanol production may decrease due to increased ethanol efficiency of Event 3272 corn.
Cropping Practices	No change in cropping practices in GE and non-GE farming systems.	No change in cropping practices for in GE and non-GE farming systems.
Pesticide Use	No change in pesticide use in GE and non-GE farming systems.	No change in pesticide use in GE and non-GE farming systems.
Specialty Corn Uses and Processing	Economic effects of misdirected specialty corn varieties may cause effects in food processing, but effects would not be caused by Event 3272 corn.	Economic effects of misdirected specialty corn varieties may cause effects in food processing, and effects may be caused by Event 3272 corn. The magnitude of the consequences of the effects has not been studied.
Ethanol Production	2.8 gallons/bushel if no	2.8 gallons/bushel + 2% or

Attribute/Measure	*Outcome if Alternative A No Action is Chose*	*Outcome if Alternative B Deregulation is Chosen*
	ethanol plants are converted for Event 3272 corn use.	greater increase when ethanol plants are converted for Event 3272 corn use.
Human and Animal Health		
Public Health: Risk to Human Health	Minimal risk due to corn consumption.	Minimal risk due to Event 3272 corn consumption.
Public Health: Risk to Worker Safety	Minimal risk due to corn production; Higher risk in ethanol production.	Minimal risk due to Event 3272 corn production; Decreased risk in Event 3272 corn converted ethanol facilities.
Animal Feed: DDGS	Minimal risk due to the use of corn in DDGS.	Minimal risk due to the use of Event 3272 corn in DDGS.
Environment		
Gene Movement	Low risk of gene flow from GE corn to non-GE corn. No risk of gene flow from GE corn to native plants.	Low risk of gene flow from GE corn to non-GE corn. No risk of gene flow from Event 3272 corn to native plants.
Water use	Water is required for production of GE and non-GE corn and for ethanol production.	The same amount of water used to grow corn under the No Action alternative is needed to grow Event 3272 corn. Less water is required for ethanol facilities converted for Event 3272 corn use.
Animals	Minimal risk due to corn consumption.	Minimal risk due to Event 3272 corn consumption.
Plants	Weeds and other plants inhabit agricultural areas surrounding corn production and will be managed.	The same amount of weed and plant management used to grow corn under the No Action alternative will occur in Event 3272 corn production.
Biological Diversity	Animals will inhabit agricultural areas surrounding corn production and will be managed.	The same amount of animal management used to grow corn under the No Action alternative will occur in Event 3272 corn production.
Soil biology	Soil modification may occur during corn production.	The same amount of soil modification used to grow corn under the No Action alternative may occur during Event 3272 corn production.
CRP Acreage	Corn acres may be enrolled or	The same amount of corn

Attribute/Measure	*Outcome if Alternative A No Action is Chose*	*Outcome if Alternative B Deregulation is Chosen*
	un-enrolled in CRP.	acres enrolled in CRP under the No Action alternative will be enrolled under this alternative. Fewer corn acres may be un-enrolled in CRP.
Other Regulatory Approvals for Event 3272 Corn		
United States	FDA consultation complete. No requirement for EPA review	
Other Countries	Canada, Philippines, Australia, New Zealand, Mexico, Japan, Taiwan, and Russia	
Compliance of Granting Nonregulated Status to Event 3272 Corn with Other Laws		
Endangered Species Act, Clean Water Act, Clean Air Act, Executive Orders	Fully compliant	

Downstream corn grain processing facilities
In the draft EA, APHIS examined the possible impacts of Event 3272 corn if it were to be misdirected into other specialty corn systems. APHIS also determined that the "closed-loop" system identified by Syngenta is consistent with practices in place for other types of specialty corn. After publication of the draft EA, considerable concern was raised over this issue and related issues by various organizations involved with the processing of corn for various commodity uses. These groups included NAMA, CRA, NGFA, NAGEA, and the Pet Food Institute. Their primary concern is regarding the impact that the thermostable enzyme could have on milling and food processing operations if material derived from Event 3272 were to be mixed after harvesting with other corn products. The specific concern is that even low presence of the enzyme could impact the production of products such as starch for food and industrial applications, and that this would have a potential significant economic impact, causing meaningful financial harm to the processing facility or disrupting supply.

USDA-APHIS has been asked by the above organizations to delay the granting of nonregulated status to Event 3272 corn until this potential impact can be adequately analyzed and resolved. APHIS has addressed many of these concerns in its response to public comments received after release of the Draft EA (see Response to Comments, 3). In light of the comments received from CRA, NAMA, NAGEA, NGFA, and the Pet Food Institute, APHIS has decided to expand the discussion in the Final EA on "Specialty Corn Uses and Processing" with a broader analysis of potential impacts of Event 3272 corn if it is misdirected outside the intended marketing channels.

Finding of No Significant Impact
The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments and agricultural workers; ethanol production systems, including plant workers; related ethanol production by-products; human food and animal feed production systems; and foreign and domestic commodity markets. As described in Chapter 4 of the EA, Event 3272 corn is genetically engineered to produce a microbial enzyme that facilitates ethanol production and, based upon information provided by Syngenta, ethanol production, and feed use of the byproducts of ethanol production (DDGS for animal consumption) are the intended use of Event 3272 corn. Therefore, APHIS environmental analysis primarily focused on those geographic areas that produce corn and are near corn ethanol plants either currently in production or under construction.

Due to the properties of Event 3272 corn, and the contractual obligations between growers and ethanol facilities, ethanol plant managers must make a manufacturing decision to use Event 3272 corn in their facility. Event 3272 corn cannot be used routinely in any and all ethanol plants. The inputs used for ethanol production are specific to each ethanol plant and margins of efficiency and efficacy are tied directly to characteristics of the locally grown corn (e.g., moisture content) and the specific parameters of other inputs used in a particular facility. Although the environmental analysis includes areas of corn production surrounding any corn ethanol plant, the scope of the affected environment is substantially smaller in reality and limited to only those corn production areas that surround an Event 3272-specific ethanol plant. Currently there is only one ethanol plant in operation prepared to accept Event 3272 corn, and two other ethanol plants may become operational in 2011, if nonregulated status is granted, out of a total of 194 corn ethanol plants.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision*:*

1. *Impacts that may be both beneficial and adverse.*
Granting nonregulated status to Event 3272 corn will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty corn varieties or corn production systems, and no significant economic impact on corn processing systems. As discussed in Chapter 4 of the EA, granting nonregulated status to Event 3272 corn will not directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. Moreover, granting nonregulated status will not change cultivation areas for corn production in the U.S or corn production practices (i.e. crop rotation, tillage practices, and pesticide use). Additionally, there are no foreseeable changes to the availability of GE, conventional, organic or specialty corn varieties on the market.

Granting nonregulated status to Event 3272 corn may provide economic benefits in terms of ethanol production and ethanol production by-products. Using Event 3272 corn in the corn ethanol process may save water and increase ethanol efficiency (more ethanol per bushel of Event 3272 corn than from non-Event 3272 corn). Because of the changes in

the corn ethanol process when Event 3272 corn is used, worker safety risks are decreased because less dangerous chemicals are used during ethanol production.

Industry stakeholders have expressed economic concerns that Event 3272 corn containing amylase enzyme could become misdirected to corn wet-milling processes, which could lead to quality-control issues in the wet-milling refining and processing of corn products. Specialty corn, like Event 3272 corn, is regularly grown, harvested, and transported to the appropriate processing facilities under closed loop or identity preservation systems. The types of economic, distribution, and quality control issues that these stakeholders are concerned about, such as misdirection of specialty corn after it has been planted, grown, harvested and transported, already exist. Based upon available information provided to APHIS as a result of 2 public comment periods and ongoing discussions with industry personnel with expertise in corn milling and processing, APHIS has not been presented with concrete evidence to support concerns related to the magnitude of economic risks to the wet-milling industry.

As discussed in response to public comment #3, because Event 3272 corn is a value-added corn product, with a price incentive for farmers to grow this product, Event 3272 corn production will be grown under a 'closed loop' system as described in the EA. Closed-loop systems are typical and familiar production methods used routinely in the production of specialty crops, including corn. Event 3272 corn is one of many specialty corn varieties that will be planted, grown, harvested, and transported off the farm using a closed-loop system. However, once the truckload of corn has left the farm, it is possible that Event 3272 corn may be delivered to an incorrect facility. The economic and marketing effects of misdirecting Event 3272 corn to a food or feed corn processing facility, as opposed to an intended corn ethanol facility, are similar to the economic and marketing effects that occur when other specialty corn is shipped to the incorrect facility, or when manufacturing ingredients end up at an incorrect processing plant.

2. *The degree to which the proposed action affects public health or safety.*

The proposed action to grant nonregulated status to Event 3272 corn would have no significant impacts on human or animal health. Alpha-amylase corn event 3272 is not materially different in composition, safety, or any other relevant parameter from corn now grown, marketed, and consumed. The data presented in the petition suggests there is no difference in compositional and nutritional quality of Event 3272 corn compared to conventional corn, apart from the presence of AMY797E and PMI. Although some of the variables measured by the applicant showed statistically significant differences between Event 3272 corn and the nontransgenic hybrid controls (Tables 6-1 to 6-6, pages 70-76, of the petition), none of the values for the forage and grain composition characteristics was outside the range of natural variability of conventional corn as found in the International Life Sciences Institute Crop Composition Database (OECD 2003, Ridley et al. 2004, ILSI 2006) or in the OECD consensus document on corn (OECD 2003) composition. Event 3272 corn does not express additional proteins, natural toxicants, allelochemicals, pheromones, hormones, etc. that could directly or indirectly affect humans or other animals. Thus, the composition of Event 3272 corn is not biologically different than conventional corn. Based on the assessment of laboratory data provided by Syngenta in the submitted petition and an analysis of the scientific literature

(USDA-APHIS 2009), along with the completion of the consultation process with FDA regarding Event 3272 corn (Appendix H of the EA), and taking into consideration that other countries have also found Event 3272 corn safe for food and feed use (Table 1 of the EA), APHIS has concluded that the proposed action to grant nonregulated status to Event 3272 corn would have no significant impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic area such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be significantly affected by the granting of nonregulated status of Event 3272 corn. Event 3272 corn will only be grown in areas suitable for the production of corn. There is no significant difference in performance or agricultural practices for the growth of Event 3272 corn compared to other common corn varieties, and no natural resources or land usage will be significantly altered through the production of Event 3272 corn.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment from the granting of nonregulated status of Event 3272 corn are not highly controversial. Although there is opposition to the granting of nonregulated status to Event 3272 corn, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. Granting nonregulated status to Event 3272 corn does not change the amount of corn production in the U.S. Event 3272 corn will not change the agronomic and cultivation practices for producing GE or non-GE corn, including cropping practices, pesticide uses, or corn acreage placed in Conservation Reserve Program. Water use during ethanol production using Event 3272 corn may decrease compared to ethanol production using non-Event 3272 corn. The effect of Event 3272 corn on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. During the public comment periods APHIS received many comments expressing generic, nonspecific concerns over possible gene flow, disruption to organic farming practices, and concerns for food and environmental safety. These public comments did not register any specific factual concerns with the data provided APHIS for this crop or its analysis. APHIS has addressed these concerns in Chapter 4 of the EA and in the response to public comments document based on scientific evidence found in peer-reviewed, scholarly, scientific journals.

As noted above, there is opposition to granting nonregulated status to Event 3272 corn because of potential economic concerns resulting from potential quality control issues in corn processing facilities. Those members of the corn processing industry are opposed to Event 3272 corn because they fear the amylase enzyme present in Event 3272 corn could become present in corn wet-milling processes, and that such misdirection could lead to quality-control issues for them in the wet-milling refining and processing of certain corn-based products. Specialty corn, like Event 3272 corn, is regularly grown, harvested, and transported to the appropriate processing facilities under closed loop or identity preservation systems. The types of economic, distribution, and quality control issues that these stakeholders are concerned about, such as misdirection of specialty corn, already

exist. Based upon available information provided to APHIS as a result of 2 public comment periods and ongoing discussions with industry personnel with expertise in corn milling and processing, APHIS has not been presented with concrete evidence to support concerns related to the magnitude of economic risks to the wet-milling industry.

As discussed in response to public comment #3, because Event 3272 corn is a similar to other value-added corn product, with a price incentive for farmers to grow this product, Event 3272 corn production will be grown under a 'closed loop' system as described in the EA. Closed-loop systems are typical and familiar production methods used routinely in the production of specialty crops, including corn. Thus the use of closed-loop systems is not controversial. Event 3272 corn is one of many specialty corn varieties that will be planted, grown, harvested, and transported off the farm using a closed-loop system. However, once the truckload of corn has left the farm, it is possible that Event 3272 corn could be delivered to an incorrect facility. The economic and marketing effects of misdirecting Event 3272 corn to a food or feed corn processing facility, as opposed to an intended corn ethanol facility, are similar to the economic and marketing effects that occur when other specialty corn is shipped to the incorrect facility, or when manufacturing ingredients end up at an incorrect processing plant. Although APHIS has not been presented with any substantial evidence to support the claims of significant risk of Event 3272 corn adversely affecting wet-milling processes, growing Event 3272 corn under a 'closed loop' system will reduce any potential economic impacts to non-event 3272 corn varieties.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. Granting nonregulated status to Event 3272 corn does not change the amount of corn production in the U.S. Event 3272 corn will not change the agronomic and cultivation practices for producing GE or non-GE corn, including cropping practices, pesticide uses, or corn acreage placed in Conservation Reserve Program. Water use during ethanol production using Event 3272 corn may decrease compared to ethanol production using non-Event 3272 corn. The effect of Event 3272 corn on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter 4 of the EA, well established management practices, production controls (including use of close loop system), and production practices (GE, conventional, and organic) are currently being used in corn production systems in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional corn, Event 3272 corn, or produce corn using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural corn production. Additionally, most of the corn (approximately 86%) grown in the U.S. is GE (http://www.ers.usda.gov/Data/biotechcrops/), and therefore GE composes the large majority of corn currently used to produce ethanol from corn. Given the extensive experience that APHIS, stakeholders, growers, and processors have in dealing with the use of GE corn products, the possible effects to the human environment from the release

of a an additional GE corn product are already well known and understood. Therefore the impacts are not highly uncertain, and do not involve unique or unknown risks. The availability of Event 3272 corn offers growers another GE choice in addition to the options already available.

