

Syngenta Request (15-124-01p) for Extension of Determination of Non-regulated Status for Herbicide-Tolerant MZHG0JG Corn

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ACRONYMS AND ABBREVIATIONS

AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
Bt	<i>Bacillus thuringiensis</i> protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH₄	methane
CRP	Conservation Reserve Program
CO	carbon monoxide
CO₂	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EA	Environmental Assessment
EFSA	European Food Safety Agency
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FWS	U.S. Fish and Wildlife Service
GE	Genetically Engineered
GHG	greenhouse gas
GMO	Genetically Modified Organism
GR	Glyphosate Resistant
HT	Herbicide Tolerant
IPCC	Intergovernmental Panel on Climate Change
IR	Insect Resistant
IWM	Integrated Weed Management
lb	pound
LMO	Living Modified Organism

ACRONYMS AND ABBREVIATIONS

MCL	Maximum Contaminant Level
µg/L	Micrograms per Liter
MMT	Million Metric Tons
N₂O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
NPS	non-point source
NRC	National Research Council
NWQI	National Water Quality Initiative
OECD	Organization for Economic Cooperation and Development
PAT	phosphinothricin acetyltransferase (enzyme)
pat	Gene from <i>Streptomyces viridochromogenes</i> that encodes the PAT enzyme
PIP	Plant-incorporated Protectant
PPRA	Plant Pest Risk Assessment
PPRSA	Plant Pest Risk Similarity Assessment
PPA	Plant Protection Act
TES	Threatened and Endangered Species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-AMS	U.S. Department of Agriculture- Agricultural Marketing Service
USDA-APHIS or APHIS	U.S. Department of Agriculture-Animal and Plant Health Inspection Service
USDA-ARMS	U.S. Department of Agriculture-Agricultural Resource Management Survey
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service

ACRONYMS AND ABBREVIATIONS

USC	U.S. Code
USFWS	U.S. Fish & Wildlife Service
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Background

Syngenta Seeds, Inc. of Research Triangle Park, NC, USA (hereafter referred to as Syngenta) submitted an extension request (15-124-01p) to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in May 2015. Syngenta requests that APHIS consider this application an extension to petitions 11-342-01p and 11-244-01p based on the phenotypic similarities of MZHG0JG corn to the antecedent organisms that are the subject of petitions 11-342-01p and 11-244-01p, VCO-Ø1981-5 glyphosate-tolerant corn (hereafter VCO-Ø1981-5 corn) and DP-ØØ4114-3 insect and glufosinate-ammonium-tolerant corn (hereafter DP-ØØ4114-3 corn).

Syngenta requests the APHIS determination of nonregulated status for VCO-Ø1981-5 corn (glyphosate-tolerant) and DP-ØØ4114-3 corn (glufosinate-tolerant) be extended to genetically engineered event MZHG0JG corn (glyphosate- and glufosinate-tolerant) and any progeny derived from crosses of MZHG0JG corn with conventional corn.¹ MZHG0JG corn (maize; *Zea mays* L.) is currently regulated under 7 CFR part 340. Interstate movements and field trials of MZHG0JG corn have been conducted under notifications and permits acknowledged by APHIS since 2010. These field trials were conducted in diverse growing regions in the U.S., or its territories, including: California, Colorado, Florida, Hawaii, Iowa, Illinois, Indiana, Kansas, Minnesota, Nebraska, North Carolina, Pennsylvania, Puerto Rico, South Dakota, Texas, Washington, and Wisconsin. Details regarding and data resulting from these field trials are described in the MZHG0JG corn request for extension (15-124-01p), and analyzed for plant pest risk in the APHIS Plant Pest Risk Similarity Assessment (PPRSA).

Under 7 CFR § 340.6(e), a person may request that APHIS extend a determination of nonregulated status to other organisms under §7 CFR 340, and APHIS may extend a previous determination of nonregulated status to additional regulated articles, based on an evaluation of the similarity of the regulated article to the antecedent organism (i.e., an organism that has already been the subject of a determination of nonregulated status by APHIS under § 340.6, used as a reference for comparison to the regulated article under consideration in an extension request). Such an extension of nonregulated status amounts to a finding that the additional regulated article does not pose a potential for plant pest risk, and should therefore not be regulated.

¹ Note that “Resistance” to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. “Tolerance” is distinguished from resistance and defined by HRAC as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. In its request to APHIS, Syngenta references MZHG0JG corn as “herbicide-tolerant” and used the term “herbicide-tolerant” throughout its documentation to describe the corn event. Throughout the EA, APHIS will use the term “tolerance” when referring to MZHG0JG corn to be consistent with language in USDA 15-124-01p. This terminology can be considered synonymous with “herbicide-resistant” (HR), as used in this EA.

Syngenta requested APHIS consider their request for a determination of nonregulated status of MZHG0JG corn an extension of prior petition 11-342-01p based on the similarities of MZHG0JG corn to the antecedent organism that is the subject of petition 11-342-01p; VCO-Ø1981-5. Like VCO-Ø1981-5 corn, MZHG0JG corn is glyphosate-tolerant due to expression of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). VCO-Ø1981-5 corn received a determination of nonregulated status from the APHIS on September 25, 2013.

Syngenta requested APHIS consider the petition 11-244-01p, submitted by Pioneer Hi-Bred International, Inc., requesting nonregulated status for DP-ØØ4114-3 corn in review of Syngenta's extension request given both DP-ØØ4114-3 and MZHG0JG corn express the phosphinothricin acetyltransferase (PAT) enzyme conferring tolerance to glufosinate. DP-ØØ4114-3 corn received a determination of nonregulated status from the APHIS on June 20, 2013.

Both of these antecedent organisms, VCO-Ø1981-5 corn and DP-ØØ4114-3 corn, were considered in USDA-APHIS' similarity assessment for MZHG0JG corn, and pertinent information available in the VCO-Ø1981-5 corn and DP-ØØ4114-3 corn NEPA documentation have been incorporated by reference into this Environmental Assessment (EA). In summary, APHIS is considering both of these prior petitions and associated NEPA documentation in evaluation of the MZHG0JG corn extension.

In the event of a determination of nonregulated status, the nonregulated status would include MZHG0JG corn, and any progeny derived from crosses between MZHG0JG corn and conventional corn, including crosses of MZHG0JG corn with other GE corn varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (PPA).

1.2 Purpose of Product

MZHG0JG corn is genetically engineered (GE) to tolerate applications of glyphosate-based and glufosinate-ammonium based herbicides. MZHG0JG corn was developed through agrobacterium-mediated transformation to stably incorporate the transgenes mepsps-02 and pat-09 into the MZHG0JG corn genome. The gene mepsps-02 encodes the enzyme modified 5-enol pyruvylshikimate-3-phosphate synthase (mEPSPS), a variant of the native EPSPS from corn (*Zea mays*), which contains two amino acid substitutions that were introduced specifically to confer tolerance to herbicides containing glyphosate. The gene pat-09 encodes the enzyme phosphinothricin acetyltransferase (PAT) derived from the soil bacterium *Streptomyces viridochromogenes*. PAT acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products.

Upon commercialization, MZHG0JG corn is anticipated to support agricultural efficiency by making available another stacked-trait corn variety to corn producers. For example, MZHG0JG corn could be combined, through traditional breeding methods, with insecticide-resistant (IR) traits in other deregulated corn varieties that protect against crop yield losses from *Lepidoptera* (e.g., moth and butterfly larvae) and/or *Coleoptera* (e.g., beetles) pests. These next-generation stacked-trait corn varieties are expected to offer the ability to improve production efficiency,

enhance grower choice, and facilitate pest and weed control in corn production (Davis, Jarrett et al. 2015).

MZHG0JG corn may also facilitate grower compliance with U.S. Environmental Protection Agency (EPA) mandated refuge requirements for corn varieties with insecticidal traits.² Because plant-incorporated protectants (PIPs) are recognized as a safe method of pest control, the EPA has imposed management requirements on registered PIPs that will prevent insects from developing resistance to Bt proteins (EPA 2015e). Insect resistance management (IRM) is the term used to describe such practices, and a key component of IRM is the planting of refuges, which is a block of non-Bt corn planted near a Bt corn field. The EPA requires all farmers who use Bt crops to plant a portion of their crop with such a refuge. The aim of this strategy is to provide an ample supply of insects that remain susceptible to the Bt toxin (EPA 2015e). The non-Bt refuge will greatly decrease the odds that a resistant insect can emerge from a Bt field and choose another resistant insect as a mate (EPA 2015e).

The EPA has authorized the use of seed blend products to facilitate grower compliance with refuge requirements. Namely, to incorporate the appropriate proportion of non-insect-resistant corn when planting corn varieties that produce EPA-registered PIPs.³ While many commercial stacked-trait insect-resistant corn varieties are tolerant to herbicides containing glyphosate and glufosinate-ammonium, not all insect-resistant-protected refuge seed varieties are also tolerant to both herbicides. Consequently, growers planting seed blend products will have more limited weed control options when the seed blend is not uniformly tolerant to the same herbicides. For this reason, MZHG0JG corn is also intended for use as the non-insect-resistant refuge component in seed blend products, offering growers the flexibility to spray their fields with either glyphosate-based and/or glufosinate-ammonium-based herbicides, depending on their weed management needs and recommended control practices.

1.3 Coordinated Framework

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

² The portion of a field planted with non-insect-protected seed to prevent or mitigate the development of insect resistance to a particular trait or traits.

³ Seed blend products are those that incorporate a specific blend of insect-protected and non-insect-protected seed. These products offer growers the convenience of planting their fields with traited seed and the required amount of refuge seed simultaneously.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of each role follows.

USDA-APHIS

APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest.

Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with the EPA.

Under FIFRA (7 U.S.C. 136 *et seq.*), the EPA regulates the use of pesticides (requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern). The EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. The Food Quality Protection Act of 1996 amended FIFRA, enabling the EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (EPA 2015p). As part of this program, both glyphosate and glufosinate are currently under registration review with EPA (EPA, 2015g; EPA, 2015m).

The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). The EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996. Relative to glyphosate- and glufosinate-resistant MZHG0JG corn; the EPA has established pesticide tolerance limits for glyphosate at 40 CFR §180.364, and glufosinate at 40 CFR §180.473. Both the FDA and USDA monitor foods for pesticide residues to enforce EPA tolerance limits (e.g., see (USDA-AMS 2015a)).

