Syngenta Biotechnology, Inc.
Insect Resistant MIR162 Corn

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Draft Environmental Assessment

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I. Summary

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 07-253-01p) from Syngenta Biotechnology, Inc. (Syngenta) regarding the regulatory status of genetically engineered (transgenic) corn resistant to lepidopteran insect feeding from transformation event MIR162. This corn is currently a regulated article under USDA regulations at 7 CFR part 340, and as such, interstate movements, importations, and field tests of MIR162 corn have been conducted under permits issued or notifications acknowledged by APHIS. Syngenta petitioned APHIS requesting a determination that MIR162 corn does not present a plant pest risk, and therefore MIR162 corn and its progeny derived from crosses with other nonregulated corn should no longer be regulated articles under these APHIS regulations.

II. Purpose and Need

"Protecting American agriculture" is the basic charge of the USDA (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.

Federal Regulatory Authority

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 Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). APHIS regulates genetically engineered (GE) organisms under the Plant Protection Act of 2000. 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). FDA regulates GE organisms 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. 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.

USDA Regulatory Authority

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect the United States' 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. 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 part 340.2) and is also considered a plant pest. A GE organism is also regulated under part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have sufficient information to determine if the GE organism is unlikely to pose a plant pest risk.

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 part 340.6 entitled "Petition for Determination of Nonregulated Status." The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. If the agency determines that the regulated article is unlikely to pose a plant pest risk, the GE organism will be granted nonregulated status. In such a case, APHIS authorizations (i.e. permits and notifications) would no longer be required for environmental release, importation, or interstate movement of the non-regulated article or its progeny.

Syngenta Biotechnology, Inc. (hereafter "Syngenta") of Research Triangle Park, NC submitted a petition to APHIS seeking a determination of nonregulated status for their transgenic event MIR162 corn (hereafter "MIR162 corn"). The MIR162 corn has been engineered to express a bacterial protein Vip3Aa20 from *Bacillus thyringiensis* that is toxic to a certain lepidopteran insect pests. This corn is also engineered to express another protein, phosphomannose isomerase (PMI) from *Escherichia coli*, which was used as a selectable marker to identify corn seedlings containing Vip3Aa20 gene during the development of MIR162 corn. The MIR162 corn is currently regulated under 7 CFR part 340. This corn has been considered a regulated article because it was genetically engineered with regulatory sequences derived from plant pests and because a plant pest was used as a vector agent to deliver those sequences to the plant. Interstate movements and field trials of the MIR162 corn have been conducted under permits issued or notifications acknowledged by APHIS.

U.S. Environmental Protection Agency and Food and Drug Administration Regulatory Authority

The MIR162 corn is also subject to regulation by other agencies. The U.S. Environmental Protection Agency (EPA) is responsible for regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. §136 et seq.). FIFRA requires that all pesticides be registered before distribution, sale, and use, unless exempted by EPA regulation. Before a product is registered as a pesticide under FIFRA, it must be shown that when used in accordance with the label, it will not result in unreasonable adverse effects on the environment. Accordingly, EPA grants permits to allow a pesticide producer to test a new pesticide product outside the laboratory under Experimental Use Permits (EUPs), which are used for large-scale (more than 10 acres of land or 1 acre of water) testing of efficacy and gathering of environmental fate, ecological effects, and crop residue chemistry (40 CFR part 172).

Syngenta obtained an experimental use permit from EPA that allowed for broad-scale field testing of the MIR162 corn; this permit was granted on March 26, 2007 and was in effect through March 31, 2008 (72 FR 34009-34010). On July 23, 2008 EPA announced receipt of a petition from Syngenta to conditionally register three pesticide products containing the new active ingredient Vip3Aa20 and the genetic material necessary for its production in corn (73 FR 42799-42801). These pesticide products included MIR162 and the two corn hybrids Bt11 x MIR162 and Bt11 x MIR162 x MIR604 (Bt11 and MIR604 contain the additional insecticidal protein active ingredients Cry1Ab and Cry3A, respectively, and both have previously been deregulated by APHIS and registered as plant-incorporated protectants by EPA). On April 30, 2009, EPA announced the approval of these conditional registrations involving MIR 162 and the hybrids (74 FR 19956-19957).

Under the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §301 et seq.), pesticides added to (or contained in) raw agricultural commodities are prohibited unless a tolerance or exemption from tolerance has been established. EPA establishes residue tolerances for pesticides under the authority of the FDCA. The FDA enforces the tolerances set by the EPA. On April 4, 2007 EPA established a temporary exemption from the requirement of a tolerance for Vip3Aa20 residues in maize commodities, pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §346a(d). On August 6, 2008, EPA granted exemption from the requirement of a tolerance for residues of *B. thuringiensis* Vip3Aa proteins (including the Vip3Aa20 variant) in or on food and feed commodities of corn (73 FR 45620-45624). On May 14, 2004, EPA granted an exemption from the requirement of a tolerance for residues in or on plant commodities of phosphomannose isomerase and the genetic material necessary for its production in all plants when applied/used as plant-incorporated protectant inert ingredients (69 FR 26770-26775). With the publication of EPA's registration document, APHIS will use this finalized information to provide additional scientific support to its consideration of potential environmental impacts.

FDA, which has primary regulatory authority over food and feed safety, published a policy statement in the Federal Register on May 29, 1992 (57 FR 22984-23005) concerning regulation of products derived from new plant varieties, including those genetically engineered. 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 a bioengineered food. Syngenta submitted a summary of their safety assessment to FDA on August 3, 2007, and additional information on December 17, 2007 and March 31, 2008. Syngenta's submissions to FDA indicated that food and feed derived from corn event MIR162 are as safe (Appendix I in this EA) and nutritious as food and feed derived from conventional corn (Appendix II in this EA). FDA completed their consultation on MIR162 on December 9, 2008 and concluded that it had "no further questions concerning grain and forage derived from corn event MIR162" (FDA BNF No. 000113).

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA)[1] (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 implementing regulations (40 CFR §§ 1500-1508, 7 CFR part 1(b), and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from the deregulation of the MIR162 corn.

III. Introduction

Corn is susceptible to attack by a variety of insects (Table 1, pg. 12 in petition) from the time it is planted until it is consumed as food or feed. Syngenta has developed a GE corn hybrid, named MIR162, that is resistant to the feeding damage caused by corn earworm (*Helicoverpa zea*), fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*), and western bean cutworm (*Striacosta albicosta*) larvae that are not controlled well with existing technology. This insect resistance in MIR162 come from a bacterial gene called Vip3Aa20 (Vip = Vegetative insecticidal protein). The MIR162 corn also contains *manA* gene from *E. coli* encoding the enzyme phosphomannose isomerase (PMI), which was used as a selectable marker during transformant selection. The *manA* gene expression confers no other benefit to the regenerated transformed corn plant.

The family of Vip3Aa proteins, in which Vip3Aa20 belongs, are produced by the bacterium *B.thuringiensis* (hereafter "Bt") (Estruch et al. 1996) that act as toxins to kill insect prey (Estruch et al. 1996; Schnepf et al. 1998). Vip3Aa proteins are similar to certain Cry proteins[2] (Höfte and Whiteley 1989) and are demonstrated to have toxic effects only on certain insects (Table 2.1 on p. 23 in Carozzi and Koziel 1997). The mechanism by which Vip proteins exert their insecticidal activity has been studied and found to be similar, but not identical, to that which has been described for the Bt Cry

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14)
[2] Cry proteins are crystal proteins that are produced within the spores of Bt bacteria. A majority of deregulated Bt crops currently available in the U.S. market express Cry proteins.

proteins that are contained in several commercial insecticide formulations and plants engineered for insect resistance. The Vip and Cry proteins bind to different receptors in the insect (Lee et al. 2003), and the insecticidal activity of Vip3Aa proteins is limited to species within selected families of the order Lepidoptera (Table 27, pg. 74-75 in petition). For example, MIR162 alone has no activity against European corn borer (*Ostrinia nubilalis*) but is efficacious in limiting feeding damage caused by the other four insect pests (corn earworm, fall armyworm, black cutworm, western bean cutworm) (Figure 21, pg. 76 in petition); whereas the Bt11 corn (containing a Cry protein) is highly efficacious against European corn borer, but it has limited or no activity against the other four insects. USDA APHIS has previously granted nonregulated status to 11 insect resistant GE corn varieties (USDA-APHIS 1997) containing Cry proteins from Bt (UASDA-APHIS 2009).

The MIR162 corn has been field tested in the United States since 1999 as authorized by APHIS. Associated notifications acknowledged and permits issued by APHIS are listed in Appendix A of the petition (pg. 127-128). The list compiles more than 20 test sites in diverse regions of the U.S. including the major corn growing area of the Midwest and winter nurseries in Hawaii. Field tests conducted under APHIS oversight allow for evaluation in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS as the agency assesses the potential for a new variety to pose a plant pest risk. The evaluated data may be found in the APHIS plant pest risk assessment (USDA-APHIS 2009).

IV. Affected Environment

A. Corn

Corn is primarily grown in warm temperate climates (Norman et al. 1995). Field corn is the leading production crop globally, with the 2009 growing season expected to yield 789 million metric tons of grain (ICG 2009). Corn is grown for animal feed, human food, vegetable oil, high fructose corn syrups, starch, fermentation into ethanol, and a multitude of industrial uses.

Zea mays L. subsp. *mays*, known as maize throughout the world, and as corn in the U.S., is a member of the *Maydeae* tribe of the grass family, *Poaceae*. It is an annual plant with separate male and female flowers on each plant (monoecious) that requires human intervention for its seed dispersal and propagation. Additional information on the biology of corn can be found within the Organisation for Economic Co-Operation and Development (OECD 2003) consensus document.

Corn is predominantly a wind-pollinated outcrossing species (OECD 2003). Transgenes in crops have the potential to move between sexually compatible populations, and more so in corn being a wind-pollinated plant with separate male and female flower bearing structures (inflorescences). Gene flow rate between corn populations is extremely variable depending on the spatial, temporal, genetic and environmental factors (Brookes and Barfoot et al. 2004; Messegue et al. 2006). Yet, available experimental evidence indicates that gene flow rates drop drastically (1%) beyond 20 meters (Henry et al. 2003; Ma et al. 2004; Messeguer et al. 2006). To maintain varietal purity, the AOSCA (Association of Official Seed Certifying Agencies) recommends 200 meters isolation to nearby corn populations for the foundation class of certified seed production (AOSCA 2003). The insect resistance trait of MIR162 has the potential to enhance the fitness of wild and weedy relatives if gene flow occurs between crop and wild or weedy corn populations. However, there are no large widely distributed wild corn plants (teosinte) in the U.S., and even a few non-weedy feral populations in the U.S. have limited opportunity for outcrossing with transgenic corn cultivars (see USDA-APHIS 2009). The only known propagation method for corn is through seed germination (i.e., there are no reports of vegetative propagation under field conditions in the United States). Mature corn seeds have no innate dormancy (Simpson 1990; Table 18, pg. 61 in petition) are sensitive to cold, and are not expected to survive in freezing winter conditions. Even if corn seeds from a previous year's crop overwinter and germinate the following year, manual or chemical measures are often applied to remove these volunteers (see Table 1 in Wright et al. 2009).

