Plant Pest Risk Assessment for Event 3272 Corn

This plant pest risk assessment is to determine whether Event 3272 corn is unlikely to pose a plant pest risk. If APHIS determines that a genetically engineered (GE) organism is not a plant pest, then the GE organism is not subject to the regulatory requirements of 7 CFR part 340.

APHIS' authority to regulate genetically engineered organisms under the Plant Protection Act (PPA) (7 U.S.C. Sec 7701 *et seq*.) is limited to those GE organisms that are plant pests as defined under Section 403(14) of the PPA (7 U.SC. 7702(14)).

> "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."

APHIS will use the information submitted by the applicant in its petition for nonregulated status, per § 340.6(c)(4), to determine the plant pest risk associated with the regulated article. Specifically, APHIS uses the information related to plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, any impacts on the weediness of any other plant with which it can interbreed, and the transfer of genetic information to organisms with which it cannot interbreed to analyze the potential plant pest risk, if any, associated with Event 3272 corn. Issues related to agricultural or cultivation practices will be considered in the Environmental Assessment for Event 3272 corn. Event 3272 corn is not genetically engineered to produce a toxin or pesticide, thus Event 3272 corn is not targeted for use against pests in corn agriculture. Thus, APHIS did not examine the effects of the regulated article on nontarget organisms. However, APHIS does examine the effects of Event 3272 corn on animals, plants, and threatened and/or endangered species (TES) species in the Environmental Assessment. APHIS has not identified any issues related to indirect plant pest effects on agricultural production caused by Event 3272 corn.

Potential impacts to be addressed in this risk assessment are those that pertain to the use of Event 3272 corn and its progeny in the absence of confinement. The genetically engineered construct inserted in Event 3272 corn was evaluated to determine if the introduced genetic sequences cause plant disease. Morphological characteristics of Event 3272 corn were analyzed to determine if this corn variety would become weedy or

invasive. The potential for gene flow to, and introgression of the genetically engineered constructs into, other corn varieties or wild relatives of corn were also evaluated to determine the potential of increased weedy or invasive characteristics in other plant species. APHIS also analyzed the propensity of Event 3272 corn to become a greater reservoir of plant pests (insects or pathogens) compared to conventional corn and potential for horizontal gene transfer.

Development of Alpha-Amylase Event 3272 Corn

Microbially-produced alpha-amylases are commonly used commercially in the starch-processing step during corn dry grind and wet milling processing. Syngenta has developed a thermostable alpha-amylase enzyme (AMY797E) expressed in Event 3272 corn grain for use in the dry grind fuel ethanol process in the U.S. The product concept of Event 3272 corn is that Event 3272 grain will serve as the source of alpha-amylase enzyme in the dry-grind ethanol process, replacing the addition of microbially-produced enzyme. Event 3272 corn will be grown using current agronomic practices, and grain expressing AMY797E alpha-amylase enzyme will be processed at the ethanol processing plant.

1. Description of inserted genetic material and potential of the material to cause plant disease.

Event 3272 corn has been genetically engineered to contain two transgenes: (1) the *amy797E* gene encoding the theromostable AMY797E alpha-amylase enzyme and (2) the *pmi* (*manA*) gene from *Escherichia coli*, which encodes the enzyme phosphomannose isomerase, used as a selectable marker. The AMY797E alpha-amylase enzyme is a chimeric, thermostable enzyme derived from three alpha-amylase genes originating from three hyperthermophilic microorganisms of the archaeal order *Thermococcales*. This enzyme was selected by Syngenta due to its increased thermostability and activity during dry grind ethanol production from corn. AMY797E is functionally similar to those thermostable, genetically engineered alpha-amylases (e.g. *Bacillus* species) currently used, and have a history of safe use in food and feed processing (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006). The expression of *amy797E* is driven by the promoter from a corn seed storage (gamma-zein) gene, which directs the accumulation of alpha-amylase in the corn kernel. The *pmi* gene is from one of the main species of bacteria living in mammal intestines, *E. coli*, and is driven by the polyubiquitin promoter from corn.

This genetic insert also contains the terminator sequences from two plant pests, cauliflower mosaic virus and *Agrobacterium tumefaciens*. Both of these sequences are well-characterized, and are non-coding regulatory regions only. These sequences will not cause Event 3272 to promote plant disease.

DNA was introduced into corn cells from a proprietary corn line using disarmed (non-plant pest causing) *Agrobacterium tumefaciens*-mediated transformation methodology with the transformation vector designated pNOV7013. Plant cells containing the introduced DNA were then selected by culturing in the presence of mannose. After the

initial incubation with *Agrobacterium*, the broad-spectrum antibiotic cefotaxime was included in the culture medium to kill any remaining *Agrobacterium*. Therefore, no part of the plant pest *A. tumefaciens* is remaining in Event 3272 corn due to the transformation method.

Data from Southern analyses demonstrate that Event 3272 plants: (1) contain a single copy of both *amy797E* (Figure 3-4, page 35 of petition) and *pmi* (Figure 3-6, page 36 of petition) genes, (2) contain a single copy of both the gamma-zein (Figure 3-8, page 37 of petition) and ubiquitin promoters (Figure 3-10, page 38 of petition), and (3) do not contain sequences from the transformation plasmid (pNOV7013) (Figure 3-12, page 40 of petition) that were not intended to be transferred to Event 3272 (i.e.'backbone sequences'). DNA sequences of Event 3272 corn confirmed that the overall integrity of the intended insert and the contiguousness of the functional elements have been maintained (page 30, Figure 3-15, and page 42 of petition). Statistical analyses over multiple generations confirm that the *amy797E* gene is stably integrated and is inherited over generations in the expected fashion (Table 3-2, page 31 of petition). Therefore, only the expected genetic material was stably inserted into Event 3272 corn, and there is no expectation that plant disease will result due to the genetic construct in Event 3272 corn.

2. Potential impacts based on the relative weediness and/or invasiveness of Event 3272 corn

APHIS assessed whether Event 3272 corn is any more likely to become a weed than the nontransgenic recipient corn line, or other corn currently cultivated. The assessment encompasses a thorough consideration of the basic biology of corn and an evaluation of unique characteristics of Event 3272 corn.

In the U.S., corn is not listed as a weed in the major weed references (Muenscher 1980, Holm et al. 1991, Holm et al. 1997) nor is it listed as a noxious weed species by the U.S. Federal Government (7 CFR part 360). Furthermore corn has been grown throughout the world without any report that it is a serious weed. Cultivated corn is unlikely to become a weed because it is not generally persistent in undisturbed environments without human intervention. Although corn volunteers are not uncommon, they are easily controlled by herbicides or mechanical means and rarely reappear in a second season. Corn also possesses few of the characteristics of plants that are notably successful weeds (Baker 1965, Keeler 1989).

Syngenta conducted agronomic 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. Field trial data (Tables 5-3, 5-4, 5-5, 5-6, 5-7, 5-8, Appendix 4 of petition) indicated that Event 3272 corn does not exhibit characteristics that would cause it to be weedier than the parental corn line. Growth habitat was not remarkably different between Event 3272 corn and the control hybrid (Table 5-3 of petition). Two measures of late season integrity of the corn plant, late season intactness and push test scores, were slightly depressed in Event 3272 plants; however a third integrity measure, percent broken stalks, was elevated in Event 3272 plants compared to the non-transgenic control hybrids. Thus, overall, growth habitat characteristics did not differ in Event 3272 corn compared to the hybrid controls.

Vegetative vigor assessments (Table 5-4 of petition) conducted by Syngenta indicate that early emergence vigor, early growth rating and ear height characteristics were all similar between Event 3272 corn and the control hybrids. Plant height was found to be significantly shorter in Event 3272 corn compared to the hybrid control plants. However, plant height reduction is unlikely to be associated with a trend toward increasing weediness.

Syngenta also evaluated the reproductive characteristics (Table 5-5 of petition) of Event 3272 corn. The percentage of barren plants was slightly elevated in Event 3272 corn compared to the nontransgenic hybrid controls, and this was the only reproductive variable that differed between the two plant types. In terms of weediness, an increase in barren plants in Event 3272 corn would not increase the risk of weediness because it does not indicate a potential increase in reproductive output.

There was no increase in weediness potential as measured by differences in primary dormancy (germination potential) or secondary dormancy (overwintering ability) (Table 5-8 of petition). There was a slight decrease in the ability of Event 3272 seeds to survive the 'winter conditions' test (5ºC) compared to the nontransgenic control plants. However, a decrease in seed survival would not correspond to an increase in secondary dormancy and increased weediness. In addition, there were no changes to abiotic stress tolerance (as measured by early root lodging, late root lodging, and percent snapped plants) (Table 5-3 of petition).

The introduced traits, increased alpha-amylase accumulation in the grain and expression of PMI, are not expected to cause Event 3272 corn to become a weed or improve the ability of this corn variety to survive without human intervention. Nor is there any foreseeable reason to conclude that these two genes would affect this variety's survival in the wild. None of the characteristics of weeds described by Baker (Baker 1965) involves increased alpha-amylase or PMI levels, and there is no reason to expect that these traits would result in increased weediness. Event 3272 corn is unchanged in its susceptibility to injury by commercially available herbicides, and thus could be chemically-controlled. Therefore, there is no selective advantage to corn containing AMY797E or PMI compared to conventional corn, and there is no increased potential for weediness or invasiveness from Event 3272 corn.

3. Potential impacts from gene flow and gene introgression from Event 3272 corn into its sexually-compatible relatives.

Zea mays L. subsp. *mays* is a member of the *Maydeae* tribe of the grass family, *Poaceae*. It is a monoecious annual plant that requires human intervention for its seed dispersal and propagation. The species is open-pollinated through wind movement of pollen. Additional information on the biology of maize can be found within the Organisation for Economic Co-Operation and Development (OECD) consensus document (OECD 2003).

In assessing the risk of gene introgression from Event 3272 corn into its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression, and 2) the potential impact of introgression.

APHIS evaluated the potential for gene introgression to occur from Event 3272 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Cultivated corn, or maize, *Zea mays* L. subsp. *mays*, is sexually compatible with other members of the genus *Zea*, and to a much lesser degree with members of the genus *Tripsacum*.

In general, gene flow from cultivated agricultural crops to domesticated, wild or weedy relatives has most likely occurred ever since the domestication of a particular crop, assuming sexually compatible species are present (Stewart Jr. et al. 2003). Based upon currently available data, there have been a relatively low number of confirmed cases of introgression (Stewart Jr. et al. 2003).

Wild diploid and tetraploid members of *Zea*, collectively referred to as teosinte, are normally confined to the tropical and subtropical regions of Mexico, Guatemala, and Nicaragua. A few isolated populations of annual (*Zea mexicana*) and perennial (*Zea perennis*) teosinte have been reported to exist in the past in Alabama, Florida, South Carolina, and Maryland (USDA-NRCS 2007), but are likely no longer in existence (US-EPA 2000), or are small isolated occurrences. None of these teosinte species has been shown to be an aggressive weed in its native or introduced habitats. The Mexican and Central America teosinte populations primarily exist within and around cultivated corn fields; they are partially dependent on agricultural niches or open habitats, and in some cases are grazed upon or fed to cattle which distribute the seed. While some teosinte may be considered to be weeds in certain instances, they are also used by some farmers for breeding improved maize (Sánchez and Ruiz 1997). Teosinte is described to be susceptible to many of the same pests and diseases which attack cultivated corn (Sánchez and Ruiz 1997)

All teosinte members can be crossed with cultivated corn to produce fertile F_1 hybrids (Wilkes 1967, Doebley 1990a). In areas of Mexico and Guatemala where teosinte and corn coexist, they have been reported to produce hybrids. Of the annual teosintes, *Z. mays* subsp. *mexicana* forms frequent hybrids with maize, *Z. luxurians* hybridizes only rarely with maize, whereas populations of *Z. mays* subsp. *parviglumis* are variable in this regard (Wilkes 1977, Doebley 1990a). Research on sympatric populations of maize and teosinte suggests introgression has occurred in the past, in particular from maize to *Z. mays* subsp. *luxurians* and *Z. mays* subsp. *diploperennis* and from annual Mexican plateau teosinte (*Z. mays* subsp. *mexicana*) to maize (Kato Y. 1997) and references therein).

Nevertheless, in the wild, introgressive hybridization from maize to teosinte is currently limited, in part, by several factors including distribution, differing degrees of genetic incompatibility, temporal separation in flowering time, differences in developmental morphology, variation in dissemination methods, and disparities in dormancy (Galinat

1988, Doebley 1990a, 1990b). First-generation hybrids are generally less fit for survival and dissemination in the wild, and show substantially reduced reproductive capacity which acts as a significant constraint on introgression.

Teosinte has coexisted and co-evolved in close proximity to corn in the Americas over thousands of years, but corn and teosinte maintain distinct genetic constitutions despite sporadic introgression (Doebley 1990a). The potential for gene introgression from Event 3272 corn into teosinte would increase if varieties are developed and approved for cultivation in locations where these teosintes are located. However, hybridization in nature is extremely unlikely because the distributions of teosinte and *Z. mays* do not overlap (http://www.maizegenetics.net/index.php?page=domestication/taxonomydistribution.html), and because of differences in developmental morphology and reproductive timing between the two species. Additionally first-generation corn-teosinte hybrids are generally less fit for survival and dissemination, and they show substantially reduced reproductive capacity. Therefore, it is very unlikely that gene introgression into a wild corn relative will occur. Moreover, since Event 3272 corn does not exhibit characteristics to cause it to be any weedier than other cultivated corn, its potential impact due to the limited potential for gene introgression into teosinte is not expected to be any different from that of other cultivated corn varieties.

The genus *Tripsacum* contains up to 16 recognized species, most of which are native to Mexico, Central and South America, but three exist or have existed as wild and/or cultivated species in the U.S. (Hitchcock 1971, USDA-NRCS 2007). Though many of these species occur where corn might be cultivated, gene introgression from Event 3272 corn under natural conditions is highly unlikely or impossible. Hybrids of *Tripsacum* species with *Zea* are difficult to obtain outside of a laboratory and are often sterile or have greatly reduced fertility, and none is able to withstand even the mildest winters (Beadle 1980, Galinat 1988). Furthermore, none of the sexually compatible relatives of corn in the U.S. is considered to be a weed in the U.S. (Holm et al. 1997). AMY797E and PMI do not confer a selective advantage to plants that contain these genes. Thus, the likelihood of introgression is extremely low. In the highly unlikely event that introgression to a wild relative would occur, acquisition of the *amy797E* or *pmi* gene would not be expected to transform the wild relative into a weed.

4. Potential of Event 3272 corn to harbor plant pests (insects and disease)

The data submitted by Syngenta indicated no significant differences between Event 3272 corn and the non-transgenic counterparts for disease (as measured by northern corn leaf blight and southern corn leaf blight observations, and gray leaf spot rating) and pest susceptibility (as measured by European corn borer damage) (Table 5-7 of petition). The data presented in the petition indicated 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), 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 (Ridley et al. 2004, ILSI 2006) or in the OECD consensus document on corn composition (OECD 2003). Therefore, the composition of Event 3272 is not biologically different than conventional corn, and is thus susceptible to the same pest population as conventional corn. Additionally, Event 3272 corn is similarly affected by typical plant diseases found in corn, and does not harbor an altered pest or pathogen community compared to other corn varieties.

5. Transfer of genetic information to organisms with which it cannot interbreed

Horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur. First, many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants, including *Agrobacterium* and *Rhizobium* (Kaneko et al. 2000, Wood et al. 2001, Kaneko et al. 2002). There is no evidence that these organisms contain genes derived from plants. Second, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale on the order of millions of years (Koonin et al. 2001, Brown 2003). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus even if horizontal gene transfer occurred, proteins corresponding to the transgenes are not likely to be produced. Fourth, the FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (http://vm.cfsan.fda.gov/~dms/opa-armg.html). Therefore APHIS concludes that horizontal gene transfer is unlikely to occur and thus poses no significant environmental or plant pest risk.

Conclusion

APHIS has reviewed and conducted a plant pest risk assessment on Event 3272 corn. Due to the lack of plant pest risk from the inserted genetic material, the lack of weediness characteristics of Event 3272 corn, the lack of atypical responses to disease or plant pests in the field, the lack of deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, APHIS concludes that Event 3272 corn is unlikely to pose a plant pest risk.

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

subparagraphs"). APHIS has determined that the alpha-amylase enzyme engineered into Event 3272 corn is not a plant pest because the alpha-amylase enzyme in Event 3272 corn is not living and thus cannot itself be a living stage of any organism listed in the PPA's plant pest definition.

APHIS has determined that neither Event 3272 corn, nor the alpha-amylase enzyme in Event 3272 corn, is a "living stage" of any of the organisms (articles) listed in subsections A-H of the PPA's plant pest definition, Moreover, neither Event 3272 corn nor the alpha-amylase enzyme in Event 3272 corn is an article that harbors plant pests.

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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.

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272

OECD Unique Identifier SYN-E3272-5

Final Environmental Assessment

February 2011

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Agency Contact:
Cynthia Eck
Document Control Officer
Biotechnology Regulatory Services
USDA APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

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I. Purpose & Need

"Protecting American agriculture" is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income.

APHIS Biotechnology Regulatory Service's (BRS) mission is 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.

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.

WHAT IS A REGULATED ORGANISM?

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 the PPA 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[1]. 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.

WHAT IS THIS PROJECT ABOUT?

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.

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.

[1] 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

OBJECTIVES FOR EVENT 3272 CORN

The Federal Energy Policy Act of 2005, signed on August 8, 2005, includes a Renewable Fuels Standard that directs the doubling of the use of ethanol and biodiesel in the U.S. fuel supply by 2012 to 7.5 billion gallons (42 USC 15801). The Energy Independence and Security Act of 2007, passed in December 2007, includes a provision to expand consumption of alternative fuels, including but not limited to ethanol, to 36 billion gallons in 2022. On October 13, 2010, the U.S. Environmental Protection Agency (EPA) waived a limitation on selling gasoline that contains more than 10 percent ethanol for model year 2007 and newer cars and light trucks. The waiver applies to fuel that contains up to 15 percent ethanol – known as E15. The waiver was extended to model year 2001 through 2006 passenger vehicles, including cars, SUVs, and light pickup trucks on January 21, 2011. (http://www.epa.gov/otaq/regs/fuels/additive/e15/, accessed February 8, 2011). With over 194 corn ethanol plants in operation in 28 different states, and at least 7 more under construction (http://www.ethanolrfa.org/bio-refinery-locations/, accessed February 7, 2011), corn-based ethanol production may be a feasible way to meet and exceed the ethanol consumption benchmark for 2012 set in the Energy Policy Act of 2005, and 2022 goals set by the Energy Independence and Security Act of 2007.

Ethanol has also become the oxygenate of choice for reformulated gasoline (RFG), due to state bans of methyl *tert*-butyl ether (MTBE) and the increased liability to oil companies for MTBE spills (Hoffman et al. 2007). As provided in the Federal Clean Air Act amendments of 1990, cities with the worst smog pollution are required to use RFG, while other cities voluntarily adopted the RFG program. The decreased use of MTBE in RFG, and the subsequent benchmark set by the Energy Policy Act of 2005, and the Energy Independence and Security Act of 2007, along with other Federal programs and policies [see (Hoffman et al. 2007) and (Schnepf 2006) for a thorough discussion], have combined to stimulate the demand for ethanol.

Event 3272 corn is expected to help the U.S. meet its goals for ethanol production. According to the company, the overall efficiency of the dry grind process with using Event 3272 grain is greater than conventional dry ethanol production, due to greater ethanol production per unit of Event 3272 grain, and greater throughput efficiency during the dry grind process itself.

Event 3272 corn has been field tested in the United States since 2002 as authorized by USDA notifications and permits listed in Table 1-1, on page 17 of the Petition. The list compiles a number of test sites in diverse regions of the U.S. including the major corn growing areas of the Midwest and winter nurseries in Hawaii and Puerto Rico. Field tests conducted under APHIS oversight allow for evaluation of Event 3272 corn in an agricultural setting while imposing measures to minimize the risk of persistence in the environment after the completion of the test. Data are gathered on multiple parameters and are used by the applicants to evaluate agronomic characteristics and product performance, and are used by APHIS to determine if the new variety poses a plant pest risk (USDA-APHIS 2009).

Once APHIS determines that a GE organism is unlikely to pose a plant pest risk, the GE variety may be traditionally bred with other conventional varieties or other GE varieties as determined by the applicant or developer, and is not subject to the regulatory requirements of 7 CFR part 340. Syngenta currently has four GE corn varieties that may be stacked[2] with Event 3272 corn:

[2] "Stacked" refers to two or more traits (e.g. herbicide tolerance and insect resistance) in one plant.

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, Mir 162 and GA21) have all been granted non-regulated status, and the environmental assessments conducted by APHIS for each of these products can be found at http://www.aphis.usda.gov/brs/not_reg.html.

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.

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), APHIS has prepared this 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 parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[3] that may result from the deregulation of Event 3272 corn.

OTHER REGULATORY APPROVALS

Event 3272 corn has successfully completed the consultation process with the FDA concerning food and feed safety (Appendix H). Event 3272 corn does not contain any genetically engineered pesticides or tolerance to herbicides; therefore, 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.

Table 1. Status of reviews. Syngenta has submitted documentation on Event 3272 corn to the appropriate officials in the following countries:

Country	Type of Submission	Date	Approval
USA	FDA Consultation	2005	2007[4]
	USDA Petition	2005	

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

[4] http://cera-gmc.org/index.php?action=gm_crop_database&mode=Submit&evidcode=Event%203272, Date Accessed: February 7, 2011

[5] http://www2.syngenta.com/en/media/mediareleases/en_100802.html and http://www.bsba.ag/BSBA/Apen.html, Date Accessed: February 7, 2011

China	Food, Feed, Processing including Environment	Currently in review	
Australia/ New Zealand	Food	2006	2008[4]
Taiwan	Food	2006	2010[5]
Korea	Environment	2006	
	Food	2006	
Canada	Food	2006	2008[4]
	Feed	2006	2008[4]
	Environment	2006	2008[4]
Japan	Food	2006	2010[5]
	Feed	2006	2010[5]
	Environment	2006	2010[5]
Switzerland	Food	2006	
	Feed	2006	
Russia	Food	2006	2010[5]
	Feed	2006	2010[5]
Philippines	Food, feed, processing	2007	2008[4]
Mexico	Food and feed	2007	2008[4]
EU	Food and feed	Currently in review	
Indonesia	Food, feed, processing	Currently in review	
Republic of South Africa	Food and feed	2006	Not approved[6]

PUBLIC INVOLVEMENT

APHIS-BRS routinely seeks public comment on draft environmental assessments. The issues discussed in this EA were developed by considering the public concern for ethanol production, as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of Event 3272 corn.

This EA and the petition submitted by Syngenta were available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Subsequently, APHIS reopened the public comment period for an additional 30-day comment period to allow interested persons additional time to submit comments on the petition, environmental assessment, and the revised PPRA to clarify APHIS' definition of a plant pest in response comments received during the initial comment period. Comments received during these two comment periods were used to analyze and inform APHIS'

[6]APHIS Docket 2007-0016; APHIS-2007-0016-0221.1 Attachment to public comment from Bill Freese, May 12, 2009

determination of whether to grant nonregulated status, and also whether there is a requirement to prepare an Environmental Impact Statement in response to Syngenta's petition for a determination of nonregulated status of Event 3272 corn.

ISSUES

As stated above, the issues considered in this EA were developed based on APHIS' review of a petition deregulate certain genetically engineered organisms, and for this particular EA, the specific deregulation of Event 3272 corn for ethanol production.

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

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 3272 corn.

II. Affected Environment

CORN PRODUCTION

Corn (*Zea mays* L.), otherwise known as maize, is the world's most widely grown cereal, reflecting its ability to adapt to a wide range of production environments (Morris 1998). Corn is an annual plant typically grown in zones of abundant rainfall and fertile soils (Morris 1998). In the U.S., corn is grown in temperate regions due to the moisture level and number of frost-free days required to reach maturity. Corn varieties having a relative maturity of 100 to 115 days are typically grown in the U.S. corn belt, which includes Iowa, Indiana, Illinois, and Ohio — approximately 50% of all corn grown in the U.S. is from these four states. The Corn Belt also includes parts of South Dakota, Nebraska, Kansas, Minnesota, Wisconsin, Michigan, Missouri, and Kentucky.

Agricultural production systems may affect the surrounding environment, and corn production is no different. Depending on the region and practices used, corn production includes inputs such as fertilizer (e.g., synthetic fertilizers, manure, and compost containing nitrogen and phosphorus) and pesticides (synthetic or NOP-approved insecticides, herbicides and fungicides), as well as irrigation. Each of these inputs can affect the environment including, but not limited to, increasing nutrient pollution in waterways, alterations in biodiversity due to pesticide inputs, and depletion of the water table or increased salinity in the fields due to irrigation.

There are available data for GE corn acreage (in parentheses for 2010) for the following corn belt states that also have ethanol facilities: Illinois (82%), Indiana (83%), Iowa (90%), Kansas (90%), Michigan (80%), Minnesota (92%), Missouri (79%), Nebraska (91%), North Dakota (93%), Ohio (71%), South Dakota (95%), Texas (85%) and Wisconsin (80%) (USDA-NASS 2010b). GE corn is currently being grown for use in ethanol plants, although data is unavailable as to the percent of GE compared to non-GE corn used in ethanol facilities.

Farming with GE and non-GE Varieties

Conventional farming covers a broad scope of farming practices, ranging from farmers who only occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular synthetic pesticide and fertilizer inputs. The use of GE varieties may be used in conventional farming, but there is also a smaller segment of conventional farmers that may grow non-GE corn for GE-sensitive markets.

United States corn production for 2010, including production of conventional and genetically engineered corn varieties, was 81 million harvested acres (USDA-NASS 2010b). Of the total corn acres planted in 2010, 86% were GE corn varieties (USDA-NASS 2010b), slightly up from the 85% of 2009, and up from 73% in 2007 (USDA-NASS 2007a), and 61% in 2006 (USDA-NASS 2006). About 5 billion bushels of corn grain, which includes both GE and non-GE varieties, were used for ethanol production in 2010 (USDA ERS 2011), which corresponds to approximately 40% of U.S. corn production.

In organic systems, the use of synthetic pesticides and fertilizers is limited[7], and genetically engineered crops are prohibited. For this EA, only organic farming systems produced using

[7] 7 CFR § 205.601 Synthetic substances allowed for use in organic crop production

methods that fall under the USDA National Organic Program definition of organic farming and are certified organic production systems will be considered. Event 3272 corn is not approved for use in organic systems because it is genetically engineered. Practices growers may use to exclude genetically engineered products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times and not pollinate each other, and employing adequate isolation distances between the organic field and the fields of neighbors to minimize the chance that pollen will be carried between the fields. Organic growers must also maintain records to show that production and handling procedures comply with USDA organic standards.

Certified organic corn acreage is a small percentage of overall corn production. Extrapolating from the most recent certified organic corn acreage data published in 2010 (USDA-NASS 2010); the estimated harvested acreage for certified organic corn in 2008 was 168,303 acres, representing 0.21% of the total corn acreage harvested for grain in the U.S. (USDA-NASS 2009a). APHIS was unable to locate any ethanol production facilities that solely use organic corn; if organic corn is used exclusively for any ethanol production it is at a very small scale.

Agronomic Practices

Today, conventional and organic growers can choose from hundreds of corn hybrids marketed by companies that produce seed (refer to Appendix A for examples of available GE varieties for use in conventional systems). Hybrids differ generally in agronomic characteristics, including disease and pest resistance and length of growing period (Olson and Sander 1988). The optimum planting date for corn is influenced by factors such as the locality, environmental conditions, seed growing period, and seed variety, and it usually occurs in April or May. Harvesting generally occurs from mid-to-late September through November; the use of a combine (mechanical harvesting) is the standard practice for grain production in both conventional and organic systems.

Crop rotations (successive planting of different crops on the same land) are used to optimize soil nutrition and fertility, and reduce pathogen loads. Crops used in rotation with corn vary regionally, but there has been an increase in the number of fields that have a corn-to-corn rotation, as opposed to rotation to another crop besides corn (Erickson and Lowenberg-DeBoer 2005). The increase in corn-to-corn rotations, mainly in conventional systems, has been attributed to the increase in corn prices due to higher demand, mainly for ethanol production (Hart 2006, Stockton et al. 2007). In some areas, the corn-to-corn rotation causes increased levels of fertilizer inputs (Sawyer 2007). Insect pests may also increase in corn-to-corn rotations as this system may provide a continual host environment for some insects and diseases. However, in a corn-soybean rotation, continuously growing corn for multiple growing seasons can decrease populations of soybean pests, such as soybean cyst nematode. Thus, corn-to-corn rotations may be used in situations outside of growing corn for ethanol production, and corn-to-corn rotation has been used prior to the relatively higher increase in corn for ethanol (Erickson and Lowenberg-DeBoer 2005).

Pesticides Use

Agronomic practices for conventional or GE corn used in food/feed production and ethanol production for fuel are similar. Corn production typically involves the extensive use of inputs and technology (Rooney and Serna-Saldivar 1987, Shaw 1988, Pollak and White 1995, White

and Pollak 1995), and the main emphasis is placed on obtaining the best yield (Thomas 2007). Organic farming systems allow the use of some synthetic pesticides, and a list these can be found at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl.

Weed control methods differ depending on a number of factors including locality, grower resources, crop trait, and farming system; the techniques may be direct (e.g. mechanical[8] and chemical[9]) or indirect (e.g. cultural[10]) (Olson and Sander 1988). (Synthetic herbicides are not allowed in organic systems; a list of approved herbicides for use in organic systems may be found at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl) Pest control (weeds and insects) in corn production is essential in order to obtain good crop yield. Generally, growers will manage a range of pests simultaneously. Therefore, growers will likely choose from a number of techniques to effectively and efficiently manage pests in their fields. In 2005, the most prevalent pest management practice was pesticide use (USDA-ERS 2005). Ultimately, the management practices utilized by a grower will depend on the types of pests in their field, the level of infestation, the cropping system, the type of soil, cost, weather, time, and labor. Practices to cope with pests, nutrient needs, and moisture and temperature requirements vary regionally.

Specialty Corn Uses and Processing

Corn produced in the United States has a wide variety of end-use functions. For the 2009/10 Market Year, of the almost 15 billion bushels of corn in U.S. supply, 11 billion bushels were consumed domestically (approximately 2 billion bushels were exported and the rest remained in supply). Of the 11 billion bushels used domestically - 5.1 billion were used for animal feed and residual purposes, 4.7 billion were used for ethanol production, 770 million were used for the production of corn syrup and other sweeteners, 250 million were used to produce starch, about 194 million were used to produce cereals and other products, and 22 million were used to produce seed for future cropping (USDA-ERS 2011). Approximately 8% (about a billion bushels) of the U.S. grown corn is specialty corn, with unique properties that are produced for a specific market or use (USGC 2006). Some examples of specialty corn include popcorn, white corn, blue corn, sweet corn, waxy corn, hard endosperm, higher fermentable corn, high protein and modified protein corn including corn with high amylose levels, high oil corn, non-GE for GE-sensitive markets, and organic corn (USGC 2006).

These corn varieties are specified by buyers including end-users of corn for specialized production, and premiums are paid for delivering a product that meets purity and quality standards for the corn variety Although some specialty corn grain is easy to tell apart (e.g., popcorn, white corn, blue corn), most specialty corn varieties look similar to traditional corn but have compositional differences that allow for specified uses. For example, waxy corn has been bred to be 99% amylopectin (one component of starch), compared to 75% in typical food grade corn. High amylose corn is 55%-70% amylose, compared to 25% in common corn. These two types of specialty corn, waxy and high amylose, are used to produce specialty starches for use in various applications such as production of plastics, textiles, adhesives, food thickeners, and candy (Thomison, no date).

[8] Includes tillage and mowing.
[9] Herbicide application.
[10] Crop rotation/spot spraying of herbicide/hand removal of weeds.

Both high amylose corn and waxy corn are grown using closed loop or identity preservation systems (similar to other specialty corn) as each of the corn varieties needs to meet the requirements and specifications of buyers (Brown et al., 1985). These value-added corn products are produced and handled in an isolated production stream meant to preserve the identity and integrity of the product. Any variation in either the composition of the corn (accidental pollination by other, non-specialty corn) or in starch processing (misdirection of the wrong corn variety to a corn processing facility, for example) can cause a failure to meet production specifications and may result in poor or failed performance at a manufacturing facility (Hallauer 2001). Mixing of specialty corn varieties with other corn types during handling or production will diminish product value and potentially disrupt downstream processing or product supply availability, for either specialty corn products or for products derived from other corn varieties. Product differentiation and market segmentation in the specialty corn industry includes mechanisms to keep track of the grain (traceability), methods for identity preservation (IP, including closed-loop systems), and quality assurance processes (e.g., ISO9001-2000 certification), as well as contracts between growers and buyers that specify delivery agreements. Corn processing facilities, such as starch processing facilities, have quality control processes in place to maintain the integrity of their processes and assure buyers that the products produced using specialty corn will be usable for specific end products.

ETHANOL PRODUCTION

Ethanol, also known as *grain alcohol* or *ethyl alcohol*, is the type of alcohol produced by fermenting and distilling simple sugars from biological sources. It is the same kind of alcohol found in all alcoholic beverages, although commercial ethanol plants add a poison (two to five percent) to make it unfit for human consumption (Morris and Hill 2006). Corn ethanol refineries account for more than 98 % of U.S. ethanol production (http://www.ethanolrfa.org, Accessed February 2011).

Approximately 40% of the 2010 corn production was used for ethanol production (USDA ERS 2011). Commercial ethanol production uses conventional or GE corn; organic corn production for ethanol is typically small scale production for herbal medicinal use. The amount of GE corn currently used for ethanol production is not tracked by the USDA National Agricultural Statistics Survey. However, biotechnology-derived varieties make up 86% of corn acreage in the U.S. (USDA-NASS 2010b), suggesting that GE corn is currently used in ethanol production.

The Federal Energy Act of 2005 includes a nationwide renewable fuels standard (RFS) that will result in the use of more than 7.5 billion gallons of ethanol and biodiesel by 2012 (42 USC 15801, page 1069). The Energy Independence and Security Act of 2007 passed in December 2007, includes a provision to expand consumption of alternative fuels, including but not limited to ethanol, to 36 billion gallons in 2022. As of February 3, 2011, there were currently 194 operational corn ethanol plants with a capacity of approximately 14 billion gallons per year (www.ethanolrfa.org). Biofuels have been championed and pilloried as an alternative, renewable energy source. Proponents believe that corn-produced ethanol can increase energy security, reduce vehicle emissions and provide a new income stream for farmers. Critics assert that corn-based ethanol will increase energy-price volatility, food prices, and even increase life-cycle emissions of greenhouse gases and decrease water table levels.

There are two types of ethanol processing plants in the U.S., dry-grind and wet-milling plants. Dry mill facilities account for 82% of ethanol production and wet mills 18% (RFA 2007). As Event 3272 corn will be produced for dry-grind ethanol production, this assessment will include only those related to dry-grind ethanol processing using corn as the feedstock.

The American Coalition for Ethanol, a pro-ethanol website, provides an interactive tour of an ethanol processing plant at http://www.ethanol.org/index.php?id=73&parentid=73 (accessed July 2008). Below is a review of the dry-grind ethanol process from information from the Renewable Fuels Association, also a proponent of ethanol, and Mosier and Ileleji (Mosier and Ileleji 2006):

There are 5 major steps in the dry-grind method of ethanol production:

1. **Milling.** In dry milling, the entire corn kernel is first ground into flour, which is referred to in the industry as "meal" and processed without separating out the various component parts of the grain. Water is added to the meal to create a slurry. Microbial enzymes (alpha-amylase) are added to the slurry to start the conversion of starch to dextrose.

2. **Liquefaction.** The slurry is processed in a high-temperature cooker to reduce bacteria levels ahead of fermentation. Jet cookers inject steam into the corn flour slurry and cook it at temperatures above 100°C. The cooked slurry, now called mash, is allowed to cool, additional microbial alpha-amylase is added, and liquefying continues. Sulfuric acid is typically added to maintain pH.

3. **Saccharification.** The mash is further cooled after liquefaction and a second microbial enzyme (glucoamylase) is added. This enzyme completes the breakdown of the starch into glucose, a simple sugar. This step often occurs as the mash is transferred to fermenters and continues throughout the next step.

4. **Fermentation.** Yeast is added and the conversion of sugar to ethanol and carbon dioxide (CO_2) begins. Ammonia is added for pH control and as a nutrient to the yeast. The fermentation process generally takes about 40 to 50 hours. During this part of the process, the mash is agitated and kept cool to facilitate the activity of the yeast. The CO_2 released during fermentation is either released into the atmosphere or captured and sold for use in carbonating soft drinks and beverages and the manufacture of dry ice.

5. **Distillation and recovery.** After fermentation, the resulting "beer" is transferred to distillation columns where the ethanol is separated from the remaining "stillage." The ethanol is concentrated to 190 proof using conventional distillation and then is dehydrated to approximately 200 proof in a molecular sieve system. The ethanol product is then blended with about 5% denaturant (such as natural gasoline) to render it undrinkable and thus not subject to beverage alcohol tax. It is then ready for shipment to gasoline terminals or retailers. The stillage is centrifuged into liquid (thin stillage) and solid (distillers' grains) fragments. Some of the thin stillage is recycled to the beginning of the dry-grind process to conserve the water used by the facility. The rest of the thin stillage passes through evaporators to remove a significant portion of the water to produce thickened syrup. Usually, the syrup is blended with the distillers' grains to produce distillers' grains with solubles (DDGS), a high quality and nutritious livestock

feed. When markets for the feed product are close the plant, the byproduct may be sold without drying as distillers' grains or wet distillers' grains. DDGS in wet form is prone to deterioration, especially in warmer weather; consequently, the use of wet DDGS is limited to producers located close to dry grind plants (Rausch and Belyea 2006).

PUBLIC HEALTH

Public health concerns surrounding field corn, like Event 3272 corn and the resultant ethanol co-product of DDGS, focus primarily on human and animal consumption. Non-GE corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for food or feed safety prior to release in the market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from Event 3272 corn must be in compliance with all applicable legal and regulatory requirements.

GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, applicants who wish to commercialize a GE variety that will be included in the food supply complete a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food; FDA evaluates the submission and responds to the developer by letter. For a list of completed consultations on GE organisms, see http://www.fda.gov/Food/Biotechnology/Submissions/default.htm (accessed February 7, 2011). FDA completed a consultation of Event 3272 on August 7, 2007 (see Appendix H).

Another potential concern is worker safety, both on the farm and at the ethanol plant. Farmers use an array of chemicals, including insecticides and herbicides, which may have toxic properties during application. Ethanol plant workers deal with hazardous chemicals such as sulfuric acid and liquid ammonia during the processing of corn grain to ethanol and DDGS.

GENE MOVEMENT

Gene movement to other corn plants

Corn plants are pollinated through wind movement of pollen to other receptive corn plants. In the U.S., there are no other species that can be pollinated by corn pollen without human intervention (e.g., manually forcing reproduction in the laboratory) (USDA-APHIS 2009). Public concern surrounding gene movement for GE corn is between GE and non-GE corn plants. Currently, 86% of the conventionally grown corn in the U.S. is GE corn (USDA-NASS 2010b). Specialty corn, those with traits of particular interest to various markets such as blue corn, waxy corn or organic corn, are typically grown with various management practices that intend to limit corn pollen from reaching the specialty corn crop during the period of time that the specialty corn crop is receptive to pollen. For example, the NOP has requirements for organic plans to address pollen flow from GE crops (Kuepper 2002, Krueger 2007, Kuepper et al. 2007). The Association of Official Seed Certifying Agencies (AOSCA) also has information for specialty corn crops, and a protocol for growing non-GE corn (AOSCA 2008). There is a price premium associated with growing these types of specialty crops in conjunction with the extra regimens in place to maximize the purity of these specialty crops. For example, in 2008, conventional field

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

A recent paper reviewed studies investigating gene flow and cross-fertilization studies in corn grain production fields, and using the data from these studies recommended 50m (approx. 164ft) as the distance needed to isolate GE corn and non-GE corn (Sanvido et al. 2008). The authors limited their analysis to studies that confirmed fertilization in the non-GE corn plants, and excluded studies on pollen dispersal (e.g., Raynor et al. 1972, Di Giovanni et al. 1995, Aylor et al. 2003) that only measured pollen flow, because pollen flow does not necessarily result in fertilization. Successful cross-fertilization requires many different biological and physical factors, such as identical timing of flowering between corn fields, viability of pollen, and presence of physical barriers; accordingly pollen dispersal is not equivalent to cross fertilization. Sanvido et al. (2008) analysis of the existing studies found that the cross-fertilization rate in non-GE corn typically remained below 0.5% at this distance, and this result was validated when analyzing cross-fertilization events in large scale studies (e.g. Henry et al. 2003, Weber et al. 2007).

There is one scientific study typically used by critics of GE crops to refute the use of distance as an isolation strategy. The study found cross-fertilization rates higher at comparable distances than other studies (Jones and Brooks 1950). For example, Jones and Brooks (1950) found cross-fertilization to be as high as 2.5 % at 660ft, which is the isolation distance used by AOSCA to isolate corn fields for seed production (AOSCA 2004). One potential reason for the discrepancy between this study and almost all other gene flow studies in corn may be due to the type of corn used in the Jones and Brooks study. Jones and Brooks (1950) investigated the appropriate isolation distance for seed production in open-pollinated varieties, and not for hybrid varieties. Due the biology of open-pollinated varieties, these types of plants may be more receptive to pollen over a longer period of time than hybrid corn plants (Sanvido et al. 2008), allowing for a greater chance of pollination events. Consequently, the results from Jones and Brooks (1950) may be an overestimation of cross-fertilization potential for hybrid corn plants.

WATER USE

Corn plants use a significant amount of water during growth. About 4,000 gallons of water are needed to produce one bushel of corn, and in 2010, 81 million acres, or approximately 12.4 billion bushels, of corn were harvested in the U.S (USDA-NASS 2010b). However only about 15% of U.S. corn acres are irrigated, receiving on average 750 gallons of water per day, which is the equivalent of about 3% of the average rainfall on each acre grown (McLaren, 2009). Most corn acreage only receives the ambient rainfall in a given area and corn plants typically transpire more water than what is retained by the plant, meaning that most of the water used by a corn plant is released to the atmosphere.

Water is also used during ethanol production; about 4.7 gallons of water are needed to produce a gallon of ethanol (Shapouri and Gallagher 2005). Water is used during the production of microbial alpha-amylase, as well as during its transport by tanker truck to ethanol plants (Appendix C).

ANIMAL AND PLANT COMMUNITIES

Animals

Corn fields have been known to be visited by birds, deer and small mammals (e.g. deer mice), and other types of wildlife species. Although many birds visit row-crop fields such as corn, numbers are low and few nest there (Patterson and Best 1996). The red-winged blackbird (*Agelaius phoeniceus*) is the most abundant bird in North America; they are often initially attracted to corn fields to feed on insect pests but then feed on the corn. Annually, this bird destroys over 360,000 tons of field corn and substantial amounts of sweet corn (Dolbeer 1990); other abundant species of birds that forage and/or nest on and around corn include the horned lark (*Eremophila alpestris*), the brown-headed cowbird (*Molothrus ater*), and the vesper sparrow (*Pooecetes gramineus*) (Patterson and Best 1996). Deer, such as the white-tailed (*Odocoileus virginianus*), find field corn attractive because it functions both as food and cover throughout the latter half of the growing season (Vercauteren and Hygnstrom 1993). Deer can significantly damage or completely destroy small corn fields that are surrounded by woody or brushy areas; however, deer damage to large corn fields is often limited to a few rows closest to the wooded areas (Neilsen 2005). The deer mouse (*Peromyscus maniculatus*) is the most common small mammal in almost any agricultural field (Stallman and Best 1996, Sterner et al. 2003). The deer mouse feeds on a wide variety of plant and animal matter depending on availability, but primarily feeds on seeds and insects. The deer mouse has been considered beneficial in agroecosystems because it consumes both weed and pest insect species. The meadow vole (*Microtus pennsylvanicus*) feeds primarily on fresh grass, sedges, and herbs, but also on seeds and grains. The meadow vole may also be considered beneficial for its role in the consumption of weeds, but can be a significant agricultural pest where abundant as they rely on cover absent from tilled agriculture. The lined ground squirrel (*Spermophilus tridecemlineatus*) feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, although it can also be considered beneficial when eating pest insects, such as grasshoppers and cutworms.

Although many of the invertebrate organisms found in corn-producing areas are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and the corn rootworm (*Diabrotica* spp.), many others are considered beneficial. Numerous insects and related arthropods perform valuable functions; they pollinate plants, contribute to the decay of organic matter, cycle soil nutrients, and attack other insects and mites that are considered to be pests.

Plants

The landscape surrounding a corn field varies depending on the region. In certain areas, corn fields may be bordered by other corn (or any other crop); fields may also be surrounded by wooden and/or pasture/grassland areas. Therefore, the types of vegetation, including weeds, around a corn field depend on the area where the corn is planted. A variety of weeds dwell in and around corn fields; those species will also vary depending on the region where the corn is planted. Weeds compete with crops for water, nutrients, light, and other growth factors. Each year in the U.S., corn yields are threatened by more than 200 weed species (Heap 2008). Weed species such as giant foxtail and barnyardgrass have been shown to reduce corn yields by up to 13 and 35%, respectively (Bosnic and Swanton 1997, Fausay et al. 1997). Common weeds that cause problems in corn fields include velvetleaf, common cocklebur, common lambsquarters (annuals) and quackgrass and Johnsongrass (perennials).

Biological Diversity

Species diversity and abundance in corn agro-ecosystems may differ between the three corn production methods; GE, conventional, or organic. Many studies over the last 10 years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (e.g., Bt crops) or herbicides (e.g., glyphosate-tolerant or glufosinate-tolerant crops). Each side of the GE debate has a multitude of studies to pick from to support their case; opponents of GE will point to studies that indicate potential decreases in biological diversity and/or abundance due to GE crops, particularly due to the presence of a pesticidal protein in some GE crops (Bt) (e.g., (Hansen Jesse and Obrycki 2000, Ponsard et al. 2002, Pilcher et al. 2005). GE-detractors will also use studies investigating how decreases in weed populations due to the use of herbicides and herbicide-tolerant crops results in decreases in animal populations that use weeds as a food or refuge source, which may reduce overall biological diversity in farm fields (Marshall et al. 2003). On the other side, supporters of GE technology will use studies that compare GE crops, such as Bt corn, to non-GE crops sprayed with insecticides to demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (e.g., (Bitzer et al. 2005, Torres and Ruberson 2005, Romeis et al. 2006, Marvier et al. 2007, Chen et al. 2008, Wolfenbarger et al. 2008) or may even increase biological diversity (e.g., (Romeis et al. 2006, Marvier et al. 2007, Wolfenbarger et al. 2008) in agro-ecosystems. GE proponents may also showcase studies that demonstrate herbicide-tolerant corn, when compared to conventional corn production, does not result in changes in arthropod abundance and may even increase species diversity during different times of the year (e.g., (Brooks et al. 2003, Haughton et al. 2003, Hawes et al. 2003, Roy et al. 2003).