Food and Drug Administration

The FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, the FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from the FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, the FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants (FDA 2006). Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with the FDA, but the information may be used later in the biotechnology consultation.

Syngenta has initiated consultation with the FDA on the potential commercial introduction of MZHG0JG corn by submitting to FDA compositional and nutritional assessments, as well characterization data on the EPSPS and PAT genes and protein products, for MZHG0JG corn. The FDA will evaluate the information submitted by Syngenta and provide a decision on nutritional qualities and safety of food and feed derived from MZHG0JG corn.

1.4 Purpose and Need for USDA-APHIS Action

Under the authority of the plant pest provisions of the PPA and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. A person may request that APHIS extend a determination of nonregulated status to other organisms under §340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk. APHIS reviewed and analyzed the information submitted in the extension request by Syngenta and has

concluded that MZHG0JG corn is similar to the antecedent organisms, VCO-Ø1981-5 corn and DP-ØØ4114-3 corn, and therefore, based on the PPRSA, APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk.

APHIS must respond to the May 2015 request for extension from Syngenta requesting an extended determination of nonregulated status for MZHG0JG corn. APHIS has prepared this EA to consider the potential environmental impacts of the agency determination of nonregulated status consistent with the Council of Environmental Quality's (CEQ) National Environmental Policy Act (NEPA) regulations and the USDA and APHIS NEPA implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the impacts on the quality of the human environment⁴ that may result from a determination of nonregulated status of MZHG0JG corn.

1.5 Public Involvement

APHIS will publish a notice in the Federal Register announcing its preliminary regulatory determination and the availability of the EA, preliminary FONSI, and Plant Pest Risk Similarity Assessment (PPRSA) for a 30-day public review period. If no substantive information is received that would warrant substantial changes to the APHIS analysis or determination, the Agency's preliminary regulatory determination will become effective upon public notification through an announcement on the APHIS website. No further Federal Register notice will be published announcing the final regulatory determination.

1.6 Issues Considered

The issues addressed in this EA were identified from public comments submitted for other EAs evaluating petitions for GE organisms, the EAs for the antecedent corn plants VCO-Ø1981-5 (petition 11-342-01p) and DP-ØØ4114-3 (petition 11-244-01p), concerns described in lawsuits, and those expressed by various stakeholders. Issues considered in this EA can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Range of Corn Production
- Agronomic Practices of Commercial Corn Production
- Organic Corn Production

Environmental Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities

⁴ Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).

- Gene Flow and Weediness
- Microorganisms
- Biodiversity

Human Health Considerations:

- Consumer Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

In addition, potential cumulative impacts relative to these issues are also considered, potential impacts on threatened and endangered species (TES), as well as adherence of the proposed action to Executive Orders, and environmental laws and regulations to which the action may be subject.

2 AFFECTED ENVIRONMENT

The Affected Environment section provides a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of MZHG0JG corn. For the purposes of this EA, those aspects of the human environment are: corn production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

2.1 Agricultural Production of Corn

2.1.1 Acreage and Area of Corn Production

Corn (*Zea mays* L.) is an economically important commodity and the most abundant crop cultivated in the U.S. Over the last seven years, around 85 to 95 million acres of corn have been planted in the U.S. on an annual basis (USDA-NASS 2014f, Westcott and Hansen 2015) (Figure 1). This comprises approximately 25% of total U.S. cropland (~394 million acres) (USDA-NASS 2014c). Corn commodities are primarily that of feed grain and fuel ethanol, which account for approximately 40% and 35% of use, respectively. The remainder of harvested corn is processed into a variety of food and industrial products such as starch, sweeteners, corn oil, and beverage and industrial alcohol; only around 10% is typically used for direct human consumption (USDA-NASS 2014a).

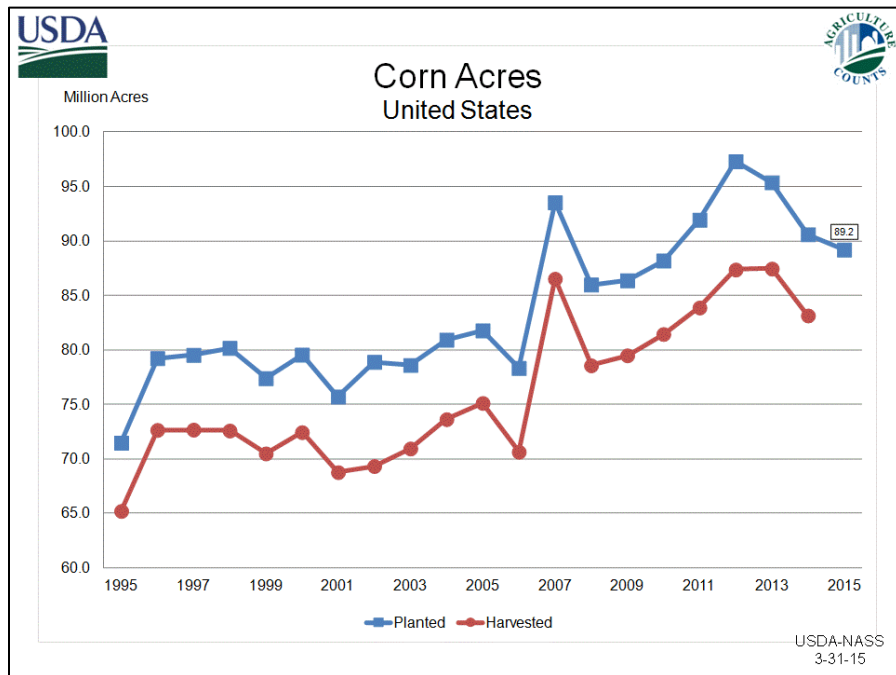


Figure 1. Planted and Harvested Acreage of Corn in the U.S., 1995-2015
(Source (USDA-NASS 2015a))

While corn is grown in all states to some extent, the majority of production occurs in the Corn Belt, generally defined as Illinois, Iowa, Indiana, southern and western Minnesota, eastern South

Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. The leading corn-producing states of Illinois, Iowa, and Nebraska account for approximately 40 % of the annual U.S. harvest (USDA-NASS 2014f). Substantial production also occurs in the Pacific Northwest, California's Central Valley, along the Mississippi River, and up the Eastern Seaboard from Georgia to Upstate New York (Figure 2).

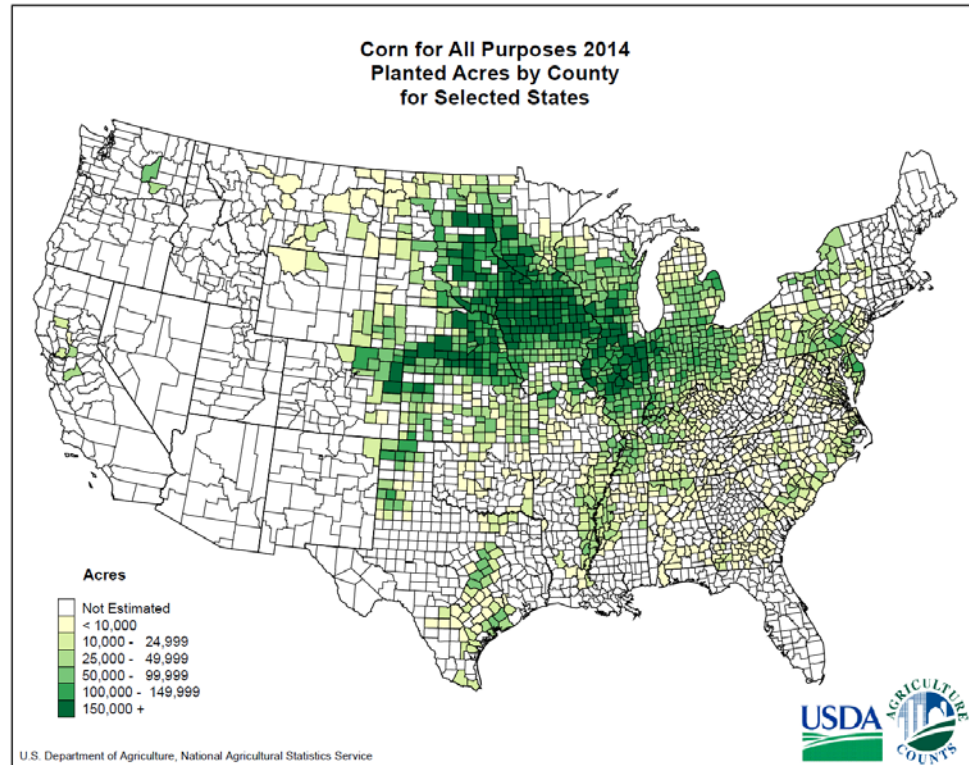


Figure 2. Corn Cultivation in the United States by County, 2014

Source: (USDA-NASS 2015b)

In the period 2006-2012 corn acreage planted annually increased as market prices favored the planting of corn over alternative crops. The demand for feed grain, and increase in demand for fuel ethanol resulted in higher corn prices, providing incentive for growers to increase corn production and acreage (USDA-ERS 2015c). In many cases, farmers increased corn acreage by adjusting crop rotations between corn and soybeans, which caused soybean plantings to decrease. Other sources of land for increased corn plantings included reduced fallow, acreage returning to production from expiring Conservation Reserve Program contracts, and shifts from other crops such as cotton (USDA-ERS 2015c).

Where corn acreage has increased, yields from corn production in the U.S. have also risen over time, particularly the last 20 years, as a result of technological improvements in seed varieties, fertilizers, pesticides, and machinery; as well as in production practices such as tillage, irrigation, crop rotations, and pest management systems (Table 1). Acreage utilized for U.S. corn production is expected to remain steady over the next decade, at around 89 million acres annually (Westcott and Hansen 2015).