As noted above, there is opposition to granting nonregulated status to Event 3272 corn because of potential economic concerns resulting from potential quality control issues in corn processing facilities. Those members of the corn processing industry are opposed to Event 3272 corn because they fear the amylase enzyme present in Event 3272 corn could become present in corn wet-milling processes, which, they believe, may lead to quality-control issues in the wet-milling refining and processing of corn products. Specialty corn, like Event 3272 corn, is regularly grown, harvested, and transported to the appropriate processing facilities under closed loop or identity preservation systems. The types of economic, distribution, and quality control issues that these stakeholders are concerned about, such as misdirection of specialty corn, already exist.

As discussed in response to public comment #3, because Event 3272 corn is a value-added corn product, with a price incentive for farmers to grow this product, Event 3272 corn production will be grown under a 'closed loop' system as described in the EA. Closed-loop systems are typical and familiar production methods used routinely in the production of specialty crops, including corn. Event 3272 corn is one of many specialty corn varieties that will be planted, grown, harvested, and transported off the farm using a closed-loop system. However, once the truckload of corn has left the farm, it is possible that Event 3272 corn could be delivered to an incorrect facility. The economic and marketing effects of misdirecting Event 3272 corn to a food or feed corn processing facility, as opposed to an intended corn ethanol facility, are similar to the economic and marketing effects that occur when other specialty corn is shipped to the incorrect facility, or when manufacturing ingredients end up at an incorrect processing plant. Based upon available information provided to APHIS as a result of 2 public comment periods and ongoing discussions with industry personnel with expertise in corn milling and processing, APHIS has not been presented with concrete evidence to support concerns related to the magnitude of these known economic risks to the wet-milling industry.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
The proposed action would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. APHIS regulations at 7 CFR part 340 regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A person may petition the agency pursuant to 7 CFR § 340.6 to evaluate submitted data, determine whether a particular regulated article is unlikely to pose a plant pest risk, and whether the agency will grant the petition for determination of nonregulated status. Following § 340.6, each petition describes information such as the plant pest components of the regulated article, if the regulated article causes disease and changes in pest susceptibilities, the composition and physical characteristics of the regulated article, agricultural and cultivation practices, and analyses of any and all deleterious effects on plants, nontarget organisms, and the environment that may have been observed during field tests of the regulated article..

After receipt of a petition, BRS makes an independent determination on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is included for each environmental issue analyzed in Chapter 4 of the EA. If granted nonregulated status, Event 3272 corn may be stacked (combined) with conventional varieties or other nonregulated GE corn varieties by traditional breeding techniques, resulting in amylase corn that, for example, may also be resistant to herbicides or insects. Syngenta currently has four GE corn varieties that may be stacked with Event 3272 corn: three varieties that have an insect-resistance trait (Bt11, Mir604, and Mir162) and one variety that has an herbicide-tolerance trait (GA21). These corn lines (Bt11, MIR604, Mir162, and GA21) have all been granted non-regulated status, and the environmental assessments and FONSI determinations conducted by APHIS for each of these products can be found at http://www.aphis.usda.gov/brs/not_reg.html. There is no guarantee that Event 3272 corn will be stacked with any particular deregulated GE variety, as company plans and market demands play a significant role in those business decisions. Postulating and predicting any and all potential combinations of stacked varieties that could be created using both deregulated GE corn varieties and also non-GE corn varieties is too hypothetical and purely speculative.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*

Granting nonregulated status to Event 3272 corn would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. Granting nonregulated status to Event 3272 corn will not cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. Event 3272 corn will also not change future cultivation areas for corn production in the U.S. This corn variety does not express new agronomic traits or resistance traits useful against a geographically limiting insect species. Consequently, growers will not likely plant new land beyond that currently or historically used for corn production if this trait is made commercially available.

9. *The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

APHIS evaluated the potential for negative effects on federal threatened and endangered species as listed by the U.S. Fish and Wildlife Service from cultivation of Event 3272 corn and its progeny and determined that the release of Event 3272 corn, following a determination of nonregulated status, would have no effect on federally listed threatened

or endangered species or species proposed for listing, nor is it expected to adversely modify designated critical habitat or habitat proposed for designation, compared to current agricultural practices (see section on Threatened and Endangered Species, pages 54-56 of the EA).

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*
The proposed action would be in compliance with all federal, state, and local laws. The proposed action to grant nonregulated status to Event 3272 corn and remove this GE corn variety from APHIS' regulatory oversight would be carried out in accordance with 7 CFR part 340. Event 3272 corn has successfully completed the consultation process with the FDA concerning the food and feed safety (Appendix H of the EA). Event 3272 corn does not contain any genetically engineered pesticides or tolerance to herbicides; thus EPA consultation is not required for this product. There are no other Federal, state, or local permits that are needed prior to the implementation of this action. A list of the current status of U.S. and international approvals is found in Table 1 of the EA.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative B (Determination that Event 3272 Corn Plants are No Longer Regulated Articles, in Whole). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative B is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with Event 3272 corn, the continued regulated status of Event 3272 corn would be inconsistent with the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. For the reasons stated above, I have determined that granting nonregulated status to Event 3272 corn will not have any significant environmental effects.

Michael C. Gregoire — 2-11-2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

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Response to Comments to Docket APHIS-2007-0016, 73 FR 69602-69604, 74 FR 26832-26835
USDA, APHIS, BRS Petition 05-280-01p
Final Environmental Assessment
Final Plant Pest Risk Assessment

On November 19, 2008, APHIS published a notice in the *Federal Register* (73 FR 69602-69604, docket No. APHIS-2007-0016) announcing the availability of a draft environmental assessment (EA), and plant pest risk assessment for a Syngenta Seeds, Inc. petition for nonregulated status of corn designated as transformation event 3272. Event 3272 corn has been genetically engineered to produce a microbial enzyme (alpha-amylase) that facilitates ethanol production. APHIS stated that the 60-day comment period would end January 20, 2009. On June 4, 2009, APHIS published a notice in the Federal Register (74 FR 26832-26835) to announce a reopening of the public comment period for this docket for an additional 30 days, closing on July 6, 2009.

APHIS reviews a petition to determine if it should continue to consider the genetically engineered (GE) organism to be a regulated article under APHIS' biotechnology regulations (7 CFR part 340). Under these regulations, a GE organism is considered to be a regulated article (as defined in § 340.1) if:

> "(1) The organism has been altered or produced through genetic engineering from an organism (donor, vector, or recipient);
>
> a. That is included in the list of genera and taxa in §340.2 and such organism meets the definition of a plant pest; or
>
> b. Is an unclassified organism and/or an organism whose classification is unknown; or
>
> (2) The product contains such an organism (described in (1)); or
>
> (3) Any other organism or product (not included in (1) or (2)) altered or produced through genetic engineering, which the Administrator determines is a plant pest or has reason to believe is a plant pest." (52 FR 22892)

Prior to making a decision on a petition to grant nonregulated status to a regulated article, APHIS prepares a risk assessment to evaluate whether the regulated article poses a risk as a plant pest. APHIS also typically prepares an EA to evaluate whether there are significant impacts on the environment arising from such a decision to grant nonregulated status ("deregulation"). APHIS prepares the EA as part of its obligation to meet the requirements of the National Environmental Policy Act (NEPA) of 1969. As part of the process, APHIS considers public comments on the petition (as stated in 7 CFR 340.6) and plant pest risk assessment, as well as the draft EA.

APHIS received over 13,000 comments on the petition, plant pest risk assessment, and the draft EA during the comment period that closed on January 20, 2009. The majority of comments, more than 12,000, opposed deregulation and was received as form letters raising essentially identical points that stated general opposition to the use of any genetically engineered plants. Several individuals and organizations opposed to granting nonregulated status to Event 3272 corn also submitted other documents, including many popular press articles or documents published by those opposed to genetic engineering of plants.

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 ethanol producers, as well as the ability to meet biofuel production mandates and to promote international trading interests. Although APHIS does not determine nonregulated status pursuant to its biotechnology regulations (Part 340) based on economic or marketing factors, the large 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 supporting 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 (e.g., evidence of decrease 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 nonregulated status for Event 3272 corn on the basis of reduced 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 significant impacts on wet distilled grains and improved dried distilled grains, and that Event 3272 corn is equivalent to currently grown corn lines in other agronomic and nutritional qualities, demonstrated through field and feed studies. The submitted scientific studies support APHIS' conclusions in the EA that the Event 3272 corn is equivalent to corn currently in production and that the Event 3272 corn likely will improve the efficiency of current ethanol production practices.

Many comments were received that oppose nonregulated status because of general opposition to development and use of GE plants, although the comments did not cite any specific environmental issues in the EA or the plant pest risk assessment for the petition for Event 3272 corn. Many of these comments simply asserted 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, although these comments did not specifically explain what they perceived 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 for food and environmental safety, but these comments did not provide specifics for those concerns. APHIS intends to respond to these general concerns through the responses to other comments that did provide more specific concerns in the related areas.

Another common comment that APHIS received regarding the determination of non-regulated 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 producing ethanol from corn is not an efficient method for achieving energy needs or meeting any alternative energy mandates for the United States.

During the initial comment period, commenters raised questions on what constituted a plant pest under APHIS regulations. Because of the important nature of these comments, the agency decided that it would be appropriate to clarify that the applicable plant pest definition is that defined in the Plant Protection Act (the statutory authority for 7 CFR part 340) and allow public comment on APHIS' clarification. APHIS published a notice in the *Federal Register* (74 FR 26832-26835) on June 4, 2009 reopening the comment period for this docket for an additional 30 days, which closed on July 6, 2009.

During the second comment period on this docket, APHIS received 52 comments; 36 comments supported nonregulated status for Event 3272, 15 comments opposed granting nonregulated status, and one comment referred to an attachment that was not present. Of the 36 comments in support of granting nonregulated status to Event 3272 corn, 19 comments were from individuals or organizations that did not submit comments during the first comment period. Most of these new comments expressed general support for nonregulated status for Event 3272 corn. The remaining supportive comments reiterated generalized support of granting nonregulated status to Event 3272 corn, and two comments voiced support of APHIS' clarification on the plant pest risks associated with Event 3272 corn. Five of the fifteen comments opposed to nonregulated status for Event 3272 corn were from organizations that made substantive points directly related to plant pest issues associated with Event 3272 corn that were described in the APHIS notice to reopen the comment period. The other 10 comments were from individuals whose comments were generally opposed to granting nonregulated status to Event 3272 corn, and these comments reiterated issues that arose during the initial comment period.

During both the first and second comment periods, APHIS received comments about specific food safety concerns such as the potential for Event 3272 corn to be allergenic. In addition, some comments expressed concerns about the potential economic and manufacturing impacts if Event 3272 corn was present in the current processes used for corn wet-milling.

APHIS' response to comments below has also been reflected in revisions and clarifications of the draft EA, so that the amended, final EA takes these issues into account. In an attempt to clarify the timing of public comments to this docket (either during the first or second comment periods), APHIS has chosen to characterize comments by using the date the comment was received.

- Comments received by January 20, 2009 were part of the first comment period.
- Comments received between June 4 and July 6, 2009, were submitted during the reopened, second comment period.

Comments provided during the second comment period typically responded to the plant pest issues clarified by APHIS in its notice of June 4, 2009.

After the official comment period closed, USDA APHIS received a letter from Syngenta (dated December 7, 2010, the letter is part of the Docket, APHIS-2007-0016-287) with additional information generated as a result of discussions between Syngenta and other commercial entities. The letter discusses both additional technical data related to the risk of the misdirection of Event 3272 corn and additional specificity about Syngenta's closed-loop system. In support of the information and analysis presented in the EA, the letter focused primarily on providing additional evidence that the deregulation of Event 3272 will not have an effect on other corn

milling processes. The letter also served to emphasize that, given the constraints of Syngenta's contract-based closed-loop system and the properties of Event 3272 corn, the risks of misdirection of Event 3272 is limited to a very few food processing systems that have specific combination of moisture, pH, time, and temperature. Specifically the letter provided:

- additional data related to both the probability and risks of the potential misdirection of Event 3272 corn.
- further details regarding Syngenta's contract-based closed-loop system in place for all users of Event 3272 corn,
- an update to the current commercial mechanisms available to rapidly test for the presence of Event 3272, and
- results of product-quality tests looking at the possible influence of Event 3272 corn on dry milling processes and milled product applications.

While this submitted information does not directly impact the regulatory determinations that will be made regarding the regulated status of Event 3272, APHIS does acknowledge receipt of the letter, and recognizes the relevance of the submitted information to the comments addressed below, particularly the third issue being addressed in this document.