SOIL BIOLOGY

The soil environment in and around corn fields is complex, rich in microorganisms and arthropods. The corn root system acts as a soil modifier due to its association with several microbial groups such as bacteria, fungi, protozoa, and mites. Bacteria typically represent the most abundant microbes in the soil followed by fungi. These microbial groups play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD 2003).

Research shows that crop soils are prone to degradation due to the disturbance and exposure of the top surface layer by certain agronomic practices. Two environmental impacts of soil degradation are the decline in water quality and the contribution to the greenhouse effect (Lal and Bruce 1999). It has been shown that a decline in soil quality and soil resilience[11] enhances the greenhouse effect through emissions of radiatively-active gases[12] (CO_2, N_2O) and depletion of the soil carbon pool (Lal 2003, US-EPA 2008) . In turn, a decrease in carbon aggregation and sequestration in the soil leads to increase runoff and soil erosion.

CONSERVATION ACREAGE

The Conservation Reserve Program (CRP) is America's largest and most effective private-lands conservation program, with more than 36 million acres enrolled. Under CRP, farmers and ranchers plant grasses and trees in crop fields and along streams. The plantings stop soil and

[11] The ability of a soil to restore itself.

[12] Gases that absorb incoming solar radiation or outgoing infrared in turn, affecting the temperature of the atmosphere.

nutrients from washing into regional waterways and provide habitat for wildlife (USDA-FSA 2007).

CRP had 33.7 million enrolled acres as of in 2009 (USDA-FSA 2009). CRP participants enroll in contracts for 10 to 15 years every three years. With the increased demand for cropland due to market demands for agricultural crops over the last few years, CRP enrollment acreage is expected to decrease. For example, of 15.7 million acres of CRP contracts that expired in 2007, only 85% were re-enrolled or extended, resulting in 2.3 million acres of cropland removed from the CRP program (USDA-FSA 2007). That trend has continued as another 3 million acres have been removed from the program since 2007 (USDA-FSA 2009). The changes of some of conservation program land to agricultural systems may alter the biodiversity on these acres.

ANIMAL FEED: DISTILLERS GRAINS WITH SOLUBLES

A bushel of corn going into an ethanol plant yields about 2.8 gallons of ethanol and 16-18 pounds of DDGS. As a result of increased ethanol production, the quantity of distillers grains available in the U.S. increased from 1.9 million metric tons in 1999 to 8.3 million metric tons in 2005 (a 340 percent increase), and then more than tripled again to over 34 million metric tons in 2010 (Hoffman and Baker, 2010).

Approximately 90% of the distillers grains produced in U.S. facilities are used in domestic animal feed. In North America, over 80% of DDGS are used in ruminant diets, but DDGS are also used for hog, swine, broiler, and turkey feed. Currently, ethanol plants do not discriminate between GE and non-GE corn. Given that 80% of corn production is GE, the DDGS produced and used as animal feed are likely produced with some GE corn varieties.

Because of the near complete fermentation of starch during the ethanol process, the remaining amino acids, fat, minerals and vitamins in DDGS increase approximately three-fold in concentration compared to levels found in corn (Rausch and Belyea 2006). This can result in concerns regarding phosphorous and animal waste disposal, sulfur diet content, and mycotoxin concentrations in DDGS.

Phosphorous concentrations in DDGS can significantly increase both phosphorus diet content as well as the resulting animal waste products when used as feed (Morse et al. 1992). Increased phosphorus in animal waste leads to waste disposal concerns (Rausch and Belyea 2006) and concerns about increased levels of phosphorus pollution of local and national bodies of water through agricultural runoff.

High dietary sulfur concentration in DDGS may also be a concern; it can lead to excessive sulfide concentrations in the rumen, and may cause a shift in the ruminal microbial population to include bacteria that produce high levels of thiaminases (Rausch and Belyea 2006). This reduces the thiamine available to be absorbed from the rumen and results in an effective thiamine deficiency which may cause brain lesions (Rausch and Belyea 2006). The bacteria also produce an analog that inhibits certain enzymes involved in energy metabolism (Kung et al. 1998).

Mycotoxins may also be concentrated in DDGS. Mycotoxins are poisons produced by some fungi (e.g., *Aspergillus*, *Fusarium*, *Penicillium*). The growth of fungi and the production of mycotoxins can be associated with stressed plants in the field (e.g., drought, pest damage) or

poor storage after harvest (Whitlow and Hagler 2005). During ethanol processing, mycotoxins are not destroyed; the toxins are concentrated three-fold during ethanol processing, resulting in DDGS that may contain significantly increased levels of mycotoxins compared to corn grain for feed (Garcia et al. 2008).

One of the mycotoxin metabolites present in corn, and potentially present in the resultant DDGS, aflatoxin M1, may be a concern to human health. If M1 is present in corn feed or DDGS and fed to dairy cattle, M1 can be passed in milk for human consumption (Garcia et al. 2008). M1, a metabolite Aflatoxin B1, is considered a potential carcinogenic compound for humans. Because of the human health concerns surrounding aflatoxins, aflatoxin is regulated by the FDA at the action level. Action levels for poisonous or deleterious substances are established by the FDA to control levels of contaminants in human food and animal feed. These action levels represent limits at or above which FDA will take legal action to remove products from the market (FDA 2000).

III. Alternatives

This EA analyzes the potential environmental consequences of a proposal to grant 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. The analysis provided in the plant pest risk assessment (USDA-APHIS 2009) demonstrates that Event 3272 corn is unlikely to pose a plant pest risk and therefore should no longer be subject to the regulatory requirements of 7 CFR part 340.

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." Because APHIS has found that Event 3272 corn is unlikely to pose a plant pest risk, there is no regulatory requirement for considering whether to approve the petition in part. The petitioner has not requested APHIS to consider approving a partial deregulation, and the petition for Event 3272 corn only requested APHIS to grant nonregulated status to one corn line, so this type of "in part" approval will not be considered. Therefore, there are two alternatives that will be considered in this EA: (1) no action and (2) grant nonregulated status to Event 3272 corn, "in whole."

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.

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.

C. Alternatives Considered but Rejected from Further Consideration

APHIS assembled a comprehensive list of alternatives that might be implemented in the decision process for Event 3272 corn. The agency individually evaluated each alternative on the basis of consistency with the current regulations, environmental safety, efficacy, and practicality to identify which alternatives would be further considered during the decision process. Based on this evaluation, 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 Event 3272 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2009).

The Secretary of Agriculture is directed, through APHIS, to facilitate—

> "… the smooth movement of enterable plants, plant products, biological control organisms, or other articles into, out of, or within the United States… (and to facilitate) exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests or noxious weeds… § 402(3)(5)."

The question as to how to balance this facilitation with the protection of U.S. agriculture is unequivocally answered by the Plant Protection Act, which states that—

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under (the Plant Protection Act) shall be based on sound science… § 402(4).

A risk-management process based on sound science must, therefore, consider a growing body of scientific evidence documenting the safe use of GE organisms in U.S. agriculture, and in the rest of the world, to determine whether their use poses any unacceptable risks. Because Congress has mandated a science-based approach in APHIS regulations and because there is no basis in science for banning the release of Event 3272 corn, a blanket prohibition of the release of Event 3272 corn would contravene congressional intent and must be rejected.

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. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE corn productions systems 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 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 involving testing or limits of GE material in non-GE systems. Such a requirement 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 any type of testing requirements is inconsistent with APHIS' regulatory policies or 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.

D. Comparison of Alternatives

Table 2, below, briefly summarizes the results for each of the issues raised in the Environmental Consequences (Section IV) by each of the alternatives described in the Alternatives section (Section III).

Table 2. Comparison of Alternatives

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	No change in U.S. corn acreage. No change in use of

Attribute/Measure	*Outcome if Alternative A No Action is Chose*	*Outcome if Alternative B Deregulation is Chosen*
	GE or non-GE corn varieties during corn production. No change in corn acreage for ethanol production.	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 ethanol plants are converted for Event 3272 corn use.	2.8 gallons/bushel + 2% or 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 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.

Attribute/Measure	*Outcome if Alternative A No Action is Chose*	*Outcome if Alternative B Deregulation is Chosen*
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 un-enrolled in CRP.	The same amount of corn 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 (Table 1)	
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	

IV. Environmental Consequences

Potential environmental impacts from the "no action" alternative and the "preferred" alternative for Event 3272 corn are described in detail throughout this section. A cumulative effects analysis is also included for each environmental issue. Certain aspects of this product and its cultivation would be no different between the alternatives; those are described below.

Methodology and Assumptions

The environmental effects analysis is greatly dependent on assumptions used for estimating effects. The following are key underlying assumptions used to estimate effects for each alternative.

SCOPE OF THE ENVIRONMENTAL ANALYSIS

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 intended use of Event 3272 corn. Therefore, APHIS will primarily focus its 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 will include 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.

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 3, 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 are constructing plants that will use corn as the input are also listed in Table 3.

Table 3. 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
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. These 2360 counties in 28 states are be 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.

GENERAL MANAGEMENT PRACTICES

One of APHIS' missions is to improve American agricultural productivity. Best management practices, such as planting dates, seeding rates, and harvest times are commonly accepted, practical ways to grow corn, regardless if the corn farmer is using conventional systems, organic practices, or using genetically engineered varieties. These well-established, widely-practiced means to produce corn can be obtained through local Cooperative Extension Service offices and their respective websites. (A summary website can be found at www.ipmcenters.org/cropprofiles/index.cfm, accessed 4/24/2008).

SPECIALTY CORN MANAGEMENT PRACTICES

It is Syngenta's intention that Event 3272 corn will be marketed and produced in a manner similar to other value-added, specialty corn products, such as popcorn, waxy corn, high oil corn,

high protein and modified protein corn, sweet corn, higher fermentable corn, and high amylase corn (USGC 2006). As discussed above in the Affected Environment section, these value-added products are typically produced with identity preservation systems that include contracts between all handlers of the grain (seed suppliers, farmers, handlers, and processors), traceability, product tracking, process verification, and separate channeling to minimize commingling.

Similar to other specialty corn varieties, Event 3272 corn will require a level of control to preserve identity and avoid inadvertent mixing with other corn products. This identity preservation will include the use of a 'closed-loop' system. The closed-loop system provides more control over the specialty crop to better protect its value and to not interfere with other corn varieties. Closed-loop production systems involve rigorous controls to maintain the identity of the crop, tight chain of custody of the crop as it moves through the stages of production (seed, planting, harvesting, and transportation to end user) and contractual requirements of each party in the system.

If Event 3272 corn will be commercialized, Syngenta will have contracts and other control mechanisms in place to establish a 'closed-loop' system for Event 3272 corn. This closed-loop system includes three principle points of contact; the producer of Event 3272 corn (Syngenta), the grower of Event 3272 corn, and the end-user of Event 3272 corn, the ethanol plant. According to Syngenta (see Appendix G), each point of contact has specific roles and responsibilities:

"Syngenta [will] (stewardship roles and responsibilities):

- license the use of Event 3272 corn product to growers;
- sell Event 3272 corn hybrids only to licensed growers with a valid contract with an ethanol plant or an approved third party grain company that supplies corn amylase to the ethanol plant;
- ensure that grain contract includes stewardship agreement;
- provide incentive to grower for producing and delivery of Event 3272 corn product;
- provide stewardship guide to producers and handlers on the cultivation and handling of the Event 3272 corn product;
- provide specific procedures for the handling of any excess grain;
- ensure the domestic consumption of DDGS prior to export market approvals;
- make available appropriate detection methods; and,
- develop and implement a communication program.

Grower [will] (stewardship roles and responsibilities):

- execute delivery contract with ethanol plant;
- execute stewardship contract with Syngenta;
- follow Syngenta stewardship guide on cultivation; and,
- follow Syngenta requirement to divert excess grain to appropriate use.

Ethanol Plant (stewardship roles and responsibilities):

- contract with growers to supply Event 3272 corn product; and,
- ensure domestic consumption of DDGS prior to export market approvals;

These stewardship roles and responsibilities in concert with the contract relationships between the entities in the closed-loop system and the backstop mechanisms minimize the risk of inadvertent delivery of Event 3272 corn and commingling."

According to Syngenta (see Appendix G), the system for Event 3272 corn will include contracts for Event 3272 corn grown in surrounding areas of an Event 3272 corn-contracted ethanol facility. Due to economic considerations, trucks dominate the local transportation of corn to ethanol facilities, limiting the geographic area for growing Event 3272 corn to approximately a 50-mile radius (Denicoff 2007). The farther corn is from the ethanol plant, the greater the transportation costs to move Event 3272 corn to the ethanol facility. As a result, there is a limit to the area around the ethanol facility that is economically feasible to effectively use Event 3272 corn.

The ethanol plant will contract either directly with Event 3272 corn growers in their geographic region or indirectly through grain suppliers. The contracts for growers will dictate the delivery location (ethanol plant or storage site within a specified radius of the field), a delivery date, and amount to be delivered. Syngenta has stated that hybrids with Event 3272 will only be available to growers with a valid contract, and who agree to the Syngenta Stewardship Agreement (see Appendix G).

Part of the Stewardship Agreement is the requirement that growers include 12 rows of non-Event 3272 corn as a pollen trap to reduce the amount of Event 3272 pollen that may leave the corn field. Syngenta has provided an analysis (Appendix D) that analyzes the effect of using border rows on the minimizing corn pollen leaving an Event 3272 corn field. Syngenta's analysis suggests that more than 99.9% of all corn pollen is captured when 12 border rows of non-Event 3272 corn plants are used and flowers are in synchrony with the Event 3272 corn field. This analysis is consistent with other gene flow and pollen flow studies in the scientific literature (Jarosz et al. 2003, Jemison and Veyda 2001, Ma 2005, Ma et al. 2004, and Westgate et al. 2003).

PRODUCTION PRACTICES

APHIS also recognizes that producers of non-GE corn, particularly producers who sell their products to markets sensitive to genetically engineered traits (e.g. organic or some export markets) can be reasonably assumed to be using practices on their farm to protect their crop from unwanted substances and maintain their price premium. For example, the National Organic Program (NOP) has recognized the practicality of protecting organically-produced crops, and the investment farmers put into their production practices, by requiring that organic production plans include methods to protect organically-produced crops.

> Organic crops must be protected from contamination by prohibited substances used on adjoining lands (for example, drifting pesticides,

fertilizer-laden runoff water, and pollen drift from genetically engineered…) (NCAT 2003).

Typically, more than one method is used under organic practices to prevent unwanted material from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT 2003). The organic plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing and transporting the crop (Riddle 2004, Krueger 2007, Kuepper et al. 2007). Organic plans should also include provisions describing how the risk of GE pollen or seed co-mingling will be monitored (Kuepper et al. 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce contamination events (NCAT 2003, Krueger 2007). Therefore, commonly used production practices for corn, and the practical methods typically used by corn farmers using organic methods to protect their crop and maximize their profits and price premiums granted to corn under organic production, currently provide many measures that greatly reduce the likelihood of accidental gene flow between Event 3272 corn and non-GE corn fields. APHIS will use the assumption that farmers are already using, or have the ability to use, these common, reasonable practices as its baseline for the analyses of the following alternatives below. Recommended organic production practices for field corn are also readily available (Kuepper 2002).

OTHER ASSUMPTIONS

The environmental consequences of the different alternatives described above have been analyzed under the assumption that farmers who produce conventional corn, Event 3272 corn, or produce corn using organic methods, are using reasonable, commonly accepted best management practices for their chosen system and varieties during agricultural corn production. However, APHIS recognizes that not all farmers follow these best management practices for corn. The analyses of the environmental effects also include the assumption that some farmers do not follow these best management practices.

OTHER INFORMATION

Syngenta provided APHIS a series of reports detailing the potential benefits and impacts of Event 3272 corn in terms of ethanol production and byproducts, corn processing, and pollen movement in corn. These are referenced in the EA and the CBI-deleted versions are found as Appendices to this EA.

Corn Production

GE and non-GE corn varieties are continually under development. Currently, 86% of the total corn acres planted in 2008 are GE corn varieties (USDA-NASS 2010b), and about 40% of the total corn production in 2010 was used for ethanol production (USDA ERS 2011). In 2010, growers harvested 81 million acres for grain, which is a slight increase from the 79.6 million acres harvested in 2009.

FARMING WITH GE AND NON-GE VARIETIES

Acreage and Areas of Corn Production

No Action: Acreage and Areas of Corn Production

The amount of GE corn planted in conventional systems in the U.S. is increasing. Of the total corn acres planted in 2010, 86% were GE corn varieties (USDA-NASS 2010b) up from 73% in 2007 (USDA-NASS 2007a), and 61% in 2006 (USDA-NASS 2006). Conventional production practices that use GE varieties will likely continue to increase without granting nonregulated status to Event 3272 under the "no action" alternative, based on current acreage trends. Currently available seed for conventional and GE varieties will remain the same under the "no action" alternative, except Event 3272 corn variety will be unavailable. Corn is currently produced in 49 states (all states but Alaska according to the 2007 Census of Agriculture), and under the "no action" alternative, this range of production will be unchanged.

GE corn has been in production since the mid-1990's, and in 2010 accounted for 86% of the acres of corn planted (USDA-NASS 2010). During this time, corn production for GE-sensitive markets has increased; for example organic corn production increased 35% between 2001 and 2005 (USGC 2006), at the same time that corn acreage using GE varieties increased from 26% of corn acreage to 52% of corn acreage (USDA-NASS 2001, 2005). The amount of GE corn planted for conventional corn production and amount of corn planted for organic production systems in the U.S. are increasing, and both production practices will likely continue to increase without granting nonregulated status to Event 3272 under the "no action" alternative. Management practices currently in used for GE and non-GE corn will remain in place and used by farmers of GE varieties and those producing corn for GE-sensitive markets. Currently available seed for conventional and GE corn varieties, and those corn varieties that are developed for organic production, will remain the same under the "no action" alternative.

Preferred Alternative: Acreage and Areas of Corn Production

In 2008, GE corn production was planted on 80% of all corn acres currently in production in the US, and the use of GE corn has been increasing over the last 3 years (USDA-NASS 2006, 2007a, 2008a, 2010b). Conventional and GE corn production occurs on land that is dedicated to crop production. Most corn is planted in fields that have been in crop production for years. Granting nonregulated status of Event 3272 corn under the "preferred" alternative is not expected to significantly alter the range of corn cultivation as the new GE trait (alpha-amylase) does not change the growth habits compared to conventional varieties (USDA-APHIS 2009). Event 3272 corn will be marketed for use in ethanol production, and this corn variety will be limited to production areas that surround ethanol production facilities (see Appendix G). Currently, there are 28 states that have corn-based ethanol production facilities, including states with facilities under construction (see Table 3). This corn variety will likely be introduced to areas where corn is currently grown for ethanol production as a replacement product to other varieties (conventional and GE) already available in the market today and used for ethanol production. Further, the acreage for Event 3272 corn is limited to areas surrounding ethanol facilities that have been contracted to accept Event 3272 corn. As a result, under the preferred alternative, granting nonregulated status to Event 3272 corn would not increase the demand for corn production, or alone cause an increase in overall GE corn acreage.

Event 3272 corn has the potential to decrease overall corn conventional (non-organic) acreage needed to meet the biofuel amounts specified in the Energy Policy Act of 2005 and the Energy Independence and Security Act of 2007. APHIS has analyzed the projections made for ethanol production efficiency submitted by Syngenta (Appendix C). Due to the changes in ethanol processing when using Event 3272 corn, Syngenta projects a 2% or greater increase in efficiency, resulting in more ethanol generated per unit grain than current ethanol processes using microbial alpha-amylase. If Event 3272 corn does result in greater efficiency during ethanol production, fewer acres of corn production may be required to meet the biofuel levels mandated by Congress.

Granting nonregulated status to Event 3272 corn has the potential to result in a decrease in acreage devoted to corn produced for ethanol production due to a projected 2% or greater increase in ethanol efficiency – fewer bushels of corn may be needed to meet the requirements of the Energy Policy Act of 2005 and the Energy Independence and Security Act of 2007.

Corn produced using organic methods has been increasing at approximately 30% a year (USGC 2006), even though there are no national requirements that GE corn varieties currently in production use mandated techniques for isolation between fields containing GE corn and those fields using organic production practices. In the Methodology and Assumptions section above, the discussion contains information related to the requirements for farmers using organic production methods under the National Organic Program. Conventional farmers growing GE varieties typically use traditional production practices, and have no requirements related to isolating pollen movement between their fields and their neighbor's field. Without any requirements in place, the production of corn using organic methods is continuing to increase.

In agricultural systems, growers may choose to grow GE or non-GE corn, and obtain price premiums for growing varieties of corn for particular markets (e.g., using organic methods for corn production or producing a specialty corn variety for particular processing needs). For example, in 2008, conventional field corn averaged $3.90/bushel (USDA-NASS, 2009b), whereas organic corn averaged $7.08/bushel (USDA-NASS 2010). USDA asserts that agricultural practices that use conventional means, organic production systems, or genetically engineered varieties can all provide benefits to the environment, consumers, and farm income. As discussed in Section II and below under the section for "Gene Movement," gene flow into and out of these specialized corn production systems has been managed using various types of buffer zones or isolation practices, such as differences in timing of planting (which results in differences in flowering and removes the ability to pollinate neighboring crops) or making sure fields are distance from other compatible crops (such as using isolation distances).

As discussed in the Methodology and Assumption methods, Syngenta has included some measures in their Stewardship Agreement that minimize pollen movement outside corn fields containing Event 3272 corn (see Gene Movement section below for further discussion and Appendix D). If corn growers using Event 3272 corn follow the measures, APHIS has determined that these additional measures to minimize pollen flow would decrease the likelihood of GE pollen movement into those corn fields that are growing non-GE corn (see Gene Movement section below for further discussion and Appendix D). However, even if growers of Event 3272 corn failed to use the mandated isolation techniques in the Stewardship Agreement, there is no indication that any current pollen flow from GE corn to non-GE corn has dampened

the organic production of corn. Currently, the use of GE corn varieties and the use of organic corn production systems are both increasing due to market demands, and these markets will likely continue to increase under the "preferred" alternative.

Cumulative Effects: Acreage and Areas of Corn Production

Under the "no action" alternative and under the "preferred" alternative, granting nonregulated status to Event 3272 corn will not change the market demands for GE corn or corn grown for GE-sensitive markets. Granting nonregulated status to Event 3272 corn will add another GE corn variety to the market. However, adding GE varieties to the market is not related to the ability of organic production systems and other GE-sensitive markets to maintain their market share. Between 2001 and 2005, although 5 GE corn varieties were granted nonregulated status, the acreage associated with the organic production of corn rose 35% (USGC 2006).

Cumulative effects on U.S. acreage and U.S. areas of corn production due to granting nonregulated status to Event 3272 corn are unlikely. Neither the no action alternative nor granting nonregulated status to Event 3272 corn will directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE or non-GE corn cultivation. Event 3272 corn will also not change cultivation areas for corn production in the U.S. Currently 86% of all corn acreages are GE corn (USDA NASS 2010), and Event 3272 corn is not expected to increase the acreage of GE corn varieties in the U.S. There are no foreseeable changes to the availability of GE and non-GE corn varieties on the market under either alternative.

Cropping practices

Crop Rotation

No Action: Crop Rotation

The current economics of corn production in GE and non-GE systems are driving the change or perceived change in crop rotation practices. Growers make choices to plant certain corn varieties and use certain crop rotation practices based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Olson and Sander 1988, Giannessi 2005). Therefore, when taking into account these factors, growers will ultimately base their choice on individual wants and needs.

As the demand for ethanol production and corn prices have increased, the frequency of corn-to-corn crop rotations conventional production systems has also increased in areas that support ethanol production (Hart 2006, Stockton et al. 2007). The average field corn prices have increased from $2.00/bushel in 2005 (USDA-NASS 2007b), to $3.04/bushel in 2006, and $4.00/bushel in 2007 (USDA-NASS 2008b). As of the end of 2010, the price for a bushel of corn is calculated at between $4.82 and $5.37 (USDA-NASS 2011). These prices are driven by demand for corn products in ethanol and for feed. Under the "no action" alternative, the demand and price increases in GE and non-GE corn will continue to increase depending on the market for field corn, and corn-to-corn rotations will continue to be used by farmers if this cropping practice meets the economic and marketing strategy for the particular farmer.

Preferred Alternative: Crop Rotation

As stated above, the current economics of corn production are driving the change or perceived change in crop rotation practices. Granting nonregulated status to Event 3272 corn is unlikely to change the entire pricing scheme of corn commodities in the U.S. Prices will continue to be set by market demand, without regard to the number or type of corn varieties available on the market. Event 3272 corn is unlikely to affect a farmer's decision to either stop using a corn-to-corn rotation, or to increase the overall use of corn-to-corn rotation as a cropping strategy with the U.S. farming community.

Cumulative Effects: Crop Rotation

Under the "no action" alternative, the cumulative effects of using crop-to-crop rotation in GE and non-GE corn production systems could be a cumulative increase level in corn pests found in corn fields or a cumulative increase in fertilizer use due to continuing use of corn crops (instead of rotating in a nitrogen-fixing crop such as alfalfa or soybean) (Sawyer 2007). (Synthetic fertilizers are not used in corn production systems using organic methods.) Granting nonregulated status to Event 3272 corn will result in similar cumulative effects as those found under the "no action" alternative, because the use of corn-to-corn rotation is based on economic decisions by the farmer and is not dependent on the corn varieties (GE or conventional) available on the market.

Tillage

No Action: Tillage

The use of tillage and the removal of soil residue are considered agriculture practices that accentuate loss of soil organic carbon (Lal and Bruce 1999). As described in Section II, this loss has negative impacts on the atmosphere and increases soil erosion, among others. Under the "no action" alternative, the use of tillage methods in U.S. agricultural production of corn (in GE, conventional or organic production systems) will remain unchanged.

Preferred Alternative: Tillage

Event 3272 corn does not change cultivation practices, including tillage, for corn production. Agronomic practices used during the production of corn for ethanol use is the same as the production of corn for grain. Granting nonregulated status to Event 3272 corn will not change the loss of soil organic carbon due to tillage in corn production systems with overall impacts similar to the No Action alternative.

Cumulative Effects: Tillage

The cumulative effects of tillage include removal of soil residues over time (Lal and Bruce 1999, Triplett and Dick 2008), and will continue independent of the status of Event 3272 corn. Event 3272 corn will not change the amount of corn acreage tilled, because it will not change acreage devoted to corn production in the U.S. Event 3272 corn will not change the management of corn fields because it will require the same agronomic practices as other conventional corn varieties.

Pesticide Use

No Action: Pesticide Use

Under the "no action" alternative, corn production, and pesticide use in corn, will remain as it is practiced today by the farming community. Growers make choices to use certain pesticides based on weed and disease pressures, cost of seed and other inputs, technology fees, human

safety, potential for crop injury, and ease and flexibility of the system (Olson and Sander 1988, Giannessi 2005). Therefore, when taking into account these factors, growers will ultimately base their choice on individual wants and needs. As an example of the pesticides used during the production of field corn, the Pesticide Action Network has an online database, including a detailed description of all the pesticides used in corn agriculture in California (Kegley et al. 2008). It lists the top 50 pesticides (e.g., herbicides, insecticides, fungicides) used in California corn production. Any effects due to pesticide use in the agricultural production of corn will remain the same under the "no action" alternative. The no action alternative will also not change the types of pesticides used in organic production of corn (see http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl for a list of approved synthetic pesticides for use in organic production).

Preferred Alternative: Pesticide Use

Event 3272 corn production uses the same agricultural inputs (e.g., pesticides, fertilizers) as corn currently grown for the ethanol production market. Event 3272 corn, and the alpha-amylase produced by Event 3272 corn has no effect on the types of pesticides that will be used in corn production. Granting nonregulated status to Event 3272 corn will not have any effect on the pesticides used in the production of corn in the U.S., compared to the "no action" alternative.

Cumulative Effects: Pesticide Use

The baseline effects of pesticides, and levels applied during the agricultural production of corn in GE, conventional, and organic systems will not change due to granting nonregulated status of Event 3272 corn. Granting nonregulated status to Event 3272 corn does not cause additional or synergistic effects of pesticide use because there is no change in pesticide use or effects compared to the current conventional production of corn, and Event 3272 corn will not change the amount of pesticides used in organic production of corn.

Specialty Corn Uses and Processing

Specialty corn, such as waxy corn, white corn, blue corn, high amylose corn, and organic corn, comprises 8% of the U.S. market (USGC 2006). Event 3272 corn is considered a specialty, value-added corn that will be grown for use in ethanol facilities. Because of the compositional differences of Event 3272 corn that increase the efficiency of ethanol production, and because Event 3272 corn is different in amylase content than other corn varieties, Event 3272 corn will be grown in a closed loop system, using contractual arrangements between growers and ethanol facilities to ensure Event 3272 corn only enters the ethanol production stream.

No Action: Specialty Corn Uses and Processing

Under the no action alternative, Event 3272 corn will remain a regulated article, and will not be grown without a permit or notification from APHIS. Compositional differences between Event 3272 corn and other specialty corn will remain, and the chance for misdirection of Event 3272 corn into other corn processing facilities will remain low.

Preferred Alternative: Specialty Corn Uses and Processing

Under the preferred alternative, Event 3272 will be granted nonregulated status and allowed to be grown without restrictions. However, as Event 3272 corn is a specialty corn variety, the closed-loop system will be used extensively to maintain the identity and value of the product for the grower, who is obtaining a price premium from the ethanol producer, and the ethanol

producer, who is paying the premium. The closed-loop system will also help to prevent the misdirection of Event 3272 to unintended downstream processing facilities. There is no benefit to either party if Event 3272 corn is mistakenly routed.

However, there is still the potential for misdirection of Event 3272 corn in the transportation stream. Because Event 3272 corn has successfully completed the food and feed consultation process with FDA (Appendix H), there are no human health concerns if Event 3272 corn enters the food supply (see section on Public Health below for more discussion). Nonetheless, because of the thermostable properties of the alpha-amylase present in Event 3272 corn, there may be undesirable effects in certain types of processed products, similar to what may happen if other types of specialty corn products are misdirected into production streams for which they were not intended.

For example, food processes that use alkaline cooking, such as processes that produce masa tortillas and corn-based snack foods, may be affected through changes in dough-handling or darkened chip color, if Event 3272 corn is mistakenly included in the process (Appendices F-H). The masa industry, like other corn grain-handling industries that depend on the specific properties of a corn variety, uses strict grain sourcing programs. Only an estimated 4% of the corn grain used for masa production is from the open market rather than through direct contracts with a grower (Appendix G). Corn hybrids used for masa production are specifically developed with improved alkaline-cooking properties, and premiums are paid for growing, delivering, and meeting and maintaining the purity and quality standards of corn for masa production (Appendix G), similar to how other specialty corn grain are handled. Both Event 3272 corn and corn hybrids for masa production are grown under strong stewardship programs, similar to other corn production processes that depend on specific and consistent grain qualities.

In the unlikely event that Event 3272 corn were to enter a masa production facility (or another corn grain processing facility), the mixing of a truck-load of Event 3272 corn into holding bin of corn for masa production would result in significant dilution (see Appendix F and Appendix G for scenario development). Further dilution is also possible if the truck-load of Event 3272 corn enters a local grain elevator, which would reduce the effects that Event 3272 corn would have on masa production (or the production of other corn grain derived products). Additionally, according to Syngenta, less than 10% of corn fields that currently support ethanol plants (areas where Event 3272 corn may be grown), are in the production area for masa-contracted corn fields (Appendix G), further reducing the opportunity for misdirection of Event 3272 corn. Similar geographic separations of production area are expected for the grain inputs to other industrial facilities that process corn grain with restrictions similar to those in place for masa production.

Geographic limitations for specialty corn varieties destined for other specific facilities are also the result of transportation costs. For example, farmers under contract to grow Event 3272 would be in violation of the grower contracts if locations are too distant from an ethanol production plant that is ready to receive Event 3272. (See discussion of Production Practices above.) Furthermore, if those contracts are not in place, growers would be less likely to grow Event 3272 corn at a great distance from an ethanol production plant, as the value of Event 3272 corn would diminish with the cost of shipping to the plant.

As stated above, many types of specialty corn such as high amylose corn and waxy corn have different compositions that require the varieties to be grown, produced, transported, and processed separately from other corn varieties. Restrictive conditions for specialty corn are in place to maintain the integrity of both the varieties during production, and to maintain the integrity of the various processing facilities that produce specific end-products for buyers. Event 3272 corn has been successfully grown, harvested, transported, and delivered to an ethanol facility while under permit. Syngenta did not report and APHIS is not aware of any misdirection to other corn processing facilities or any harm to those facilities.

Although a closed-loop system and other identity preservation systems are standard operating procedures and meet current best management practices for the production of specialty corn, there is a chance that growers will fail to follow the contractual obligations and instead produce Event 3272 corn such that the identity of the grain is not preserved. The potential economic consequences of producing and misdirecting Event 3272 corn to a food or feed corn processing facility, as opposed to an ethanol facility, are similar to when other specialty corn is not produced and shipped to the appropriate facility, such as if waxy corn were to be misdirected to a high amylose corn processing facility. There may be economic consequences of those actions. However, the magnitude of the economic effects, and the amount of corn needed to present detrimental effects, may be different for Event 3272 corn compared to other specialty corn varieties.

Cumulative Effects: Specialty Corn and Processing

Under the no action and preferred alternative, specialty corn will be grown, harvested, and transported to specialized processing facilities. The mechanisms currently in place to protect the identity of specialty corn varieties, including Event 3272 corn, will not be affected by granting nonregulated status to Event 3272 corn. There are no cumulative effects to the natural and physical environment through the use of another specialty corn crop such as Event 3272 corn. Planting, harvesting, and transporting of Event 3272 corn will occur under rigid closed loop systems currently used for other specialty corn varieties. The potential economic consequences of producing and misdirecting Event 3272 corn to a food or feed corn processing facility, as opposed to an intended corn ethanol facility, are similar to when other specialty corn is shipped to the incorrect facility. Specialty corn production, and corn production in the U.S. in general, is currently successful and thrives, even with the understanding of economic risks of sending the wrong corn variety to the wrong place. Event 3272 corn is another specialty corn variety that will be planted, grown, harvested, and transported off the farm using a closed-loop system, and any cumulative effects to specialty corn and processing of corn is minimal.

Ethanol Production

Ethanol production is an integral part of meeting the renewable fuels standard (RFS) in the U.S. The Federal Energy Policy Act of 2005, signed on August 8, 2005, includes a Renewable Fuels Standard that directs the doubling of the use of ethanol and biodiesel in the U.S. fuel supply by 2012 to 7.5 billion gallons (42 USC 15801, page 1069). The Energy Independence and Security Act of 2007 passed in December 2007, includes a provision to expand consumption of alternative fuels, including but not limited to ethanol, to 36 billion gallons in 2022. With at least 194 corn ethanol plants in operation in 28 different states, corn-based ethanol production may be a feasible way to meet the ethanol consumption benchmark for 2012 set in the Energy Policy Act

of 2005.Based on the production output of ethanol production refineries operating at the end of 2010, more than 98% of ethanol produced in the U.S. is made from corn (http://www.ethanolrfa.org, Accessed February 7, 2011). According to the U.S. Energy Information Administration, ethanol production is projected to increase by 50,000 barrels per day (bbl/d) to 910,000 bbl/d in 2011 and then grow by an additional 10,000 bbl/d in 2012. (http://www.eia.doe.gov/emeu/steo/pub/contents.html, Accessed February 9, 2011).

No Action: Ethanol Production

Under the "no action" alternative, the process used for ethanol production would remain the same. Efficiency of ethanol production would remain at 2.8 gallons/bushel of corn. Corn-based ethanol production would still be used as one method to meet the benchmarks set by Congress in terms of biofuel consumption in the U.S.

Preferred Alternative: Ethanol Production

The use of Event 3272 corn in ethanol facilities that agree to receive Event 3272 corn could result in changes in inputs, methods, and capital costs during ethanol production. Each of the potential changes is due to the substitution of Event 3272 corn grain, containing a thermostable alpha-amylase, for microbial alpha-amylase in the liquefaction stage of ethanol production. Appendix C contains a report submitted on behalf of Syngenta, and reviewed by APHIS, that outlines these changes in detail, and what is required of ethanol plants to efficiently and effectively use Event 3272 corn, including potential re-design of ethanol facilities. A brief summary of the potential changes discussed in the report are identified as issues associated with Public Health, Animal Feed and DDGS, and Water Use, which are discussed below.

In particular, cooking temperatures may be lowered during the liquefaction stage with Event 3272 corn ethanol production, which potentially may result in decreases in energy usage, and has the added benefit of increasing ethanol yields. Ultimately, Syngenta believes that the changes associated with using Event 3272 corn in ethanol processing, instead of adding microbial alpha-amylase during the process, will result in a 2% or greater increase in ethanol efficiency per bushel of corn. However, if the efficiency projected by Syngenta is not met, then ethanol production would likely remain at 2.8 gallons/bushel of corn, as in the "no action" alternative.

Cumulative Effects: Ethanol Production

Under both the "no action" alternative and the "preferred" alternative, expansion of ethanol production is expected to occur to meet renewable fuel standards. The increase in production is expected to be similar under both alternatives. There are no other petitions submitted for nonregulated status for GE organisms related to ethanol production. If granted nonregulated status, Event 3272 would be the only GE corn variety available specifically for ethanol production, and Event 3272 corn is likely limited to those ethanol plants that are contracted to receive Event 3272 corn.

Public Health

Human Health

Under FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from Event 3272 corn must be

in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

Syngenta provided the FDA with information on identity, function, and characterization of the genes, as well the expression levels of the gene products. They also provided information on the potential allergenicity and toxicity of the expressed proteins. The FDA considers Syngenta's consultation on alpha-amylase Event 3272 corn to be complete (Appendix H). Syngenta also submitted information on identity, function, characterization of genes, expression levels of gene products, as well as information on the potential allergenicity and toxicity of the expressed proteins to APHIS. APHIS' assessment of the safety of this product for humans and animals focuses on plant pest risk (USDA-APHIS 2009) and the effects on wildlife and threatened and endangered species (see section on Animals and Threatened and Endangered Species, pages 50-52), and those analyses are based on the comparison of the GE-corn to its non-GE counterpart.

No Action: Human Health

Syngenta has successfully completed the consultation process with the FDA for Event 3272 corn (Appendix H). The status of the FDA consultation will not change under the "no action" alternative. Other countries have also found Event 3272 corn safe for food and feed, including Australia, Canada, Mexico, Russia, and the Philippines (see http://cera-gmc.org/index.php?action=gm_crop_database&mode=Submit&evidcode=Event%203272, Date Accessed: February 7, 2011).

Preferred Alternative: Human Health

APHIS evaluated risks to human and other animal health that may result from the consumption and exposure of Event 3272 corn. Risk is a combination of hazard and exposure. APHIS first conducted hazard identification for Event 3272 corn. APHIS assessed the composition and nutritional quality of Event 3272 corn, and compared the composition of Event 3272 to the composition of a non-genetically engineered control corn line and the natural variation found in commercial corn varieties. If the composition of Event 3272 corn is similar to other commercial corn plants, it is unlikely that Event 3272 poses an additional health hazard. If no hazards are identified, then the risk of Event 3272 corn causing harm is unlikely, regardless of exposure route. APHIS also assessed the exposure data presented by Syngenta to further evaluate any possible risk posed by Event 3272 corn to human or animal health.

Event 3272 corn is genetically engineered to produce a thermostable alpha-amylase. Additionally, alpha-amylases are ubiquitous enzymes found in microorganisms, plants, and animals (Janeček et al. 1999) to which humans and other animals are frequently exposed. These enzymes play a key role in many cellular metabolic processes by catalyzing the breakdown of starch, such as in germinating seed of cereal plants (Yu et al. 1996) or in the microbial decomposition of organic matter to provide carbon and energy for microbial growth processes (Rothstein et al. 1986). Many types of commercial food processing, feed ingredient applications, and industrial applications also utilize alpha-amylase enzymes, including the production of fuel and potable alcohol (brewing, distillation processes), and corn syrups (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006).

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 were 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 is not biologically different than conventional corn.

Given that the composition of Event 3272 corn was found to be consistent with the natural variation found in conventional corn varieties, the applicant conducted studies to confirm the absence of deleterious effects for animals when feeding on Event 3272 corn. AMY797E is predominantly found in the corn kernels of Event 3272 plants (1627 µg/g fresh weight in the dough stage), with minute amounts found in the roots during the whole stage (<0.1 µg/g fresh weight) and in the leaves during senescence (<1 µg/g fresh weight) (Table 3-3 of petition). Animals that feed primarily on corn kernels are seed-feeding insects and rodents found in agricultural fields. During field trials, the applicant found no changes in insect feeding damage (Table 5-7 of petition), indicating similar insect susceptibility for Event 3272 corn compared to conventional corn.

Rodents, such as mice or squirrels, may seasonally feed exclusively on corn kernels. Accordingly, these animals are most likely to have a diet containing large amounts of corn kernels. Using dietary calculations (pages 93-94 of petition) along with the results of a mouse toxicity study (page 50 of petition and page 6 of the response letter from Syngenta), the applicant determined that the No Observed Effect Dose (NOED) of AMY797E was greater than 2 times the maximum amount of alpha-amylase corn a rodent might consume daily (page 94 of petition). Additionally, the applicant also evaluated the effects of AMY797E on birds by feeding broiler chickens diets that contained up to 65% of Event 3272 grain for 49 days (page 94 of petition and page 6 of response letter). The applicant reported no harmful effects to chickens from a diet extremely high in AMY797E. Humans and feed animals would have a significantly lower exposure to AMY797E because of feeding habits and diverse food sources.

AMY797E also does not have any significant sequence identity to any known toxins (page 7 of response letter from Syngenta). AMY797E is functionally similar to thermostable alpha-amylases already safely used in food and feed processing (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006), indicating that Event 3272 corn is unlikely to produce toxins that would negatively affect humans or other animals that may eat corn kernels or plants containing AMY797E.

Concerns regarding the allergenicity of Event 3272 corn were raised by opponents of genetic engineering (Freese and Mayet 2006) centered around two components: 1) allergenicity of fungal-derived alpha-amylases and 2) thermostability of alpha-amylases.

Fungal-derived alpha-amylases are one of the occupational allergens in the bakery industry (Houba et al. 1996, Houba et al. 1997). Syngenta assessed the potential allergenicity of the AMY797E alpha-amylase and phosphomannose isomerase (PMI) proteins by searching for amino acid homology between these proteins and known allergen protein sequences. These searches were conducted using a database comprised of identified or putative allergen sequences from publicly available databases (GenPept, PIR, SWISS-PROT, FAARP and IUIS) and additional putative allergen sequences from the scientific literature. Syngenta reported that for alpha-amylase in Event 3272 corn, there were no significant similarities between the alpha-amylase found in Event 3272 corn and other allergens. There was one small section of the enzyme that corresponded with an allergen from an insect (American cockroach), but Syngenta maintains that this sequence identity is not biologically relevant and has no implication for the allergenic potential of the AMY797E alpha-amylase. AMY797E is a thermostable protein, which may be a consideration of what compounds are allergenic (Sampson 1999, Taylor and Hefle 2001). However Syngenta conducted digestibility experiments and found that AMY797E is not stable to digestion (Appendix H), and concluded that the AMY797E is unlikely to become allergenic. The FDA did not question the conclusion that AMY797E and PMI are not likely to become allergenic (Appendix H). APHIS has concluded that these studies are sufficient and agrees with the findings of the FDA.

Organisms exposed to AMY797E will also be exposed to PMI. The *pmi* (*manA*) gene comes from *E. coli* and encodes the PMI enzyme. *Pmi* serves as a marker gene that enables selection of lines that are genetically modified, providing the plant with the ability to utilize mannose as a sole carbon source. Table 3-4 of the petition gives the PMI expression data for Event 3272 corn. PMI expression was examined during 5 developmental stages of Event 3272 corn (whorl, anthesis, kernel dough, kernel maturity, and senescence). In Event 3272 corn, PMI is expressed in leaves during all stages except senescence, with maximum expression during the kernel dough stage (5.7 µg/g fresh weight). Expression of PMI in the roots occurs during all developmental stages with the highest expression of 1.0 µg/g fresh weight during the whorl stage. The highest PMI expression for kernels occurred during the kernel dough stage (0.8 µg/g fresh weight), and 8.5 µg/g fresh weight of PMI was expressed in the pollen. The expression of PMI protein in corn plants is not expected to have deleterious effects or significant impacts on humans or other animals, based on the data provided in the petition. 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.

Additionally, the EPA has granted an exemption from the requirement of a tolerance for the PMI protein as an inert ingredient in all plants (69 FR 26770-26775). The DNA encoding the PMI protein is not toxic. At the 80-amino acid peptide level, the PMI protein shares no significant homology with proteins known to be toxic or allergenic. Within one of the 80-amino acid windows, there was one region of sequence homology of eight contiguous amino-acids between PMI and a known allergen, α-parvalbumin from a *Rana* (frog) species. Further testing found no cross-reactivity between PMI and the human serum immunoglobulin E (IgE) and Bovine Serum Albumin (BSA), indicating that the low degree of sequence identity between the PMI used in Event 3272 corn and α-parvalbumin from *Rana* sp. is not biologically relevant.

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), and consideration that other countries have also found Event 3272 safe for food and feed use (Table 1), APHIS has concluded that under this alternative, the proposed action to grant nonregulated status to Event 3272 corn would have no significant impacts on human or animal health.

Cumulative Effects: Human Health

There are no significant impacts on human or animal health related to the no action alternative or granting nonregulated status to Event 3272 corn, and no cumulative effects have been identified.

Worker Safety

No Action: Worker Safety

During agricultural production of corn, farmers may be exposed to pesticides during application of these chemicals to crops. Under the "no action" alternative, exposure to these agricultural chemicals during corn production would remain the same.

