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Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272

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Draft Environmental Assessment

November 6, 2008

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I. Purpose & Need

REGULATORY AUTHORITY

"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.

In 1986, the Federal Government's Office of Science and Technology Policy (OSTP) published a policy document known as the Coordinated Framework for the Regulation of Biotechnology. This document specifies three Federal agencies that are responsible for regulating biotechnology in the U.S.: USDA's APHIS, the U.S. Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). APHIS regulates genetically engineered (GE) organisms under the Plant Protection Act of 2000. FDA regulates under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Products are regulated according to their intended use and some products are regulated by more than one agency. The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment. USDA, EPA, and FDA enforce agency-specific regulations to products of biotechnology that are based on the specific nature of each GE organism.

WHAT IS A REGULATED ORGANISM?

The APHIS Biotechnology Research Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR § 340.2) and is also considered a plant pest.

A person may petition the agency to evaluate submitted data and determine that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should no longer be regulated under 7 CFR § 340.6 "Petition for Determination of Nonregulated Status." The petitioner is required to provide information (§ 340.6(c)(4)) related to plant pest risk that the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. If, based on this information, the agency determines that the article is unlikely to pose a plant pest risk, the article may be granted deregulated status.

WHAT IS THIS PROJECT ABOUT?

APHIS has received a petition from Syngenta Seeds, Inc. (Syngenta) 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 shall no longer be considered regulated articles under 7 CFR part 340.

NEED 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, 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 over 161 ethanol plants in operation in 26 different states, and more than 40 more under construction, 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, 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.

OBJECTIVES FOR EVENT 3272 CORN

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 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 a natural 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 2008).

Once APHIS determines that a GE organism is unlikely to pose a plant pest risk, APHIS does not have any regulatory authority over the GE variety and it may be traditionally bred with other conventional varieties or other GE varieties as determined by the applicant or developer. Syngenta currently has 3 GE corn varieties that may be stacked[1] with Event 3272 corn: two varieties that have an insect-resistance trait (Bt11 and Mir604) and one variety an herbicide-tolerance trait (GA21). These corn lines (Bt11, MIR604, 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. Syngenta has submitted a petition for nonregulated status for another insect resistant corn variety, Mir162 (petition 07-253-01p), and it is possible that Event 3272 corn may be stacked with Mir162, if Mir162 is determined to be unlikely to pose a plant pest risk.

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 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 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[2] 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 the food and feed safety (Appendix H). 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.

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	August 2005	August 2007
	USDA Petition	October 2005	
China	Food, Feed, Processing including Environment	Will be submitted after US approvals	

[1] Two or more traits (e.g. herbicide tolerance and insect resistance) in one plant.
[2] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with the environment" (40 CFR § 1508.14).

Australia/ New Zealand	Food	March 2006	March 2008
Taiwan	Food	March 2006	
Korea	Environment	April 2006	
	Food	December 2006	
Canada	Food	May 2006	March 2008
	Feed	May 2006	March 2008
	Environment	May 2006	March 2008
Japan	Food	May 2006	
	Feed	May 2006	
	Environment	June 2006	
Switzerland	Food	June 2006	
	Feed	June 2006	
Russia	Food	June 2006	
Philippines	Food, feed, processing		February 2008
Republic of South Africa			Not approved

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 genetically engineered corn, the potential coexistence of all types of agricultural 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 will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform APHIS to grant nonregulated status in whole, or that an Environmental Impact Statement of Event 3272 corn is necessary prior to the decision of whether to grant nonregulated status to this corn variety.

ISSUES
As stated above, the issues considered in this EA were developed based on APHIS' determination to 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
- Coexistence
- Impact to Other Specialty Corn Products
- 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
- Soil
- Conservation Reserve Program

DECISIONS TO BE MADE

APHIS will make a determination to grant nonregulated status for Event 3272 corn, given that Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2008). APHIS will also use the information from this EA, and the comments received, to inform APHIS' decisionmaker in determining whether to grant nonregulated status in whole, or to not to grant nonregulated status, or that an Environmental Impact Statement of Event 3272 corn is necessary prior to the decision of whether to grant nonregulated status to this corn variety.

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.

Conventional Farming

Conventional farming includes any farming system where synthetic pesticides or fertilizers may be used. The definition of conventional farming usually includes the use of genetically engineered (GE) varieties, but this document will consider the impacts of Event 3272 corn, a GE corn variety, separately and in comparison to the use of conventional corn varieties in conventional farming systems. 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 pesticide and fertilizer inputs.

United States corn production for 2007, including production of conventional and genetically engineered corn varieties, was 13.1 billion bushels from 86.5 million harvested acres (USDA-NASS 2007a). In 2008, growers expect to harvest 78.9 million acres for grain, down 9 percent from 2007. Of the total corn acres planted in 2008, 80% were GE corn varieties (USDA-NASS 2008a) up from 73% in 2007 (USDA-NASS 2007a), and 61% in 2006 (USDA-NASS 2006). Over 3 billion bushels of corn grain, which includes both GE and non-GE varieties, were used for ethanol production in 2007 (Trostle 2008, USDA-ERS 2008b), which corresponds to over 20% of U.S. corn production.

Agronomic Practices

Today, growers can choose from hundreds of corn hybrids marketed by companies that produce seed (refer to Appendix A for examples of available GE varieties). 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.

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 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).

Weed control methods differ depending on a number of factors including locality, grower resources, and crop trait; the techniques may be direct (e.g. mechanical[3] and chemical[4]) or indirect (e.g. cultural[5]) (Olson and Sander 1988). 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 chose 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.

Organic Farming

For this EA, only corn produced using production systems that fall under the USDA National Organic Program definition of organic farming and are certified organic production systems will be considered. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops is strictly limited. 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 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 2005 (USDA-ERS 2008a); the estimated acreage for certified organic corn in 2007 may be over 220,000 acres, potentially representing 0.26% of the corn acreage in the US. This calculation assumes the 30% increase in organic corn acreage between 2004 and 2005 was sustained to 2007. Corn may be produced using organic practices for ethanol, but on a small scale as a solvent in herbal medicine manufacturing, and not on large scale biofuel production.

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[3] Includes tillage and mowing.
[4] Herbicide application.
[5] Crop rotation/spot spraying of herbicide/hand removal of weeds.

Agricultural production systems may effect 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 effect 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.

Specialty corn systems

The vast majority of corn grown in the U.S. is grown as grain for animal feed. However, approximately 8% of corn grown is specialty corn produced for a specific market or use (USGC 2006). Examples of specialty corn include white corn, waxy corn, hard endosperm, high oil, non-GE, and organic corn (USGC 2006). The uses of these corn varieties include human consumption, food processing (waxy corn) or specialty product (white corn, blue corn). These corn varieties are specified by buyers and end-users of corn for production, and premiums are paid for delivering a product that meets purity and quality standards for the corn variety. 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.

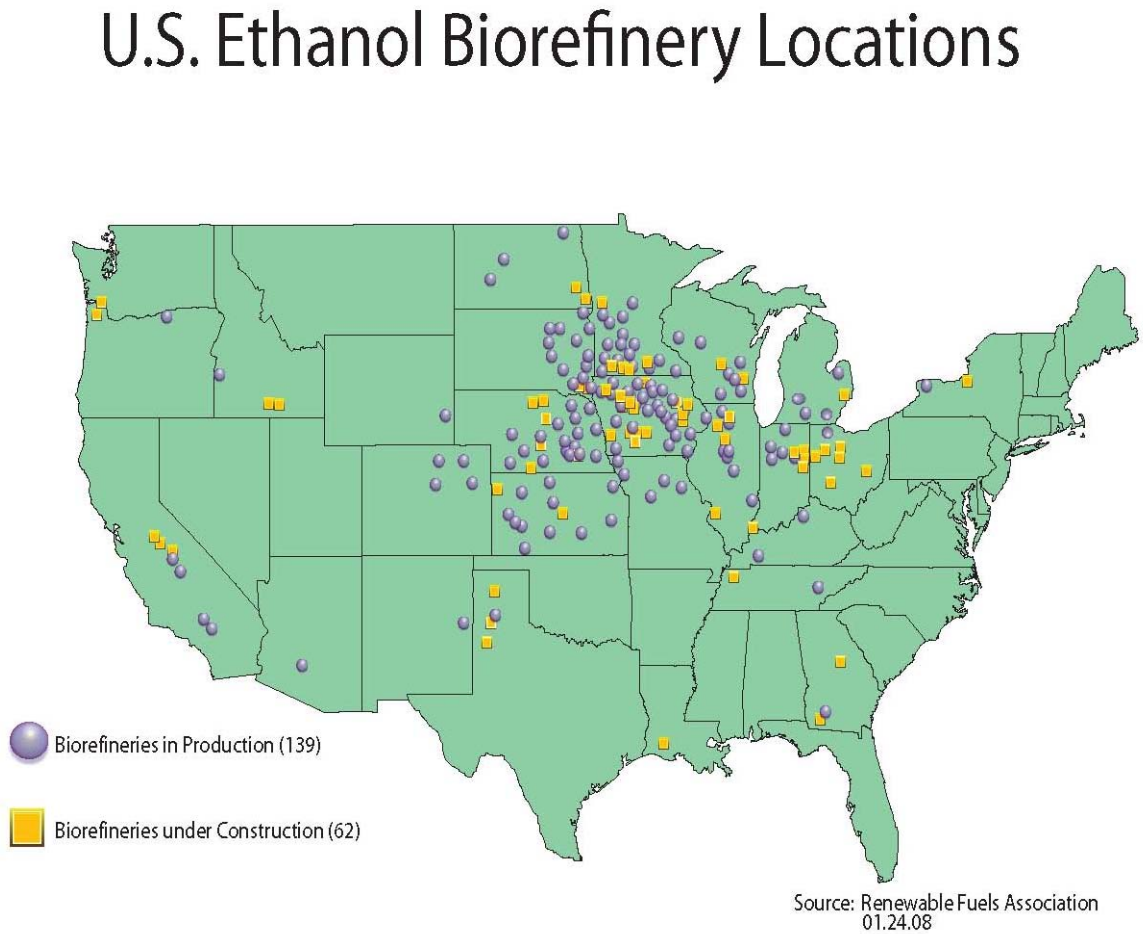
Ethanol Production

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). More than 90 % of U.S. ethanol is made from corn (Morris and Hill 2006).

Over 20% of the 2007 corn production was used for ethanol production (Trostle 2008, USDA-ERS 2008b). 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 80% of corn acreage in the U.S. (USDA-NASS 2008a), 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 July 8, 2008, there were currently 161 operational ethanol plants with a capacity of 9.3 billion gallons per year (bgy) (www.ethanolrfa.org, Figure 1). Another 42 plants are under construction, and 7 are under expansion (Figure 1). The completion of these projects would bring the total ethanol capacity to 13.6 bgy (www.ethanolrfa.org).

Figure 1. Location of the ethanol biorefineries in the US.



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, has an interactive tour of an ethanol processing plants at http://www.ethanol.org/index.php?id=73&parentid=73 (accessed 7/8/08). 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 drygrind 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.cfsan.fda.gov/~lrd/biocon.html (access September 7, 2008).

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 2008). Thus, the public concern surrounding gene movement for GE corn is between GE and non-GE corn plants. Currently, 80% of the conventionally grown corn in the U.S. is GE corn (USDA-NASS 2008a). 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 2007, conventional corn averaged $4.00/bushel (USDA-NASS 2008b), whereas organic corn averaged $10.00/bushel (Alexander 2007).

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 synchrony of flowering between corn fields, viability of pollen, and presence of physical barriers, and thus pollen dispersal is not equivalent to cross fertilization. Sandivo 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. Thus 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 1 bushel of corn (NCGA 2007), and in 2007, 13.3 million bushels of corn were harvested in the U.S (USDA-NASS 2008a). About 20% of corn acres are irrigated, and the rest of corn acreage only receive the ambient rainfall in a given area (NCGA 2007). Water use is the same for across agricultural production systems.

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) (Nielsen, 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[6] enhances the greenhouse effect through emissions of radiatively-active gases[7] (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 nutrients from washing into regional waterways and provide habitat for wildlife (USDA-FSA 2007).