B. Agricultural Production of Corn

The U.S. accounts for nearly 41% of global corn production. Corn is the largest crop grown in the U.S. in terms of both volume and value. Approximately 86 million acres were planted in 2008 growing season, yielding 12 billion bushels (305 million metric tons) with a gross crop value of $47 billion ($3.9/bushel) (USDA-NASS 2008a; USDA-NASS 2008b). The upper Midwest region of the U.S. provides an ideal combination of temperature, rainfall, and soil type for the cultivation of corn. Iowa, Illinois, Nebraska, Minnesota, Indiana, Ohio, Wisconsin, Missouri, Kansas, and South Dakota are major corn growing states. Production in these ten states accounts for 77% of total annual production (USDA-NASS 2008b). Other than food, feed and industrial use, corn as a source of fuel ethanol has increased dramatically over the past two years and is expected to continue doing so as the U.S. focuses on utilizing renewable sources of energy. By 2010, U.S. ethanol production could displace the equivalent of 311,000 barrels of imported crude oil per day.

The U.S. is by far the world's largest exporter of corn, accounting for 68% of global exports. Total U.S. agricultural exports in 2006 were valued at $71 billion, 10% of which was attributable to corn (Brooks 2007). Agricultural exports generate employment, income, and purchasing power in both farm and nonfarm sectors of the economy. Production from almost one-third of U.S. cropland moved into export channels in 2005 and generated $166.1 billion in business activity. Technology advances increase agricultural productivity and keep domestic growers competitive in the global market.

Based on USDA survey data, adoption of genetically engineered insect-resistant corn increased from zero percent of the U.S. corn acreage in 1996 to 63 percent in 2009 (USDA-ERS 2009). The rapid commercialization of GE insect-resistant corn (IR corn) varieties by corn growers is attributed to benefits offered by those corn varieties in terms of reduced conventional insecticide use, increased profits, and improved grain quality (Fernandez-Coejo and Caswell 2006).

In addition to IR corn cultivation, the U.S. farmers also planted herbicide tolerant (HT) corn varieties since 1996. A few corn cultivars contain both IR and HT traits. Among GE varieties of corn (IR and HT corn cutlivars), 68% of all corn planted contained a herbicide tolerant (HT) trait. Herbicides were applied to 97 percent of the corn planted acreage in 2005 (USDA-NASS 2006). Atrazine was applied to 66% of acres, glyphosate was applied to 31% of planted acres, *S*-metolachlor and acetochlor were each applied to 23% of planted corn acres (USDA-NASS 2006). The insect resistant MIR162 corn is not expected to alter corn weed control practices, as the main introduced trait in MIR162 is expcted to provide resistance to certain group of insect pests. Therefore, except for change in the insect resistance management, all other agricultural practices of the MIR162 corn, including corn weed control practices, are not expected to be different from that of conventional corn cultivation

According to USDA-ERS (2009) report, 15% (~13 million acres) of the U.S. corn acreage has been planted with the non-GE corn varieties in the year 2009. Likewise, according to USDA-ERS latest data on organic corn production, in 2005 less than 1 percent (0.16%) of corn cropped area was devoted to organic corn (http://www.ers.usda.gov/data/organic/Data/Certified%20and%20total%20US%20acreage%20selected%20crops%20livestock%2095-05.xls). Under the USDA National Organic Program guideline, the use of synthetic pesticides, fertilizers, and genetically engineered crops is strictly limited. The MIR162 corn is not approved for use in organic systems because it is genetically engineered. Maintaining the integrity of the organic production process is important to producers of organic corn. There are many practices organic producers use to prevent movement of GE corn or the pollen from GE corn into their organic production fields. Growers may use plant only organic seed, reducing the potential of GE corn seeds enter their fields. Organic farmers may plant earlier or later than neighboring farmers who may be using GE crops, ensuring that the flowering times between GE and organically produced crops will differ, thus minimizing the change of pollen movement between fields. Organic producers may also employ 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 (7 CFR part 205).

C. Corn Lepidopteran Pests

Corn crop is susceptible to attack by a variety of insects throughout its life cycle (see pg. 12 in petition). The most widespread and damaging insects of corn in the U.S. Corn Belt are the European corn borer and corn rootworms. Although a few insect control practices (chemical and microbial insecticides, crop rotation etc.) have been available for corn insect pests, the stalk boring insects such as the European corn borer were difficult to control and very few growers used chemical control against such insect pests. However, conventional insecticide and crop rotation proved effective in controlling the damage caused by corn rootworms. Prior to the introduction of rootworm-protected Bt varieties in 2003, an estimated 14 million acres were treated annually with conventional insecticides to control corn rootworms (Ward et al. 2005), which accounted for the largest single use of insecticides in the U.S. The conventional insecticide treatment is less effective for the above-ground corn insect pests, as pests are shielded from aerial chemical applications.

In addition to direct damage caused by feeding on plant tissue, the corn insect pests are known to play an important role in the transmission and dissemination of pathogenic organisms during corn development (Dowd 1998). For example, it has been shown that insect feeding damage enhances mycotoxin contamination of corn crop (Williams et al. 2002) that have toxic and carcinogenic effects in humans and animals (see Wu 2006 for details). The introduction of Bt corn varieties has shown to have provided growers solutions to some of the above-mentioned pest problem by limiting damage caused by certain lepidopteran insect pests (Hurley et al. 2006) and fungal disease (Wu 2006) without posing any significant risk to the environment or to human health (Mendelsohn et al. 2003).

V. Alternatives

This EA analyzes the potential environmental consequences of a proposal to grant nonregulated status to the MIR162 corn. In order for the corn under consideration to be granted nonregulated status, APHIS must determine that the corn is unlikely to pose a plant pest risk. The analysis by APHIS in its plant pest risk assessment (USDA-APHIS, 2009) demonstrates that there were sufficient data to determine that the MIR162 corn is unlikely to pose a plant pest risk and therefore is eligible for nonregulated status.

The regulations at 7 CFR part 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." Because APHIS has found that the MIR162 corn is unlikely to pose a plant pest risk, the only action alternative considered in this EA is to grant nonregulated status “in whole” to the corn line under consideration. An “in part” deregulation can be given if there is a plant pest risk associated with some, but not all lines requested in a petition. The petition for the MIR162 corn only requested APHIS to grant nonregulated status to a single corn event, therefore, an “in part” determination is not an appropriate consideration. Under another “in part” determination option, the petition may be considered with geographic restrictions if there is a geographic variation in plant pest risk. There are no geographic differences in plant pest risks for the MIR162 corn (USDA-APHIS, 2009). Thus, only two alternatives will be considered in this EA: (1) no action, or (2) to grant nonregulated status to MIR162 corn “in whole.”

A. No Action: Continuation as a Regulated Article

Under the “no action” alternative, APHIS would come to a determination that the MIR162 corn and its progeny should continue to be regulated under 7 CFR part 340. Permits issued or acknowledgment of notifications from APHIS would still be required for their introduction. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of the MIR162 corn and its progeny. Under this no action alternative, growers and other parties who are involved in production, handling, processing or consumption of corn would continue to have access to existing deregulated GE insect resistant corn as well as conventional corn varieties. However, growers would not have widespread access to the MIR162 corn since it would continue to be regulated under part 340. This alternative is not the preferred alternative because APHIS’ evaluation of MIR162 data in the plant pest risk assessment (USDA-APHIS, 2009) and this EA show that the MIR162 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 the MIR162 corn is unlikely to pose a plant pest risk.

B. Preferred Alternative: Determination that Syngenta MIR162 Corn is No Longer a Regulated Article

Under this alternative, the MIR162 corn and its progeny would no longer be considered regulated articles under 7 CFR part 340. Permits or notifications to APHIS would no longer be required for introductions in the United States and its territories of the MIR162 corn or its progeny. A basis for this determination would be a finding that MIR162 is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived based on information submitted in the petition as stipulated in 7 CFR § 340.6(c) and other information that the Administrator believes to be relevant to a determination. If Syngenta received regulatory approval from all appropriate agencies, it will make the MIR162 corn available to growers and breeders. The MIR162 corn will likely be introduced in areas where corn is currently grown, therefore MIR162 introduction is not expected to significantly alter the range of corn cultivation. APHIS has chosen Alternative B as the preferred alternative. This is based on the lack of plant pest characteristics in MIR162 corn as documented in the petition and as analyzed in APHIS’ plant pest risk assessment (USDA-APHIS 2009) and this EA. APHIS has assessed the potential for environmental impacts for each alternative in the “Potential Environmental Consequences” sections below.

VI. Potential Environmental Consequences

According to APHIS regulations at 7 CFR part 340, an organism is no longer subject to regulatory requirements when it is demonstrated not to present a plant pest risk. Under the regulations, APHIS is required to render a determination on a petition for nonregulated status. This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and from unconfined cultivation of the MIR162 corn.

A. No Action

Under the Federal "no action" alternative, MIR162 corn hybrids would continue to be a regulated article and so growers would not be able to plant these hybrids, which have been developed with added insect-resistance benefit that are not presented in products available in the market today.

A-1. Corn

Under the 'no action' alternative, conventional and GE transgenic corn hybrids crop husbandry will remain unchanged, while MIR162 corn hybrids will remain a regulated article.

A-2. Agricultural Production of Corn

Most of the corn acreage in the U.S. is planted to GE corn hybrids. Of the total corn acres planted in 2008, 85% were GE corn hybrids that were either herbicide tolerant, insect resistant, or both (USDA-ERS 2009). Conventional production practices that use GE varieties will still dominate in terms of acreage, or perhaps increase in acreage, without granting nonregulated status to the MIR162 corn under the "no action" alternative. Currently available seed for conventional varieties will remain the same under the "no action" alternative, except that the MIR162 corn hybrids will not be available for the commercial use. Corn is currently produced in all 50 states (USDA-NASS 2008), and under the "no action" alternative, this range of production will be unchanged.