Ethanol processing of corn grain into ethanol involves the use of hazardous chemicals. In standard ethanol production, pH is adjusted at several stages to maintain efficient processing using sulfuric acid and liquid ammonia during different ethanol processing steps for pH adjustment. Under the "no action" alternative, exposure to these ethanol processing chemicals would remain the same.

Preferred Alternative: Worker Safety

Worker safety issues related to the use of pesticides during agricultural production of Event 3272 corn would remain the same as the "no action" alternative. As discussed under the issue of "Pesticide Use", Event 3272 corn does not change the agronomic practices, or use of chemicals such as pesticides, associated with corn production.

The use of Event 3272 corn in ethanol production could result in changes in inputs and methods during ethanol production in those ethanol facilities that receive Event 3272 corn. Each of the potential changes is due to the substitution of Event 3272 corn grain, containing a thermostable alpha-amylase, for microbial alpha-amylase in the liquefaction stage of ethanol production. Appendix C contains a report submitted on behalf of Syngenta, and reviewed by APHIS, that outlines these changes in detail. A brief summary of the potential changes suggested to worker safety is provided below.

Using Event 3272 corn in the ethanol production process, instead of standard field corn with microbial alpha-amylase added, may eliminate constant adjustment of pH during processing. In standard ethanol production, pH is adjusted at several stages to maintain efficient processing. With the use of Event 3272 corn, and the potential consistency in pH during ethanol production, the use of sulfuric acid may be reduced by half because less sulfuric acid is needed to maintain pH. Urea may also be used as a substitute for liquid ammonia for additional pH balancing, because of the pH properties of ethanol processing due to the use of Event 3272 corn. Thus, the possible replacement and reduction of these hazardous chemicals (sulfuric acid and liquid ammonia) would reduce both environmental and workplace safety exposure.

Cumulative Effects: Worker Safety

Worker safety issues related to the use of pesticides during agricultural production of corn would continue and remain the same under both alternatives. As discussed under the issue of "Pesticide Use", Event 3272 corn does not change the agronomic practices, or use of chemicals such as pesticides, associated with corn production. Worker safety issues related to ethanol production would continue to occur under both alternatives. The use of Event 3272 would reduce worker exposure to some hazardous chemicals used in ethanol production. There are no cumulative effects identified for this issue.

Animal Feed - DDGS

Dried distillers grains with solubles (DDGS) is a co-product of ethanol production, and is mainly used domestically as feed for dairy cattle, but also for hogs, swines, broilers and turkeys. As a result of increased ethanol production, the quantity of distillers grains marketed for use in animal feed has increased from 1.89 million metric tons in 1999 to 8.35 million metric tons in 2005 (a 340 percent increase) and then more than tripled again to over 34 million metric tons in 2010 (Hoffman and Baker, 2010).

Approximately 90% of the distillers grains produced in U.S. facilities are used in domestic animal feed. Currently, ethanol plants do not discriminate between GE and non-GE corn. Given that 80% of corn production is GE, the DDGS produced and used as animal feed are likely produced with some GE corn varieties.

Because of the near complete fermentation of starch during the ethanol process, the remaining amino acids, fat, minerals and vitamins in DDGS increase approximately three-fold in concentration compared to levels found in corn (Rausch and Belyea 2006). This can result in concerns regarding phosphorous and animal waste dispose, sulfur diet content, and mycotoxin concentrations in DDGS.

No Action: Animal Feed - DDGS

Under the "no action" alternative, DDGS will still be produced during ethanol production. Concerns will still surround DDGS nutritional content in terms of increased phosphorus concentration and the disposal of the resulting animal waste, high sulfur diet content, and increased mycotoxin concentrations as discussed in Section II. The successful completion of the consultation with FDA for Event 3272 corn (Appendix H) will not change under the "no action" alternative.

Preferred Alternative: Animal Feed - DDGS

DDGS are currently made with GE corn, so the use of a new GE corn variety in ethanol production will not change the availability of GE DDGS as an animal feed. Syngenta has completed the consultation process on Event 3272 corn with FDA (Appendix H), and has concluded that Event 3272 corn is considered safe for use in food and feed. Based on this FDA consultation, APHIS supports this conclusion.

Overall, the use of Event 3272 corn is not anticipated to change the composition of DDGS. Ethanol production experiments at a laboratory scale conducted with Event 3272 corn found no difference in DDGS produced with conventional corn and with Event 3272 corn (Singh et al. 2006). However, the experiments were run using only 3% of Event 3272 corn during the ethanol

processing, and no comparisons of DDGS composition were conducted using 100% Event 3272 corn.

The use of Event 3272 corn in ethanol production is not anticipated to change the phosphorous or mycotoxin concerns surrounding the use of DDGS as animal feed, as discussed in Section II. However, if the use of Event 3272 corn in ethanol production decreased the use of sulfuric acid, the resultant DDGS may have a reduced sulfur content. This reduction in sulfur content in DDGS is a potential benefit as DDGS produced using the current ethanol production process could have a sulfur content that results in toxicity to animals (Rausch and Belyea 2006).

Under the "preferred" alternative, Event 3272 corn would be available for ethanol processing, and has the potential to alleviate some of the concerns surrounding sulfur content in DDGS, an ethanol by-product used for animal feed. If the reductions in sulfuric acid during ethanol processing due to Event 3272 corn are not realized impacts regarding sulfur content would be similar to the no action alternative. Overall, the use of Event 3272 corn would still be considered safe for food and feed use, including DDGS (Appendix H).

Cumulative Effects: Animal Feed - DDGS

DDGS are currently made with GE corn and this production is expected to continue. The use of a new GE corn variety in ethanol production will not change the availability of GE DDGS as an animal feed. Syngenta has completed the consultation process on Event 3272 corn with FDA (Appendix H), and Event 3272 corn is considered safe for use in food and feed. There are no cumulative effects identified for this issue.

Gene Movement

Gene flow is the transfer of genetic information between different individuals and/or populations. Pollen flow, or the movement of genes from one plant to another, occurs between plants that are sexually-compatible, or able to receive pollen at the appropriate time during the appropriate plant stage. Corn does not have sexually-compatible relatives found in 'natural' area; corn is only able to reproduce with other corn plants in the U.S. (USDA-APHIS 2009).

Corn pollen moves by the wind to other corn fields that are nearby. Successful gene movement from one plant to another requires many different biological and physical factors, such as timing of flowering between corn fields, viability of pollen, and presence of physical barriers; consequently pollen movement is not equivalent to gene movement. A recent paper (Sanvido et al. 2008) reviewed studies investigating gene flow and gene movement studies in corn grain production fields, and using the data found that the gene movement from GE corn to non-GE corn typically remained below 0.5% at 50m (approx. 164 feet), and this result was validated when analyzing cross-fertilization events in large scale studies (Henry et al. 2003, Weber et al. 2007).

One study found cross-fertilization rates higher at comparable distances than other studies (Jones and Brooks 1950). Jones and Brooks (1950) found successful gene movement to be as high as 2.5 % at 660ft. One potential reason for the discrepancy between this study and almost all other gene flow studies in corn may be due to the type of corn used in this study. Jones and Brooks (1950) investigated the appropriate isolation distance for seed production in open-pollinated varieties, and not for hybrid varieties. Due the biology of open-pollinated varieties, these types

of plants may be more receptive to pollen over a longer period of time than hybrid corn plants (Sanvido et al. 2008), allowing for a greater chance of pollination events. Therefore, the results from Jones and Brooks (1950) may be an overestimation of cross-fertilization potential for hybrid corn plants.

No Action: Gene Movement

Under the "no action" alternative, Event 3272 corn would remain a regulated article and would require a permit or notification for release into the environment. Under regulated releases, GE corn is typically separated from non-regulated corn by a distance of 660ft, based on distances set for seed production (AOSCA 2004), if distance is the only method used to prevent movement of pollen or genes. APHIS has concluded this separation distance is sufficient to limit gene movement from occurring outside the release site.

Preferred Alternative: Gene Movement

In 2008, GE corn production was planted on 80% of all corn acres currently in production in the US, and the use of GE corn has been increasing over the last 3 years (USDA-NASS 2006, 2007a, 2008a, 2010b). Concurrently, organic corn acreage is also increasing at approximately 30% a year (USDA-ERS 2008a), even though there are no requirements that GE corn currently in production use mandated techniques for separation between the two types of corn varieties. There are also no mandated separation distances between other corn types. Syngenta has included some mandatory measures in their Stewardship Agreement, including measures to minimize pollen movement outside corn fields containing Event 3272 corn.

Best management guidelines for Event 3272 corn (Appendix D and Appendix G) require 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. The border rows of non-Event 3272 corn are used as a 'pollen trap.' Corn pollen is heavy and most pollen does not travel far from the corn field (Sanvido et al. 2008). When pollen does move from Event 3272 corn, the border rows of corn will 'catch' the pollen in a 'trap,' and prevent the movement of pollen, and subsequently genes, outside of the field of Event 3272 corn. Additionally, Event 3272 corn is being grown as a specialty corn crop; maintaining the purity of this corn variety is also important. Hence, to a lesser degree, the border rows also act as a 'pollen trap' to prevent other corn pollen from entering the field of Event 3272 corn. The use of border rows may result in a reduction of up to more than 99.9% of Event 3272 corn pollen leaving the corn field (Appendix D).

In agricultural systems, growers may choose to grow GE or non-GE corn, and obtain price premiums for growing particular varieties of corn for particular markets. In 2008, conventional field corn averaged $3.90/bushel (USDA-NASS, 2009b), whereas organic corn averaged $7.08/bushel (USDA-NASS 2010). USDA asserts that agricultural practices that use conventional means, organic production systems, or genetically engineered varieties can all provide benefits to the environment, consumers, and farm income. Gene movement into and out of these specialized corn production systems have been managed using various types of buffer zones or isolation practices, such as differences in planting (which results in differences in flowering) or making sure fields are distance from other compatible crops (such as using isolation distances).

For example, besides the typical identity preservation and closed loop systems in place for specialty crops, those farmers using organic production also put in place measures to maintain purity for their crops. Typically, more than one method is used by farmers using organic methods to prevent unwanted material from entering their fields including; isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT 2003). The plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing and transporting the crop (Riddle 2004, Krueger 2007, Kuepper et al. 2007). Plans for organic systems also should include of how the risk of GMO contamination will be monitored (Kuepper et al. 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the farmer reduce contamination events (NCAT 2003, Krueger 2007). Commonly used production practices for corn and the practical methods typically used by corn farmers who use organic methods, or those that grown specialty crops, to protect their crop and maximize their profits and premiums granted to corn produced using approved plans currently provide many measures that will greatly reduce the likelihood of accidental gene flow between Event 3272 corn and other corn fields.

As more and more corn acreage is using GE varieties, corn production for GE-sensitive markets has increased; for example corn produced using organic methods increased 35% between 2001 and 2005 (USGC 2006), at the same time that corn acreage using GE varieties increased by 50% (USDA-NASS 2001, 2005). During this time, there was no mandated use of separation distance or other measures to minimize gene movement between corn fields, except for those measures taken by farmers who use organic production practices. No acreage data for corn production under organic methods is available since 2005, thus no further trend comparisons were conducted.

Based on the 2005 information, if growers of Event 3272 corn fail to use the separation techniques mandated in their contract with Syngenta, there is no indication that any pollen flow from GE corn to non-GE corn would dampen the organic production of corn. Event 3272 corn will be one of many GE varieties already in the marketplace, and GE corn already accounts for 86% of corn planted in the U.S. Event 3272 corn will not increase the acreage of GE corn planted in the U.S. There are no new procedures or requirements that growers of non-GE varieties may need to implement as baseline market and economic conditions are already in place to account for GE varieties in U.S. corn production. Acreage using GE varieties has increased by 40% since 2005, and there is no corresponding data for acres of corn production under organic methods. Overall impacts of gene movement would be similar to the no action alternative. The pollen flow prevention measures in place for Event 3272 corn, along with geographic isolation and other factors that will be part of the closed-loop production system for Event 3272 corn will also minimize gene flow to other conventional and specialty corn varieties (See Production Practices above).

Cumulative Effect: Gene Movement

Event 3272 corn would be an additional GE and specialty corn variety that may be available to the farming community. Currently, GE corn is approximately 86% of all acreage of corn production in the U.S. The production area for Event 3272 corn will likely be limited to areas in

states that currently have ethanol production facilities because this GE corn variety has been specifically developed for that purpose. Because GE corn is currently used in ethanol production, and Event 3272 corn will not change the amount of GE corn produced in the U.S., the availability of Event 3272 corn will not result in cumulative effects on gene movement. Event 3272 corn does not change the amount of GE pollen in the environment.

Water Use in Ethanol Production

Ethanol production is an integral part of meeting the renewable fuels standard (RFS) in the U.S. Almost all (more than 98%) of U.S. ethanol is made from corn (http://www.ethanolrfa.org, Accessed February 7, 2011). Ethanol production typically uses 4.7 gallons of water to produce 1 gallon of ethanol (Shapouri and Gallagher 2005). Water is also used during the manufacturing and transport of microbial alpha-amylase for conventional ethanol production.

No Action: Water Use in Ethanol Production

Under the "no action" alternative, there is no change in the conventional processes used for ethanol production. Water would still be used during the manufacturing and transport of microbial alpha-amylase for conventional ethanol production, and approximately 4.7 gallons of water would be used to produce 1 gallon of ethanol.

Preferred Alternative: Water Use in Ethanol Production

The use of Event 3272 corn could result in the water conservation in two ways. There is a potential for a decrease in water usage during ethanol production during the saccharification phase due to the properties of Event 3272 corn (Appendix C). However, large-scale ethanol plant research and development have not verified this potential savings. The use of Event 3272 corn may result in the same water use in ethanol production as now [4.7 gallons of water for 1 gallon of ethanol, (Shapouri and Gallagher 2005)].

Currently, water is intensively used during the production of microbial alpha-amylase and microbial alpha-amylase is also transported to the ethanol facility in a water solution. If Event 3272 corn was used in ethanol production, water usage could be reduced because microbial alpha-amylase would not be needed in ethanol production due to the replacement by the alpha-amylase in Event 3272 corn.

Cumulative Effect: Water Use in Ethanol Production

Water is currently used in the production of ethanol and this practice will continue with the availability of Event 3272 corn. Ethanol production typically uses 4.7 gallons of water to produce 1 gallon of ethanol (Shapouri and Gallagher 2005). Water is also used during the manufacturing and transport of microbial alpha-amylase for conventional ethanol production. Granting nonregulated status to Event 3272 corn may potentially decrease water use. However, no cumulative effects have been identified for this issue.

Animal and Plant Communities

Animals

Corn production systems in agriculture are host many animal species. Mammals and birds may seasonally use grain, and invertebrates can feed on the plant during the entire growing season.

The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

No Action: Animals

Under the "no action" alternative, environmental releases of Event 3272 corn would be under regulation. Animal incursions are limited during regulated field trials, but may occur. However, the consultation with FDA has been successfully completed for Event 3272 corn (Appendix H), which addressed any concerns of composition, as well as demonstrated a lack of toxicity and allergenicity, of Event 3272 corn for human and animal consumption. Based upon the FDA consultation, APHIS supports Syngenta's conclusions that Event 3272 corn is considered safe for animal consumption.

Preferred Alternative: Animals

APHIS has reviewed and accepts the data submitted by the applicant that confirmed the absence of deleterious effects for wildlife when feeding on Event 3272 corn. The data are similar to what was submitted during the FDA consultation process for Event 3272 corn (Appendix H). Agronomic practices used to produce Event 3272 corn will be the same as those used to produce conventionally grown corn, and the effects discussion for Event 3272 corn on animals will focus solely on the effects of the introduced proteins in Event 3272 corn, the alpha-amylase enzyme and the phosphomannose enzyme (used as a selectable marker for Event 3272 corn).

Event 3272 corn contains the alpha-amylase protein, AMY797E, which is found predominantly in the corn kernels of Event 3272 corn plants (1627 µg/g fresh weight in the dough stage), with minute amounts found in the roots during the whole stage (<0.1 µg/g fresh weight) and in the leaves during senescence (<1 µg/g fresh weight) (Table 3-3 of petition). Animals that feed primarily on corn kernels are seed-feeding insects and rodents found in agricultural fields. During field trials, the applicant found no changes in insect feeding damage (Table 5-7 of petition), indicating similar insect susceptibility for Event 3272 corn compared to conventional corn. Event 3272 corn has not been genetically engineered to produce any pesticides.

Rodents, such as mice or squirrels, may seasonally feed exclusively on corn kernels. Accordingly, these animals are most likely to have a diet containing large amounts of corn kernels. Using the dietary calculations (pages 93-94 of petition) along with the results of a mouse toxicity study (page 50 of petition and page 6 of response letter), the applicant determined that the no observed effect dose (NOED) of AMY797E was greater than 2 times the maximum amount of alpha-amylase corn a rodent might consume daily (page 94 of petition). Other mammals, such as deer, would have even lower exposure to AMY797E because of feeding habits; for example, deer nibble on tips of corn ears as opposed to kernels (Steffey et al. 1999). APHIS has reviewed this information and has determined that there would be no negative effects to mammals that forage in Event 3272 corn.

The applicant also evaluated the effects of AMY797E on birds by feeding broiler chickens diets that contained up to 65% of Event 3272 grain for 49 days (page 94 of petition and page 6 of response letter). The applicant reported no harmful effects to chickens from a diet extremely high in AMY797E. Moreover, given that diets high in AMY797E do not result in harmful effects, the diets of wild birds that occasionally forage in corn fields are unlikely to contain high amounts of AMY797E for 49 consecutive days as corn availability is limited by seed

germination and harvest. APHIS has reviewed this information and has determined that there would be no negative effects to birds that forage in Event 3272 corn.

Additionally, animals have been previously exposed to alpha-amylases in the environment, as they are ubiquitous enzymes found in microorganisms, plants, and animals (Janeček et al. 1999). AMY797E also does not have any significant sequence identity to any known toxins (page 7 of response letter). As stated earlier, AMY797E is functionally similar to thermostable alpha-amylases already safely used in food and feed processing (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006), indicating that Event 3272 corn is unlikely to produce toxins that would negatively affect animals that may eat corn kernels or plants containing AMY797E.

Organisms exposed to the AMY797E protein in Event 3272 corn will also be exposed to PMI, a protein used by the applicant to select genetically engineered plants during breeding. Additional species, such as leaf-feeding animals, butterflies and bees, may not be exposed to AMY797E but will be exposed to PMI because of its expression in vegetative tissue and pollen (Table 3-4 of petition). The *pmi* (*manA*) gene comes from *E. coli* and encodes the enzyme phosphomannose isomerase (PMI). *Pmi* serves as a marker gene that enables selection of lines that are genetically engineered, providing the plant with the ability to utilize mannose as a sole carbon source. Table 3-4 of the petition gives the PMI expression data for Event 3272 corn. PMI expression was examined during 5 developmental stages of Event 3272 corn (whorl, anthesis, kernel dough, kernel maturity, and senescence). In Event 3272 corn, PMI is expressed in leaves during all stages except senescence, with maximum expression during the kernel dough stage (5.7 µg/g fresh weight). Expression of PMI in the roots occurs during all developmental stages with the highest expression of 1.0 µg/g fresh weight during the whorl stage. The highest PMI expression for kernels occurred during the kernel dough stage (0.8 µg/g fresh weight), and 8.5 µg/g fresh weight of PMI was expressed in the pollen. The expression of PMI protein in corn plants is not expected to have deleterious effects or significant impacts on non-target organisms or TES organisms, based on the data provided in the petition. 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, including threatened and endangered species.

Additionally, the EPA has granted an exemption from the requirement of a tolerance for the PMI protein as an inert ingredient in all plants (69 FR 26770-26775). The DNA encoding the PMI protein is not toxic. At the 80-amino acid peptide level, the PMI protein shares no significant homology with proteins known to be toxic or allergenic. Within one of the 80-amino acid windows, there was one region of sequence homology of eight contiguous amino-acids between PMI and a known allergen, α-parvalbumin from a *Rana* (frog) species. Further testing found no cross-reactivity between PMI and the human serum immunoglobulin E (IgE) and Bovine Serum Albumin (BSA), indicating that the low degree of sequence identity between the PMI used in Event 3272 corn and α-parvalbumin from *Rana* sp. is not biologically relevant.

Plants

Corn production systems in agriculture are host many plant species as well. The landscape surrounding a corn field varies depending on the region. In certain areas, corn fields may be bordered by other corn (or any other crop); fields may also be surrounded by wooden and/or

pasture/grassland areas. Therefore, the types of vegetation, including weeds, around a corn field depend on the area where the corn is planted. A variety of weeds dwell in and around corn fields; those species will also vary depending on the region where the corn is planted. Corn itself is not sexually compatible with any other plant species found in the U.S. (USDA-APHIS 2009). The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

No Action: Plants

Under the "no action" alternative, environmental releases of Event 3272 corn would be under regulation. Plant species that typically inhabit corn production systems will be managed as in conventional corn production, including the use of mechanical, cultural, and chemical control methods.

Preferred Alternative: Plants

If Event 3272 corn was granted nonregulated status, agricultural practices used for conventional corn would be used for plant management during the cultivation of Event 3272 corn. Impacts would be similar to the no action alternative. Event 3272 corn does not exhibit characteristics associated with weedy growth and will not compete with plants found outside of agricultural production. Weeds within fields of Event 3272 corn will be managed using mechanical, cultural, and chemical control, as weeds are now managed in conventional corn systems. As there are no toxic effects on animals (see Animals discussion above), there are no toxic effects on animals that could be pollinators of other plants in or around fields cultivated with Event 3272 corn. Event 3272 corn has not been genetically engineered to be tolerant to any herbicides.

Biological Diversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and may have even been bred for a particular purpose. In the case of corn agriculture, corn varieties have been developed for food processing needs (e.g., waxy corn), varietal development (e.g., blue corn or white corn), or for use as a vegetable (e.g. sweet corn). In conventional agriculture, farmers want to encourage high yields from their corn crop, and will intensively manage the 'plant communities', or weeds, found in corn crops through chemical, cultural, or mechanical means. Animals, particularly insect and other pest species will also be managed through chemical and cultural controls to protect the crop from destruction by animals. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats. The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

No Action: Biological Diversity

Under the "no action" alternative, environmental releases of Event 3272 corn would be under regulation. Animal and plant species that typically inhabit corn production systems will be managed as in conventional corn production, including the use of mechanical, cultural, and chemical control methods.

Preferred Alternative: Biological Diversity

Under the "preferred" alternative cultivation of Event 3272 corn requires the same agronomic practices as conventional corn production. Animal and plant species that typically inhabit corn

production systems will be managed as in conventional corn production, likely with the use of mechanical, cultural, and chemical control methods. Overall impacts would be similar to the no action alternative.

Cumulative Effects: Animals, Plants, Biodiversity

Event 3272 corn has not been genetically engineered to produce a toxin or pesticide, and has not been genetically engineered to be tolerant to an herbicide. Although some studies have found both increases and decreases in animal and plant diversity and abundance in the agro-ecosystem due to the use of GE crops (Hansen Jesse and Obrycki 2000, Ponsard et al. 2002, Brooks et al. 2003, Haughton et al. 2003, Hawes et al. 2003, Marshall et al. 2003, Roy et al. 2003, Romeis et al. 2004, Sisterson et al. 2004, Bitzer et al. 2005, Pilcher et al. 2005, Torres and Ruberson 2005, Romeis et al. 2006, Marvier et al. 2007, Chen et al. 2008, Wolfenbarger et al. 2008), Event 3272 corn is unlikely to affect the animal or plant communities found in conventional corn production systems because of the lack of toxicity and allergenicity, and because there is no change to agronomic practices due to the cultivation of Event 3272 corn.

Soil Biology

The soil environment in and around corn fields is complex, rich in microorganisms and arthropods. The corn root system acts as a soil modifier due to its association with several microbial groups such as bacteria, fungi, protozoa, and mites. Bacteria typically represent the most abundant microbes in the soil followed by fungi. These microbial groups play an important and particular role in the ecology of the soil, including nutrimental cycling and the availability of nutrients for plant growth.

Research shows that crop soils are prone to degradation due to the disturbance and exposure of the top surface layer by certain agronomic practices. Two environmental impacts of soil degradation are the decline in water quality and the contribution to the greenhouse effect (Lal and Bruce 1999).

No Action: Soil Biology

Under the “no action” alternative, environmental releases of Event 3272 corn would be under regulation. Interactions with the soil would be limited to the areas that were approved for regulated releases. Cultivation practices associated with regulated releases of Event 3272 corn would be the same as conventional corn production. The soil environment would be modified by corn roots and crop soils would still be affected by agronomic practices associated with conventional corn cultivation.

Preferred Alternative: Soil Biology

Under the “preferred” alternative, soil interactions with Event 3272 corn would occur at a large scale. Cultivation practices associated with regulated releases of Event 3272 corn would be the same as conventional corn production. The soil environment would be modified by corn roots and crop soils would still be affected by agronomic practices associated with conventional corn cultivation. Overall impacts would be similar to the no action alternative.

Event 3272 corn was engineered in such a way that the alpha-amylase protein is produced nearly exclusively in the grain. This is important in the case of roots, because they are in contact with

the soil and could possibly affect soil biology. The protein was detected in the roots of four out of ten plants tested at the whorl stage, but not in any plants at any later stages of development. The level was extremely low, less than0.1 µg/g fresh weight, which is more than two thousand fold lower than in kernels. For this reason, roots are not likely to contribute biologically significant amounts of alpha-amylase to the soil.

Because roots are not likely to contribute alpha-amylase to the soil, and because larger amounts are found in grain, the degradation of grain is the main avenue for alpha amylase to find its way into the soil. Event 3272 grain contains 1627 µg/g fresh weight of alpha-amylase in the grain in the dough stage (Table 3-3, page 44 of Petition). It has been estimated (Wolt and Karaman, 2007) that approximately 1% of grain is lost during harvest, which falls to the ground in the field. Wolt and Karaman (2007) estimated potential amounts of alpha-amylase that might accumulate in agricultural soils over time and space due to the use of Event 3272 corn. The study assumed levels of alpha-amylase in grain, leaves, and roots to extrapolate and estimate environmental amounts of alpha-amylase that might accumulate in corn fields in Iowa. According to their calculations, they projected an order of magnitude increase in the amount of alpha-amylase, due to increased amounts of alpha-amylase, in soils in Iowa corn fields. However, the authors did not present any empirical evidence to suggest that alpha-amylase would persist, and more importantly, did not consider the potential for natural degradation of alpha-amylase. An abstract was cited (Kosaki et al. 2006) that found soil persistence of another thermostable protein, however, the comparison between the two proteins was based solely on the thermostability of each of the proteins, and not the degradability of the proteins. Thermostability in and of itself is not a characteristic related to the ability of an enzyme to degrade, or persist for that matter, in agricultural soils.

Amylases, including alpha-amylases, are enzymes that are ubiquitous in nature and naturally occur in soils. In soil, a high diversity of alpha-amylases are commonly found (Rondon et al. 2000). The microbial soil community and activity is complex, with a multitude of chemical and enzymatic interactions. Soils that have healthy microbial activity produce sufficient levels of proteases to degrade most proteins (Marx et al. 2005). Digestibility data presented to APHIS and FDA (Appendix H) by Syngenta show degradation of alpha-amylase from Event 3272 corn by a single protease, pepsin. Although pepsin is not normally found in soils, the data do suggest that alpha-amylase is not inherently indigestible or non-degradable.

Degradation of grain would have to occur before alpha-amylase would be released into soil. Grain left in the field does not immediately result in the increased amounts of alpha-amylase in soil. Even if present, amylase would have no effect unless specific conditions for enzyme activity are met including substrate availability, inducers, availability of other nutrients, physical and chemical parameters such as moisture, temperature, and pH. These characteristics vary in time and space and from one microenvironment to another. Additionally, according to Syngenta, alpha-amylase from Event 3272 is constructed for maximum activity at 176ºF (80ºC), and only has 10% of its maximal activity under 86ºF (30ºC). None of these limiting factors were considered in the estimations and conjecture of potential contributes of Event 3272 grain to alpha-amylase levels in the soil by Wolt and Karaman (2007).

Cumulative Effects: Soil Biology

The impacts to soil biology under the preferred alternative are unlikely to differ significantly from the No Action Alternative. Soil environments where Event 3272 corn is grown will not be significantly changed by the increased exposure to amylase. Alpha-amylase from Event 3272 corn will not have significant activity within soils, and is expected to be readily degraded by microorganisms. No cumulative effects are identified for this issue.

Conservation Reserve Program

The Conservation Reserve Program (CRP), administered by the USDA, is the largest private-lands conservation program in the U.S. According to the Farm Service Agency:

> CRP plantings and practices offer our nation vast environmental benefits, including reducing soil erosion, improving surface and ground water quality, creating wildlife habitat, restoring wetlands, sequestering carbon, preserving soil productivity, and reducing offsite wind erosion damages. Some of CRP's substantial 2007 accomplishments include:
>
> • Reducing runoff of sediment (207 million tons), nitrogen (480 million pounds), and phosphorus (108 million pounds) from agricultural soils.
> • Restoring and protecting 2.1 million acres of wetlands and adjacent buffers.
> • Establishing 1.9 million acres of grass and forested buffers along the nation's rivers and streams.
> • Improving populations of Prairie Pothole ducks, ring-necked pheasants, sage grouse, bobwhite quail, and other grassland birds.
> • Sequestering over 50 million tons of carbon. (USDA-FSA 2007)

There is public concern that the demand for ethanol production, and subsequent corn prices, are a catalyst resulting in removing acreage from the Conservation Reserve Program to place into corn production (Hart 2006).

No Action: Conservation Reserve Program

Acres removed or maintained in the Conservation Reserve Program will not change under the "no action" alternative. Demands for ethanol production and corn prices may result in growers removing acres from the CRP and placing them into corn production, under the "no action" alternative. Market demands and corn prices are the drivers behind decisions made by growers to remove acres from CRP (Hart 2006).

Preferred Alternative: Conservation Reserve Program

As stated in Section II, the demands for ethanol production and increased corn prices may result in growers removing acres from the CRP and place them into corn production, independent of granting Event 3272 nonregulated status. Overall impacts on the Conservation Reserve Program are similar to the no action alternative.

Cumulative Effects: Conservation Reserve Program

The demands for ethanol production and increased corn prices are likely greater factors in determining if a farmer would remove acres from the CRP and place them into corn production, than granting Event 3272 nonregulated status. No cumulative effects identified for this issue.

Role of Assumptions in Environmental Consequences Analyses

Event 3272 corn will be grown under strict contractual agreements and a closed loop system to protect the value of the corn for ethanol production, similar to how other specialty corn varieties are grown, harvested, transported, and marketed in the U.S. However, APHIS recognizes that there is a small chance that some members of the system may not live up to the contractual obligations. Each of the above issues was analyzed with the consideration that the assumptions made by APHIS were not met. Failure to follow contractual agreements will not result in significant environmental impacts in terms of corn production, ethanol production, public health, water use in ethanol production, animal and plant communities, soil biology, and Conservation Reserve Program acreage. Event 3272 corn is planted, grown, and harvested similar to other conventional corn. Event 3272 corn does not change the acreage devoted to corn production in the U.S., does not change where corn can be produced in the U.S., and will not change the acreage of corn planted to GE varieties (86% of corn acreage in the U.S. is planted to GE varieties, which is also used in corn ethanol facilities).

Planting, harvesting, and transporting of Event 3272 corn will occur under rigid closed loop systems currently used for other specialty corn varieties. The potential economic consequences of lapses of the close-loop system have been analyzed. As stated above, there is no harm to the natural or physical environment of planting, growing, or harvesting Event 3272 corn. 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. There is the potential for economic and marketing harms for food processing facilities when material ends up at an unintended facility, whether it is high amylose corn, waxy corn, or Event 3272 corn.

Other Cumulative Effects

All potential cumulative effects regarding specific issues have been analyzed and addressed above. No further potential cumulative effects have been identified. Stacked varieties, those crop varieties that may contain more than one trait, are currently found in the marketplace and in agricultural production. If granted nonregulated status, Event 3272 corn may be combined with other GE corn varieties by traditional breeding techniques, resulting in amylase corn that, for example, may also be resistant to herbicides or insects. Some GE corn varieties used for any commercial breeding program have already been found not to pose a plant pest risk, and have been granted nonregulated status by APHIS. Syngenta currently has 4 GE corn varieties that may be stacked with Event 3272 corn: three varieties that have an insect-resistance trait (Bt11 and Mir604) and one variety that has an herbicide-tolerance trait (GA21). These corn lines (Bt11, MIR604, GA21, MIR 162) 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. APHIS current regulations at 7 CFR part 340 do not provide for Agency oversight of these GE corn varieties previously granted nonregulated status, nor over stacked varieties combining deregulated GE varieties unless it can be positively shown that such stacked varieties were somehow likely to

pose a plant pest risk. Further, 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. Moreover, Event 3272 corn could even be combined with non-GE corn varieties. Thus, 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.

Threatened and Endangered Species

APHIS evaluated the potential for negative effects on Federal Threatened and Endangered Species (TES) as listed by the U.S. Fish and Wildlife Service (FWS) (http://ecos.fws.gov/tess_public/pub/SpeciesReport.do?dsource=animals, http://ecos.fws.gov/tess_public/pub/SpeciesReport.do?dsource=plants, accessed 8/12/08 and 2/7/11), from cultivation of Event 3272 corn and its progeny. To identify negative effects or significant impacts on TES animal species, APHIS evaluated the risks to TES animals from consuming Event 3272 corn. Risk is a combination of hazard and exposure. APHIS first conducted hazard identification for Event 3272 corn. APHIS assessed the composition and nutritional quality of Event 3272 corn, and compared the composition of Event 3272 to the composition of a non-genetically engineered control corn line and the natural variation found in commercial corn varieties. Corn is a feed common for many livestock and wildlife (e.g., birds, deer, and rodents). If the composition of Event 3272 corn is similar to other commercial corn plants, it is unlikely that Event 3272 poses a hazard to TES animal species. If no hazards are identified, then the risk of Event 3272 corn harming TES animal species is also unlikely, regardless of exposure. However, APHIS also assessed the exposure data presented by Syngenta to further elucidate the exposure posed by Event 3272 corn to TES animals.

Event 3272 corn is genetically engineered to produce a thermostable alpha-amylase. Alpha-amylases are ubiquitous in the environment, being naturally present in microorganisms, plants and animals (Janeček et al. 1999). These enzymes play a key role in many cellular metabolic processes by catalyzing the breakdown of starch, such as in germinating seed of cereal plants (Yu et al. 1996) or in the microbial decomposition of organic matter to provide carbon and energy for microbial growth processes (Rothstein et al. 1986). Many types of commercial food processing, feed ingredient applications, and industrial applications also utilize alpha-amylase enzymes, including the production of fuel and potable alcohol (brewing, distillation processes), and corn syrups (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006).

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 were 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 a listed TES or species proposed for listing. Thus, the composition of Event 3272 is not biologically different than conventional corn.

Given that the composition of Event 3272 corn was found to be consistent with the natural variation found in conventional corn varieties, the applicant conducted studies to confirm the absence of deleterious effects for animals when feeding on Event 3272 corn. AMY797E is predominantly found in the corn kernels of Event 3272 plants (1627 µg/g fresh weight in the

dough stage), with minute amounts found in the roots during the whole stage (<0.1 µg/g fresh weight) and in the leaves during senescence (<1 µg/g fresh weight) (Table 3-3 of petition). Animals that feed primarily on corn kernels are seed-feeding insects and rodents found in agricultural fields. During field trials, the applicant found no changes in insect feeding damage (Table 5-7 of petition), indicating similar insect susceptibility for Event 3272 corn compared to conventional corn.

Rodents, such as mice or squirrels, may seasonally feed exclusively on corn kernels. Accordingly, these animals are most likely to have a diet containing large amounts of corn kernels. Using dietary calculations (pages 93-94 of petition) along with the results of a mouse toxicity study (page 50 of petition and page 6 of response letter from Syngenta), the applicant determined that the No Observed Effect Dose (NOED) of AMY797E was greater than 2 times the maximum amount of alpha-amylase corn a rodent might consume daily (page 94 of petition). Other mammals, such as deer, would have even lower exposure to AMY797E because of feeding habits; for example, deer nibble on tips of corn ears as opposed to kernels (Steffey et al. 1999). Therefore, there would be no negative impact to TES mammals that forage in Event 3272 corn.

The applicant also evaluated the effects of AMY797E on birds by feeding broiler chickens diets that contained up to 65% of Event 3272 grain for 49 days (page 94 of petition and page 6 of response letter). The applicant reported no harmful effects to chickens from a diet extremely high in AMY797E. Moreover, given that diets high in AMY797E do not result in harmful effects, the diets of wild birds that occasionally forage in corn fields, including threatened and endangered species such as the whooping crane, are unlikely to contain high amounts of AMY797E for 49 consecutive days as corn availability is limited by seed germination and harvest.

Additionally, threatened and endangered species have been previously exposed to alpha-amylases in the environment, as they are ubiquitous enzymes found in microorganisms, plants, and animals (Janeček et al. 1999). AMY797E also does not have any significant sequence identity to any known toxins (page 7 of response letter from Syngenta). As stated earlier, AMY797E is functionally similar to thermostable alpha-amylases already safely used in food and feed processing (Janeček et al. 1999, Lévêque et al. 2000, Pariza and Johnson 2001, Olempska-Beer et al. 2006), indicating that Event 3272 corn is unlikely to produce toxins that would negatively affect animals that may eat corn kernels or plants containing AMY797E.

Organisms exposed to AMY797E will also be exposed to PMI. Additional species, such as leaf-feeding animals, butterflies and bees, may not be exposed to AMY797E but will be exposed to PMI because of its expression in vegetative tissue and pollen (Table 3-4 of petition). The *pmi* (*manA*) gene comes from *E. coli* and encodes the enzyme PMI. *Pmi* serves as a marker gene that enables selection of lines that are genetically modified, providing the plant with the ability to utilize mannose as a sole carbon source. Table 3-4 of the petition gives the PMI expression data for Event 3272 corn. PMI expression was examined during 5 developmental stages of Event 3272 corn (whorl, anthesis, kernel dough, kernel maturity, and senescence). In Event 3272 corn, PMI is expressed in leaves during all stages except senescence, with maximum expression during the kernel dough stage (5.7 µg/g fresh weight). Expression of PMI in the roots occurs during all developmental stages with the highest expression of 1.0 µg/g fresh weight during the whorl stage. The highest PMI expression for kernels occurred during the kernel dough stage (0.8 µg/g

fresh weight), and 8.5 µg/g fresh weight of PMI was expressed in the pollen. The expression of PMI protein in corn plants is not expected to have deleterious effects or significant impacts on TES organisms, based on the data provided in the petition. 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 for threatened and endangered species.

Additionally, the EPA has granted an exemption from the requirement of a tolerance for the PMI protein as an inert ingredient in all plants (69 FR 26770-26775). The DNA encoding the PMI protein is not toxic. At the 80-amino acid peptide level, the PMI protein shares no significant homology with proteins known to be toxic or allergenic. Within one of the 80-amino acid windows, there was one region of sequence homology of eight contiguous amino-acids between PMI and a known allergen, α-parvalbumin from a *Rana* (frog) species. Further testing found no cross-reactivity between PMI and the human serum immunoglobulin E (IgE) and Bovine Serum Albumin (BSA), indicating that the low degree of sequence identity between the PMI used in Event 3272 corn and α-parvalbumin from *Rana* sp. is not biologically relevant.

Corn itself is not sexually compatible with any TES plant species; therefore there is no potential for a direct effect of Event 3272 corn on TES plants. Indirect effects of Event 3272 corn on TES plant species were also evaluated. As stated above, Event 3272 corn has no negative effect on animals, including animals such as insects or bats, which may be pollinators for TES plants. As a result, there are no indirect effects of Event 3272 corn on TES plant species.

Cultivation of Event 3272 corn is not expected to differ from typical corn cultivation. Event 3272 corn is not genetically engineered to produce a toxin or pesticide, and is not genetically engineered to be tolerant to an herbicide. Although the extent to which Event 3272 corn will be grown is ultimately unknown, this product is expected to replace other GE and non-GE corn varieties currently grown for the ethanol market. After reviewing the possible effects of granting nonregulated status to Event 3272 corn, APHIS has not identified any stressor caused directly by this product that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. The potential environmental impacts on TES of this product are those associated with typical corn agriculture. Growers planting Event 3272 corn, as with any other corn variety, genetically engineered or not, should consider the environmental impacts of agronomic practices on those TES found in and around their corn field.

After reviewing possible effects of granting nonregulated status to Event 3272 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Consequently, an exposure analysis for individual species is not necessary. APHIS has considered the effect of Event 3272 corn production on designated critical habitat or habitat proposed for designation and could identify no difference from affects that would occur from the production of other corn varieties. APHIS has reached a conclusion 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. Consequently, a written concurrence or formal consultation with the USFWS is not required for this action. Based on this analysis, there

is no apparent potential for significant impact on threatened or endangered species if APHIS were to grant the petition for nonregulated status to Event 3272 corn.

Compliance with Statutes, Executive Orders and Regulations

Executive Order (EO) 12898 (US-NARA 2008), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations", requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. EO 13045 (US-NARA 2008), "Protection of Children from Environmental Health Risks and Safety Risks", acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) required each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. Each alternative was analyzed with respect to EO 12898 and 13045. Based on the information submitted by the applicant and assessed by APHIS, Event 3272 corn is not significantly different than conventional corn and has successfully completed FDA consultation for food and feed use. Therefore, Event 3272 corn is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

EO 13112 (US-NARA 2008), "Invasive Species", states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause. Both non-GE and GE corn varieties that have been granted nonregulated status are widely grown in the U.S. Based on historical experience with corn and the data submitted by the applicant and assessed by APHIS, Event 3272 corn plants are very similar in fitness characteristics to other corn varieties currently grown and are not expected to become weedy or invasive. (USDA-APHIS 2009) .

EO 13186 (US-NARA 2008), "Responsibilities of Federal Agencies to Protect Migratory Birds", states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations. Data submitted by the applicant has shown no difference in compositional and nutritional quality of Event 3272 corn compared to conventional corn, apart from the presence of AMY797E and PMI. Syngenta also conducted feeding experiments on broiler chickens to evaluate the effects of AMY797E on birds (page 94 of petition and page 6 of response letter). The applicant reported no harmful effects to chickens from a diet extremely high in AMY797E. Moreover, given that diets high in AMY797E do not result in harmful effects, the diets of migratory birds that occasionally forage in corn fields are unlikely to contain high amounts of AMY797E as corn availability is limited by seed germination and harvest. Based on APHIS' assessment of Event 3272 corn it is unlikely that granting nonregulated status to this corn variety will have a negative effect on migratory bird populations.

INTERNATIONAL IMPLICATIONS

EO 12114 (US-NARA 2008), "Environmental Effects Abroad of Major Federal Actions", requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the U.S. should nonregulated status be granted to Event 3272 corn. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340. Any international traffic of Event 3272 corn subsequent to a determination of nonregulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPP 2008); the protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (177 countries as of February 2011). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of February 2011 (CBD 2011) . Although the U.S. is not a party to the CBD, and therefore not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with domestic regulations that importing countries that are Parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11 Parties must post

decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII 2008). These data will be available to the Biosafety Clearinghouse. APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO 2008). APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea.

COMPLIANCE WITH CLEAN WATER ACT AND CLEAN AIR ACT

This Environmental Assessment evaluated the changes in corn production due to the unrestricted use of Event 3272 corn. Event 3272 corn will not lead to the increased production of corn in U.S. agriculture. There is no expected change in water use due to the production of Event 3272 corn, nor is it expected that air quality will change to do the production of Event 3272 corn. If APHIS grants nonregulated status to Event 3272 corn, APHIS will be fully compliant with the Clean Water Act and the Clean Air Act.