1. As stated above, comments received during the initial comment period which closed on January 20, 2009 questioned APHIS' assessment that Event 3272 corn is not a plant pest and is unlikely to pose a plant pest risk. For example, in a comment submitted on January 16, 2009, the Corn Refiner's Association (CRA) expressed concerns that:

> **"Activation of residual levels of alpha-amylase enzyme present in corn starch can interfere with [the ability to form pastes and gels in processed or manufactured plant products] by breaking the chemical linkages between the long-chain anhydroglucose units that make up the starch molecule. We believe that this direct and indirect injury and damage to a manufactured or processed plant product has the ability to render Event 3272 a plant pest under current APHIS policy."**

In a subsequent comment on January 20, 2009, CRA expanded their argument that Event 3272 corn was a plant pest:

> **"We believe that, based on the evidence currently in the docket, deregulation of this event would be counter to APHIS' long-stated policy 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 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. "**

This sentiment was echoed by a comment submitted on January 20, 2009 by a consortium including the National Grain and Feed Association (NGFA), North American Export Grain Association (NAEGA), and North American Millers' Association (NAMA), who claimed that if APHIS granted nonregulated status to Event 3272 corn, this GE corn would have the potential to become a plant pest, causing damage that could extend to all users of corn for food, feed and processing.

Additionally, Tate & Lyle Ingredients Americas, Inc., submitted a comment on January 20th claiming that there should be 'no doubt' that Event 3272 corn is a plant pest because it can cause damage to plant products, whether natural, manufactured or processed.

On July 6, 2009, the Center for Food Safety (CFS) submitted a comment that referred to the comments that APHIS received during the initial comment period that "argue that Event 3272 corn is a 'plant pest' because it will injure or damage processed and manufactured corn products when event 3272 corn is inadvertently mixed with non-GE corn in wet-milling processes. ….we agree with the corn industry that Event 3272 corn must be characterized as a "plant pest" and therefore not deregulated.[4]"

Response:

In preface to our response to these comments, APHIS is providing further background and analysis regarding definitions of plant pest, our authority to regulate genetically engineered plants that may pose a plant pest risk, and the basis for our determination of nonregulated status under our regulations at 7 CFR part 340 and under the authority of the Plant Protection Act (PPA).

In the June 4, 2009 FR notice reopening the comment period, APHIS stated:

> "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"….and "…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."

As APHIS stated in the notice to reopen the comment period, the definition of a plant pest and article according to the Plant Protection Act are as follows:

> "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."

[4] The public comment submitted on January 20, 2009 by CFS did not question the regulatory or scientific determination that Event 3272 corn is not a plant pest, nor is Event 3272 corn unlikely to pose a plant pest risk. CFS chose the reopening of the comment period to question APHIS' assessment that Event 3272 corn is not a plant pest.

"Article – The term 'article' means any material or tangible object that could harbor plant pests or noxious weeds."

The term "article", as used within the statutory definition of the term "plant pest" was not meant to be interpreted according to the statutory definition of the term "article" set forth in the PPA at 7 U.S.C. 7702(1), as may have been implied or interpreted in our FR notice to reopen the comment period (FR 74, No. 106, pp 26832-26835). The term "articles", as used in the statutory definition of a plant pest referred back to the various organisms previously listed in 7 U.S.C. 7702(14). Aside from the use of the term "article" in the PPA definition of "plant pest", the term "article" elsewhere in the PPA is meant to include anything that may need to be regulated that could carry/harbor a plant pest or noxious weed (e.g. wood packing material that harbors wood-boring pests, brassware shipments that can contain khapra beetles, etc.). Sec. 412 of the PPA indicates that the Secretary may issue regulations to prohibit or restrict the importation, entry, exportation or movement in interstate commerce of "articles" to prevent the introduction and dissemination within the United States of plant pests and noxious weeds. Nonetheless, as indicated in this FR notice, APHIS evaluated the ability of Event 3272 corn to harbor plant pests in the Plant Pest Risk Assessment.

Regardless of which definition of plant pest is used (i.e. the definition in the PPA or 7 CFR 340.1[5]) APHIS provides the rationale for why Event 3272 corn, the regulated article in question, does not meet either definition of plant pest nor does it pose a plant pest risk.

CFS and a group composed of NGFA, NAEGA, NAMA (and including the Pet Food Institute as of July 6th) argue that APHIS should construct a regulatory and scientific decision that Event 3272 corn is a plant pest.

CFS repeatedly refers to a part of both the statutory definition and the regulatory definition of a plant pest in an attempt to assert that Event 3272 corn is a plant pest because it may "injure or damage plant or plant products." However, CFS is only using a portion of the PPA's definition of a plant pest. Under the PPA, only certain organisms may be considered plant pests, independent of the damage that is caused. APHIS, when evaluating a GE organism that is one of the organisms listed in A-H, determines if that GE organism can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product. However, in order to be a plant pest the GE organism in question must be one of the organisms listed in the plant pest definition in the PPA or an article similar to or allied with one of the listed organisms. Event 3272 corn is not an organism listed in the definition of plant pest and therefore is not itself a plant pest. Furthermore, Event 3272 corn does not harbor any living stage of any of the organisms (articles) that are defined as potential plant pests, nor does Event 3272 corn act as an article and increase susceptibility to plant disease or insect pests and harbor plant pests. Collectively, these scientific facts led APHIS to the conclusion that Event 3272 corn does not meet the definition of a plant

[5] Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants. § 340.1

pest and its unrestricted movement and use will not result in the introduction or dissemination of plant pests.

CFS continues to claim in their July 6, 2009 comment that "based on the plain language of the PPA's definition of 'plant pest,' Event 3272 corn must be considered a 'plant pest' here." However, according to the text of the PPA, only certain organisms can be plant pests. Event 3272 corn is not an organism listed in the definition of plant pest and therefore is not itself a plant pest and, furthermore, Event 3272 corn does not harbor any living stage of any of the organisms (articles) that are defined as potential plant pests. Nor does Event 3272 corn act as an article and increase susceptibility to plant disease or insect pests and harbor plant pests. Collectively, these scientific facts led APHIS to the conclusion that Event 3272 corn does not meet the definition of a plant pest and its unrestricted movement and use will not result in the introduction or dissemination of plant pests.

The CFS comment on July 6, 2009 then returns to the idea of 'allied with' from the plant pest definition of the PPA to claim that Event 3272 corn is

> "…'allied with' both a bacteri[um], namely *Agrobacterium tumefaciens*, as well as a virus, namely the cauliflower mosaic virus."

Although it isn't clear from their comment, CFS seems to be equating the presence of DNA sequences used during the development of Event 3272 corn to an actual living bacterium and virus. Regulated articles as defined in 7 CFR 340.1 include those GE organisms engineered to contain DNA sequences from a plant pest. The plant pest risk assessment conducted by APHIS evaluates the plant pest risk of these sequences by assessing the likelihood that these DNA sequences result in plant pest organisms or infectious agents or pathogens that could directly or indirectly cause disease, damage, or injury to plants or plant products which could be disseminated by the widespread cultivation of Event 3272 corn. APHIS has concluded that the plant pest DNA sequences in Event 3272 corn are not entire plant pest genomes. According to the PPA, the organisms 'allied with' a plant pest must be living organisms. Only small bits of DNA from *Agrobacterium tumefaciens* and the cauliflower mosaic virus are used in Event 3272 corn – not the entire genome. APHIS was not provided, nor did it locate during its literature review, scientific evidence to assert that these small sequences of DNA from plant pest organisms used to create Event 3272 corn result in living organisms, or in infectious agents that could be disseminated by Event 3272 corn. Therefore, Event 3272 corn is not allied with 'a bacterium and a virus'. Thus, the engineered plant pest sequences in Event 3272 corn do not pose a plant pest risk (USDA APHIS 2009).

Finally, CFS claims that the plant pest definition essentially rests solely on claims of damage and injury to plants or plant products. This assertion is also echoed in comments submitted on July 6th by a group comprised of NGFA, NAEGA, NAMA and the Pet Food Institute. In their comment submitted on July 6, 2009 this group claims that crop varieties that have 'unique functional characteristics' alone "…are potential plant pests, absent a proper risk assessment, risk management, and risk responsibility plan", and even further, that "Neither Syngenta nor APHIS have provided adequate information to assess whether or not Event 3272 represents a genetic sequence that, when expressed in plant or plant products at some point in the future, might prove to be a plant pest." APHIS has assessed risks associated with the unique functional characteristics associated with Event 3272 corn; however, unique functional characteristics do

not constitute plant pests. These arguments submitted by CFS and the group comprised of NGFA, NAEGA, NAMA and the Pet Food Institute do not consider the fact that under the PPA or 7 CFR part 340.1 definition, a plant pest must be a living organism, virus, viroid, or infectious agent or pathogen as listed under these definitions or similar to allied with those listed. Event 3272 corn is not an organism virus, viroid, or infectious agent or pathogen listed in either definition of plant pest and therefore is not itself a plant pest and, furthermore, Event 3272 corn does not harbor any living stage of any of the organisms (articles) that are defined as potential plant pests. Nor does Event 3272 corn act as an article and increase susceptibility to plant disease or insect pests and harbor plant pests. Collectively, these scientific facts led APHIS to the conclusion that Event 3272 corn does not meet the definition of a plant pest and its unrestricted movement and use will not result in the introduction or dissemination of plant pests.

Although CRA submitted a comment in January 2009 that Event 3272 is a plant pest, CRA comments during the second comment period did not respond to the detailed rationale against this claim that APHIS made when reopening the comment period and requesting specific public comments on the APHIS rebuttal of the claim maintained in the CRA comment of January 2009

None of the comments submitted during the first or second comment period questioned the rest of the plant pest risk assessment conducted by APHIS for Event 3272 corn. APHIS has concluded that Event 3272 corn is not a plant pest, Event 3272 corn does not contain plant pests and its cultivations would not result in the introduction or dissemination of plant pests.

USDA-APHIS. 2009. Plant pest risk assessment for Event 3272 corn. USDA APHIS Biotechnology Regulatory Services, Riverdale, Maryland.

2. Many commenters were concerned that APHIS' interpretation of the plant pest definition of the PPA stated that GE plants are not under the jurisdiction of the PPA or of APHIS regulations at 7 CFR 340.

For example, the July 6th comment submitted jointly by NGFA, NAEGA, NAMA and the Pet Food Institute states that the logical, simple reading of the plant pest definition:

> "…promotes the notion that the APHIS process is optional and events such as Event 3272 corn could simply certify that the enzyme if not living and therefore falls under no regulatory requirements of APHIS. Under such a result, even those events that APHIS routinely and historically has exercised its authority over, such as glyphosate resistant soybeans, could automatically fall outside the APHIS regime."

CFS agrees with the above comment in their July 6th submission to the docket:

> "…APHIS so narrowly interprets the statutory definition of "plant pests" here, setting a new precedent that could virtually exclude all GE crops from APHIS' plant pest authority in the future."

The comment submitted on July 6, 2009 by the Union of Concerned Scientists (UCS) takes a similar view of APHIS' interpretation of the plant pest definition of the PPA:

> "Developers of the vast majority of GE crops would be able to show that their products are not parasitic plants, do not meet the definition of a plant pest, and thus are not subject to APHIS oversight under PPA regulations."

The claims in these comments contradict the plain language of the regulations at 7 CFR part 340. GE organisms are subject to the regulations if they are considered regulated articles. Under §340.1 a regulated article is any organism which has been altered or produced through genetic engineering (modified by recombinant DNA techniques), and either the donor, recipient, or vector agent is a plant pest or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. If a GE organism meets the definition of a regulated article, the regulated article remains such until APHIS determines that the regulated article is unlikely to pose a plant pest risk.

As stated by the UCS comment submitted on July 6th, to determine if a regulated article is unlikely to pose a plant pest risk APHIS examines

> "substantial data packages submitted by the developer demonstrating that the crop posses no plant pest *risk* {emphasis by UCS}…At the end of the process APHIS typically finds that a GE crop does not present a plant pest risk and therefore is no longer considered a regulated article under the PPA regulations."

APHIS receives petitions requesting nonregulated status for a regulated article that the petitioner believes is unlikely to pose a plant pest risk. The information requirements in § 340.6(c) clearly state the types of information and data to be submitted for such a petition. None of these regulatory requirements have changed. APHIS has, and continues to have, jurisdiction over GE plants which meet the definition of a regulated article in 7 CFR part 340. The comment submitted by CFS recognizes this regulatory requirement, noting that "Once APHIS determines that a GE crop is a *regulated article* (emphasis by APHIS), APHIS must evaluate whether a GE crop poses risks associated with a 'plant pest'…"

APHIS emphasizes that the scope of our regulations and the definition of a regulated article in 7 CFR part 340, did not change with the publication of the notice to reopen the public comment period on this docket. Rather, APHIS was clarifying the scope of these regulations. All GE organisms that are regulated articles (including GE plants like Event 3272 corn) must conform to the requirements stated in 7 CFR part 340. Such GE plants are regulated, and all regulated articles must be under permit or notification if they are imported, moved interstate, or released into the environment in the United States unless and until such time that APHIS makes a determination of nonregulated status.