Yield losses due to weeds diseases were substantial until the introduction of crop protection chemicals in the 1960s. Weeds compete with crops for light, nutrients, water, and other growth factors. The large-scale commercial cultivation of herbicide tolerant (glyphosate tolerant) corn crop acreage has steadily increased from 1996 accounting for nearly 68 percent of corn acreage in 2009 (USAD-ERS 2009). Glyphosate is a highly effective, nonselective, broad-spectrum herbicide and in general, considered "environmentally friendly" when compared to other herbicides. There would not be any affect on the availability or use of herbicide-tolerant corn under the 'no action' alternative. In addition, a corn crop is susceptible to attack by a variety of insects from the time it is planted until it is consumed as food or feed. Under no action alternative, the weed and insect management will remain same.

A-3. Corn Lepidopteran Pests

Corn is susceptible to a variety of insect pest damage throughout its developmental cycle. The corn insect pests are categorized as major and consistent pests, major and sporadic pests, and moderate to minor pests based on annual destructiveness and their geographic distribution (pg. 12 in petition). Yield losses due to insect pests are unpredictable and challenging for conventional corn farmers and insect pest problems have the potential to drastically reduce crop yield and quality. Crop losses attributable to the European corn borer and corn rootworm infestations have been well characterized and are significant. The introduction of transgenic cultivars which encode proteins (Cry proteins from *B. thuringiensis*) that are toxic to these species have provided U.S. corn growers with a powerful tool for effectively protecting crop yields and environmental benefits (Marvier et al. 2007). Therefore, it is reasonable to expect additional benefits to corn growers on wide range of insect pest protection when Cry and Vip proteins are combined in a single corn cultivar. Under this "no action" alternative, insecticides will still be used against those lepidopteran insect pests that would otherwise be controlled by the MIR162 insect resistance trait, based on the need and effectiveness on different insect species in the corn field.

The large-scale commercial cultivation of both insect resistant (Bt resistant) and herbicide tolerant (glyphosate tolerant) corn crop acreage has steadily increased from 1996, accounting for 85 % of corn acreage in 2009 (USAD-ERS 2009). The primary reason that farmers have switched to GE corn hybrids is because they protect the inherent yield potential of corn crops by reducing growers input costs. Furthermore, the planting of insect-protected corn hybrids benefited the environment by decreasing the conventional pesticide applications by more than 20 million pounds annually (Figure 8 in Fernandez-Cornejo and Caswell 2006; Benbrook 2004). There would not be any affect on the availability or use of Bt-resistant corn under the 'no action' alternative. These GE varieties will remain non-regulated GE corn varieties.

B. Preferred Alternative

Under this alternative, the MIR162 corn would no longer be a regulated article under 7 CFR part 340. Permits issued and/or notifications acknowledged by APHIS would no longer be required for introductions of the MIR162 corn. APHIS has chosen the preferred alternative for the proposed action because the MIR162 corn lacks plant pest characteristics, as determined in APHIS' Plant Pest Risk Assessment (USDA-APHIS 2009) and this EA. APHIS' assessment of environmental consequences under the preferred alternative is described below.

B-1. Corn

Under this alternative, the MIR162 corn would be available to growers. A potential environmental impact to be considered as a result of planting this corn hybrid, as with any other commercially-available corn hybrid, is the potential impacts arising from gene introgression of the MIR162 corn with other sexually compatible related species. APHIS evaluated the potential for gene introgression to occur from the MIR162 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness in wild relatives considering various morphological and/or agronomic traits, such as seed dormancy, vegetative and reproductive traits, volunteering potential, disease and pest susceptibility, and the fitness advantage of Vip3Aa20 gene of

MIR162 corn. Based on the scientific analysis of weediness data in the plant pest risk assessment APHIS has determined that the MIR162 corn is no more likely to become a weed than other cultivated corn varieties; it is not a plant pest; and gene flow between the MIR162 corn and weedy and wild relatives is not going to occur in the United States (USDA-APHIS 2009). Based on the above considerations, APHIS decision to grant nonregulated status to the MIR162 corn will not adversely impact sexually compatible wild relatives or their weediness potential.

The food/feed nutritional and safety assessment for the MIR162 corn has been reviewed by the FDA. Under 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 the MIR162 corn must be in compliance with all applicable legal and regulatory requirements. FDA completed their consultation on MIR162 on December 9, 2008 and concluded that it had "no further questions concerning grain and forage derived from corn event MIR162" (FDA BNF No. 000113). APHIS' assessment of the safety of this product focuses on its potential to pose a plant pest risk, and that analysis is based on the comparison of the GE corn to its non-GE counterpart (USDA-APHIS 2009).

B-2. Agricultural Production of Corn

In 2009, GE insect-resistant corn occupied 63 percent of the corn acreage (USDA-ERS 2009). 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. Syngenta field tested the MIR162 corn since 1999 across 20 representative corn growing areas (pg. 127 in petition). However, the majority of agronomic data were collected during the 2005 and 2006 growing seasons across 6-10 locations representative of the major corn-growing areas of the upper mid-west U.S. For the majority of the traits assessed (Tables 22 & 23, pg. 65-66 in petition), there were no statistically significant differences between MIR162-derived hybrids and their control counterparts.

APHIS assessed whether the MIR162 corn is any more likely to become a weed than the isogenic nontransgenic corn line, or other corn varieties currently under cultivation (USDA-APHIS 2009). The assessment encompasses a thorough consideration of the basic biology of corn and an evaluation of the unique characteristics of the MIR162 corn evaluated under field conditions (USDA-APHIS 2009). Based on the agronomic field data and literature survey about corn weediness potential, the MIR162 corn lacks ability to persist as troublesome weed. If MIR162 corn is granted nonregulated status, there also would be no direct impact on corn weed management practices.

B-3. Potential Impacts of Line MIR162 Corn on Insect Control Practices

Insect control options available to corn growers include conventional insecticide applications, microbial insecticide applications, crop rotation, and planting of insect resistant cultivars. Before the introduction of GE corn varieties, the corn growers had difficulty controlling European corn borer, one of the most widespread and damaging insect of corn in the U.S. Corn Belt. The introduction of the first Bt corn hybrids in 1996 provided growers with an effective means of limiting damage caused by European corn borer. Bt corn use grew from about zero percent of corn acreage in 1996 to 85 percent in 2008 (USDA-ERS 2009). These hybrids express either a *cry1Ab* or *cry1F* gene from *B. thuringiensis*, both of which encode proteins that are highly toxic to European corn borer.

Controlling above-ground insects presents a challenge for corn growers, as many pests are shielded from aerial chemical applications. As a consequence, the majority of corn fields are not treated for control of leaf-, stalk-, and ear-feeding insects. The MIR162 corn has the potential to control certain above-ground insect pests that are not controlled by the Bt corn varieties expressing Cry proteins. Data obtained from the 2005 and 2006 Doane Marketing Research AgroTrak studies (Doane Marketing Research 2006) indicate that growers are currently treating approximately three million acres a year with conventional insecticides for control of corn earworm, black cutworm, western bean cutworm, and fall armyworm with an estimated grower cost of 20 to 23 million dollars (Table 32, pg. 94 in petition). Compared to the total number of corn acres planted annually in the U.S., this represents a relatively small use of conventional pesticides; however, three million acres treated represents a significant use compared to chemical usage in other crops (Gianessi and Reigner 2006).

In addition to direct damage caused by feeding on plant tissue, insects play an important role in the transmission and dissemination of pathogenic organisms during corn development. Feeding by *Diabrotica* rootworms has been associated with increased frequencies of *Fusarium* fungal infection (Dicke and Guthrie 1988), and rootworm feeding may also lead to increased incidences of stalk rots. Ear, kernel, and cob rots occur wherever corn is grown and result in reduced test weight, poor grain quality, and mycotoxin contamination of food and feed. *Fusarium* kernel or ear rot is the most widespread disease of corn ears and is frequently associated with insect feeding damage. Mycotoxin contamination of corn grain presents a potential threat to livestock health and it is occasionally necessary to reject or reformulate feed lots because of contamination. These pathogenic infections can lead to reduced crop quality, ability to harvest, and yield.

Growers only have a very narrow time window during which insecticides can be applied because many of the above-ground feeding insects are shielded from contact with the insecticides by virtue of their feeding location on the plant. The MIR162 corn provides excellent protection against feeding damage caused by corn earworm, black cutworm, western bean cutworm, and fall armyworm. For this reason, the MIR162 corn introduction will have a positive impact on current corn insect control practices. This product has the potential to displace many conventional insecticide applications on corn (see pg. 92-96 in petition).

B-4. Organic and Other Non-transgenic Corn Production

The National Organic Program (NOP) is administered by USDA's Agricultural Marketing Service (AMS). Organic production operations must develop and maintain an organic production system plan approved by an accredited certifying agent in order to obtain certification. Organic certification of a production or handling operation is a process claim, not a product claim. Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. Oversight by a certifying agent includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records.

The organic system plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods, unless a certifying agent has reasonable suspicion that a prohibited substance or excluded method was used. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards.

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic grain, will be significantly impacted by the expected commercial use of this product since nontransgenic corn will likely still be sold and will be readily available to those who wish to plant. Despite the introduction and adoption of transgenic corn cultivars over the past decade, including multiple varieties of Bt corn, specialty and organic corn remains readily available. In 2006, there were at least 18 seed companies in the U.S. specializing in organic corn seed (see pg. 110-111 in petition).

Organic and other farmers have expressed concern that the widespread planting of Bt corn plants will hasten the development of pest resistance to pesticidal Bt endotoxins. Farmers purchasing seed will know this product is transgenic because it will be marketed as Vip3aA20 lepidopteran resistant; and based on the EPA insect resistance management (IRM)[1] policy (BPPD-EPA 2001), farmers will be educated by the Syngenta's stewardship plan about recommended management practices on MIR162 corn cultivation. Transgenic corn lines resistant to lepidopteran insects, and/or tolerant to specific herbicides are already in widespread use by farmers. This particular product should not present new and different issues than existing insect resistant Bt corn cultivars with respect to impacts on organic farmers.

APHIS has considered that corn is open-pollinating and it is possible that the engineered genes could move via wind-blown pollen to an adjacent field . All corn, whether genetically engineered or not, can transmit pollen to nearby fields, and a very small influx of pollen originating from a given corn variety does not appreciably change the characteristics of corn in adjacent fields. As described previously in this assessment,

[1] Insect resistance management (IRM) is the term used to describe practices aimed at reducing the potential for insect pests to become resistant to a pesticide. Specific IRM strategies, such as the high dose/structured refuge strategy, developed by EPA are expected to mitigate insect resistance to specific Bt proteins produced in corn

the rate of cross-pollination from one field to another is expected to be quite low, even if flowering times coincide. The frequency of such an occurrence decreases with increasing distance from the pollen source such that it sufficiently low at 660 feet away to be considered adequate for production of certified corn seeds.