Table 1. Field Corn Production in the U.S. 2000-2014					
Year	Corn Acres Planted (×1000)	Corn Acres Harvested (×1000)	Average Yield (bushels/acre)	Total Production (×1000 bushels)	Value (\$ billion)
2014	90,597	83,136	171.1	14,215,532	52.38
2012	97,291	87,375	123.4	10,780,296	74.33
2010	88,192	81,446	152.8	12,446,865	64.64
2008	85,982	78,570	153.9	12,091,648	49.31
2006	78,327	70,638	149.1	10,531,123	32.08
2004	80,929	73,631	160.3	11,805,581	24.38
2002	78,894	69,330	129.3	8,966,787	20.88
2000	79,551	72,440	136.9	9,915,051	18.50

(Source: (USDA-NASS 2015c))

Adoption of GE corn expanded rapidly since introduction of GE varieties in 1996, and now comprises the majority of corn crops produced in the U.S. (Figure 3). Most GE-corn varieties are either herbicide-tolerant (HT) or insect-resistant (IR). In 2000, 25% of U.S. corn production was from GE varieties. IR (18%) and HT (6%) accounted for most of this; only 1% contained both traits (USDA-ERS 2015c). In 2002, stacked-trait hybrids were introduced, and this led to a further increase in acreage of GE corn (Fernandez-Cornejo, Wechsler et al. 2014). By 2014, 89% of the 87.6-million-acre crop was produced from GE HT corn, and 80% from IR.

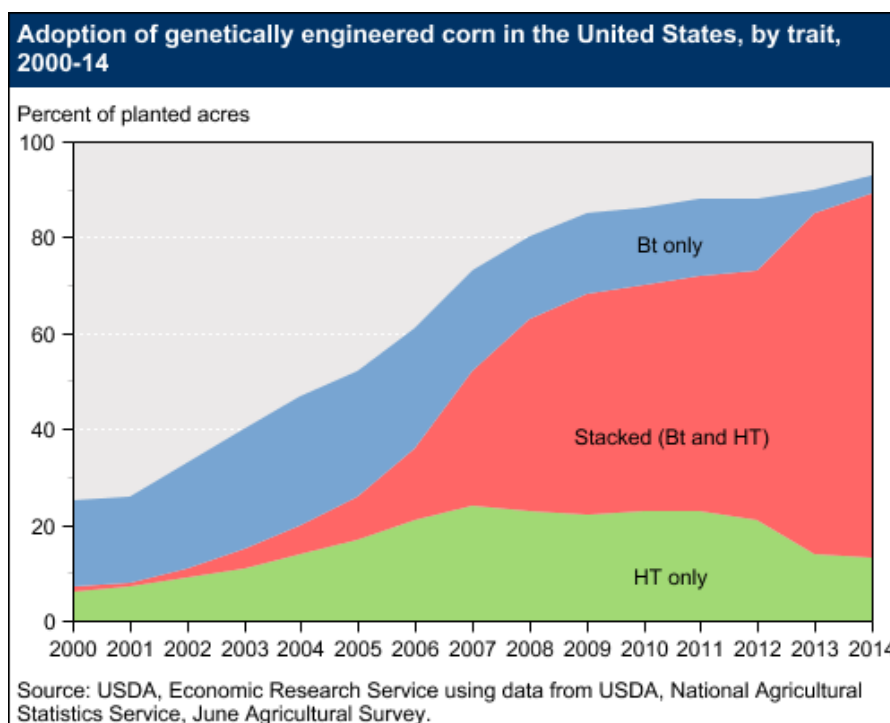


Figure 3. GE Corn Traits Planted in the United States, 2000-2013

Source: (USDA-ERS 2015b)

Stacked-trait varieties with both IR and HT traits accounted for 76% of the 2014 crop. Only 13% contained an HT trait, and 4% IR (USDA-ERS 2015c). Table 2 provides summary information

on the percentage of acres planted with GE IR, HT, and stacked-trait varieties for selected states in 2014.

State	Corn Acreage Planted (1,000 acres)	Insect Resistant (Bt) Only (%)	Herbicide Tolerant Only (%)	Stacked Trait Varieties (%)	All GE Varieties (%)	Total Acreage of GE Varieties (1,000 acres)
Illinois	11,900	3	5	83	91	10,829
Indiana	6,000	2	8	78	88	5,280
Iowa	13,600	4	8	83	95	12,920
Kansas	4,300	5	18	72	95	4,085
Michigan	2,600	2	15	76	93	2,418
Minnesota	8,600	2	10	81	93	7,998
Missouri	3,350	4	10	79	93	3,115
Nebraska	9,950	4	15	77	96	9,552
North Dakota	3,850	6	22	68	96	3,696
Ohio	3,900	3	14	69	86	3,354
South Dakota	6,200	3	14	80	97	6,014
Texas	2,350	12	17	62	91	2,138
Wisconsin	4,100	3	17	72	92	3,772
Other States	9,897	6	19	66	91	9,006
U.S.	90,597	4	13	76	93	84,255

(Source: (USDA-ERS 2015a))

2.1.2 Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs

Corn production utilizes a variety of agronomic practices to maximum crop yield and quality. Conventional crop production includes the occasional or regular application manure, synthetic fertilizers and pesticides, tillage practices, and crop rotation. Conventional farming may also include the use of GE varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Organic farming systems exclude certain production methods, such as use of synthetic agricultural inputs and GE crop varieties. Although specific crop production practices vary according to region and end-use market (e.g., food, animal feed, ethanol production), they share in common tillage practices, crop rotation, agricultural inputs, and seed production. The following subsections summarize the basic agronomic practices commonly employed to produce corn in the United States.

Tillage

Tillage of the crop field is used to prepare the soil for seeding, control weeds, incorporate nutrients, manage crop residues, and manage water movement (drainage) in fields in order to provide a suitable environment for seed germination and plant growth. The primary tillage systems employed in the U.S. are conventional tillage, reduced tillage, and conservation tillage. These practices are characterized, in part, by the amount of plant residue that is left remaining on the field after harvest, and potential to preserve soil quality and erosion capacity. Conventional

tillage involves intensive plowing leaving less than 15% crop residue in the field; reduced tillage leaves 15 to 30% crop residue; and conservation tillage involves leaving at least 30% crop residue.

Conventional tillage includes intensive disking, plowing, and other methods of tilling up crop residue left behind after harvest. Where it can be effective in preparation of the seed bed, it is also associated with increased soil erosion and run-off, and reductions in soil quality. Reduced tillage, leaving up to 30% crop residue on the field, lessens soil disturbance and erosional potential, and can improve soil quality. Conservation tillage, which includes mulch-till, ridge-till, and no-till, is even less intensive and, as the name implies, can help conserve soils by minimizing erosion potential, and preserving soil biodiversity and fertility.

The amount and type of tillage used in crop production is a key issue for farmers and policymakers due to fluctuating fuel prices, air and water quality issues, soil erosion, and the carbon sequestration potential of agricultural soils. Conservation tillage that maintains residue cover provides a variety of agronomic and economic benefits. The reduction in fuel and labor expenditures due to fewer tillage passes over the field can boost net returns on crop production. Additionally, farms using conservation tillage practices retain more moisture by trapping snow, decreasing water evaporation from the top layer of soil, and improving water infiltration to plant root systems. Reductions in tillage also reduce the erosional capacity of soils, and water pollution.

In general, since 2000, corn acreage under conservation tillage, particularly no-till, has increased, as well as continuous corn and corn-inclusive rotations. In 2012, farmers applied tillage practices on 278.8 million acres; this included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres (USDA 2012). Increases in total acres dedicated to conservation tillage have been attributed, in part, to an increased use of herbicide tolerant (HT) crops, including corn, reducing the need for mechanical weed control (Towery and Werblow 2010, USDA-ERS 2012a). However, availability of HT crops is not the only driving factor in adoption of these practices, as many corn growers adopted conservation tillage practices well before herbicide-tolerant corn varieties were introduced to the market (Givens, Shaw et al. 2009). Factors contributing to farmer choice on tillage practice include:

- Desired yields
- Soil type and moisture storage capacity
- Crop rotation pattern
- Prevalence of insect and weed pests
- Cost of pesticides, including herbicides
- Cost to fuel tilling equipment
- Risk of soil compaction and erosion
- The need for crop residue or animal waste disposal
- Increasing environmental awareness of soil erosion as source of off-site water pollution
- Management and time constraints

Crop Rotation

Crop rotation is used to maximize economic returns and sustain the productivity of an agricultural system over time. The benefits of rotating crops include (1) maintain or increasing soil organic matter; (2) reducing plant pest loads (e.g., disease, insects); (3) controlling weeds, and limiting the potential for weeds to develop resistance to herbicides; (4) managing excess nutrients; and (5) controlling volunteer plants.⁵ Diversifying crop rotation is also used to spread weather and commodity price risks, manage workloads and equipment resources, reduce fixed costs per unit of production, and access alternative markets.

Crop rotations may consist of strictly spring-planted crops, or may involve fall-planted crops or cover crops. The most common rotation, corn and soybeans, is exemplary of several major agronomic and environmental advantages to crop rotation. By alternating nitrogen-dependent grain (corn) with a nitrogen-fixing legume (soybeans), nitrogen fertilizer needs are reduced. Weeds, insects, and disease are typically disrupted by crop rotation, which can reduce pesticide application costs for farmers. Rotating closely grown crops, such as small grains with row crops, can also reduce soil losses from water and wind erosion, thereby reducing nutrient and pesticide runoff into waterways (USDA-ERS 2012a).

In general, corn can be grown more successfully in conservation tillage systems if rotated with other crops, such as wheat or soybean, which may reduce some of the potential problems encountered with conservation tillage (e.g., increased soil compaction, perennial weeds, plant diseases). A rotation of corn following soybeans will often yield 5-20% more than corn in continuous cultivation. Other crops used in rotation with corn vary regionally and may include cotton, oats, canola, sugar beets, peanut, rye, barley and forage.

Many factors at the individual farm level affect the crop rotation practices chosen, including the soil type present in a given field, the expected commodity price, the need to hire labor, the price of fuel, the price of seed, and the price of agricultural inputs (Duffy 2015, Wallander 2015). Market factors, particularly commodity and input prices, can greatly affect crop rotation decisions. For instance, high corn prices could lead to more continuous corn planting (e.g., production of corn based fuel ethanol), while a desire to contain fertilizer expenses could encourage rotation of crops that require less fertilizer.

Most recently, the high global demand for corn-produced ethanol increased corn prices relative to soybean prices. Increased demand for corn and higher commodity prices have encouraged more corn-to-corn acreage (Figure 4), rather than corn-soybean rotations, which in turn contributed to overall increases in U.S. corn acreage (Wallander 2015). Currently, around 84% of corn is farmed using alternate crop rotations, and 16% using continuous corn (corn-to-corn rotations) rotations. Continuous corn in the Corn Belt frequently requires at-planting or pre-plant pesticide treatments to control corn pests and pathogens, as well as supplemental fertilizer treatments to replace diminished soil nitrogen levels (Duffy 2011). Corn-to-corn rotations may also require a change in tillage practices, due to substantially greater quantities of field residue. Additionally, continuous corn rotations generally require more fertilizer treatments to replace diminished soil nitrogen levels and more pesticide applications.