3. Comments submitted at the close of the original comment period by the Corn Refiner's Association (CRA), Tate & Lyle Ingredients Americas, and a group consisting of National Grain and Feed Association (NGFA), North American Export Grain Association (NAEGA), and North American Millers' Association (NAMA) all described concerns regarding potential effects of Event 3272 corn on corn refining (wet-milling), a process that

leads to the production of starches, sweeteners, and corn oil. As stated in a comment submitted by CRA on January 20th:

> **"We believe it is possible that the presence of alpha-amylase enzyme from Event 3272 corn delivered to a corn wet milling facility that produces manufactured and processed plant products could cause direct or indirect injury to these products."**

More specifically, in a comment submitted on January 20th, NGFA, NAEGA, and NAMA state that:

> **"…the docket and petition for deregulation lacks adequate scientific data or documentation necessary to evaluate the possible impacts on food and feed functionality should this maize event be comingled with commodity supplies of corn."**

Response: These industry stakeholders are expressing concern that the amylase enzyme present in Event 3272 corn could become present in corn wet-milling processes, which the commenters are concerned could lead to quality-control issues for them in the wet-milling refining and processing of corn products. Because the commenters believe there is a potential effect of Event 3272 corn on plant products (i.e. corn products), they stated that this is sufficient rationale for Event 3272 corn to be considered a plant pest. APHIS has already elaborated above on its conclusion that Event 3272 is not a plant pest (see Responses 1 and 2).

The comment submitted on July 6th from NGFA, NAEGA, NAMA, and the Pet Food Institute also claims that APHIS believes data on effects of GE crops on food processing "to be relevant to the deregulatory authority", that a "legal precedent establishes that APHIS has a duty to assess economic risks to the food chain". This comment also claims that information on the effects of Event 3272 on food products was discussed in the docket because "APHIS believe[s] th[ese] data to be relevant to the deregulatory authority."

As APHIS stated in Responses 1 and 2 above, and in the APHIS notice to reopen the comment period for Event 3272 corn, and as clarified in the preface to the response to these comments, the APHIS authority to grant nonregulated status is based on the regulations at 7 CFR part 340 as allowed under the Plant Protection Act and an evaluation of the potential for Event 3272 corn to pose a risk as a plant pest. As stated in the Plant Pest Risk Assessment and in the APHIS notice to reopen the comment period for this petition, if APHIS determines that the regulated article Event 3272 corn is unlikely to pose a risk as a plant pest, APHIS must grant nonregulated status to Event 3272 corn. There is no provision in the Plant Protection Act that establishes an assessment of economic risks to the food chain as the basis for decision-making.

APHIS appreciates the commenters' concerns over potential unknown effects that might arise if Event 3272 corn becomes mixed with other corn in wet-milling processes, but APHIS disagrees that APHIS' scientific evaluation and decision, which is based on plant health risks, should be used for the purposes of addressing the economic interests of the commenters. Conflicts arise when stakeholders wish to transform a regulatory structure based on the plant biology, plant health, and concerns of plant pests into a regulatory structure based instead on possible market impacts.

Economic concerns were also raised in a comment submitted by the Grocery Manufacturers' Association (GMA) on July 6, 2009. In this comment, GMA describes a plan for new GE plant varieties that are 'functional food crops,' insisting that APHIS require the following information in the petition for nonregulated status for future regulated articles that are 'functional food crops':

> "…companies developing food/feed crops with output traits that may have a functional impact on downstream processing should examine the potential impacts. This review of impacts should include consultation with downstream stakeholders."

Further:

> "GMA strongly encourages APHIS to provide oversight and guidance in managing current and future developments in specialty crops with output traits where functional impacts are raised."

Specialty, non-GE corn crops, such as waxy or high amylopectin corn, are grown and produced for specific food processing functions without regulatory management by a government agency. No regulatory oversight is provided to prevent or remedy potential problems with quality control and the resulting economic impacts if these functional foods accidentally enter the commodity stream. Event 3272 will be treated as a specialty crop, and similar mechanisms exist to prevent and remedy quality control issues. The fact that Event 3272 corn is also a GE crop is not sufficient reason to add additional discrimination or restrictions compared to non-GE specialty crops.

A petition is submitted by an applicant to describe how a regulated article is unlikely to pose a plant pest risk. Information submitted in the petition is provided solely to support the argument that a regulated article should be granted nonregulated status. Although APHIS recognizes the concerns of stakeholders, APHIS' grants nonregulated status to a regulated article if the GE organism is not a plant pest and is unlikely to pose a plant pest risk. The PPA and the regulations at 7 CFR part 340 were promulgated to prevent the introduction and dissemination of plant pests, not to regulate marketing, economic impacts, or quality control in manufacturing in food processing.

The comments of GMA, CRA, CFS, UCS, NGFA, NAEGA, NAMA, and the Pet Food Institute describe their expectations, to varying degrees, that APHIS should use the PPA and the regulations at 7 CFR part 340 to regulate perceived risks to product damage, quality control, economic damage, and marketing that may potentially arise from Event 3272 corn. APHIS is responsible for regulating GE organisms to protect American agriculture and the environment from the introduction and dissemination of plant pests[6].

APHIS acknowledges the challenges and concerns raised by these comments. APHIS' environmental assessment discusses specifically the impacts on dry-milling (the processing sector for which Event 3272 corn is designed and intended to be used), and the record also includes analyses of the potential impacts of Event 3272 corn on wet-milling. The masa example included in the EA illustrates what might happen in the event of the misdirection of a non-

[6] On page 7 of their comment submitted on July 6th, CFS incorrectly states the basis for the promulgation of regulations for GE organisms. APHIS promulgated regulations for GE organisms to prevent the introduction and dissemination of plant pests.

ethanol production use – in either the dry- or wet-milling sector. As quoted by NGFA, NAEGA, NAMA, and the Pet Food Institute, in their comment submitted on July 6, 2009, the Food Standards Australia New Zealand (FSANZ) cited potential impacts of Event 3272 corn on "shelf life and quality of finished food products." This quotation cited by NGFA, NAEGA, NAMA, and the Pet Food Institute implies that the statement by FSANZ should thus result in APHIS denying the petition to grant nonregulated status for Event 3272 corn. However, the concern voiced by FSANZ did not lead to it denying approval of Event 3272 corn. FSANZ ultimately completed its review of Event 3272 corn, and this product was approved by FSANZ for food and feed use in March 2008[7].

During the second comment period on this docket, CRA reiterated their concerns regarding the deregulation of Event 3272 corn and requested that APHIS complete a new EA prior to completion of a decision on whether to grant nonregulated status to Event 3272 corn. In a similar fashion, NGFA, NAEGA, NAMA, and the Pet Food Institute, in their comment submitted on July 6, 2009, present a detailed argument why their particular market concerns merit an Environmental Impact Statement[8].

APHIS understands the concerns raised by these stakeholders, however, because Event 3272 corn is a value-added corn product, with a price incentive for farmers to grow this product, Event 3272 corn production will be grown under a 'closed loop' system as described in the EA. As noted in the EA, Syngenta will sell hybrids with Event 3272 only to growers with a valid contract with an ethanol plant and who execute a Syngenta Stewardship Agreement that will ensure and facilitate appropriate cultivation, handling, detection, communication, inspection, and audits. The contracts in this closed-loop system will contain legal and financial incentives for compliance. Once a contract is agreed upon, then the farmer and the ethanol facility will have legally enforceable contractual obligations, which include following Syngenta's stewardship obligations, in order to obtain, grow, and use Event 3272 corn.[9] Growing Event 3272 corn under a 'closed loop' system will minimize potential impacts that to non-event 3272 corn varieties and will minimize unintended misdirection of Event 3272 corn into the corn commodity stream or inadvertently mixing with corn destined for wet-milling.

As discussed in the EA (section on Gene Movement in the EA, as well as appendices D and G), these stewardship obligations include the requirement that farmers plant 12 border rows of non-Event 3272 corn surrounding an Event 3272 corn field. These border rows will greatly reduce the potential for pollen movement outside of Event 3272 corn fields; up to 99.9% of Event 3272 corn pollen will likely remain within the Event 3272 corn field[10,11]. These legally enforceable[12]

[7] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa580foodd3243.cfm

[8] The comment submitted by NGFA, NAEGA, NAMA, and the Pet Food Institute on July 6, 2009 also incorrectly claim that issues evaluated in an EA or an EIS are equivalent to issues addressed to determine if a GE organism is a plant pest. The plant pest risk assessment determines if a GE organism is a plant pest. Issues that may affect the quality of the human environment are addressed an EA or an EIS.

[9] Comment submitted by Syngenta on July 6, 2009.

[10] Union of Concerned Scientists incorrectly stated in their July 6, 2009 comment that there were no measures to control the spread of Event 3272 corn pollen.

[11] The comment submitted by NGFA, NAEGA, NAMA, and the Pet Food Institute on July 6th failed to comment or consider that, given the contractual obligation for farmers to use border rows of non-Event 3272 corn, pollen flow outside the corn field is minimized.

stewardship and contractual obligations also involve a premium paid to the farmer by the ethanol facility for growing Event 3272 corn. The assumption made by APHIS is that farmers will abide by the contractual obligations, and will only receive the price premium when those contractual obligations are met. It is important to reiterate that, as stated in the EA, APHIS is not involved in and has no control over decisions regarding what is or is not contained in stewardship obligations or contracts for Event 3272 corn, or any price premiums paid for producing Event 3272 corn[13].

Organizations are concerned over leaks in this closed- loop system, but it is speculative and hypothetical that breakdowns would immediately result in measurable ways. However, Event 3272 corn has fully completed the voluntary consultation to evaluate food and feed safety (EA, Appendix H), and is safe for human and animal consumption. There is no food safety reason to prevent commingling between Event 3272 corn and other corn varieties. Event 3272 corn is assumed by APHIS to be grown and handled in a specific manner because of the price premiums paid by the ethanol facility to the farmer. There are specific contractual, legal obligations, along with a price incentive, that APHIS assumes will be followed when growing Event 3272 corn.

Because Event 3272 corn is a value-added corn product, with a price incentive for farmers to grow this product, Event 3272 corn production will be grown under a 'closed loop' system as described in the EA. As mentioned above, Event 3272 corn will be grown under contracts involving the developer, the ethanol facility, and the farmer. Closed loop systems are in place for many value-added corn products, including specialty, non-GE, corn varieties such as waxy corn (grown for wet-milling processes), high-oil corn, and high-lysine corn. There are certain characteristics of specialty corns that warrant consideration of proper handling and disposition, similar to the care needed to produce Event 3272 corn. Steps must be taken to avoid cross pollination with normal hybrids. If cross pollination occurs, the cross-pollinated ears of the waxy, high-amylose and high-lysine hybrids will produce normal seed and the seed of the high-oil hybrid will have an oil percentage intermediate between the normal and high-oil hybrid. Waxy corn, high-oil corn, and high-lysine corn grown under contract are usually tested for possible contamination with field corn. Extension agents suggest that to avoid cross pollination, specialty hybrids should be grown in an isolated field or the grain from the border six to ten rows should be harvested separately from the rest of the field[14].

Many farmers are well-versed in growing specialty crops under contract, and Event 3272 corn is no different. Approximately 20% of farmers surveyed grew some type of value-added corn in 2005 (USGC 2006). Farmers growing specialty crops do not want other corn genes from outside their field fertilizing their crop, and thus reducing the purity of their crop. Nor do farmers want to affect their neighbors' corn crop through inadvertent pollen movement. However, pollen movement does not equate to movement of genes into corn (or any other plant). In order for Event 3272 corn genes to enter another corn genome and inadvertently affect either purity of another corn crop or potentially impact corn wet-milling processes, first, the pollen must reach

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[12] These contracts are between the developers and members of the ethanol production stream, and are legally enforceable contracts through means other than the PPA.

[13] Once APHIS has determined that Event 3272 corn is not a plant pest, is unlikely to pose a plant pest risk, and has granted nonregulated status, APHIS cannot mandate any regulatory requirements based on 7 CFR part 340 for Event 3272 corn.

[14] http://ohioline.osu.edu/agf-fact/0112.html

another, non-Event 3272 corn plant. This means that the Event 3272 corn pollen must breach the 12 border rows of non-Event 3272 corn that is a legal, contractual obligation of the farmer. According to the analysis conducted by the developer and reviewed by APHIS, it is estimated that only 0.1% of Event 3272 corn pollen in a field might be available to pollinate another corn field. Pollen is shed typically in the morning hours for one week, and the pollen is viable for only approximately 20 minutes once it leaves the plant.[15] Then, that small amount of pollen must reach receptive non-Event 3272 corn plant in only 20 minutes for fertilization to potentially occur.

Other measures in the closed loop system include specifying permissible channels for disposition of any excess Event 3272 corn, instead of directing of Event 3272 corn to corn wet-milling facilities. Additionally, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [P.L.107-188] requires one-step forward, one-step back source material recordkeeping of all domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food. Examples of 'food[16]' include raw agricultural commodities for use as food or components of food, as well as animal feed[17]. Event 3272 corn falls into this category, as well as other corn varieties used for general food processing (including wet-milling) and specialty processes. The recordkeeping requirements will work to minimize misdirection of Event 3272 corn, as well as to verify that appropriate corn varieties enter specific channels for specific processing. In the unlikely event that all the processes described above breakdown, there would be opportunity for identification and detection of Event 3272 corn in the corn commodity stream, similar to testing for other specialty hybrids such as waxy corn. Detection test methods are readily available for grain handlers and processors to detect Event 3272 corn, and such methods can readily identify Event 3272 corn inadvertently mixed with corn destined for wet-milling.