Methods of spatial and temporal isolation are widely used when seed producers are seeking to minimize the influx of pollen from sources outside the seed production field. These methods are readily applicable for the production of certified organic corn seed. Data provided in the petition from agronomic trials conducted in 2005 and 2006 in a variety of locations in the U.S. demonstrated that the MIR162 corn is not significantly different in yield from its nontransgenic counterpart (Petition Tables 22 and 23, pg. 65-66), and the MIR162 corn hybrids were not significantly different from control lines in terms of pollen viability, morphology, and diameter (Table 24, pg. 67 in petition). Therefore, MIR162 corn hybrids are not expected to have an increased ability to cross-pollinate other corn varieties.

If APHIS chooses the no action alternative there would be no direct impact on organic or other non-transgenic corn farmers. The current cultivation practices are unlikely to change and 85% of the corn produced would likely continue to be planted with the current biotech corn hybrids. If the MIR162 corn is granted nonregulated status, there also would be no direct impact on organic or other non-transgenic corn farmers as the market share of transgenic corn is unlikely to change by the introduction of MIR162 corn.

B-5. Potential Impact on Non-target Organisms, Including Beneficial Organisms and Threatened or Endangered Species

APHIS evaluated the potential for the MIR162 corn plants and their products to have damaging or toxic effects directly or indirectly on non-target organisms (USDA-APHIS 2009). Non-target organisms considered were those representative of the agricultural environment, including those that are recognized as beneficial to agriculture (Table 31, pg. 89 in petition) or as threatened or endangered in the U.S. APHIS also considered potential impacts on other "non-target" pests, since such impacts could potentially change agricultural practices. The technical details of the experiment on non-target organisms have been described in the Plant Pest Risk Assessment of MIR162 corn (USDA-APHIS 2009; see also pg. 85-88 in petition for details).

Different types (variants) of Vip proteins occur in nature, and three variants of Vip protein (Vip3Aa1, Vip3Aa19, Vip3Aa20) are used for the nontarget impact investigations. The three protein variants (Vip3Aa1, Vip3Aa19, Vip3Aa20) differ from each other by 1-2 amino acids (Table 12, pg. 48 in petition), and all three are found be biochemically and functionally equivalent (see Table 13 and explanation thereof on pg. 50 in petition). The Vip3Aa19 variant is present in Syngenta's deregulated cotton event COT102. Likewise, the Vip3Aa19 variant was also present in corn cultivar Pacha maize. Syngenta discontinued Pacha maize due to agronomic performance reasons and replaced its commercial development by MIR162 maize. Therefore each one of the nontarget exposure investigation, detailed in the following paragraphs, was carried out using one of the three Vip variant proteins (Table 30, pg. 84 in petition)

Potential impacts of Vip3Aa on higher animals. In the bird (bobwhite quail, *Colinus virginianus*), mammal (mouse, *Mus musculus*), and honey bee (*Apis mellifera*) study conducted by Syngenta, there were no observable adverse effects or differences in survival noted at doses of Vip3A proteins that were well above those expected from exposure to the Vip3Aa20 protein from the MIR162 corn planted in the field (Table 31, pg. 89 of petition).

Potential impacts of Vip3Aa on above-ground arthropods. Adult pink spotted ladybird beetle *(Coleomegilla maculata),* seven-spot ladybird beetle (*Coccinella septempunctata),* second-instar minute pirate bug (*Orius insidiosus*), adult green lacewings (*Chrysoperla carnea)*, two- to three-day old *C. carnea* larvae were exposed to Vip3Aa19 protein. The difference in survival of the beetles in the treatment and control groups was not statistically significant (see pg. 86 in petition).

Potential impacts on threatened and endangered arthropods. Given the narrow specificity of the Vip3Aa20 activity, species outside the insect order Lepidoptera are not expected to be affected by Vip3Aa20 protein toxicity. Its receptor-mediated mechanism of action and absence of activity in bioassays with multiple species outside of the order Lepidoptera, as discussed in preceeding paragraphs, support this conclusion. Furthermore, Syngenta observed no harmful effects of Vip3Aa proteins in nontarget organism hazard identification studies that used a wide range of taxa and at expected environmental concentrations and the test results indicated a lack of risk associated with exposure to Vip3Aa20 in the MIR162 corn (Table 31, pg. 89-90 in petition).

APHIS coordinates review of petitions with other agencies that have regulatory oversight on these same products. With respect to threatened and endangered species, EPA also plays a role in the evaluation. The Endangered Species Protection Program (ESPP) of EPA places geographically specific use limitations on pesticides in order to protect endangered and threatened species from pesticides (EPA 2009). The Vip3Aa20 protein is selectively toxic to a few species of insect pests belonging to the order Lepidoptera. The only endangered or threatened lepidopteran species with potential for exposure to insecticidal proteins in corn is the Karner blue butterfly (*Lycaeides melissa samuelis*) (EPA 2001; USFWS 2007). The Karner blue requires wild lupine *(Lupinus perennis)* as an oviposition substrate and larval food source, while the adults feed on wild flowers. The potential route of exposure is consumption of maize pollen that has settled on the leaves of its food plant, the wild lupine (*Lupinus perennis*). Karner blue is known to exist along the northern extent of the range of wild lupine, where there are prolonged periods of winter snowpack, in parts of Wisconsin, Michigan, Minnesota, Indiana, New Hampshire, New York, and Illinois (Haack 1993). Although there are two counties in Wisconsin that have been identified as having a potential overlap between corn pollen shed and the presence of Karner blue larvae (Peterson et al. 2006), there is no evidence of Karner blue exposure to corn pollen in these locations. According to Peterson et al. (2006) the exposure of the Karner blue to maize pollen was minimal in all other locations because most lupine populations are separated from maize fields by at least 500 metres, and because maize anthesis usually occurs after the Karner blue has finished feeding. Although not an endangered or threatened species, *Danaus plexippus* (monarch butterfly) is a species of high conservation interest, and there has been concern that it may be harmed by consuming pollen from transgenic insect-protected corn. However, the restriction of toxicity of Vip3Aa20 to Lepidoptera, and the minimal exposure of endangered Lepidoptera to corn, indicates that Vip3Aa20 in the MIR162 corn is not expected to have any harmful effects on any endangered or threatened species in the U.S.

APHIS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service (FWS) to determine when a consultation, as required under section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the unconfined release following a determination of nonregulated status would have no effect on, or not likely to adversely affect, federally listed threatened and endangered species and species proposed for listing, or designed critical habitat or habitat proposed for designation (USDA-APHIS 2009).

*Environmental fate in soil and effects on soil dwelling organisms***.** The purpose of the soil fate study was to test the inherent degradability of Vip3Aa20 in a soil typical of corn-growing areas with healthy microbial activity. Most proteins do not persist or accumulate in soil because they are inherently degradable in soils (Burns 1982; Marx et al. 2005). Multiple investigations have demonstrated that Bt Cry proteins are rapidly degraded in a variety of soil types and that the proteins do not accumulate (EPA 2001; Head et al. 2002; Dubelman et al. 2005). Vip proteins are similar to Cry proteins in that they are also found in naturally occurring soil bacteria and commercial microbial insecticides (de Maagd et al. 2001). There is no evidence that they accumulate in soil or are protected from the activity of proteases in soil.

Syngenta provided data on the effects of Vip3Aa protein on a set of representative soil-dwelling nontarget organisms (earthworms, *Eisenia foetida*; collembolan, *Folsomia candida*; rove beetles, *Aleochara bilineata*) (see p. 32 in petition), as residual corn plant material is oftentimes incorporated into the soil after harvest. Syngenta conducted a laboratory study to determine the degradability of Vip3Aa19 (Vip3Aa19 and Vip3Aa20 are functionally equivalent, see earlier text) protein in five soils (clay, sandy clay, loam, sandy loam, silt loam). A rapid decline in the levels of Vip3Aa19 was observed in all soil types, wherein degradation was measured as loss of insecticidal activity. The time to 50% dissipation (DT_{50}) was estimated to be between 6.0 and 12.6 days across soil types and test concentrations. The results of this study showed that Vip3Aa protein is rapidly degradable in normal soils. Thus, the Syngenta's soil study data indicate that that there will not be a significant environmental impact on the soil environment by granting nonregulated status in whole to MIR162 due to limited persistence of Vip3Aa20 in the soil. Thus, the inclusion of the MIR162 corn into corn hybrids and their use in agriculture is not expected to have an adverse effect on soil or water quality, water use, or air quality, and is expected to continue to provide improvements in water quality due the potential for continued reduction in use of more hazardous chemical pesticides, many of which are toxic to aquatic organisms. It should also reduce human and environmental exposure to more toxic insecticides that can be used to control target pests.

Based on the analysis of field and laboratory data provided by Syngenta, scientific literature (Appendix I), and safety data available on earlier insect-resistant GE corn hybrids, APHIS has concluded that the proposed action to deregulate the MIR162 corn would have no significant impacts on human or animal health.

B-6. Cumulative Effects

APHIS considered whether the proposed action could lead to significant cumulative impacts, when considered in light of other past, present, and reasonably foreseeable future actions, regardless of what agency or person initiated such actions.
APHIS has evaluated the potential cumulative impacts of granting nonregulated status to the MIR162 corn. Both petitioner's data and the USDA-APHIS review do not indicate any cumulative impact on the environment as a result of the MIR 162 corn deregulation as discussed in the following paragraphs (see pg. 104-108 in petition for details).

As indicated earlier, GE insect resistant corn acreage has been steadily increasing for the last 13 years, (0 to 63%) (USDA-ERS 2009). The MIR162 is not the first Bt corn product to be granted nonregulated status. APHIS has previously made determinations of nonregulated status for several other Bt corn cultivars (petition numbers:
94-319-01p at http://www.aphis.usda.gov/brs/aphisdocs2/94_31901p_com.pdf;
95-093-01p at http://www.aphis.usda.gov/brs/aphisdocs2/95_09301p_com.pdf;
95-195-01p at http://www.aphis.usda.gov/brs/aphisdocs2/95_19501p_com.pdf;
96-291-01p at http://www.aphis.usda.gov/brs/aphisdocs2/96_29101p_com.pdf;
97-013-01p at http://www.aphis.usda.gov/brs/aphisdocs2/97_01301p_com.pdf;
97-265-01p at http://www.aphis.usda.gov/brs/aphisdocs2/97_26501p_com.pdf;
00-136-01p at http://www.aphis.usda.gov/brs/aphisdocs2/00_13601p_com.pd;
01-137-01p at http://www.aphis.usda.gov/brs/aphisdocs2/01_13701p_com.pdf;
03-181-01p at http://www.aphis.usda.gov/brs/aphisdocs2/03_18101p_com.pdf;
04-125-01p at http://www.aphis.usda.gov/brs/aphisdocs2/04_12501p_com.pdf;
04-362-01p at http://www.aphis.usda.gov/brs/aphisdocs2/04_36201p_com.pdf;
06-298-01p at http://www.aphis.usda.gov/brs/aphisdocs2/06_29801p_com.pdf;

According to Syngenta, the combined-trait Bt11xMIR162 hybrids are very efficacious against five major insect pests (European corn borer, corn earworm, fall armyworm, black cutworm, western bean cutworm) and such hybrids have the potential to provide growers the means of protecting their corn crops from damage caused by a broader range of lepidopteran pests (USDA-APHIS 2009).