CRP had 36.8 million enrolled acres as of 2007 (USDA-FSA 2007), and enrollment is limited to 39.2 million acres. CRP participants are required by the program to re-enroll or extend their contracts, most of which are set to expire between 2007 and 2010. 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). An estimated 4.9 million acres in CRP contracts will exit CRP between 2007 and 2010 (USDA-FSA 2007). Of the 4.9 million acres, approximately 1.4 million acres are located in major corn producing states. The change from 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 2.7 gallons of ethanol and 16-18 pounds of DDGS. 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 is expected to continue to increase in the future. As biofuel production grows to the 7.5 billion gallons mandated in the Energy Policy Act of 2005, DDGS production is expected to grow to more than 15 million tons (EIA 2007).

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

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

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

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.

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 pose a plant pest risk. The analysis provided in the plant pest risk assessment (USDA-APHIS 2008) demonstrates that there was sufficient data to determine that Event 3272 corn is unlikely to pose a plant pest risk; thus APHIS has no regulatory authority over Event 3272 corn and this GE corn variety is eligible for nonregulated status.

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, the only action alternative considered in this EA is to granting nonregulated status “in whole” to Event 3272 corn. Approval in part can be given if there is a plant pest risk associated with some but not all lines requested in a petition. The petition for Event 3272 corn only requested APHIS to grant nonregulated status to one corn line, so this type “in part” approval will not be considered. Under another type of approval “in part,” the petition may be approved with geographic restrictions if there is a geographic variation in plant pest risk. There are no geographic differences in plant pest risks for Event 3272 corn (USDA-APHIS 2008). Thus, there are two alternatives that will be considered in this EA: (1) no action and (2) to grant nonregulated status to Event 3272 corn, “in whole.”

A. No Action: Continuation as a Regulated Article

Under the "no action" alternative, APHIS would not change the regulated status of Event 3272 corn under the regulations in 7 CFR part 340. The company would have to continue to request permits and notifications for new introductions of Event 3272 corn plants. As such, it would be difficult for the company to commercialize Event 3272 corn under the permit or notification process. Thus, it would be unlikely that Event 3272 corn could effectively increase the efficiency of ethanol production. This alternative is not the preferred alternative because APHIS has already determined through a plant pest risk assessment (USDA-APHIS 2008) that Event 3272 corn is unlikely to pose a plant pest risk. Choosing this alternative would hinder 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 is eligible for nonregulated status because APHIS has determined that this GE organism is unlikely to pose a plant pest risk (USDA-APHIS 2008), thus APHIS has no regulatory authority over Event 3272 corn. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Event 3272 corn, or progeny derived from these events. By granting nonregulated status to Event 3272 corn, the purpose and need to allow the safe development and use of GE organisms is met.

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 legality, 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 in that Event 3272 corn has been determined in APHIS' Plant Pest Risk Assessment not to be a likely plant pest (USDA-APHIS 2008). APHIS has no jurisdiction over plants that have been deemed not to be plant pests.

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 Congress, which states that—

> "…decisions 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
In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance greater than 660ft separating Event 3272 corn from non-GE corn production. However, because Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2008), APHIS has no regulatory authority over Event 3272 corn and is unable to require management practices for this GE corn variety.

Geographic restrictions
In response to public concerns of gene movement between GE and non-GE plants, APHIS considered 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. State-level and county-level restrictions of Event 3272 corn, as well as the establishment of GE-free corn production zones were rejected because Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2008). Therefore APHIS has no regulatory authority over Event 3272 corn and is unable to impose restrictions on this GE corn variety.

Requirement of testing for Event 3272 corn
During the comment periods for other petitions for granting nonregulated status, some commenters have requested that USDA 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. As a member of the Biotechnology Industry Organization (BIO), Syngenta is pledging to work with the framework of the new BIO Quality Management Program (www.bio.org), and has stated to APHIS that a detection method or test that enables event identity for Event 3272 corn will be made available to the public prior to commercialization (see Appendix G). Additionally, because Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2008), APHIS has no regulatory authority over Event 3272 corn and is unable to impose restrictions on this GE corn variety.

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	*Alternative A* *No Action*	*Alternative B* *Deregulation in Whole*
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS 2008)
Management Practices		
Corn Production	Unchanged	**Unchanged**, may **decrease need for corn acreage** due to increased ethanol efficiency
Cropping practices	Unchanged	**Unchanged**
Pesticide use	Unchanged	**Unchanged**
Coexistence	Yes	Yes with good farming practices in place
Farmer choice	Not available commercially	No restrictions
Impact to Specialty Corn	Minimal	Minimal with conditions for closed loop system
Ethanol Production	2.7 gallons/bushel	2.7 gallons/bushel + 2% or greater **increase**
Human and Animal Health		
Public Health: Risk to Human Health	Minimal	Minimal
Public Health: Risk to Worker Safety	Minimal	**Minimal** during corn production; **Decreased** during ethanol production
Animal Feed: DDGS	Unchanged	**Unchanged**
Environment		

Gene Movement	Minimal	Minimal
Water use	Unchanged	**Unchanged** in corn production; **Decrease** during ethanol production
Animals	Unchanged	**Unchanged**
Plants	Unchanged	**Unchanged**
Soil biology	Unchanged	**Unchanged**
CRP Acreage	Unchanged	**Unchanged**; may allow **more acres** to remain in CRP
Other Regulatory Approvals		
U. S.	Completion of FDA consultation	Completion of FDA consultation
Foreign Trade	Approvals from Canada, Philippines, Australia (Table 1)	Approvals from Canada, Philippines, Australia (Table 1)
Compliance with Other Laws		
CWW, CAA. EOs	Fully compliant	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 use to estimate effects for each alternative.

SCOPE OF THE ENVIRONMENTAL ANALYSIS

Although the preferred alternative would allow for new plantings of Event 3272 corn to occur anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support corn production. 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). The 2002 Census data is the most current, publically accessible county-level data available. At the time of developing these alternatives, the 2007 Census of Agriculture was not yet complete.

The list of 49 states that produce corn grain is found in Table 3, according to the 2002 Census of Agriculture. As of July 2008, there are 161 operational ethanol plants, another 42 plants are under construction, and 7 are under expansion (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 3.

Table 3. States that grow corn according to the 2002 Census of Agriculture, and whether the state also has an active corn ethanol facility or one under construction. 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	No
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	No
Michigan	Yes	Washington	Yes
Minnesota	Yes	West Virginia	No
Mississippi	No	Wisconsin	Yes
Missouri	Yes	Wyoming	Yes
Montana	No		

The corn-growing counties within the 26 states that have a corn ethanol plant or one under construction are listed in Appendix B. These 1826 counties in 26 states will be included in the environmental effects analysis for the alternatives. California counties of Marin, Mendocino, Santa Cruz, and Trinity have all passed legislation banning the use of genetically engineered crops. These counties will not be included in the environmental analyses, as Event 3272 corn will not be grown in these counties.

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).

PRODUCT CONTROLS

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 (high amylopectin) corn, high oil corn, high protein and modified protein corn, sweet corn, Indian corn, higher fermentable corn, white corn, blue corn, and high amylase corn (USGC 2006). As discussed above, production of 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.

USE OF CLOSE-LOOPED SYSTEM

Another level of potential control involves utilizing a 'closed-loop' system for specialty grain production. The closed-loop system is a more restrictive system to provide more control over the specialty crop to better protect its value. Syngenta anticipates that Event 3272 corn will be commercialized with the use of contracts and other control mechanisms to establish a 'closed-loop' system for Event 3272 corn. This closed loop system has 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 (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 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. ”

According to Syngenta (see Appendix G), the system for Event 3272 corn will include contracts for Event 3272 corn grown only within the geographic footprint of an ethanol plant. The ethanol plant will contract with growers for Event 3272 corn either directly with 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.

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 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 of 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). Thus, 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

Thus the environmental consequences of the different alternatives described above will be 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. Thus, the analyses of the environmental affects will 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, 80% of the total corn acres planted in 2008 are GE corn varieties (USDA-NASS 2008a), and over 20% of the total corn production in 2007 was used for ethanol production (Trostle 2008, USDA-ERS 2008b). In 2008, growers expect to harvest 78.9 million acres for grain, down 9 percent from 2007.

CONVENTIONAL FARMING

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 2008, 80% were GE corn varieties (USDA-NASS 2008a) up from 73% in 2007 (USDA-NASS 2007a), and 61% in 2006 (USDA-NASS 2006). Conventional production practices that use GE varieties will 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 2002 Census of Agriculture), and under the "no action" alternative, this range of production will be unchanged.

Preferred Alternative: Acreage and Areas of Corn Production

In 2008, GE corn production is planted on 80% of all corn acres currently in production in the US, and the use of GE corn has been steadily increasing over the last 3 years (USDA-NASS 2006, 2007a, 2008a). 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 2008). Additionally, because Event 3272 corn will be marketed for use in ethanol production, this corn variety will be limited to production areas that surround ethanol production facilities. Currently, there are 26 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.

Event 3272 corn has the potential to decrease overall corn 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.

Thus, 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. 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.

Cumulative Effects: Acreage and Areas of Corn Production

Cumulative effects of granting nonregulated status to Event 3272 corn are unlikely. 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. There are no foreseeable changes to the availability of GE and conventional corn varieties on the market.

Cropping practices

Crop Rotation

No Action: Crop Rotation

The current economics of corn production 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 has increased, the frequency of corn-to-corn crop rotations has also increased in areas that support ethanol production (Hart 2006, Stockton et al. 2007), to derive the benefits associated with the increases in corn prices on the commodity market. 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). These prices are driven by demand for corn products in ethanol and for feed. Under the "no action" alternative, the demands and price increases in 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 could be an cumulative increase level in corn pests found in corn fields or an 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). Granting nonregulated status to Event 3272 corn will not change the cumulative effects 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 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.

Cumulative Effects: Tillage

The cumulative effects of tillage include removal of soil residues over time (Lal and Bruce 1999, Triplett and Dick 2008). This cumulative effect of tillage 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 effect corn acreage in the U.S., or 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) using 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.

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 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.

Organic Farming

Coexistence

No Action: Coexistence

GE corn has been in production since the mid-1990's, and in 2008 accounted for 80% of the 87.3 million acres of corn planted (USDA-NASS 2008a). 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 in conventional and organic production systems in the U.S. is increasing, and both production practices will likely continue to increase without granting nonregulated status to Event 3272 under the "no action" alternative. Coexistence measures as discussed in the Methodology and Assumptions section above are expected to continue. 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: Coexistence

Corn produced using organic methods is 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. Without any requirements in place, the production of corn using organic method 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 2007, conventional corn averaged $4.00/bushel (USDA-NASS 2008b), whereas organic corn averaged $10.00/bushel (Alexander 2007). 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 planting (which results in differences in flowering) 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 mandatory measures in their Stewardship Agreement that would facilitate coexistence, including measures to 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 mandatory 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: Coexistence

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 produced using organic methods. 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 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).

Specialty Corn

Specialty corn, such as waxy corn, white corn, blue corn, and organic corn, comprises 8% of the U.S. market (USGC 2006). These specialty corn products intensively use systems to maintain the purity of the corn product, based on the demands of the end-user (e.g., food processing plant). Systems used by specialty corn growers and end-users include to maintain identity of the production include contracts, tracking and traceability systems, quality assurance processes, closed-loop systems, and identity preservation systems.

No Action: Specialty Corn

The availability of methods used to separate specialty corn products from corn used as grain would be the same as currently used in corn production systems under the "no action" alternative.

Preferred Alternative: Specialty Corn

Granting nonregulated status to Event 3272 corn under the "preferred" alternative would not change the availability of using closed-loop systems for specialty corn production. For Event 3272 corn, as 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. There is no benefit to either party if Event 3272 corn is mistakenly routed to a non-ethanol facility.

However, there is 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). However, because of the thermostable properties of the alpha-amylase, Event 3272 corn may have undesirable effects in certain types of processed food products, similar to what may happen if other types of specialty corn products are misdirected into production streams for which they were not intended. In the case of Event 3272 corn, 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 accidently included in the process (Appendices F-H). However, the masa industry also uses strict grain sourcing programs, and only an estimated 4% of the corn used in masa production is from the open market (and not 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 maintain the purity and quality standards of corn for masa production (Appendix G). Thus both Event 3272 corn and corn hybrids for masa production are grown under strong stewardship programs.