Finally, a scientific study (Singh et al., 2006b) suggests that the presence of Event 3272 corn (up to 10%) in regular yellow dent corn would result in no difference in yields for wet- or dry-milling processes. In this study, no differences were observed in wet- or dry-milling yields among the control (no Event 3272 corn) and 0.1, 1.0, and 10% Event 3272 corn treatments. Visually, no qualitative differences were observed in wet- or dry-milling characteristics for any of the amylase corn treatments, including discoloration (no browning occurred when wet-milled corn fractions were dried in an oven). However, CRA cites this research in the January 20, 2009 comment to suggest a potential issue with the presence of Event 3272 corn in corn destined for wet-milling processes. CRA did not elaborate why this scientific study, using up to 10% Event 3272 corn, did not find any differences in the wet-milling processes, or how the findings of this study would directly support the impacts CRA believes may occur to corn wet-milling processes. Additionally, a scientific study indicates that only 3% of Event 3272 corn is needed to produce equivalent amounts of ethanol compared to using a microbial amylase (Singh et al. 2006a). The comments from NGFA, NAEGA, NAMA, (January 20th) and NGFA, NAEGA, NAMA, and the

[15] http://www.maizegdb.org/IMP/WEB/pollen.htm
[16] Food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."
[17] http://www.fda.gov/Food/FoodDefense/Bioterrorism/Recordkeeping/ucm061476.htm

Pet Food Institute (July 6th) are both devoid of data to support their contention that the hypothetical effects are likely to occur.

Singh, V., C. J. Batie, G. W. Aux, K. D. Rausch, and C. Miller. 2006a. Dry-grind processing of corn with endogenous liquefaction enzymes. Cereal Chemistry. 83: 317-320.

Singh, V., C. J. Batie, K. D. Rausch, and C. Miller. 2006b. Wet-milling and dry-milling properties of dent corn with addition of amylase corn. Cereal Chemistry. 83: 321-323.

4. **Commenters claim that Event 3272 corn is an 'industrial product' and therefore should not be granted non-regulated status. For example, the July 6, 2009 comment from NGFA, NAEGA, NAMA, and the Pet Food Institute states:**

> **"Deregulation of Syngenta's Alpha-Amylase Maize Event 3272, based on 7 CFR Section 340.6, is not warranted under the very guidance issued by APHIS. According to a Biotechnology Regulatory Services (BRS) Factsheet published by APHIS in February 2006:**
>
> > **A pharmaceutical or industrial crop is a plant that has been genetically engineered to produce a medical or industrial product, including a human or veterinary drug, biologic, industrial or research chemical, or enzyme…BRS policy makes clear that these GE plants are handled differently than those being developed for use as food or feed.**
>
> **Pursuant to Syngenta's application it is clear that Event 3272 has been developed exclusively for use in the production of ethanol – an industrial product. The fact that Syngenta sought a nutritional equivalence finding from the FDA does not change the fact that Event 3272 is designed solely for industrial use. By APHIS's own rules, it has no choice but to regulate Event 3272 as a Plant Made Industrial Product."**

The July 6, 2009 and January 20, 2009 comment from UCS repeatedly refers to Event 3272 corn as an 'industrial food crop'. CFS also weighs in on this issue in their July 6th comment: "There can be no doubt that Event 3272 is an industrial crop."

Response: In a Federal Register notice[18] on August 6, 2003, APHIS defined those plants engineered to produce industrial compounds to include those plants that meet all three of the following criteria: (1) the plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. Examples provided in the notice include detergent manufacturing, paper production, and mineral recovery.

Event 3272 corn does not meet the criteria to be considered an industrial plant. Event 3272 corn produces alpha-amylase that will facilitate ethanol production. All corn plants naturally produce alpha-amylases (Scandalios et al. 1978), thus alpha-amylases are not unique compounds to Event 3272 corn. Alpha-amylases similar to the one expressed by Event 3272 corn are commonly used in food processing, such as brewing and distilling processes for drinkable alcohol, and the creation of corn syrups (Janeček et al, 1999, Lévêque et al., 2000, Pariza and Johnson 2001,

[18] 68 FR 46434-46436

Olempska-Beer et al., 2006). Event 3272 corn will be used in ethanol production, which is a non-food, non-feed use, in addition to a feed product. Distiller's grains with solubles (DDGS) is an important feed product produced during ethanol production. This feedstock is sold by the ethanol plant and is an important component of the economic viability of an ethanol facility. Ethanol facilities that use Event 3272 corn will create DDGS containing Event 3272 corn. Event 3272 corn may also be used on-farm as a feed grain. The voluntary consultation with FDA regarding Event 3272 corn has been successfully completed (EA, Appendix H). Thus Event 3272 corn will also be used for feed and for ethanol production.

To grant nonregulated status to a regulated article, APHIS evaluates whether the regulated article is unlikely to pose a plant pest risk. APHIS conducted a plant pest risk assessment (USDA APHIS 2009) and found that Event 3272 corn is not a plant pest and is unlikely to pose a plant pest risk.

Janeček, Š., E. Lévêque, A. Belarbi, and B. Haye. 1999. Close evolutionary relatedness of α-amylases from archaea and plants. Journal of Molecular Evolution **48**:421-426.

Lévêque, E., Š. Janeček, B. Haye, and A. Belarbi. 2000. Thermophilic archaeal amylolytic enzymes. Enzyme and Microbial Technology **26**:3-14.

Olempska-Beer, Z. S., R. I. Merker, M. D. Ditto, and M. J. DiNovi. 2006. Food-processing enzymes from recombinant microorganisms - a review. Regulatory Toxicology and Pharmacology **45**:144-158.

Pariza, M. W., and E. A. Johnson. 2001. Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century. Regulatory Toxicology and Pharmacology **33**:173-186.

Scandalios, J. G., S. E. Chao, and J. C. Melville. 1978. Biochemical characterization of the major amylase form coded by the *Amy-1* gene in maize. Journal of Heredity. 69: 149-154.

USDA-APHIS. 2009. Plant pest risk assessment for Event 3272 corn. USDA APHIS Biotechnology Regulatory Services, Riverdale, Maryland.

5. Many comments were submitted from organic growers or those who support organic agriculture through either their work or their purchase of organic products. The concern expressed in these comments is that pollen drifting from nearby farms would pollinate crops on organic operations and that, through no fault of their own, organic farmers would lose the premium for their organic products. APHIS considered these comments as a whole and also included other associated issues of gene flow and other potential impacts of Event 3272 on both organic and conventional agriculture.

APHIS did address issues associated with organic and conventional agriculture in its draft EA (Section II: "Corn Production" and "Gene Movement;" Section IV: "Methods and Assumptions," "Production Practices," and "Corn Production") and referenced relevant information for growers of organic field corn (Krueger 2007, Kuepper 2002, Kuepper et al. 2007, NCAT 2003, and

Riddle 2004). Gene flow is addressed in those references, and the provided information would also be directly applicable to conventional corn growers who are concerned with cross pollination of non-GE corn with GE corn pollen. Farmers using organic production methods are currently coexisting with farmers using GE varieties, and methods have proven useful; the acreage of organically-produced corn has been increasing in concert with the acreage dedicated to GE corn varieties (see Section IV, "Gene Movement"). Recommendations on how farmers using organic production methods can coexist with farmers using GE varieties are provided in the references listed above and can be simplified into four points: (1) Use seed that is from a known, non-GE stock (lists of organic seed suppliers can be found at www.attra.org); (2) Use temporal buffers such that corn being produced organically is receptive to pollen at a different time of year than when the neighboring corn sheds pollen; (3) Maintain physical isolation from GE corn (either through distance or natural barrier (e.g., tree rows)); (4) Plant corn rows at the edge of the corn field to act as a trap for GE pollen and harvest these buffer rows separately. Additionally, one of the above cited documents (Krueger 2007), also cited in the EA, specifically addresses a variety of issues, many of a legal nature, that are associated with GE crops, organic agriculture, and certifying agents - including testing, the presence of excluded methods, and tolerance levels for the presence of excluded methods.

One comment expressed concern over 'biological contamination' which was defined in the comment as an "unintended comingling of GE and non-GE crops." The EA discusses in detail the ability of corn to pollinate neighboring corn crops (Sections II and IV: "Gene Movement," and Appendix D), as well as the "Closed Loop System" developed by Syngenta to minimize comingling of Event 3272 seed and non-Event 3272 seed (see "Use of the Closed Loop System" and "Gene Movement" in Section IV of the EA, along with Appendices D and G). As noted in the EA and above references, methods to minimize the likelihood of the presence of GE corn material in non-GE corn fields are well understood, and are in place not only in farms using organic production methods, but also those producing specialty corn varieties, such as waxy, sweet, and high amylopectin corn. As noted by Ronald and Fouche (2006), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet diverse market requirements."

The best management guidelines and contractual stewardship agreement for Event 3272 corn requires the use of 12 border rows of non-Event 3272 corn to reduce the likelihood of gene movement between Event 3272 corn and other corn fields (EA, Appendix G). These border rows of non-Event 3272 corn are used as a "pollen trap." Corn pollen is relatively larger than other grass pollen and does not travel far from the corn field (Jarosz et al. 2003). For pollen that does move beyond any planted Event 3272 corn, the border rows of corn will significantly hinder the movement of that pollen beyond the field boundaries. The use of border rows results in a reduction of up to more than 99.9% of Event 3272 corn pollen from leaving the corn field. (see Section IV, "Gene Movement" and Appendix D).

Brookes and Barfoot (2004) studied the extent to which organic soybean, corn, and canola producers in North America have faced difficulties because of the predominant GE production of these crops. Even given the significant concentration of organic production in many States with

an above-average GE crop presence, the study found that U.S. organic farmers have had very limited problems coexisting with growers of GE crops.

It has always been the responsibility of organic operations to manage the potential contact of organic products with other substances not approved for use in organic production systems, whether from the non-organic portion of a split operation or from neighboring farms. The organic system plan, developed individually by a grower, must outline the steps taken to avoid contact or mixing, and it is the organic producers who are ultimately obligated to manage their operations so as to avoid unintentional contact with non-organic material. This was explicitly affirmed in response to public comment on the establishment of the National Organic Program (NOP) (Federal Register, Volume 65, p. 80556). The NOP specifically discusses buffer zones and defines them as areas located between a certified organic production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas and the organic grower can incur costs associated with the establishment of these buffer zones. The possible cost to organic producers resulting from proximity to GE-based agriculture is dependent upon the acceptable level of GE material that may be inadvertently present and on consumers' expectations and perceptions. The NOP identifies four levels of product composition for organic agriculture certification (7 CFR 205.301): 1) 100 percent organic; 2) 95 percent or more organic; 3) 70 to 95 percent organic; and 4) less than 70 percent organic. If there is a negative public perception of the adventitious presence of GE material in organically-produced products, profitability of an organic enterprise may be diminished through the loss of price premiums earned by these products.

Survey evidence presented in the Brookes and Barfoot (2004) study showed that the vast majority (92 percent) of U.S. organic farmers had not incurred any direct additional costs or incurred losses due to GE crops having been grown near their crops. According to the report, four percent had experienced lost organic sales or downgrading of produce as a result of GE organism presence and the remaining four percent of farmers had incurred small additional costs only for testing.

Brookes and Barfoot (2004) also noted that an examination of trends in the planting of GE and organic crops suggests that the growth of the crop area used for GE plants has not impeded the development of the organic sector in North America. Both organic corn and organic soybean acreages more than doubled between 1997 and 2001. Similarly, in Section IV "Gene Movement," APHIS found that organic production of corn varieties increased 35% between 2001 and 2005 (USGC 2006), concurrent with five GE corn varieties being granted nonregulated status, and the acreage used for GE corn varieties increasing by 50%.

However, as observed in Apted and Mazur (2007), the Brookes and Barfoot (2004) study was not able to quantify the impact of measures undertaken by organic producers to avoid GE material coming into contact with organic crops. Nonetheless, there is data to indicate that farmers using organic production systems are being compensated for the unidentified costs associated with meeting any contractual obligations and NOP standards for corn produced through organic systems. For example, as stated in the EA (Section IV, "Gene Movement") in

2008, conventional corn averaged $3.90/bushel (USDA-NASS 2009), whereas organic corn averaged $7.08/bushel (USDA-NASS 2010).

The National Organic Program specifically addressed the potential of the accidental occurrence of genetically-engineered material in organic production in the preamble to the final rule for the establishment of the National Organic Program:

> "Drift[19] has been a difficult issue for organic producers from the beginning. Organic operations have always had to worry about the potential for drift from neighboring operations, particularly drift of synthetic chemical pesticides. As the number of organic farms increases, so does the potential for conflict between organic and non-organic[20] operations.
>
> It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use[21] in organic production systems, whether from the non-organic portion of a split operation or from neighboring farms. The organic system plan must outline steps that an organic operation will take to avoid this kind of unintentional contact.
>
> When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the [Organic Foods Protection] Act and the [National Organic Program] regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation."
>
> 65 Federal Register 80556

This concept is fully supported by documents published by the University of California at Davis (Ronald and Fouche, 2006) and others (Krueger 2007).

The demand for organic products by certain consumers is derived from their perceived health, safety, and environmental concerns (Cicia et al. 2006, Durham and Andrade 2005, Naspetti and Zanoli 2006, Zhang et al. 2006). Perceived health concerns regarding GE food crops contribute to this demand and the higher prices some consumers are willing to pay for organic food. Apted and Mazur (2007) also noted that GE agriculture may benefit organic producers. For example, if the use of GE crops results in either the use of less persistent agricultural chemicals or a reduction in the volume of agricultural chemicals used, this will help to reduce the general level of these chemicals in the environment and organic producers may need to implement less costly contact avoidance measures.

[19] Drift is defined here as something moving along in a current of air (e.g., pesticide sprays or pollen are typically noted as being relevant in this discussion).
[20] 'Non-organic' may include conventional and GE products.
[21] GE products are not approved for intentional use in organic production, and is considered an 'excluded method'.

GE agriculture, as well as conventional agriculture, contributes to the demand for organically produced commodities and the price premiums they earn. At the same time, organic producers may bear costs associated with preventing the adventitious presence of GE organisms in their crops as well as substances used in conventional agriculture but not approved for organic agriculture, given organic agriculture's dependence on some consumer expectations and perceptions.