Genetic purity of corn germplasm. The deregulation of MIR162 is unlikely to affect the genetic purity and diversity of non-GE corn cultivars and germplasm. The genetic purity and diversity has been a feature of corn improvement cultivation for decades as part of hybrid seed and specialty corn production, and multiple Bt corn events have not significantly affected these processes, even considering the effects of these transgenic events cumulatively. Many methods are used effectively to produce quality hybrid seed, including the following: maintaining isolation distances to prevent pollen movement from other corn, planting border or barrier rows to intercept pollen, employing natural barriers to pollen movement such as treelines, manual or mechanical detasseling, genetic male sterility, and staggered planting dates. In general, all the management practices used in conventional seed production to ensure quality standards are also employed in, and are sufficient to meet standards for the production of specialty corn seed. Prior to the introduction of transgenic corn products, the corn industry developed effective methods and means to maintain product segmentation and genetic purity standards. As a result, these widespread practices have served to ensure that the broad adoption of transgenic corn in the U.S. (including the sale and cultivation of multiple Bt corn varieties over more than a decade) has had no significant impact, even in the aggregate, on the production of corn seed and specialty corn products. APHIS does not foresee a cumulative impact on the genetic purity and diversity of non-GE corn cultivars and germplasm from granting nonregulated status in whole to MIR162 corn (see pg. 105 in petition).

Genetic diversity of corn. Genetically distinct corn hybrids have always been developed for various geographies and purposes, and are continually improved by plant breeding. In addition, the adoption of genetically engineered corn was preceded by worldwide efforts to identify and preserve sources of corn genetic diversity, and to make these resources available for utilization by public and private corn breeders. Among these efforts are the Germplasm Enhancement of Maize program ("GEM"), a cooperative effort undertaken by USDA, public and private plant sector breeders, NGOs (Non Governmental Organizations) and international public cooperators, which was established to further identify corn genetic diversity and to provide it in useful form in order to broaden the genetic base of this crop. Thus, APHIS' observation of numerous other transgenic corn products indicates that the genetic diversity of corn has been maintained in coexistence with these events. APHIS does not foresee significant cumulative impacts on the genetic diversity or on the availability of diverse corn germplasm resources because of the adoption of multiple varieties of transgenic corn.

Multiple Bt corn events and insect resistance developing in the field. As MIR162 corn provides no protection against feeding damage caused by European corn borer, therefore Syngenta intends to commercialize the MIR162 corn as a combined-trait hybrid with Syngenta's Bt11 (contains Cry1Ab Bt protein to control European corn borer damage) corn event to control a variety of lepidopteran insect pests, such as European corn borer, corn earworm, black cutworm, western bean cutworm, and fall armyworm. Syngenta has submitted an Insect Resistant Management (IRM) plan for Bt11xMIR162 corn that requires growers to plant a 20% structured refuge (see BBPD-EPA 2001 for details) that can be planted as strips within or surrounding the Bt corn field or as a block within, adjacent to, or up to 0.5 mile away. The proposed refuge requirements are the same in the Corn Belt and cotton growing areas (see BBPD-EPA 2001 for details).and, so far, those refuge strategies either delayed or prevented the development of certain lepidopteran insect pest developing resistance to Bt (Bates et al. 2005).

According to Syngenta, the combined-trait hybrid, such as Bt11xMIR162, has a unique benefit. In this case, the combined-trait containing Cry1Ab and Vip3Aa20 proteins have been demonstrated to provide high-dose control of European corn borer, corn earworm , and fall armyworm. There have been no documented instances of confirmed insect resistance to Bt corn having developed in the field, and Syngenta is not aware of any studies showing insect resistance to Bt corn products, despite the introduction of multiple previous cultivars over the past decade.

Potential impacts on threatened and endangered species. The restriction of toxicity of Vip3Aa20 to Lepidoptera, and the minimal exposure of engendered Lepidoptera to corn, indicates that planting of the MIR162 corn is expected to have no harmful effects on any endangered or threatened species in the U.S.

Potential impacts on biodiversity. The importance of corn as a food crop, and its dependence on human management, has produced a long history of great care to protect germplasm lines of corn. Decades prior to the introduction of transgenic corn products, the corn industry developed effective methods and means to maintain product segmentation and genetic purity standards. Specialty corns, for example, were successfully isolated for years and continue to be grown today, even with transgenic corn widely adopted in the U.S. Moreover, with respect to both conventional and transgenic corn, the ability to protect and maintain the genetic purity of breeding lines is critical to seed companies and developers of new varieties such as MIR162. Consequently, seed companies routinely apply standard breeding techniques – including physical and temporal isolation – that have proven effective at maintaining the genetic purity of breeding lines. Genetically engineered corn lines with Bt traits (both Cry and Vip proteins) have been available on the market since 1994 and the body of evidence in peer-reviewed literature does not suggest any negative effect on biodiversity. The APHIS review and analysis of Syngenta's data (USDA-APHIS 2009) indicate that the line MIR162 corn exhibits no traits that would cause increased weediness, that its unconfined cultivation should not lead to increased weediness of other cultivated corn or other sexually compatible relatives, and that it is unlikely to harm non-target organisms common to the agricultural ecosystem or threatened or endangered species recognized by the U.S. Fish and Wildlife Service.

Based on this information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which the MIR162 corn is planted.

B-7. Socioeconomic Analysis

The main body of information on socioeconomic analysis described in the following paragraphs comes from Syngenta's socioeconomic analysis (see pg. 108-112 and Appendix 1 in petition); the Environmental Protection Agency's (EPA) Biopesticide Registration Action Document, Vip3Aa20 corn (BPPD 2009: http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/brad_006599.pdf); USDA-Economic Research Service' (USDA-ERS) report, "The First Decade of Genetically Engineered Crops in the United States" (Fernandez-Cornejo and Caswell

2006); and BioTech InfoNet Technical Paper, "Genetically Engineered Crops and Pesticide Use in the United States" (Benbrook 2004). The APHIS/BRS assessment on the petitioner's socioeconomic analysis is restricted to the MIR162 corn and its stacked hybrids with other Bt traits (Bt11xMIR162, Bt11xMIR162xMIR604).

The increased adoption of Bt corn cultivars since its introduction in the mid 1990s (USDA-ERS 2009) could imply that insect resistance varieties provide benefits to corn farmers. This is more so since the early 2000's when the Bt corn varieties that are effective against European corn borer were complemented with a second generation Bt corn cultivar that provide protection against corn root worm. According to USDA's Agricultural and Resource Management Surveys (ARMS) conducted in 2001-03 (see Figure 7 in Fernandez-Cornejo and Caswell 2006) most of the farmers adopting GE corn, cotton, and soybeans indicated that they did so mainly to increase yields through improved pest control. Because the MIR162 corn is effective against two major corn insect pests, corn earworm and western bean cutworm, which are not effectively controlled by earlier Bt corn cultivars, it is reasonable to assume that likewise, potential benefits do exist for farmers adopting the MIR162 corn cultivars. Although it is difficult at this time to accurately predict the magnitude of economic benefits of the MIR162 corn hybrids in the marketplace, because such hybrids are not currently in commercial production, the improved pest protection profile of Bt11xMIR162 corn may translate into correspondingly higher overall economic benefits to growers, consumers, and other downstream users of corn products.

Syngenta has suggested that their stacked hybrids Bt11 x MIR162 x MIR604 will provide unsurpassed control of target pests and that the product's "broad-lepidopteran control, particularly for corn earworm and western bean cutworm, potentially results in better performance than those of competitors. However, EPA's Biopesticides and Pollution Prevention Division (BPPD) notes that these statements are unverified assumptions. Although the data support that the stack containing the Bt11, MIR162, and MIR604 traits produces reasonably good efficacy against western bean cutworm, the MIR604 trait when combined with the MIR162 trait showed some evidence of a possible synergistic effect in the control of corn rootworm. BPPD reasons that the sample size used by Syngenta for the investigation is too small to delineate individual Bt traits impact in stacked hybrids. According to BPPD, Syngenta's specific economic benefits are based on best-case assumptions (i.e., quick and broad adoption of the product in the marketplace). Competition from previously registered Bt corn products (already established in the market) and farmer familiarity with these products may reduce the overall adoption, and as such the potential benefits, for MIR162 corn and its associated products. Despite this shortcoming however, BPPD notes that both the stack and/or pyramid products, and the single-trait product appear to provide good protection against European corn borer and corn earworm. For many growers, the potential broad lepidopteran control expected by Bt11xMIR162 hybrids may provide added benefits than currently available Bt corn cultivars, as corn growers with multiple pest problems are expected to be protected from major corn pests.

So far, Bt hybrids have mixed responses when it comes to monetary benefits to corn growers. In 2006, USDA-ERS published a report on "The First Decade of Genetically Engineered Crops in the United States" focusing on GE crops and their adoption in the United States over the past 10 years (Fernandez-Cornejo and Caswell 2006). The economic analysis in that report mainly focused on the field data from 1997 and 1998 (see Table 1). On average, BT technology benefitted corn farmers with 5% higher yields in the United States, and yield effects were larger in years with high pest pressures as noted earlier by other investigators (Carpenter et al. 2002). Many field tests and farm surveys have also examined the yield and cost effects of using Bt corn crops (Table 1). The majority of the results show Bt corn crops produce higher yields than conventional crops. A more recent ERS study using 2001 survey data found that, on average, actual corn yield was 12.5 bushels per acre higher for Bt corn than for conventional corn, an increase of 9% (Fernandez-Cornejo and Li 2005).

The economic benefits of growing Bt corn do not appeared to be consistent across growing seasons. There was a negative association between adoption of Bt corn and producer net returns in 1998. According to Fernandez-Cornejo and Caswell (2006) this negative trend suggests that Bt corn may have been used on some acreage where the value of protection against the European corn borer was lower than the premium paid for the Bt seed. Because pest infestations vary from one region to another and from one year to another, the economic benefits of Bt corn are likely to be greatest where pest pressures are most severe (Carpenter et al. 2002; Shelton et al. 2002). Farmers must decide to use Bt corn before they know what the European corn borer pest pressure will be that year. For that reason management practices are tailored accordingly (Mason et al. 1996). Because of this unpredictable variation, many farmers generally ignored European corn borer infestation and accepted the losses it caused (Shelton et al. 2002).