V. Listing of Agencies and Persons Consulted

Dr. Levis Handley
Biotechnology Regulatory Services
APHIS

Rhey Solomon
E&T Solutions, LLP

Rhonda Solomon
Environmental Services
APHIS

Dr. Michael Watson
Biotechnology Regulatory Services
APHIS

Office of General Counsel
USDA

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Appendix A. Biotech Seed Products Available for the 2011 Planting Season[1,2,3]

PRODUCT REGISTRANT TRADE NAME	CHARACTERISTIC	EVENT	JAPAN APPROVED	EU FOOD APPROVAL	EU PROCESSED FEED APPROVAL
Syngenta Agrisure™ CB/LL	Cry1Ab, Corn Borer Glufosinate herbicide Tolerance	Bt11	Yes	Yes	Yes
Agrisure Viptera™ 3110	Vip3A, Cry1Ab, European and Southwestern Corn Borers, Southern Cornstalk Borer, Fall and Beet Armyworm, Black and Western Bean Cutworm, Sugarcane Borer, Common Stalk borer and Dingy Cutworm protection Glyphosate tolerance Glufosinate tolerance	MIR162+Bt11+GA21	Yes	No	XVII. No
Agrisure Viptera™ 3111	Vip3A, Cry1Ab, European and Southwestern Corn Borers, Southern cornstalk borer, Fall and Beet armyworm, Black and Western Bean Cutworm, Sugarcane borer, Western, Northern and Mexican corn rootworm, Common stalk borer and Dingy cutworm protection	MIR162+Bt11+GA21+MIR604	Yes	No	No

	Glyphosate tolerance Glufosinate tolerance				
DowAgrosciences Pioneer Hi-Bred Herculex® I	Cry1F, Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance Glufosinate herbicide tolerance.	TC1507	Yes	Yes	Yes
Monsanto YieldGard® Corn Borer	Cry1Ab, European and Southwestern Corn Borers, Sugarcane Borer and Southern Cornstalk Borer protection.	Mon810	Yes	Yes	Yes
Monsanto YieldGard® Corn Borer with Roundup Ready® Corn 2	Cry1Ab, European and Southwestern Southwestern Corn Borers, Sugarcane Borer and Southern Cornstalk Borer protection. Glyphosate herbicide tolerance.	Mon810+NK603	Yes	Yes	Yes
Monsanto YieldGard® Rootworm with Roundup Ready® Corn 2	Cry3Bb1, Western, Northern and Mexican Corn Rootworm Protection. Glyphosate herbicide tolerance.	Mon863+NK603	Yes	Yes	Yes
Monsanto YieldGard® Rootworm	Cry3Bb1, Western, Northern and Mexican, Corn Rootworm protection. Glyphosate herbicide tolerance.	Mon863	Yes	Yes	Yes
Monsanto Roundup Ready® Corn 2	Glyphosate herbicide tolerance.	NK603	Yes	Yes	Yes

Bayer CropScience LibertyLink®	Glufosinate herbicide tolerance.	XVIII. T25	Yes	Yes	Yes
Monsanto YieldGard® Plus	Cry1Ab, Cry3Bb1, European and Southwestern, Corn Borers, Sugarcane Borer, Southern Cornstalk Borer, , and Western, Northern and Mexican Corn Rootworm protection.	Mon810+Mon863	Yes	Yes	Yes
Monsanto YieldGard® Plus with Roundup Ready® Corn 2	Cry1Ab, Cry3Bb1, European and Southwestern Corn Borers, Sugarcane Borer, Southern Cornstalk Borer, and Western, Northern and Mexican Corn Rootworm protection. Glyphosate herbicide tolerance.	XIX. Mon810+Mon863+NK603	XX. Yes	XXI. Yes	XXII. Yes
DowAgrosciences Pioneer Hi-Bred Herculex® I Monsanto Roundup Ready® Corn 2	Cry1F, Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance. Glyphosate herbicide tolerance Glufosinate herbicide tolerance.	TC1507+NK603	Yes	Yes	Yes
Syngenta Agrisure® GT	Glyphosate herbicide tolerance.	SYTGA21	Yes	Yes	Yes
Syngenta Agrisure® GT/CB/LL	Cry1AB, European and Southwestern Corn borer protection Glyphosate herbicide tolerance Glufosinate herbicide tolerance.	Bt11+GA21	Yes	Yes	Yes

Dow AgroSciences Pioneer Hi-Bred Herculex® RW	Cry34/35Ab1, Western Corn Rootworm, Northern Corn Rootworm protection. Glufosinate herbicide tolerance.	DAS59122-7	Yes	Yes	Yes
Dow AgroSciences Pioneer Hi-Bred Herculex® Xtra	Cry1F, Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance Northern Corn Rootworm. Western Corn Rootworm protection. Glufosinate herbicide tolerance.	TC1507+DAS59122-7	Yes	Yes	Yes
Dow AgroSciences Pioneer Hi-Bred Herculex® RW Monsanto Roundup Ready® Corn 2	Cry34/35Ab1, Western Corn Rootworm, Northern Corn Rootworm protection. Glufosinate herbicide tolerance. Glyphosate herbicide tolerance. .	DAS59122-7+NK603	Yes	Yes	Yes
Dow AgroSciences Pioneer Hi-Bred Herculex® Xtra Monsanto Roundup® Corn 2	Cry1F, Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance. Glufosinate herbicide tolerance. Cry34/35Ab1, Western Corn Rootworm Northern Corn Rootworm Protection. Glyphosate herbicide tolerance.	TC1507+DAS59122-7+NK603	Yes	Yes	Yes
Monsanto YieldGard VT™ Rootworm/RR2®	Cry3Bb1, Western, Northern, and Mexican Corn Rootworm protection.	Mon88017	Yes	Yes	Yes

	Glyphosate Herbicide Tolerance.				
Monsanto YieldGard VT™ Triple	Cry1Ab, Cry3Bb1, European and Southwestern Corn Borer, Sugarcane Borer and Southern Cornstalk Borer and Western, Northern, and Mexican Corn Rootworm protection. Glyphosate herbicide tolerance.	Mon810+Mon88017	Yes	Yes	Yes
XXIII. Syngenta Agrisure® RW	XXIV. Modified Cry3A, Protection of Western, Northern and Mexican Corn Rootworm.	XXV. MIR604	Yes	Yes	Yes
Syngenta® GT/RW	Modified Cry3A, Protection of Western, Northern and Mexican Corn Rootworm Glyphosate herbicide tolerance	MIR604+SYTGA21	Yes	No	No
Syngenta Agrisure® CB/LL/RW	Cry1Ab, Corn Borer protection Modified Cry3A, Protection of Western, Northern and Mexican Corn Rootworm Glufosinate herbicide tolerance.	Bt11+MIR604	Yes	No	No
Syngenta Agrisure® 3000GT	XXVI. Cry1Ab, Corn Borer protection. Modified Cry3A, Protection of Western,	XXVII. SYTGA21+Bt11+MIR604	Yes	No	No

	Northern and Mexican Corn Rootworm. Glufosinate herbicide tolerance. Glyphosate tolerance.				
Monsanto Genuity™ VT Double PRO™	Cry1A.105, Cry2Ab2, European and Southwestern Corn Borers, Sugarcane Borer, Southern Cornstalk Borer, Corn Earworm, and Fall Armyworm protection. Glyphosate herbicide tolerance.	Mon89034+NK603	Yes	No	No
Monsanto Genuity™ VT Triple PRO™	Cry1A.105, Cry2Ab2, Cry3Bb1, European and Southwestern Corn Borers, Sugarcane Borer, Southern Cornstalk Borer, Corn Earworm, Fall Armyworm, Western Corn Rootworm, Northern Corn Rootworm, and Mexican Corn Rootworm protection. Glyphosate herbicide tolerance.	Mon88017+Mon89034	Yes	XXVIII. No	XXIX. No
Monsanto Genuity™SmartStax™ DowAgrosciences SmartStax™	Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Western, Northern, and Mexican Corn Rootworms, European and Southwestern Corn Borers, Sugarcane Borer, Southern Cornstalk Borer, Western Bean and Black Cutworms, Corn Earworm, Fall				

	Armyworm protection. Glyphosate herbicide tolerance. Glufosinate herbicide tolerance.				

[1]This list is representative of available products but may not include all corn biotechnology hybrids currently available.
[2] All of the hybrids listed have full food and feed approval in the United States.
[3] Not all varieties are approved for all export market uses.

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Appendix B. Corn-producing counties in the 28 states that have corn ethanol facilities

State/County	State/County	State/County	State/County
Arizona\Apache	Iowa\Marion	Missouri\Perry	South Dakota\Grant
Arizona\Cochise	Iowa\Marshall	Missouri\Pettis	South Dakota\Gregory
Arizona\Coconino	Iowa\Mills	Missouri\Phelps	South Dakota\Haakon
Arizona\Gila	Iowa\Mitchell	Missouri\Pike	South Dakota\Hamlin
Arizona\Graham	Iowa\Monona	Missouri\Platte	South Dakota\Hand
Arizona\Greenlee	Iowa\Monroe	Missouri\Polk	South Dakota\Hanson
Arizona\La Paz	Iowa\Montgomery	Missouri\Pulaski	South Dakota\Harding
Arizona\Maricopa	Iowa\Muscatine	Missouri\Putnam	South Dakota\Hughes
Arizona\Mohave	Iowa\O'Brien	Missouri\Ralls	South Dakota\Hutchinson
Arizona\Navajo	Iowa\Osceola	Missouri\Randolph	South Dakota\Hyde
Arizona\Pima	Iowa\Page	Missouri\Ray	South Dakota\Jackson
Arizona\Pinal	Iowa\Palo Alto	Missouri\Reynolds	South Dakota\Jerauld
Arizona\Santa Cruz	Iowa\Plymouth	Missouri\Ripley	South Dakota\Jones
Arizona\Yavapai	Iowa\Pocahontas	Missouri\St. Charles	South Dakota\Kingsbury
Arizona\Yuma	Iowa\Polk	Missouri\St. Clair	South Dakota\Lake
California\Alameda	Iowa\Pottawattamie	Missouri\Ste. Genevieve	South Dakota\Lawrence
California\Alpine	Iowa\Poweshiek	Missouri\St. Francois	South Dakota\Lincoln
California\Amador	Iowa\Ringgold	Missouri\St. Louis	South Dakota\Lyman
California\Butte	Iowa\Sac	Missouri\Saline	South Dakota\McCook
California\Calaveras	Iowa\Scott	Missouri\Schuyler	South Dakota\McPherson
California\Colusa	Iowa\Shelby	Missouri\Scotland	South Dakota\Marshall
California\Contra Costa	Iowa\Sioux	Missouri\Scott	South Dakota\Meade
California\Del Norte	Iowa\Story	Missouri\Shannon	South Dakota\Mellette
California\El Dorado	Iowa\Tama	Missouri\Shelby	South Dakota\Miner
California\Fresno	Iowa\Taylor	Missouri\Stoddard	South Dakota\Minnehaha
California\Glenn	Iowa\Union	Missouri\Stone	South Dakota\Moody
California\Humboldt	Iowa\Van Buren	Missouri\Sullivan	South Dakota\Pennington
California\Imperial	Iowa\Wapello	Missouri\Taney	South Dakota\Perkins
California\Inyo	Iowa\Warren	Missouri\Texas	South Dakota\Potter
California\Kern	Iowa\Washington	Missouri\Vernon	South Dakota\Roberts
California\Kings	Iowa\Wayne	Missouri\Warren	South Dakota\Sanborn
California\Lake	Iowa\Webster	Missouri\Washington	South Dakota\Shannon
California\Lassen	Iowa\Winnebago	Missouri\Wayne	South Dakota\Spink
California\Los Angeles	Iowa\Winneshiek	Missouri\Webster	South Dakota\Stanley
California\Madera	Iowa\Woodbury	Missouri\Worth	South Dakota\Sully
California\Mariposa	Iowa\Worth	Missouri\Wright	South Dakota\Todd
California\Merced	Iowa\Wright	Nebraska\Adams	South Dakota\Tripp
California\Modoc	Kansas\Allen	Nebraska\Antelope	South Dakota\Turner
California\Mono	Kansas\Anderson	Nebraska\Arthur	South Dakota\Union
California\Monterey	Kansas\Atchison	Nebraska\Banner	South Dakota\Walworth
California\Napa	Kansas\Barber	Nebraska\Blaine	South Dakota\Yankton
California\Nevada	Kansas\Barton	Nebraska\Boone	South Dakota\Ziebach
California\Orange	Kansas\Bourbon	Nebraska\Box Butte	Tennessee\Anderson

State/County	State/County	State/County	State/County
California\Placer	Kansas\Brown	Nebraska\Boyd	Tennessee\Bedford
California\Plumas	Kansas\Butler	Nebraska\Brown	Tennessee\Benton
California\Riverside	Kansas\Chase	Nebraska\Buffalo	Tennessee\Bledsoe
California\Sacramento	Kansas\Chautauqua	Nebraska\Burt	Tennessee\Blount
California\San Benito	Kansas\Cherokee	Nebraska\Butler	Tennessee\Bradley
California\San Bernardino	Kansas\Cheyenne	Nebraska\Cass	Tennessee\Campbell
California\San Diego	Kansas\Clark	Nebraska\Cedar	Tennessee\Cannon
California\San Francisco	Kansas\Clay	Nebraska\Chase	Tennessee\Carroll
California\San Joaquin	Kansas\Cloud	Nebraska\Cherry	Tennessee\Carter
California\San Luis Obispo	Kansas\Coffey	Nebraska\Cheyenne	Tennessee\Cheatham
California\San Mateo	Kansas\Comanche	Nebraska\Clay	Tennessee\Chester
California\Santa Barbara	Kansas\Cowley	Nebraska\Colfax	Tennessee\Claiborne
California\Santa Clara	Kansas\Crawford	Nebraska\Cuming	Tennessee\Clay
California\Shasta	Kansas\Decatur	Nebraska\Custer	Tennessee\Cocke
California\Sierra	Kansas\Dickinson	Nebraska\Dakota	Tennessee\Coffee
California\Siskiyou	Kansas\Doniphan	Nebraska\Dawes	Tennessee\Crockett
California\Solano	Kansas\Douglas	Nebraska\Dawson	Tennessee\Cumberland
California\Sonoma	Kansas\Edwards	Nebraska\Deuel	Tennessee\Davidson
California\Stanislaus	Kansas\Elk	Nebraska\Dixon	Tennessee\Decatur
California\Sutter	Kansas\Ellis	Nebraska\Dodge	Tennessee\DeKalb
California\Tehama	Kansas\Ellsworth	Nebraska\Douglas	Tennessee\Dickson
California\Tulare	Kansas\Finney	Nebraska\Dundy	Tennessee\Dyer
California\Tuolumne	Kansas\Ford	Nebraska\Fillmore	Tennessee\Fayette
California\Ventura	Kansas\Franklin	Nebraska\Franklin	Tennessee\Fentress
California\Yolo	Kansas\Geary	Nebraska\Frontier	Tennessee\Franklin
California\Yuba	Kansas\Gove	Nebraska\Furnas	Tennessee\Gibson
Colorado\Adams	Kansas\Graham	Nebraska\Gage	Tennessee\Giles
Colorado\Alamosa	Kansas\Grant	Nebraska\Garden	Tennessee\Grainger
Colorado\Arapahoe	Kansas\Gray	Nebraska\Garfield	Tennessee\Greene
Colorado\Archuleta	Kansas\Greeley	Nebraska\Gosper	Tennessee\Grundy
Colorado\Baca	Kansas\Greenwood	Nebraska\Grant	Tennessee\Hamblen
Colorado\Bent	Kansas\Hamilton	Nebraska\Greeley	Tennessee\Hamilton
Colorado\Boulder	Kansas\Harper	Nebraska\Hall	Tennessee\Hancock
Colorado\Broomfield	Kansas\Harvey	Nebraska\Hamilton	Tennessee\Hardeman
Colorado\Chaffee	Kansas\Haskell	Nebraska\Harlan	Tennessee\Hardin
Colorado\Cheyenne	Kansas\Hodgeman	Nebraska\Hayes	Tennessee\Hawkins
Colorado\Clear Creek	Kansas\Jackson	Nebraska\Hitchcock	Tennessee\Haywood
Colorado\Conejos	Kansas\Jefferson	Nebraska\Holt	Tennessee\Henderson
Colorado\Costilla	Kansas\Jewell	Nebraska\Hooker	Tennessee\Henry
Colorado\Crowley	Kansas\Johnson	Nebraska\Howard	Tennessee\Hickman
Colorado\Custer	Kansas\Kearny	Nebraska\Jefferson	Tennessee\Houston
Colorado\Delta	Kansas\Kingman	Nebraska\Johnson	Tennessee\Humphreys
Colorado\Denver	Kansas\Kiowa	Nebraska\Kearney	Tennessee\Jackson

State/County	State/County	State/County	State/County
Colorado\Dolores	Kansas\Labette	Nebraska\Keith	Tennessee\Jefferson
Colorado\Douglas	Kansas\Lane	Nebraska\Keya Paha	Tennessee\Johnson
Colorado\Eagle	Kansas\Leavenworth	Nebraska\Kimball	Tennessee\Knox
Colorado\Elbert	Kansas\Lincoln	Nebraska\Knox	Tennessee\Lake
Colorado\El Paso	Kansas\Linn	Nebraska\Lancaster	Tennessee\Lauderdale
Colorado\Fremont	Kansas\Logan	Nebraska\Lincoln	Tennessee\Lawrence
Colorado\Garfield	Kansas\Lyon	Nebraska\Logan	Tennessee\Lewis
Colorado\Gilpin	Kansas\McPherson	Nebraska\Loup	Tennessee\Lincoln
Colorado\Grand	Kansas\Marion	Nebraska\McPherson	Tennessee\Loudon
Colorado\Gunnison	Kansas\Marshall	Nebraska\Madison	Tennessee\McMinn
Colorado\Hinsdale	Kansas\Meade	Nebraska\Merrick	Tennessee\McNairy
Colorado\Huerfano	Kansas\Miami	Nebraska\Morrill	Tennessee\Macon
Colorado\Jackson	Kansas\Mitchell	Nebraska\Nance	Tennessee\Madison
Colorado\Jefferson	Kansas\Montgomery	Nebraska\Nemaha	Tennessee\Marion
Colorado\Kiowa	Kansas\Morris	Nebraska\Nuckolls	Tennessee\Marshall
Colorado\Kit Carson	Kansas\Morton	Nebraska\Otoe	Tennessee\Maury
Colorado\Lake	Kansas\Nemaha	Nebraska\Pawnee	Tennessee\Meigs
Colorado\La Plata	Kansas\Neosho	Nebraska\Perkins	Tennessee\Monroe
Colorado\Larimer	Kansas\Ness	Nebraska\Phelps	Tennessee\Montgomery
Colorado\Las Animas	Kansas\Norton	Nebraska\Pierce	Tennessee\Moore
Colorado\Lincoln	Kansas\Osage	Nebraska\Platte	Tennessee\Morgan
Colorado\Logan	Kansas\Osborne	Nebraska\Polk	Tennessee\Obion
Colorado\Mesa	Kansas\Ottawa	Nebraska\Red Willow	Tennessee\Overton
Colorado\Mineral	Kansas\Pawnee	Nebraska\Richardson	Tennessee\Perry
Colorado\Moffat	Kansas\Phillips	Nebraska\Rock	Tennessee\Pickett
Colorado\Montezuma	Kansas\Pottawatomie	Nebraska\Saline	Tennessee\Polk
Colorado\Montrose	Kansas\Pratt	Nebraska\Sarpy	Tennessee\Putnam
Colorado\Morgan	Kansas\Rawlins	Nebraska\Saunders	Tennessee\Rhea
Colorado\Otero	Kansas\Reno	Nebraska\Scotts Bluff	Tennessee\Roane
Colorado\Ouray	Kansas\Republic	Nebraska\Seward	Tennessee\Robertson
Colorado\Park	Kansas\Rice	Nebraska\Sheridan	Tennessee\Rutherford
Colorado\Phillips	Kansas\Riley	Nebraska\Sherman	Tennessee\Scott
Colorado\Pitkin	Kansas\Rooks	Nebraska\Sioux	Tennessee\Sequatchie
Colorado\Prowers	Kansas\Rush	Nebraska\Stanton	Tennessee\Sevier
Colorado\Pueblo	Kansas\Russell	Nebraska\Thayer	Tennessee\Shelby
Colorado\Rio Blanco	Kansas\Saline	Nebraska\Thomas	Tennessee\Smith
Colorado\Rio Grande	Kansas\Scott	Nebraska\Thurston	Tennessee\Stewart
Colorado\Routt	Kansas\Sedgwick	Nebraska\Valley	Tennessee\Sullivan
Colorado\Saguache	Kansas\Seward	Nebraska\Washington	Tennessee\Sumner
Colorado\San Juan	Kansas\Shawnee	Nebraska\Wayne	Tennessee\Tipton
Colorado\San Miguel	Kansas\Sheridan	Nebraska\Webster	Tennessee\Trousdale
Colorado\Sedgwick	Kansas\Sherman	Nebraska\Wheeler	Tennessee\Unicoi
Colorado\Summit	Kansas\Smith	Nebraska\York	Tennessee\Union
Colorado\Teller	Kansas\Stafford	New Mexico\Bernalillo	Tennessee\Van Buren
Colorado\Washington	Kansas\Stanton	New Mexico\Catron	Tennessee\Warren
Colorado\Weld	Kansas\Stevens	New Mexico\Chaves	Tennessee\Washington

State/County	State/County	State/County	State/County
Colorado\Yuma	Kansas\Sumner	New Mexico\Cibola	Tennessee\Wayne
Georgia\Appling	Kansas\Thomas	New Mexico\Colfax	Tennessee\Weakley
Georgia\Atkinson	Kansas\Trego	New Mexico\Curry	Tennessee\White
Georgia\Bacon	Kansas\Wabaunsee	New Mexico\De Baca	Tennessee\Williamson
Georgia\Baker	Kansas\Wallace	New Mexico\Dona Ana	Tennessee\Wilson
Georgia\Baldwin	Kansas\Washington	New Mexico\Eddy	Texas\Anderson
Georgia\Banks	Kansas\Wichita	New Mexico\Grant	Texas\Andrews
Georgia\Barrow	Kansas\Wilson	New Mexico\Guadalupe	Texas\Angelina
Georgia\Bartow	Kansas\Woodson	New Mexico\Harding	Texas\Aransas
Georgia\Ben Hill	Kansas\Wyandotte	New Mexico\Hidalgo	Texas\Archer
Georgia\Berrien	Kentucky\Adair	New Mexico\Lea	Texas\Armstrong
Georgia\Bibb	Kentucky\Allen	New Mexico\Lincoln	Texas\Atascosa
Georgia\Bleckley	Kentucky\Anderson	New Mexico\Los Alamos	Texas\Austin
Georgia\Brantley	Kentucky\Ballard	New Mexico\Luna	Texas\Bailey
Georgia\Brooks	Kentucky\Barren	New Mexico\McKinley	Texas\Bandera
Georgia\Bryan	Kentucky\Bath	New Mexico\Mora	Texas\Bastrop
Georgia\Bulloch	Kentucky\Bell	New Mexico\Otero	Texas\Baylor
Georgia\Burke	Kentucky\Boone	New Mexico\Quay	Texas\Bee
Georgia\Butts	Kentucky\Bourbon	New Mexico\Rio Arriba	Texas\Bell
Georgia\Calhoun	Kentucky\Boyd	New Mexico\Roosevelt	Texas\Bexar
Georgia\Camden	Kentucky\Boyle	New Mexico\Sandoval	Texas\Blanco
Georgia\Candler	Kentucky\Bracken	New Mexico\San Juan	Texas\Borden
Georgia\Carroll	Kentucky\Breathitt	New Mexico\San Miguel	Texas\Bosque
Georgia\Catoosa	Kentucky\Breckinridge	New Mexico\Santa Fe	Texas\Bowie
Georgia\Charlton	Kentucky\Bullitt	New Mexico\Sierra	Texas\Brazoria
Georgia\Chatham	Kentucky\Butler	New Mexico\Socorro	Texas\Brazos
Georgia\Chattahoochee	Kentucky\Caldwell	New Mexico\Taos	Texas\Brewster
Georgia\Chattooga	Kentucky\Calloway	New Mexico\Torrance	Texas\Briscoe
Georgia\Cherokee	Kentucky\Campbell	New Mexico\Union	Texas\Brooks
Georgia\Clarke	Kentucky\Carlisle	New Mexico\Valencia	Texas\Brown
Georgia\Clay	Kentucky\Carroll	New York\Albany	Texas\Burleson
Georgia\Clayton	Kentucky\Carter	New York\Allegany	Texas\Burnet
Georgia\Clinch	Kentucky\Casey	New York\Bronx	Texas\Caldwell
Georgia\Cobb	Kentucky\Christian	New York\Broome	Texas\Calhoun
Georgia\Coffee	Kentucky\Clark	New York\Cattaraugus	Texas\Callahan
Georgia\Colquitt	Kentucky\Clay	New York\Cayuga	Texas\Cameron
Georgia\Columbia	Kentucky\Clinton	New York\Chautauqua	Texas\Camp
Georgia\Cook	Kentucky\Crittenden	New York\Chemung	Texas\Carson
Georgia\Coweta	Kentucky\Cumberland	New York\Chenango	Texas\Cass
Georgia\Crawford	Kentucky\Daviess	New York\Clinton	Texas\Castro
Georgia\Crisp	Kentucky\Edmonson	New York\Columbia	Texas\Chambers
Georgia\Dade	Kentucky\Elliott	New York\Cortland	Texas\Cherokee
Georgia\Dawson	Kentucky\Estill	New York\Delaware	Texas\Childress
Georgia\Decatur	Kentucky\Fayette	New York\Dutchess	Texas\Clay
Georgia\DeKalb	Kentucky\Fleming	New York\Erie	Texas\Cochran
Georgia\Dodge	Kentucky\Floyd	New York\Essex	Texas\Coke

State/County	State/County	State/County	State/County
Georgia\Dooly	Kentucky\Franklin	New York\Franklin	Texas\Coleman
Georgia\Dougherty	Kentucky\Fulton	New York\Fulton	Texas\Collin
Georgia\Douglas	Kentucky\Gallatin	New York\Genesee	Texas\Collingsworth
Georgia\Early	Kentucky\Garrard	New York\Greene	Texas\Colorado
Georgia\Echols	Kentucky\Grant	New York\Hamilton	Texas\Comal
Georgia\Effingham	Kentucky\Graves	New York\Herkimer	Texas\Comanche
Georgia\Elbert	Kentucky\Grayson	New York\Jefferson	Texas\Concho
Georgia\Emanuel	Kentucky\Green	New York\Kings	Texas\Cooke
Georgia\Evans	Kentucky\Greenup	New York\Lewis	Texas\Coryell
Georgia\Fannin	Kentucky\Hancock	New York\Livingston	Texas\Cottle
Georgia\Fayette	Kentucky\Hardin	New York\Madison	Texas\Crane
Georgia\Floyd	Kentucky\Harlan	New York\Monroe	Texas\Crockett
Georgia\Forsyth	Kentucky\Harrison	New York\Montgomery	Texas\Crosby
Georgia\Franklin	Kentucky\Hart	New York\Nassau	Texas\Culberson
Georgia\Fulton	Kentucky\Henderson	New York\New York	Texas\Dallam
Georgia\Gilmer	Kentucky\Henry	New York\Niagara	Texas\Dallas
Georgia\Glascock	Kentucky\Hickman	New York\Oneida	Texas\Dawson
Georgia\Glynn	Kentucky\Hopkins	New York\Onondaga	Texas\Deaf Smith
Georgia\Gordon	Kentucky\Jackson	New York\Ontario	Texas\Delta
Georgia\Grady	Kentucky\Jefferson	New York\Orange	Texas\Denton
Georgia\Greene	Kentucky\Jessamine	New York\Orleans	Texas\DeWitt
Georgia\Gwinnett	Kentucky\Johnson	New York\Oswego	Texas\Dickens
Georgia\Habersham	Kentucky\Kenton	New York\Otsego	Texas\Dimmit
Georgia\Hall	Kentucky\Knott	New York\Putnam	Texas\Donley
Georgia\Hancock	Kentucky\Knox	New York\Queens	Texas\Duval
Georgia\Haralson	Kentucky\Larue	New York\Rensselaer	Texas\Eastland
Georgia\Harris	Kentucky\Laurel	New York\Richmond	Texas\Ector
Georgia\Hart	Kentucky\Lawrence	New York\Rockland	Texas\Edwards
Georgia\Heard	Kentucky\Lee	New York\St. Lawrence	Texas\Ellis
Georgia\Henry	Kentucky\Leslie	New York\Saratoga	Texas\El Paso
Georgia\Houston	Kentucky\Letcher	New York\Schenectady	Texas\Erath
Georgia\Irwin	Kentucky\Lewis	New York\Schoharie	Texas\Falls
Georgia\Jackson	Kentucky\Lincoln	New York\Schuyler	Texas\Fannin
Georgia\Jasper	Kentucky\Livingston	New York\Seneca	Texas\Fayette
Georgia\Jeff Davis	Kentucky\Logan	New York\Steuben	Texas\Fisher
Georgia\Jefferson	Kentucky\Lyon	New York\Suffolk	Texas\Floyd
Georgia\Jenkins	Kentucky\McCracken	New York\Sullivan	Texas\Foard
Georgia\Johnson	Kentucky\McCreary	New York\Tioga	Texas\Fort Bend
Georgia\Jones	Kentucky\McLean	New York\Tompkins	Texas\Franklin
Georgia\Lamar	Kentucky\Madison	New York\Ulster	Texas\Freestone
Georgia\Lanier	Kentucky\Magoffin	New York\Warren	Texas\Frio
Georgia\Laurens	Kentucky\Marion	New York\Washington	Texas\Gaines
Georgia\Lee	Kentucky\Marshall	New York\Wayne	Texas\Galveston
Georgia\Liberty	Kentucky\Martin	New York\Westchester	Texas\Garza
Georgia\Lincoln	Kentucky\Mason	New York\Wyoming	Texas\Gillespie
Georgia\Long	Kentucky\Meade	New York\Yates	Texas\Glasscock

State/County	State/County	State/County	State/County
Georgia\Lowndes	Kentucky\Menifee	North Carolina\Alamance	Texas\Goliad
Georgia\Lumpkin	Kentucky\Mercer	North Carolina\Alexander	Texas\Gonzales
Georgia\McDuffie	Kentucky\Metcalfe	North Carolina\Alleghany	Texas\Gray
Georgia\McIntosh	Kentucky\Monroe	North Carolina\Anson	Texas\Grayson
Georgia\Macon	Kentucky\Montgomery	North Carolina\Ashe	Texas\Gregg
Georgia\Madison	Kentucky\Morgan	North Carolina\Avery	Texas\Grimes
Georgia\Marion	Kentucky\Muhlenberg	North Carolina\Beaufort	Texas\Guadalupe
Georgia\Meriwether	Kentucky\Nelson	North Carolina\Bertie	Texas\Hale
Georgia\Miller	Kentucky\Nicholas	North Carolina\Bladen	Texas\Hall
Georgia\Mitchell	Kentucky\Ohio	North Carolina\Brunswick	Texas\Hamilton
Georgia\Monroe	Kentucky\Oldham	North Carolina\Buncombe	Texas\Hansford
Georgia\Montgomery	Kentucky\Owen	North Carolina\Burke	Texas\Hardeman
Georgia\Morgan	Kentucky\Owsley	North Carolina\Cabarrus	Texas\Hardin
Georgia\Murray	Kentucky\Pendleton	North Carolina\Caldwell	Texas\Harris
Georgia\Muscogee	Kentucky\Perry	North Carolina\Camden	Texas\Harrison
Georgia\Newton	Kentucky\Pike	North Carolina\Carteret	Texas\Hartley
Georgia\Oconee	Kentucky\Powell	North Carolina\Caswell	Texas\Haskell
Georgia\Oglethorpe	Kentucky\Pulaski	North Carolina\Catawba	Texas\Hays
Georgia\Paulding	Kentucky\Robertson	North Carolina\Chatham	Texas\Hemphill
Georgia\Peach	Kentucky\Rockcastle	North Carolina\Cherokee	Texas\Henderson
Georgia\Pickens	Kentucky\Rowan	North Carolina\Chowan	Texas\Hidalgo
Georgia\Pierce	Kentucky\Russell	North Carolina\Clay	Texas\Hill
Georgia\Pike	Kentucky\Scott	North Carolina\Cleveland	Texas\Hockley
Georgia\Polk	Kentucky\Shelby	North Carolina\Columbus	Texas\Hood
Georgia\Pulaski	Kentucky\Simpson	North Carolina\Craven	Texas\Hopkins
Georgia\Putnam	Kentucky\Spencer	North Carolina\Cumberland	Texas\Houston
Georgia\Quitman	Kentucky\Taylor	North Carolina\Currituck	Texas\Howard
Georgia\Rabun	Kentucky\Todd	North Carolina\Dare	Texas\Hudspeth
Georgia\Randolph	Kentucky\Trigg	North Carolina\Davidson	Texas\Hunt
Georgia\Richmond	Kentucky\Trimble	North Carolina\Davie	Texas\Hutchinson
Georgia\Rockdale	Kentucky\Union	North Carolina\Duplin	Texas\Irion
Georgia\Schley	Kentucky\Warren	North Carolina\Durham	Texas\Jack
Georgia\Screven	Kentucky\Washington	North Carolina\Edgecombe	Texas\Jackson
Georgia\Seminole	Kentucky\Wayne	North Carolina\Forsyth	Texas\Jasper
Georgia\Spalding	Kentucky\Webster	North Carolina\Franklin	Texas\Jeff Davis
Georgia\Stephens	Kentucky\Whitley	North Carolina\Gaston	Texas\Jefferson
Georgia\Stewart	Kentucky\Wolfe	North Carolina\Gates	Texas\Jim Hogg
Georgia\Sumter	Kentucky\Woodford	North Carolina\Graham	Texas\Jim Wells
Georgia\Talbot	Michigan\Alcona	North Carolina\Granville	Texas\Johnson
Georgia\Taliaferro	Michigan\Alger	North Carolina\Greene	Texas\Jones
Georgia\Tattnall	Michigan\Allegan	North Carolina\Guilford	Texas\Karnes
Georgia\Taylor	Michigan\Alpena	North Carolina\Halifax	Texas\Kaufman
Georgia\Telfair	Michigan\Antrim	North Carolina\Harnett	Texas\Kendall
Georgia\Terrell	Michigan\Arenac	North Carolina\Haywood	Texas\Kenedy
Georgia\Thomas	Michigan\Baraga	North Carolina\Henderson	Texas\Kent
Georgia\Tift	Michigan\Barry	North Carolina\Hertford	Texas\Kerr

State/County	State/County	State/County	State/County
Georgia\Toombs	Michigan\Bay	North Carolina\Hoke	Texas\Kimble
Georgia\Towns	Michigan\Benzie	North Carolina\Hyde	Texas\King
Georgia\Treutlen	Michigan\Berrien	North Carolina\Iredell	Texas\Kinney
Georgia\Troup	Michigan\Branch	North Carolina\Jackson	Texas\Kleberg
Georgia\Turner	Michigan\Calhoun	North Carolina\Johnston	Texas\Knox
Georgia\Twiggs	Michigan\Cass	North Carolina\Jones	Texas\Lamar
Georgia\Union	Michigan\Charlevoix	North Carolina\Lee	Texas\Lamb
Georgia\Upson	Michigan\Cheboygan	North Carolina\Lenoir	Texas\Lampasas
Georgia\Walker	Michigan\Chippewa	North Carolina\Lincoln	Texas\La Salle
Georgia\Walton	Michigan\Clare	North Carolina\McDowell	Texas\Lavaca
Georgia\Ware	Michigan\Clinton	North Carolina\Macon	Texas\Lee
Georgia\Warren	Michigan\Crawford	North Carolina\Madison	Texas\Leon
Georgia\Washington	Michigan\Delta	North Carolina\Martin	Texas\Liberty
Georgia\Wayne	Michigan\Dickinson	North Carolina\Mecklenburg	Texas\Limestone
Georgia\Webster	Michigan\Eaton	North Carolina\Mitchell	Texas\Lipscomb
Georgia\Wheeler	Michigan\Emmet	North Carolina\Montgomery	Texas\Live Oak
Georgia\White	Michigan\Genesee	North Carolina\Moore	Texas\Llano
Georgia\Whitfield	Michigan\Gladwin	North Carolina\Nash	Texas\Loving
Georgia\Wilcox	Michigan\Gogebic	North Carolina\New Hanover	Texas\Lubbock
Georgia\Wilkes	Michigan\Grand Traverse	North Carolina\Northampton	Texas\Lynn
Georgia\Wilkinson	Michigan\Gratiot	North Carolina\Onslow	Texas\McCulloch
Georgia\Worth	Michigan\Hillsdale	North Carolina\Orange	Texas\McLennan
Idaho\Ada	Michigan\Houghton	North Carolina\Pamlico	Texas\McMullen
Idaho\Adams	Michigan\Huron	North Carolina\Pasquotank	Texas\Madison
Idaho\Bannock	Michigan\Ingham	North Carolina\Pender	Texas\Marion
Idaho\Bear Lake	Michigan\Ionia	North Carolina\Perquimans	Texas\Martin
Idaho\Benewah	Michigan\Iosco	North Carolina\Person	Texas\Mason
Idaho\Bingham	Michigan\Iron	North Carolina\Pitt	Texas\Matagorda
Idaho\Blaine	Michigan\Isabella	North Carolina\Polk	Texas\Maverick
Idaho\Boise	Michigan\Jackson	North Carolina\Randolph	Texas\Medina
Idaho\Bonner	Michigan\Kalamazoo	North Carolina\Richmond	Texas\Menard
Idaho\Bonneville	Michigan\Kalkaska	North Carolina\Robeson	Texas\Midland
Idaho\Boundary	Michigan\Kent	North Carolina\Rockingham	Texas\Milam
Idaho\Butte	Michigan\Keweenaw	North Carolina\Rowan	Texas\Mills
Idaho\Camas	Michigan\Lake	North Carolina\Rutherford	Texas\Mitchell
Idaho\Canyon	Michigan\Lapeer	North Carolina\Sampson	Texas\Montague
Idaho\Caribou	Michigan\Leelanau	North Carolina\Scotland	Texas\Montgomery
Idaho\Cassia	Michigan\Lenawee	North Carolina\Stanly	Texas\Moore
Idaho\Clark	Michigan\Livingston	North Carolina\Stokes	Texas\Morris
Idaho\Clearwater	Michigan\Luce	North Carolina\Surry	Texas\Motley
Idaho\Custer	Michigan\Mackinac	North Carolina\Swain	Texas\Nacogdoches
Idaho\Elmore	Michigan\Macomb	North Carolina\Transylvania	Texas\Navarro
Idaho\Franklin	Michigan\Manistee	North Carolina\Tyrrell	Texas\Newton
Idaho\Fremont	Michigan\Marquette	North Carolina\Union	Texas\Nolan
Idaho\Gem	Michigan\Mason	North Carolina\Vance	Texas\Nueces
Idaho\Gooding	Michigan\Mecosta	North Carolina\Wake	Texas\Ochiltree

State/County	State/County	State/County	State/County
Idaho\Idaho	Michigan\Menominee	North Carolina\Warren	Texas\Oldham
Idaho\Jefferson	Michigan\Midland	North Carolina\Washington	Texas\Orange
Idaho\Jerome	Michigan\Missaukee	North Carolina\Watauga	Texas\Palo Pinto
Idaho\Kootenai	Michigan\Monroe	North Carolina\Wayne	Texas\Panola
Idaho\Latah	Michigan\Montcalm	North Carolina\Wilkes	Texas\Parker
Idaho\Lemhi	Michigan\Montmorency	North Carolina\Wilson	Texas\Parmer
Idaho\Lewis	Michigan\Muskegon	North Carolina\Yadkin	Texas\Pecos
Idaho\Lincoln	Michigan\Newaygo	North Carolina\Yancey	Texas\Polk
Idaho\Madison	Michigan\Oakland	North Dakota\Adams	Texas\Potter
Idaho\Minidoka	Michigan\Oceana	North Dakota\Barnes	Texas\Presidio
Idaho\Nez Perce	Michigan\Ogemaw	North Dakota\Benson	Texas\Rains
Idaho\Oneida	Michigan\Ontonagon	North Dakota\Billings	Texas\Randall
Idaho\Owyhee	Michigan\Osceola	North Dakota\Bottineau	Texas\Reagan
Idaho\Payette	Michigan\Oscoda	North Dakota\Bowman	Texas\Real
Idaho\Power	Michigan\Otsego	North Dakota\Burke	Texas\Red River
Idaho\Shoshone	Michigan\Ottawa	North Dakota\Burleigh	Texas\Reeves
Idaho\Teton	Michigan\Presque Isle	North Dakota\Cass	Texas\Refugio
Idaho\Twin Falls	Michigan\Roscommon	North Dakota\Cavalier	Texas\Roberts
Idaho\Valley	Michigan\Saginaw	North Dakota\Dickey	Texas\Robertson
Idaho\Washington	Michigan\St. Clair	North Dakota\Divide	Texas\Rockwall
Illinois\Adams	Michigan\St. Joseph	North Dakota\Dunn	Texas\Runnels
Illinois\Alexander	Michigan\Sanilac	North Dakota\Eddy	Texas\Rusk
Illinois\Bond	Michigan\Schoolcraft	North Dakota\Emmons	Texas\Sabine
Illinois\Boone	Michigan\Shiawassee	North Dakota\Foster	Texas\San Augustine
Illinois\Brown	Michigan\Tuscola	North Dakota\Golden Valley	Texas\San Jacinto
Illinois\Bureau	Michigan\Van Buren	North Dakota\Grand Forks	Texas\San Patricio
Illinois\Calhoun	Michigan\Washtenaw	North Dakota\Grant	Texas\San Saba
Illinois\Carroll	Michigan\Wayne	North Dakota\Griggs	Texas\Schleicher
Illinois\Cass	Michigan\Wexford	North Dakota\Hettinger	Texas\Scurry
Illinois\Champaign	Minnesota\Aitkin	North Dakota\Kidder	Texas\Shackelford
Illinois\Christian	Minnesota\Anoka	North Dakota\LaMoure	Texas\Shelby
Illinois\Clark	Minnesota\Becker	North Dakota\Logan	Texas\Sherman
Illinois\Clay	Minnesota\Beltrami	North Dakota\McHenry	Texas\Smith
Illinois\Clinton	Minnesota\Benton	North Dakota\McIntosh	Texas\Somervell
Illinois\Coles	Minnesota\Big Stone	North Dakota\McKenzie	Texas\Starr
Illinois\Cook	Minnesota\Blue Earth	North Dakota\McLean	Texas\Stephens
Illinois\Crawford	Minnesota\Brown	North Dakota\Mercer	Texas\Sterling
Illinois\Cumberland	Minnesota\Carlton	North Dakota\Morton	Texas\Stonewall
Illinois\De Kalb	Minnesota\Carver	North Dakota\Mountrail	Texas\Sutton
Illinois\De Witt	Minnesota\Cass	North Dakota\Nelson	Texas\Swisher
Illinois\Douglas	Minnesota\Chippewa	North Dakota\Oliver	Texas\Tarrant
Illinois\Du Page	Minnesota\Chisago	North Dakota\Pembina	Texas\Taylor
Illinois\Edgar	Minnesota\Clay	North Dakota\Pierce	Texas\Terrell
Illinois\Edwards	Minnesota\Clearwater	North Dakota\Ramsey	Texas\Terry
Illinois\Effingham	Minnesota\Cook	North Dakota\Ransom	Texas\Throckmorton
Illinois\Fayette	Minnesota\Cottonwood	North Dakota\Renville	Texas\Titus

State/County	State/County	State/County	State/County
Illinois\Ford	Minnesota\Crow Wing	North Dakota\Richland	Texas\Tom Green
Illinois\Franklin	Minnesota\Dakota	North Dakota\Rolette	Texas\Travis
Illinois\Fulton	Minnesota\Dodge	North Dakota\Sargent	Texas\Trinity
Illinois\Gallatin	Minnesota\Douglas	North Dakota\Sheridan	Texas\Tyler
Illinois\Greene	Minnesota\Faribault	North Dakota\Sioux	Texas\Upshur
Illinois\Grundy	Minnesota\Fillmore	North Dakota\Slope	Texas\Upton
Illinois\Hamilton	Minnesota\Freeborn	North Dakota\Stark	Texas\Uvalde
Illinois\Hancock	Minnesota\Goodhue	North Dakota\Steele	Texas\Val Verde
Illinois\Hardin	Minnesota\Grant	North Dakota\Stutsman	Texas\Van Zandt
Illinois\Henderson	Minnesota\Hennepin	North Dakota\Towner	Texas\Victoria
Illinois\Henry	Minnesota\Houston	North Dakota\Traill	Texas\Walker
Illinois\Iroquois	Minnesota\Hubbard	North Dakota\Walsh	Texas\Waller
Illinois\Jackson	Minnesota\Isanti	North Dakota\Ward	Texas\Ward
Illinois\Jasper	Minnesota\Itasca	North Dakota\Wells	Texas\Washington
Illinois\Jefferson	Minnesota\Jackson	North Dakota\Williams	Texas\Webb
Illinois\Jersey	Minnesota\Kanabec	Ohio\Adams	Texas\Wharton
Illinois\Jo Daviess	Minnesota\Kandiyohi	Ohio\Allen	Texas\Wheeler
Illinois\Johnson	Minnesota\Kittson	Ohio\Ashland	Texas\Wichita
Illinois\Kane	Minnesota\Koochiching	Ohio\Ashtabula	Texas\Wilbarger
Illinois\Kankakee	Minnesota\Lac qui Parle	Ohio\Athens	Texas\Willacy
Illinois\Kendall	Minnesota\Lake	Ohio\Auglaize	Texas\Williamson
Illinois\Knox	Minnesota\Lake of the Woods	Ohio\Belmont	Texas\Wilson
Illinois\Lake	Minnesota\Le Sueur	Ohio\Brown	Texas\Winkler
Illinois\La Salle	Minnesota\Lincoln	Ohio\Butler	Texas\Wise
Illinois\Lawrence	Minnesota\Lyon	Ohio\Carroll	Texas\Wood
Illinois\Lee	Minnesota\McLeod	Ohio\Champaign	Texas\Yoakum
Illinois\Livingston	Minnesota\Mahnomen	Ohio\Clark	Texas\Young
Illinois\Logan	Minnesota\Marshall	Ohio\Clermont	Texas\Zapata
Illinois\McDonough	Minnesota\Martin	Ohio\Clinton	Texas\Zavala
Illinois\McHenry	Minnesota\Meeker	Ohio\Columbiana	Virginia\Accomack
Illinois\McLean	Minnesota\Mille Lacs	Ohio\Coshocton	Virginia\Albemarle
Illinois\Macon	Minnesota\Morrison	Ohio\Crawford	Virginia\Alleghany
Illinois\Macoupin	Minnesota\Mower	Ohio\Cuyahoga	Virginia\Amelia
Illinois\Madison	Minnesota\Murray	Ohio\Darke	Virginia\Amherst
Illinois\Marion	Minnesota\Nicollet	Ohio\Defiance	Virginia\Appomattox
Illinois\Marshall	Minnesota\Nobles	Ohio\Delaware	Virginia\Arlington
Illinois\Mason	Minnesota\Norman	Ohio\Erie	Virginia\Augusta
Illinois\Massac	Minnesota\Olmsted	Ohio\Fairfield	Virginia\Bath
Illinois\Menard	Minnesota\Otter Tail	Ohio\Fayette	Virginia\Bedford
Illinois\Mercer	Minnesota\Pennington	Ohio\Franklin	Virginia\Bland
Illinois\Monroe	Minnesota\Pine	Ohio\Fulton	Virginia\Botetourt
Illinois\Montgomery	Minnesota\Pipestone	Ohio\Gallia	Virginia\Brunswick
Illinois\Morgan	Minnesota\Polk	Ohio\Geauga	Virginia\Buchanan
Illinois\Moultrie	Minnesota\Pope	Ohio\Greene	Virginia\Buckingham
Illinois\Ogle	Minnesota\Ramsey	Ohio\Guernsey	Virginia\Campbell