⁵ See Subsection 2.3.3 – Gene Flow and Weediness of Corn

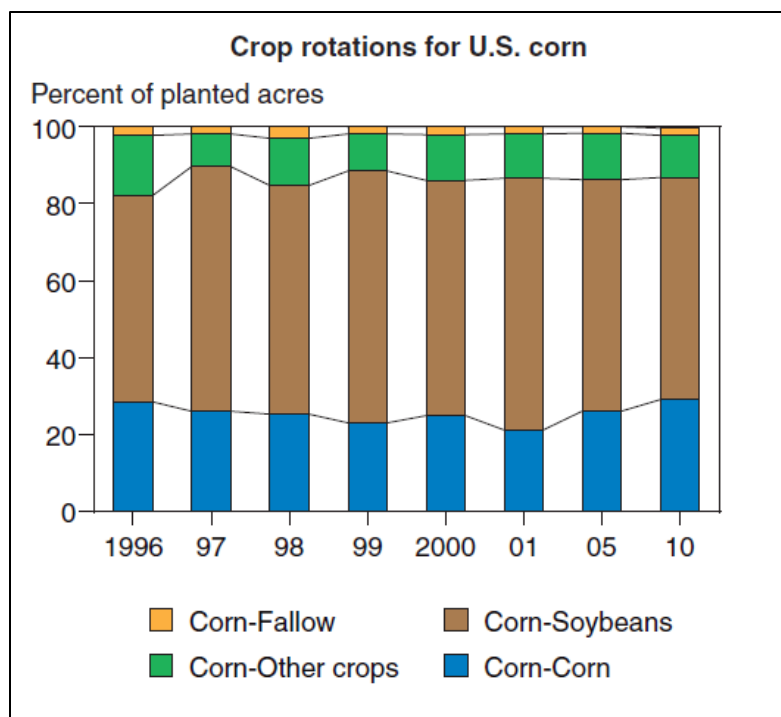


Figure 4. Corn Crop Rotations, 1996-2010

Source: (Osteen and Fernandez-Cornejo 2013)

In general, farmer choices between monoculture and rotating different crops on the same land will depend on a range of economic and physical factors. Planned crop rotations can increase yields, improve soil quality, reduce soil loss, conserve soil moisture, reduce fertilizer and pesticide needs, and provide other environmental and economic benefits. However, the choice of rotation frequently affects the volume and type of fertilizer and pesticides used, and crop rotations can reduce net returns when the acreage and frequency of highly profitable crops are replaced with crops that produce lower returns (USDA-NRCS 2009, Roth 2015).

Agronomic Inputs

Corn production typically involves the extensive use of agronomic inputs to maximize grain yield. Agronomic inputs may include fertilizers to augment soil nutrients; pesticides to reduce plant pest and weed populations; and water (irrigation) to ensure optimal plant growth and crop yield. Fertilizer and pesticide use is discussed in this subsection; irrigation is discussed in Subsection 2.2.2 – Water Resources.

Fertilizers

Given the importance of nutrient availability to corn growth, fertilization with nitrogen, phosphorus, and potassium is practiced widely in the U.S. Corn accounts for 45% of U.S. crop acreage receiving manure, and 65% of the 8.7 million tons of nitrogen applied by farmers each year (Ribaudo 2011), with the Corn-Belt receiving the bulk of fertilizer application for corn. For the 2014 crop year, 97% of planted acres were fertilized with nitrogen at an average rate of 144 pounds/acre, totaling of 11.2 billion pounds. Phosphate was applied to 80% of planted acres, and potash to 65% (Table 3) (USDA-NASS 2014d). Where nitrogen is an important agricultural

input in crop production, the introduction of large amounts of nitrogen into the environment has a number of undesirable impacts on water, terrestrial, and atmospheric resources (discussed in the following relevant sections).

Table 3. Fertilizer Applied to Corn Planted Acres, 2014 Crop Year			
Fertilizer	% of Planted Acres	Avg. Rate for Year (lbs/acre)	Total Applied (billion lbs)
Nitrogen (N)	97	144	11.2
Phosphate (P2O5)	80	64	4.1
Potash (K2O)	65	82	4.3

(Source: (USDA-NASS 2014d))

Pesticides

Pest and weed management is an integral part of all corn production systems in the U.S., GE and non-GE cropping systems; essential to maximizing both crop yield and quality, and grower net returns. Properly applied, pesticides contribute to higher yields and optimal product quality by controlling weeds, insects, nematodes, and plant pathogens (Fernandez-Cornejo, Nehring et al. 2014b). Herbicides also reduce the amount of labor, machinery, and fuel required for the manual control of weeds. However, some pesticides may be potentially harmful to humans and the environment when not properly used.

Common corn pests include *Coleoptera* species (beetles), *Lepidoptera* species (moth and butterfly larvae), pathogenic fungi (e.g., Corn Leaf Blight), bacteria (e.g., stalk rot), and viruses (e.g., Dwarf Mosaic Virus). Numerous weeds species across the U.S. require annual management in corn cropping systems. There are over 17 principle weed species that can have substantial impacts on corn production (Heap 2015), and a variety of less problematic, but economically important species that require management.

Pesticide use increased considerably from 1960 to 2008 (the most recent year for which complete data are currently available) (Figure 5). Over this period the total quantity of pesticides applied to crops was largely due to the increase in the total planted acreage of corn, wheat, and, in particular, soybeans (Fernandez-Cornejo, Nehring et al. 2014a). Currently, fungicides, insecticides, and herbicides are the most commonly used pesticides on U.S. corn acreage (USDA-NASS 2011a). Of these, herbicides are used most extensively used, applied to 97% of planted corn acres in 2014, while insecticides and fungicides were applied to around 13% and 12% of planted acres, respectively (USDA-NASS 2014d).

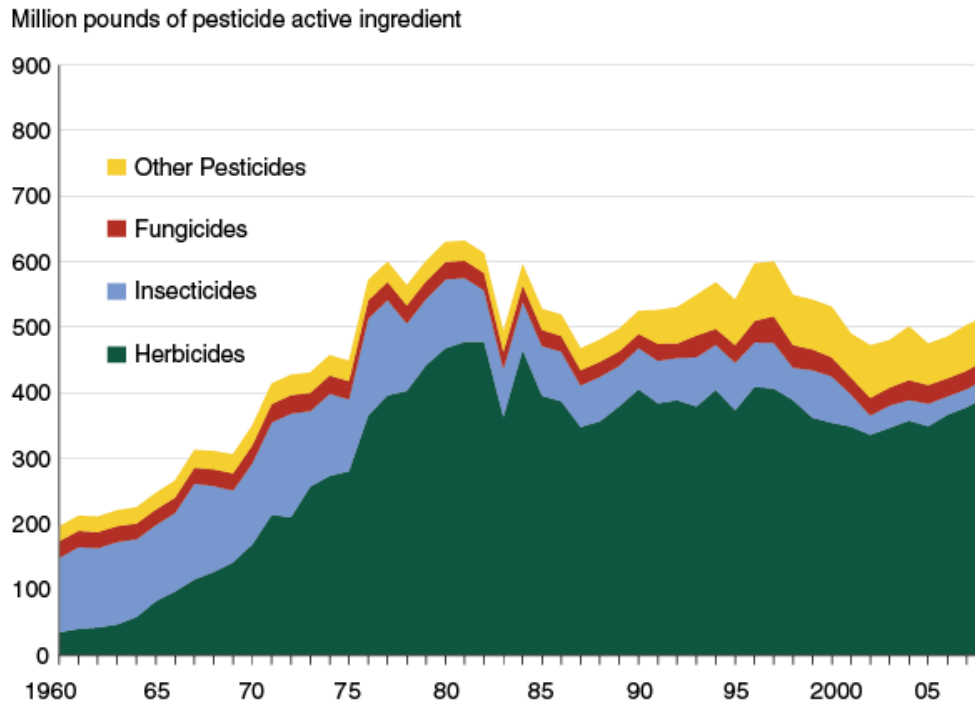


Figure 5. Pesticide Use in U.S. Agriculture, 1960 – 2008

Source: (Fernandez-Cornejo, Nehring et al. 2014a)

Fungicides

Fungicides can be an effective tool for controlling corn plant diseases where genetic resistance is inadequate, and when fungal disease pressure is high. Historically, foliar applications of fungicides were not common, and fungal disease management was focused on selection of disease-resistant hybrids, crop rotation to break disease cycles, and tillage to facilitate decomposition of crop residues that can serve reservoirs for pathogenic fungi.

However, corn-to-corn rotations discussed previously, along with expanded use of reduced or no-till practices, have resulted in an increased risk of fungal diseases in some areas of the U.S. Both factors have contributed to an increase in the amount of corn residue, which can serve as a source of inoculum for several important foliar diseases such as gray leaf spot, northern leaf blight, and eyespot. Consequently, there has been an increase in the use fungicides since around 2007 (Wise and Mueller 2011).

Due to recent increases in the value of corn commodities, there can be less incentive in selecting corn hybrids with strong disease resistance, and more incentive in selecting hybrids with high-yield potential. As such, the net result is an increased reliance on fungicides for protecting the corn crop, as where high corn yields can increase net returns on crop production (e.g., (Robertson and Mueller 2007, Robertson 2007)).

Insecticides

Corn is subject to damage by insects throughout its developmental stages, with several types of insects capable of feeding on the seeds, roots, stalk, leaf, or ears (Hoeft et al., 2000). Insects considered pests to a corn crop are managed by insecticide treatment of seeds or soil, over-the-top application of insecticides, or use of a number of crop rotation or integrated pest management practices.

Since the introduction of GE corn containing Cry proteins from *B. thuringiensis* (Bt) in the 1990s there has been a steady decline in the use of insecticides to protect corn crops (Brookes and Barfoot 2010, Fernandez-Cornejo, Wechsler et al. 2014). The Cry proteins from Bt are generally target specific (e.g., *Lepidoptera* vs. *Coleoptera*), which allows a grower to select a corn variety containing a Cry protein specific to a particular type of insect pest. The advantage of this target specificity is that the grower can avoid the application of broad-spectrum insecticides, consequently allowing them to reduce total insecticide application to crops. This provides benefits to growers and the environment as a result of reduction of potential exposure to insecticides, and a corresponding reduction in costs associated with insecticide purchase and application (Brookes and Barfoot 2010, EPA 2010b, Fernandez-Cornejo, Nehring et al. 2014a, Fernandez-Cornejo, Wechsler et al. 2014).