In the unlikely event that Event 3272 corn enters a masa facility, mixing of a truck-load of Event 3272 corn into holding bin of corn for masa production results in a dilution of 5x (see Appendix F and Appendix G for scenario development). Further dilution is possible if the truck-load of Event 3272 corn entered a local grain elevator, which may reduce the effects that Event 3272 corn may have on masa production. According to Syngenta, an additional consideration is that less than 10% of corn fields that currently support ethanol plants (areas where Event 3272 corn will be grown), are in the production area for masa-contracted corn fields (Appendix G). Thus, the potential for the misdirection of Event 3272 corn to a masa facility is likely remote.

Cumulative Effects: Specialty Corn
The availability of methods used to separate specialty corn products from corn used as grain would be the same as currently used in corn production systems, and are no changes are foreseeable. No cumulative effects identified for this issue.

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 over 161 ethanol plants in operation in 26 different states, and more than 40 more under construction, 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. Currently, more than 90 % of U.S. ethanol is made from corn (Morris and Hill 2006).

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 2.7 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 production 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. 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 2.7 gallons/bushel of corn, as in the "no action" alternative.

Cumulative Effects: Ethanol Production
There are no other petitions submitted for nonregulated status for GE organisms related to ethanol production. If granted nonregulated status, Event 3272 corn could be the only GE variety available for ethanol production.

Public Heath

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.

No Action: Human Health
Syngenta has successfully completed the consultation process with the FDA for Event 3272 corn (Appendix H). The status of the consultation will not change under the "no action" alternative.

Preferred Alternative: Human Health
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). 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).

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 2008) and effects on wildlife and threatened and endangered species (section on Animals and Threatened and Endangered Species), and those analyses are based on the comparison of the GE-corn to its non-GE counterpart. Other countries have also found Event 3272 corn safe for food and feed, including Canada (2008), Australia (2008), and the Philippines (2008).

In 2006, South Africa denied Syngenta's submission for Event 3272 corn's use for food and feed. It is unclear exactly the reasons for the South African denial of Syngenta's initial submission regarding Event 3272 corn. However, concerns regarding the allergenicity of Event 3272 corn were raised by opponents of genetic engineering (Freese and Mayet 2006). The comments 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 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 thus 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.

Based on the assessment of laboratory data provided by Syngenta and scientific literature [Section E for review, (USDA-APHIS 2008)], 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 (Australia, Canada, and the Phillipines), 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.

<u>Cumulative Effects: Human Health</u>

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

Worker Safety

<u>No Action: Worker Safety</u>

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. 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 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. There are no cumulative effects identified for this issue.

Animal Feed - DDGS

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 is expected to continue to increase in the future. As biofuel production grows to the 7.5 billion gallons mandated in the Energy Policy Act of 2005, DDGS production is expected to grow to more than 15 million tons (EIA 2007).

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.

<u>No Action: Animal Feed - DDGS</u>
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) is not changed under the "no action" alternative.

<u>Preferred Alternative: Animal Feed - DDGS</u>
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 Event 3272 corn is considered safe for use in food and feed.

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 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, the use of Event 3272 corn is still safe for food and feed use, including DDGS (Appendix H).

<u>Cumulative Effects: Animal Feed - DDGS</u>
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 Event

3272 corn is considered safe for use in food and feed. There are no cumulative effects identified for this issue.

Gene Movement

A potential environmental impact to consider as a result of planting this corn variety is the potential for gene flow (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. [see (USDA-APHIS 2008)].

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 synchrony of flowering between corn fields, viability of pollen, and presence of physical barriers; thus 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. 164ft), and this result was validated when analyzing cross-fertilization events in large scale studies (e.g. (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. Thus the results from Jones and Brooks (1950) may be an overestimation of cross-fertilization potential for hybrid corn plants.

<u>No Action: Gene Movement</u>
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.

<u>Preferred Alternative: Gene Movement</u>
In 2008, GE corn production is planted on 80% of all corn acres currently in production in the US, and the use of GE corn has been steadily increasing (USDA-NASS 2006, 2007a, 2008a). 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.

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 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, and thus maintaining the purity of this corn variety is also important. Thus, 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 these 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 2007, conventional corn averaged $4.00/bushel (USDA-NASS 2008b), whereas organic corn averaged $10.00/bushel (Alexander 2007). 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). Thus, commonly used production practices for corn and the practical methods typically used by corn farmers who use organic methods to protect their crop and maximize their profits and premiums granted to corn produced using approved plans currently provide many measures that greatly reduce the likelihood of accidental gene flow between Event 3272 corn and non-GE 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 dampened the organic production of corn. Acreage using GE varieties has increased by 40% since 2005, and there is no corresponding data for acres of corn production under organic methods.

Cumulative Effect: Gene Movement

Event 3272 corn would be an additional GE corn variety that may be available to the farming community. The production area for Event 3272 corn is likely limited to areas in 26 states that have ethanol production facilities because this GE corn variety has been specifically developed for that purpose. The majority of ethanol plants are in the 'corn belt' of the U.S., where the most of the U.S. field corn is grown. There is available GE acreage data (in parentheses) for the following corn belt states that also have ethanol facilities: Indiana (78%), Iowa (84%), Illinois (80%), Ohio (66%), South Dakota (95%), Nebraska (86%), Kansas (90%), Minnesota (88%), Wisconsin (75%), Michigan (72%), and Missouri (70%). 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.

Water Use in Ethanol Production

Ethanol production is an integral part of meeting the renewable fuels standard (RFS) in the U.S. More than 90 % of U.S. ethanol is made from corn (Morris and Hill 2006). 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. Thus, 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
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.

Preferred Alternative: Animals
APHIS has reviewed 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 used to production conventionally grown corn, thus 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. Thus, 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 effect 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 2008). The cumulative effects analysis for this issue is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

<u>No Action: Plants</u>

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, likely with the use of mechanical, cultural, and chemical control methods.

<u>Preferred Alternative: Plants</u>

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. 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, likely with the use of mechanical, cultural, and chemical control methods.

Preferred Alternative: Biological Diversity
Under the “preferred” alternative, environmental releases of Event 3272 corn not require authorization by APHIS. 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.

Cumulative Effects: Animals, Plants, Biodiversity
Event 3272 corn is a new GE corn variety that would be allowed for environmental release without the need for a permit or notification, if granted nonregulated status under the “preferred” alternative. Event 3272 corn has not been genetically engineered to produce a toxin orpesticide, 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 allergencity, 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

If Event 3272 corn is granted nonregulated status under the "preferred" alternative, soil interactions with Event 3272 corn would happen 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.

Cumulative Effects: Soil Biology

Event 3272 corn was found to have small amounts of the alpha-amylase protein (AMY797E) in the roots during the whole stage (<0.1 µg/g fresh weight). One concern may be the potential of additional amounts of AMY797E contributes to alpha-amylase levels in agricultural soils.

One study estimated potential amounts of alpha-amylase in agricultural soils over time and space due to the use of Event 3272 corn. Wolt and Karaman (Wolt and Karaman 2007) assumed levels of AMY797E in grain, leaves, and roots to extrapolate and estimate environmental amounts of alpha-amylase 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 AMY797E, in soils in Iowa corn fields. According to the authors, the potential environmental consequence of the increased loading of alpha-amylase due to AMY797E in agricultural soils was conjectured to be possibly connected to changes in carbon cycling, which in turn may possibly affect the microbial soil community (Wolt and Karaman 2007).

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). 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. Although the calculations by Wolt and Karaman (2007) suggest the potential for increased environmental amounts of alpha-amylase in agricultural crops where Event 3272 corn is grown, the calculations fail to consider the potential for natural degradation of AMY797E. Digestibility data presented to APHIS and FDA (Appendix H) by Syngenta show degradation of AMY797E by a single protease, pepsin. Although pepsin is not normally found in soils, the data do suggest that AMY797E is not inherently indigestible or non-degradable.

Wolt and Karaman (2007) did not present any empirical evidence to suggest that AMY797E would persist. 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 on the thermostability of each of the proteins, and not the degradability of the proteins. The authors also did not present empirical evidence that AMY797E will accumulate in soil.

Because small amounts of AMY797E are found in the roots (<0.1 µg/g fresh weight), the main avenue for AMY797E to find its way into the soil is through the degradation of grain. Grain is the main source of AMY797E, and Event 3272 corn was engineered to produce alpha-amylase in the grain because ethanol production uses grain as the starting material. Event 3272 grain contains 1627 µg/g fresh weight of alpha-amylase in the dough stage (Table 3-3, page 44 of Petition). According to Wolt and Karaman (2007), approximately 1% of grain is lost during harvest, which falls to the ground in the field. These grain residues will need to degrade prior to the release of AMY797E into soil. Thus, grain left in the field does not immediately result in the increased amounts of alpha-amylase in soil. The study does also not test the activity of AMY797E in soil, or if AMY797E is likely to be active in agricultural soils. AMY797E, like other enzymes, have specific requirements as to 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, AMY797E is constructed for maximum activity at 176ºF (80ºC), and only has 10% of its maximal activity under 86ºF (30ºC). None of these factors were considered in the estimations and conjecture of potential contributes of AMY797E to alpha-amylase levels in the soil by Wolt and Karaman (2007).

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).

<u>No Action: Conservation Reserve Program</u>

Acres removed or maintained in the Conservation Reserve Program will not be affected under the "no action" alternative. Demands for ethanol production and corn prices may still result in growers removing acres from the CRP and placing them into corn production, under the "no action" alternative.

<u>Preferred Alternative: Conservation Reserve Program</u>

As stated in Section II, the demands for ethanol production and increased corn prices may still result in growers removing acres from the CRP and place them into corn production, independent of granting Event 3272 nonregulated status. Because Event 3272 corn may provide a potential increase in ethanol production efficiency (Appendix C), fewer acres of corn production may be needed to meet ethanol demands if Event 3272 corn is an available variety. If ethanol demands could be met with fewer acres of corn production, this may translate into less acreage removed from the CRP program to meet the mandated amounts of ethanol production. Thus, under the "preferred" alternative, Event 3272 corn would be available to growers, and could be used as a potential method to keep more acres in CRP and still meet the mandated goals for ethanol production. However, even if the use of Event 3272 corn did not result in a measurable increase in ethanol efficiency during production, granting Event 3272 corn nonregulated status would not result in the increase of acreage being removed from the CRP program. Market demands and corn prices are the drivers behind decisions made by growers to remove acres from CRP (Hart 2006).

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.

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. APHIS does not have any regulatory authority over these GE corn varieties previously granted nonregulated status, and has no regulatory jurisdiction over stacked varieties combining deregulated GE varieties unless it could be positively shown that such stacked varieties somehow posed a likely 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), 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 in found 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 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), 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. Thus, 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). Thus, 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). 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 effect 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 phosphomannose isomerase (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. Thus 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 a 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 [see (USDA-APHIS 2008) for the plant pest risk assessment of Event 3272 corn].