According to Gurian-Sherman (2009) there was a 3-4 percent yield advantage for Bt corn varieties in the U.S. for combining the benefits of European corn borer and corn root worm resistance. However, Gurian-Sherman's analysis also showed that Bt corn yield benefits were not much different from what was achieved through traditional breeding. For example, corn yield has been increasing on average 1 percent per year over the past several decades, and Bt corn crops had the same yearly improvement in the last 14 years since the introduction of first Bt crop in 1996. Several approaches, such as organic cultivation, wheat-corn rotation etc, other than current pesticide regimes and GE have the potential to reduce yield loss from corn borer and rootworm in corn. These approaches are also thought of as having other associated benefits such as lower levels of pesticide use, improved soil, carbon sequestration, and improved water quality (but also see the comments on the report by Sheridan 2009).

Adoption of GE crops is associated with reduced pesticide use. Insecticide use on fields planted to Bt corn substantially decreased since its introduction in mid 1990s (Figure 1; also see figure 8 in Fernandez-Cornejo and Caswell 2006) use rates (in terms of active ingredient) on corn has declined since the introduction of GE corn in1996. More recently, using 2001 data, USDA-ERS found that insecticide use was 8 percent lower per planted acre for adopters of Bt corn than for nonadopters (Fernandez-Cornejo and Li 2005). The USDA-ERS results generally agree with field-test and other farm surveys that have examined the effects of using GE crops (Table 1).

Table 1. Summary of primary studies on the effects of genetically engineered Bt corn on yields, pesticide use, and returns (Modified from Fernandez-Coejo and Caswell 2006).

Reference	**Data Source**	**Effects on** (NA = Not analyzed in the study)		
		Yield	**Pesticide Use**	**Returns**
Rice and Pilcher, 1998	Survey	Increase	Decrease	Depends on infestation
Marra et al., 1998	Survey	Increase	Decrease	Increase
Benbrook, 2001	Survey	Increase	NA	Decrease
McBride & El-Osta, 2002	Survey	NA	NA	Decrease
Duffy, 2001	Survey	Increase	NA	Same
Pilcher et al., 2002	Survey	Increase	Decrease	NA
Baute, Sears, and Schaafsma, 2002	Experiments	Increase	NA	Depends on infestation
Dillehay et al., 2004	Experiments	Increase	NA	NA
Fernandez-Cornejo & Li, 2005	Survey	Increase	Decrease	NA

The MIR162 corn and stacked hybrids may further reduce the insecticide use if the current trend in insecticide usage continues (Figure 8 in Fernandez-Cornejo and Caswell 2006). But according to Benbrook (2004) the insecticide reduction rate appears to have plateaued (Figure 1), and any further reduction in insecticide use from new Bt corn cultivars may be marginal. For example, the amount of insecticide saved per acre of Bt corn in 1996 was 0.16 pounds of active ingredient. As more acres of Bt corn were planted, insecticide use was reduced on a smaller share of these Bt acres, leading to a lower average reduction in insecticide use across all acres planted to Bt corn. In recent years, the reduction has been only 0.02 pounds per acre (see figure 1; Benbrook 2004). Besides the monetary benefits, Fernandez-Cornejo and Caswell (2006) noted that there are several other beneficial factors, such as ease of operation and time savings, which may have made GE crops attractive to farmers. Despite the mixed results on Bt benefits, from the corn growers' perspective, as reflected in the increased rate of adoption of Bt corn cultivars ever since 1996, the farm profitability has gradually been increasing through higher yields and/or lower costs (e.g., operator labor, energy savings, pesticide purchases) by growing Bt corn crops.

Another potential economic benefit for growers and downstream consumers is increased competition in the marketplace for pest-control products, including hybrid seed from multiple marketers of lepidopteran-tolerant Bt corn varieties. The commercial availability of MIR162 hybrid corn seed may represent a significant new pest control option and tool for growers. Increased grower choice may exert downward pressure on the cost of products that offer control of lepidopteran pests (see pg. 110 in petition).

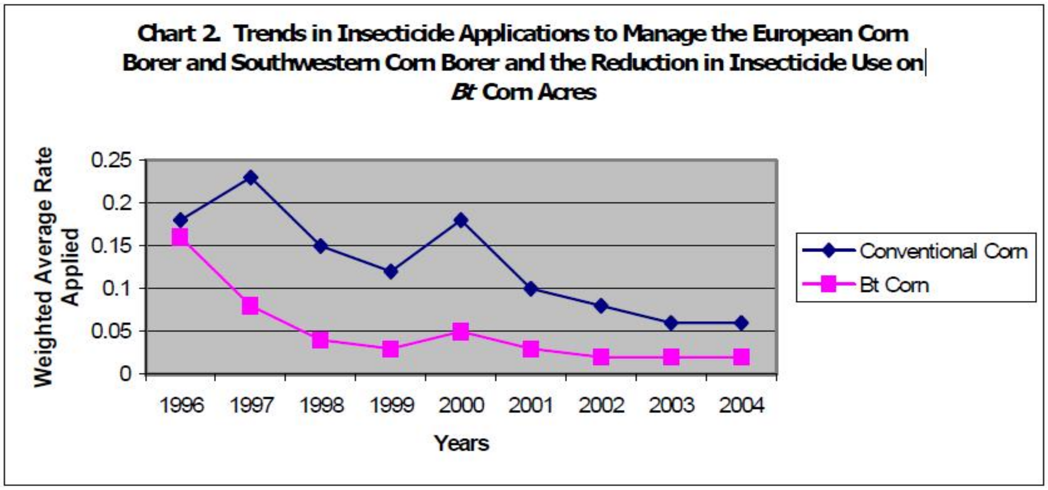

Figure 1. Reproduced from Benbrook 2004 "Chart 2. Trends in Insecticide Applications to Manage the European Corn Borer and Southwestern Corn Borer and the Reduction in Insecticide Use on Bt Corn Acres".

Human Health and Environmental Benefits. There is no human health concerns with respect to toxicity or allergenicity and no unreasonable environmental concerns with respect to toxicity of the insecticidal proteins expressed in the MIR162 corn (Appendix I in this EA; http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad.htm). Also, use of Bt corn can decrease farm worker exposure to Bt sprays and chemical insecticides and reduce the mold infestation on corn seeds (Carpenter et al. 2002). Consequently, any reduction in mold toxins resulting from use of Bt corn can provide direct benefits to people and corn-fed livestock. In a variety of field studies, other insect protected corn expressing Bt proteins have been shown to have significantly lower levels of common mycotoxins that are produced by fungal pathogens (Wu 2006); however, the mycotoxin levels in MIR 162 corn in commercial cultivation is not available at this time.

Insect Resistance Management Benefits. According to EPA the MIR162 corn and its stacked Bt hybrids have the potential to delay development of resistance in other corn varieties expressing Cry toxins. The introduction of MIR162 corn and its stacks and/or pyramids may have an additional benefit of prolonging the lifetime of other corn Plant Incorporated Protectants (PIP) technologies by providing another mode of action for European corn borer, corn earworm, fall armyworm, and corn rootworm.

Effects on the Export Market. Syngenta does not expect any effects on the United States corn export market by the cultivation of the MIR162 cultivars since Syngenta is actively pursuing regulatory approvals for the MIR162 corn in countries that import corn from the United States or Canada. Regulatory filings for the MIR162 corn are in process for

Colombia, Japan, South Korea, Taiwan, China, the Philippines, Australia and New Zealand, South Africa, the European Union, Russia, and Switzerland. Syngenta's stewardship agreements with growers will include a term requiring growers to divert this product away from export markets (i.e. channeling) where the grain has not yet received regulatory approval for import. Syngenta will communicate these requirements to growers using a wide-ranging grower education campaign (e.g., grower Stewardship Guide (see pg. 111 in the petition).

C. Consideration of Executive Orders, Standards and Treaties Relating to Environmental Impacts

Executive Order (EO) 12898, "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 and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

EO 13045, "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) requires 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. None of the alternatives are expected to have a disproportionate adverse effect on minorities, low-income populations, or children. Collectively, the available mammalian toxicity, along with the history of safe use of microbial Bt products and other corn varieties expressing Bt proteins, establishes the safety of the corn line MIR162 and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken. None of the impacts on agricultural practices expected to be associated with deregulation of the corn line MIR162 described above are expected to have a disproportionate adverse effect on minorities, low income populations, or children. As noted above, the cultivation of previously deregulated corn varieties with similar insect resistant traits has been associated with a decrease and/or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity. If pesticide applications are reduced, there may be a beneficial effect on children and low income populations that might be exposed to the chemicals. These populations might include migrant farm workers and their families, and other rural dwelling individuals who are exposed to pesticides through ground-water contamination or other means of exposure. It is expected that EPA and USDA Economic Research Service would monitor the use of this product to determine impacts on agricultural practices such as chemical use as they have done previously for Bt products.

EO 13112, "Invasive Species", states that Federal agencies take action to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause. Nonengineered corn as well as other Bt and herbicide tolerant corn varieties are widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, the engineered plant is sufficiently similar in fitness characteristics to other corn varieties currently grown, and it is not expected to have an increased invasive potential (see USDA-APHIS 2009).

EO 12114, "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 determined for the corn line MIR162 or if the other alternatives are chosen. 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 in MIR162 corn subsequent to a determination of non-regulated status for the line MIR162 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" (http://www.ippc.int/IPP/En/default.jsp). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (173 countries as of August 2009). In April, 2004, a standard for pest risk analysis 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 bioengineered 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 156 countries are parties to it as of June 24, 2009 (see http://www.biodiv.org/biosafety/default.aspx). 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 US Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (http://usbiotechreg.nbii.gov). 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 in the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (see http://www.nappo.org/Standards/Std-e.html). 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. Many countries, e.g. Argentina, Australia, Canada, China, Japan, Korea, Philippines, South Africa, Switzerland, the United Kingdom, and the European Union have already approved Bt corn varieties to be grown or imported for food or feed (http://www.agbios.com/dbase.php). There should be no effects on the U.S. corn export market since Syngenta is actively pursuing regulatory approvals for the MIR162 corn in countries with functioning regulatory systems for genetically modified organisms and that import corn from the U.S. or Canada. Regulatory filings for the MIR162 corn are in process for Colombia, Japan, South Korea, Taiwan, China, the Philippines, Australia and New Zealand, South Africa, the European Union, Russia, and Switzerland.

VI. REFERENCES

AOSCA (Association of Official Seed Certifying Agencies). 2003. Operational Procedures, Crop Standards and Service Programs Publications. Meridian, Idaho.

Bates, S., J-Z, Zhao, R. T. Roush, and A. M. Shelton. 2005. Insect resistance management in GM crops: past, present and future. Nature Biotechnology 23: 57-62.