State/County	State/County	State/County	State/County
Illinois\Peoria	Minnesota\Red Lake	Ohio\Hamilton	Virginia\Caroline
Illinois\Perry	Minnesota\Redwood	Ohio\Hancock	Virginia\Carroll
Illinois\Piatt	Minnesota\Renville	Ohio\Hardin	Virginia\Charles City
Illinois\Pike	Minnesota\Rice	Ohio\Harrison	Virginia\Charlotte
Illinois\Pope	Minnesota\Rock	Ohio\Henry	Virginia\Chesterfield
Illinois\Pulaski	Minnesota\Roseau	Ohio\Highland	Virginia\Clarke
Illinois\Putnam	Minnesota\St. Louis	Ohio\Hocking	Virginia\Craig
Illinois\Randolph	Minnesota\Scott	Ohio\Holmes	Virginia\Culpeper
Illinois\Richland	Minnesota\Sherburne	Ohio\Huron	Virginia\Cumberland
Illinois\Rock Island	Minnesota\Sibley	Ohio\Jackson	Virginia\Dickenson
Illinois\St. Clair	Minnesota\Stearns	Ohio\Jefferson	Virginia\Dinwiddie
Illinois\Saline	Minnesota\Steele	Ohio\Knox	Virginia\Essex
Illinois\Sangamon	Minnesota\Stevens	Ohio\Lake	Virginia\Fairfax
Illinois\Schuyler	Minnesota\Swift	Ohio\Lawrence	Virginia\Fauquier
Illinois\Scott	Minnesota\Todd	Ohio\Licking	Virginia\Floyd
Illinois\Shelby	Minnesota\Traverse	Ohio\Logan	Virginia\Fluvanna
Illinois\Stark	Minnesota\Wabasha	Ohio\Lorain	Virginia\Franklin
Illinois\Stephenson	Minnesota\Wadena	Ohio\Lucas	Virginia\Frederick
Illinois\Tazewell	Minnesota\Waseca	Ohio\Madison	Virginia\Giles
Illinois\Union	Minnesota\Washington	Ohio\Mahoning	Virginia\Gloucester
Illinois\Vermilion	Minnesota\Watonwan	Ohio\Marion	Virginia\Goochland
Illinois\Wabash	Minnesota\Wilkin	Ohio\Medina	Virginia\Grayson
Illinois\Warren	Minnesota\Winona	Ohio\Meigs	Virginia\Greene
Illinois\Washington	Minnesota\Wright	Ohio\Mercer	Virginia\Greensville
Illinois\Wayne	Minnesota\Yellow Medicine	Ohio\Miami	Virginia\Halifax
Illinois\White	Mississippi\Adams	Ohio\Monroe	Virginia\Hanover
Illinois\Whiteside	Mississippi\Alcorn	Ohio\Montgomery	Virginia\Henrico
Illinois\Will	Mississippi\Amite	Ohio\Morgan	Virginia\Henry
Illinois\Williamson	Mississippi\Attala	Ohio\Morrow	Virginia\Highland
Illinois\Winnebago	Mississippi\Benton	Ohio\Muskingum	Virginia\Isle of Wight
Illinois\Woodford	Mississippi\Bolivar	Ohio\Noble	Virginia\James City
Indiana\Adams	Mississippi\Calhoun	Ohio\Ottawa	Virginia\King and Queen
Indiana\Allen	Mississippi\Carroll	Ohio\Paulding	Virginia\King George
Indiana\Bartholomew	Mississippi\Chickasaw	Ohio\Perry	Virginia\King William
Indiana\Benton	Mississippi\Choctaw	Ohio\Pickaway	Virginia\Lancaster
Indiana\Blackford	Mississippi\Claiborne	Ohio\Pike	Virginia\Lee
Indiana\Boone	Mississippi\Clarke	Ohio\Portage	Virginia\Loudoun
Indiana\Brown	Mississippi\Clay	Ohio\Preble	Virginia\Louisa
Indiana\Carroll	Mississippi\Coahoma	Ohio\Putnam	Virginia\Lunenburg
Indiana\Cass	Mississippi\Copiah	Ohio\Richland	Virginia\Madison
Indiana\Clark	Mississippi\Covington	Ohio\Ross	Virginia\Mathews
Indiana\Clay	Mississippi\DeSoto	Ohio\Sandusky	Virginia\Mecklenburg
Indiana\Clinton	Mississippi\Forrest	Ohio\Scioto	Virginia\Middlesex
Indiana\Crawford	Mississippi\Franklin	Ohio\Seneca	Virginia\Montgomery
Indiana\Daviess	Mississippi\George	Ohio\Shelby	Virginia\Nelson
Indiana\Dearborn	Mississippi\Greene	Ohio\Stark	Virginia\New Kent

State/County	State/County	State/County	State/County
Indiana\Decatur	Mississippi\Grenada	Ohio\Summit	Virginia\Northampton
Indiana\DeKalb	Mississippi\Hancock	Ohio\Trumbull	Virginia\Northumberland
Indiana\Delaware	Mississippi\Harrison	Ohio\Tuscarawas	Virginia\Nottoway
Indiana\Dubois	Mississippi\Hinds	Ohio\Union	Virginia\Orange
Indiana\Elkhart	Mississippi\Holmes	Ohio\Van Wert	Virginia\Page
Indiana\Fayette	Mississippi\Humphreys	Ohio\Vinton	Virginia\Patrick
Indiana\Floyd	Mississippi\Issaquena	Ohio\Warren	Virginia\Pittsylvania
Indiana\Fountain	Mississippi\Itawamba	Ohio\Washington	Virginia\Powhatan
Indiana\Franklin	Mississippi\Jackson	Ohio\Wayne	Virginia\Prince Edward
Indiana\Fulton	Mississippi\Jasper	Ohio\Williams	Virginia\Prince George
Indiana\Gibson	Mississippi\Jefferson	Ohio\Wood	Virginia\Prince William
Indiana\Grant	Mississippi\Jefferson Davis	Ohio\Wyandot	Virginia\Pulaski
Indiana\Greene	Mississippi\Jones	Oregon\Baker	Virginia\Rappahannock
Indiana\Hamilton	Mississippi\Kemper	Oregon\Benton	Virginia\Richmond
Indiana\Hancock	Mississippi\Lafayette	Oregon\Clackamas	Virginia\Roanoke
Indiana\Harrison	Mississippi\Lamar	Oregon\Clatsop	Virginia\Rockbridge
Indiana\Hendricks	Mississippi\Lauderdale	Oregon\Columbia	Virginia\Rockingham
Indiana\Henry	Mississippi\Lawrence	Oregon\Coos	Virginia\Russell
Indiana\Howard	Mississippi\Leake	Oregon\Crook	Virginia\Scott
Indiana\Huntington	Mississippi\Lee	Oregon\Curry	Virginia\Shenandoah
Indiana\Jackson	Mississippi\Leflore	Oregon\Deschutes	Virginia\Smyth
Indiana\Jasper	Mississippi\Lincoln	Oregon\Douglas	Virginia\Southampton
Indiana\Jay	Mississippi\Lowndes	Oregon\Gilliam	Virginia\Spotsylvania
Indiana\Jefferson	Mississippi\Madison	Oregon\Grant	Virginia\Stafford
Indiana\Jennings	Mississippi\Marion	Oregon\Harney	Virginia\Surry
Indiana\Johnson	Mississippi\Marshall	Oregon\Hood River	Virginia\Sussex
Indiana\Knox	Mississippi\Monroe	Oregon\Jackson	Virginia\Tazewell
Indiana\Kosciusko	Mississippi\Montgomery	Oregon\Jefferson	Virginia\Warren
Indiana\LaGrange	Mississippi\Neshoba	Oregon\Josephine	Virginia\Washington
Indiana\Lake	Mississippi\Newton	Oregon\Klamath	Virginia\Westmoreland
Indiana\LaPorte	Mississippi\Noxubee	Oregon\Lake	Virginia\Wise
Indiana\Lawrence	Mississippi\Oktibbeha	Oregon\Lane	Virginia\Wythe
Indiana\Madison	Mississippi\Panola	Oregon\Lincoln	Virginia\York
Indiana\Marion	Mississippi\Pearl River	Oregon\Linn	Virginia\Chesapeake City
Indiana\Marshall	Mississippi\Perry	Oregon\Malheur	Virginia\Suffolk
Indiana\Martin	Mississippi\Pike	Oregon\Marion	Virginia\Virginia Beach City
Indiana\Miami	Mississippi\Pontotoc	Oregon\Morrow	Wisconsin\Adams
Indiana\Monroe	Mississippi\Prentiss	Oregon\Multnomah	Wisconsin\Ashland
Indiana\Montgomery	Mississippi\Quitman	Oregon\Polk	Wisconsin\Barron
Indiana\Morgan	Mississippi\Rankin	Oregon\Sherman	Wisconsin\Bayfield
Indiana\Newton	Mississippi\Scott	Oregon\Tillamook	Wisconsin\Brown
Indiana\Noble	Mississippi\Sharkey	Oregon\Umatilla	Wisconsin\Buffalo
Indiana\Ohio	Mississippi\Simpson	Oregon\Union	Wisconsin\Burnett
Indiana\Orange	Mississippi\Smith	Oregon\Wallowa	Wisconsin\Calumet
Indiana\Owen	Mississippi\Stone	Oregon\Wasco	Wisconsin\Chippewa
Indiana\Parke	Mississippi\Sunflower	Oregon\Washington	Wisconsin\Clark

State/County	State/County	State/County	State/County
Indiana\Perry	Mississippi\Tallahatchie	Oregon\Wheeler	Wisconsin\Columbia
Indiana\Pike	Mississippi\Tate	Oregon\Yamhill	Wisconsin\Crawford
Indiana\Porter	Mississippi\Tippah	Pennsylvania\Adams	Wisconsin\Dane
Indiana\Posey	Mississippi\Tishomingo	Pennsylvania\Allegheny	Wisconsin\Dodge
Indiana\Pulaski	Mississippi\Tunica	Pennsylvania\Armstrong	Wisconsin\Door
Indiana\Putnam	Mississippi\Union	Pennsylvania\Beaver	Wisconsin\Douglas
Indiana\Randolph	Mississippi\Walthall	Pennsylvania\Bedford	Wisconsin\Dunn
Indiana\Ripley	Mississippi\Warren	Pennsylvania\Berks	Wisconsin\Eau Claire
Indiana\Rush	Mississippi\Washington	Pennsylvania\Blair	Wisconsin\Florence
Indiana\St. Joseph	Mississippi\Wayne	Pennsylvania\Bradford	Wisconsin\Fond du Lac
Indiana\Scott	Mississippi\Webster	Pennsylvania\Bucks	Wisconsin\Forest
Indiana\Shelby	Mississippi\Wilkinson	Pennsylvania\Butler	Wisconsin\Grant
Indiana\Spencer	Mississippi\Winston	Pennsylvania\Cambria	Wisconsin\Green
Indiana\Starke	Mississippi\Yalobusha	Pennsylvania\Cameron	Wisconsin\Green Lake
Indiana\Steuben	Mississippi\Yazoo	Pennsylvania\Carbon	Wisconsin\Iowa
Indiana\Sullivan	Missouri\Adair	Pennsylvania\Centre	Wisconsin\Iron
Indiana\Switzerland	Missouri\Andrew	Pennsylvania\Chester	Wisconsin\Jackson
Indiana\Tippecanoe	Missouri\Atchison	Pennsylvania\Clarion	Wisconsin\Jefferson
Indiana\Tipton	Missouri\Audrain	Pennsylvania\Clearfield	Wisconsin\Juneau
Indiana\Union	Missouri\Barry	Pennsylvania\Clinton	Wisconsin\Kenosha
Indiana\Vanderburgh	Missouri\Barton	Pennsylvania\Columbia	Wisconsin\Kewaunee
Indiana\Vermillion	Missouri\Bates	Pennsylvania\Crawford	Wisconsin\La Crosse
Indiana\Vigo	Missouri\Benton	Pennsylvania\Cumberland	Wisconsin\Lafayette
Indiana\Wabash	Missouri\Bollinger	Pennsylvania\Dauphin	Wisconsin\Langlade
Indiana\Warren	Missouri\Boone	Pennsylvania\Delaware	Wisconsin\Lincoln
Indiana\Warrick	Missouri\Buchanan	Pennsylvania\Elk	Wisconsin\Manitowoc
Indiana\Washington	Missouri\Butler	Pennsylvania\Erie	Wisconsin\Marathon
Indiana\Wayne	Missouri\Caldwell	Pennsylvania\Fayette	Wisconsin\Marinette
Indiana\Wells	Missouri\Callaway	Pennsylvania\Forest	Wisconsin\Marquette
Indiana\White	Missouri\Camden	Pennsylvania\Franklin	Wisconsin\Menominee
Indiana\Whitley	Missouri\Cape Girardeau	Pennsylvania\Fulton	Wisconsin\Milwaukee
Iowa\Adair	Missouri\Carroll	Pennsylvania\Greene	Wisconsin\Monroe
Iowa\Adams	Missouri\Carter	Pennsylvania\Huntingdon	Wisconsin\Oconto
Iowa\Allamakee	Missouri\Cass	Pennsylvania\Indiana	Wisconsin\Oneida
Iowa\Appanoose	Missouri\Cedar	Pennsylvania\Jefferson	Wisconsin\Outagamie
Iowa\Audubon	Missouri\Chariton	Pennsylvania\Juniata	Wisconsin\Ozaukee
Iowa\Benton	Missouri\Christian	Pennsylvania\Lackawanna	Wisconsin\Pepin
Iowa\Black Hawk	Missouri\Clark	Pennsylvania\Lancaster	Wisconsin\Pierce
Iowa\Boone	Missouri\Clay	Pennsylvania\Lawrence	Wisconsin\Polk
Iowa\Bremer	Missouri\Clinton	Pennsylvania\Lebanon	Wisconsin\Portage
Iowa\Buchanan	Missouri\Cole	Pennsylvania\Lehigh	Wisconsin\Price
Iowa\Buena Vista	Missouri\Cooper	Pennsylvania\Luzerne	Wisconsin\Racine
Iowa\Butler	Missouri\Crawford	Pennsylvania\Lycoming	Wisconsin\Richland
Iowa\Calhoun	Missouri\Dade	Pennsylvania\McKean	Wisconsin\Rock
Iowa\Carroll	Missouri\Dallas	Pennsylvania\Mercer	Wisconsin\Rusk
Iowa\Cass	Missouri\Daviess	Pennsylvania\Mifflin	Wisconsin\St. Croix

State/County	State/County	State/County	State/County
Iowa\Cedar	Missouri\DeKalb	Pennsylvania\Monroe	Wisconsin\Sauk
Iowa\Cerro Gordo	Missouri\Dent	Pennsylvania\Montgomery	Wisconsin\Sawyer
Iowa\Cherokee	Missouri\Douglas	Pennsylvania\Montour	Wisconsin\Shawano
Iowa\Chickasaw	Missouri\Dunklin	Pennsylvania\Northampton	Wisconsin\Sheboygan
Iowa\Clarke	Missouri\Franklin	Pennsylvania\Northumberland	Wisconsin\Taylor
Iowa\Clay	Missouri\Gasconade	Pennsylvania\Perry	Wisconsin\Trempealeau
Iowa\Clayton	Missouri\Gentry	Pennsylvania\Philadelphia	Wisconsin\Vernon
Iowa\Clinton	Missouri\Greene	Pennsylvania\Pike	Wisconsin\Vilas
Iowa\Crawford	Missouri\Grundy	Pennsylvania\Potter	Wisconsin\Walworth
Iowa\Dallas	Missouri\Harrison	Pennsylvania\Schuylkill	Wisconsin\Washburn
Iowa\Davis	Missouri\Henry	Pennsylvania\Snyder	Wisconsin\Washington
Iowa\Decatur	Missouri\Hickory	Pennsylvania\Somerset	Wisconsin\Waukesha
Iowa\Delaware	Missouri\Holt	Pennsylvania\Sullivan	Wisconsin\Waupaca
Iowa\Des Moines	Missouri\Howard	Pennsylvania\Susquehanna	Wisconsin\Waushara
Iowa\Dickinson	Missouri\Howell	Pennsylvania\Tioga	Wisconsin\Winnebago
Iowa\Dubuque	Missouri\Iron	Pennsylvania\Union	Wisconsin\Wood
Iowa\Emmet	Missouri\Jackson	Pennsylvania\Venango	Wyoming\Albany
Iowa\Fayette	Missouri\Jasper	Pennsylvania\Warren	Wyoming\Big Horn
Iowa\Floyd	Missouri\Jefferson	Pennsylvania\Washington	Wyoming\Campbell
Iowa\Franklin	Missouri\Johnson	Pennsylvania\Wayne	Wyoming\Carbon
Iowa\Fremont	Missouri\Knox	Pennsylvania\Westmoreland	Wyoming\Converse
Iowa\Greene	Missouri\Laclede	Pennsylvania\Wyoming	Wyoming\Crook
Iowa\Grundy	Missouri\Lafayette	Pennsylvania\York	Wyoming\Fremont
Iowa\Guthrie	Missouri\Lawrence	South Dakota\Aurora	Wyoming\Goshen
Iowa\Hamilton	Missouri\Lewis	South Dakota\Beadle	Wyoming\Hot Springs
Iowa\Hancock	Missouri\Lincoln	South Dakota\Bennett	Wyoming\Johnson
Iowa\Hardin	Missouri\Linn	South Dakota\Bon Homme	Wyoming\Laramie
Iowa\Harrison	Missouri\Livingston	South Dakota\Brookings	Wyoming\Lincoln
Iowa\Henry	Missouri\McDonald	South Dakota\Brown	Wyoming\Natrona
Iowa\Howard	Missouri\Macon	South Dakota\Brule	Wyoming\Niobrara
Iowa\Humboldt	Missouri\Madison	South Dakota\Buffalo	Wyoming\Park
Iowa\Ida	Missouri\Maries	South Dakota\Butte	Wyoming\Platte
Iowa\Iowa	Missouri\Marion	South Dakota\Campbell	Wyoming\Sheridan
Iowa\Jackson	Missouri\Mercer	South Dakota\Charles Mix	Wyoming\Sublette
Iowa\Jasper	Missouri\Miller	South Dakota\Clark	Wyoming\Sweetwater
Iowa\Jefferson	Missouri\Mississippi	South Dakota\Clay	Wyoming\Teton
Iowa\Johnson	Missouri\Moniteau	South Dakota\Codington	Wyoming\Uinta
Iowa\Jones	Missouri\Monroe	South Dakota\Corson	Wyoming\Washakie
Iowa\Keokuk	Missouri\Montgomery	South Dakota\Custer	Wyoming\Weston
Iowa\Kossuth	Missouri\Morgan	South Dakota\Davison	
Iowa\Lee	Missouri\New Madrid	South Dakota\Day	
Iowa\Linn	Missouri\Newton	South Dakota\Deuel	
Iowa\Louisa	Missouri\Nodaway	South Dakota\Dewey	
Iowa\Lucas	Missouri\Oregon	South Dakota\Douglas	
Iowa\Lyon	Missouri\Osage	South Dakota\Edmunds	
Iowa\Madison	Missouri\Ozark	South Dakota\Fall River	

State/County	State/County	State/County	State/County
Iowa\Mahaska	Missouri\Pemiscot	South Dakota\Faulk	

Appendix C. Economic Impact Report submitted by Sygenta

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Economic Impact Analysis of Event 3272 Corn on Dry Mill Ethanol Production

Prepared for:

Syngenta Biotechnology, Inc.

July 2007

Prepared by:

John M. Urbanchuk
Director

LECG, LLC.
1255 Drummers Lane
Suite 320
Wayne, PA 19087

LECG

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Economic Impact Event 3272 Corn on Dry Mill Ethanol Production

Syngenta Biotechnology Inc. has developed a novel transgenic corn variety, designated as Event 3272. This product is agronomically equivalent to No. 2 Yellow Corn, but also contains a genetically inserted thermostable alpha-amylase enzyme. While Event 3272 has been shown to be as safe for human and animal consumption as conventional yellow corn, its unique properties make it especially suited for use as a feedstock for ethanol produced by the dry grind process.

Alpha-amylase is one of two enzymes (the other being glucoamylase) that convert the starch in corn to sugar which is then fermented and distilled into ethanol. Microbial produced alpha-amylase is already commonly used commercially in the starch to sugar step of the dry grind and wet mill process of ethanol production. The Syngenta innovation prompts corn to produce its own heat-resistant alpha-amylase, thus eliminating the need for externally applied microbial alpha-amylase. Ethanol producers using Event 3272 corn will be able to reduce their costs of production through the [ ], and reduced energy and water requirements. In addition, the Event 3272 produced alpha-amylase may increase the conversion of starch to sugar [ ].

This study outlines the impact of Event 3272 corn on ethanol producers at the microeconomic (e.g. individual ethanol plant) level, and also how that impact will affect the U.S. economy on a macroeconomic scale.

1255 Drummers Lane, Suite 320, Wayne, PA 19087
main 610.254.4700 fax 610.254.1188 www.lecg.com

I. Background on Ethanol

Ethanol is an alcohol produced by fermentation of sugars found in grains and other biomass. Throughout the world ethanol has been successfully produced from a variety of starch based feedstocks. However, in the U.S. well over 90 percent of all ethanol is manufactured from corn.[1] The American ethanol industry has grown and changed considerably in the last quarter century. In only 25 years, the industry has expanded from a total production capacity of 175 million gallons in 1980, to include 122 production facilities with an annual capacity of nearly 6.4 billion gallons in July 2007.[2] The structure of the ethanol industry has changed dramatically as well. In 1991, 35 plants produced 865 million gallons of ethanol. Two-thirds of capacity was accounted for by wet mill plants that had an average capacity of 95.5 MGY. The 20 operating dry mill plants had an average capacity of 16.5 MGY. By July 2007, dry mill plants accounted for over 83 percent of capacity with an average size of 45 MGY.[3] This shift toward dry mill production has been a reaction to the higher capital costs associated with wet mill plants. Wet mill plants can be used to produce a variety of corn based products other than ethanol. These products include high fructose corn syrup, corn oil, corn starch, and others. However, due to the difference in capital costs and increasing demand for ethanol, all new plants built in the U.S. since 2000 have been dry mill facilities.

Much of the most recent growth in the industry has been spurred by two factors: The removal of MTBE from the nation's motor fuel supply and the passing of the Federal Energy Policy Act of 2005 ("EPACT05"). Ethanol was used to replace MTBE as an oxygenate in motor fuel beginning in 2004 due to environmental concerns associated

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[1] Renewable Fuels Association
[2] http://www.ethanolrfa.org
[3] BBI International Annual Ethanol Industry Survey; Ethanol Industry Outlook, various issues. Renewable Fuels Association

with MTBE.[4] This created an immediate increase in demand for ethanol in areas of the country that require Reformulated Gasoline (RFG) and/or oxygenated fuel.

EPACT05 provided several incentives for the use of renewable fuels. Among the many incentives was the Renewable Fuel Standard that requires a minimum of 7.5 billion gallons of renewable fuels to be used in the nation's highway fuel supply by 2012.[5] Since the passing of EPACT05, President Bush has announced plans to replace 20 percent of U.S. gasoline consumption with biofuels by 2017, equating to a supply of 35 billion gallons of renewable fuels. This proposal is embodied in the Energy Bill (CLEAN Energy Act of 2007) currently being debated in Congress. With current technologies, this goal presents a great challenge to agriculture and the ethanol industry. However, continued advancement in dry grind process innovation and developments in cellulose technology are expected to provide the means to meet the expanded renewable fuels target. The use of Event 3272 corn will allow the ethanol industry to produce a larger quantity of ethanol for the same amount of corn, and at a reduced cost.

II. The Dry Grind Ethanol Production Process

Traditional dry grind ethanol production can be divided into seven general phases: Feedstock preparation, cooking, liquefaction, saccharification, fermentation, distillation, and co-product processing. Event 3272 creates efficiencies in the dry grind process that affect[ ]phases. These benefits come in the form of reduced raw material inputs, energy and water use, and capital costs. Ethanol quality is also expected to increase slightly due to a reduction in sulfur content.

[4] Energy Information Administration. "Eliminating MTBE in Gasoline in 2006". February 22, 2006. http://www.eia.doe.gov/pub/oil_gas/petroleum/feature_articles/2006/mtbe2006/mtbe2006.pdf

[5] Energy Policy Act of 2005. 42 USC 15801. 119 Stat 594. Public Law 109-58. August 8, 2005. p. 1069. www.epa.gov/oust/fedlaws/publ_109-058.pdf

A. Process Benefits of Event 3272

While efficiencies from Event 3272 are gained throughout the ethanol production process, the greatest benefits are realized within the starch-to-sugar conversion phase. The most apparent of these benefits is the elimination of microbial alpha-amylase as a raw material input. Alpha-amylase is used in the liquefaction stage to break down the starch component of the corn into short chain dextrins, or complex sugars. Glucoamylase is then added during saccharification to further break down dextrins into simple sugars that can be fermented into ethanol. Because the alpha-amylase enzyme is already present in the corn kernel of Event 3272, this input is eliminated from the process.

Event 3272 also creates efficiencies in pH and temperature requirements. When conventional yellow corn is used in a dry grind plant, pH must be adjusted at several stages to create optimal conditions for chemical reactions to take place. With Event 3272 corn, pH is maintained at a constant level of approximately 4.8 throughout the production process. This reduces the use of sulfuric acid by half, providing direct economic savings. Event 3272 also makes it possible to replace liquid ammonia (used for pH adjustment and as a source of nitrogen for fermentation) with urea, which does not provide direct economic savings due to their equivalent cost. However, both sulfuric acid and liquid ammonia are hazardous substances and their replacement or reduction in use reduces environmental and workplace safety risks.

The unique properties of Event 3272 also make it possible to reduce the cooking temperature[ ]. This creates savings in the heating and cooking process, as well as in the cooling process after cooking is complete. It is anticipated that this reduction in heat demand will [ ]. Reduced temperature reduces energy use [ ]

[ ] this could increase ethanol yields by a range of two[ ]percent.

Event 3272 provides an additional benefit to the ethanol production process by increasing solids content in the starch-to-sugar phase by [ ]. An increased solids/liquid ratio decreases water use and will increase throughput. Throughput is a measure of the amount of corn that can be processed into ethanol during a production run. The ability to increase throughput provides the ethanol plant manager with a greater degree of flexibility. When using Event 3272 corn the manager will have the ability to increase output by processing more corn than would be possible with conventional No. 2 Yellow corn. Alternatively, he could reduce the plant's operating rate and still maintain the same quantity of ethanol as with conventional No. 2 Yellow corn. A reduced operating rate would lower stress on machinery and equipment and potentially reduce repair and maintenance costs.

B. Modeling the Changes

LECG economists used the USDA/ARS Eastern Regional Research Center (ERRC) Dry Grind Ethanol Process Model to assess the process and economic impacts of these benefits. The model allows the user to adjust all equipment, inputs, and processes involved in the production of ethanol in a typical state-of-the-art 40 MGY dry grind plant.[6] The USDA/ERRC model produces detailed economic evaluation and itemized cost reports that make it possible to compare financial results. The model was first used to establish a benchmark for the production process using 2007 input and capital costs. Changes were then made to the baseline assumptions to simulate the process differences made possible by using Event 3272. The principal changes imposed on the model include:

[6] Kwiatkowski, J., McAloon, A., Taylor, F., Johnston, D. "Modeling the process and costs of fuel ethanol production by the corn dry-grind process." *Industrial Crops and Products* 23 (2006) 288-296.

- Eliminating inputs of alpha-amylase (283 tons), and 50 percent of sulfuric acid (402 tons)
- Removing an alpha-amylase storage tank and associated pump
- Decreasing water use in starch-to-sugar conversion by an estimated [ ]
- Removing a heat exchanger, 50 psi steam, holding tank, and cooling water from cooking stage.

Changes were made to the cooking stage to reflect the temperature requirements discussed above. In the ERRC model, a product temperature of 85^0C is maintained leading into the cooking phase. [ ] the use of Event 3272 corn permits a reduction in energy use for heating and cooling. [ ] In order to reflect the changes discussed, a heat exchanger [ ] was eliminated.

As indicated the USDA model is tailored to a 40 MGY capacity. However, most new dry mill ethanol plants being built will have annual capacities closer to 100 MGY when completed.[7] While there are relatively few economies of scale in production, new plants can realize lower capital costs per gallon of ethanol than smaller plants. To reflect this dynamic LECG economists consulted with USDA cost engineers to accurately scale up the model results in order to evaluate the impact of Event 3272 corn on a 40 MGY plant as well as a 100 MGY plant.[8]

[7] Renewable Fuels Association. http://www.ethanolrfa.org/industry/locations Accessed on July 2, 2007. RFA statistics indicate that the average size of existing plants is 52.3 million gallons and the average size of plants under construction is 76.2 million gallons.

[8] Personal communication with Andrew J. McAloon, Cost Engineer, USDA/ERRC.

III. Firm-level economic impacts

A. Capital requirements

As indicated earlier the use of Event 3272 corn will reduce capital requirements for a new 40 MGY dry mill ethanol plant by $4.2 million, or 7.3 percent, and by $8 million for a 100 MGY plant. The primary reductions involve the elimination of amylase storage tanks and associated pumps; the elimination of a heat transfer unit [ ]; and elimination of other storage tanks and associated equipment. As shown in Table 1, the elimination of tanks, pumps, and heat transfer units has the largest impact on the starch to sugar conversion stage of processing.

It is important to note that the reductions in capital equipment only affect new dry mill plants designed specifically for the use of Event 3272. Existing plants would not realize these cost saving benefits.[9]

The primary financial impact from equipment savings for new plants that are designed and built to use Event 3272 corn will be provided by a lower depreciation expense and financing costs. This is the result of a smaller capital asset base to be financed and reduced repair and maintenance costs.

[9] Even in the case of new plants, the expected reductions in equipment will not occur immediately. Investors, operators, and builders are likely to wait to evaluate the acceptance of Event 3272 corn before forgoing this equipment.

Table 1
Impact of Event 3272 Corn on Plant and Equipment Costs
For a New Dry Mill Plant (Mil $)

	ERRC 40 MGY Baseline	40 MGY with Event 3272	100 MGY Baseline	100 MGY with Event 3272	Percent Difference From Baseline
Grain handling & milling	$4.161	$4.164	$7.902	$7.908	0.1%
Starch to sugar	$4.959	$3.807	$9.418	$7.230	-23.2%
Fermentation	$12.141	$11.472	$23.058	$21.787	-5.5%
Ethanol processing	$9.750	$9.573	$18.517	$18.181	-1.8%
Co-product processing	$24.084	$21.885	$45.739	$41.563	-9.1%
Common support systems	$2.200	$2.200	$4.178	$4.178	0.0%
Total Direct Fixed Capital	$57.295	$53.101	$108.811	$100.846	-7.3%

B. Operating costs

The economic benefits to ethanol producers using Event 3272 in place of conventional No. 2 yellow corn and microbial alpha-amylase are significant and the impact grows as the potential ethanol yield increases. In order to estimate these impacts we imposed the changes discussed above on the USDA/ERRC model to determine the implications for operating costs. The reduced cooking temperatures and [

] are expected to increase ethanol yields for a plant using Event 3272 corn. In order to estimate the implications of higher ethanol output in addition to process savings, we exogenously increased ethanol yields by two percent,[ ] from the USDA/ERRC baseline level of 2.8 gallons per bushel while holding corn use constant.

a. Event 3272 corn without increased ethanol yields

The principal operational cost savings from using Event 3272 corn are derived from the elimination of microbial alpha-amylase, a 50 percent reduction in sulfuric acid,

and reduced utility costs (electricity, natural gas, steam and water). The use of Event 3272 corn would permit the replacement of liquid ammonia with urea. At current prices this does not provide a direct cost savings. However, eliminating hazardous liquid ammonia provides important worker safety benefits and reduces environmental risks. The comparison of the 40 MGY and 100 MGY Baseline with the use of Event 3272 corn assuming no ethanol yield increase is summarized in Table 2.

Table 2
Impact of Event 3272 Corn on Costs and Profitability
For a New Dry-Mill Ethanol Plant[10]

ASSUMPTIONS	**40 MGY Baseline**	**40 MGY Event 3272**	**% Diff**	**100 MGY Baseline**	**100 MGY Event 3272**	**% Diff**
Capacity (Mil gal)	40.0	40.0		100.0	100.0	
Denatured Prod (Mil gal)	40.9	40.9		102.2	102.2	
OPERATING COSTS	**($/gal)**	**($/gal)**		**($/gal)**	**($/gal)**	
Corn	$1.237	$1.237	0.0%	$1.237	$1.237	0.0%
Alpha-amylase	$0.014	$0.000	-100.0%	$0.014	$0.000	-100.0%
Glucoamylase	$0.020	$0.020	0.0%	$0.020	$0.020	0.0%
Yeast	$0.004	$0.004	0.0%	$0.004	$0.004	0.0%
Liquid Ammonia/Urea	$0.004	$0.004	0.0%	$0.004	$0.004	0.0%
Sulfuric Acid	$0.002	$0.001	-50.3%	$0.002	$0.001	-50.3%
Caustic	$0.005	$0.005	0.0%	$0.005	$0.005	0.0%
Denaturant	$0.042	$0.042	-0.6%	$0.042	$0.042	-0.6%
Electricity	$0.036	$0.036	-1.8%	$0.036	$0.036	-1.8%
Natural Gas	$0.005	$0.005	-0.6%	$0.005	$0.005	-0.6%
Steam	$0.165	$0.151	-8.6%	$0.165	$0.151	-8.6%
Water	$0.001	$0.001	-0.8%	$0.001	$0.001	-0.8%
Labor	$0.050	$0.050	0.0%	$0.025	$0.025	0.0%
Repair & Maint.	$0.110	$0.102	-7.3%	$0.084	$0.078	-7.3%
Net Operating Costs	**$1.699**	**$1.660**	-2.3%	**$1.648**	**$1.610**	-2.3%

[10]Per gallon costs, revenue, and profitability are calculated using denatured ethanol production.

Table 2 Continued

	40 MGY Baseline	40 MGY Event 3272	% Diff		100 MGY Baseline	100 MGY Event 3272	% Diff
Revenue	**($/gal)**	**($/gal)**			**($/gal)**	**($/gal)**	
Ethanol	$1.943	$1.943	0.0%		$1.943	$1.943	0.0%
DDG	$0.309	$0.309	0.0%		$0.309	$0.309	0.0%
Total Revenue	**$2.252**	**$2.252**	0.0%		**$2.252**	**$2.252**	0.0%
EBIDTA	**$0.553**	**$0.592**	7.1%		**$0.604**	**$0.642**	6.2%
Less Depreciation	$0.093	$0.087	-7.3%		$0.071	$0.066	-7.3%
Less Interest Expense	$0.045	$0.042	-7.5%		$0.035	$0.032	-7.5%
NET INCOME	**$0.414**	**$0.463**	12.0%		**$0.499**	**$0.544**	9.1%
Return on Investment	29.5%	35.7%			46.8%	55.1%	

The use of Event 3272 corn in a 100 MGY plant provides a 3.7 cent per gallon (2.3 percent) reduction in annual net operating costs. Energy is the second largest cost component of producing ethanol and reduced steam use leads to a reduction in the cost of energy to produce ethanol by 11 percent.[11] Facilities costs (maintenance and repair) decline 7.3 percent as a result of reduced cooking temperatures and the elimination of equipment.

Since the quantity of corn used is held constant Distiller's grains (DG) production and the revenue associated with marketing DG is unchanged from Baseline levels. Similarly since no increase in ethanol yields is assumed in this scenario, ethanol production and revenue remains unchanged. When the reduced operations costs are subtracted from total revenue, Event 3272 corn provides a 3.7 cent per gallon (or 6.2 percent) increase in earnings before interest, depreciation and taxes (EBIDTA). The reduced capital requirements for a new ethanol plant lower depreciation charges and

[11] Hosein Shapouri and Paul Gallagher. "USDA's 2002 Ethanol Cost-of- Production Survey". USDA AER 841, July 2005. www.usda.gov/agency/oce/reports/energy/USDA_2002_ETHANOL.pdf

interest expense. This allows for a 9.1 percent increase in net income and a significant improvement in project ROI.[12]

b. Event 3272 corn with ethanol yield increases

It is anticipated that Event 3272 corn will result in higher ethanol yields due in large part to the reduced temperatures [ ]. The USDA/ERRC model does not permit an exogenous increase in ethanol yields. In order to simulate the impact on profitability of increased ethanol yields we imposed a two[ ] percent increase in ethanol yields over Baseline levels keeping corn use constant.

As indicated earlier increased solids will permit a higher level of throughput. For purposes of this analysis we have kept throughput constant for each of the yield scenarios. Therefore, since the operational costs for each of these scenarios are the same as for the no yield increase scenario, but the amount of ethanol output increases (due to higher ethanol yields), the cost per gallon of ethanol declines. Also, since more ethanol is produced, total revenue increases resulting in higher levels of EBITDA, net income, and ROI. The comparison of the various yield scenarios is summarized in Table 3.

[12] In this analysis we applied a straight line depreciation of fixed capital over 15 years. We assumed that 60 percent of fixed capital would be financed (40 percent equity) at nine percent over a ten-year period. The depreciation and interest charges reflect a ten-year average. Return on Investment (ROI) is a measure of the efficiency of an investment and is calculated by dividing the benefits (e.g. net income) provided by an investment by the cost of the investment. Ideally an investor would choose an investment opportunity with the highest ROI.

Table 3
Impact of Alternative Ethanol Yield Increases from Event 3272 Corn on Dry Mill Ethanol Costs and Profitability (New 100 MGY Plant)

	100 MGY Baseline	Event 3272 Yield Increase			
		0%	2%	[	
Production (Mil gal)	100.0	100.0	102.0		
Denatured Production (Mil gal)	102.2	102.2	104.2		
Corn Requirement (Mil bu)	36.1	36.1	36.1		
Ethanol Yield (Gal/bu)	2.767	2.767	2.822		
Net Operating Costs ($/gal)	**$1.338**	**$1.301**	**$1.275**		
Diff from Baseline (%)		-2.8%	-4.7%		
Total Revenue ($/gal)	$2.252	$2.252	$2.246		
EBIDTA ($/gal)	**$0.914**	**$0.951**	**$0.971**		
Diff from Baseline (%)		4.1%	6.2%		
NET INCOME ($/gal)	**$0.499**	**$0.544**	**$0.571**		
Diff from Baseline (%)		9.1%	14.6%		
Return on Investment	46.8%	55.1%	59.1%		]

IV. Macroeconomic implications of Event 3272 corn

The firm-level, or microeconomic, implications of Event 3272 corn for dry mill ethanol production are clear: producers who use Event 3272 corn stand to gain between 4.6 cents per gallon[ ]in additional net income compared to producers using conventional No.2 Yellow corn and microbial alpha-amylase. These economics provide a significant incentive for the use of Event 3272 corn.

The economic implications for the ethanol industry will be dictated by the share of the dry-mill ethanol market Event 3272 corn attains. For purposes of this analysis we relied [ ]assumption that Event 3272 corn enters the market[ ]and attains a 30 percent market share of dry-mill corn production by 2012. As shown in Table 4, total ethanol production is projected to reach nearly 13.8 billion bushels by 2012, with corn accounting for almost 93 percent of all feedstocks and dry-milling providing for 85 percent of corn ethanol.

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Table 4
Projected Ethanol Capacity and Production
2006-2012

	ETOH Capacity (MGY) /1	Net New Capacity (MGY) /2	Capacity Utilization (Pct)	ETOH Production (MGY)	ETOH From Corn (MGY)	From Advanced Biofuels (MGY)	Dry Mill Ethanol Yield (Gal/bu)
2006	4,336	1,157	99%	4,857	4,614	243	2.70
2007	5,493	3,250	95%	6,762	6,492	270	2.75
2008	8,743	2,900	95%	9,684	9,411	273	2.77
2009	11,643	1,000	95%	11,536	11,160	376	2.79
2010	12,643	750	95%	12,367	11,888	479	2.81
2011	13,393	750	95%	13,080	12,199	881	2.83
2012	14,143	750	95%	13,792	12,792	1,000	2.85

1. Jan 1 capacity
2. Capacity added during year
Source: LECG LLC. June 29, 2007

Conversations with corn growers, ethanol producers and plant designers lead us to expect that baseline dry mill ethanol yields are likely to improve modestly over the next decade. These gains will be provided by better process technology as well as improvements in corn varieties. Reflecting this we project industry average dry mill ethanol yields to increase from 2.75 gallons per bushel today to 2.85 gallons per bushel by 2012.

The impact of Event 3272 corn on dry-mill ethanol production is summarized in Table 5. Dry mill ethanol production is projected to total 10.9 billion gallons by 2012. Not all of this ethanol will be produced from corn as the feedstock. We are assuming that two billion gallons of ethanol will be produced from raw starch leaving a corn dry mill market of 8.9 billion gallons. A 30 percent market share for Event 3272 corn amounts to 2.689 billion gallons which, at a 2.85 gallon per bushel yield, equates to 943 million bushels.

Using the current USDA Long-term forecast for corn production of 13.465 billion bushels by 2012, this is equivalent to about seven percent of U.S. corn production.[13]

Table 5
Event 3272 Corn and Dry Mill Ethanol Production in 2012

		Yield Increase		
	Base	**2%**	[	
Total Ethanol Production (Mil gal)	**13,792**	**13,860**		
Corn share	92.7%	92.7%		
Ethanol from corn (Mil gal)	12,792	12,855		
Dry Mill share	85.7%	85.7%		
Corn Dry Mill Ethanol (Mil gal)	10,963	11,017		
Raw Starch Ethanol (Mil gal)	2,000	2,000		
Net Dry Mill Ethanol Production (Mil gal)	**8,963**	**9,017**		
Event 3272 Market Share	30%	30%		
Ethanol from conventional corn (Mil gal)	6,274	6,274		
Ethanol from Event 3272 corn (Mil gal)	2,689	2,743		
Weighted Average EtOH Yield (gal/bu)	2.85	2.87		
Event 3272 EtOH Yield (gal/bu)	2.85	2.91		
Corn for Dry Mill EtOH (Mil bu)	3,145	3,145		
Conventional Corn (Mil bu)	2,201	2,201		
Event 3272 Corn (Mil bu)	943	943		
Average Corn Yield (Bu/ac)	162.6	162.6		
Acreage (Mil ac)	19.341	19.341		
Conventional Corn (Mil ac)	13.539	13.539		
Event 3272 Corn (Mil ac)	5.802	5.802		]

The use of Event 3272 corn will provide several major macroeconomic, or industry-wide, benefits.

1. First, the process improvements discussed earlier will reduce the use of energy, and water as well as hazardous inputs such as liquid ammonia and sulfuric acid. Specifically, a 30 percent market share for Event 3272 corn to produce 2.687 billion gallons of ethanol will:

[13] *USDA Agricultural Projections to 2016*. USDA/WAOB OCE-2007-1. February 2007. Table 8. http://www.ers.usda.gov/Publications/OCE071/. The USDA forecast for 2012 is based on 90.0 million planted acres, 82.8 million harvested and an average yield of 162.6 bushels per acre.

By using Event 3272 corn a 100 MGY plant will reduce natural gas consumption by approximately 9,500 thousand cubic feet (mcf), and save roughly $64,000. At a 30 percent market share, this equates to an industry wide savings of over 253,000 mcf annually or enough natural gas to heat 3,700 homes for one year.[17]

- Reduce the demand for microbial alpha-amylase by almost 19,000 tons per year.

When compared to other non-grain inputs necessary for ethanol production, microbial alpha-amylase is a relatively safe substance to transport and handle. Alpha-amylase is a non-toxic, biodegradable enzyme that is supplied in liquid form to ethanol producers. Microbial alpha-amylase is manufactured through a fermentation process which requires water as its primary input. The alpha-amylase is then shipped in a water solution by truck to its final destination. At a 30 percent market share, Event 3272 corn would eliminate the need for 19,000 tons of microbial alpha-amylase solution per year. By doing so, Event 3272 corn would help to conserve 4.32 million gallons of water per year, or the equivalent of more than 69 million glasses of drinking water. Fossil fuel use would also decrease proportionately by eliminating the need for 950-20 ton truck shipments.

- Eliminate the use of 26,864 tons of sulfuric acid

Each year 40 million tons of sulfuric acid (H_2SO_4) is manufactured in the U.S. for industrial use, and approximately 74,000 tons are released into the environment.[18] Sulfuric acid typically is delivered via 100-ton capacity rail cars for large loads, and by 24-ton or 35-ton capacity trucks for smaller

[17] U.S. Department of Energy-EIA. Residential Natural Gas Prices: What Consumers Should Know. Table 1. http://www.eia.doe.gov/oil_gas/natural_gas/analysis_publications/natbro/gasprices.htm

[18] Edison Electric Institute. Straight answers about the Toxics Release Inventory. April 2006. http://www.eei.org/industry_issues/environment/air/Toxics_Release_Inventory/sulfuric.pdf

loads.[19] At a market share of 30 percent, Event 3272 corn will eliminate the equivalent of 270 rail car or 900 truck loads annually. This decrease in demand will serve to reduce transportation, handling, and exposure risk associated with the toxic liquid, not only while the product is en-route to the final destination, but also after the product arrives onsite. Fossil fuel use for transport will also be reduced.

- Enable the replacement of liquid ammonia with safer urea

  Ammonia is a highly toxic, corrosive material that is commonly used in agricultural and industrial applications. According to the Centers for Disease Control and Prevention (CDC), anhydrous ammonia is the most frequently released chemical in the U.S., and release events often have multiple victims.[20] CDC data indicates that from 2002 to 2005 there were 2,128 reported ammonia release events, which resulted in 755 victims. Syngenta's Event 3272 corn makes it possible to substitute the use of ammonia in ethanol production with urea, which is 10,000 times less toxic than ammonia.[21] At a market share of 30 percent, Event 3272 would make it possible to eliminate the use of 54,082 tons of ammonia annually, as it is replaced by the much safer urea. According to the Transportation Security Administration, approximately 40,764 rail tank cars are used to transport liquid ammonia each year.[22] Given the assumption that liquid ammonia is commonly shipped in 90

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[19] Kennecott Utah Copper Corporation. Sulfuric Acid Environmental Profile, Life Cycle Assessment. December 2004.
http://www.kennecott.com/pdf/Sulfuric_Acid_Environmental_Profile_Declaration.pdf

[20] Centers for Disease Control and Prevention. 2006 National Environmental Public Health Conference session abstracts. Session A 15: "Uncontrolled Releases of Anhydrous Ammonia: Causes, Victims, and Prevention".
http://www.cdc.gov/nceh/conference/2006_conference/abstracts/session_A15.html

[21] Charles Sturt University. Biology resources syllabus available from New South Wales HSC Online.
http://hsc.csu.edu.au/biology/core/balance/9_2_3/923net.html

[22] Aherne, J. "Enhancing Freight Rail Highway Transportation Security." U.S. Department of Homeland Security, Transportation Security Administration. 2007.
http://projects.battelle.org/trbhazmat/Presentations/TRB2007-JA.ppt

- Reduce water use by 106.8 million gallons

  Water availability and use is becoming an issue of concern for many communities in the U.S. Ethanol production is a relatively water-intensive activity. USDA estimates indicate that it takes about 4.7 gallons of water to produce a gallon of ethanol.[14] Most new dry grind ethanol plants are designed and operated as closed-loop systems for water. This design features recycling and minimizes release and discharge. The use of Event 3272 corn has the potential to reduce water use in dry mill ethanol production. At a 30 percent market share, the use of Event 3272 corn would require 106.8 million fewer gallons of water annually for ethanol production. This is the equivalent of 5.5 glasses of drinking water for every American. Looked at another way, 106.8 million gallons would supply the annual cooking and drinking water requirements for the entire population of a city larger than Cedar Rapids, IA.[15]

- Reduce industrial demand for electricity and natural gas

  By using Event 3272 corn as a feedstock, ethanol producers will reduce their energy use, and therefore decrease their utility costs. On average, a 100 MGY plant will reduce electricity use by 1.32 million kilowatt-hours (kWh) and save $66,000. If Event 3272 corn achieves a 30 percent market share this translates into 35.3 million less kilowatt-hours of electricity. This forgone electricity would be enough to light nearly 38,000 homes for a full year.[16]

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[14]Hosein Shapouri and Paul Gallagher. "USDA's 2002 Ethanol Cost-of- Production Survey". USDA AER 841, July 2005.