In 2014, 80% of the total U.S. corn acreage was planted to corn varieties containing at least one Bt trait (USDA-NASS 2014e). The EPA reviews PIPs, such as the Cry proteins, pursuant to FIFRA, and publishes tolerances or exemptions from a tolerance pursuant to its authority under FFDCA. Since 1995, the EPA has registered over 39 crops expressing one or more proteins derived from Bt (EPA 2011), and has published tolerance exemptions for the Cry proteins (EPA 2007a).

Herbicides

The introduction of HT corn in the late 1990s substantially affected how pesticides are used in maximizing crop yield and quality (Figure 6). HT corn allows growers to make post-emergent applications of certain herbicides to control weeds, and can potentially provide growers simpler, more efficient, and cost effective weed management strategies, compared to what would be required for most non-GE corn varieties (Brookes and Barfoot 2010, Owen 2011, Mortensen, Egan et al. 2012, USDA-ERS 2012a, Fernandez-Cornejo and Osteen 2015).

Where there are certain advantages with HT corn, adoption of HT corn by growers has had mixed impact on the volume of herbicide use and development of herbicide-resistant (HR) weeds. Herbicide use on corn fell from about 2.6 pounds per acre in the early years of HT corn adoption to less than 2 pounds per acre in 2002, but has increased moderately since 2006 (Figure 6) (Fernandez-Cornejo, Wechsler et al. 2014). While the adoption of HT crops has led to the use of more environmentally benign herbicides, such as glyphosate, (NRC 2010), and HT adoption likely reduced herbicide use initially, overreliance on a limited number of herbicides accelerated weed resistance to those herbicides; namely glyphosate. Consequently, the emergence of resistance among weed populations may have induced farmers to raise application rates in recent years, thus offsetting some of the economic and environmental advantages of HT corn in regard to herbicide use (Fernandez-Cornejo, Nehring et al. 2014a).

Pounds of herbicide active ingredient (a.i.) per planted acre and percent acres of herbicide-tolerant corn, 1996-2008

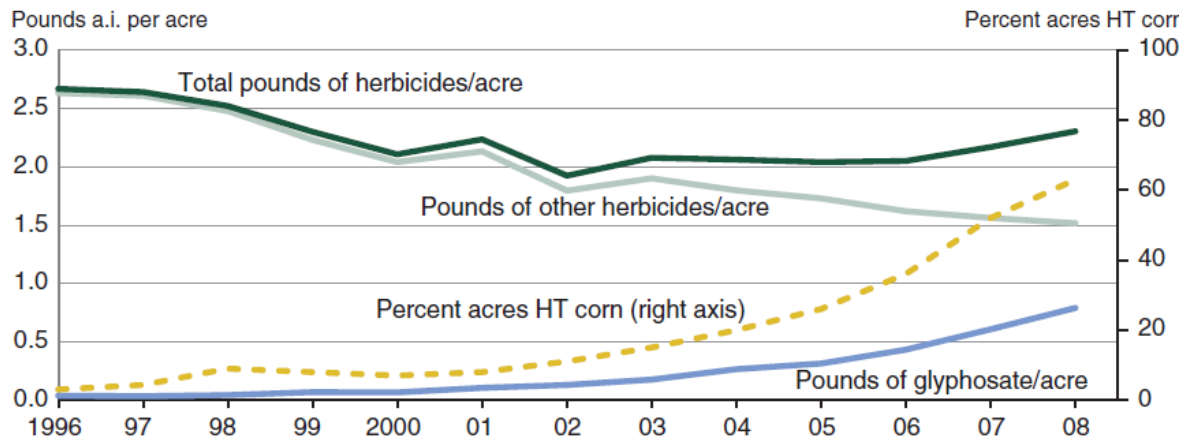


Figure 6. Herbicide Use on Corn, 1996-2008

Source: (Fernandez-Cornejo, Nehring et al. 2014a)

In particular, glyphosate-tolerant (GT) corn varieties were adopted widely since their introduction in the mid-late 1990s (Figure 7), for several reasons. Glyphosate works non-selectively on a wide range of plant pest species, is a relatively low-cost herbicide, facilitates conservation tillage practices, and has minimal human health and environmental impacts (Busse, Ratcliff et al. 2001, Duke and Powles 2008, Dinehart, Smith et al. 2009, Camberato, Casteel et al. 2011, Fernandez-Cornejo and Osteen 2015). In 2010, glyphosate (alone or with other herbicides) was applied to approximately 73% of U.S. corn acreage (Fernandez-Cornejo and Osteen 2015). Where GT-corn has not substantially affected the percentage of corn acreage managed with herbicides, the introduction of GT-corn has resulted in replacement other herbicides registered for use on corn with glyphosate, and in some crops, the singular use of glyphosate (Vencill, Nichols et al. 2012). The fact that the majority of soybean acres over the years have been treated with glyphosate alone could be an important factor in the emergence of GR weeds.

In addition to glyphosate-tolerant corn varieties, glufosinate-tolerant corn varieties are also cultivated in the United States. Glyphosate- and glufosinate-tolerant corn varieties are in fact the most common HT corn varieties currently grown. Although glufosinate-tolerant corn has been available since 1996, the use of glufosinate on total corn acres has remained relatively low over the past decade. In 2010, 515,000 lbs. of glufosinate was applied to 2% of U.S. corn acreage (USDA-NASS 2011b), and in 2014, 49.8 million lbs. of glyphosate was applied to 62% of U.S. corn acres (USDA-NASS 2014d).

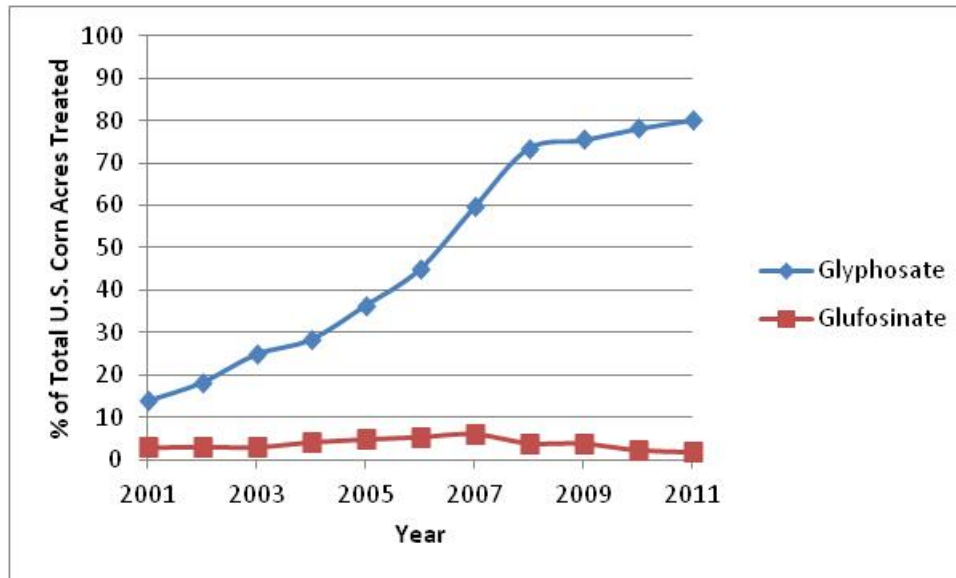


Figure 7. Glyphosate and Glufosinate Use on Corn, 2001-2011

(Source: (USDA-NASS, 2011))

In general, increased selection pressure resulting from the wide-spread adoption of GT crops, and reductions in the variety of herbicides used in weed management (i.e., modes of action) has resulted in both weed population shifts and increasing GR among some weed populations (Owen 2008, Duke and Powles 2009). However, the emergence of resistant weeds is not unique to those associated with GT crops, as there are over 10 classes of herbicides used in commercial crop production (e.g., ACCase inhibitors, ALS inhibitors, Synthetic auxins), with documented weed species resistant to all herbicide groups (Owen 2012, Heap 2015). Table 4 summarizes those herbicides most commonly used in corn production during 2014.

Active Ingredient	Total Applied (lbs)	Rate (lbs/acre/year)	% of Planted Acres
Atrazine	45,231,000	1.018	55
Acetochlor	28,685,000	1.256	29
Glyphosate iso. salt	27,221,000	0.889	38
S-Metolachlor	23,600,000	1.106	27
Glyphosate pot. salt	22,560,000	1.159	24
Glyphosate	7,979,000	0.907	11
Glyphosate dim. salt	3,604,000	1.113	4
2,4-D, 2-EHE	2,601,000	0.599	5
Mesotrione	2,529,000	0.115	27
Dimethenamid-P	2,130,000	0.63	4
2,4-D, dimeth. salt	1,630,000	0.62	3
Simazine	1,430,000	1.037	2
Metolachlor	935,000	1.175	1
Clopyralid	752,000	0.072	13
Pendimethalin	553,000	1.082	1
Dicamba, dimet. salt	513,000	0.305	2

Isoxaflutole	506,000	0.059	11
Dicamba, sodium salt	472,000	0.092	6
Alachlor	444,000	2.348	< 0.5
Tembotrione	336,000	0.072	6
Flumetsulam	315,000	0.03	13
Glufosinate-Ammonium	234,000	0.432	1
Paraquat	227,000	0.553	1
Dicamba, pot. salt	183,000	0.197	1
Saflufenacil	178,000	0.06	4
Diflufenzopyr-sodium	177,000	0.036	6
Trifluralin	169,000	0.691	< 0.5
Thiencarbazone-methy	167,000	0.023	9
Dicamba, digly. salt	117,000	0.186	1
Fomesafen	68,000	0.207	< 0.5
Pyroxasulfone	66,000	0.139	1
Rimsulfuron	60,000	0.017	4
Sulfentrazone	46,000	0.196	< 0.5
Bromoxynil Octanoate	45,000	0.335	< 0.5
Topramezone	31,000	0.015	3
Fluroxypyr 1-MHE	25,000	0.087	< 0.5
Flumioxazin	24,000	0.154	< 0.5
Clopyralid, mono salt	21,000	0.083	< 0.5
Dicamba	19,000	0.116	< 0.5
Clopyralid, potassium	17,000	0.084	< 0.5
Clethodim	15,000	0.073	< 0.5
Nicosulfuron	12,000	0.012	1
Thifensulfuron	10,000	0.008	2
Imazethapyr	5,000	0.02	< 0.5
Primisulfuron	5,000	0.022	< 0.5
Fluthiacet-methyl	2,000	0.004	1
Prosulfuron	1,000	0.009	< 0.5

(1) Program states surveyed - Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Pennsylvania, South Dakota, Texas, and Wisconsin.
Source: (USDA-NASS 2015e)

To deter development of herbicide-resistant weeds, and sustain the efficacy of current herbicides, growers are implementing integrated weed management (IWM) strategies suggested by weed scientists, in response to the emergence of resistant weeds (Owen 2011, Vencill, Nichols et al. 2012). IWM practices include using multiple herbicides with different modes of action, rotating crops, planting weed-free seed, scouting fields routinely, cleaning equipment to reduce the transmission of weeds to other fields, and maintaining field borders. The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-resistant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations (Dill, Cajacob et al. 2008, Duke and Powles 2008, Owen 2008, Duke and Powles 2009, Owen 2011, Norsworthy, Ward et al. 2012, Vencill, Nichols et al. 2012).