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 (169 countries as of September 2008). 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 147 countries are Parties to it as of September 1, 2008 (CBD 2008) . Although the U.S. is not a party to the CBD, and thus 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

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Appendix A. Biotech Seed Products Available for the 2008 Planting Season[1,2,3]

PRODUCT REGISTRANT TRADE NAME	CHARACTERISTIC	EVENT
Syngenta Agrisure CB/LL	Cry1Ab Corn borer protection Glufosinate herbicide tolerance	Bt11
DowAgrosciences Pioneer Hi-Bred Herculex I	Cry1F Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance Glufosinate herbicide tolerance	TC1507
MonsantoYieldGard	Cry1Ab Corn borer protection	MON 810
MonsantoYieldGard Roundup Ready 2	Cry1Ab Corn borer protection Glyphosate Herbicide Tolerance	MON 810+Nk603
YieldGard Corn Rootworm Protection Roundup Ready 2	Corn Rootworm Protection Glyphosate Herbicide Tolerance	MON 863+Nk603
YieldGard Corn Rootworm Protection	Corn Rootworm Protection	MON 863
Monsanto Roundup Ready 2	Glyphosate Herbicide Tolerance	Nk603
Bayer CropScience LibertyLink®	Glufosinate herbicide tolerance	T25
MonsantoYieldGard Plus	Cry1Ab Corn borer protection Corn Rootworm Protection	MON 810+MON 863
MonsantoYieldGard Plus with Roundup Ready 2	Cry1Ab Corn borer protection Corn Rootworm Protection Glyphosate Herbicide Tolerance	MON 810+MON 863+NK603
Herculex I Roundup Ready 2	Cry1F Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance Glyphosate Herbicide Tolerance Glufosinate herbicide tolerance	TC1507+NK603
Syngenta Agrisure GT	Glyphosate Herbicide Tolerance	SYTGA21
Syngenta Agrisure GT/CB/LL	Cry1Ab Corn borer protection Glyphosate Herbicide Tolerance Glufosinate herbicide tolerance	SYTGA21 + Bt11
MonsantoYieldGard Roundup Ready	Cry1Ab corn borer resistance Glyphosate Herbicide Tolerance	MON 810+SYTGA21
Dow AgroSciences Pioneer Hi-Bred Herculex RW	Cry34/35Ab1 Western Corn Rootworm Northern Corn Rootworm Mexican Corn Glufosinate herbicide tolerance	DAS-59122-7
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 Mexican Corn Rootworm Resistance Glufosinate Herbicide Tolerance	TC1507 + DAS 59122-7
Dow AgroSciences Pioneer Hi-Bred Herculex Rootworm Monsanto Roundup Ready 2	Cry34/35Ab1 Western Corn Rootworm Northern Corn Rootworm Mexican Corn Glyphosate Herbicide Tolerance	DAS-59122-7 + NK603

Dow AgroSciences Pioneer Hi-Bred Herculex Xtra Monsanto Roundup Ready 2	Cry1F Western Bean Cutworm, Corn Borer, Black Cutworm and Fall Armyworm resistance Glufosinate herbicide tolerance Cry34/35Ab1 Western Corn Rootworm Northern Corn Rootworm Mexican Corn Glyphosate Herbicide Tolerance	TC1507 + DAS 59122-7 + NK603
YieldGard VT™ Rootworm/RR2	Corn Rootworm Protection Glyphosate Herbicide Tolerance	MON 88017
YieldGard VT™ Triple	Cry1Ab Corn borer protection Corn Rootworm Protection Glyphosate Herbicide Tolerance	MON 810 + MON 88017
Syngenta Agrisure RW	Modified Cry3A, Protection of Western, Northern and Mexican corn rootworm	MIR604
Syngenta Agrisure GT/RW	Modified Cry3A, Protection of Western, Northern and Mexican corn rootworm and Glyphosate herbicide tolerance	MIR604+SYTGA21
Syngenta Agrisure CB/LL/RW	Cry1Ab Corn borer protection Modified Cry3A, Protection of Western, Northern and Mexican corn rootworm and Glufosinate herbicide tolerance	Bt11+MIR604
Syngenta Agrisure 3000GT	Glyphosate Herbicide Tolerance Cry1Ab Corn borer protection Modified Cry3A, Protection of Western, Northern and Mexican corn rootworm and Glufosinate herbicide tolerance	SYTGA21+Bt11+MIR604

[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 26 states that have corn ethanol facilities

State/County	State/County	State/County	State/County
Arizona\Apache	Colorado\Kiowa	Georgia\Coweta	Georgia\Long
Arizona\Cochise	Colorado\Kit Carson	Georgia\Crawford	Georgia\Lowndes
Arizona\Coconino	Colorado\La Plata	Georgia\Crisp	Georgia\Lumpkin
Arizona\Graham	Colorado\Larimer	Georgia\Dade	Georgia\McDuffie
Arizona\Greenlee	Colorado\Lincoln	Georgia\Dawson	Georgia\Macon
Arizona\La Paz	Colorado\Logan	Georgia\Decatur	Georgia\Madison
Arizona\Maricopa	Colorado\Mesa	Georgia\Dodge	Georgia\Marion
Arizona\Navajo	Colorado\Montrose	Georgia\Dooly	Georgia\Meriwether
Arizona\Pinal	Colorado\Morgan	Georgia\Dougherty	Georgia\Miller
Arizona\Yavapai	Colorado\Otero	Georgia\Douglas	Georgia\Mitchell
Arizona\Yuma	Colorado\Phillips	Georgia\Early	Georgia\Montgomery
California\Alameda	Colorado\Prowers	Georgia\Echols	Georgia\Murray
California\Amador	Colorado\Pueblo	Georgia\Effingham	Georgia\Newton
California\Butte	Colorado\Routt	Georgia\Elbert	Georgia\Oconee
California\Colusa	Colorado\Sedgwick	Georgia\Emanuel	Georgia\Oglethorpe
California\Contra Costa	Colorado\Washington	Georgia\Evans	Georgia\Peach
California\Fresno	Colorado\Weld	Georgia\Fannin	Georgia\Pickens
California\Glenn	Colorado\Yuma	Georgia\Fayette	Georgia\Pierce
California\Imperial	Georgia\Appling	Georgia\Floyd	Georgia\Pike
California\Kern	Georgia\Atkinson	Georgia\Forsyth	Georgia\Polk
California\Kings	Georgia\Bacon	Georgia\Franklin	Georgia\Pulaski
California\Madera	Georgia\Baker	Georgia\Fulton	Georgia\Putnam
California\Mendocino	Georgia\Baldwin	Georgia\Gilmer	Georgia\Quitman
California\Merced	Georgia\Banks	Georgia\Glynn	Georgia\Rabun
California\Monterey	Georgia\Bartow	Georgia\Gordon	Georgia\Randolph
California\Riverside	Georgia\Ben Hill	Georgia\Grady	Georgia\Richmond
California\Sacramento	Georgia\Berrien	Georgia\Greene	Georgia\Schley
California\San Joaquin	Georgia\Bibb	Georgia\Gwinnett	Georgia\Screven
California\San Luis Obispo	Georgia\Bleckley	Georgia\Habersham	Georgia\Seminole
California\Santa Barbara	Georgia\Brantley	Georgia\Hall	Georgia\Stephens
California\Santa Clara	Georgia\Brooks	Georgia\Hancock	Georgia\Stewart
California\Shasta	Georgia\Bryan	Georgia\Haralson	Georgia\Sumter
California\Solano	Georgia\Bulloch	Georgia\Harris	Georgia\Talbot
California\Sonoma	Georgia\Burke	Georgia\Hart	Georgia\Taliaferro
California\Stanislaus	Georgia\Butts	Georgia\Heard	Georgia\Tattnall
California\Sutter	Georgia\Calhoun	Georgia\Henry	Georgia\Taylor
California\Tehama	Georgia\Camden	Georgia\Houston	Georgia\Telfair
California\Tulare	Georgia\Candler	Georgia\Irwin	Georgia\Terrell
California\Ventura	Georgia\Carroll	Georgia\Jackson	Georgia\Thomas
California\Yolo	Georgia\Catoosa	Georgia\Jasper	Georgia\Tift
California\Yuba	Georgia\Charlton	Georgia\Jeff Davis	Georgia\Toombs
Colorado\Adams	Georgia\Chatham	Georgia\Jefferson	Georgia\Towns
Colorado\Arapahoe	Georgia\Chattooga	Georgia\Jenkins	Georgia\Treutlen
Colorado\Baca	Georgia\Cherokee	Georgia\Johnson	Georgia\Turner
Colorado\Bent	Georgia\Clay	Georgia\Jones	Georgia\Twiggs
Colorado\Boulder	Georgia\Clinch	Georgia\Lamar	Georgia\Union
Colorado\Cheyenne	Georgia\Cobb	Georgia\Lanier	Georgia\Upson
Colorado\Crowley	Georgia\Coffee	Georgia\Laurens	Georgia\Walker
Colorado\Delta	Georgia\Colquitt	Georgia\Lee	Georgia\Walton
Colorado\Dolores	Georgia\Columbia	Georgia\Liberty	Georgia\Ware
Colorado\Elbert	Georgia\Cook	Georgia\Lincoln	Georgia\Warren

State/County	State/County	State/County	State/County
Georgia\Washington	Illinois\Edgar	Illinois\Piatt	Indiana\Fountain
Georgia\Wayne	Illinois\Edwards	Illinois\Pike	Indiana\Franklin
Georgia\Webster	Illinois\Effingham	Illinois\Pope	Indiana\Fulton
Georgia\Wheeler	Illinois\Fayette	Illinois\Pulaski	Indiana\Gibson
Georgia\White	Illinois\Ford	Illinois\Putnam	Indiana\Grant
Georgia\Whitfield	Illinois\Franklin	Illinois\Randolph	Indiana\Greene
Georgia\Wilcox	Illinois\Fulton	Illinois\Richland	Indiana\Hamilton
Georgia\Wilkes	Illinois\Gallatin	Illinois\Rock Island	Indiana\Hancock
Georgia\Wilkinson	Illinois\Greene	Illinois\St. Clair	Indiana\Harrison
Georgia\Worth	Illinois\Grundy	Illinois\Saline	Indiana\Hendricks
Idaho\Ada	Illinois\Hamilton	Illinois\Sangamon	Indiana\Henry
Idaho\Bingham	Illinois\Hancock	Illinois\Schuyler	Indiana\Howard
Idaho\Blaine	Illinois\Hardin	Illinois\Scott	Indiana\Huntington
Idaho\Boundary	Illinois\Henderson	Illinois\Shelby	Indiana\Jackson
Idaho\Canyon	Illinois\Henry	Illinois\Stark	Indiana\Jasper
Idaho\Cassia	Illinois\Iroquois	Illinois\Stephenson	Indiana\Jay
Idaho\Elmore	Illinois\Jackson	Illinois\Tazewell	Indiana\Jefferson
Idaho\Franklin	Illinois\Jasper	Illinois\Union	Indiana\Jennings
Idaho\Gem	Illinois\Jefferson	Illinois\Vermilion	Indiana\Johnson
Idaho\Gooding	Illinois\Jersey	Illinois\Wabash	Indiana\Knox
Idaho\Jerome	Illinois\Jo Daviess	Illinois\Warren	Indiana\Kosciusko
Idaho\Lincoln	Illinois\Johnson	Illinois\Washington	Indiana\LaGrange
Idaho\Minidoka	Illinois\Kane	Illinois\Wayne	Indiana\Lake
Idaho\Nez Perce	Illinois\Kankakee	Illinois\White	Indiana\LaPorte
Idaho\Owyhee	Illinois\Kendall	Illinois\Whiteside	Indiana\Lawrence
Idaho\Payette	Illinois\Knox	Illinois\Will	Indiana\Madison
Idaho\Power	Illinois\Lake	Illinois\Williamson	Indiana\Marion
Idaho\Twin Falls	Illinois\La Salle	Illinois\Winnebago	Indiana\Marshall
Idaho\Washington	Illinois\Lawrence	Illinois\Woodford	Indiana\Martin
Illinois\Adams	Illinois\Lee	Indiana\Adams	Indiana\Miami
Illinois\Alexander	Illinois\Livingston	Indiana\Allen	Indiana\Monroe
Illinois\Bond	Illinois\Logan	Indiana\Bartholomew	Indiana\Montgomery
Illinois\Boone	Illinois\McDonough	Indiana\Benton	Indiana\Morgan
Illinois\Brown	Illinois\McHenry	Indiana\Blackford	Indiana\Newton
Illinois\Bureau	Illinois\McLean	Indiana\Boone	Indiana\Noble
Illinois\Calhoun	Illinois\Macon	Indiana\Brown	Indiana\Ohio
Illinois\Carroll	Illinois\Macoupin	Indiana\Carroll	Indiana\Orange
Illinois\Cass	Illinois\Madison	Indiana\Cass	Indiana\Owen
Illinois\Champaign	Illinois\Marion	Indiana\Clark	Indiana\Parke
Illinois\Christian	Illinois\Marshall	Indiana\Clay	Indiana\Perry
Illinois\Clark	Illinois\Mason	Indiana\Clinton	Indiana\Pike
Illinois\Clay	Illinois\Massac	Indiana\Crawford	Indiana\Porter
Illinois\Clinton	Illinois\Menard	Indiana\Daviess	Indiana\Posey
Illinois\Coles	Illinois\Mercer	Indiana\Dearborn	Indiana\Pulaski
Illinois\Cook	Illinois\Monroe	Indiana\Decatur	Indiana\Putnam
Illinois\Crawford	Illinois\Montgomery	Indiana\DeKalb	Indiana\Randolph
Illinois\Cumberland	Illinois\Morgan	Indiana\Delaware	Indiana\Ripley
Illinois\DeKalb	Illinois\Moultrie	Indiana\Dubois	Indiana\Rush
Illinois\De Witt	Illinois\Ogle	Indiana\Elkhart	Indiana\St. Joseph
Illinois\Douglas	Illinois\Peoria	Indiana\Fayette	Indiana\Scott
Illinois\DuPage	Illinois\Perry	Indiana\Floyd	Indiana\Shelby