[15] "Common Household Use of Drinking Water". http://www.freedrinkingwater.com/water_quality/common-daily-water-usage.com; Table 4: Annual Estimates of the Population for Incorporated Places in Iowa, Listed Alphabetically: April 1, 2000 to July 1, 2006. (SUB-EST 2006-04-19). Population Division, U.S. Census Bureau. Released June 28, 2007.

[16] U.S. Department of Energy-EIA. End-Use Consumption of Electricity 2001. Table 2. http://www.eia.doe.gov/emeu/recs/recs2001/enduse2001/enduse2001.html

ton cars, Event 3272 could reduce the number of cars used to ship ammonia by 600 per year. This reduces risk of release and exposure to all workers involved with the transportation, loading and unloading, storage, and final application of the material.

2. Event 3272 corn will reduce the burden on corn production from increased ethanol output. Event 3272 corn will allow the production of a larger amount of ethanol from the same quantity of corn. As shown in Table 5, [ ] Event 3272 corn is expected to increase industry average dry mill ethanol yields from 2.85 gallons per bushel to [ ]in 2012.[23] As a consequence, Event 3272 corn will produce between 68 million and [ ]more gallons of ethanol using 3.143 billion bushels of corn.

   The benefits of this are straightforward: the ability to increase ethanol yields will enable the U.S. to more easily meet Renewable Fuel Standard targets with less pressure on agricultural or CRP land use. Essentially ethanol production can be increased without an equivalent increase in corn area.

   - <u>This will reduce the risk of runoff and ground and surface water contamination by fertilizers and crop protection chemicals</u>.

     Looked at another way, using Event 3272 corn to produce 30 percent of dry mill ethanol production would require between 114,000 and [ ] fewer acres of corn to produce the same amount of ethanol that would be provided by conventional No. 2 Yellow corn and microbial alpha-amylase.[24] The use

[23] This is a weighted average calculated by adding the average ethanol yield for conventional corn (2.85 gal/bu) by the share of dry mill ethanol accounted for by conventional corn to the average ethanol yield for Event 3272 corn (2.85 [base], 2.91 [+2%],[ ]gal/bu) by Event 3272 corn market share. For example if Event 3272 corn has a 30 percent market share and provides a 2% ethanol yield increase, the weighted average dry mill ethanol yield would be 2.87 (.7*2.85+.3*2.91).

[24] The acreage "savings" were estimated by holding ethanol production for both conventional and Event 3272 corn constant and calculating the number of acres that would be required to plant assuming a 2%,[

of Event 3272 corn would reduce applications of fertilizers (NPK and sulfur) by between 13,368 tons and [ ] tons. Also, herbicide applications would be reduced by between 234,000 pounds (a.i.) and[ ]pounds (a.i.) while insecticide use would be between 7,000 pounds (a.i.) and[ ]pounds (a.i.) lower.[25]

- Additional land will be available to plant to soybeans and rotational crops.

  The use of Event 3272 corn would make between 114,000 and[ ]acres of land available for planting to soybeans and rotational crops such as alfalfa.

- Energy use for planting, cultivation and harvesting will be reduced as will soil compaction.

  Acreage reductions resulting from the higher ethanol yields provided by Event 3272 corn will reduce the amount of energy used by corn farmers. Fewer acres needed for corn production equates to less fuel and electricity use for field work. Diesel fuel use will be reduced by a range of 706,800 to [ ]gallons per year. Gasoline use will decline by a range of 193,800 to [ ]gallons annually. Propane use will also decrease by a range of 535,800 to [ ]gallons per year. The use of electricity will decrease by a range of 4.77 million to [ ] kWh. And natural gas consumption will decrease by a range of 43,662 to [ ] mcf.[26]

]ethanol yield increase from Event 3272 corn. This amounts to 114,000 acres less corn acreage required if Event 3272 provides a 2% ethanol yield increase;[ ].

[25] Fertilizer and crop protection chemical use estimated using application data for corn published in the USDA/NASS Agricultural Chemical Usage 2005 Field Crops Summary. Ag Ch 1 (06) May 2006. http://www.pestmanagement.info/nass/app_usage.cfm

[26] USDA-Economic Research Service. Commodity Costs and Returns: U.S. and Regional Cost and Return Data: Energy Use on Major Field Crops in Surveyed States. http://www.ers.usda.gov/Data/CostsAndReturns/Fuelbystate.xls

Soil compaction is a common concern for crop farmers in the U.S. Multiple machinery passes through fields for tillage and treatments can compact soil over time, and reduce its productivity. By reducing the amount of corn necessary to produce a gallon of ethanol, Event 3272 corn could also contribute to soil conservation. Event 3272 corn could alleviate pressure on the additional land that would otherwise necessarily be in corn production, and farmers would have greater flexibility in land management practices.

- Increasing ethanol production will have a smaller impact on corn prices which will limit the impact of increased ethanol production on livestock, poultry and dairy profitability.

  Event 3272 corn is expected to increase ethanol yields and provide the dry mill ethanol producer the ability to produce the same quantity of ethanol from fewer bushels of corn. Reducing corn demand for ethanol will reduce pressure on corn prices. At a two percent yield increase Event 3272 corn would require 18 million fewer bushels of corn to produce 2.7 million gallons of ethanol;[

  ].

  Using a corn price elasticity of -0.36, this suggests that all other things held constant, Event 3272 corn at a 30 percent market share could reduce average corn prices by between $0.014 and[ ] cents per bushel.[27] This reduction in price will directly benefit livestock, poultry and dairy producers.

3. The successful introduction and use of Event 3272 corn will provide an important precedent that will have a significant positive impact on innovation and

[27]"The Economic Impact of the Demand for Ethanol" Michael K. Evans. Kellogg School of Management, Northwestern University.. Prepared for the Governor's Ethanol Coalition. January 31, 1997. Evans finds that a 600 million bushel increase in corn demand for ethanol production raises corn prices $0.45 per bushel. This translates to $0.0008 per bushel. Multiplying this by the estimated reduction in the number of bushels required to produce ethanol with Event 3272 corn provides the corn price reduction (i.e. $0.0008 times 18 million bushels "saved" with a 2% yield increase equals $0.014 per bushel).

technology development. Success of Event 3272 corn will stimulate investment in research and development into other genetic modifications that hold the promise of improving crop and product yields, reducing operating costs, and improving profitability.

4. Improved profitability for dry-mill ethanol production will stimulate investment in new production facilities and expansion and improvement of existing facilities. This investment will most likely take place in rural communities whose economies will benefit from increased ethanol production.[28] Ethanol has been shown to provide a significant contribution to the economy of the communities where plants are located. For example, the annual operations of a new 50 MGY dry mill ethanol plant generates $123 million of additional GDP and $44 million in new household income. Assuming that a 50 MGY plant employs about 25 people, the plant would support the creation of 305 jobs in the local community.[29] These and other benefits provided by the ethanol industry are detailed in "The American Ethanol Scrapbook: Tales from the Heartland" compiled and published by the Renewable Fuels Association.

[28] Dan Campbell, "Producer ownership of ethanol a major plus for rural America". *Rural Cooperatives*. May/June 2007.
[29] John M. Urbanchuk. "Economic Impacts on the Farm Community of Cooperative Ownership of Ethanol Production". February 2007. USDA Agricultural Outlook Forum 2007. March 2007.

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Conclusion

Event 3272 corn will provide significant process advantages that result in lower production costs and increased profitability for dry mill ethanol producers. These advantages will reduce the use of hazardous inputs such as liquid ammonia and sulfuric acid thereby limiting risk to both worker safety and the environment. Additionally, the use of Event 3272 corn will reduce water use in ethanol production. As water resources become increasingly stressed, this will negate a major element of public opposition to the location of ethanol plants.

The use of Event 3272 corn also will reduce pressure on corn production and enable the U.S. to more easily meet RFS targets and continue to displace gasoline made from imported crude oil.

1255 Drummers Lane, Suite 320, Wayne, PA 19087
main 610.254.4700 fax 610.254.1188 www.lecg.com

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APPENDIX A

JOHN M. URBANCHUK, DIRECTOR, LECG

1255 Drummers Lane, Ste. 320
Wayne, PA 19087
Telephone: 610-254-4021
Fax: 610-254-1188
E-Mail: jurbanchuk@lecg.com

EDUCATION

M.A. Economics, Temple University, 1974.
Completed all Ph.D. course work in Economics, Temple University, Philadelphia, PA.
B.S. Economics, The Pennsylvania State University, University Park, PA, 1967.
Certificate, Cooperative Executives Management Course. Penn State University. 1998.
Graduate, U.S. Army Command and General Staff College, Ft. Leavenworth, KS, 1979.
Graduate, U.S. Army Foreign Area Officer Program, JFKCENMA, Ft. Bragg, NC, 1982.

PRESENT POSITION

LECG, LLC, Wayne, PA
Director 10/02 to present

Design and execute consulting projects involving the application of economic science to a wide range of industries including agriculture and food, renewable fuels, biotechnology and crop protection, and consumer products. Functional specializations include econometric modeling and forecasting, valuation issues and estimation of reasonable royalty rates and economic damages resulting from infringement of patents and other intellectual property. Projects include preparation of feasibility studies and business plans, domestic and international market and pricing analysis, business and marketing strategy development, technology assessment, corporate development, public policy and regulatory issues analysis, and regional economic impact analysis. Prepare and deliver testimony as an expert witness before judicial bodies, Congressional committees, state legislative bodies, and regulatory agencies.

TEACHING EXPERIENCE

Erivan K. Haub School of Business, Saint Joseph's University, Philadelphia, PA

Lecturer in Marketing 1/92-Preser

Teach graduate courses in Industrial Policy and Emerging Markets.

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Delaware Valley College, Doylestown, PA

Adjunct Professor 1/05 - Present
Teach graduate level course in agricultural price analysis.

OTHER POSITIONS HELD

AUS Consultants, Inc., Moorestown, NJ

Executive Vice President 7/94 to 10/0
Vice President 8/91-7/9
Manage consulting practice in applied economics specializing in agriculture and food, renewable fuels, biotechnology and crop protection, consumer finance, housing, and consumer products. Provided consulting for valuation issues and estimation of reasonable royalty rates and economic damages resulting from infringement of patents and other intellectual property.

Hill and Knowlton, Inc., Washington, DC

Senior Vice President and Chief Economist 12/88-8/91
Vice President 8/87-12/88
Responsible for managing firm's economics consulting division that provided clients with a full range of economic and public policy consulting services. Provided counseling to clients in the areas of economic policy analysis and corporate planning. Participated as a member of firm's Management Committee and supported corporate senior management with economic support for corporate planning activities.

Wharton Econometric Forecasting Associates, Philadelphia, PA
Vice President 4/87-7/87
Director, International Agriculture Service 3/80-4/87
Managed WEFA International Agriculture Model and all consulting activities in the agriculture and the food industry. Member of firm's Professional Board.

Campbell Soup Company, Camden, NJ
Manager, Economic Research 5/76-3/80

The Penn Mutual Life Insurance Company, Philadelphia, PA
Business Research Associate, Corporate Planning and Research Department 9/73-5/76

The Philadelphia National Bank, Philadelphia, PA
Planning Staff Member 3/70-9/73

Military Service: Army of the United States
Infantry Officer 12/67-1/7
Vietnam service as Public Administration Advisor, MACV-CORDS (I Corps)
Politico-Military Officer (Eurasia) 2/70-4/85

Politico-Military Division, Strategy Plans and Policy Directorate, DCSOPS, HQDA (1981-1985).
Current Status: Major, USAR (Retired)
Highest Security Clearance: Top Secret (SCI)
Decorations: Bronze Star Medal, Army Commendation Medal, Republic of Vietnam Civic Action Honor Medal, First Class

PROFESSIONAL ASSOCIATIONS

Conference of Business Economists
American Agricultural Economics Association
U.S. Congressional Budget Office Agriculture Review Panel
Philadelphia Society for Promoting Agriculture

PUBLISHED ARTICLES

"Estimating Damages for Infringement of Agricultural Biotechnology-Derived Products (New)" In Parr, Russell, L. *Intellectual Property Infringement Damages: A Litigation Support Handbook.* Second Edition 2001 Cumulative Supplement. John Wiley & Sons, Inc. New York. 2001.

"Commodity Markets, Farm-Retail Spreads, and Macroeconomic Condition Assumptions in Food Price Forecasting" *American Journal of Agricultural Economics*, 79, No. 5, 1997

"Is the U.S. Falling Behind in Farm Technology?" in Dennis T. Avery (ed.), *Global Food Progress 1991*, Hudson Institute, Indianapolis, 1991.

"Planting Seeds for the New Farm Bill." *Executive Challenge*, Spring 1990.

"Developments in U.S. Agricultural Policy and Implications for the European Community," *Identifying Change in European Agriculture: The Contribution of Marketing Research*, E.S.O.M.A.R., Strasbourg, May 1987.

"Economic Condition and Prospects for Agriculture and Rural Business" *Toward the Next Generation of Farm Policy*, Vol. 2, Joint Economic Committee of Congress, Washington, D.C., 1983.

SELECTED RESEARCH REPORTS AND PROJECTS

Economic Impact of Eliminating the Biodiesel Tax Credit for Biodiesel Exports. Client: National Biodiesel Board. July 2007.

The Relative Impact of Corn and Energy Prices in the Grocery Aisle. Client: The Renewable Fuels Association. June 2007.

The Economic Feasibility of Dry Mill Ethanol Production in Grand Island, Nebraska. May 2007.

The Economic Impact of Starbucks Retail Operations on Local Communities. (with George R. Schink). March 2007

Expert Report in the Matter of Masterfoods, USA, Inc. v. We-Clean, Inc. Case No. cv06-00888, Department 1. Second Judicial District Court, State of Nevada, in and for the County of Washoe County. March 2007.

Economic Importance of Federal Tax Incentives for Ethanol. Client: Renewable Fuels Association. February 2007.

Alternative Fuels and Agriculture. Client: Renewable Fuels Association. February 2007.

Contribution of the Biofuels Industry to the Economy of Iowa. Client: Iowa Renewable Fuels Association. January 2007.

Contribution of the Ethanol Industry to the Economy of the United States. Client: Renewable Fuels Association. December 2006.

Expert Report Regarding Damages Resulting from a Disputed Supply Option Agreement for Raw Sugar in the Matter Southern Minnesota Beet Sugar Cooperative v. Imperial Sugar Company. AAA Case No. 77 489 Y 00084 06JRJ. October 2006.

The Economics of Producing Ethanol from Sorghum and Cane Sugar in Santa Rosa, TX. October 2006.

Business Plan for Green Renewable Energy Tremont, Pennsylvania 100 MGY Dry Mill Ethanol Plant. September 2006

Economic Impacts on the Farm Community of Cooperative Ownership of Ethanol Production. Client: National Corn Growers Association. September 2006.

Economic Feasibility of Biodiesel Production in the Red River Valley. August 2006

Feasibility Study of Ethanol Production in the Banana Shire (with George Barker and Richard Tooth). Client: The Gladstone State Development, Trade and Innovation Centre. July 2006

Economic Feasibility of Converting Sucrose to Ethanol in the United States. July 2006

Contribution of the Biodiesel Industry to the Economy of the United States. Client: The National Biodiesel Board. June 2006

Economic Impact of the Increased Use of Biofuels and Coal Derived Transportation Fuels for the Commonwealth of Pennsylvania. Client: Citizens for Pennsylvania's Future (PennFuture). May 2006

Economic Feasibility of a 100 MGY Dry Mill Ethanol Plant in Tremont, Pennsylvania. Client: Green Renewable Energy, Ethanol & Nutrition - Holding, LLC, May 2006

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Economic Impact of Ethanol and Biodiesel Production on the Economy of Northwest Texas. May 2006.

Contribution of the Ethanol Industry to the Economy of the United States. February 2006. Client: Renewable Fuels Association.

Economic Feasibility of Converting Sucrose to Ethanol in the United States. February 2006.

Economic Impact of Four New Ethanol Plants on the Economy of Southwest Kansas. January 2006.

Impact of an Expanding Biodiesel Industry from Soybeans on the Iowa Economy. January 2005. Client: Iowa Soybean Association.

Iowa Renewable Fuels: Expected Market Impact 2005-2015. *December 2005. Client: Iowa Corn Growers Association and Iowa Renewable Fuels Association.*

Ethanol, Corn, and Co-Products Supply, Demand, and Price Analysis: U.S. and California. July 2005.

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Economics of a Queensland Ethanol Industry (with George Barker and William Wells). Client: Queensland Department of State Development and Innovation. May 2005

Ethanol and the Consumer. Client: The Renewable Fuels Association. February 2005.

Impact on the South Dakota Economy of Legislative Proposals to Stimulate the Demand for Biodiesel Fuel. Client: South Dakota Soybean Council. February 2005.

Economic Benefits and Business Case for the Fungicide Cyazofamid on Ornamentals and Turf. Forthcoming.

Impact of Ethanol on Consumers in Atlanta, Georgia. Client: The Renewable Fuels Association. November 2004.

The Economic Feasibility of Dry Mill Ethanol Production in Central Indiana. November 2004.

A Comparison of the Subsidies Provided by Canadian Governments to the Oil and Ethanol Industries (with Geroge R. Schink and William Toms). Client: The Canadian Renewable Fuels Association. October 2004.

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The U.S. Market for Ethanol. July 2004.

Impact of an Ethanol Mandate on Retail Level Gasoline Prices in Ontario. Client: The Canadian Renewable Fuels Association. July 2004.

The Contribution of the Ethanol Industry to the American Economy. Client: The Renewable Fuels Association. March 2004.

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Statewide Feasibility Study for a Potential New York State Biodiesel Industry. Client: NYSERDA, February 2004.

Ethanol for Georgia: The Economic Feasibility of Dry Mill Ethanol Production in Georgia. August 2003.

Pineapple Production in Hawaii and Costa Rica. Expert Report in the matter of Maui Pineapple Company, Ltd. v.Del Monte Fresh Produce. Civil No. 01-1-0173 (1). Circuit Court of the Second Circuit, State of Hawaii. Client: Maui Pineapple Company. August 2003.

Economic Impact of the New York State MTBE Ban. Expert report in the matter of Case No. 00-CV-1073 (NAM-RWS). Oxygenated Fuels Association v.George Pataki and Eliott Spitzer. In the United States District Court for the Northern District of New York. Client: New York State Office of Attorney General. July 2003.

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Consumer Impacts of the Renewable Fuel Standard. Client: The National Corn Growers Association. April 2003.

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Independent Technical Review of the Upper Mississippi River and Illinois Waterway Navigation Study: Economic Scenarios and Resulting Demand for Barge Transportation. Client: U.S. Army Corps of Engineers. November 2002.

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Estimation of reasonable royalty rates for certain trademarks and other intellectual property for purposes of an intracompany transfer of licensing transactions. April 2002.

An Economic Analysis of Legislation for a Renewable Fuels Requirement for Highway Motor Fuels. Client: The Renewable Fuels Association, National Corn Growers Association and American Soybean Association. March 2002

California Electricity Prices: An Economic Impact Analysis. Client: the California Manufacturer's and Technology Association. February 2002.

Macroeconomic Impacts of S.1058: Legislation to provide a biofuels credit. Client: National Biodiesel Board. January 2002.

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Valuation of the Global Market for Cellulose Acetate Wound Dressings. October 2000.

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Agricultural Input Market Analysis for the Seaway Grain Processors, Inc. Cornwall, Ontario Ethanol Plant: Grain and Co-Product Supply, Demand, and Price Outlook 2000-2010. August 2000.

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Assessment of the Market Potential for Zeolite A (Sodium Alumino Silicate Hydrate) in Companion Animals, Livestock, and Poultry. April 2000.

Soybean Meal Use in the U.S. Swine and Poultry Industries. Client: American Soybean Association and United Soybean Board. March 2000.

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Implications for the New Mexico Economy of Investment in Broadband Telecommunications Infrastructure. November 1999.

Economic Implication of a Shortage of Technical Support Specialists in the Information Technology Sector. August 1999.

Report of Damages Regarding Patent Infringement Damages Specific to Home Care Industries, Inc. v. Fitzpatrick. File No. 8740, July 1999.

Report of Damages in the Matter of Design By Us Company v. Best Foods, Inc. and Sherri Cup, Inc. Civil Action No. 98CV736. (July 1999)

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Administration, Office of Integrated Forecasting and Analysis, U.S. Department of Energy, May 1998.

Implications for the California Economy of Increased Telecommunications Bandwidth. February 1998.

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Soya as a Functional Food. Paper presented to the Latin American Congress on Nutrition, Latin American Nutrition Society. Guatemala City. November 1997.

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Public Interest Document for Fosthiazate Use on Potatoes, Peanuts, Tobacco, and Tomatoes. April 1997.

Economic Contribution of the California Hass Avocado Industry. Prepared for the California Avocado Commission. July 1996.

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Public Interest Document for Sulfentrazone: Soybeans. March 1996.

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Impact of the 1993 Midwest Floods on Triphenyltin Hydroxide Use on Sugar Beets In Minnesota. January 1995.

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Economic Implications for Pennsylvania of Extending the Sales and Use Tax for Agriculture to the Commercial Horse Industry. Prepared for the Pennsylvania Live Horse Racing Council, November 1995.

Economic Incentive to Transship Imported Mexican Avocados from Restricted Northern Markets. October 1995.

Economic Feasibility, Benefit and Market Potential of Polyhydroxyalkanoic acids (PHA) Polymer Derived from Soybeans. May 1995.

An Analysis of the Full Implications for Federal Government Revenues and Outlays of the Partial Exemption for Alcohol Fuels from the Excise Tax on Motor Fuels. Client: Renewable Fuels Association, March 1995.

Value of CIPC on Potatoes in the United States. Analysis to support FIFRA Data Compensation Arbitration. CIPC Task Force v. Pin Nip. Inc. 1994

Contribution of the Commercial Horse Industry to the Economy of the Commonwealth of Pennsylvania (with Dr. Cathy Smith, Associate Professor of Agricultural Economics, Penn State University). Research study prepared for the Pennsylvania Live Horse Racing Association, December 1994.

Potential Effects of River Boat Gaming on the Pennsylvania Race Horse Industry and the Pennsylvania Economy. Study prepared for the Pennsylvania Live Horse Racing Association, December 1994

Impact for the Washington Economy of an Elimination of the 8 Percent Combined State and Local Sales and Use Tax on Capital Equipment Spending. Study prepared for the Association of Washington Business,
November 1994.

The Impact of Sega of America's Operations on the Economy of the San Francisco Metropolitan Area and California, June 1994.

Impact for the California Economy of an Exemption for the Manufacturing Sector from a 6 Percent Sales Tax on Machinery and Equipment Spending. Study prepared for Southern California Edison to support testimony before the California State Assembly, August 1993.

Potential for Irreparable Damage to CertainTeed Corporation Resulting from a Listing of Fiberglass on the National Toxicology Program Report on Carcinogens, June 1993.

The Impact of Nintendo of America's Operations on the Economy of the Seattle, Washington Metropolitan Area, February 1993.

Cotton and the Environment. December 1992.

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main 610.254.4700 fax 610.254.1188 www.lecg.com

Consumer Perceptions and Attitudes Regarding California Seafood and the California Seafood Industry and Recommended Marketing Strategies to Improve the Image of the Industry and Increase Consumption. Research study conducted for the California Seafood Council, September 1992.

Economic Implications of the Commercial Introduction of the Polygalacturonase Gene for Fresh Tomatoes in the United States. February 1991.

Metropolitan Area Demand for Gasoline and Ethanol: Implications of the Clean Air Act Amendments of 1990. Research report prepared for the National Corn Growers Association, February 1991.

A Proposed Tariffication Regime for Banana Imports into the European Community. December 1990.

Economic Implications of the Food Safety and Pesticide Provisions of the California Environmental Protection Act of 1990. Research report prepared for The Western Agricultural Chemicals Association, February 1990.

Economic Contribution of the Animal Health Drug Industry. Research report prepared for The Research Coalition for Animal Health and Productivity, September 1988.

TESTIMONY

Testimony before the U.S. House of Representatives Committee on Small Business regarding the impact of renewable energy production on rural America. Washington, DC. May 3, 2007.

Direct testimony and deposition in the matter of *Southern Minnesota Beet Sugar Cooperative v. Imperial Sugar Company.* AAA Case No. 77 489 Y 00084 06JRJ. March 2007.

Deposition in the matter of Methyl Tertiary Butyl Ether (MTBE) Product Liability Litigation. MDL No. 1358. Master File C.A. No. 1-00-1898 (SAS). United Stated District Court for the Southern District of New York. October 2005.

Deposition testimony regarding the economic impact of the New York State MTBE Ban in the matter of Case No. 00-CV-1073 (NAM-RWS). Oxygenated Fuels Association v.George Pataki and Eliott Spitzer. In the United States District Court for the Northern District of New York. Client: New York State Office of Attorney General. September 2003.

Testimony before the New Mexico State Economic, Rural Development and Telecommunications Committee Regarding the Implications for the New Mexico Economy of Investment in Broadband Telecommunications Infrastructure. November 1999.

Deposition testimony regarding economic damages in the matter of Design By Us Company v. Best Foods, Inc. and Sherri Cup, Inc. Civil Action No. 98CV736. September 1999.

Testimony before the Michigan Public Service Commission, Case No. U-11916 Regarding Proper Transfer Pricing Rules for Affiliate Transactions, July 1999.

Deposition testimony Regarding Economic Damages Regarding Patent Infringement in the Matter of Fort James Corporation v. Sweetheart Cup Company, Inc. Civil Action No. 97-C-1221. United States District Court for the Eastern District of Wisconsin.

Testimony before the Commonwealth of Pennsylvania, Department of State, Board of Vehicle Manufacturers, Dealers and Salespersons, Board File No. 98-60-03572, Scott Imports, Inc. d/b/a Main Line Honda v. American Honda Motor, Co., Inc. Harrisburg, PA. April 1999.

Plant Genetics Systems v. Novartis Seeds, Inc., Civil Action No. 96-459, United States District Court for the District of Delaware (Farnan, J.). Expert witness testimony for plaintiff on the issue of infringement damages regarding agricultural-genetic patented invention, November 1998.

Plant Genetics Systems, N.V. v. Ciba Seeds, Mycogen Plant Science Inc. and Agrigenetics, Inc., Civil Action No. 1:95CV00741, United States District Court, Middle District of North Carolina, Durham Division (Osteen, J.). Deposition testimony on the issue of economic damages to Plant Genetic Systems, N.V., resulting from infringement of United States Patent Nos. 5,254,799 and 5,545,565 (corn seeds genetically altered to produce toxins from the *Bacillus thuringiensis* bacterium), January 1998.

"Potential Economic Impact of the Expansion of Gambling on the Horse Racing and Commercial Horse Industries and the Commonwealth of Pennsylvania". Testimony before the Commonwealth of Pennsylvania Judiciary Committee of the House of Representatives. Pittsburgh, May 29, 1996.

"Contribution of the Commercial Horse Industry to the Economy of Pennsylvania." Testimony before the Committee on Agriculture and Rural Affairs of the Senate of Pennsylvania. Harrisburg, March 22, 1995.

Deposition Regarding the Economic Damages to Plant Genetic Systems, Inc. Resulting from Infringement of United States Letters Patent Nos. 5,254,799 and 5,545,565 (corn seeds genetically altered to produce the Bacillus thuringiensis bacterium) in the Matter of Civil Action No.1:95CV00741, January 1998.

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"Implications of the Crown-Vista Energy Project for the Economy of New Jersey." Testimony before the State of New Jersey General Assembly and Rules Committee, June 1995.

"Contribution of the Commercial Horse Industry to the Economy of Pennsylvania." Testimony before the Committee on Agriculture and Rural Affairs of the Senate of Pennsylvania. Harrisburg, March 1995.

"Implications for the Washington Economy of Eliminating the Eight Percent Combined State and Local Sales and Use Tax for Manufacturers." Testimony before the Committee on Ways and Means of the Washington State Senate. Olympia, January 1995.

"Deposition, Direct Testimony, and Cross-Examination on the Economic Impacts of EBDC Label Restrictions." Administrative Court, U.S. Environmental Protection Agency. Washington, D.C., May 1994.

"Impact of AB1313, A Bill to Create a Six Percent Tax Credit for Firms Locating or Expanding Corporate Headquarters in California." Testimony before the Committee on Revenue and Finance of the California Assembly. Sacramento, May 1994.

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"Economic Analysis of the Impacts of a Change in State Sales and Use Taxes." Testimony before the Capital Equipment Advisory Council of the Minnesota State Legislature. St. Paul, November 1993.

"Economic Implications of the Asset Disposition and Revitalization Credit to Reduce RTC Debt." Testimony before the Subcommittee on Taxation of the Senate Finance Committee hearings on S.1787. Washington, D.C., October 1991.

"California Pesticide Residue Initiative: Probable Effects on U.S. International Trade in Agricultural Food Products." Testimony presented before the United States International Trade Commission on Investigation No. 332-292. Washington, D.C., July 1990.

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"Macroeconomic Implications of Mandatory Production Controls for U.S. Agriculture." Testimony before the House Agriculture Committee, Wheat, Soybeans and Feed Grains Subcommittee. Washington, D.C., March 1987.

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"Economic Implications of the Chernobyl Nuclear Disaster." Testimony before the Senate Agriculture Committee (in closed session). Washington, D.C., May 1986.

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"Impact of the Packwood/Senate Finance Committee Tax Reform Proposal on U.S. Agriculture." Testimony before the Subcommittee on Agriculture and Transportation of the Joint Economic Committee of Congress. Washington, D.C., April 1986.

"Economy-Wide Impacts of Agriculture Sector Loan Losses." Testimony before the Subcommittee on Economic Stabilization of the House Banking, Finance, and Urban Affairs Committee. Washington, D.C., October 1985.

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SELECTED CONFERENCE PRESENTATIONS

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Economic Consequences of Biofuels Expansion. Farm Foundation/USDA Biofuels, Food and Feed Tradeoffs Conference. St. Louis, April 2007.

Economic Impacts on the Farm Community of Cooperative Ownership of Ethanol Production. USDA Agricultural Outlook Forum 2007. Crystal City, VA. March 2007.

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LECG

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Daniel J. Kowalski

1255 Drummers Lane, Ste. 320
Wayne, PA 19087
Telephone: 610-254-4032
Fax: 610-254-1188
E-Mail: dkowalski@lecg.com

EDUCATION

M.Agr. Agricultural, Environmental, & Regional Economics, The Pennsylvania State University, University Park, PA, 2006

B.S. Natural Resource Management; Minors: Resource Economics, Biology, University of Delaware, Newark, DE, 2002

PRESENT POSITION

LECG LLC, Wayne, PA

Associate 9/06-Present

- Assisted in the preparation of economic feasibility studies for biofuels financing projects
- Provided economic and report writing support for product liability litigation related to consumer product goods and fuel additives
- Managed store-level financial data and an impact multiplier model as part of an effort to determine the effects of a global coffee retailer on its local communities
- Prepared time-series econometric analyses to support litigation related to historic commodity prices
- Conducted extensive research related to historical and current issues affecting the ethanol industry

PREVIOUS POSITIONS

The Pennsylvania State University, University Park, PA

Research Associate 9/04-6/06

- Conducted research on commodity price elasticity and the related effects on consumer demand
- Gathered local, state, and federal pricing data and calculated statistical results

- Evaluated economic impacts of agricultural/environmental practices on the drinking water supply of New York City
- Created a presentation to highlight our research at a national conference
- Performed comprehensive academic literature reviews of past research
- Collaborated efforts with researchers from other agencies and universities
- Worked with a cooperative association to analyze the financial benefits of membership; results will be used for recruiting and marketing purposes

SECOR International Inc., Exton, PA

Staff Consultant 2/03-4/05

- Prepared quarterly and ad hoc progress reports for clients and regulatory agencies
- Formulated cost/benefit analyses for the refining industry
- Assisted in the management of complex, multi-contractor construction projects
- Assisted in the development of multiple projects from proposal to completion
- Analyzed extensive data to identify trends that would demand change in management strategy

Researched historic sensitive legal documentation as part of a litigation support team

Appendix D. Pollen-mediated gene flow report submitted by Syngenta

Minimization of Pollen-Mediated Gene Flow from Corn Amylase Corn through Planting Border Rows

Over the past several years a number of studies have been published on the distribution of corn pollen and the potential transgenes to fertilize other corn. The USDA APHIS BRS reviewed this topic in their Draft Programmatic Environmental Impact Statement on the Introduction of Genetically Engineered Organisms (USDA 2007). Syngenta's analysis of pollen-mediated gene flow (PMGF) from corn amylase corn (CA) to non-corn amylase corn (NCA) is built upon several published studies, i.e., Jarosz et al. (2003), Jemison and Veyda (2001), Ma (2005), Ma et al. (2004) and Westgate et al. (2003). However, emphasis was placed upon the work of Dr. Ma, Eastern Cereal and Oilseed Research Center, Agriculture and Agri-Food Canada (http://www.isb.vt.edu/articles/feb0502.htm). Dr. Ma's findings were consistent with or more conservative than the other studies, i.e., the potential for pollen movement over a longer distance and a greater probability for PMGF at the same distance. Furthermore, Dr. Ma's exponential decline model indicates essentially a zero probability of detecting PMGF beyond six hundred and sixty-six feet (200 meters) (Table 1).

Using Dr. Ma's model, Syngenta calculated the probability of PMGF from a 75-acre field of 100% CA corn to NCA corn planted on all four sides. The analysis was performed with and without 12 NCA corn border rows surrounding the CA field. The NCA corn was planted immediately adjacent to the CA corn (Scenario 1, Figure 1) or the 12th border row (Scenario 2, Figure 2). As previously communicated to APHIS BRS on September 6, 2007, Syngenta, post-commercialization, will instruct growers to plant 12 border rows around each CA field.

The following assumptions were made in calculating PMGF in these two scenarios:

1. CA corn pollen will flow to the NCA corn bordering all four sides and corners of the CA field.

2. The probability of CA corn PMGF beyond the edge of the CA field or 12th border to 200 meters in the NCA corn fields was calculated using Dr. Ma's exponential decline model (Ma 2005).

3. 100% of the corn in the CA field contains the corn amylase trait.

Based on these assumptions, and the Ma exponential decline model, under Scenario 1, Syngenta calculates that 0.19% of the NCA corn planted adjacent to the CA corn to 200 meters will contain the CA gene (Table 1, Row 1). Under Scenario 2, 0.005% of the NCA corn planted adjacent to the 12th border row to 200 meters will contain the CA gene (Table 1, Row 12). Consequently, the 12 border rows surrounding the CA corn field capture 97.2% of all CA pollen (0.190% - 0.005%) / (0.190%) = 97.2%.

By blending the border rows with the harvested CA corn, >99.9% of all CA is captured. For example, assume 100 acres of CA is planted and 170 acres of NCA is planted adjacent to the CA corn to achieve the 200 meters distance cited by Ma (Figure 1).

With yields of 180 bushels per acre (bpa), the total production of CA would be:

100 CA acres x 180 bpa = 18,000 CA bushels

170 NCA acres x 180 bpa = 30,600 NCA bushels x 0.19% adventitious CA = 58 bushels

Total CA bushels from 100 acre CA field and 170 acre NCA field = 18,058 bushels

With 12 border rows the CA production beyond the 12 border rows is 1.5 bushels (170 acres x 180 bpa x 0.005% adventitious CA). Therefore, the total CA capture is 18,058 bushels less the 1.5 bushels divided by 18,058 = 99.99%.

Literature cited

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Figure 1. Planting configuration of corn amylase (CA) and non-corn amylase (NCA) corn without 12 separating border rows (Scenario 1).

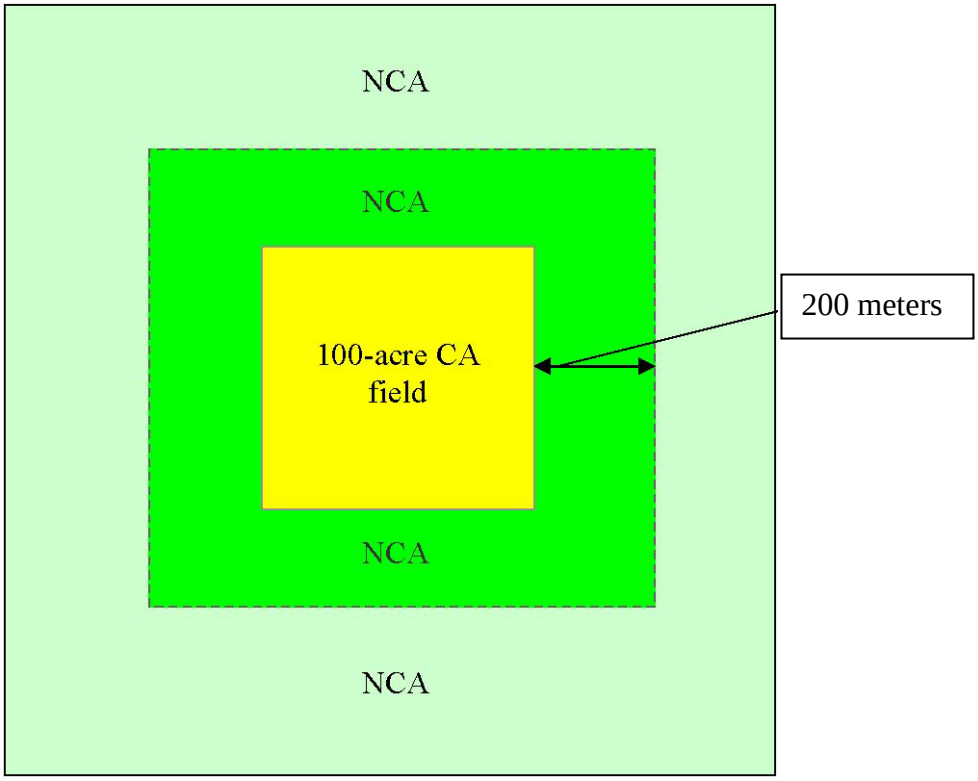

Figure 2. Planting configuration of corn amylase (CA) and non-corn amylase (NCA) corn with 12 separating border rows (Scenario 2).

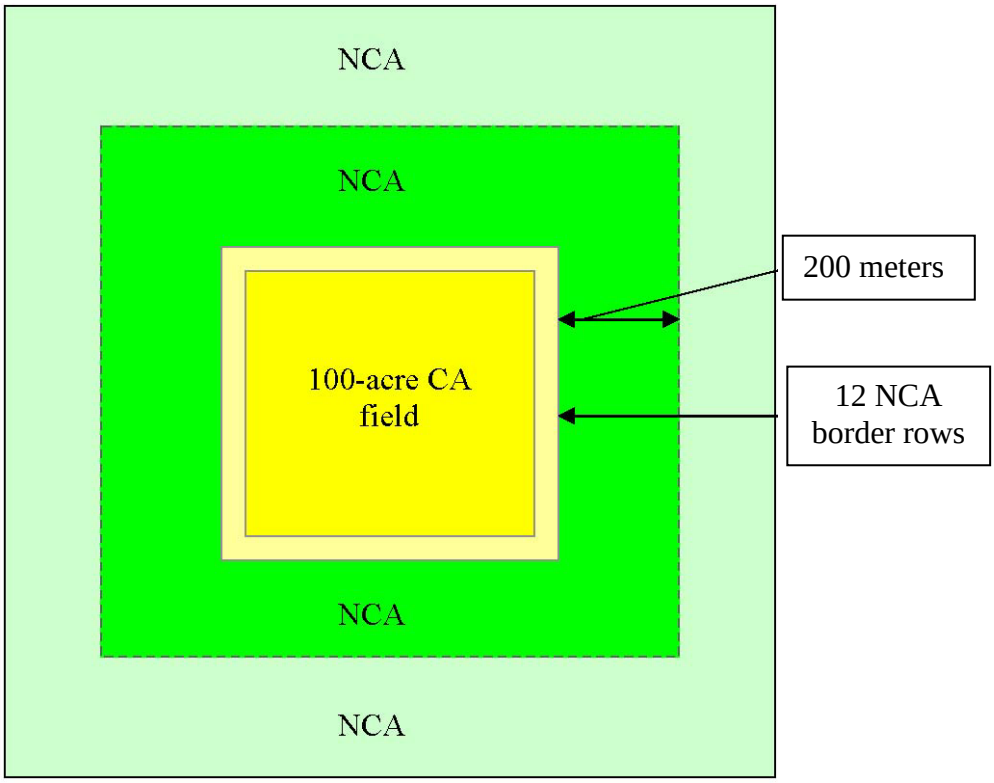

Table 1. Percent pollen-mediated gene flow downwind and upwind of source corn pollen as extrapolated from Ma (2005)[1].

Row #[2]	Distance (meters)	Downwind	Upwind	Downwind Mean	Upwind Mean	Overall Mean	Beyond Mean[3]
0	0.00	0.00%	0.00%	0.00%	0.00%	0.00%	0.19%
1	**0.75**	**20.35%**	**9.47%**	**20.35%**	**9.47%**	**14.91%**	**0.19%**
2	1.50	14.96%	5.83%	17.66%	7.65%	12.65%	0.13%
3	2.25	11.00%	3.59%	15.44%	6.30%	10.87%	0.10%
4	3.00	8.09%	2.21%	13.60%	5.27%	9.44%	0.07%
5	3.75	5.95%	1.36%	12.07%	4.49%	8.28%	0.05%
6	4.50	4.38%	0.84%	10.79%	3.88%	7.34%	0.04%
7	5.25	3.22%	0.52%	9.71%	3.40%	6.55%	0.03%
8	6.00	2.37%	0.32%	8.79%	3.02%	5.90%	0.02%
9	6.75	1.74%	0.20%	8.01%	2.70%	5.35%	0.01%
10	7.50	1.28%	0.12%	7.33%	2.44%	4.89%	0.01%
11	8.25	0.94%	0.07%	6.75%	2.23%	4.49%	0.01%
12	**9.00**	**0.69%**	**0.05%**	**6.25%**	**2.05%**	**4.15%**	**0.005%**
13	9.75	0.51%	0.03%	5.81%	1.89%	3.85%	0.00%
14	10.50	0.37%	0.02%	5.42%	1.76%	3.59%	0.00%
15	11.25	0.28%	0.01%	5.08%	1.64%	3.36%	0.00%
16	12.00	0.20%	0.01%	4.77%	1.54%	3.16%	0.00%
17	12.75	0.15%	0.00%	4.50%	1.45%	2.97%	0.00%
18	13.50	0.11%	0.00%	4.26%	1.37%	2.81%	0.00%
19	14.25	0.08%	0.00%	4.04%	1.30%	2.67%	0.00%
20	15.00	0.06%	0.00%	3.84%	1.23%	2.53%	0.00%
30	22.50	0.00%	0.00%	2.56%	0.82%	1.69%	0.00%
40	30.00	0.00%	0.00%	1.92%	0.62%	1.27%	0.00%
50	37.50	0.00%	0.00%	1.54%	0.49%	1.02%	0.00%
60	45.00	0.00%	0.00%	1.28%	0.41%	0.85%	0.00%
70	52.50	0.00%	0.00%	1.10%	0.35%	0.73%	0.00%
80	60.00	0.00%	0.00%	0.96%	0.31%	0.63%	0.00%
90	67.50	0.00%	0.00%	0.85%	0.27%	0.56%	0.00%
100	75.00	0.00%	0.00%	0.77%	0.25%	0.51%	0.00%
120	90.00	0.00%	0.00%	0.64%	0.21%	0.42%	0.00%
140	105.00	0.00%	0.00%	0.55%	0.18%	0.36%	0.00%
160	120.00	0.00%	0.00%	0.48%	0.15%	0.32%	0.00%
180	135.00	0.00%	0.00%	0.43%	0.14%	0.28%	0.00%
200	150.00	0.00%	0.00%	0.38%	0.12%	0.25%	0.00%
220	165.00	0.00%	0.00%	0.35%	0.11%	0.23%	0.00%
240	180.00	0.00%	0.00%	0.32%	0.10%	0.21%	0.00%
260	195.00	0.00%	0.00%	0.30%	0.09%	0.20%	0.00%
267	200.25	0.00%	0.00%	0.29%	0.09%	0.19%	0.00%

[1] Data presented in this table was calculated using the exponential decline model described in Ma (2005, http://www.isb.vt.edu/articles/feb0502.htm).

[2] Number of rows from the edge of the Corn Amylase (CA) field into a field of non-CA corn.

[3] The "Beyond Mean" refers to the percent of pollen mediated gene flow in non-CA corn from the distance indicated to 200 meters from the edge of the CA field.

Appendix E. Food processing report submitted by Syngenta

Event 3272 Corn and Food Processing

Event 3272 corn expresses the thermostable AMY797E alpha-amylase in the endosperm of the grain. This enzyme hydrolyzes starch to sugar during the liquefaction phase of dry grind ethanol production. As presented in Syngenta's petition 05-280-01p, the compositional analysis of Event 3272 corn demonstrated it is not materially different from commercial corn hybrids. Although the presence of this alpha-amylase may have an impact on certain processed corn products due to the conversion of starch to dextrins and sugars during processing, neither the starch itself nor any other nutritional component of Event 3272 corn has been altered by the genetic modification. Furthermore, as demonstrated by Syngenta's concluded consultation with the FDA (BNF 0095), there is no food safety issue associated with the possible presence of the AMY797E alpha-amylase enzyme in foods.