In 2014, scouting for weeds was the most widely reported monitoring practice, used on 92% of corn planted acres (Table 5). Among pest management practices, crop rotation was practiced on 84% of planted acres. The most widely used prevention practice was no-till or minimum till (67%). Maintaining ground cover, mulching, or using other physical barriers was the most reported suppression practice (47%) (USDA-NASS 2014d). These were also the top practices in each category in 2010, the last time USDA-NASS conducted a corn chemical use survey.

Table 5. Top Practices in Pest Management, 2014 Crop Year	
	% of corn planted acres
Monitoring: Scouted for weeds	92
Avoidance: Rotated crops during last three years	84
Prevention: Used no-till or minimum till	67
Suppression: Maintained ground cover, mulched, or used other physical barriers	47

Source: (USDA-NASS 2014d)

2.1.3 Organic Corn Production

Organic farmers, ranchers, and food processors follow a defined set of standards to produce organic food and fiber. Congress described general organic principles in the Organic Foods Production Act, and the USDA defines specific organic standards. These standards cover the product from farm to table, including soil and water quality, pest control, livestock practices, and rules for food additives (USDA 2015c).

In the U.S., organic corn must be produced and certified using those methods specified by the USDA’s Agricultural Marketing Service (AMS) National Organic Program (NOP) (USDA-AMS 2015c). Organic certification verifies that a farm or handling facility complies with the USDA organic regulations. This certification allows a producer to sell, label, and represent their products as organic.

To have “organic” certification, growers are required to maintain records demonstrating their agronomic procedures comply with USDA NOP standards. Overall, USDA oversees organic farmers and businesses to make sure that organic food is produced with organic methods. Each year, organic farmers update a farm plan and complete an inspection to confirm that their practices match their records. The farmer must correct any issues to continue certification. Organic food processors meet similar requirements.

Organic certification is a process-based certification (not certification of the end product from an organic crop) that verifies, through inspection, the methods and procedures by which an agricultural product is produced. Credited certifying agents conduct annual on-site inspections of organic farming systems, inclusive of records, to certify the production system is compliance with NOP standards. These standards prohibit certain methods of production, which are provided in 7 CFR Section 205.105:

...to be sold or labeled as “100 percent organic”, “organic” or “made with organic (specified ingredients or group(s)),” the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients,
- (e) Excluded methods,

Excluded methods are defined in 7 CFR Section 205.2 as:

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 and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

To facilitate certification organic operations are required to have distinct, well defined boundaries and buffer zones to prevent unintended contact from other cropping systems using excluded methods on adjoining lands. Organic operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the organic operation to achieve and document compliance with National Organic Standards (USDA-AMS 2015c).

Common practices organic operations use to exclude GE products include planting only organic seed, staggering plantings so flowering and pollination does not coincide with that of GE crops in neighboring fields, and maintaining adequate buffers (distances) between organic and GE crops to eliminate or minimize the potential for cross-pollination (NCAT 2003).

NOP standards do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. If the unintentional presence of the products of excluded methods is detected in an organically produced product, it will not affect the status of the product or operation when the operation has not used excluded methods, and has taken reasonable steps to avoid contact with the products of excluded methods, as detailed in their approved organic system plan (Ronald and Fouche 2006, USDA-AMS 2015c).

Where certified organic corn acreage is substantially less than that of conventional and GE corn acreage, approximately 234,000 acres or 0.25% of corn acres planted for grain in 2011 (USDA-NASS, 2012a), and organic corn yields (i.e., bushels per acre) tend to be less than conventional or GE crops, the profit per acre of organic corn is greater because of the premium organic growers receive for their products (U-Minn 2010, USDA-ERS 2015e).

Specialty Corn

Specialty corn varieties have been developed and marketed as Value Enhanced Corn (VEC) and include high oil, white, waxy, blue corn, hard endosperm/food grade, high-amylose, high lysine, high oleic oil, low phytate, nutritionally enhanced, high extractable starch, high total fermentable

(for ethanol), popcorn, pharmaceutical and industrial corns, and organic. The leading specialty corn states include Illinois, Iowa, Nebraska, and Indiana.

Similar to the production of conventional seed, industry quality standards for specialty crop products have prompted these seed producers and growers to use a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford 2006). Common practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, and employing natural vegetative barriers to pollen, including fallow fields and hedgerows.

Regulations (7 CFR §201, *et seq.*) of the Federal Seed Act provide additional details on seed production and certification. Field monitoring for off-types is generally carried out by company staff and state crop improvement associations. Seed handling standards are established by the American Organization of Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning. In general, the conventional management practices used for conventional seed production are sufficient to meet standards for the production of specialty crop seed (Bradford 2006).

2.2 Physical Environment

2.2.1 Soil Quality

Corn is cultivated in a wide variety of soils across the U.S. (see, e.g., (IPM 2015)), and in an agricultural setting concerns regarding soil quality are primarily the potential for tillage practices and agronomic inputs to affect soil fertility, erosion, off-site transport of sediments into aquatic ecosystems, and disturbance of soil biodiversity. Tillage systems influence the biological, physical, and chemical properties of soil and have a substantial impact on soil fertility and sustainability. Agronomic inputs such as pesticides and fertilizers can affect soil biota, which can in turn, impact the fertility and sustainability of soil.

Where soil erosion can occur through natural processes, the rates of which are determined by soil type, local ecology, and weather, certain tillage practices, primarily conventional tillage, can result in degradation of soil quality, and contribute to the erosional quality of soils (Berhe and Kleber 2013, Brevik 2013, Gomiero 2013). Conversely, soils under conservation tillage systems have substantial higher soil quality, and exhibit less erosion, as compared with conventionally tilled soils (Roger-Estrade, Anger et al. 2010, He, Li et al. 2011, Sharma and Abrol 2012, Abdalla, Osborne et al. 2013, Van Eerd, Congreves et al. 2014). Consequently, soil management and conservation is a key aspect of current agronomic practices, particularly in the Corn Belt region, and the majority of U.S. farmers are moving away from conventional to conservation tillage practices (USDA-NRCS 2006c, CTIC 2015).

Consequently, soil management and conservation is a key aspect of current agronomic practices, particularly in the corn-belt region., and the majority of U.S. farmers are moving away from conventional to conservation tillage practices (USDA-NRCS 2006c, CTIC 2015). Soil conservation practices, such as conservation tillage, aim to reduce field tillage, sustain soil quality, and prevent soil loss. Conservation tillage, which leaves at least 30% of previous year's crop residue on fields, reduces erosion and runoff, preserves soil organic matter and beneficial

biota, nutrients, water-retention capacity, reduces erosion, and requires less time and labor in preparation of the field for planting.

Conservation tillage methods include no-till, strip-till, ridge-till, and mulch-till. These practices reduce erosion and runoff; preserve soil organic matter, beneficial biota, and nutrients; improve water-retention capacity; and require less time and labor in preparation of the field for planting (Roger-Estrade, Anger et al. 2010, He, Li et al. 2011, Sharma and Abrol 2012, Van Eerd, Congreves et al. 2014). In general, there has been a corresponding overall improvement in the quality of U.S. agricultural soils, after the introduction of conservation tillage practices. Over the last 3 decades conservation tillage practices increased, and total soil loss on erodible croplands in the U.S. decreased from 462 million tons per year to 281 million tons per year, or by 39 % (USDA-NRCS 2006b). This decrease in soil erosion carries with it a corresponding decrease in non-point source (NPS) pollution run-off of fertilizer and pesticides (NCGA 2007). In 2012, farmers applied tillage practices on 278.8 million acres of cropland, which included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres (USDA 2012).

While erosion has decreased through adoption of conservation tillage and other practices, erosion remains a key issue in some areas of the U.S. Excessively eroding cropland soils are concentrated in Midwest and Northern Plain States, and in the Southern High Plains of Texas (Figure 8). Farmers, including corn growers, producing crops on highly erodible land are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (USDA-ERS 2012b). These soil conservation plans are prepared by the grower pursuant to the 1985 Food Security Act Conservation Compliance and Sodbuster programs to minimize soil erosion. Corn farmers also are actively involved in state, local, and national programs that idle environmentally sensitive land from crop production, including the Conservation Reserve Program, the Conservation Reserve Enhancement Program, and the Farmable Wetlands Program (USDA-FSA 2015)

Soils also play a fundamental role in biochemical processes such degradation of pesticides and organic matter, and the biogeochemical cycling of carbon, nitrogen. In many cases, crop and soil management practices that increase soil organic matter and plant residues, such as conservation tillage, impart attributes to soil that can hinder pesticide movement and enhance pesticide degradation (Locke and Zablotowicz 2004), and facilitate the natural cycles of soil nutrients.

In summary, land management practices for corn cultivation can affect soil quality and erosion, both beneficially and adversely. Tillage practices, pesticide application, crop rotation, soil amendment, and other practices can improve soils, but must be applied using sound resource management practices to avoid degrading soil quality (Montgomery 2007, Berhe and Kleber 2013, Gomiero 2013, USDA-NRCS 2015c).