Brookes, G. and P. Barfoot. 2004. Coexistence of GM and Non GM Crops: Case Study of Maize Grown in Spain. Dorchester, UK: PG Economics Ltd. http://www.pgeconomics.co.uk.

Burns, R.G. 1982. Enzyme activity in soil: location and possible role in microbial ecology. Soil Biology and Biochemistry 14: 423-427.

Benbrook, C. M. 2004. Genetically Engineered Crops and Pesticide Use in the United States: BioTech InfoNet Technical Paper Number 7, October 2004. The First Nine Years (http://www.biotech-info.net/Full_version_first_nine.pdf).

BPPD-EPA. 2001. Insect Resistance Management. Pp. IID1-153 *In,* Bt Plant-Incorporated Protectants, October 15, 2001. Biopesticides Registration Action Document, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. (http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/4-irm.pdf) (Last updated: October 15th, 2008).

BPPD-EPA. 2009. Benefits and public interest finding. Pp. 115-134 *In, Bacillus thuringiensis* Vip3Aa20 Insecticidal Protein and the Genetic Material Necessary for Its Production (*via* Elements of Vector pNOV1300) in Event MIR162 Maize (OECD Unique Identifier: SYN-IR162-4), Biopesticides Registration Action Document, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U.S. Environmental Protection Agency. (http://www.epa.gov/oppbppd1/biopesticides/ingredients/tech_docs/ brad_006599.pdf) (Last updated: March 2009).

Carozzi, N., and M. Koziel. 1997. Advances in Insect Control. Taylor & Francis Ltd., Bristol, PA.

Carpenter, J., A. Felsot, T. Goode, M. Hammig, D. Onstad, and S. Sankula. 2002. Comparative Environmental Impacts of Biotechnology-derived and Traditional Soybean, Corn, and Cotton Crops. Council for Agricultural Science and Technology, Ames, Iowa. www.cast-science.org. Sponsored by the United Soybean Board (www.unitedsoybean.org). http://www.soyconnection.com/soybean_oil/pdf/EnvironmentalImpactStudy-ExecutiveSummary-English.pdf de Maagd, R. A., A Bravo, and N. Crickmore. 2001. How *Bacillus thuringiensis* has evolved specific toxins to colonize the insect world. Trends in Genetics 17: 193-199.

Dicke, F. F. and W. D. Guthrie. 1988. The most important corn insects. Pp. 767-867 *In* Sprague, G. F. and J. W. Dudley (eds.) Corn and Corn Improvement (3rd edition). American Society of Agronomy-Crop Science Society of America-Soil Science Society of America, Madison, Wisconsin.

Doane Marketing Research. 2006. U.S. Seed corn TraitTrak Study. A Doane Marketing Research Syndicated Tracking Study. St. Louis, Missouri.

Dowd, P. F. 1998. Involvement of arthropods in the establishment of mycotoxigenic fungi under field conditions. Pp. 307- 350 *In* K. K. Sinha and D. Bhatnagar (eds.) Mycotoxins in Agriculture and Food Safety. Marcel Dekkar, Inc. New York.

Dubelman, S., B. R. Ayden, B. M. Bader, C. R. Brown, C. Jiang, and D. Vlachos. 2005. Cry1Ab protein does not persist in soil after 3 years of sustained *Bt* corn use. Environmental Entomology 34: 915-921.

Estruch, J. J., G. W. Warren, M. A. Mullins, G. J. Nye, J. A. Craig, and M. G. Koziel. 1996. Vip3A, a novel *Bacillus thuringiensis* vegetative insecticidal protein with a wide spectrum of activities against lepidopteran insects. Proceedings of the National Academy of Sciences (USA) 93: 5389–5394.

EPA. 2001. Biopesticides Registration Action Document – *Bacillus thuringiensis* Plant Incorporated Protectants. United States Environmental Protection Agency. (http://www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm) (Last updated: 10/15/2008)

EPA. 2009. Pesticides: Endangered Species Protection Program. United States Environmental Protection Agency. (http://www.epa.gov/espp/coloring/especies.htm (Last updated: 2/9/2009)

Fernandez-Cornejo, J., and J. Li. 2005. The Impacts of Adopting Genetically Engineered Crops in the USA: The Case of Bt Corn. Paper presented at the American Agricultural Economics Association meetings. Providence. (http://www.ers.usda.gov/publications/eib11/eib11.pdf)

Fernandez-Cornejo, J., and M. Caswell. 2006. First Decade of Engineered Crops in the United States. USDA-ERS Economic Information Bulletin 11, April 2006. (http://www.ers.usda.gov/publications/eib11/eib11.pdf)

Gianessi, L., and N. Reigner. 2006. Pesticide use in U.S. crop production:2002. A report prepared by CropLife Foundation (www.croplifefoundation.org), Washington, D.C. (http://www.croplifefoundation.org/Documents/PUD/NPUD%202002/ Inst%20and%20OP%20Data%20Report.pdf)

Gurian-Sherman, D. 2009. Failure to yield: evaluationg the performance of genetically engineered crops. USC (Union of Concerned Scientists) Publications, Cambridge, MA. (http://www.ucsusa.org/assets/documents/food_and_agriculture/failure-to-yield.pdf)

Haack, R.A., 1993. The Endangered Karner Blue Butterfly (Lepidoptera: Lycaenidae): Biology, management considerations, and data gaps. Pp 83-110 *In* Gillespie, A.R., G.R. Parker, P.E. Pope and G. Rink (eds). Proceedings 9th Central Hardwood Forest Conference. General Technical Report NC-161. USDA-Forest Service, North Central Forest Experiment Station, St. Paul. MN.

Head, G., J. B. Surber, J. A. Watson, J. W. Martin, and J. J. Duan. 2002. No detection of Cry1Ac protein in soil after multiple years of *Bt* cotton (Bollgard) use. Environmental Entomology 31:30-36.

Henry, C., D. Morgan, R. Weekes, R. Daniels and C. Boffey. 2003. Farm Scale Evaluations of GM Crops: Monitoring Gene Flow from GM Crops to Non-GM Equivalent Crops in the Vicinity. Contract Reference EPG 1/5/138. Final Report 2000/2003. (http://www.defra.gov.uk/environment/gm/research/pdf/epg_1-5-138.pdf).

Höfte, H., and H. R. White. 989. Insecticidal crystal proteins of *Bacillus thuringiensis*. Microbiology and Molecular Biology Reviews 53: 242-255.

Hurley, T. M., I. Langrock, and K. Ostlie. 2006. Estimating the benefits of Bt corn and cost of insect resistance management ex ante. Journal of Agricultural and Resource Economics 31: 355-375.

ICG (International Grains Council). 2009. Grain Market Report (GMR No. 394, 29 Oct 2009). (http://www.igc.org.uk/en/downloads/gmrsummary/gmrsumme.pdf)

Lee, M., F. Walters, H. Hart, N. Palekar, and J. Chen. 2003. The mode of action of the *Bacillus thuringiensis* vegetative insecticidal protein Vip3A differs from that of Cry1Ab δ-endotoxin. Appl. Environ. Microbiol. 69:4648-4657.

Ma, B.L., K. D. Subedi, and L. M. Reid. 2004. Extent of crossfertilization in maize by pollen from neighbouring transgenic hybrids. Crop Sci. 44:1273–1282.

Marra, M., G. Carlson, and B. Hubbell. 1998. Economic impacts of the first crop biotechnologies. (http://www.ag.econ.ncsu.edu/faculty/marra/firstcrop/imp001.gif)

Marvier, M., C. McCreedy, J. Regetz, and P. Kareiva. 2007. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. Science 316:1475-1477.

Marx, M-C., E. Kandeler, M. Wood, N. Wermbter, and S. C. Jarvis. 2005. Exploring the enzymatic landscape: distribution and kinetics of hydrolytic enzymes in soil particle-size fractions. Soil Biology and Biochemistry 37:35-48.

Mason, C. E., M. E. Rice, D. D. Calvin, J. W. Van Duyn, W. B. Showers, W. D. Hutchison, J. F. Witkowski, R. A. Higgins, D. W. Onstad, and G. P. Dively. 1996. European corn borer ecology and management. North Central Regional Extension Publication No 327. Iowa State University, Ames, Iowa. 57 pp.

Messeguer, J., G. Peñas, J. Ballester, M. Bas, J. Serra, and J. Salvia. 2006. Pollen-mediated gene flow in maize in real situations of coexistence. Plant Biotechnology Journal 4: 633–645.

Mendelsohn, M., J. Kough, Z. Vaituzis, and K. matthews. 2003. Are *Bt* crops safe? Nature Biotechnology 21: 1003-1009.

Norman, M. J. T., C. J. Pearson, and P. G. E. Searle. 1995. The Ecology of Tropical Food Crops (2nd edition). Cambridge University Press, Cambridge, U.K., pp 126-144.

OECD (Organization for Economic Co-operation and Development). 2003. Consensus document on the biology of *Zea mays* subsp. *mays* (maize). Series on Harmonisation of Regulatory Oversight in Biotechnology, No. 27, OECD, Paris. (http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/$FILE/JT00147699.PDF. (Last Modified: 23 July, 2003)

Peterson, R. K., S. J. Meyer, A. T. Wolf, J. D. Wolt, and P. M. Davies. 2006. Genetically engineered plants, endangered species, and risk: A temporal and spatial exposure assessment for Karner blue butterfly larvae and *Bt* maize pollen. Risk Analysis 26: 845-858.

Schnepf, E. N., J. C, J. Van Rie, D. Lereclus, J. Baum, J. Feitelson, D. R. Zeigler, and D. H. Dean. 1998. *Bacillus thuringiensis* and its pesticidal crystal proteins. Microbiology and Molecular Biology Reviews 62: 775–806.

Shelton, A. M., J.-Z. Zhao, and R. T. Roush. 2002. Economic, ecological, food safety, and social consequences of the development of Bt transgenic plants. Annual Review of Entomology 47: 845-881.

Sheridan, C. 2009. Report claims no yield advantage for Bt crops. Nature Biotechnology 27: 588-589.

Simpson, G. M. 1990. Seed Dormancy in Grasses. Cambridge University Press, New York.