While beneficial for ethanol production, the activity of AMY797E alpha-amylase may either have no effect or potentially may have desirable or undesirable effects on certain types of processed corn food products. AMY797E alpha-amylase is not able to act on the starch in the intact kernel. However, during or after processing with the addition of water and heat, enzyme activity could result in the conversion of some starch to dextrins and sugars. It is this potential for alpha-amylase starch hydrolyzing activity, during or after processing, that may impact properties of the corn or its components used in food.

However, the quality and properties of processed corn (e.g. dough handling characteristics) and finished processed food products (e.g. corn chips) are dependent on many factors. These include the characteristics and condition of the raw corn as well as specific process variables such as, cooking time, temperature, type of equipment, degree of grinding (particle size), moisture content and baking time. Furthermore, commercial hybrid seed companies have specifically developed corn hybrids with improved properties desirable by the food industry, e.g. (white, waxy, hard endosperm, high oil, low temperature dried, high extractable starch, etc.) that have good yield and are adapted across regions of the U.S. corn belt. These hybrids are specified by buyers and end-users of corn for production and premiums are paid for growing, delivering, and meeting and maintaining the purity and quality standards of the corn. In addition to grain sourcing, a number of additional measures are employed throughout the food process including inspection and grading of the corn, cooking the corn, formulation and testing of the final food product. These commonly employed quality control measures ensure that corn food products are acceptable to consumers.

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Hallauer, A.R., *Specialty Corn*, Second Edition CRC Press, 2000.

Appendix F. Food processing report specific to masa submitted by Syngenta

Dilution of Corn in Masa Supply Chain

To estimate the dilution effect of Corn amylase (CA) corn in non-CA (NCA) corn that could potentially reach a masa production facility, Syngenta conducted interviews with grain merchandisers to understand the movement of corn and the commingling with other corn that occurs during transport and storage. This information was further supplemented with Syngenta internal analysis of grain dilution patterns.

Masa facilities typically source their grains from within 50 miles of the plant (C. Morley, Global Risk Management, Eden Prairie, MN,). White corn comprises approximately 80% of the grain used for masa and is typically contracted because it is higher in density, protein and oil and lower in moisture, thins and starch basis in comparison to yellow corn (Sparks 2003; U.S. Grains Council 2007). Yellow corn may also be contracted and is used for color and texture (Sparks 2003). While both white and yellow corn varieties are often contracted (up to 80%; C. Morley), if bought on the open market , the grain would either be obtained directly from a grower, local elevator or other local third party supplier. These same distribution channels would also apply to CA grain that is mistakenly delivered to a masa plant. Considering these likely distribution paths, Syngenta analyzed the grain dilution that occurs for each.

The first case assumes a CA grower delivers a truck load of CA grain directly from a production field or on-farm silo to a masa plant. In this case the truck contains only CA corn was and is unloaded into a holding bin of non-CA corn at the plant. Drawing corn through a bin will commingle the grain 3x to 16x depending on bin size and fullness at the time of delivery (Syngenta unpubl. data). To be conservative, Syngenta estimates a dilution rate of 5x for direct delivery. If, however, the grain first went to a local elevator and then later delivered to a masa facility it would have be drawn through two bins and one truck before being used by the facility. This dilution factor is estimated at approximately 50x, i.e., approximately 10x at the local elevator (larger bins) and 5x at the masa storage bin (10x time 5x = 50x).

It is important to note that there is no food safety issue associated with the possible presence of the alpha-amylase enzyme in foods as demonstrated by Syngenta's concluded consultation with the FDA (BNF 0095). Furthermore, the likelihood of grain being mistakenly delivered directly to a masa plant by a grower from their farm is very remote. Growers will be contracted and paid a premium for producing CA grain and consequently, will have both contractual and financial incentives to deliver this grain to the ethanol plant. In addition, a large percentage of both white and yellow grain (up to 80%) is contracted and yellow represents just 20% of the total used to produce masa. Nonetheless, if a masa plant or other

food processing company desires to determine whether their grain contains the alpha-amylase enzyme a test method will be available for their use.

References:

U.S. Grains Council, *Value Enhanced Corns Report 2005/2006*, available at http://www.grains.org/galleries/technical_publications/USGC%20Value%20Enhanced%20Corn%20Report%202006%20%20(English).pdf

Sparks Companies, Inc., *The US Corn Masa Industry: Structure and Implications for the Great Plains Region*, Prepared for Agricultural Marketing Resource Center (http://www.agmrc.org), Kansas State University, 2003. Available at http://www.agmrc.org/NR/rdonlyres/EC8E389D-7085-40ED-B8B2-0B02B0AC4552/0/sparkswhitecornpaper.pdf

Appendix G. Bryson and Roberts report submitted by Syngenta

The Role of the Specialty Grain, Closed-Loop Production System for Event 3272 in Supporting a Finding of No Significant Impact Under the National Environmental Policy Act

By
Nancy S. Bryson
and
Michael T. Roberts

December 19, 2007

I.

Introduction

The deregulation of new plant biotechnology events by APHIS is a federal action that requires evaluation under the National Environmental Policy Act ("NEPA").[13] APHIS has historically found that the deregulation of such events in corn have not been "major federal actions significantly affecting the human environment."[14] NEPA compliance has been effectuated through an environmental assessment taking the "hard look" at the environmental effects of the action that has been required by reviewing courts,[15] and a finding of no significant impact.

Event 3272 fits comfortably into this body of NEPA analysis. Event 3272 corn is a novel transgenic corn variety that contains a genetically inserted thermostable alpha-amylase enzyme that facilitates the production of ethanol by the dry grind process. Alpha-amylases are ubiquitous in the environment. They have a long history of safe consumption by humans and animals and the particular alpha-amylase incorporated in Event 3272 has successfully completed the Food and Drug Administration (FDA) food safety consultation process.

Event 3272 presents no unique or novel issues relating to the environmental impacts that have been identified by APHIS as relevant environmental effects for NEPA analysis.[16] Like other specialty corns in the marketplace, Event 3272 may not be suitable for use in some processing applications, but this does not change the NEPA analysis. Event 3272 will be grown and managed in the marketplace as a specialty grain produced in a tightly-controlled, closed loop system. This system will prevent any effect arising from a lack of suitability for uses for which it is not intended from rising to a level of "significance" under the relevant NEPA factors of context and intensity. Accordingly, the deregulation of this event will not significantly affect the human environment within the meaning of NEPA.

The commercial value of Event 3272 is for dedicated ethanol production in the dry grind process. The realization of that value will be ensured by a closed-loop system that reliably channels this corn from the production field into dry grind ethanol production and

[13] 42 U.S.C.§§ 4321 et seq.

[14] 42 U.S.C. § 4332(2)(C).

[15] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).

[16] USDA, Animal and Plant Health Inspection Service (APHIS), *Introduction of Genetically Engineered Organisms, Draft Programmatic Environmental Impact Statement – July 2007*, 67– 90 ("DEIS").

away from the commercial channels intended for the production of processed corn food products such as masa. This process includes the Event 3272-specific Syngenta Stewardship Program, the well-established and recognized ability of the existing commercial marketplace to manage specialty grain product under contract and quality management systems, the enhanced legal traceability recordkeeping requirements of the Bioterrorism Act, and a reliable and widely available Event 3272 detection test.

Event 3272 will be deregulated in the context of a market replete with numerous other specialty grain products produced and marketed in the U.S. under well-defined identity preservation and traceability systems. As another specialty grain product, the intensity of the impact of its deregulation will be very low. As such, a finding of no significant impact can be made on the basis of the robust controls that govern these systems.

II.

Requirements of the National Environmental Policy Act (NEPA)

NEPA requires that agencies undertaking a major Federal action "significantly affecting the quality of the human environment" provide a detailed statement of the environmental impact of the proposed action, any adverse environmental effects that cannot be avoided, and alternatives to the action."[17] Where the significance of an action is uncertain, agencies may use an Environmental Assessment ("EA") to identify, analyze, and evaluate the impacts of the proposed action. The EA will satisfy the NEPA obligation where it provides sufficient evidence and analysis to support a "finding of no significant impact ("FONSI")."[18]

In order to support such a finding, the agency must have:

- accurately identified the relevant environmental concern;
- taken a hard look at the problem in preparing the environmental assessment, and
- made a convincing case for the FONSI.

If there is an impact of true significance, the preparation of an environmental impact statement can be avoided only if changes are made that reduce the impacts of the action to a minimum.[19] The test of whether an action "significantly" affects the environment requires

[17] *Id.*

[18] *See e.g., Coalition on Sensible Transp., Inc. v. Dole*, 826 F. 2d 60 (D.C. Cir. 1987).

[19] *Grand Canyon Trust v. FAA*, 290 F. 3d 339, 340-41 (D.C. Cir. 2002).

considerations of both context and intensity.[20] The term "context" refers to the setting within which the proposed action takes place.[21] In considering context, an agency must look at the significance of an action "analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality."[22] The term "intensity" refers to "the severity of the impact."[23]

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[20] 40 C.F.R. § 1508.27.

[21] 40 C.F.R. § 1508.27(a).

[22] *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 374 (1989) (quoting 40 C.F.R. § 1508.27).

[23] *Id.* With regard to the intensity element of the "significance" determination, the Council on Environmental Quality (CEQ) regulations provide the following ten (10) factors to guide the analysis:

(1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.

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

(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.

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

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

(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.

(7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts.

(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.

(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.

(10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

A recent unreported decision[24] from the Northern District of California in *Geertson Seed Farms v. Johanns* held that APHIS was required to prepare an Environmental Impact Statement (EIS) to support a decision to grant deregulation to a glyphosate-resistant (i.e., Round-up Ready) alfalfa product, and rejected the APHIS EA and FONSI as insufficient.[25] The court examined the factors of "context" and "intensity" in light of the NEPA goals of "attaining the widest range of beneficial uses of the environment without degradation, risk to health and safety, or other undesirable and unintended consequences" and "maintain[ing], wherever possible, an environment which supports diversity and variety of individual choice."[26] The court concluded that substantial and unanswered questions existed regarding gene transmission to non-genetically engineered alfalfa, the development of alfalfa weeds resistant to herbicides, and increased use of glyphosate.[27] The court held that the possibility that the deregulation of Round-up Ready alfalfa will degrade the human environment by eliminating a farmer's choice to grow non-genetically engineered alfalfa and a consumer's choice to consume such food is a significant impact that requires an EIS.

By contrast, the Syngenta Event 3272 presents a fundamentally different situation. Unlike the alfalfa industry, the segmentation and specialization of corn production has generated a suite of standard industry practices in the U.S. grain marketing system that has been shown to facilitate coexistence among different varieties and obviate the potential gene flow consequences posed by alfalfa, as addressed in *Geertson*. Event 3272 corn is being released in an environment in which the diversity of corn is closely guarded, and continually enhanced. This is evident from the commercial channels and identity preservation programs that have been developed in this modern grain system to manage the co-existence of a variety of corn products.

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40 C.F.R. § 1508.27(b).

[24] Unreported decisions issued by the courts are binding on the parties, but are not generally accepted as precedent - even by the issuing court.

[25] *Geertson Seed Farms v. Johanns*, No. C 06-01075 (N.D. Cal., Civ. Feb. 13, 2007).

[26] 42 U.S.C. § 4331(b)(3)-(4).

[27] *Geertson, supra* note 13.

III.

Modern U.S. Grain System: Identity Preservation and Co-Existence

A. Factors Enabling Identity Preservation and Co-Existence

The modern U.S. grain system is characterized by identity preservation, product differentiation, and market segmentation.[28] This system has evolved in response to the development of a variety of specialty grain crops that require some form of segregation from conventional grain commodities in order to maintain their value to the end users. Examples include popcorn, waxy (high amylopectin) corn, high oil corn, high protein and modified protein corn, sweet corn, white corn, blue corn, Indian corn, higher fermentable corn and high amylose corn.[29] As a result, robust identity preservation systems with separate marketing channels prevent inadvertent commingling of specialty crops.

A number of factors have helped create this segmented market, including biotechnology, consumer preferences and demand, global concerns for safety and quality, and the increasing demand for food products originating from diverse sources.[30] For example, the corn wet-milling industry produces starches and sweeteners or syrups tailored to specific food and industrial uses. This has led to an increased demand for trait-specific corn types such as high-amylose corn.[31]

Innovations in transportation, logistics, and information technologies and changes in the international regulatory environment have also facilitated the marketing of differentiated grains. Web-based monitoring software can remotely assess the quantity and quality of grain

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[28] *See generally Aziz* Elbehri, *The Changing Face of the U.S. Grain System: Differentiation and Identity Preservation Trends*, USDA ERS (Feb 2007) at 1, *available at* www.ers.usda.gov/publications/err35/err35.pdf.

[29] U.S. Grains Council, *Value Enhanced Corns Report 2005/2006, available at* www.grains.org/.../technical_publications/USGC%20Value%20Enhanced%20Corn%20Report%202006%20%20(English).pdf

[30] *See* Linus U. Opara, *Traceability in agriculture and food supply: a review of basic concepts, technological implications, and future prospects*, Food and Agriculture & Environment Vol. 1 (1), 101 (2003).

[31] *See generally* Kevin B. Hicks, et al., *Potential New Uses for Corn Fiber*, Corn Utilization and Technology Conference (2002), *available at* *http://www.ars.usda.gov/research/publications/publications.htm?SEQ_NO_115=132521;* Corn Refiners Association, *Starch Products, available at* www.corn.org/starch.htm; Corn Refiners Association, *Sweeteners, available at* *http://www.corn.org/sweeteners.htm.*

inventories in a supplier's storage facilities. Communication networks and increased reliance on the Internet are cutting the costs of differentiation.[32] The implementation of the European Union food traceability and labeling directives[33] and the Cartagena Protocol on Biosafety[34] have compelled agribusinesses, particularly grain elevators and grain warehouses at the front of the supply chain, to track closely shipments and supplies.[35]

B. Identity Preservation Tools

Identity preservation or product differentiation relies on source verification – traceability, product tracking, and process verification. Traceability then is an important tool that "helps facilitate the identification of product(s) and/or batches."[36] Agricultural traceability has been defined as the

> collection, documentation, maintenance, and application of information related to all processes in the supply chain in a manner that provides guarantees to the consumer and other stakeholders on the origin, location, and life history of a product as well as assisting in crises management in the event of a safety and quality breach.[37]

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[32] Elberhri, *supra* note 16, at 5.

[33] *See generally* Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food, and Feed in the European Union* , 1 J. OF FOOD L. & POL'Y 43 (2005) (discussing traceability, labeling, and coexistence measures in the European Union).

[34] The Cartagena Protocol on Biosafety was adopted on January 29, 2000, signed by 107 parties, and by September 2003 was ratified by 50 countries, the minimum required for the Protocol to enter into force. Countries that ratified the Protocol became Parties to the Protocol and are required to comply with and implement all of its provisions. Countries that have not signed but that export Living Modified Organisms (LMOs) to member countries are encouraged to comply with the Protocol's provisions implemented in the importing country.

[35] *See* Elberhri, *supra* note 16, at 25.

[36] Opara, *supra* note 18, at 103.

[37] *Id.* at 102.

A major feature in a traceable supply chain is the ability to trace-back or trace-forward and track the physical location of the product in the overall supply chain.[38]

Commercial contracts provide another important tool for product differentiation in the modern grain system. Contracts for identity preserved grains govern relations and establish stewardship controls between farmers and seed suppliers, handlers, intermediary firms, and processors. These contracts are typically uniform and establish terms for specific variety, delivery time, delivery place, dedicated storage, and quality control.[39]

C. Private Market Initiatives

To retain their competitive advantage in the global market and to address domestic food safety and quality issues, U.S. grain producers and handlers have relied on the contract and traceability tools described above to implement methods to produce, handle, and market trait specific grains, including documentation systems that trace raw materials back to the farm. Traceability and documentation are considered core competencies for grain operations.[40]

These competencies are especially well developed for value-added grains or specialty corn products. These value-added products are produced in large volumes and are segregated by channeling.[41] Segregation by channeling flows from the farm to the transporting truck to the grain elevator and commingling is minimized by running equipment empty before switching varieties or designating certain days of the week or alternate sites for receiving and shipping these specialty crops.[42] Crops handled by this method include a variety of value-added crops, such as white, waxy, yellow food-grade, high-oil, non-GM corn, and durum wheat grown in the Southwest.[43]

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[38] *See id.*

[39] *See* Elbehri, *supra* note 16, at 18.

[40] *See* Tim Herrman, *White Paper on Traceability in the U.S. Grain and Plant Protein Feed Ingredient Industries* (July 2, 2002), at 1, *available at* www.oznet.ksu.edu/grsiext/White%20Paper%20CVM.PDF.

[41] *See* Elbehri, *supra* note 16, at 6.

[42] *Id.* at 6-7.

[43] *Id.* at 7.

Additional identity-preservation controls are found in what is commonly referred to as a "closed-loop system." This system is used to preserve the identity of value-added grain products, such as high-amylose corn. As noted by the Economic Research Service (ERS) for the USDA, a closed-loop delivery system has distinct advantages over segregation by channeling:

> A closed-loop system provides more controls than mere channeling, and better protects the value of a specialty crop such as high-sucrose soybeans, high-oleic soybeans, or high-amylose corn. Production occurs almost exclusively under a contract between the grower and end-user. Typically, these production contracts mandate delivery of all production to a specified location, and require midseason inspections and return of all unused seed to the seed company. Third-party auditors also verify that the system is in fact a closed loop and that all requirements have been adhered to throughout the system.[44]

This closed-loop system for the delivery of value-added, specialized corn or grain product clearly contrasts with the marketing of commodity corn, primarily yellow dent corn. Commodity corn is used for animal feed and is processed by wet and dry milling industries for numerous and diverse food and industrial products, including ethanol. Specialty corn, on the other hand, especially in the closed-loop system, is handled differently than commodity corn throughout the supply chain – from seed production to grain handling – in order to ensure that a sufficient quantity of high quality corn is produced and delivered to the end-user for its particular use. This control also helps to ensure that the specialty corn is not used in unsuitable applications, which could result in process breakdowns or products with altered or undesired characteristics.

D. Supplemental Mechanisms, Standards, and Recordkeeping Requirements

In addition to private initiatives, a variety of supporting mechanisms, standards, and legal requirements support product identification and the management of coexistence in the U.S. grain system today.

1. BIO Quality Management Program Guide

The Biotechnology Industry Organization (BIO) recently launched a new

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[44] *Id.* at 7.

program, *Excellence Through Stewardship: Advancing Best Practices in Agricultural Biotechnology*, the first industry-coordinated effort to address product stewardship and quality management.[45] This industry stewardship program is described in the *Quality Management Program Guide to Maintaining Plant Product Integrity*.[46] The guide is for member companies and others involved in agricultural biotechnology research and development to use in understanding and implementing their own best practices. The Guide provides detailed guidance on how to develop and implement a quality management program that will assist product developers in maintaining plant product integrity from discovery to commercialization and post-market activities. It includes a series of comprehensive and informative educational modules that can be adapted to the specific activities pertinent to the user's own operations, including incorporation into existing quality management systems. Common to all of the modules is an emphasis on the importance of product identification and traceability.[47]

Syngenta supports the new BIO stewardship program. As a company, Syngenta has adopted the following best practices and quality management principles to serve as a guide when it launches new products:

- Syngenta will conduct market and trade assessments to identify key import markets for all of its biotech products prior to product commercialization.

- For each biotech product, at the time U.S. submissions are completed, Syngenta will begin to consult with the major, relevant trade and value chain stakeholders on detailed plans for pre-commercial activities, and full-scale commercialization.

- Syngenta will meet all necessary regulatory requirements in key exporting countries (where the seed will be commercialized) and importing countries that have functioning regulatory systems, which currently include the United States, Canada and Japan, prior to commercialization, unless determined otherwise in consultation with

[45] *See* Excellence Through Stewardship website, *BIO Launches Excellence Through StewardshipSM Program Initiative Introduces Best Practices For Quality Management of Plant Biotechnology Products*, July 25, 2007, *available at* http://excellencethroughstewardship.org/press/newsitem.asp?id=2007_0725_01.

[46] *See id.*

[47] *See id.*

the value chain that a dedicated grain management system is workable for a specific product.

- Syngenta will make available prior to commercialization a reliable detection method or test that enables event identity in the crop.

- Syngenta is committed to the principles of good stewardship, which are exemplified through the responsible management of Syngenta products across their lifecycle, from research through development and commercialization to their discontinuation and withdrawal from the market.

- Syngenta will continue to work at the global level with the value chain to engage in efforts to harmonize science-based agriculture biotechnology regulatory approaches to achieve Global Adventitious Presence tolerances and synchronous authorizations.[48]

2. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)

The Food and Drug Administration (FDA) is responsible for assuring that food is not adulterated – i.e. poisonous, deleterious, unclean, decomposed, exposed to unsanitary conditions, or contaminated with filth.[49] Following the September 11, 2001, terrorist attacks, the FDA's authority to deter, prevent, and respond expeditiously to food safety emergencies was enhanced by enactment of the Bioterrorism Act.[50] The Act adopts the central feature of a traceable supply chain by requiring "step-back/step-forward" recordkeeping for all grain product moving within commercial channels.[51] Entities in the grain industry, including grain elevators, feed mills, grain processors, feed ingredient manufacturers, retail feed stores, feed

[48] Syngenta website, *Biotech Launch Policy Syngenta Implementation Principles, available at* http://www.syngenta-us.com/scenter/index.asp?nav=biotech_policy_main.

[49] *See* 21 U.S.C. § 342(a)(1)-(7), (c).

[50] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188 (codified in scattered sections of 42 U.S.C.).

[51] *See* 21 U.S.C. § 350(c).

dealers, and transporters (truckers, railroads, and barge lines) are required to establish and maintain records containing information to help identify the grain product's immediate previous sources and the immediate subsequent recipients.[52] Guidance from the FDA and grain industry provides useful, practical guidance on how to deal with commingling, lot code or numbers, and an adequate description of product to ensure that the recordkeeping requirements are lawfully met.[53]

As more fully outlined in the companion white paper detailing these recordkeeping requirements, the Bioterrorism Act further bolsters identity preservation in the U.S. value-added grain industry.[54]

3. American Institute of Baking Quality Systems Management Program Guide (AIB)

The American Institute of Baking (AIB) is a non-profit corporation, founded in 1919 by the North American wholesale and retail baking industries as a technology center for bakers and food processors.[55] The AIB has introduced to the grain handling industry its Quality Systems Evaluation (QSE), a comprehensive audit that thoroughly evaluates a supplier's quality system.[56] The QSE covers such elements as raw materials, process control, process verification, finished product acceptability, storage and shipping, training, plant programs, and quality policies. Each grain facility is expected to pass an AIB Food Safety audit. In 2000, Farmland Grain Division first adopted QSE as its quality management system.

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[52] *See* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71, 561-62 (Dec. 9, 2004) (codified at 21 C.F.R. pts. 1, 11).

[53] *See* FDA, *Questions and Answers Regarding Establishment and Maintenance of Records* (Edition 4) (Sept. 2006), *available at* http://www.cfsan.fda.gov/~dms/recguid4.html; *See* National Grain and Feed Association (NGFA), *FDA's Bioterrorism Recordkeeping Requirements . . . A Compliance Guide for Grain Elevators, Feed Manufacturers, Feed Dealers, Integrators, Grain Processors and Transporters . . .* , April 2006.

[54] *See* White Paper, *The Bioterrorism Act of 2002: A Valuable Tool to Identity Preservation in the U.S. Value-Add Grain Industry* (Dec. 2007).

[55] *See* AIB website, https://www.aibonline.org/.

[56] *See* P.F. Stevenson, *AIB's Quality Systems Evaluation*, presented at International Quality Grains Conference, July 2004, *available at* http://cobweb.ecn.purdue.edu/~grainlab/IQGC1/proc/text/stevenson.htm.

Since then, many other grain handlers have utilized QSE as their template to achieve AIB or ISO recognition.[57]

4. USDA Initiatives

The mission of the USDA GIPSA is to facilitate the marketing of grains, oilseeds, and related agricultural commodities.[58] The process Verification Program offered by GIPSA ensures traceability and managing risk to settle disputes. GIPSA recently implemented a Proficiency Program to evaluate the performance of laboratories that test cereals, oilseeds, and feed ingredients for the presence of GM events in the U.S.[59] Other USDA initiatives are documented in recent ERS reports.[60]

5. American Seed Trade Association (ASTA) Guide to Seed Quality Management Practices

The American Seed Trade Association (ASTA) was founded in 1883 and consists of about 850 companies involved in seed production and distribution, plant breeding, and related industries.[61] ASTA is drafting a Guide to Seed Quality Management Practices that provides general guidance for the development of quality management practices for use in the development and production of seed products intended for food, feed, or fiber use. The guide is intended to establish and maintain the specific identity of a seed product and the purity of that seed product by using appropriate quality management measures.[62] Syngenta supports the

[57] *See id.*

[58] *See* USDA GIPSA website, http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=landing&topic=landing

[59] *See* United States Department of Agriculture Grain Inspection, Packers and Stockyards Administration, Federal Grain Inspection Service Directive No. 9180.79, Jan. 29, 2007, *available at* 151.121.3.117/reference-library/directives/9180-79.pdf.

[60] *See e.g.*, USDA ERS Report, *Traceability in the U.S. Food Supply: Economic Theory and Industry Studies*, Mar. 2004 (Grains and Oilseeds, pp. 22-26), *available at http://www.ers.usda.gov/Publications/AER830/*.

[61] *See* American Seed Trade Association website, *About ASTA*, *available at http://www.amseed.com/about.asp*.

[62] The Guide to Seed Quality Management Practices is still in the form of a working draft and has not yet been published.

efforts of ASTA, as it provides another example of efforts in the food industry to preserve product identification.

IV.

Syngenta Stewardship Program for Event 3272 Corn

A. Description of Event 3272 Corn

Event 3272 corn has been genetically modified to express an optimized alpha-amylase enzyme specifically developed for use in dry grind ethanol production. This product will serve as a source of the amylase enzyme in the dry grind ethanol process, replacing the addition of liquid microbially produced enzyme and significantly improving the overall efficiency of dry grind ethanol production.[63] In addition, it will enable process flexibility that could generate real benefits at multiple points in the ethanol plant, such as increased ethanol yield, reduced energy costs, reduced water usage, and reduced chemical usage. Commercialization could also increase energy yield of corn per acre, ease current tight markets for corn, and contribute substantially to the advancement of next generation biofuels.[64]

Alpha-amylases are ubiquitous in the environment and are safe. There is a long history of safe consumption by humans and animals and/or exposure to both naturally occurring and commercially produced alpha-amylases. They are naturally present in microorganisms, plants (including corn), and animals. They are commercially produced for food processing uses such as baking bread, brewing beer, and producing corn syrup. In addition, a co-product of ethanol production is sold as an animal feed ingredient. Event 3272 has successfully completed the FDA food safety consultation process.[65] There is no food safety issue associated with the possible presence of the AMY797E alpha-amylase enzyme in foods.

[63] Enzymes such as alpha-amylase and glucoamylase are added during the ethanol production process because they provide a fast, safe and economical conversion of starch to sugars. A more efficient conversion of starch translates into process efficiencies in ethanol production. The improved alpha-amylase facilitates this more efficient starch to ethanol conversion.

[64] *See generally* John M. Urbanchuk, *Economic Impact Analysis of Event 3272 Corn on Dry Mill Ethanol Production*, CBI Deleted Copy prepared for Syngenta Biotechology, Inc. (July 2007). The United States ethanol industry has grown at a tremendous rate, driven by energy security, the high price of foreign oil, the renewable energy mandates of the Energy Bill of 2005, and the President's Biofuels Initiative. More than over 100 dry mill ethanol plants (the majority of capacity) are currently dedicated specifically to the production of ethanol, with a minimum of an additional 50 planned or under construction. The ethanol industry used an estimated 1.5 billion bushels of corn in 2005 (14% of total corn demand), with ethanol currently representing the third most important market for US corn, after feed and export uses. This explosive growth in ethanol has created a significant domestic market for US corn producers. *See id.*

[65] *See* Letter from Laura M. Tarantino, Ph.D., Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, to Ann Tuttle, Manager, Regulatory Affairs, Syngenta Seeds, Inc. (Aug. 2007) (acknowledging that based on the information available, Event 3272 corn did not raise safety or other issues that would require pre-market review or approval by the FDA).

B. Utilization of Event 3272 Corn

Notwithstanding its safety as food, Event 3272 will be commercialized for the value it brings to ethanol production. In order to capture the highest value of Event 3272 corn, it will be branded, marketed, and sold for that use – i.e., with an indication of its unique characteristic relating to the expression of an alpha-amylase. This commercial approach is comparable to the marketing of many other specialty corns.

It is expected that Event 3272 corn may be unsuitable for some processing applications for which it will not be branded, marketed or sold. Specialty corns, such as waxy corn, are developed for a specific purpose and generally are unsuitable for use in other applications. The AMY797E alpha-amylase enzyme in Event 3272 corn is not able to act on the starch in the intact kernel and neither the starch itself nor any other nutritional or functional component of Event 3272 corn has been altered by the genetic modification.[66] However, during or after processing, enzyme activity could result in the conversion of some starch to dextrins and sugars. It is this potential for alpha-amylase starch hydrolyzing activity, during or after processing, that may make it unsuitable for some applications. For example, Event 3272 could have an effect in alkaline cooking, the process used to produce masa. Masa flour and dough are used to make tortillas and chips. The effect decreases the handling characteristics of the masa dough and the acceptability of the appearance of the finished product produced from that dough.[67]

The strict grain sourcing procedures in the masa industry make it highly unlikely that Event 3272 corn would be diverted to a masa facility. The masa industry has developed quality control measures to meet production requirements,

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[66] As presented in the Syngenta Petition for deregulation of Event 3272 corn, compositional analysis demonstrated it is not materially different from commercial corn hybrids. This is in contrast to the specialty corns in which the starch, oil, protein, or color content itself is intentionally modified. *See Syngenta Petition for the Determination of Non-Regulated Status: Corn Rootworm Protected Transformation Event MIR 604*, APHIS, Docket No. 2006-0157-0003 (Jan. 10, 2007), *available at* *http://www.regulations.gov/fdmspublic/component/main*.

[67] The information contained in this paragraph is documented by the September 5, 2007 Syngenta presentation to BRS. *See generally*, L.W. Rooney & S.O. Serna-Saldivar, *Food Use of Whole Corn and Dry-Milled Fractions in Corn: Chemistry and Technology*, (P.J. White & L.A. Johnson eds.) (2003); U.S. Grains Council, *Value Enhanced Corns Report 2005/2006*, *available at* www.grains.org/.../technical_publications/USGC%20Value%20Enhanced%20Corn%20Report%202006%20%20(English).pdf; A.R. Hallauer, *Specialty Corn*, (2nd ed. CRC Press 2000); Sparks Companies, Inc., *The US Corn Masa Industry: Structure and Implications for the Great Plains Region*, Prepared for Agricultural Marketing Resource Center, http://www.agmrc.org, Kansas State Univ. (2003), *available at* www.agmrc.org/NR/rdonlyres/EC8E389D-7085-40ED-B8B2-0B02B0AC4552/0/sparkswhitecornpaper.pdf.

prevent process disruptions, and ensure industry standards for finished products are maintained. The use of dedicated supply contracts limits the total supply of food-quality yellow corn from the open market used in masa production to 4%.[68] Commercial hybrid seed companies have specifically developed corn hybrids with improved alkaline-cooking properties such as hard endosperm corn that have good yield and are adapted across regions of the U.S. corn belt. These hybrids are specified by buyers and end-users of corn for masa production and premiums are paid for growing, delivering, and meeting and maintaining the purity and quality standards of this corn. In addition to grain sourcing, a number of additional measures are employed throughout the process including grading, inspection of the corn, cooking the corn, handling the masa, formulation, and testing of the final food product. These commonly employed quality control measures ensure that masa products and finished food products meet industry standards.[69] These market controls in the masa industry make the likelihood of Event 3272 corn being mistakenly delivered directly to a masa plant by a grower from their farm extremely remote.

Even if corn is somehow diverted to a masa facility, other checks reduce the possibility of an effect. Syngenta will make available prior to commercialization a reliable detection method or test that enables crop identity verification for intended use by corn food processors capable of detecting Event 3272 in any yellow corn purchased from the open-market, the only possible source of Event 3272 in the corn supply. Finally, dilution rates would further minimize the possible effect. In the unlikely event that corn were directly delivered from the farm to a masa facility, it would be co-mingled in a masa storage bin, and depending on the actual size of the bin and fullness at the time of delivery, the dilution rate would be a conservative estimate of 5x. Corn entering a masa facility through a local elevator would be drawn through two bins and one truck before being used by the facility. The dilution rate would be approximately 50x, 10x at the local elevator (due to larger bins) and 5x at the masa storage bin (10x times 5x = 50x).[70]

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[68] Approximately 80% of the corn used in masa production is food-quality white corn, while food-quality yellow corn constitutes only 20% of the total used to produce masa. Both types of corn are typically grown by producers under contract with major buyers or end-users. In fact, of the 20% drawn from the yellow corn market, 80% is grown under dedicated supply contracts with the masa plant, leaving only 20% as sourced from the open market. This means that only 4% of the total supply of corn used in masa production is food-quality yellow corn from the open market.

[69] *See generally* L.W. Rooney, *supra* note 55; U.S. Grains Council, *supra* note 55; Sparks, *supra* note 55.

[70] These dilution factors were calculated based on Syngenta's interviews with grain merchandisers to understand the movement of corn and the commingling with other corn that occurs during transport and storage. This information was further supplemented with Syngenta's internal analysis of grain dilution patterns.

C. Closed-Loop System

The already low likelihood that Event 3272 corn would be diverted from the farm to the ethanol plant is reduced even further by the strict controls evident in the commercial system developed by Syngenta for this product. Event 3272 will be commercialized solely in a traditional closed-loop system, replete with effective control points. The system relies on concentrated acreage, contract grown product within the geographic footprint of the ethanol plant, stewardship mandates, and grower agreements for delivery to ensure a smooth, uninterrupted, and verifiable supply of grain to end users – dry grind ethanol plants.

These dry grain ethanol plants will contract directly with growers in their geographic area or indirectly through third party grain suppliers for the production and delivery of the Event 3272 corn. These grower grain contracts will specify a delivery location that either will be an ethanol plant or a storage site (country elevator) within a specified radius, a delivery date for which a window for delivery will be specified, and the acres or bushels per acre to be delivered. [71] The delivery will be made either by the growers delivering the corn directly to the ethanol plant or to an elevator or truck transporter. 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.

Syngenta's closed-loop system diverts Event 3272 away from the production of processed corn food products such as masa (tortillas and chips). The stewardship controls imposed in Syngenta's closed-loop system are designed to prevent the contracted grower from inadvertently delivering Event 3272 to a masa facility or to a local elevator that is an open-market supplier to a masa facility.

D. Stewardship Roles and Responsibilities Within Closed-Loop System

In this closed-loop system, the principle contract actors – the producer, the grower, and the ethanol plant (end user) – each have specific stewardship roles and responsibilities. These stewardship roles and responsibilities are consistent with Syngenta's adoption of the best practices and quality management principles derived from the BIO stewardship program and are delineated below.

Syngenta (stewardship roles and responsibilities):

[71] A "country grain elevator" is a grain elevator that services a limited geographic area. *See* John S. Seitz, Memorandum, Nov. 1995 at 3, *available at* www.epa.gov/ttncaaa1/t5/memoranda/grainfnl.pdf. It is very rare even in the commodity corn market for corn to be delivered from distances greater than 100 miles from the plants and only occurs where there is a shortage of local corn due to drought.

- license the use of Event 3272 corn product to growers;
- sell Event 3272 corn hybrids only to licensed growers with a valid contract with an ethanol plant or approved third party grain company that supplies corn amylase to the ethanol plant;
- ensure that grain contract includes stewardship agreement;
- provide incentive to grower for producing and delivery of Event 3272 corn product;
- provide stewardship guide to producers and handlers on the cultivation and handling of the Event 3272 corn product;
- provide specific procedures for the handling of any excess grain;
- ensure the domestic consumption of DDGS prior to export market approvals;
- make available appropriate detection methods; and,
- develop and implement a communication program.

Grower (stewardship roles and responsibilities):

- execute delivery contract with ethanol plant;
- execute stewardship contract with Syngenta;
- follow Syngenta stewardship guide on cultivation; and,
- follow Syngenta requirement to divert excess grain to appropriate use.

Ethanol Plant (stewardship roles and responsibilities):

- contract with growers to supply Event 3272 corn product; and,
- ensure domestic consumption of DDGS prior to export market approvals;

These stewardship roles and responsibilities in concert with the contract relationships between the entities in the closed-loop system and the backstop mechanisms minimize the risk of inadvertent delivery of Event 3272 corn and commingling.

V.

The Deregulation of Event 3272 is not a Major Federal Action

As demonstrated above, the deregulation of Event 3272 will result in the market entry of another specialty corn product that is identity preserved, safe for food and feed, produced in a closed loop system, and carefully managed consistent with the robust suite of safeguards in place in the market for value-added specialty grain products. NEPA analysis for this event necessarily begins with an identification of the relevant environmental concerns, a hard look at the significance of those concerns for a specialty grain product, and an explanation of the conclusions resulting from that hard look.[72]

A. Identification of Relevant Environmental Concerns

As described in the July 7, 2007 draft programmatic EIS, APHIS has identified three general categories of effects that are relevant to its assessment of risks to the human environment under NEPA. These include potential changes in weediness and invasiveness (including gene flow and persistence in the environment); potential effects of plants on the soil; and impacts on human health (including human allergenicity).[73]

B. A "Hard-Look" Analysis of the Effect of the Identity-Preserved, Closed-Loop Specialty Grain Management System, Legal Recordkeeping Requirements and Supporting Quality Management Systems.

The hard look required of the agency prior to issuing a FONSI is a critical evaluation of whether the impacts of the action are significant in terms of context and intensity. Context refers to the setting within which the proposed action takes place.[74] In considering context, an agency must look at the significance of an action analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality."[75] The term "intensity" refers to "the severity of the impact"[76] judged on a number of factors. As demonstrated below, the deregulation of Event 3272 is not significant on either factor.

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[72] *Grand Canyon Trust v. FAA, supra* note 3, at 340 – 41.

[73] DEIS, *supra* note 4, at 67 – 90.

[74] 49 C.F.R. §1508.27(a).

[75] *Marsh, supra* note 10, at 374 (quoting 40 C.F.R. §1508.27).

[76] *Id*.

1. Potential Changes in Weediness and Invasiveness

Event 3272 contains an added alpha-amylase enzyme that facilitates ethanol production. This creates a valuable output trait – better suiting this specialty corn to the production of ethanol in the dry grind process – but it does nothing to make it a better competitor vis-à-vis other corn. Accordingly, it presents none of the weediness and invasiveness concerns associated with plant-incorporated protectants that provide resistance to pests or herbicides.

Event 3272 does present the same gene flow potential between itself and other corn varieties that is acknowledged as a scientific reality in the draft EIS.[77] This is not a concern respecting gene flow between corn and other species. As noted in the environmental assessment supporting the deregulation of MIR604 (corn rootworm), corn does not have weedy relatives with which it outcrosses in the United States.[78] With respect to the impact of gene flow between different varieties of corn, it is important to note that corn is an intensively cultivated and managed crop with which producers have a great deal of experience. The draft EIS documents the well-understood mechanisms for effective management of this gene flow potential in seed production, noting that "[I]solation and borders effectively limit the level of unintended off-types in the final product and their use is supported by decades of experience with plant breeders and the seed industry."[79]

The record shows that with respect to the potential for gene flow between Event 3272 corn and other corn varieties, the Syngenta Stewardship Program provides for all contracted growers to include 12 border rows in the harvest of Event 3272 corn to address adventitious pollination. The record further shows that 97.12% of adventitious pollination occurs in the first 12 rows. This preventative measure means that, by including the first 12 non-corn-amylase rows on all sides of the field in the harvest of the Event 3272 corn, 99.9% of amylase containing grain will be accounted for in the dedicated grain supply system and directed to dry grind ethanol production.[80]

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[77] *See* DEIS, *supra* note 4, at 64.

[78] *See Environmental Assessment for Prosposed Determination of Nonregulated Status for Corn Gentically Engineered for Insect Resistance,* APHIS, Docket No. 2006-0157-0003 (Jan. 10, 2007), *available at* http://www.regulations.gov/fdmspublic/component/main.

[79] DEIS, *supra* note 4, at 64.

[80] This point was developed in the September 6, 2007 Syngenta presentation to the Biotechnology Regulatory Service (BRS) and in the November 16, 2007 Syngenta presentation to USDA.

To the extent adventitious pollination result in corn amylase entering the yellow dent corn commodity supply, it will be limited to 0.1% of the grown corn amylase. As discussed above, these minute quantities will present no food safety issues and will not affect the suitability of yellow dent commodity corn for corn processing. This 0.1% will be diluted at least 5 times, and possibly up to 50 times, with non-amylase yellow dent corn prior to entering masa production. This is far below the 0.1% at which corn amylase begins to affect masa production. Moreover, as affirmed by APHIS, it will not become a seed production issue given the sophistication of current seed production techniques, isolation distances, and the like.

Accordingly, this effect is not significant in either context or intensity.

2. Potential Effects of Plants on the Soil

There is no suggestion in the scientific evidence presented in support of Syngenta's petition to deregulate or in the literature that Event 3272 corn would have any effect on the soil.[81] What the record does show is that alpha amylases are ubiquitous in the environment and are safe. They are naturally present in microorganisms, plants (including corn), and animals. The FDA food safety consultation process indicates that the Event 3272 corn presents no different issues for toxicity or allergenicity.[82]

Accordingly, this effect is not significant in either context or intensity.

3. Impacts on Human Health

As discussed above, the successful conclusion of the FDA food safety consultation demonstrates that there are no effects of concern for human health.[83] Accordingly, this effect is not significant in either context or intensity.

4. Functionality of Event 3272 for Production of Processed Corn Products

The suitability of a new specialty corn biotechnology event for use in markets for which it is not intended has not been identified by APHIS as a factor considered to be a

[81] *See* Syngenta Petition, *supra* note 54, at 87-88; 94-95.

[82] *See* FDA Letter, *supra* note 53.

[83] *See id.*

relevant environmental effect in the draft EIS for purposes of NEPA analysis in support of deregulation.[84] This approach is consistent with Supreme Court precedent on the types of environmental effects that trigger the NEPA procedural assessment requirements. "[T]he theme of [§ 4332(c) of NEPA] is sounded by the adjective 'environmental' . . . the context of the statute shows that Congress was talking about the physical environment – the world around us, so to speak."[85]

The suitability effect is a commercial use issue, not an effect on the physical environment. Unlike the *Geerston* court's evaluation of the alfalfa deregulation decision, the deregulation of Event 3272 does not present any substantial or unanswered questions regarding gene transmission to non-genetically engineered corn. Corn is an intensively managed annual crop into which multiple biotech events have already been introduced. Alfalfa, by contrast, is a perennial crop pollinated by bees to which herbicide tolerance is being newly introduced. Nor does deregulation of Event 3272 present any issue relating to the development of additional pesticide resistance or increased use of herbicides. Event 3272 introduces a special output trait. As noted above, it does not enhance the competitiveness or resistance of this corn plant.

Moreover, even if APHIS were to determine that commercial use issues should be included in its analysis of relevant environmental effects, the functionality effects of Event 3272 have been effectively mitigated by requiring steps to ensure that this specialty grain is directed to its economically productive use and away from use as an ingredient in certain applications. The identity-preserved, closed-loop specialty grain management systems, grain traceability recordkeeping requirements, and supporting quality management systems in use in the grain management industry today are fully capable of ensuring the separation necessary to avoid any unintended commingling and associated commercial use effect. Treated as mitigation measures, these steps are sufficient to bring the potential adverse suitability impacts below the level of significance.

Accordingly, Syngenta's decision to commercialize Event 3272 as a specialty grain produced in a closed-loop system would be fully supported by an EA and FONSI even if the functionality effect were considered to be an effect on the human environment for purposes of NEPA analysis. It is well-established that even where an effect may be considered to be significant if unmitigated, an EA and FONSI will satisfy NEPA's "hard look" requirements where mitigation can reduce those effects below the level of significance.[86]

The masa example provides an excellent example of how the mitigation created by the closed-loop production system reduces the significance of the effects of Event 3272 on

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[84] *See* DEIS, *supra* note 4, at 69-90.

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[85] *See Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 772 (1983); *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 96 (1983).

[86] *Robertson v. Methow Valley Citizens Counsel*, 490 U.S. 322 (1989)

non-target users. There are three scenarios under which the dedicated grain supply system between the seed supplier, the contracted grower and the ethanol plant for Event 3272 could be breached, creating the possibility for Event 3272 to enter the yellow corn commodity market. First, adventitious pollination could result in Event 3272 growing in neighboring fields. Second, a contracted grower could inadvertently deliver Event 3272 corn directly to a masa production facility. Third, the contracted grower could inadvertently deliver Event 3272 to a local elevator that is an open-market supplier to a masa production facility.

As discussed above, the probability of the first scenario is remote. First, less than 10% of corn fields supporting ethanol plants (the geographic area in which Event 3272 will be grown) are in the vicinity of masa plants. The twelve border row requirement for harvest assures that 99.9% of the grown corn amylase will be accounted for in the Event 3272 dedicated grain supply system. This level, even before the certain dilution with other yellow-dent corn bound for the masa facility, is below the level which would impact masa production.

The likelihood of the second and third scenarios is effectively reduced by the series of supply-chain control points between the field and the masa facility. These control points include those in the masa industry and those in the closed-loop system for Event 3272 corn. The controls in the masa industry make it highly unlikely that Event 3272 corn would be diverted to a masa facility. Even if a diversion occurs, testing and dilution rates further minimize the risk. The controls in the closed-loop system build stewardship responsibilities for the farm, the transporters, and the ethanol plants that substantially reduce this risk even more. Whatever risk there is even further reduced by the mechanisms, standards, and recordkeeping requirements in the modern grain system that promote product segregation and identity preservation.

It is important to note that the context and intensity effects as analyzed in this hard-look analysis do not differ from those associated with other specialty corns in commerce today. Many of these specialty corn products are unsuitable for some generic corn uses. For example, waxy corn starch has a unique starch matrix of more than 98% amylopectin starch. It delivers a unique functionality that differs from normal yellow dent corn starch, which is a blend of 70% amylopectin and 30% amylose. Should waxy corn be introduced into a wet mill that produces starch products from standard yellow dent corn, the products will not meet commercial specifications.