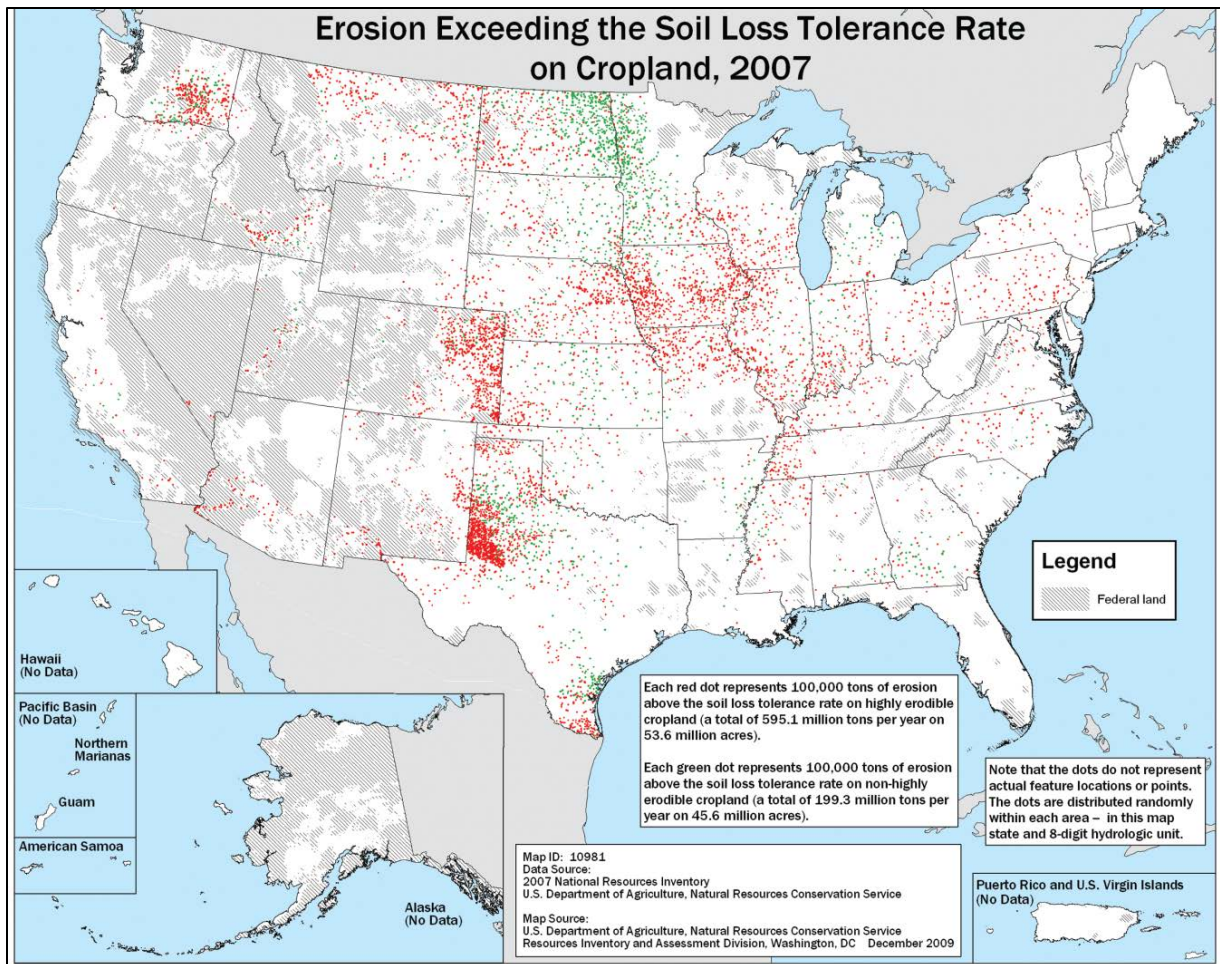


Figure 8. Locations and Status of U.S. Croplands Subject to Erosion
 (Source: (USDA-NRCS 2011))

2.2.2 Water Resources

Crop Irrigation

Corn is a water sensitive crop with a low tolerance for drought, and irrigation is a substantial source of water consumption in corn production. Water requirements for corn crops vary during development, and adequate water supply, particularly during critical periods of development, is a basic requirement for both optimal crop quality and yield.

In general, corn requires around 20 to 22 inches of rainfall for optimal yield, which must be met by irrigation if rainfall is inadequate. In other terms, corn requires approximately 4,000 gallons through the growing season to produce 1 bushel of grain (U-Illinois 2015). Groundwater is the major source of water for irrigation and used on almost 90% of irrigated corn acreage in the U.S. (USDA-NASS 2013). Groundwater sources are particularly important for irrigation in the western U.S. and Mississippi River Valley corn growing regions, with seven states (California, Nebraska, Arkansas, Texas, Idaho, Kansas, and Colorado) typically accounting for over 70% of total groundwater withdrawals (Figure 9).

Irrigation water used in corn production rose from 15.4 million acre-feet in 2008 to 17.9 million acre-feet in 2013, approximately 88% of which was from groundwater sources, with the remainder from on-farm and off-farm surface water sources (USDA-NASS 2013). Increases in irrigation were due in part to the increased use of corn for ethanol production (e.g., roughly 30% of U.S. corn is currently used for ethanol), and resulting growth in harvested acres of corn, which increased by roughly 7.2 million acres between 2000 and 2009 (USDA-ERS 2011, Barton and Clark 2014), largely in Western States that can be unpredictably arid and vulnerable to water stress (USDA 2008). Another factor is that irrigated corn yields are almost 30% higher than non-irrigated yields; accounting for approximately 20% of total U.S. corn production, while occupying only 15% of total agriculture acres (USDA-ERS 2012a). Efficient irrigation can not only increase corn yields, it can help reduce runoff and deep percolation (leaching) losses.

While just around 6% to 10% of all harvested cropland in the U.S. is irrigated, this acreage generates nearly half the value of all crops sold. In 2007, approximately 57 million U.S. acres were irrigated; while this was only 7.5% of all cropland and pastureland, it accounted for 54.5% (\$78.3 billion) of the value of all crop products sold (Schaible and Aillery 2012).

Irrigation of corn crops is likely to remain important to production, with commensurate demands on surface and ground water resources. However, continued changes in the irrigation sector are anticipated in response to increasing water demands for urban and environmental uses, as well as evolving institutions governing farm programs and water allocations. Water withdrawals for agricultural production are expected to decline with introduction of new technologies and improved water application efficiencies (Wiebe and Gollehon 2006, USDA 2008). However, demands on agricultural water supplies are expected to increase over time as nonfarm uses of water will continue to expand (Schaible and Aillery 2012).

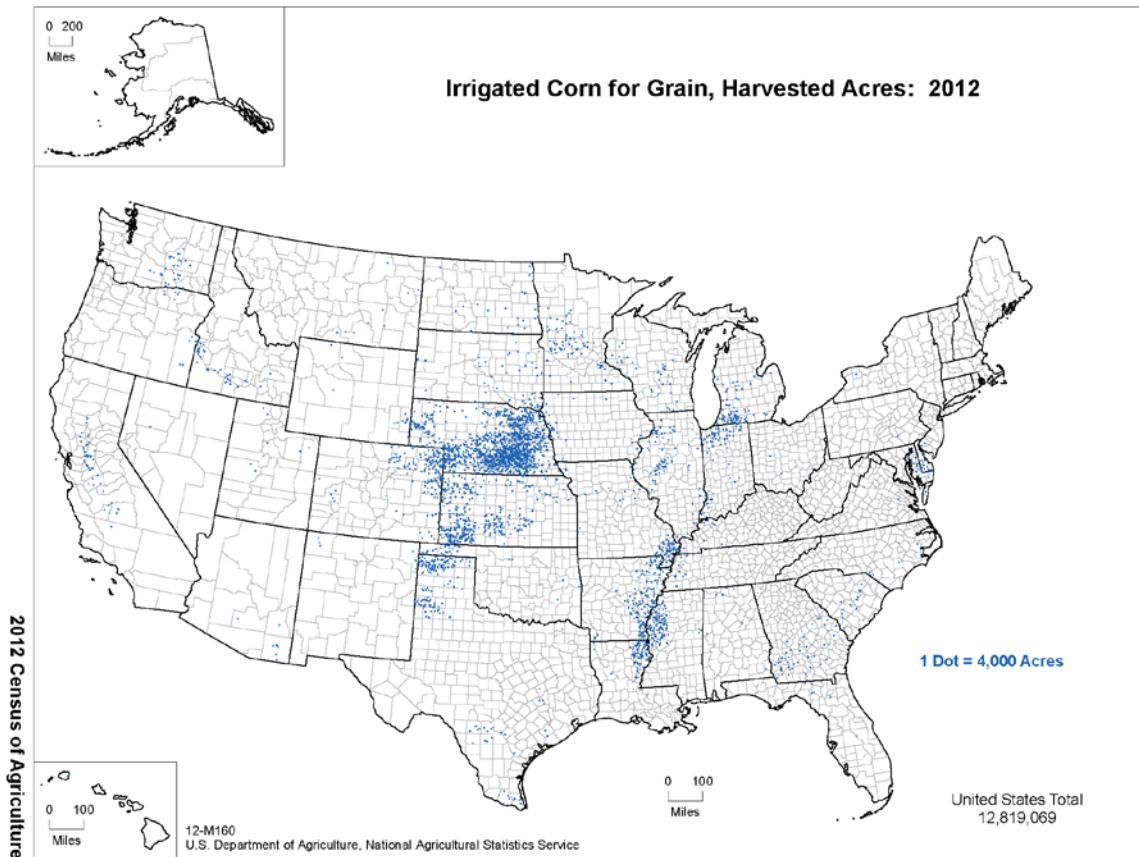


Figure 9. U.S. Irrigated Acres of Harvested Corn, 2012

Source: (USDA-NASS 2014b))

Water Quality

Surface waters in the U.S. provide for drinking, non-agricultural irrigation, industrial, recreational, and other public uses. About 66% of water withdraws for public uses in the U.S. are from fresh surface water sources, with the remainder being from groundwater (Schaible and Aillery 2012). Almost half of the U.S. population, around 47%, depend on groundwater as their drinking water supply, be it from either a public source or private well (Maupin, Kenny et al. 2014).