Additionally, conventional growers, similar to organic growers who desire to minimize cross pollination from GE corn into their plantings, have the same basic options for avoiding pollination from other corn. The same methods (e.g., increased distance to GE fields, use of buffer zones or rows, planting at different times to avoid overlap in pollen flow from GE corn fields) can be expected to be effective for excluding pollination from Event 3272 corn.

Apted, S. and K. Mazur. 2007. Potential economic impacts from the introduction of GM canola on organic farming in Australia. ABARE Research Report 07.11 Prepared for the Australian Government Department of Agriculture, Fisheries and Forestry, Canberra, May.

Brookes, G. and P. Barfoot. 2004. Co-existence in North American agriculture: can GM crops be grown with conventional and organic crops? PG Economics. Dorchester, UK. (http://www.pgeconomics.co.uk/pdf/CoexistencereportNAmericafinalJune2004.pdf)

Cicia, G., T. Del Giudice, I. Ramunno and C. Tagliafierro. 2006. Splitting consumer's willingness to pay premium price for organic products over main purchase motivations. Paper prepared for the 98th EAAE Seminar 'Marketing Dynamics within the Global Trading System: New Perspectives', Chania, Crete, Greece.

Durham, C. A. and Andrade, A. (2005) Health vs. Environmental Motivation in Organic Preferences and Purchases. Selected paper prepared for presentation at the American Agricultural Ecnonomics Association Annual Meeting. Providence, Rhode Island, July 24-27.

Jarosz, N., B. Loubet, B. Durand, A. McCartney, X. Foueillassar, and L. Huber. 2003. Field measurements of airborne concentration and deposition rate of maize pollen. Agricultural and Forest Meteorology. 119: 37-51.

Krueger, J. E. 2007. If your farm is organic, must it be GMO free? Organic farmers, genetically modified organisms and the law. Farmer's Legal Action Group, Inc, St. Paul, Minnesota.

Kuepper, G. 2002. Organic field corn production. National Sustainable Agricultural Information Service. http://attra.ncat.org/attra-pub/fieldcorn.html. Date Accessed: August 25, 2009.

Kuepper, G., H. Born, and L. Gegner. 2007. Organic systems plan (OSP) templates for certifiers. National Sustainable Agricultural Information Service. http://attra.ncat.org/attra-pub/PDF/OSPtemplates.pdf. Date Accessed: August 25, 2009.

Naspetti, S. and R. Zanoli. 2006. Organic Food Quality & Safety Perception Throughout Europe. Paper prepared for the 98th EAAE Seminar 'Marketing Dynamics within the Global Trading System: New Perspectives', Chania, Crete, Greece.

NCAT. 2003. NCAT's Organic Crops Workbook: a guide to sustainable and allowed practices. National Center for Appropriate Technology. http://attra.ncat.org/attrapub/PDF/cropsworkbook.pdf. Date Accessed: February 24, 2009.

Riddle, J. A. 2004. Best management practices for producers of GMO and non-GMO crops. University of Minnesota, School of Agriculture.

Ronald, P. and B. Fouche. 2006. Genetic Engineering and Organic Production Systems. Publication 8188. Regents of the University of California, Division of Agriculture and Natural Resources. (http://anrcatalog.ucdavis.edu)

USDA-NASS. 2009b. Crop Values 2008 Summary. United States Department of Agriculture, National Agricultural Statistics Service. http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1050. Date Accessed: February 16, 2010.

USDA-NASS. 2010. 2007 Census of Agriculture: Organic Production Survey (2008). United States Department of Agriculture, National Agriculture Statistics Survey.

USGC. 2006. Value-enhanced corn report. 2005/2006. U. S. Grains Council. http://www.agmrc.org/media/cms/USGC_Value_Enhanced_Corn_Report_200_08C7959C2B1E6.pdf. Date Accessed: August 31, 2009.

Zhang, F., Huang, C.L., Lin, B-H, and Epperson, J.E. 2006. National Demand for Fresh Organic and Conventional Vegetables: Scanner Data Evidence. Research in Agricultural and Applied Economics. Paper presented at AAEA 2006 annual meeting, July 23-26, Long Beach, CA (http://purl.umn.edu/21107)

6. APHIS received numerous comments that expressed concern regarding the human health effects and allergenicity of Event 3272 corn, the validity of tests conducted, and many comments claim that an EIS is required to address these concerns.

Response: Under the authority of 7 CFR part 340, APHIS is responsible for the safe development and use of genetically engineered organisms under the plant pest provisions of the Plant Protection Act. APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including genetically engineered crop plants such as Event 3272 corn. If a petition for nonregulated status is submitted, APHIS must make a determination regarding whether the genetically engineered organism is likely to pose a plant pest risk (EA, p. 7).

Developers of genetically engineered (GE) plants used for food and feed may participate in the U.S. Food and Drug Administration's (FDA) voluntary consultation procedures for food and

feed derived from GE plants to ensure that such food and feed are safe and legal prior to marketing. The FDA considers, based on agency scientists' evaluations of the available information, if there are any unresolved issues regarding the food derived from the new plant variety that would necessitate legal action by the agency if the product were introduced into commerce. The FDA considers a consultation to be completed when all safety and regulatory issues are resolved. (http://www.cfsan.fda.gov/~lrd/biocon.html). Syngenta's consultation with FDA included, along with other data, information on the identity, function, and characterization of the genes and gene products, toxicity and allergenicity information of the gene products, as well as the expression levels of the gene products (EA, p. 34). Based on the information Syngenta presented to FDA, FDA had no further questions concerning grain and forage from Event 3272 corn. APHIS included information regarding Syngenta's completed consultation with FDA (BNF 0095) in Appendix H of the draft EA.

Furthermore, in fulfilling its NEPA obligations, APHIS did not simply rely on Syngenta's completed consultation with FDA regarding the safety of food and feed derived from Event 3272 corn. APHIS' consideration of Syngenta's completed consultation with FDA was one of several factors used by APHIS to determine that Event 3272 corn would have no likely adverse impacts on human health. APHIS also examined the history of safe consumption of alpha-amylases, including those that are functionally similar to other alpha-amylases used in food processing (EA, p. 48). APHIS also independently reviewed and evaluated the information submitted by Syngenta in their petition, including data on the expression levels of AMY797E and PMI, the composition of Event 3272 corn, and the potential toxicity and allergenicity of Event 3272 corn. A summary of these data are found in the EA on pages 48-50, and includes an evaluation of the toxicity studies conducted by Syngenta. APHIS will amend the EA to introduce this information earlier in the EA under the Public Health heading, and will repeat the information in the Threatened and Endangered Species section. APHIS has reviewed and evaluated the studies submitted to APHIS by Syngenta, including the above information as well as information provided in public documents from other countries that have approved Event 3272 corn, and has concluded that it is unlikely that Event 3272 corn poses a hazard to human health (EA p. 35).

APHIS agrees with commenters that food allergies are a serious concern. In assessing the potential allergenicity of the AMY797E alpha-amylase, Syngenta considered several relevant categories of data and information. In its petition and as discussed in the EA (pg. 34-35), Syngenta notes that the donor organisms (*Thermococcus*/*Pyrococcus*) used to develop the AMY797E alpha-amylase protein are not known to be sources of allergenic proteins. Syngenta also reported that the AMY797E alpha-amylase protein is rapidly degraded (within 5 minutes) in simulated gastric fluid containing pepsin. Syngenta did report that the AMY797E alpha-amylase protein is a thermostable protein, but noted that the heat-stability alone, has no implications for human safety. Additionally, analysis of the AMY797E alpha-amylase protein as expressed in Event 3272 corn revealed no evidence of post-translational glycosylation.

Syngenta also assessed the potential allergenicity of AMY797E alpha-amylase by searching for amino acid similarity between this protein and sequences of known and putative protein allergens (Syngenta petition, p. 115-116; EA, pg. 34-35, 48-50). Different searches were conducted using databases comprised of identified putative allergen sequences from publicly available databases and from the scientific literature. For the AMY797E protein, sequence

identity was first examined by comparing sequential 80-amino acid peptides of the AMY797E protein to allergen sequences, to determine if any 80-amino acid peptide had significant similarity (greater than 35% amino acid identity) to a known or putative allergen sequence. It was determined that there was no significant sequence identity between any of the sequential AMY797E 80-amino acid peptides and any entries in the allergen databases (Syngenta petition, p. 115; EA, p. 35). The AMY797E protein sequence was further screened for every possible match of 8 or more contiguous amino acid peptides with allergen sequences in the databases (Syngenta petition, p. 115). This analysis screened for short, local regions of amino acid identity that might indicate the presence of common IgE-binding epitopes.

One comment suggested a different method of screening (Center for Food Safety, January 20th). However, there are no regulatory, mandated, or otherwise authoritative tests for determining allergenicity, and neither NEPA nor any other applicable statute or convention requires APHIS to use any particular test or procedure to determine allergenicity. The screening methods used by Syngenta and evaluated by FDA and APHIS are recognized internationally as valid methods (Codex 2008).

One region of eight contiguous amino acids in AMY797E does share identity to an allergen from an insect ("Per a 3", from the American cockroach). Syngenta maintains that this sequence identity is not biologically relevant and has no implication for the allergenic potential of the AMY797E alpha-amylase because there is no overlap between the IgE binding epitopes of the insect protein and the region of sequence identity of AMY797E alpha-amylase (Syngenta petition, p. 115; EA, pg. 35). APHIS has determined that Syngenta has provided sufficient information concerning the sources and methods used to determine a low likelihood of allergenicity.

Another submitted comment concerned the prevalence of fungus-derived occupational allergens as also acknowledged in the EA (p. 35). Syngenta provides evidence that although AMY797E shows functional similarity with a range of amylases derived from *Aspergillus oryzae*, there is no reason to assume that proteins with similar enzyme activity, per se, are allergenic (Syngenta petition, p. 127). As stated above, Syngenta's data provided in the petition assessed the potential allergenicity of the AMY797E alpha-amylase protein by searching for amino acid sequence homology between the AMY797E protein and that of known and putative allergen sequences. These searches were conducted using a database comprised of identified putative allergen sequences from publicly available databases and additional putative allergen sequences from the scientific literature. Syngenta reported that there were no significant similarities between the alpha-amylase found in Event 3272 corn and other allergens, including fungus-derived allergens. The potential allergenicity of AMY797E was considered during Syngenta's consultation with FDA regarding food and feed derived from Event 3272 corn. Based on the information Syngenta presented to FDA, FDA had no further questions concerning grain and forage from Event 3272 corn.

Finally, APHIS did not simply rely on the FDA's evaluation of the environmental effects of Event 3272 corn to fulfill its NEPA obligations. APHIS' consideration of the completed FDA consultation process was one of several factors. APHIS also evaluated the safety of alpha-amylases in food production and products, the compositional and nutritional data from Event

3272 corn in comparison to other corn varieties, the lack of toxicity and allergenicity of Event 3272 corn, and other safety assessments of Event 3272 corn conducted in other countries, to determine that Event 3272 corn that it is unlikely that Event 3272 corn poses a hazard to human health (EA, p. 35).

Codex. 2008. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. http://www.codexalimentarius.net/web/standard_list.do?lang=en (Accessed August 10, 2009).

7. Comments also indicated a concern about "unintended effects" on genetically engineered plants due to the process of genetic engineering. Comments submitted also suggest that genetic engineering is extremely imprecise, inaccurate and uncontrolled and it creates a set of risks and hazards that are poorly understood today due to lack of adequate research.

Response: Much of the data submitted by the developer is designed to address possible unintended effects that might occur as a result of inserting the genetic construct into Event 3272 corn. APHIS reviewed and evaluated these data and information, including an insertion analysis of the gene construct, gene sequence information about the inserted DNA, genetic inheritance data, protein expression data, disease and pest resistance characteristics, growth habit, vegetative vigor, reproductive characteristics, yield and grain characteristics, stress adaptation, and the nutritional composition of Event 3272 corn. The nutritional composition analysis included an evaluation of the levels of protein, fat, ash, carbohydrates, moisture, acid detergent fiber, neutral detergent fiber, calcium, phosphorus in Event 3272 corn forage and levels of protein, fat, ash, carbohydrates, acid detergent fiber, neutral detergent fiber, total dietary fiber, starch, calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium, zinc, selenium, provitamin A, folic acid, thiamine, riboflavin, niacin, vitamin B6, vitamin E, fatty acids (16:0 palmitic, 18:0 stearic, 18:1 oleic, 18:2 linoleic, 18:3 linolenic), amino acids, antinutrients (phytic acid, raffinose, and trypsin inhibitor) and secondary maize metabolites (furfural, ferulic acid, and *p*-coumaric acid) in Event 3272 corn grain. The analyses found no differences in levels of these components in Event 3272 corn plants or plant parts compared to other corn varieties (EA, pg. 48-50). Additionally, mouse and bird feeding.studies were conducted with Event 3272 corn and no adverse effects were found (EA, pg. 48-50).

In their January 20th comment, the Center for Food Safety (CFS) suggests that a chemical found in all corn varieties, tetrahydrofuran-diol and leukotoxin-diol should be evaluated in Event 3272 corn. These chemicals, found in corn, corn cobs, distiller's grains and solubles, and corn oil, have been hypothesized as endocrine distruptors (e.g., Markaverich et al. 2002a, Markaverich et al. 2002b). These chemicals, found in all corn varieties, are derivatives of linoleic acid. The level of linoleic acid in Event 3272 corn was analyzed (Syngenta petition, pg. 141) and found to be similar to levels of linoleic acid in conventional corn varieties. CFS did not provide any potential mechanisms by which the levels of these chemicals that are already found in all corn varieties would be found at different levels in Event 3272 corn. Therefore there is no basis to

suggest that Event 3272 corn is significantly different in its linoleic acid derivative composition compared to any other corn varieties currently in production.