State/County	State/County	State/County	State/County
Indiana\Spencer	Iowa\Fayette	Iowa\Sioux	Kansas\Greeley
Indiana\Starke	Iowa\Floyd	Iowa\Story	Kansas\Greenwood
Indiana\Steuben	Iowa\Franklin	Iowa\Tama	Kansas\Hamilton
Indiana\Sullivan	Iowa\Fremont	Iowa\Taylor	Kansas\Harper
Indiana\Switzerland	Iowa\Greene	Iowa\Union	Kansas\Harvey
Indiana\Tippecanoe	Iowa\Grundy	Iowa\Van Buren	Kansas\Haskell
Indiana\Tipton	Iowa\Guthrie	Iowa\Wapello	Kansas\Hodgeman
Indiana\Union	Iowa\Hamilton	Iowa\Warren	Kansas\Jackson
Indiana\Vanderburgh	Iowa\Hancock	Iowa\Washington	Kansas\Jefferson
Indiana\Vermillion	Iowa\Hardin	Iowa\Wayne	Kansas\Jewell
Indiana\Vigo	Iowa\Harrison	Iowa\Webster	Kansas\Johnson
Indiana\Wabash	Iowa\Henry	Iowa\Winnebago	Kansas\Kearny
Indiana\Warren	Iowa\Howard	Iowa\Winneshiek	Kansas\Kingman
Indiana\Warrick	Iowa\Humboldt	Iowa\Woodbury	Kansas\Kiowa
Indiana\Washington	Iowa\Ida	Iowa\Worth	Kansas\Labette
Indiana\Wayne	Iowa\Iowa	Iowa\Wright	Kansas\Lane
Indiana\Wells	Iowa\Jackson	Kansas\Allen	Kansas\Leavenworth
Indiana\White	Iowa\Jasper	Kansas\Anderson	Kansas\Lincoln
Indiana\Whitley	Iowa\Jefferson	Kansas\Atchison	Kansas\Linn
Iowa\Adair	Iowa\Johnson	Kansas\Barber	Kansas\Logan
Iowa\Adams	Iowa\Jones	Kansas\Barton	Kansas\Lyon
Iowa\Allamakee	Iowa\Keokuk	Kansas\Bourbon	Kansas\McPherson
Iowa\Appanoose	Iowa\Kossuth	Kansas\Brown	Kansas\Marion
Iowa\Audubon	Iowa\Lee	Kansas\Butler	Kansas\Marshall
Iowa\Benton	Iowa\Linn	Kansas\Chase	Kansas\Meade
Iowa\Black Hawk	Iowa\Louisa	Kansas\Chautauqua	Kansas\Miami
Iowa\Boone	Iowa\Lucas	Kansas\Cherokee	Kansas\Mitchell
Iowa\Bremer	Iowa\Lyon	Kansas\Cheyenne	Kansas\Montgomery
Iowa\Buchanan	Iowa\Madison	Kansas\Clark	Kansas\Morris
Iowa\Buena Vista	Iowa\Mahaska	Kansas\Clay	Kansas\Morton
Iowa\Butler	Iowa\Marion	Kansas\Cloud	Kansas\Nemaha
Iowa\Calhoun	Iowa\Marshall	Kansas\Coffey	Kansas\Neosho
Iowa\Carroll	Iowa\Mills	Kansas\Comanche	Kansas\Ness
Iowa\Cass	Iowa\Mitchell	Kansas\Cowley	Kansas\Norton
Iowa\Cedar	Iowa\Monona	Kansas\Crawford	Kansas\Osage
Iowa\Cerro Gordo	Iowa\Monroe	Kansas\Decatur	Kansas\Osborne
Iowa\Cherokee	Iowa\Montgomery	Kansas\Dickinson	Kansas\Ottawa
Iowa\Chickasaw	Iowa\Muscatine	Kansas\Doniphan	Kansas\Pawnee
Iowa\Clarke	Iowa\O"Brien	Kansas\Douglas	Kansas\Phillips
Iowa\Clay	Iowa\Osceola	Kansas\Edwards	Kansas\Pottawatomie
Iowa\Clayton	Iowa\Page	Kansas\Elk	Kansas\Pratt
Iowa\Clinton	Iowa\Palo Alto	Kansas\Ellis	Kansas\Rawlins
Iowa\Crawford	Iowa\Plymouth	Kansas\Ellsworth	Kansas\Reno
Iowa\Dallas	Iowa\Pocahontas	Kansas\Finney	Kansas\Republic
Iowa\Davis	Iowa\Polk	Kansas\Ford	Kansas\Rice
Iowa\Decatur	Iowa\Pottawattamie	Kansas\Franklin	Kansas\Riley
Iowa\Delaware	Iowa\Poweshiek	Kansas\Geary	Kansas\Rooks
Iowa\Des Moines	Iowa\Ringgold	Kansas\Gove	Kansas\Rush
Iowa\Dickinson	Iowa\Sac	Kansas\Graham	Kansas\Russell
Iowa\Dubuque	Iowa\Scott	Kansas\Grant	Kansas\Saline
Iowa\Emmet	Iowa\Shelby	Kansas\Gray	Kansas\Scott

State/County	State/County	State/County	State/County
Kansas\Sedgwick	Kentucky\Estill	Kentucky\Montgomery	Michigan\Clare
Kansas\Seward	Kentucky\Fayette	Kentucky\Morgan	Michigan\Clinton
Kansas\Shawnee	Kentucky\Fleming	Kentucky\Muhlenberg	Michigan\Crawford
Kansas\Sheridan	Kentucky\Floyd	Kentucky\Nelson	Michigan\Delta
Kansas\Sherman	Kentucky\Franklin	Kentucky\Nicholas	Michigan\Dickinson
Kansas\Smith	Kentucky\Fulton	Kentucky\Ohio	Michigan\Eaton
Kansas\Stafford	Kentucky\Gallatin	Kentucky\Oldham	Michigan\Emmet
Kansas\Stanton	Kentucky\Garrard	Kentucky\Owen	Michigan\Genesee
Kansas\Stevens	Kentucky\Grant	Kentucky\Owsley	Michigan\Gladwin
Kansas\Sumner	Kentucky\Graves	Kentucky\Pendleton	Michigan\Grand Traverse
Kansas\Thomas	Kentucky\Grayson	Kentucky\Perry	Michigan\Gratiot
Kansas\Trego	Kentucky\Green	Kentucky\Pike	Michigan\Hillsdale
Kansas\Wabaunsee	Kentucky\Greenup	Kentucky\Powell	Michigan\Houghton
Kansas\Wallace	Kentucky\Hancock	Kentucky\Pulaski	Michigan\Huron
Kansas\Washington	Kentucky\Hardin	Kentucky\Robertson	Michigan\Ingham
Kansas\Wichita	Kentucky\Harrison	Kentucky\Rockcastle	Michigan\Ionia
Kansas\Wilson	Kentucky\Hart	Kentucky\Rowan	Michigan\Iosco
Kansas\Woodson	Kentucky\Henderson	Kentucky\Russell	Michigan\Isabella
Kansas\Wyandotte	Kentucky\Henry	Kentucky\Scott	Michigan\Jackson
Kentucky\Adair	Kentucky\Hickman	Kentucky\Shelby	Michigan\Kalamazoo
Kentucky\Allen	Kentucky\Hopkins	Kentucky\Simpson	Michigan\Kalkaska
Kentucky\Anderson	Kentucky\Jackson	Kentucky\Spencer	Michigan\Kent
Kentucky\Ballard	Kentucky\Jefferson	Kentucky\Taylor	Michigan\Lake
Kentucky\Barren	Kentucky\Jessamine	Kentucky\Todd	Michigan\Lapeer
Kentucky\Bath	Kentucky\Johnson	Kentucky\Trigg	Michigan\Leelanau
Kentucky\Bell	Kentucky\Kenton	Kentucky\Trimble	Michigan\Lenawee
Kentucky\Boone	Kentucky\Knox	Kentucky\Union	Michigan\Livingston
Kentucky\Bourbon	Kentucky\Larue	Kentucky\Warren	Michigan\Luce
Kentucky\Boyd	Kentucky\Laurel	Kentucky\Washington	Michigan\Mackinac
Kentucky\Boyle	Kentucky\Lawrence	Kentucky\Wayne	Michigan\Macomb
Kentucky\Bracken	Kentucky\Lee	Kentucky\Webster	Michigan\Manistee
Kentucky\Breathitt	Kentucky\Letcher	Kentucky\Whitley	Michigan\Marquette
Kentucky\Breckinridge	Kentucky\Lewis	Kentucky\Wolfe	Michigan\Mason
Kentucky\Bullitt	Kentucky\Lincoln	Kentucky\Woodford	Michigan\Mecosta
Kentucky\Butler	Kentucky\Livingston	Michigan\Alcona	Michigan\Menominee
Kentucky\Caldwell	Kentucky\Logan	Michigan\Alger	Michigan\Midland
Kentucky\Calloway	Kentucky\Lyon	Michigan\Allegan	Michigan\Missaukee
Kentucky\Campbell	Kentucky\McCracken	Michigan\Alpena	Michigan\Monroe
Kentucky\Carlisle	Kentucky\McCreary	Michigan\Antrim	Michigan\Montcalm
Kentucky\Carroll	Kentucky\McLean	Michigan\Arenac	Michigan\Montmorency
Kentucky\Carter	Kentucky\Madison	Michigan\Baraga	Michigan\Muskegon
Kentucky\Casey	Kentucky\Magoffin	Michigan\Barry	Michigan\Newaygo
Kentucky\Christian	Kentucky\Marion	Michigan\Bay	Michigan\Oakland
Kentucky\Clark	Kentucky\Marshall	Michigan\Benzie	Michigan\Oceana
Kentucky\Clay	Kentucky\Martin	Michigan\Berrien	Michigan\Ogemaw
Kentucky\Clinton	Kentucky\Mason	Michigan\Branch	Michigan\Ontonagon
Kentucky\Crittenden	Kentucky\Meade	Michigan\Calhoun	Michigan\Osceola
Kentucky\Cumberland	Kentucky\Menifee	Michigan\Cass	Michigan\Oscoda
Kentucky\Daviess	Kentucky\Mercer	Michigan\Charlevoix	Michigan\Otsego
Kentucky\Edmonson	Kentucky\Metcalfe	Michigan\Cheboygan	Michigan\Ottawa
Kentucky\Elliott	Kentucky\Monroe	Michigan\Chippewa	Michigan\Presque Isle