Based on the hard-look analysis of the context of introduction of Event 3272 as a specialty grain and the intensity of its impact, the effect is not significant. The Syngenta Stewardship Program, the sophisticated ability of the U.S. grain supply system to manage and distribute differentiated specialty corn grain, and the traceability record-keeping provisions of the Bioterrorism Act all support a determination that the deregulation of Event 3272 will not significantly affect the human environment.

VI.

Conclusion

For the foregoing reasons, the deregulation of Event 3272 will not significantly affect the human environment and Syngenta's petition should be granted based upon a finding of no significant impact.

Appendix H. FDA memo on Event 3272 corn consultation

CFSAN/Office of Food Additive Safety August 7, 2007

Biotechnology Consultation Note to the File BNF No. 000095

Date: August 7, 2007

Subject: Biotechnology Notification File (BNF) 000095, corn transformation event 3272.

Keywords: *Zea mays* L., maize, corn, corn event 3272, AMY797E, alpha-amylase, amylase, *Agrobacterium tumefaciens*, PMI, phosphomannose isomerase

1. Introduction

In a submission dated August 31, 2005, Syngenta Seeds, Inc. (Syngenta) provided to the Food and Drug Administration (FDA) a safety and nutritional assessment of genetically engineered AMY797E alpha-amylase corn designated as corn event 3272. Syngenta provided additional information to the FDA on May 1, 2006, August 2, 2006, November 8, 2006, January 19, 2007, March 2, 2007, March 6, 2007, March 7, 2007, May 31, 2007, July 11, 2007 and July 12, 2007. Syngenta concluded that food and feed derived from corn event 3272 are as safe and nutritious as food and feed derived from conventional corn varieties.

2. Intended Effect

Corn event 3272 was genetically engineered to contain a chimeric, thermostable, alpha-amylase gene derived from alpha-amylase genes from three hyperthermophilic microorganisms within the order *Thermococcales*. The resulting transformed corn is intended to be mixed with other corn for use in dry grind fuel ethanol production as a source of alpha-amylase, replacing the need for the addition of microbially-

produced amylase during processing. The enzyme catalyzes the hydrolysis of the alpha-1,4-glucosidic bonds of amylase and amylopectin polymers into dextrins, maltose, and glucose. The recombinant enzyme is stable and active at high temperatures of dry grind ethanol production.

Syngenta states that, based on its safety assessment, corn event 3272 is as safe as other corn lines, and as such may be used as food, feed or in the production of food products or ingredients. However, Syngenta states that grain from corn event 3272 is primarily targeted for the dry grind fuel ethanol production industry in the United States.

http://www.cfsan.fda.gov/~rdb/bnfm095.html

3. Genetic Modifications and Characterization

3.1 Transformation Plasmid and Parential Variety

Syngenta constructed the plasmid vector pNOV7013. The plasmid contains two expression cassettes within its T-DNA region. The T-DNA region contains a single copy of the *amy797E* alpha-amylase expression cassette and a single copy of the phosphomannose isomerase (*pmi*) expression cassette as a selectable marker. The T-DNA region of pNOV7013 was incorporated into immature corn embryo cells from a proprietary corn line (NP2499/NP2500) using *Agrobacterium*-mediated transformation. The T-DNA region of pNOV7013 contains the following genetic elements.

Table 1. Genetic elements contained in the T-DNA region of the plasmid vector pNOV7013.

Cassette Grouping	Genetic Elements	Description
	Right Border	

	Right border sequence from nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.
GZein	
	Promoter region from the *Zea mays* storage protein gene (zein).
amy797E (*amy797GL3*, GZein ss, ER rs)	
	Chimeric alpha-amylase gene (*amy797GL3*) derived from order *Thermococcales* microbes. Also contains N-terminal maize gamma-zein signal sequence (GZein ss) and a C-terminal SEKDEL endoplasmic reticulum retention sequence (ER rs).
PEPC9	
	Intron #9 from the phosphoenolpyruvate carboxylase gene from *Zea mays*.
35S terminator	
	Terminator sequence from the 35S RNA from the cauliflower mosaic virus genome.
amy797E	
ZmUbiInt	
	Promoter region from *Zea mays* polyubiquitin gene. Contains the first intron.

pmi	
	E. coli manA gene encoding phosphomannose isomerase.
NOS	
	Terminator sequence from the nopaline synthase gene of *Agrobacterium tumefaciens*.
pmi	

Left Border	Left border sequence from the nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.
	Left border sequence from the nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.
	Left border sequence from the nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.

Cassette Grouping	Genetic Elements	Description
	Right Border	Right border sequence from nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.
amy797E	GZein	Promoter region from the *Zea mays* storage protein gene (zein).
	amy797E (*amy797GL3*, GZein ss, ER rs)	Chimeric alpha-amylase gene (*amy797GL3*) derived from order *Thermococcales* microbes. Also contains N-terminal maize gamma-zein signal sequence (GZein ss) and a C-terminal SEKDEL endoplasmic reticulum retention sequence (ER rs).
	PEPC9	Intron #9 from the phosphoenolpyruvate carboxylase gene from *Zea mays*.
	35S terminator	Terminator sequence from the 35S RNA from the cauliflower mosaic virus genome.
pmi	ZmUbiInt	Promoter region from *Zea mays* polyubiquitin gene. Contains the first intron.
	pmi	*E. coli manA* gene encoding phosphomannose isomerase.
	NOS	Terminator sequence from the nopaline synthase gene of *Agrobacterium tumefaciens*.
	Left Border	Left border sequence from the nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.

Cassette Grouping	Genetic Elements	Description
	Right Border	Right border sequence from nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.
amy797E	GZein	Promoter region from the *Zea mays* storage protein gene (zein).
	amy797E (*amy797GL3*, GZein ss, ER rs)	Chimeric alpha-amylase gene (*amy797GL3*) derived from order *Thermococcales* microbes. Also contains N-terminal maize gamma-zein signal sequence (GZein ss) and a C-terminal SEKDEL endoplasmic reticulum retention sequence (ER rs).
	PEPC9	Intron #9 from the phosphoenolpyruvate carboxylase gene from *Zea mays*.
	35S terminator	Terminator sequence from the 35S RNA from the cauliflower mosaic virus genome.
pmi	ZmUbiInt	Promoter region from *Zea mays* polyubiquitin gene. Contains the first intron.
	pmi	*E. coli manA* gene encoding phosphomannose isomerase.
	NOS	Terminator sequence from the nopaline synthase gene of *Agrobacterium tumefaciens*.
	Left Border	Left border sequence from the nopaline Ti plasmid. Delineates the T-DNA region for *Agrobacterium*-mediated transformation.

Plasmid pNOV7013 contains several genes on its plasmid backbone necessary for maintenance and selection of the plasmid. These sequences are not intended for transfer into the plant genome. The plasmid backbone of pNOV7013 contains origins of replication that allow replication of the plasmid in both *Agrobacterium tumefaciens* and *Escherichia coli*. The plasmid contains the *spec* gene encoding the Tn7 adenylyltransferase conferring resistance to erythromycin, streptomycin and spectinomycin. pNOV7013 also contains the *virG* gene, which is a gene involved in regulation of virulence in *A. tumefaciens*, and the *repA* gene, which is a gene responsible for plasmid replication in Gram-negative, plant-associated bacteria.

3.2 Characterization, Stability and Inheritance of the Introduced DNA

Syngenta performed polymerase chain reaction (PCR), restriction digests, and Southern blot analysis to support its conclusion that corn event 3272 contains one intact copy of its *amy797E* and *pmi* expression cassette. Syngenta determined the nucleotide sequence of the T-DNA region present in corn event 3272 to demonstrate the integrity of the insert.

Syngenta reports that corn event 3272 contains no detectable genetic material from the pNOV7013 backbone, including the *spec*, *virG*, and *repA* genes.

Syngenta examined the stability and inheritance pattern of the introduced traits through conventional breeding over five generations consisting of four rounds of backcrossing to conventional inbred lines. Syngenta reported no significant differences in the observed-to-expected segregation ratios for the *amy797E* gene over five generations, as demonstrated by the

chi-square (χ^2) values. Syngenta reported that these segregation data indicate a single-locus, Mendelian inheritance pattern for the insert in corn event 3272.

4. Introduced Substances - AMY797E Alpha-Amylase and PMI Enzymes

Syngenta provided information on the identity, function, and characterization of the genes as well the expression levels of the gene products. They also provided information on the potential allergenicity and toxicity of the expressed proteins.

4.1 Identity, Function, and Characterization

4.1.1 AMY797E Alpha-Amylase

Syngenta compared the amino acid sequence of the AMY797E alpha-amylase protein to other alpha-amylases, stating that AMY797E shared a 93% homology to a microbially derived alpha-amylase BD5088 (Innovase LLC) produced through a similar recombination technique as AMY797E. The BD5088 alpha-amylase was the subject of a generally recognized as safe (GRAS) notice (GRN 126) for use in food. Syngenta also provided the complete amino acid sequence of AMY797E. Additionally, Syngenta provided information about the functional activity of AMY797E to demonstrate its functionality as an alpha-amylase.

4.1.2 PMI

The *pmi* gene, introduced as a selectable marker into corn event 3272, encodes a phosphomannose isomerase (PMI) enzyme that catalyzes the inter-conversion of mannose-6phosphate and fructose-6-phosphate. The expression of the *pmi* gene in the plant allows the plant to survive and grow on media containing only mannose as the only or primary carbon source, which facilitates selection of transformed plants.
Syngenta reports that PMI enzymes exist widely in nature among both prokaryotes and eukaryotes. Syngenta states that PMI enzymes have been found in plants such as tobacco, walnut, and soybean and other legumes, although Syngenta notes that sequence homology for the *pmi* gene introduced into event 3272 is highest for enteric Gram-negative bacteria (70-100% homology).

4.2 Expression Levels

4.2.1 AMY797E Alpha-Amylase

Syngenta reports that AMY797E alpha-amylase expression levels were measured by enzyme-linked immunosorbent assay (ELISA) in several tissues at various stages of development. Syngenta notes that expression of AMY797E is directed primarily to the kernel by the maize gamma-zein promoter, and as expected, the highest concentration of AMY797E alpha-amylase is in the kernel. Mean concentration measured in mature or senescent kernels ranged from 838 ± 268 µg/g fresh weight (fw) (1004 ± 322 µg/g dry weight (dw)) to 955 ± 225 µg/g fw (1335 ± 358 µg/g dw). Mean concentration in younger "dough" stage (R4) kernels ranged from 874 ± 160 µg/g fw (1994 ± 228 µg/g dw) to 1627 ± 338 µg/g fw (3365 ± 780 µg/g dw). Concentration of AMY797E alpha-amylase varied in whole plant samples, at various growth stages, from < 12 µg/g fw (< 37 µg/g dw) to 281 ± 108 µg/g fw (668 ± 248 µg/g dw).

4.2.2 PMI

PMI protein concentrations were also measured in various tissues and developmental stages. PMI was detected in most tissues tested and concentrations were similar regardless of the developmental stage tested. The highest levels were detected in pollen, with concentrations ranging from 8.0 to 8.5 µg/g fw (17.0 - 18.2 µg/g dw). Mean concentrations of PMI in kernels over all growth stages ranged from < 0.4 µg/g fw (< 0.5 µg/g dw) to 0.8 ± 0.1 µg/g fw (1.8 ± 0.4 µg/g dw). Concentrations of PMI in whole plant samples from all developmental stages ranged from < 0.3 µg/g fw (< 0.6 µg/dw) to 1.5 ± 0.3 µg/g fw (3.6 ± 0.9 µg/g dw).

4.3. Assessment of Potential Allergenicity

Syngenta states that the potential allergenicity of the AMY797E alpha-amylase and PMI proteins were assessed by searching for amino acid homology between these proteins and known allergen protein sequences. These searches were conducted using a database comprised of identified or putative allergen sequences from publicly available databases (GenPept, PIR, SWISS-PROT, FAARP and IUIS) and additional putative allergen sequences from the scientific literature. Syngenta also assessed the stability of the AMY797E and PMI proteins using *in vitro* digestibility assays.

4.3.1 AMY797E Alpha-Amylase

Syngenta reports that the donor organisms (*Thermococcus*/*Pyrococcus*) used to develop AMY797E alpha-amylase protein are not known to be allergenic.

Syngenta reports that for AMY797E, there were no amino acid sequence identities of greater than 35% in segments of 80 amino acids with any entries in the database. Syngenta does note that there was a single segment of 8 contiguous amino acids in AMY797E that matched a known allergenic sequence derived from an insect. However, Syngenta notes that the allergenic epitopes are known for this allergen (American cockroach, Per a 3) and there is no overlap between these binding epitopes and the eight amino acid region of sequence identity with AMY797E alpha-amylase. Therefore, Syngenta maintains that this sequence identity is not biologically relevant and has no implication for the allergenic

potential of the AMY797E alpha-amylase.

Syngenta provides data on the *in vitro* digestibility of AMY797E. Syngenta reports that AMY797E was susceptible to proteolytic degradation in simulated gastric fluid (SGF) containing pepsin, indicating that AMY797E is degraded within 5 minutes. Syngenta states that AMY797E is not stable to digestion and is therefore unlikely to become allergenic.

Syngenta notes that AMY797E is a thermostable protein. In addition, Syngenta reports that analysis of AMY797E as expressed in corn event 3272 does not reveal evidence of posttranslational glycosylation.

4.3.2 PMI

Syngenta reports that the donor organism (*E. coli*) used to develop the PMI protein is not known to be allergenic.

Syngenta reports that for PMI, there were no amino acid sequence identities of greater than 35% in segments of 80 amino acids with any entries in the database. Syngenta does note that there was a single segment of 8 contiguous amino acids in the PMI protein that matched a known allergen, α-parvalbumin from *Rana* species CH2001, an edible frog. Syngenta reports that further investigation of PMI using serum from one known α-parvalbumin-sensitive individual demonstrated a lack of reactivity with PMI. Syngenta therefore concluded that the sequence identity between PMI and α-parvalbumin is not biologically relevant.

Syngenta provides data on the *in vitro* digestibility of PMI. Syngenta reports that the PMI protein was found to be degraded when sampled immediately after time zero. Syngenta states that PMI is not stable to digestion and is therefore unlikely to become allergenic.

Syngenta notes that the PMI protein is labile to heat. In addition, Syngenta reports that PMI is unlikely to be glycosylated, given that the PMI protein does not contain consensus amino acid sequences required for *N*-glycosylation and the protein is not targeted to a cellular glycosylation pathway.

4.4 Assessment of Potential Toxicity

4.4.1 AMY797E Alpha-Amylase

Syngenta reported results from an acute oral toxicity study in mice where 1511 milligrams/kilogram body weight (mg/kg bw) AMY797E protein, or a control, was given by gavage. Syngenta indicates that the AMY797E test substance was prepared from event-3272 grain and was determined to be 42% AMY797E protein. Syngenta states that the animals were monitored for 14 days and were sacrificed. Syngenta reports that there were no effects of treatment on any observation, including body weight, food consumption, organ weight, or histopathology.

Syngenta reports that the potential toxicity of AMY797E was also assessed by comparing

its amino acid sequence against all publicly available protein sequences identified as toxins in the National Center for Biotechnology Information Entrez Protein Database. Syngenta reports that no significant sequence homology to any known toxins was identified.

4.4.2 PMI

Syngenta reports results from an acute oral toxicity study where PMI protein was given to mice by gavage at a dose of 3030 mg/kg bw. Syngenta notes that the PMI protein used in this study was obtained by over-expressing the protein in *E. coli*. Syngenta states that the animals were monitored for 14 days and were sacrificed. Syngenta reports that there were no effects of treatment on any observation, including body weight, food consumption, organ weight, or histopathology.

Syngenta reports that the potential toxicity of PMI was also assessed comparing its amino acid sequence against all publicly available protein sequences identified as toxins in the National Center for Biotechnology Information Entrez Protein Database. Syngenta reports that no significant sequence homology to any known toxins was identified.

5. Food and Feed Uses of Corn

Syngenta notes that corn grown in the U.S. is primarily the yellow dent type, a commodity crop used primarily to feed domestic animals, either as grain or forage. The remainder of the crop being exported or processed by wet or dry milling to yield human food products such as high fructose corn syrup, starch or oil, grits and flour. The by-products of wet and dry milling are commonly used in animal feed.

6. Compositional Analysis

Syngenta evaluated the composition of forage and grain from event 3272-derived corn hybrids relative to negative segregant (near-isogenic) control corn hybrids of similar genetic background.

Compositional analyses were performed on forage and grain. Syngenta analyzed corn grown at 10 different locations over a two year period, with three replicate plots of each genotype [1] planted at each location in randomized complete blocks. Grain was harvested from 6 locations
in both years and forage was harvested from 6 locations in 2003 and 7 locations in 2004. Three of the locations used in 2003 were again used in 2004 for growing corn grain, and four of the locations used in 2003 were again used for growing corn forage in 2004. Two hybrid pairs [2]
were grown in 2003 and one hybrid pair was grown in 2004. The data were combined for statistical analysis across locations, hybrid pairs, and growing seasons. Compositional data were statistically analyzed using a mixed model analysis of variance with locations serving as blocks. Statistical significance was assigned at $p < 0.05$ indicating that the difference between the treatments was statistically different at the 5% customary level. Syngenta

compared the compositional data with published literature values for each analyte to assess whether statistically significant differences in the composition of the event 3272-derived hybrids and the corresponding near-isogenic control maize were biologically meaningful.

6.1 Forage Composition

Syngenta determined the levels of the following analytes in forage from corn event 3272derived and the near-isogenic control hybrids collected at the R4 development stage. The following groups of analytes were measured:

- z Proximates
- z Minerals

A list of specific analytes contained in each group is shown in Table 2. Syngenta reported mean values for these analytes fell within published literature ranges.[3,4] Syngenta conducted a combined statistical analysis of forage data from all three field trials for analytes[5] marked with
an asterisk (*) in Table 2, and found statistically significant differences between the event 3272derived hybrids and their near-isogenic control lines for protein, carbohydrate and acid detergent fiber (ADF). Protein levels were statistically significantly higher, and carbohydrates and ADF were significantly lower in event 3272-derived hybrids than their respective near-isogenic control lines. Syngenta concluded that these differences were not biologically meaningful.

Table 2. Components measured in event 3272-derived forage and grain

Proximates	Minerals	Amino Acids	Fatty Acids	Anti-Nutrients	Secondary Metabolites	Vitamins
ash* fat moisture* protein* carbohydrate* acid detergent fiber (ADF)* neutral detergent fiber (NDF)* total dietary fiber (TDF) starch (grain only)	calcium* copper iron magnesium manganese phosphorus* potassium sodium zinc selenium	methionine cysteine lysine tryptophan threonine isoleucine histidine valine alanine leucine arginine phenylalanine glycine aspartic acid glutamic acid proline serine tyrosine	palmitic (16:0) stearic (18:0) oleic (18:1) linoleic (18:2) linolenic (18:3)	phytic acid trypsin inhibitor raffinose	furfural *p*-coumaric acid ferulic acid inositol	beta-carotene beta-cryptoxanthin folic acid vitamin B_1 vitamin B_2 vitamin B_3 vitamin B_6 vitamin C tocopherols (α-,β-,γ-,δ-)

6.2 Grain Composition

Syngenta determined the levels of the following analytes in grain from corn event 3272-derived and the near-isogenic control hybrids collected at the R6 growth stage (maturity). The following groups of analytes were measured:

- z Proximates
- z Minerals
- z Amino Acids
- z Fatty Acids
- z Anti-nutrients
- z Secondary metabolites
- z Vitamins

A list of specific components contained in each group is shown in Table 2. Syngenta reported mean values were within published literature ranges, with minor exceptions noted.[6,7], Syngenta conducted a combined statistical analysis of grain data from all field trials for all analytes listed in Table 2, excluding γ-tocopherol and β-cryptoxanthin[8] and the nine analytes below the limit
of quantitation. Exclusion of these analytes did not, however, affect Syngenta's conclusions. Low levels of these nutrients and anti-nutrients are consistent with values reported in the published literature and variable levels of certain nutrients (e.g. selenium) found in soil throughout the U.S.

Syngenta reported statistically significant differences in mean values between event 3272-

derived hybrids and controls for protein and manganese, which were higher in event 3272-derived hybrids than near-isogenic control hybrids. Syngenta also reported statistically significant differences in the mean values of carbohydrates, total dietary fiber, neutral detergent fiber, vitamin B_6, β-carotene, inositol, and ferulic acid, which were lower in event 3272-derived

hybrids. Event 3272-derived hybrids had significantly higher levels of almost all amino acids compared to the near-isogenic control lines, with the exception of arginine, cysteine, and lysine which were not different. Syngenta has compared all mean values to published literature ranges and concludes differences between event 3272-derived and near-isogenic control hybrids are not biologically meaningful.

7. Wholesomeness Study

Syngenta reports results from a 42-day broiler chicken feeding study comparing birds fed event3272 grain versus the near-isogenic control and commercially-available corn. Syngenta indicates that all of the diets derived from treatment and control diets supported rapid growth with low mortality rates and excellent feed conversion ratios.[9] Syngenta also reports no evidence of biologically-significant differences in growth or feed conversion in chickens fed event-3272 grain compared to near-isogenic control or commercially available corn. Furthermore, Syngenta notes the absence of any adverse nutritional or toxic effects in chickens fed these diets.

8. Conclusions

Syngenta has concluded that AMY797E alpha-amylase corn event 3272 is not materially different in composition, safety, or any other relevant parameter from corn now grown, marketed, and consumed. At this time, based on Syngenta's data and information, the agency

considers Syngenta's consultation on AMY797E alpha-amylase corn event 3272 to be complete.

Richard E. Bonnette

[(1)] The term genotype is used by Syngenta to refer only to the presence or absence of Event 3272.

[(2)] Syngenta defines hybrid pairs as the result of an initial cross-breeding of event 3272 and a non-transgenic line followed by self-crossing or cross-breeding of the resulting progeny one or more times and the selection of homozygous trait positive and negative segregants.

[3] Syngenta reported fat levels below the 0.1% limit of quantification in forage from both event 3272-derived hybrids and their respective near-isogenic control lines at a single field site. Excluding data from this site, reported mean values for fat were within published literature ranges.

[4] Values were within the ranges found in the International Life Sciences Institute Crop Composition Database (version 3.0, released April 10, 2006, available at: www.cropcomposition.org). Excluding phosphorous, means for all analytes also fell within values cited by the Organisation for Economic Co-operation and Development (OECD) "Consensus Document on Compositional Considerations for New Varieties of Maize (Zea Mays): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites." (Series on the Safety of Novel Foods and Feeds, No. 6, 2002).

[5] Syngenta limited forage analytes in the combined statistical analysis to those suggested by the OECD (2002). Fat was excluded from the combined statistical analysis due to levels below the limit of detection.

[6] The following 9 grain analytes had one or more observations below the limit of quantitation of the assay: sodium, selenium, raffinose, phytic acid, furfural, tocopherols (α-, β- and γ-), and vitamin C. An observation represents the mean of 3 replicate plots per location, with grain from 15 plants pooled from each plot.

[7] Values were within the ranges found in the International Life Sciences Institute Crop Composition Database (version 3.0, released April 10, 2006, available at: www.cropcomposition.org). Fatty acids mean values were within ranges cited by OECD (2002).

[8] For several of the analytes, Syngenta reported that the treatment (genotype) effect differed by location. However, based on the statistical model used, the interpretation of the data was not affected.

[9] Syngenta notes that the non-transgenic control grain appeared to contain low levels (approximately 1.6-2.6%) of event-3272 corn.

Appendix I. Report on DDGS submitted by Syngenta

Impact of Event 3272 Corn on Distillers Grains

John M. Urbanchuk

Director, LECG LLC

December 4, 2007

Syngenta Biotechnology Inc. has developed a novel transgenic corn variety, designated as Event 3272 that contains a genetically inserted thermostable alpha-amylase enzyme. Event 3272 is agronomically equivalent to No. 2 Yellow Corn and has been shown to be as safe for human and animal consumption as conventional yellow corn; its unique properties make it especially suited for use as a feedstock for ethanol produced by the dry grind process.

Dry Grind Ethanol Production

Ethanol is produced from corn and other grains using one of two production processes: wet milling and dry milling. The main difference between the two is the initial treatment of the grain. Most new ethanol facilities built in the U.S. in recent years have been dry grind plants. According to the Renewable Fuels Association dry mill facilities account for 82 percent of ethanol production and wet mills 18 percent.

In the typical dry grind process, the entire corn kernel is ground into a meal or flour and is processed without separating out the various component parts of the grain. Water is added to form a mash to which enzymes are added to convert the starch to dextrose, a simple sugar. Ammonia is added for pH control and as a nutrient for the yeast. The mash is processed in a high-temperature cooker to reduce bacteria levels ahead of fermentation. The mash is cooled and transferred to fermenters where yeast is added and the conversion of sugar to ethanol and carbon dioxide (CO_2) begins.

After fermentation, the resulting mixture called “beer” is transferred to distillation columns where the ethanol is separated out. The ethanol is concentrated to 190 proof using conventional distillation and then is dehydrated to approximately 200 proof in a molecular sieve system. The anhydrous ethanol is then blended with a denaturant such as regular gasoline to render it non potable and thus not subject to beverage alcohol tax. It is then ready for shipment to gasoline terminals for blending with gasoline.

After the fermented mash is distilled to remove the alcohol, the remaining slurry contains 5 to 10 percent dry matter called whole or spent stillage. Whole stillage is processed by various techniques to remove the large volume of water associated with the residual dry matter. The first step involves screening and pressing, or centrifuging to remove the solids composed of coarser grain particles. These solids, called Distillers’ Grains - DG, can be subsequently handled in several ways but are ultimately sold in various forms for animal feed. The distillers grains can be sold as a wet product (Wet Distillers’ Grains – WDG) or can be dried (Dried Distillers’ Grains – DDG). The liquid remaining after screening or centrifuging the whole stillage contains fine grain particles and yeast cells and is called thin stillage. Thin stillage is generally evaporated to produce a syrup called solubles which may be added back to the distillers grains. The mixture is then dried to produce Dried Distillers Grains with Solubles (DDGS), a high quality, medium-protein livestock feed.

Alpha-amylase is one of two enzymes (the other being glucoamylase) that convert the starch in corn to sugar which is then fermented and distilled into ethanol. Microbial produced alpha-amylase is already used commercially in the starch to sugar step of the dry grind and wet mill process of ethanol production. The Syngenta innovation prompts corn to produce its own heat-resistant alpha-amylase, thus eliminating the need for externally applied microbial alpha-amylase.

Impact of Event 3272 on Distillers grains

While efficiencies from Event 3272 are gained throughout the ethanol production process, the greatest benefits are realized within the starch-to-sugar conversion phase. The most apparent of these benefits is the elimination of microbial alpha-amylase as a raw material input. Alpha-amylase is used to break down the starch component of the corn into short chain dextrins, or complex sugars. Glucoamylase is then added during saccharification to further break down dextrins into simple sugars that can be fermented into ethanol. Because the alpha-amylase enzyme is already present in the corn kernel of Event 3272, this input is eliminated from the process.

The alpha-amylase enzyme produced by Event 3272 catalyzes the same reaction as other microbial alpha-amylases. The enzyme, whether exogenously introduced in microbial form or provided by the corn via Event 3272, only directly affects the conversion of starch to sugar, which eventually becomes ethanol. Use of Event 3272 corn is unlikely to have any adverse impact on the composition or quality of the coarse grain (distillers grains) or solubles left after distillation that, when added to distillers grains, become DDGS.

However, the use of Event 3272 corn will provide important efficiencies to the ethanol production process that may result in direct benefits to the distillers grains produced from Event 3272 corn.

- The first of these is a reduction by half in sulfuric acid used to maintain pH levels. When conventional yellow corn is used in a dry grind plant, pH must be adjusted at several stages to create optimal conditions for chemical reactions to take place. With Event 3272 corn, pH is maintained at a constant level of approximately 4.8 throughout the production process. This reduces the use of sulfuric acid by half. Sulfuric acid ultimately becomes a sulfur salt in the DDGS product. According to research conducted at the University of Minnesota the sulfur content of distillers grains can be both very high and highly variable. “If not managed properly, high S concentrations in the diet, coupled with S from drinking water, may negatively affect

both animal performance and animal health".[87] The effect of reducing sulfuric acid use in dry grind ethanol production through the use of Event 3272 corn will enable feedlot operators to more effectively manage sulfur concentrations and avoid potential toxicity issues associated with conventional distillers grains.

- Event 3272 provides an additional benefit to the ethanol production process by increasing solids content in the starch-to-sugar phase. An increased solids/liquid ratio decreases water use which may also reduce the amount of drying required to evaporate the water in the stillage to produce a marketable distillers grains product. Reduced drying requirements may both improve consistency and quality of distillers grains. One of the most commonly cited problems with DDGS is scorching or burning that result in darkening of the distillers grains, creating an offensive odor, and a potential degradation of nutritional properties.[88] The use of Event 3272 corn may enable ethanol producers to avoid these problems.

[87] Grant Crawford. "Managing High Sulfur Concentrations in Beef Cattle Feedlot Rations". University of Minnesota Beef Center. 2007. Available online at www.extension.umn.edu/beef

[88] D.O. Connor. "The Impact of Changes in the Ethanol Production Process on the Nutritional Value of Distillers Grains". $(S\&T)^2$ Consultants. 2007.

Appendix J. Glossary

	A
Abiotic Stress	Stress due to non-living, environmental factors such as cold, heat, drought, flooding, salinity, toxic substances, and ultraviolet light.
Agrobacterium tumefaciens	A bacterium that causes crown gall disease in some plants. The bacterium characteristically infects a wound and incorporates a piece of its own DNA into the host plant genome, causing the host cell to grow into a tumor-like structure. This DNA-transfer mechanism is commonly exploited in the genetic engineering of plants.
Agrobacterium Tumefaciens-mediated Transformation	The process of DNA transfer from *Agrobacterium tumefaciens* to plants, which occurs naturally during crown gall disease and can be used as a method of transformation.
Allergen	Any substance that causes an allergic reaction.
Alpha-amylase	The major form of amylase found in humans and other mammals. **Amylase** is the name given to glycoside hydrolase enzymes that break down starch into glucose molecules.
Anthesis	Time at which the corn sheds pollen.
Antibiotic Resistance Marker Gene	Genes (usually of bacterial origin) used as selection markers in transformation because their presence allows cell survival in the presence of normally toxic antibiotic agents.
Antinutritional or Antinutritive Compound	A compound in food or animal feed that has a negative impact on nutrition or the absorption of nutrients.
APHIS	Animal and Plant Health Inspection Service.
Archael order Thermococcales	In taxonomy, the **Thermococcales** are an order of the Thermococci, in the Archaea domain. **Archaea** are a major division of microorganisms. Like bacteria, archaea are single-celled organisms lacking nuclei and are therefore prokaryotes, classified as belonging to kingdom Monera in the traditional five-kingdom taxonomy. Although there is still uncertainty in the approximate phylogeny of the groups, Archaea, Eukaryota and Bacteria are the fundamental classifications in what is called the three-domain system. Despite being prokaryotes, archaea are more closely related to eukaryotes than to bacteria.
	B
Barren plants	Corn plants that do not develop an ear.
Benefical organisms	Any organism directly or indirectly advantageous to commodities, including biological control agents [ISPM No. 3, 2005].
Biotechnology	Making specific modifications to the genome of an organism using techniques based on molecular biology, such as gene manipulation, gene transfer, DNA typing, and cloning of plants and animals.
Breeding	The process of sexual reproduction and production of offspring. Plant breeding is an applied science for the development of plants suited for

	the use of humans, rather than their ability to survive in the wild.
BRS	Biotechnology Regulatory Services (USDA–APHIS).
	C
CFR	Code of Federal Regulations (U.S.).
Conservation Tillage	A broad range of soil tillage systems that leave crop residue on the soil surface, substantially reducing the effects of soil erosion from wind and water.
Constitutive Expression	Describing a gene that is expressed (i.e., "turned on") at a relatively constant level in all cells of an organism without regard to cell environmental conditions.
Counterpart	A plant variety (or varieties) that represents the closest appropriate genotype to the transgenic plant in question and is a suitable control taking into account the breeding history of the transgenic plant. In some instances, it may be appropriate to use a transgenic progenitor plant as a counterpart in addition to, or as a substitute for, a non-transgenic counterpart. (NAPPO, RSPM No. 14, Transgenic Materials).
	D
DNA	See Deoxyribonucleic Acid.
Deoxyribonucleic Acid	A nucleic acid that carries the genetic information of a cell. The structure of DNA is two long chains, consisting of chemical building blocks called 'nucleotides,' twisted into a double helix. The order of nucleotides determines hereditary characteristics.
Diploid	The status of having two complete sets of chromosomes, most commonly one set of paternal origin and the other of maternal origin. Somatic tissues of higher plants and animals are ordinarily diploid in chromosome constitution, in contrast with the haploid gametes (FAO).
Donor	An organism that provides a gene or gene fragment used in the genetic transformation of another organism, called the "recipient."
Dry-grind ethanol process	In dry milling, the entire corn kernel or other starchy grain is first ground into flour, which is referred to in the industry as "meal" and processed without separating out the various component parts of the grain. In contrast, wet-milling involves soaking or steeping the grain in water and dilute sulfurous acid for 24 to 48 hours. (RFA website http://www.ethanolrfa.org/resource/made/)
	E
Early root lodging	Percent of plants per plot leaning greater than 30 degrees from vertical at the root prior to anthesis.
ELISA (enzyme-linked immunosorbent serologic assay)	A sensitive assay for detecting a specific protein that uses antibodies to bind to the protein.
EPA	U.S. Environmental Protection Agency.
Event	See Transformation Event.

Expression	The means by which a gene's information stored in DNA (or RNA in some viruses) is turned into biochemical information such as RNA or protein.
	F
F_1 Hybrid	Abbreviation for filial generation 1. The initial hybrid generation resulting from a cross between two parents (FAO).
FDA	Food and Drug Administration.
FFDCA	Federal Food, Drug, and Cosmetic Act.
Flanking Region	The DNA sequences extending on either side of a specific sequence.
FPPA	Federal Plant Pest Act.
	G
GE	See Genetically Engineered.
Gene	The basic unit of heredity transmitted from generation to generation during sexual or asexual reproduction; an ordered sequence of nucleotide bases, comprising of a segment of DNA. A gene contains the sequence of DNA that encodes an individual RNA or protein.
Gene Expression	The process by which a gene produces mRNA and protein and ultimately exerts its effect on the phenotype of an organism.
Gene Flow	The spread of genes from one population to another by the movement of individuals, gametes, seeds, or spores.
Gene Introgression	See Introgression.
Genetic Engineering	Genetic engineering refers to the process in which one or more genes and other genetic elements from one or more organism(s) are inserted into the genetic material of a second organism using recombinant DNA techniques.
Genetically Engineered (GE)	Modified in genotype and, hence, phenotype using recombinant DNA techniques.
GE Organism	Genetically engineered organisms. (See Genetically Engineered.)
GE Plant	Genetically engineered plant. (See Genetically Engineered.)
Genetic Marker	A gene that is a reliable indicator that a particular organism possesses a specific trait of interest. Markers may be used to select certain individual organisms, e.g., cells that have inherited resistance to an antibiotic will be the only ones in a population that survive an antibiotic treatment.
Genetic Transformation	See Transformation.
Genome	All of the hereditary material in a cell including DNA present in the cell nucleus, as well as in other locations such as plant chloroplasts and mitochondria.
Genotype	The total genetic makeup that an individual receives from its parents.
Germination	The initial stages in the growth of a seed to form a seedling (FAO).
GRAS	Generally recognized as safe.

	H
Herbicide Resistance or Tolerance	The ability of a plant to remain relatively unaffected by the application of what would otherwise be a highly damaging dose of an herbicide.
HGT	Horizontal gene transfer
Horizontal Gene Transfer	The transfer of genetic material from one organism (the donor) to another organism (the recipient) that is not sexually compatible with the donor.
Hybrid	The offspring of two genetically dissimilar organisms.
Hyperthermophilic	organism that thrives in extremely hot environments (Hyperthermophile)
	I
Industrial Plant	A plant genetically engineered with a gene whose effect is primarily of industrial use, as opposed to an agricultural or nutritional purpose.
Inserted Gene	A piece of DNA that has been inserted into an organism using recombinant DNA technology.
Introgression	The introduction of genes from one species into the gene pool of another via sexual crossing. The process begins with hybridization between the two species, followed by repeated backcrossing to one of the parent species.
	K
Kernel dough	About 24 to 28 days after silking, the kernel's milky inner fluid is changing to a 'doughy' consistency as starch accumulation continues in the endosperm. The shelled cob is now light red or pink. By dough stage, four embryonic leaves have formed and about half of the mature kernel dry weight is now in place. Kernel abortion is much less likely once kernels have reached early dough stage, but severe stress can continue to affect eventual yield by reducing kernel weight. Kernel moisture content is approximately 70 percent. http://www.ces.purdue.edu/extmedia/CL/CL-10.html
Kernel maturity	About 55 to 65 days after silking, kernel dry weight usually reaches its maximum and kernels are said to be physiologically mature and safe from frost. Physiological maturity occurs shortly after the kernel milk line disappears and just before the kernel black layer forms at the tip of the kernels. Severe stress after physiological maturity has little effect on grain yield, unless the integrity of the stalk or ear is compromised (e.g., ECB damage or stalk rots). Kernel moisture content at physiological maturity averages 30 percent, but can vary from 25 to 40 percent grain moisture. http://www.ces.purdue.edu/extmedia/CL/CL-10.html
	L
Late root lodging	Percent of plants per plot leaning greater than 30 degrees from vertical at the root after anthesis. Used as a measure of abiotic stress tolerance.
Late season	Rating of late-season integrity of the plant above the ear

intactness	
	M
Marker Gene	A gene of known function or known location that is inherited in Mendelian fashion and facilitates the study of inheritance of a nearby gene.
Microorganism	An organism that is microscopic (too small to be seen by the human eye).
Monocot	A flowering plant with only one embryonic seed leaf. Examples include grasses, irises, lilies, and onions. (See Dicot.)
Monoecious	A plant species that has separate male and female flowers on the same plant (e.g. maize) (FAO)
MOU	Memorandum of Understanding.
	N
NEPA	The National Environmental Policy Act of 1969 and subsequent amentments.
NOI	Notice of Intent.
Non-target organisms	An organism which is affected by a treatment (e.g. pesticide application) for which it was not the intended recipient (FAO).
Northern corn leaf blight	Corn disease caused by the fungus *Exserohilum turcicum*
Notification	An administratively-streamlined alternative to a permit for the introduction of a regulated GE plant. The GE plant must meet specified eligibility criteria, and the introduction must meet certain pre-defined performance standards.
	O
OECD	Organisation for Economic Co-operation and Development.
Outcrossing	The tendency of a plant species to produce offspring that result from the mating of two different individual plants. (See Self-pollinated.)
Overwintering	Time at which plants experience 'winter conditions' where growth of vegetative tissues and reproductive structures becomes minimal or ceases completely. (wiki)
	P
Percent snapped plants	Percent of plants per plot broken prior to anthesis due to adverse environmental conditions, such as high wind speeds. Used as a measure of abiotic stress tolerance.
Permits	An application to BRS for the introduction of GE organisms that pose a plant pest risk, including plants, insects, or microbes.
Persistence	Ability of an organism to remain in a particular setting for a period of time after it is introduced (FAO)
Phenotype	The appearance or other characteristics of an organism, resulting from the interaction of its genetic constitution with the environment.
Phosphomannose isomerase	Phosphomannose isomerase (PMI), an enzyme not present in many plants, catalyzes the reversible interconversion of mannose 6-phosphate and fructose 6-phosphate. Plant cells lacking this enzyme

	are incapable of surviving on synthetic medium containing mannose.
Phytosanitary	Plant health, including quarantine (FAO)
Plant Pest	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. (7 CFR 340.1)
Plasmid	An circular self-replicating non-chromosomal DNA molecule found in many bacteria, capable of transfer between bacterial cells of the same species, and occasionally of different species. Antibiotic resistance genes are frequently located on plasmids. Plasmids are particularly important as vectors for genetic engineering (FAO)
PPA	Plant Protection Act.
PPQ	Plant Protection and Quarantine (USDA, APHIS).
Proline	An amino acid. Some plant cells accumulate proline as an osmoprotectant.
Promoter	A region of DNA located upstream of a gene that controls to what degree, where, and/or when a gene is expressed.
Push Test Scores	The number of plants out of 10 plants tested that break at the stalk or have root failure after pushing to 45 degrees from vertical.
	R
Recombinant DNA Technology	The manipulation of DNA in which DNA, including DNA from different organisms, is cut apart and recombined using enzymes.
Recombination	The physical exchange of genetic material between two genetic sequences that produces new combinations of genetic information. (See Homologous recombination and Non-homologous recombination.)
Regulated Article	Subject to APHIS regulation under 7 CFR part 340.
Regulatory sequence	A DNA sequence involved in regulating the expression of a gene, e.g. a promoter or operator region (in the DNA molecule) (FAO)
Ribonucleic Acid (RNA)	A nucleic acid composed of a long, often single-stranded chain of chemical building blocks called 'nucleotides.' RNA has multiple functions in the process of translating information stored in genes (DNA) into proteins.
Ribonucleic Acid	See RNA.
Rotation	In crop production, the cycle of crops grown in successive years in the same field. Rotations are instituted to limit the spread and accumulation of diseases (especially soil-borne diseases) and pests and to manage plant nutrients.
	S

Self-pollinated	The tendency of a plant species to produce offspring that result from a flower pollinating itself. (See Outcrossing.)
Senescence	A late stage in the development of multicellular organisms, during which irreversible loss of function and degradation of biological components occur. The physiological ageing process in which cells and tissues deteriorate and finally die (FAO).
Southern corn leaf blight	Corn disease caused by the fungus *Bipolaris maydis*
Stratification	Chilling or warming seeds, for a period of time, to improve germination.
Sympatric populations	Species undergoing sympatric speciation are not geographically isolated by, for example, a mountain or a river. The diverging populations generally share the same territory. (wiki)
Synergy	The interaction of two or more factors so that their combined effect is greater than the sum of their individual effects.
	T
TES	Threatened and Endangered Species.
Tetraploid	An organism, or a tissue whose cells contain four haploid sets of chromosomes (FAO)
Thermostable	A molecule which retains its biological activity at some specified higher temperature (FAO)
Trait	A characteristic of an organism that manifests itself in the phenotype. Traits may be the result of a single gene or may be polygenic, resulting from the simultaneous expression of more than one gene.
Transformant	A cell or organism that has been genetically altered through the integration of a transgene(s). A “primary” transformant is the first generation following the transformation event.
Transformation	The uptake and integration of DNA in a cell’s genome, in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner.
Transformation Event	A single successful integration of a gene or gene fragment into a cell or a successful deletion of a gene or gene fragment from a cell.
Transgene	A foreign gene that is inserted into the genome of a cell via recombinant DNA techniques.
Transgenic Organism	An organism whose genome has been modified via the stable incorporation of a piece of foreign DNA (a transgene).
	U
	V
Vector	The agent, such as a plasmid, used by researchers to carry new genes into cells.
Vigor	A measure of plant growth, health and robustness during the vegetative growth stage

Volunteer	Plants resulting from crop seed that escapes harvest and remains in the field until subsequent seasons, where it germinates along with the succeeding crop.
	W
Weediness	The ability of a plant to colonize a disturbed habitat and compete with cultivated species.
Whorl	Vegetative stage of the corn plant

Determination of Nonregulated Status for Syngenta Seeds Event 3272 Corn (Alpha-amylase and phosphomannose isomerase corn)

In response to petition 05-280-01p from Syngenta Seeds, Inc., the Animal and Plant Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Event 3272 corn and progeny derived from it are unlikely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that Event 3272 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of Event 3272 corn. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation of Event 3272 corn and its progeny are no longer required. Importation of Event 3272 seeds and other propagative material will still be subject to APHIS foreign quarantine notices in 7 CFR part 319 and Federal Seed Act regulations in 7 CFR part 201.

This determination for Event 3272 is based on APHIS' analysis of field and laboratory data submitted by Syngenta, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for Event 3272 corn. The Final Environmental Assessment (EA), the Finding of No Significant Impacts (FONSI), and the Response to Public Comments on the Draft Environmental Assessment (EA) indicate and confirm that Event 3272 corn is unlikely to pose a plant pest risk.

The Plant Pest Risk Assessment conducted on Event 3272 corn concluded that it is no more a plant pest than conventional corn cultivars, it does not pose a plant pest risk, and it should be granted nonregulated status for the following reasons: (1) the disarmed *Agrobacterium* plant transformation vector used to introduce the genetic material into Event 3272 corn was eliminated and neither the transformation vector nor the introduced genetic material can cause or promote disease, damage or injury to plants; (2) it exhibits no characteristics that would cause it to be weedier or more difficult to control as a weed than the non-genetically engineered corn hybrids evaluated or any other cultivated corn; (3) gene introgression from Event 3272 corn into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other specialty corn varieties; (4) agronomic performance, disease and insect susceptibility, and overall compositional profiles of Event 3272 corn are similar to those of its non-genetically engineered corn counterparts and/or other corn cultivars grown in the U.S., and therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected; and (5) horizontal gene transfer is unlikely to occur between Event 3272 corn and soil bacteria.

Finally, with respect to plant pest risk, the Event 3272 corn and the alpha-amylase enzyme produced by Event 3272 corn are not and cannot be a living stage(s) of any article similar to or allied with any of the articles specified in subparagraphs (A) through (G) of 7 U.S.C. 7702(14) in the Plant Protection Act of 2000 (PPA), and thus do not fall

within the statutory definition of a plant pest as listed in subparagraph (H) of the PPA's plant pest definition.

In addition to our finding that Event 3272 corn is unlikely to pose a plant pest risk, APHIS has completed a Final EA and FONSI for this action and has determined that granting nonregulated status to Event 3272 corn and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats (http://www.aphis.usda.gov/brs/not_reg.html). APHIS also concludes in its PPRA that new varieties derived from Event 3272 corn are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for Event 3272 corn, or those observed for other corn varieties not considered regulated articles under 7 CFR part 340. The commercial cultivation of Event 3272 corn as a specialty corn for ethanol production is unlikely to change agricultural or land use practices for conventional, specialty, or organic corn production (such as pest and weed control, soil conservation, irrigation, crop rotations, etc.) in such a way as to have a significant adverse effect on plants, plant cultivation, plant health, or plant biodiversity.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Service, I have determined and decided that this determination to approve nonregulated status for Event 3272 corn is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

2-11-2011

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

Date