No other comment was submitted that cited specific concerns about unintended effects resulting from process of genetic engineering in Event 3272. Other comments discussed only hypothetical, generic, and unidentified 'risks' or 'hazards' that are the result of the process of engineering Event 3272. APHIS evaluated the data submitted by the developer to determine if any "unintended effects" could be identified. APHIS did not identify any "unintended effects" resulting from insertion of the gene construct and concludes that the likelihood of increased production of new allergens, new toxins, or other "novel substances" in Event 3272 corn is extremely low. AMY797E and PMI proteins are not considered to be toxic to other organisms. Therefore, APHIS concludes that no further assessment or testing on Event 3272 corn is warranted.

Markaverich B, Alejandro M, Markaverich D, Zitzow L, Casajuna N, Camarao N, et al. 2002a. Identification of an endocrine disrupting agent from corn with mitogenic activity. Biochem Biophys Res Commun 291:692–700.

Markaverich B, Mani S, Alejandro MA, Mitchell A, Markaverich D, Brown T, et al. 2002b. A novel endocrinedisrupting agent in corn with mitogenic activity in human breast and prostatic cancer cells. Environ Health Perspect 110:169–177.

8. A commenter provided a link to food safety assessment of products derived from Event 3272 conducted under the Food Standards Australia New Zealand Act 1991 (http://www.foodstandards.gov.au/foodstandards/applications/) The commenter used this assessment (Application A580) as a support for concerns about food safety related to Event 3272. The commenter expressed a desire to have more independent and peer-reviewed safety studies, including long-term (more than 90 days) feeding studies.

Response: The commenter pasted a quote from the linked document which appears to contradict the commenter's concerns of food safety:

> "The assessment of this application identified no public health and safety concerns. On the basis of the available evidence, including detailed studies provided by the Applicant, food derived from amylase-modified corn line 3272 is considered to be as safe and as wholesome as food derived from other commercial corn varieties."

The comments also express a desire to have products made from Event 3272 corn labeled. APHIS regulates GE organisms (7 CFR part 340) by authority granted by the Plant Protection Act (PPA). The PPA grants authority to regulate plant pests and noxious weeds. The PPA does not grant APHIS authority to label foods.

Regarding the comments requesting more testing and food safety analysis, this is not the purview of APHIS in its determination of nonregulated status. Under the PPA, APHIS is required to consider plant pest risks alone as a factor in determining whether or not to deregulate a regulated article. APHIS evaluated the effects of Event 3272 corn on public health. The compositional

and nutritional studies conducted by Syngenta are consistent with international standards (OECD 2002), and found that Event 3272 corn is similar in composition and nutrition to any other corn variety. Syngenta has completed a consultation with the Food and Drug Administration (BNF 0095, Appendix H of the EA). APHIS has reviewed and evaluated the studies submitted to APHIS by Syngenta and concluded that it is unlikely that Event 3272 corn poses a hazard to human health (EA p. 35).

OECD. 2002. Consensus document on compositional considerations for new varieties of maize (*Zea mays*): key food and feed nutrients, anti-nutrients and secondary plant metabolites. Publication No. 6, 2002. ENV/JM/MONO (2002) 25.

9. Comments from interest groups and other members of the public suggested that APHIS is not compliant with the Endangered Species Act, and that the EA did not adequately assess impacts on threatened and endangered species.

Response: APHIS evaluated the potential for negative effects on Federal Endangered Species Act (ESA) (16 U.S.C. Sec 1531 *et seq*.) organisms listed by the U.S. Fish and Wildlife Service (USFWS) or the National Marine Fisheries Service (NMFS) from cultivation of Event 3272 corn and its progeny (EA p. 48-50).

Given that the composition of Event 3272 corn was found to be consistent with the natural variation found in conventional corn varieties, Syngenta also conducted studies to confirm the absence of deleterious effects for animals when feeding on Event 3272 corn. During field trials Syngenta found no changes in insect feeding damage or change in insect susceptibility for Event 3272 corn compared to conventional corn (EA, p. 49). Similarly, there were no negative impacts to mammals or birds that forage on Event 3272 corn (EA, p. 49). Studies indicated that Event 3272 corn is unlikely to produce toxins that would negatively affect animals that may eat corn kernels or other plant parts containing AMY797E (EA, p. 49). Calculations to determine the daily dietary dose of phosphomannose isomerase (PMI), along with data from mouse and bird toxicity studies, indicate that PMI levels in Event 3272 corn do not cause increased harm to threatened and endangered species (EA, p. 50). Also corn plants are not sexually compatible with any threatened or endangered plant species.

APHIS obtained a nationwide list of Threatened and Endangered species and of species proposed to be listed (EA, pg. 48) and evaluated the potential hazards that Event 3272 corn might pose to these species, as along with any potential effects on critical habitat. APHIS concluded that the release of Event 3272 corn, following a determination of nonregulated status, would have no effect on federally listed threatened or endangered species or species proposed for listing, nor is Event 3272 corn expected to adversely modify designated critical habitat or habitat proposed for designation. Consequently, a written concurrence or formal consultation with the USFWS or NMFS is not required for this action (EA, pg. 50). APHIS fully complied with the ESA in its analysis of whether to grant Event 3272 corn nonregulated status.

10. Some commenters, including interest groups, expressed concerns about the influence of the transgenic plants on honey bee populations.

This concern was addressed on pages 42 and 49 of the EA and on pages 92 and 95 of the petition. Because corn does not produce nectar, foraging honeybees would only come into contact with pollen. Event 3272 corn does not express amylase in pollen, but the selectable marker protein phosphomannose isomerase (PMI) is expressed in pollen (Table 3-4 of petition). PMI proteins are commonly found in nature and no harmful effects of exposure are known. PMI does not have significant amino acid similarity to any proteins known to be toxins, and there is no evidence or reason to suspect or conclude that there would be any harmful effects. Dietary calculations to determine the daily dietary dose of PMI (page 93 of petition) and data from the mouse and bird toxicity studies (page 94 of petition) indicate that PMI levels in Event 3272 corn do not cause harm in wildlife populations. Additionally the EPA has granted an "exception from the requirement of a tolerance" for PMI in all crops (EPA, 2004; 69 FR 26770-26775). PMI is regarded as an 'inert' component of a pesticide, which means that the EPA was satisfied that there is a "reasonable certainty that no harm will result from aggregate exposure."

EPA (2004). Phosphomannose isomerase and the genetic material necessary for its production in all plants; Exemption from the requirement of a tolerance.
40 CFR Part 180. *Fed. Reg*. 69(94), 26770-26775, May 14, 2004.

11. A comment expressed concern over impact of Event 3272 corn on soil biology. The comment requests APHIS conduct soil biology studies.

Response: APHIS regulates GE organisms, based on the authority granted in the Plant Protection Act, to prevent the introduction and dissemination of plant pests. APHIS evaluated the potential effects of Event 3272 corn on soil biology in agricultural systems under the National Environmental Policy Act (NEPA). APHIS' determination to grant nonregulated status to Event 3272 corn rests on whether this corn variety is a plant pest.

The comment and EA (pg. 45 and 46) evaluated a scientific study that speculated on the soil activity of an amylase protein (AMY797E) that is found in Event 3272 corn (Wolt and Karaman 2007). The study only hypothesized on the potential for AMY797E to be found in agricultural soils; the study did not test the activity of AMY797E in soil, and did not evaluate if AMY797E is likely to be active in agricultural soils. AMY797E, like most enzymes, has specific requirements for activity, including substrate availability, inducers, nutrient availability, physical and chemical parameters such as moisture and pH. These characteristic requirements also vary from one microenvironment to another and none of these requirements were analyzed in the above referenced soil activity study. Additionally, although the study speculated on the potential amount of AMY797E that might be found in agricultural soils without conducting empirical studies, the study did not also consider the temperature requirements for this enzyme. AMY797E is constructed for maximum activity at 176 degrees F (80 degrees C) and only has 10% of its maximal activity under 86 degrees F (30 degrees C) (EA p. 46). The authors acknowledge that the study does not recognize or evaluate any of the specific requirements needed for AMY797E to be active in the soil, and fails to provide any reasonably foreseeable,

scientifically plausible rationale how the hypothetical loads, given the specific requirements for AMY797E, could lead to any negative impacts on soil biology.

Wolt, J. D. and Karaman, S. 2007. Estimated environmental loads of alpha-amylase from transgenic high-amylase maize. Biomass and Bioenergy. **31**:831-835.

12. Many comments contained sentiments that the use of Event 3272 corn, or corn in general, as a source for ethanol production is not a desired use of crop lands. These comments posit that using corn as an ethanol source will lead to increased food prices, climate change, and reduced water availability. Further, some comments implicate that APHIS did not sufficiently fulfill the NEPA requirement to address alternatives to Event 3272 corn, including alternatives to ethanol production from corn and alternatives to the use of the AMY797E enzyme produced in Event 3272 corn.

APHIS did not examine the general concerns of the use of corn (conventional, organic, or GE) as an appropriate or inappropriate feedstock for ethanol, nor any relationship between corn produced for ethanol and the environment or food prices. While APHIS does recognize that there are proponents and critics to corn-produced ethanol (EA, Section II), investigating the general attributes and characteristics of using corn for the production of ethanol, independent of whether Event 3272 corn itself might be considered a plant pest, is not within the scope of the statutory authority of Plant Protection Act (7 U.S.C. Sec. 7701 et seq.) or within the regulatory authority of APHIS.

The Plant Protection Act (PPA) was enacted to prevent the introduction and dissemination of plant pests. Through 7 CFR part 340, APHIS is responsible for the safe development and use of genetically engineered organisms that are regulated articles, and must respond to petitioners that request a determination of the regulated status of a genetically engineered organisms, including genetically engineered crop plants such as Event 3272 corn, independent of the use of the final product (EA, Section I). APHIS does not base the determination on the appropriateness or effectiveness of an end product, unless that end product is a plant pest

The possible impacts of Event 3272 corn on the use of corn for ethanol production, and any ramifications resulting from the use of corn in general as a feedstock for ethanol purposes are "too remote from the physical environment" to be included in a NEPA analysis. If a harm does not have a sufficiently close connection to the physical environment, NEPA does not apply. Under the PPA, APHIS is required to consider plant pest risks alone as a factor in determining whether to deregulate a regulated article.

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.), APHIS has prepared an environmental assessment (EA) to consider the potential environmental effects of this proposed action granting nonregulated status and the reasonable alternatives to that action consistent with NEPA regulations (40 CFR 1500-1508, 7 CFR 1b, and 7 CFR part 372). The EA was prepared to specifically evaluate the effects on the quality of the human environment that may result from the deregulation of Event 3272 corn (EA,

Section I). This EA was not prepared to evaluate the appropriateness of corn for ethanol production.

With regards to the concerns of environmental inputs and outputs related specifically to Event 3272 corn, one of the impacts of granting nonregulated status to Event 3272 corn is more efficient production of ethanol compared to current methods. As detailed in the petition, use of Event 3272 corn can reduce energy and water use when producing ethanol from corn grain (EA: Section IV, Appendix C). Nonetheless, while more effective methods for the production of fuel may be or may become available, the role of APHIS is limited to determining if a genetically engineered organism is likely to pose a plant pest risk. Additionally, because APHIS has concluded that the deregulation of Event 3272 corn is not likely to result in a substantial increase in corn acreage grown (EA, Section IV "Corn Production"), the use of Event 3272 corn does not pose an increased environmental impact compared to current production practice. Assessing the potential cumulative effects of increasing biofuel production and its impact on climate change would be too attenuated and speculative to be analyzed in the EA.

Some of the comments on this issue were based on the word choice for a heading of a section in the EA called "Need for Event 3272 Corn." The comments suggest that the APHIS action to determine nonregulated status is due to this need. However, the *necessity* of a GE product to the U.S. economy is not a valid consideration under the PPA. The 'Need for APHIS Action' section accurately describes the Purpose and Need for action to determine the consequences of nonregulated Event 3272 corn with respect to NEPA. Due to the confusion this section heading caused, APHIS will delete the section heading "Need for Event 3272 Corn" and instead label this section "Objectives for Event 3272 Corn." The "Need for APHIS Action" section of Chapter 1, Purpose and Need, will remain the same.

13. Comments suggested that Event 3272 corn is not needed or preferred for meeting any energy-based, United States government mandates, and thus APHIS should not grant nonregulated status to this GE corn variety.

Response: As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.), APHIS has prepared an environmental assessment (EA) to consider the potential environmental effects of this proposed action granting nonregulated status and the reasonable alternatives to that action consistent with NEPA regulations (40 CFR 1500-1508, 7 CFR 1b, and 7 CFR 372). The EA was prepared to specifically evaluate the effects on the quality of the human environment that may result from the deregulation of Event 3272 corn (EA, p. 7.

Under the authority of the Plant Protection Act (7 U.S.C. Sec. 7701 et seq.), APHIS is responsible for the safe development and use of genetically engineered organisms and it must respond to petitioners that request a determination of the regulated status of a genetically engineered organisms, including genetically engineered crop plants such as Event 3272 corn. If a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is likely to pose a plant pest risk. (EA, p. 7) APHIS does not evaluate the economic merit or economic need for the GE product during its evaluation. The

necessity of a GE product to the U.S. economy is not a valid consideration under the Plant Protection Act. Under the Plant Protection Act, APHIS is required to consider plant pest risks alone as a factor in determining whether or not to deregulate a regulated article.