USDA-APHIS. 2009. Plant Pest Risk Analysis for Syngenta MIR162 corn. USDA, APHIS, Biotechnology Regulatory Service. Riverdale, MD (URL: http://www.aphis.usda.gov/brs/not_reg.html)

USDA-ERS. 2009. Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties. United States Department of Agriculture, Economic Research Service, (Updated July 1, 2009) (Accessed August 10, 2009:) (http://www.ers.usda.gov/data/BiotechCrops/ExtentofAdoptionTable1.htm)

USDA-NASS. 2006. Agricultural Chemical Usage 2005 Field Crops Summary. United States Department of Agriculture, National Agricultural Statistics Service, May 2006. (http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2006/AgriChemUsFC-05-17-2006.pdf)

USDA-NASS. 2007. Crop Production. United States Department of Agriculture, National Agricultural Statistics, February 2007. (http://usda.mannlib.cornell.edu/usda/nass/CropProd//2000s/2007/CropProd-02-09-2007.pdf)

USDA-NASS. 2008a. Statistics of Grain and Feed. United States Department of Agriculture, National Agricultural Statistics Service, Washington, D.C. (http://www.nass.usda.gov/Publications/Ag_Statistics/2008/Chap01.pdf)

USDA-NASS. 2008b. Acreage. United States Department of Agriculture, National Agricultural Statistics Service, Washington, D.C. (http://usda.mannlib.cornell.edu/usda/nass/Acre//2000s/2008/Acre-06-30-2008.pdf)

USFWS. 2007. Threatened and endangered species system. A database developed by the U.S. Fish and Wildlife Service. (http://ecos.fws.gov/tess_public/SpeciesReport.do?groups=I&listingType=L&mapstatus=1)

Ward, D., T. De Gooyer, T. Vaughn, G. Head, M. McKee, J. Astwood, and J. Pershing. 2005. Genetically enhanced maize as a potential management option for corn rootworm: YieldGard® rootworm maize case study. Pp 239-262 *In* S. Vidal, U. Kuhlmann, and C. Edwards (eds.)Western Corn Rootworm: Ecology and Management.CAB International, Wallingford, U.K.

Williams, P. W., P. M. Buckley, and G. L. Windham. 2002. Southwestern corn borer (Lepidoptera: Crambidae) damage and aflatoxin accumulation in maize. Journal of Economic Entomology 95:1049-1053.

Wright, B., M. Bernards, and L. Sandell. 2009. Volunteer corn presents new challenges. Crop. Crop Watch News Service, University of Nebraska-Lincoln Extension, Institute of Agriculture and Natural Resources, Lincoln, Nebraska. (http://cropwatch.unl.edu/archives/2009/crop22/weeds_volunteer_corn.htm)

Wu, F. 2006. Mycotoxin reduction in Bt corn: potential economic, health, and regulatory impacts. Transgenic Research 15:277-289.

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VIII. APPENDIX

Appendix I. Environmental and Human Health Safety of Vip3Aa20 Protein

Previously deregulated Bt corn cultivars have resulted in reduced conventional pesticide use, as farmers find Bt products more effective in mitigating lepidopteran insect feeding damage. It is reasonable to expect that deregulation and commercialization of the MIR162 corn will result in further reductions in the use of conventional pesticides. This reduction in conventional pesticide use would diminish the environmental risks of chemical pesticide insect control, as the chemical alternatives to MIR162 present well-characterized risks to humans and other wildlife, whereas Vip3Aa20 presents no such risk. Substantial data support a conclusion that Vip3Aa20 toxicity will be limited to sensitive lepidopteran species that are sufficiently exposed to the protein (USDA-APHIS 2009).

The toxicity of insecticidal Bt proteins, such as Vip3a20, depends on their binding to specific receptors present in the insect midgut. Research demonstrates that this specificity limits the proteins' toxic effect to certain lepidopteran species. A discussion on the mechanism of action for Vip3Aa20, its spectrum of activity, and its lack of toxicity to non-lepidopteran species is presented in the petition (pg. 47-50).

Health and safety studies have been conducted with the novel proteins contained in MIR162 corn. A comprehensive assessment of the safety of the introduced proteins, Vip3Aa20 and PMI, demonstrate that both proteins are nontoxic to mammalian species and are unlikely to be food allergens (69 FR 26770-26775; 73 FR 45620-45624; FDA BNF No. 000113). The Vip3Aa20 protein is considered nontoxic because it does not share significant amino acid homology with known protein toxins, is nontoxic to mice at a very high dose of 1250 mg Vip3Aa20/kg bw, is rapidly degraded in simulated mammalian gastric fluid, and its insecticidal mode of action for Vip3Aa20 is not relevant to mammals.

Vip3Aa20 is also not likely to be a food allergen because it is not derived from a known source of allergenic proteins, it does not have any significant amino acid sequence identity to known allergenic proteins, it is rapidly degraded in simulated mammalian gastric fluid, and it is labile upon heating at temperatures of 65ºC and above. The PMI protein is considered nontoxic because it does not share significant amino acid homology with known protein toxins, it is nontoxic to mice at a very high dose of 3030 mg PMI/kg bw, and it is rapidly degraded in simulated mammalian gastric fluid. PMI is not likely to be a food allergen because it is not derived from a known source of allergenic proteins, it does not have any significant amino acid sequence identity to known allergenic proteins with implications for its allergenic potential, it is rapidly degraded in simulated mammalian gastric fluid, and it is labile upon heating at temperatures of 37ºC and above.

A permanent exemption from the requirement of a food tolerance currently exists under 73 FR 45620-4562440 for Vip3Aa20 in maize and under 40 CFR §180.1252 for PMI in all plants.

USDA-APHIS. 2009. Plant Pest Risk Analysis for Syngenta MIR162 corn. USDA, APHIS, Biotechnology Regulatory Service. Riverdale, MD (URL: http://www.aphis.usda.gov/brs/not_reg.html)

Appendix II. Syngenta MIR162 Corn Forage and Grain Compositional Analysis

The data for the discussion and interpretation on the composition analysis of the MIR162 corn come from Syngenta's petition (Petition Appendix E, pages 158-180 for experimental details and statistical analyses, and pages 69-73 for the interpretation and discussion of results) and was reviewed by APHIS. The rationale for the composition analysis of forage and grain is to identify any changes in nutrient or anti-nutrient content of the new crop in the context of its use as food or feed and to assess its biochemical equivalence and similarity to conventional maize. Assessment of the plant's composition also allows the developer and APHIS to evaluate possible unintended effects that might arise from insertion of the Vip3Aa20 and PMI genes into the plant's genome. This assessment was undertaken by performing quantitative analyses of 65 components (Table 25, pg. 70 in petition) both from MIR162 hybrid corn and a nontransgenic control variety. The analytes measured in this study were selected based on recommendations of the Organisation for Economic Co-operation and Development (OECD, 2002) for comparative assessment of composition of new varieties of maize. The plant materials for the analysis come from six diverse corn growing regions of the U.S. (Appendix Table E-1, pg. 158 in petition) during 2005. Plants were self-pollinated by hand and the developing ears were bagged to avoid cross-pollination. All analyses were conducted using methods published and approved by the Association of Analytical Communities (AOAC) International or other industry-standard analytical methods.

Nine components of corn forage were measured; the difference between MIR162 and control mean values was found to be statistically significant for one of these analytes. Fifty-six components of grain were measured; the difference between MIR162 and control mean values was found to be statistically significant for 13 of these analytes. The results for these 14 analytes that had a statistically significant outcome for genotype effect (Table 26, pg. 72 in petition) have been discussed in the following paragraphs.

The forage compositional analyses for proximates and minerals revealed a single statistically significant difference between MIR162 and control mean values. The mean value for MIR162 Neutral Detergent Fiber (NDF) was 11.34% higher than the corresponding control value. This difference is considered relatively small and the MIR162 mean falls well within the range of normal values reported by International Life Sciences Institute (ILSI) (Ridley et al. 2004; ILSI 2006) and Organisation for Economic Co-operation and Development (OECD). No statistically significant genotype by location interactions were noted for the forage compositional analyses.

Compositional analyses of grain revealed no statistically significant differences between MIR162 and control means for 43 of the 56 analytes examined in across-location comparisons. Statistically significant differences were noted for levels of the proximates ash, NDF, starch, three grain minerals (calcium, iron, and phosphorus), levels of vitamin A (β-carotene), vitamin B_6 (pyridoxine), and vitamin E (α-tocopherol), linoleic and linolenic fatty acids. These differences were small (< 8%) and the MIR162 mean values were well within the ranges of normal values for the control maize. Additionally, the average values for all proximates were within the ranges reported by ILSI and OECD.

Statistically significant differences were noted between MIR162 and control mean levels of vitamin A (β-carotene), vitamin B_6 (pyridoxine), and vitamin E (α-tocopherol). These differences were small (< 7%) and the mean values observed for these vitamins in the MIR162 grain were well within the range of values observed for the control grain. Additionally, the MIR162 means for all vitamins fell within the normal range of values reported for conventional maize by ILSI and OECD. For vitamin A and vitamin B_9 a statistically significant genotype-by-location interaction was noted, which suggests that the effect of genotype was not consistent across locations, hence, the comparison of genotypes averaged across locations may not be valid. Individual location means for the two analytes are provided in Table E-8 (Appendix E). The vitamin A and vitamin B_9 levels at all locations were within the ranges reported in the literature.

There were no significant differences noted for any of the 18 amino acids or anti-nutrients measured and all average values were within the ranges reported by ILSI and OECD (Appedix E, pg. 158-180 in petition).

Statistically significant differences were noted for linoleic and linolenic fatty acids. These differences were very small (< 4%) and the MIR162 mean values observed for these fatty acids were within the ranges of values observed for the control grain. Furthermore, the average values for all fatty acids were within the range of normal values reported for conventional maize by ILSI and OECD.

Statistically significant differences were noted in the secondary metabolites ferulic acid and *ρ*-coumaric acid. These differences were relatively small (< 15%) and the MIR162 mean values for these secondary metabolites were within the ranges of values observed for the control grain. Additionally, the mean values for all MIR162 secondary metabolites and anti-nutrients were within the normal range of values reported for conventional maize by ILSI and OECD.

Collectively, the observed differences between MIR162 and control means are considered of no biological significance and represent typical random variance. The magnitude of the differences was small, all MIR162 values fell within normal ranges for conventional maize, and the MIR162 and control data ranges significantly overlapped. MIR162 is therefore, not compositionally different from conventional maize.

References

ILSI. 2006. International Life Sciences Institue Crop Composition Database, 3.0. International Life Sciences Institute. http://www.cropcomposition.org/. Access date: 7/26/2009.

OECD (Organization for Economic Co-operation and Development). 2002. Consensus document on the compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, anti-nutirents and secondary metabolites. Series on the Safety of Novel Foods and Feeds, No. 6. OECD Environment Directorate. Joint meeting of the chemicals committee and the working party on chemicals, pesticides and biotechnology. Paris, 42 pp.

Ridley, W. P., R. D. Shillito, I. Coats, H.-Y. Steiner, M. Shawgo, A. Phillips, P. Dussold, and L. Kurtyak. 2004. Development of the International Life Sciences Institue Crop Composition Database. Journal of Food Composition and Analysis. 17:423-438.