State/County	State/County	State/County	State/County
Michigan\Roscommon	Minnesota\Lyon	Missouri\Bates	Missouri\Madison
Michigan\Saginaw	Minnesota\McLeod	Missouri\Benton	Missouri\Maries
Michigan\St. Clair	Minnesota\Mahnomen	Missouri\Bollinger	Missouri\Marion
Michigan\St. Joseph	Minnesota\Marshall	Missouri\Boone	Missouri\Mercer
Michigan\Sanilac	Minnesota\Martin	Missouri\Buchanan	Missouri\Miller
Michigan\Schoolcraft	Minnesota\Meeker	Missouri\Butler	Missouri\Mississippi
Michigan\Shiawassee	Minnesota\Mille Lacs	Missouri\Caldwell	Missouri\Moniteau
Michigan\Tuscola	Minnesota\Morrison	Missouri\Callaway	Missouri\Monroe
Michigan\Van Buren	Minnesota\Mower	Missouri\Camden	Missouri\Montgomery
Michigan\Washtenaw	Minnesota\Murray	Missouri\Cape Girardeau	Missouri\Morgan
Michigan\Wayne	Minnesota\Nicollet	Missouri\Carroll	Missouri\New Madrid
Michigan\Wexford	Minnesota\Nobles	Missouri\Cass	Missouri\Newton
Minnesota\Aitkin	Minnesota\Norman	Missouri\Cedar	Missouri\Nodaway
Minnesota\Anoka	Minnesota\Olmsted	Missouri\Chariton	Missouri\Oregon
Minnesota\Becker	Minnesota\Otter Tail	Missouri\Christian	Missouri\Osage
Minnesota\Beltrami	Minnesota\Pennington	Missouri\Clark	Missouri\Ozark
Minnesota\Benton	Minnesota\Pine	Missouri\Clay	Missouri\Pemiscot
Minnesota\Big Stone	Minnesota\Pipestone	Missouri\Clinton	Missouri\Perry
Minnesota\Blue Earth	Minnesota\Polk	Missouri\Cole	Missouri\Pettis
Minnesota\Brown	Minnesota\Pope	Missouri\Cooper	Missouri\Phelps
Minnesota\Carlton	Minnesota\Red Lake	Missouri\Crawford	Missouri\Pike
Minnesota\Carver	Minnesota\Redwood	Missouri\Dade	Missouri\Platte
Minnesota\Cass	Minnesota\Renville	Missouri\Dallas	Missouri\Polk
Minnesota\Chippewa	Minnesota\Rice	Missouri\Daviess	Missouri\Pulaski
Minnesota\Chisago	Minnesota\Rock	Missouri\DeKalb	Missouri\Putnam
Minnesota\Clay	Minnesota\Roseau	Missouri\Dent	Missouri\Ralls
Minnesota\Clearwater	Minnesota\St. Louis	Missouri\Dunklin	Missouri\Randolph
Minnesota\Cook	Minnesota\Scott	Missouri\Franklin	Missouri\Ray
Minnesota\Cottonwood	Minnesota\Sherburne	Missouri\Gasconade	Missouri\Ripley
Minnesota\Crow Wing	Minnesota\Sibley	Missouri\Gentry	Missouri\St. Charles
Minnesota\Dakota	Minnesota\Stearns	Missouri\Greene	Missouri\St. Clair
Minnesota\Dodge	Minnesota\Steele	Missouri\Grundy	Missouri\Ste. Genevieve
Minnesota\Douglas	Minnesota\Stevens	Missouri\Harrison	Missouri\St. Francois
Minnesota\Faribault	Minnesota\Swift	Missouri\Henry	Missouri\St Louis
Minnesota\Fillmore	Minnesota\Todd	Missouri\Hickory	Missouri\Saline
Minnesota\Freeborn	Minnesota\Traverse	Missouri\Holt	Missouri\Schuyler
Minnesota\Goodhue	Minnesota\Wabasha	Missouri\Howard	Missouri\Scotland
Minnesota\Grant	Minnesota\Wadena	Missouri\Howell	Missouri\Scott
Minnesota\Hennepin	Minnesota\Waseca	Missouri\Jackson	Missouri\Shelby
Minnesota\Houston	Minnesota\Washington	Missouri\Jasper	Missouri\Stoddard
Minnesota\Hubbard	Minnesota\Watonwan	Missouri\Jefferson	Missouri\Sullivan
Minnesota\Isanti	Minnesota\Wilkin	Missouri\Johnson	Missouri\Taney
Minnesota\Itasca	Minnesota\Winona	Missouri\Knox	Missouri\Texas
Minnesota\Jackson	Minnesota\Wright	Missouri\Laclede	Missouri\Vernon
Minnesota\Kanabec	Minnesota\Yellow Medicine	Missouri\Lafayette	Missouri\Warren
Minnesota\Kandiyohi	Missouri\Adair	Missouri\Lawrence	Missouri\Washington
Minnesota\Kittson	Missouri\Andrew	Missouri\Lewis	Missouri\Wayne
Minnesota\Koochiching	Missouri\Atchison	Missouri\Lincoln	Missouri\Webster
Minnesota\Lac qui Parle	Missouri\Audrain	Missouri\Linn	Missouri\Worth
Minnesota\Le Sueur	Missouri\Barry	Missouri\Livingston	Missouri\Wright
Minnesota\Lincoln	Missouri\Barton	Missouri\Macon	Nebraska\Adams

State/County	State/County	State/County	State/County
Nebraska\Antelope	Nebraska\Kimball	New Mexico\Rio Arriba	New York\Steuben
Nebraska\Arthur	Nebraska\Knox	New Mexico\Roosevelt	New York\Suffolk
Nebraska\Banner	Nebraska\Lancaster	New Mexico\Sandoval	New York\Sullivan
Nebraska\Blaine	Nebraska\Lincoln	New Mexico\San Juan	New York\Tioga
Nebraska\Boone	Nebraska\Logan	New Mexico\San Miguel	New York\Tompkins
Nebraska\Box Butte	Nebraska\Loup	New Mexico\Santa Fe	New York\Ulster
Nebraska\Boyd	Nebraska\McPherson	New Mexico\Socorro	New York\Washington
Nebraska\Brown	Nebraska\Madison	New Mexico\Taos	New York\Wayne
Nebraska\Buffalo	Nebraska\Merrick	New Mexico\Torrance	New York\Wyoming
Nebraska\Burt	Nebraska\Morrill	New Mexico\Union	New York\Yates
Nebraska\Butler	Nebraska\Nance	New York\Albany	North Dakota\Adams
Nebraska\Cass	Nebraska\Nemaha	New York\Allegany	North Dakota\Barnes
Nebraska\Cedar	Nebraska\Nuckolls	New York\Broome	North Dakota\Benson
Nebraska\Chase	Nebraska\Otoe	New York\Cattaraugus	North Dakota\Billings
Nebraska\Cherry	Nebraska\Pawnee	New York\Cayuga	North Dakota\Bottineau
Nebraska\Cheyenne	Nebraska\Perkins	New York\Chautauqua	North Dakota\Bowman
Nebraska\Clay	Nebraska\Phelps	New York\Chemung	North Dakota\Burke
Nebraska\Colfax	Nebraska\Pierce	New York\Chenango	North Dakota\Burleigh
Nebraska\Cuming	Nebraska\Platte	New York\Clinton	North Dakota\Cass
Nebraska\Custer	Nebraska\Polk	New York\Columbia	North Dakota\Cavalier
Nebraska\Dakota	Nebraska\Red Willow	New York\Cortland	North Dakota\Dickey
Nebraska\Dawes	Nebraska\Richardson	New York\Delaware	North Dakota\Divide
Nebraska\Dawson	Nebraska\Rock	New York\Dutchess	North Dakota\Dunn
Nebraska\Deuel	Nebraska\Saline	New York\Erie	North Dakota\Eddy
Nebraska\Dixon	Nebraska\Sarpy	New York\Essex	North Dakota\Emmons
Nebraska\Dodge	Nebraska\Saunders	New York\Franklin	North Dakota\Foster
Nebraska\Douglas	Nebraska\Scotts Bluff	New York\Fulton	North Dakota\Golden Valley
Nebraska\Dundy	Nebraska\Seward	New York\Genesee	North Dakota\Grand Forks
Nebraska\Fillmore	Nebraska\Sheridan	New York\Greene	North Dakota\Grant
Nebraska\Franklin	Nebraska\Sherman	New York\Herkimer	North Dakota\Griggs
Nebraska\Frontier	Nebraska\Sioux	New York\Jefferson	North Dakota\Hettinger
Nebraska\Furnas	Nebraska\Stanton	New York\Lewis	North Dakota\Kidder
Nebraska\Gage	Nebraska\Thayer	New York\Livingston	North Dakota\LaMoure
Nebraska\Garden	Nebraska\Thomas	New York\Madison	North Dakota\Logan
Nebraska\Garfield	Nebraska\Thurston	New York\Monroe	North Dakota\McHenry
Nebraska\Gosper	Nebraska\Valley	New York\Montgomery	North Dakota\McIntosh
Nebraska\Grant	Nebraska\Washington	New York\Niagara	North Dakota\McKenzie
Nebraska\Greeley	Nebraska\Wayne	New York\Oneida	North Dakota\McLean
Nebraska\Hall	Nebraska\Webster	New York\Onondaga	North Dakota\Mercer
Nebraska\Hamilton	Nebraska\Wheeler	New York\Ontario	North Dakota\Morton
Nebraska\Harlan	Nebraska\York	New York\Orange	North Dakota\Mountrail
Nebraska\Hayes	New Mexico\Bernalillo	New York\Orleans	North Dakota\Nelson
Nebraska\Hitchcock	New Mexico\Cibola	New York\Oswego	North Dakota\Oliver
Nebraska\Holt	New Mexico\Curry	New York\Otsego	North Dakota\Pembina
Nebraska\Hooker	New Mexico\Dona Ana	New York\Rensselaer	North Dakota\Pierce
Nebraska\Howard	New Mexico\Guadalupe	New York\St. Lawrence	North Dakota\Ramsey
Nebraska\Jefferson	New Mexico\Hidalgo	New York\Saratoga	North Dakota\Ransom
Nebraska\Johnson	New Mexico\Lea	New York\Schenectady	North Dakota\Renville
Nebraska\Kearney	New Mexico\Luna	New York\Schoharie	North Dakota\Richland
Nebraska\Keith	New Mexico\McKinley	New York\Schuyler	North Dakota\Rolette
Nebraska\Keya Paha	New Mexico\Quay	New York\Seneca	North Dakota\Sargent

State/County	State/County	State/County	State/County
North Dakota\Sheridan	Ohio\Jackson	Oregon\Columbia	Pennsylvania\Luzerne
North Dakota\Sioux	Ohio\Jefferson	Oregon\Deschutes	Pennsylvania\Lycoming
North Dakota\Slope	Ohio\Knox	Oregon\Douglas	Pennsylvania\McKean
North Dakota\Stark	Ohio\Lake	Oregon\Gilliam	Pennsylvania\Mercer
North Dakota\Steele	Ohio\Lawrence	Oregon\Lake	Pennsylvania\Mifflin
North Dakota\Stutsman	Ohio\Licking	Oregon\Malheur	Pennsylvania\Monroe
North Dakota\Towner	Ohio\Logan	Oregon\Marion	Pennsylvania\Montgomery
North Dakota\Traill	Ohio\Lorain	Oregon\Morrow	Pennsylvania\Montour
North Dakota\Walsh	Ohio\Lucas	Oregon\Multnomah	Pennsylvania\Northampton
North Dakota\Ward	Ohio\Madison	Oregon\Umatilla	Pennsylvania\Northumberland
North Dakota\Wells	Ohio\Mahoning	Oregon\Union	Pennsylvania\Perry
North Dakota\Williams	Ohio\Marion	Oregon\Washington	Pennsylvania\Pike
Ohio\Adams	Ohio\Medina	Pennsylvania\Adams	Pennsylvania\Potter
Ohio\Allen	Ohio\Meigs	Pennsylvania\Allegheny	Pennsylvania\Schuylkill
Ohio\Ashland	Ohio\Mercer	Pennsylvania\Armstrong	Pennsylvania\Snyder
Ohio\Ashtabula	Ohio\Miami	Pennsylvania\Beaver	Pennsylvania\Somerset
Ohio\Athens	Ohio\Monroe	Pennsylvania\Bedford	Pennsylvania\Sullivan
Ohio\Auglaize	Ohio\Montgomery	Pennsylvania\Berks	Pennsylvania\Susquehanna
Ohio\Belmont	Ohio\Morgan	Pennsylvania\Blair	Pennsylvania\Tioga
Ohio\Brown	Ohio\Morrow	Pennsylvania\Bradford	Pennsylvania\Union
Ohio\Butler	Ohio\Muskingum	Pennsylvania\Bucks	Pennsylvania\Venango
Ohio\Carroll	Ohio\Noble	Pennsylvania\Butler	Pennsylvania\Warren
Ohio\Champaign	Ohio\Ottawa	Pennsylvania\Cambria	Pennsylvania\Washington
Ohio\Clark	Ohio\Paulding	Pennsylvania\Cameron	Pennsylvania\Wayne
Ohio\Clermont	Ohio\Perry	Pennsylvania\Carbon	Pennsylvania\Westmoreland
Ohio\Clinton	Ohio\Pickaway	Pennsylvania\Centre	Pennsylvania\Wyoming
Ohio\Columbiana	Ohio\Pike	Pennsylvania\Chester	Pennsylvania\York
Ohio\Coshocton	Ohio\Portage	Pennsylvania\Clarion	South Dakota\Aurora
Ohio\Crawford	Ohio\Preble	Pennsylvania\Clearfield	South Dakota\Beadle
Ohio\Cuyahoga	Ohio\Putnam	Pennsylvania\Clinton	South Dakota\Bennett
Ohio\Darke	Ohio\Richland	Pennsylvania\Columbia	South Dakota\Bon Homme
Ohio\Defiance	Ohio\Ross	Pennsylvania\Crawford	South Dakota\Brookings
Ohio\Delaware	Ohio\Sandusky	Pennsylvania\Cumberland	South Dakota\Brown
Ohio\Erie	Ohio\Scioto	Pennsylvania\Dauphin	South Dakota\Brule
Ohio\Fairfield	Ohio\Seneca	Pennsylvania\Delaware	South Dakota\Buffalo
Ohio\Fayette	Ohio\Shelby	Pennsylvania\Elk	South Dakota\Butte
Ohio\Franklin	Ohio\Stark	Pennsylvania\Erie	South Dakota\Campbell
Ohio\Fulton	Ohio\Summit	Pennsylvania\Fayette	South Dakota\Charles Mix
Ohio\Gallia	Ohio\Trumbull	Pennsylvania\Forest	South Dakota\Clark
Ohio\Geauga	Ohio\Tuscarawas	Pennsylvania\Franklin	South Dakota\Clay
Ohio\Greene	Ohio\Union	Pennsylvania\Fulton	South Dakota\Codington
Ohio\Guernsey	Ohio\Van Wert	Pennsylvania\Greene	South Dakota\Corson
Ohio\Hamilton	Ohio\Vinton	Pennsylvania\Huntingdon	South Dakota\Custer
Ohio\Hancock	Ohio\Warren	Pennsylvania\Indiana	South Dakota\Davison
Ohio\Hardin	Ohio\Washington	Pennsylvania\Jefferson	South Dakota\Day
Ohio\Harrison	Ohio\Wayne	Pennsylvania\Juniata	South Dakota\Deuel
Ohio\Henry	Ohio\Williams	Pennsylvania\Lackawanna	South Dakota\Dewey
Ohio\Highland	Ohio\Wood	Pennsylvania\Lancaster	South Dakota\Douglas
Ohio\Hocking	Ohio\Wyandot	Pennsylvania\Lawrence	South Dakota\Edmunds
Ohio\Holmes	Oregon\Baker	Pennsylvania\Lebanon	South Dakota\Fall River
Ohio\Huron	Oregon\Clackamas	Pennsylvania\Lehigh	South Dakota\Faulk