The comments on this issue were based on the word choice for the heading of a section called "Need for Event 3272 Corn." The comments suggest that the APHIS action is due to this need. However, the 'Need for APHIS Action' section accurately describes the Purpose and Need for action of determining nonregulated status for Event 3272 corn with respect to NEPA. Due to the confusion this section heading caused, APHIS will delete this section heading and instead label this section "Objectives for Event 3272 Corn." The "Need for APHIS Action" section of Chapter 1, Purpose and Need, will remain the same.

14. Several comments were made regarding the potential rejection of corn produced in the United States by certain foreign markets that have not approved Event 3272 corn.

In the EA, APHIS has discussed the socio-economic impacts it deemed relevant to this deregulation and admitted that foreign markets that have not yet approved Event 3272 corn may reject import of Event 3272 corn. As stated in the EA, the following countries have approved Event 3272 corn for food and feed imports: Australia, Canada, and the Philippines. Since the publication of the EA, Mexico has also approved Event 3272 corn for food/and or feed use. Of the many GE varieties of corn currently grown by farmers, some are approved for import into other countries, but many have not been approved to all countries, particularly for export to countries within the European Union. When farmers choose to grow a GE variety of corn, the approval status in foreign counties is only one of many considerations for producing corn for export. Because this issue is well known to farmers, distributors, and exporters, there are already mechanisms in place for directing the diversity of corn types produced to the appropriate markets (http://ncga.com/know-you-grow). Furthermore, when a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is likely to pose a plant pest risk. (EA p. 7) APHIS does not evaluate the economic merit or economic need for the GE product during its evaluation. The necessity of a GE product to the U.S. economy is not a valid consideration under the Plant Protection Act. Under the Plant Protection Act, APHIS is required to consider plant pest risks alone as a factor in determining whether or not to deregulate a regulated article.

15. Comments were made that suggest APHIS has not fully complied with its NEPA requirement to examine the potential environmental impacts of wide-spread use of Event 3272 corn, that the EA is conclusory and generally inadequate to meet the standards of NEPA, and that a more detailed EA or an EIS is needed.

The Council on Environmental Quality (CEQ) NEPA regulations for implementing NEPA documentation make clear that socioeconomic impacts need only be addressed if and only if the "economic or social and natural or physical environmental effects are interrelated." 40 C.F.R. 1508.14. This means that there must be a causal interrelationship between a specific change in the natural or physical environment resulting from the proposed federal action and the claimed

socio-economic effects resulting from the same proposed federal action. In the APHIS determination for Event 3272, as in other APHIS deregulation decisions for GE crops, there are no specific economic impacts directly interrelated with any specific *physical* environmental change resulting from a proposed deregulation decision itself. If there are any potential economic impacts at all, they would be the result of human changes, as opposed to natural or physical changes, resulting from either choices of certain farmers to grow or not grow certain types of corn lines and the preferences of consumers.

APHIS has addressed all of the NEPA requirements in its EA in a complete, reasoned, and adequate manner, including giving a full analysis of all alternatives. APHIS has adequately addressed in the EA the potential for any impacts to human health, including cumulative impacts resulting from its proposed deregulation of Event 3272 corn. APHIS has concluded that there are unlikely to be any significant environmental impacts from the deregulation of Event 3272 corn and therefore an EIS is not required.

Based on the Plant Protection Act and 7 CFR part 340, APHIS' assessment is limited to plant pest risks only. Further, the court in *Geertson Seed Farms, et al v. Johanns* (N.D. Cal. Feb. 13, 2007) did not require APHIS to prepare an EIS for every deregulation of a regulated article.

APHIS cannot predict or hypothesize on the exact extent of the future commercialization of any additional crops once Event 3272 corn is deregulated by APHIS. Nevertheless, APHIS is not aware of any reliable data establishing or confirming that such prospective commercialization will significantly affect the environment. APHIS does not have any reason to foresee that the United States will increase or decrease the total acreage devoted to corn production, or that there will be a significant economic impact. APHIS is not required to cumulatively analyze every conceivable impact potentially resulting from the deregulation of Event 3272 corn. Deeper analyses of cumulative effects would result in values that are too attenuated and too remote from the physical environment to be required under NEPA. If a harm does not have a sufficiently close connection to the physical environment, NEPA does not apply.

16. One commenter expressed concern that transgenic crops in general have not been adequately researched for potential impacts on environmental and public health. The commenter referred to a publication in the *Journal of Proteomic Research* (Zolla et al. 2008) that researches the impact of genetic engineering on the levels of proteins in corn plants, and postulates through that reference that plants genetically engineered for food or feed need to be more thoroughly tested.

Though Zolla et al. (2008) finds some interesting results analyzing the possible impacts of a single gene insert on protein levels in corn, these results do not diminish the Finding of No Significant Impact determined in the EA for several reasons. The nutritional and agronomic data provided by the applicant demonstrate that the Event 3272 corn is equivalent to traditional varieties of hybrid corn. The genetic engineering of the Event 3272 corn has not resulted in characteristics that increase the plant pest risk or potential harm to the environment compared to conventional corn. Even if there are changes in levels or characteristics of other corn proteins in Event 3272, nothing in the evaluation of Event 3272 corn suggests that any changes that might

have occurred are significantly impacting the health or safety of the corn plants or are posing a plant pest or environmental risk.

Zolla L, Rinalducci S, Antonioli P, Righetti PG. 2008. Proteomics as a complementary tool for identifying unintended side effects occurring in transgenic maize seeds as a result of genetic modifications. *J Proteome Res.* 7(5):1850-61

17. One comment inferred that Event 3272 corn should be considered "an inherently weedy characteristic" because of the potential to cross-pollinate other corn. Additionally the comment mentioned that plants in the Gramineae family are characteristically weedy.

The agronomic properties of Event 3272 corn were analyzed in detail for changes in agronomic characteristics that would cause the plant to have increased weedy attributes (Chapters 5 and 8 in the petition). In the Plant Pest Risk Assessment for Event 3272 corn (USDA APHIS 2009), APHIS assessed whether Event 3272 corn is any more likely to become a weed than the non-transgenic recipient corn line, or other corn currently cultivated. The assessment encompasses a thorough consideration of the basic biology of corn and an evaluation of the characteristics of Event 3272 corn. APHIS examined the historical evidence documenting that corn is not a weed. Event 3272, like all corn, is not persistent in undisturbed environments without human intervention and the fact that Event 3272 can cross-pollinate other corn varieties does not signify that it possesses a weedy characteristic.

APHIS examined the agronomic data from field trials of Event 3272 corn at a total of 25 locations in the U.S. corn belt during the 2003 and 2004 growing seasons submitted by the developer Syngenta. These trials compared the growth habit, vegetative vigor, reproductive characteristics, and other agronomic data of Event 3272 corn to conventional corn. APHIS determined that the agronomic characteristics of Event 3272 corn are no different than other corn varieties and that Event 3272 does not possess any weedy characteristics (USDA APHIS 2009).

USDA APHIS. 2009. Plant pest risk assessment for Event 3272 corn. Biotechnology Regulatory Services, Riverdale MD.

18. A commenter postulates that in discussing potential impacts on biodiversity (EA at 44) APHIS gives a cursory review of effects to biodiversity. The commenter further takes the position that Event 3272 corn may have "undesirable and unintended consequences" because of possible impacts to corn markets and the diversity choices for farmers.

As explained in other responses to public comments on the docket, and based on the information reviewed and analyzed by APHIS, there is no expectation of any significant impacts on growers of organic or conventional corn lines resulting from APHIS' regulatory decision to deregulate Event 3272 corn. There is no reason to expect that Event 3272 corn will be grown anywhere other than on land that has been in agricultural production for many years. The planting of Event 3272 corn would not have any direct impact on the conversion of land use. Decisions to change land use are based on determinates and market forces outside of APHIS authority. Additionally,

Syngenta has stated "it is anticipated that Event 3272 hybrids will be grown in the same areas as current commercial maize hybrids" and that Event 3272 is not "intended to confer any competitive advantage or extend the range of maize cultivation outside of cultivation areas" (Page 84 of the petition). Because Event 3272 corn reduces the inputs needed to produce ethanol, it is foreseeable that less corn acreage will be required to match current ethanol production levels. Furthermore, most of the corn (more than 80%) grown is in the U.S. is GE (http://www.ers.usda.gov/Data/biotechcrops/), and therefore GE composes the large majority of corn currently used to produce ethanol from corn. The availability of Event 3272 corn offers growers another choice in addition to the options already available.

The commenter makes note of a 2007 court ruling related to GE alfalfa in making assertions related to biodiversity and consumer choice. APHIS takes the position that the ruling regarding alfalfa is not relevant to APHIS' comprehensive evaluation of, and the subsequent decision to deregulate, Event 3272 corn. Alfalfa is biologically different than corn, reproductively different than corn, and GE corn has been grown in the U.S. for over 10 years. Further, more than 20 different GE corn events have been granted nonregulated status by USDA APHIS, and as stated previously, GE corn has been favorable adopted by U.S. farmer; more than 80% of the corn acres grown in the United States is GE corn. Moreover, growers and exporters in the United States have adapted to inclusion of GE corn into the commerce stream. GE corn exists (as the overwhelming majority of corn grown within the U.S.), is consumed domestically, and is shipped to a variety of foreign markets. Additionally, a market exists for non-GE corn that is also consumed locally and shipped to foreign markets. This leads APHIS to conclude that significant impacts related to both biodiversity and consumer choices are unlikely to occur as a result of introduction of Event 3272.

19. A comment was made suggesting that a determination of Event 3272 granting nonregulated status would be based on a flawed scientific analysis because of a failure to consider the Precautionary Principle.

Discussions and writings about the use of the "Precautionary Principle" in decision-making continue to influence numerous venues in modern society (http://en.wikipedia.org/wiki/Precautionary_principle; http://www.sourcewatch.org/index.php?title=Precautionary_principle; http://www.heritage.org/Research/Regulation/hl818.cfm, accessed 2/27/09; Foster et al. 2000; Kriebel et al 2001; Gray and Bewers 1996; Sunstein 2002). One can find numerous writings, scholarly articles and books debating the use and value of considering the "Precautionary Principle" in decision-making with no clear consensus either about its value or its exact definition. APHIS always analyzes environmental issues in its regulatory decisions regarding the regulation of GE organisms. In considering Event 3272, different U.S. government agencies (USDA and FDA) ultimately consider extensive scientific data and information produced by the developer regarding this product and make determinations based on that data as well as other relevant data known to the Agencies. The FDA has concluded its food safety analysis of this product and indicated to the developer that it had no further questions (http://www.cfsan.fda.gov/~lrd/biocon.html, BNF No. 95, completed August 7, 2007).

APHIS reviewed scientific data and information provided by the developer (both quantitative and qualitative) that it believes are adequate to make a regulatory decision about Event 3272. APHIS has also addressed relevant environmental issues and believes that specific data collection suggested by the commenter would not provide further useful insight into either relevant plant pest or environmental issues.

Foster, K.R., P. Vecchia, M.H. Repacholi. 2000. Risk Management: Science and the Precautionary Principle. Science 288: 979-981. DOI: 10.1126/science.288.5468.979

Gray, J.S. and J.M. Bewers. 1996. Towards a Scientific Definition of the Precautionary Principle. Marine Pollution Bull 32:768-771.

Kriebel, D., J. Tickner, P. Epstein, J. Lemons, R. Levins, E.L. Loechler, M. Quinn, R. Rudel, T. Schettler, and M. Stoto. 2001. The Precautionary Principle in Environmental Science. Environ Health Perspectives 109: 871-876.

Sunstein, C.R. 2002. The Paralyzing Principle. *Regulation* Winter 32-37.

20. A commenter expressed concern over possible breeding combinations that may occur with Event 3272 corn and other corn lines already granted non-regulated status. The commenter postulates that these possible combinations need to also be evaluated by APHIS. Additionally a comment was made that requests that APHIS do an analysis of the rate at which the mixing of Event 3272 corn might mix or breed with other corn varieties.

APHIS admits that Event 3272 corn could potentially be combined with other GE varieties, however, predicting any and all possible permutations and potential combinations of products that Event 3272 corn could be "stacked" with, and the possible environmental impacts are too hypothetical and speculative. If the harm does not have a sufficiently close connection to the physical environment, NEPA does not apply.
GE corn plants that have been previously deregulated by APHIS have been evaluated and are unlikely to pose a plant pest risk or do not have an environmental impact greater than other, non-GE corn that is grown. Additionally, GE corn is now more than 80% of the corn that is cultivated. The AMY797E and PMI proteins that are produced as a result of the genetic material inserted in Event 3272 will not interact nor influence the expression of genes inserted or be affected by genetic material that was inserted into other deregulated lines. Therefore, if Event 3272 is bred with another non-regulated GE corn variety, or any corn variety for that matter, there will be no change in phenotypic properties beyond those of the parental lines, which have already been determined to be as safe as any other commonly grown corn. Of course, if Event 3272 is genetically engineered with recombinant DNA or if Event 3272 is bred with a regulated article, the progeny would be considered a regulated article, and would be subject to APHIS jurisdiction.

Furthermore, the reproductive characteristics of Event 3272 corn were analyzed and the results presented in the petition (Chapter 5, Phenotypic Evaluation). Event 3272 corn does not possess any characteristics that would lead to a change in the rate of pollination or other reproductive

factors compared to other corn genotypes. The concern of cross-fertilization of Event 3272 with other corn varieties has already been considered.