State/County	State/County	State/County	State/County
South Dakota\Grant	Tennessee\Cheatham	Tennessee\Montgomery	Texas\Caldwell
South Dakota\Gregory	Tennessee\Chester	Tennessee\Moore	Texas\Calhoun
South Dakota\Haakon	Tennessee\Claiborne	Tennessee\Morgan	Texas\Callahan
South Dakota\Hamlin	Tennessee\Clay	Tennessee\Obion	Texas\Cameron
South Dakota\Hand	Tennessee\Cocke	Tennessee\Overton	Texas\Carson
South Dakota\Hanson	Tennessee\Coffee	Tennessee\Perry	Texas\Castro
South Dakota\Harding	Tennessee\Crockett	Tennessee\Pickett	Texas\Chambers
South Dakota\Hughes	Tennessee\Cumberland	Tennessee\Polk	Texas\Cherokee
South Dakota\Hutchinson	Tennessee\Decatur	Tennessee\Putnam	Texas\Clay
South Dakota\Hyde	Tennessee\DeKalb	Tennessee\Rhea	Texas\Coleman
South Dakota\Jackson	Tennessee\Dickson	Tennessee\Roane	Texas\Collin
South Dakota\Jerauld	Tennessee\Dyer	Tennessee\Robertson	Texas\Collingsworth
South Dakota\Jones	Tennessee\Fayette	Tennessee\Rutherford	Texas\Colorado
South Dakota\Kingsbury	Tennessee\Fentress	Tennessee\Scott	Texas\Comal
South Dakota\Lake	Tennessee\Franklin	Tennessee\Sequatchie	Texas\Comanche
South Dakota\Lincoln	Tennessee\Gibson	Tennessee\Sevier	Texas\Concho
South Dakota\Lyman	Tennessee\Giles	Tennessee\Shelby	Texas\Cooke
South Dakota\McCook	Tennessee\Grainger	Tennessee\Smith	Texas\Coryell
South Dakota\McPherson	Tennessee\Greene	Tennessee\Stewart	Texas\Culberson
South Dakota\Marshall	Tennessee\Grundy	Tennessee\Sullivan	Texas\Dallam
South Dakota\Meade	Tennessee\Hamblen	Tennessee\Sumner	Texas\Dallas
South Dakota\Mellette	Tennessee\Hamilton	Tennessee\Tipton	Texas\Deaf Smith
South Dakota\Miner	Tennessee\Hancock	Tennessee\Trousdale	Texas\Delta
South Dakota\Minnehaha	Tennessee\Hardeman	Tennessee\Unicoi	Texas\Denton
South Dakota\Moody	Tennessee\Hardin	Tennessee\Union	Texas\DeWitt
South Dakota\Pennington	Tennessee\Hawkins	Tennessee\Van Buren	Texas\Dimmit
South Dakota\Perkins	Tennessee\Haywood	Tennessee\Warren	Texas\Donley
South Dakota\Potter	Tennessee\Henderson	Tennessee\Washington	Texas\Duval
South Dakota\Roberts	Tennessee\Henry	Tennessee\Wayne	Texas\Eastland
South Dakota\Sanborn	Tennessee\Hickman	Tennessee\Weakley	Texas\Ellis
South Dakota\Shannon	Tennessee\Houston	Tennessee\White	Texas\El Paso
South Dakota\Spink	Tennessee\Humphreys	Tennessee\Williamson	Texas\Erath
South Dakota\Stanley	Tennessee\Jackson	Tennessee\Wilson	Texas\Falls
South Dakota\Sully	Tennessee\Jefferson	Texas\Anderson	Texas\Fannin
South Dakota\Todd	Tennessee\Johnson	Texas\Angelina	Texas\Fayette
South Dakota\Tripp	Tennessee\Knox	Texas\Armstrong	Texas\Floyd
South Dakota\Turner	Tennessee\Lake	Texas\Atascosa	Texas\Fort Bend
South Dakota\Union	Tennessee\Lauderdale	Texas\Austin	Texas\Franklin
South Dakota\Walworth	Tennessee\Lawrence	Texas\Bailey	Texas\Freestone
South Dakota\Yankton	Tennessee\Lewis	Texas\Bastrop	Texas\Frio
South Dakota\Ziebach	Tennessee\Lincoln	Texas\Bee	Texas\Gaines
Tennessee\Anderson	Tennessee\Loudon	Texas\Bell	Texas\Gillespie
Tennessee\Bedford	Tennessee\McMinn	Texas\Bexar	Texas\Goliad
Tennessee\Benton	Tennessee\McNairy	Texas\Blanco	Texas\Gonzales
Tennessee\Bledsoe	Tennessee\Macon	Texas\Bosque	Texas\Gray
Tennessee\Blount	Tennessee\Madison	Texas\Bowie	Texas\Grayson
Tennessee\Bradley	Tennessee\Marion	Texas\Brazoria	Texas\Gregg
Tennessee\Campbell	Tennessee\Marshall	Texas\Brazos	Texas\Grimes
Tennessee\Cannon	Tennessee\Maury	Texas\Brewster	Texas\Guadalupe
Tennessee\Carroll	Tennessee\Meigs	Texas\Brown	Texas\Hale
Tennessee\Carter	Tennessee\Monroe	Texas\Burleson	Texas\Hamilton

State/County	State/County	State/County	State/County
Texas\Hansford	Texas\Ochiltree	Washington\Douglas	Wisconsin\Monroe
Texas\Hardin	Texas\Oldham	Washington\Franklin	Wisconsin\Oconto
Texas\Harris	Texas\Palo Pinto	Washington\Grant	Wisconsin\Oneida
Texas\Harrison	Texas\Panola	Washington\Kittitas	Wisconsin\Outagamie
Texas\Hartley	Texas\Parker	Washington\Klickitat	Wisconsin\Ozaukee
Texas\Haskell	Texas\Parmer	Washington\Lincoln	Wisconsin\Pepin
Texas\Hays	Texas\Pecos	Washington\Okanogan	Wisconsin\Pierce
Texas\Hemphill	Texas\Polk	Washington\Spokane	Wisconsin\Polk
Texas\Henderson	Texas\Potter	Washington\Stevens	Wisconsin\Portage
Texas\Hidalgo	Texas\Rains	Washington\Walla Walla	Wisconsin\Price
Texas\Hill	Texas\Randall	Washington\Whitman	Wisconsin\Racine
Texas\Hood	Texas\Red River	Washington\Yakima	Wisconsin\Richland
Texas\Houston	Texas\Refugio	Wisconsin\Adams	Wisconsin\Rock
Texas\Hudspeth	Texas\Roberts	Wisconsin\Ashland	Wisconsin\Rusk
Texas\Hunt	Texas\Robertson	Wisconsin\Barron	Wisconsin\St. Croix
Texas\Hutchinson	Texas\Rusk	Wisconsin\Bayfield	Wisconsin\Sauk
Texas\Jackson	Texas\San Augustine	Wisconsin\Brown	Wisconsin\Sawyer
Texas\Jasper	Texas\San Patricio	Wisconsin\Buffalo	Wisconsin\Shawano
Texas\Jefferson	Texas\San Saba	Wisconsin\Burnett	Wisconsin\Sheboygan
Texas\Jim Wells	Texas\Sherman	Wisconsin\Calumet	Wisconsin\Taylor
Texas\Johnson	Texas\Smith	Wisconsin\Chippewa	Wisconsin\Trempealeau
Texas\Karnes	Texas\Sutton	Wisconsin\Clark	Wisconsin\Vernon
Texas\Kaufman	Texas\Swisher	Wisconsin\Columbia	Wisconsin\Walworth
Texas\Kleberg	Texas\Tarrant	Wisconsin\Crawford	Wisconsin\Washburn
Texas\Lamar	Texas\Taylor	Wisconsin\Dane	Wisconsin\Washington
Texas\Lamb	Texas\Terry	Wisconsin\Dodge	Wisconsin\Waukesha
Texas\Lampasas	Texas\Tom Green	Wisconsin\Door	Wisconsin\Waupaca
Texas\La Salle	Texas\Travis	Wisconsin\Dunn	Wisconsin\Waushara
Texas\Lavaca	Texas\Tyler	Wisconsin\Eau Claire	Wisconsin\Winnebago
Texas\Lee	Texas\Uvalde	Wisconsin\Florence	Wisconsin\Wood
Texas\Leon	Texas\Victoria	Wisconsin\Fond du Lac	Wyoming\Big Horn
Texas\Liberty	Texas\Walker	Wisconsin\Forest	Wyoming\Converse
Texas\Limestone	Texas\Waller	Wisconsin\Grant	Wyoming\Fremont
Texas\Lipscomb	Texas\Washington	Wisconsin\Green	Wyoming\Goshen
Texas\Live Oak	Texas\Webb	Wisconsin\Green Lake	Wyoming\Hot Springs
Texas\Lubbock	Texas\Wharton	Wisconsin\Iowa	Wyoming\Laramie
Texas\Lynn	Texas\Wheeler	Wisconsin\Jackson	Wyoming\Natrona
Texas\McCulloch	Texas\Wichita	Wisconsin\Jefferson	Wyoming\Niobrara
Texas\McLennan	Texas\Wilbarger	Wisconsin\Juneau	Wyoming\Park
Texas\Madison	Texas\Willacy	Wisconsin\Kenosha	Wyoming\Platte
Texas\Mason	Texas\Williamson	Wisconsin\Kewaunee	Wyoming\Washakie
Texas\Matagorda	Texas\Wilson	Wisconsin\La Crosse	
Texas\Maverick	Texas\Wise	Wisconsin\Lafayette	
Texas\Medina	Texas\Wood	Wisconsin\Langlade	
Texas\Midland	Texas\Yoakum	Wisconsin\Lincoln	
Texas\Milam	Texas\Young	Wisconsin\Manitowoc	
Texas\Mills	Texas\Zavala	Wisconsin\Marathon	
Texas\Montague	Washington\Adams	Wisconsin\Marinette	
Texas\Moore	Washington\Benton	Wisconsin\Marquette	
Texas\Navarro	Washington\Chelan	Wisconsin\Menominee	
Texas\Nueces	Washington\Columbia	Wisconsin\Milwaukee	

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

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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.

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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.

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[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

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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 [ ]

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[ ] 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:

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[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. <u>Event 3272 corn without increased ethanol yields</u>

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.

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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.

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:

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[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.

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APPENDIX A

JOHN M. URBANCHUK, DIRECTOR, LECG

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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-Presen

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

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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

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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

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.

Economic Impact for Iowa of an 8 Billion-Gallon RFS. Analysis prepared at the request of Sen. Tom Harkin. June 2005.

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.

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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.

Technical Review of the Business Plan for the Empire Biofuels, LLC New York Ethanol Project. February 2004.

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

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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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The Economic Impacts on California of the Proposed Mattress Flammability Standard. (with George R. Schink). Client: International Sleep Products Association. April 2003.

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Economic Benefits of Flonicamid F1785 50DF Insecticide to Support Reduced Risk Application on Pome Fruit, Stone Fruit, Leafy Vegetables, Fruiting Vegetables, Cucurbits, Potatoes, and Cotton. January 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 Fuel*s. 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.

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Legal and Environmental Issues Facing New Ethanol Producers. Client: The National Corn Growers Association. June 2001

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

Export Guide to Pennsylvania Agriculture: Identifying Export Opportunities for Pennsylvania Agriculture. (with Dr. Nancy M. Childs). Client: The Pennsylvania Department of Agriculture. October 2000.

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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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.

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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.

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.

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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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Expert Witness Testimony before the American Arbitration Association, Case No. 39-188-00075-97, Schilling Jeep-Eagle, Inc. v. Chrysler Corporation in support of dealer protest of a new open point. Memphis, TN, January 1998.

"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.

"Deposition and Direct Testimony Regarding the Economic Effects on New Jersey of Freehold Cogeneration Associates (FCA) Cogeneration Facility." In the matter of the application of Jersey Central Power & Light Company for approval of the power purchase agreement between Jersey Central Power & Light Company and Freehold Cogeneration Associates, L.P. State of New Jersey Board of Regulatory Commissioners. BRC Docket No. EM 92030359, March 1994.

"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.

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"The Impact of Bovine Somatotropin (bST) on Agriculture and the U.S. Economy." Testimony before the Committee on Science and Technology of the Wisconsin State Assembly. Madison, May 1989.

"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.

"Impact of Removing United States Government Price and Income Support Programs on the U.S. Corn Sector." Testimony presented before the Canadian Import Tribunal in the matter of the corn countervail investigation. Ottawa, February 1987.

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"Impact of the Chernobyl Nuclear Disaster on Soviet Agriculture, World Food Supplies, and the U.S. Farm Economy." Testimony before the Subcommittee on Agriculture and Transportation of the Joint Economic Committee of Congress. Washington, D.C., May 1986.

"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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Implications for Distillers Grains from Continued Expansion of Ethanol from Corn. 11th Distillers Grains Symposium May 2007.Louisville, KY

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

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LECG

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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

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- 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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Westgate ME, J. Lizaso and W. Batchelor. 2003. Quantitative relationship between pollen-shed density and grain yield in maize. Crop Sci. 43, 934-942.

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

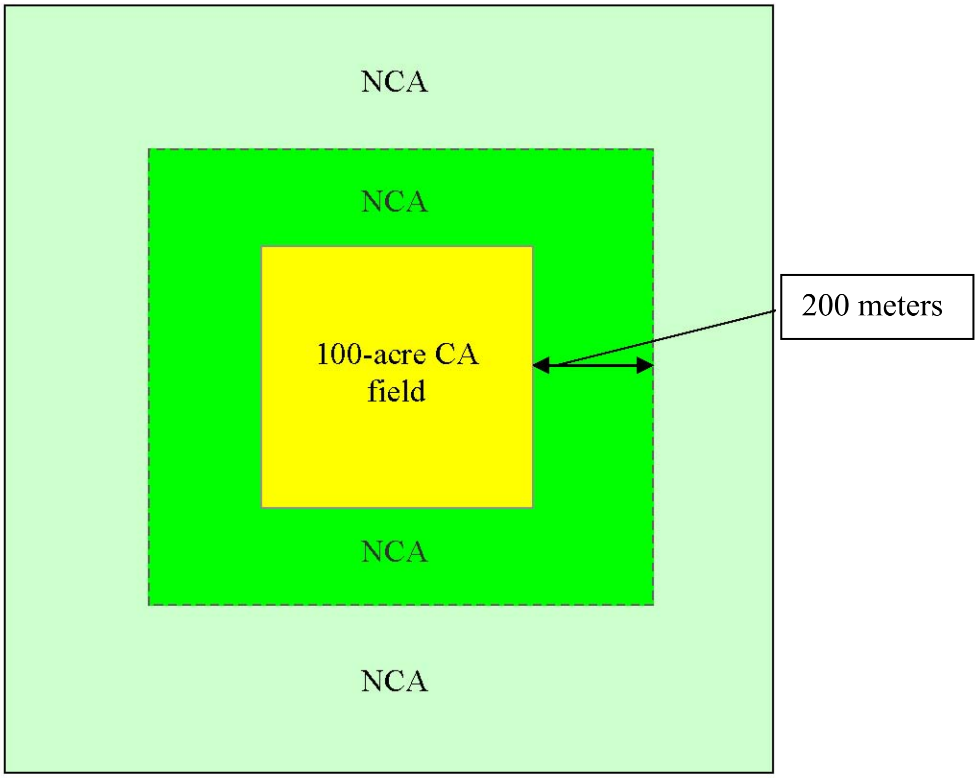

Figure 2. Planting configuration of corn amylase (CA) and non-corn amylase (NCA) corn with 12 separating border rows (Scenario 2).

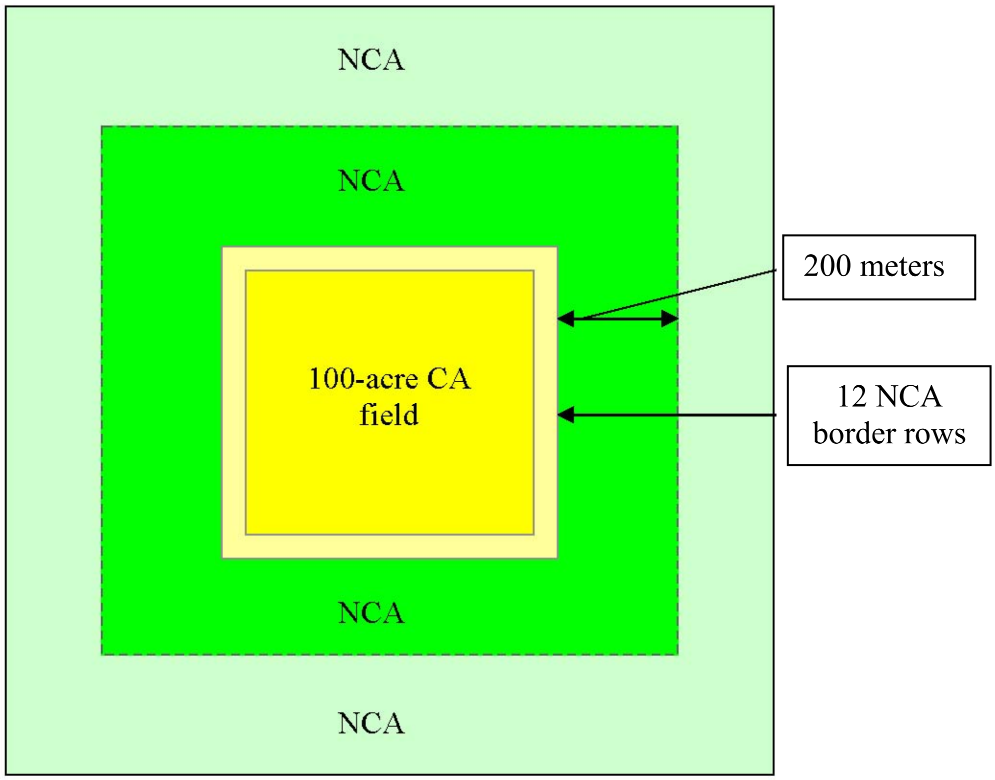

Table 1. Percent pollen-mediated gene flow downwind and upwind of source corn pollen as extrapolated from Ma (2005)[1].

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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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").[8] APHIS has historically found that the deregulation of such events in corn have not been "major federal actions significantly affecting the human environment."[9] 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,[10] 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.[11] 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

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[8] 42 U.S.C.§§ 4321 et seq.

[9] 42 U.S.C. § 4332(2)(C).

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

[11] 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."[12] 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")."[13]

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.[14] The test of whether an action "significantly" affects the environment requires

[12] *Id.*

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

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

considerations of both context and intensity.[15] The term "context" refers to the setting within which the proposed action takes place.[16] 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."[17] The term "intensity" refers to "the severity of the impact."[18]

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[15] 40 C.F.R. § 1508.27.

[16] 40 C.F.R. § 1508.27(a).

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

[18] *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[19] 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.[20] 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."[21] 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.[22] 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).

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

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

[21] 42 U.S.C. § 4331(b)(3)-(4).

[22] *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.[23] 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.[24] 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.[25] 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.[26]

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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[23] *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.

[24] 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

[25] *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).

[26] *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.[27] The implementation of the European Union food traceability and labeling directives[28] and the Cartagena Protocol on Biosafety[29] have compelled agribusinesses, particularly grain elevators and grain warehouses at the front of the supply chain, to track closely shipments and supplies.[30]

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."[31] 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.[32]

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

[28] *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).

[29] 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.

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

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

[32] *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.[33]

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.[34]

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.[35]

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.[36] 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.[37] 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.[38]

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[33] *See id.*

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

[35] *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.

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

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

[38] *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.[39]

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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[39] *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.[40] This industry stewardship program is described in the *Quality Management Program Guide to Maintaining Plant Product Integrity*.[41] 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.[42]

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

[40] *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.

[41] *See id.*

[42] *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.[43]

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.[44] 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.[45] 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.[46] Entities in the grain industry, including grain elevators, feed mills, grain processors, feed ingredient manufacturers, retail feed stores, feed

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

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

[45] 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.).

[46] *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.[47] 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.[48]

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.[49]

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.[50] 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.[51] 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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[47] *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).

[48] *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.

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

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

[51] *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.[52]

4. USDA Initiatives

The mission of the USDA GIPSA is to facilitate the marketing of grains, oilseeds, and related agricultural commodities.[53] 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.[54] Other USDA initiatives are documented in recent ERS reports.[55]

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.[56] 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.[57] Syngenta supports the

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[52] *See id.*

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

[54] *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.

[55] *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/*.

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

[57] 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.[58] 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.[59]

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.[60] There is no food safety issue associated with the possible presence of the AMY797E alpha-amylase enzyme in foods.

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[58] 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.

[59] *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.*

[60] *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.[61] 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.[62]

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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[61] 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*.

[62] 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%.[63] 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.[64] 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).[65]

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[63] 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.

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

[65] 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.[66] 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.

<u>Syngenta</u> (stewardship roles and responsibilities):

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[66] 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.[67]

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).[68]

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.[69] 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."[70] The term "intensity" refers to "the severity of the impact"[71] judged on a number of factors. As demonstrated below, the deregulation of Event 3272 is not significant on either factor.

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

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

[69] 49 C.F.R. §1508.27(a).

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

[71] *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.[72] 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.[73] 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."[74]

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.[75]

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

[73] *See Environmental Assessment for Prospoosed 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.

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

[75] 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.[76] 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.[77]

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.[78] 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

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

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

[78] *See id.*

relevant environmental effect in the draft EIS for purposes of NEPA analysis in support of deregulation.[79] 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."[80]

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.[81]

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

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[80] *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).

[81] *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

U.S. Food and Drug Administration

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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

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(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.

FDA/Center for Food Safety & Applied Nutrition
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Appendix I. Report on DDGS submitted by Syngenta

Impact of Event 3272 Corn on Distillers Grains

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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".[82] 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.[83] The use of Event 3272 corn may enable ethanol producers to avoid these problems.

[82] 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

[83] 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	The ability of a plant to remain relatively unaffected by the application

Resistance or Tolerance	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.
	J
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 intactness	Rating of late-season integrity of the plant above the ear

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 analyses

Southern corn leaf blight Corn disease caused by the fungus *Bipolaris maydis*

Stably integrated

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