While not intended by farmers, agriculture can potentially impair water quality, both surface and ground waters, through soil erosion and run-off, and leaching of agricultural inputs to groundwater. Agricultural run-off is a primary source of non-point source (NPS) contaminants impacting fresh surface waters such as rivers and lakes, and the third most noted cause of impairment of water quality in estuaries (EPA 2008c, EPA 2015c). The most common contaminants in agricultural run-off are sediment, nitrogen and other nutrients from fertilizers, and pesticides; all of which can adversely impact aquatic and terrestrial wildlife, and ecosystem

dynamics. The EPA lists sediments as the second most frequent cause of impairment of stream sand rivers, nutrients second, and pesticides sixteenth (EPA 2015s).

Agricultural nutrient losses to streams are a primary concern in the U.S. Corn Belt (Ribaudó, Delgado et al. 2011), particularly in relation to the adverse effects of nutrient loads on hypoxia in the Gulf of Mexico (Wiebe and Gollehon 2006). In total, agricultural sources contribute more than 70% of the nitrogen and phosphorus delivered to the Gulf, versus only 9% to 12% from urban sources (Alexander, Smith et al. 2008). Corn accounts for 45% of U.S. crop acreage receiving manure and 65% of the 8.7 million tons of nitrogen applied by farmers each year (Ribaudó, Delgado et al. 2011). Nitrogen run-off from cornfields, in particular, is the single largest source of nutrient pollution to the Gulf of Mexico's "dead zone" (Ribaudó, Delgado et al. 2011).

Agricultural management practices and factors that determine erosion and NPS pollution include the type of crop cultivated; plowing, tillage, and irrigation practices; pesticide, herbicide, and fertilizer application practices (e.g., type, quantity, methods); weather; and regional environment (i.e., the biotic and abiotic properties governing biological, physical, and chemical process). Where corn production operations are sustainably managed they can help protect watersheds by reducing run-off. By example, conservation tillage practices can reduce the erosional potential of agricultural lands (USDA-NRCS 2006b, CEFS 2015).

Due to the potential impacts of agriculture on water resources, various National and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself (EPA 2008c, USDA-NRCS 2015c, USDA-NRCS 2015d, USDA-NRCS 2015b, USDA 2015b). Similarly, the effectiveness of public water conservation programs depends on how these programs work with corn belt agricultural operations to monitor and track the environmental results of state nutrient reduction activities, as well as the extent to which programs complement other watershed conservation and environmental programs and policies (EPA 2014).

2.2.3 Air Quality

The EPA establishes National Ambient Air Quality Standards (NAAQSs) pursuant to the Clean Air Act (CAA) that are intended to protect public health and the environment. NAAQS are established for six criteria pollutants: ozone (O₃), nitrogen dioxide (NO₂), carbon monoxide (CO), sulfur dioxide (SO₂), lead (Pb), and particulate matter (PM). In addition to criteria pollutants, the EPA regulates hazardous air pollutants (HAPs) such as ammonia and hydrogen sulfide. States enforce the NAAQS s through creation of state implementation plans (SIPs), which are designed to achieve EPA established NAAQS.

Crop production practices can generate air pollutants that can potentially affect the environment and human health, and challenge regional NAAQS (EPA 2013b, EPA 2015a)(EPA 2013b, EPA 2015a)(EPA 2013b, EPA 2015a)(EPA 2013b, EPA 2015a). Agricultural emission sources from corn production include: smoke from agricultural burning (PM); fossil fuel consumption associated with equipment used in tillage and harvest (CO₂, NO_x, SO_x); soil particulates from tillage (PM); pesticide volatilization or drift; and soil nitrous oxide (N₂O) emissions from the use of fertilizers (Aneja, Schlesinger et al. 2009, EPA 2013b).

Drift, and volatilization of pesticides from soil and plant surfaces, can result in introduction of these chemicals to the air. Volatilization is dependent on soil wetness and temperature. Herbicide loss through volatilization loss can be up to 25 times larger than losses from surface runoff (Gish, Prueger et al. 2011). Drift is dependent on wind conditions and applicator practices, to include application equipment features such as nozzle size. Drift and volatilization of pesticides can be a source of concern to both farmers and the general public in regard to potential environmental and human health effects.

The EPA's Office of Pesticide Programs (OPP), which regulates the use of pesticides, including herbicides, introduced initiatives to help pesticide applicators minimize off-target drift. The EPA's voluntary Drift Reduction Technology (DRT) Program was developed to encourage the manufacture, marketing, and use of spray technologies scientifically verified to substantially reduce pesticide drift. EPA is also working with pesticide manufacturers through the registration and registration review programs on improvements to pesticide label instructions to reduce drift (e.g., see (EPA 2015o). In October of 2012 the EPA and USDA published a reference guide that further provides options for improving air quality on agricultural lands (USDA-NRCS 2012).

Over the past several years, the EPA has developed USDA-approved measures to manage air emissions from cropping systems and general land management sources to help satisfy SIP requirements. In the 2006 Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS) and 2008 Ozone NAAQS preambles, EPA recommended that in areas where agricultural activities have been identified as a contributor to a violation of the NAAQS, when properly implemented to control airborne emissions of the desired NAAQS pollutant, USDA-approved conservation systems and activities may be implemented to achieve reasonably available control measure (RACM) and best available control measure (BACM) levels of control.

The USDA and EPA provide regional, state, and local regulatory agencies technical tools and information on how to manage agricultural air emissions with USDA approved measures and USDA and EPA expertise. These measures allow stakeholders the flexibility in choosing which measures are best suited for their specific situations/conditions and desired purposes (USDA-EPA 2012).

Current practices used in corn production used to minimize emissions include conservation tillage, residue management, wind breaks, burn management, manure management, integrated pest management, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), and conservation irrigation (USDA-NRCS 2006b, USDA-NRCS 2006a).

2.2.4 Climate Change

Agriculture can influence climate change through various aspects of the production process: combustion of fossil fuels in farm equipment, pesticide and fertilizer application, tillage and manure management practices, and decomposition of agricultural waste products can all result emission of greenhouse gases (GHG) to the atmosphere. The major sources of GHG emissions associated with corn production are soil derived nitrous oxide (N₂O) emissions, particulate

matter (PM) derived from tillage and agricultural inputs, and carbon dioxide (CO₂) emissions associated with farm equipment operation.

Greenhouse gas emissions from agriculture have increased by approximately 17% since 1990, and agriculture is currently responsible for an estimated 8% of total greenhouse gas emissions in the U.S. (EPA 2013b). Methane and N₂O are the primary greenhouse gases emitted by agricultural activities. Methane from emissions from enteric fermentation and manure management represents 25.9% of emissions from anthropogenic activities. Agricultural soil management activities such as fertilizer application and other cropping practices are the largest source of N₂O emissions nationally, accounting for 74.2%. CO₂, to a much lesser degree, is also a GHG associated with agricultural land uses and energy consumption.

Factors influencing agricultural GHG emissions are those related to the agronomic practices specific to various types of corn production systems, region in which commodities are grown, and the individual choices made by growers. For example, emissions of N₂O, produced naturally in soils through microbial nitrification and denitrification, can be influenced by fertilizer application practices, cultivation of nitrogen-fixing crops and forage, retention of crop residues (e.g., conservation tillage), irrigation, and fallowing of land (EPA 2013b). Similarly, on-site emissions associated with fossil fuel burning farm machinery can be reduced by half for some crops when changing from conventional tillage to no-till systems (Nelson, Hellwinckel et al. 2009).

Corn crops can both contribute to GHG emissions, as well as result in carbon capture and sequestration. The magnitude of effect of emissions and sequestration on climate change is, however, difficult to quantify, and will depend on the cropping system, production practices, soil types, and individual grower decisions. Where corn cultivation has been estimated to produce higher total CO₂ emissions than soybean, on-site emissions can be reduced by half for some crops by replacing conventional with no-till systems (Nelson, Hellwinckel et al. 2009). Conservation tillage, in particular, has been observed to contribute to soil carbon sequestration on croplands through the conservation of biomass (Franzluebbers 2005). Similarly, rotation of corn crops, such as with legumes, and reduced nitrogen inputs, has been noted to result in carbon footprint reduction of corn crops (Ma, Liang et al. 2012). No-till practices generally sequester more carbon in the soil due to less soil disturbance, higher soil moisture, and increased biomass inputs from surface residues. In general, the carbon footprint for corn production has been estimated to be approximately 300 pounds of CO₂ equivalent emission per acre (Nelson, Hellwinckel et al. 2009). However, modeling suggests that conversion to no-till practices can reduce carbon emissions by approximately 17,325 kg/ha, or 15,279 lbs/acre (West N.D.).

Climate change can also affect agricultural crop production through changing patterns in precipitation, temperature, and duration of growing season, as well as through influencing weed and pest pressure, or lack thereof (Backlund, Janetos et al. 2008, IPCC 2014). By example, the current range of various species of agricultural weeds and pests are expected to shift in response to changes in regional climates, which could present new challenges to crop production in certain areas (Backlund 2008). On the other hand, Field et al. found that most studies projected likely climate-related yield increases of 5% to 20% on the agricultural output of corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains (Field, Mortsch et al. 2007). However, such a beneficial impact would not be observed to be evenly distributed across

all geographic areas as certain regions of the U.S. are expected to be negatively impacted by substantial reductions and/or variability in water resources.

2.3 Biological Resources

2.3.1 Animal Communities

Birds and Mammals

Intensively cultivated lands, such as a cornfield, provide less suitable habitat for wildlife use than that found in fallow fields or adjacent natural areas. As such, the types and numbers of animal species found in cornfields are less diverse as compared to unmanaged lands. Cornfields, however, can provide both food and cover for wildlife, including a variety of birds as well as large and small mammals. Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction, but most of the birds and mammals that use cornfields are ground-foraging omnivores that feed on the corn remaining in the fields following harvest.

The types and numbers of birds that inhabit cornfields vary regionally and seasonally but for the most part the numbers are low. Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species more commonly observed in corn fields include (Best, Whitmore et al. 1990):

- Red-winged blackbird (*Agelaius phoeniceus*)
- Grackle (*Quiscalus quiscula*)
- Horned lark (*Eremophila alpestris*)
- Brown-headed cowbird (*Molothrus ater*)
- Vesper sparrow (*Pooecetes gramineus*)
- Ring-necked pheasant (*Phasianus colchicus*)
- Wild turkey (*Meleagris gallopavo*)
- American crow (*Corvus brachyrhynchos*)
- Various quail species.

Following harvest, it is also common to find large flocks of migratory bird species foraging in cornfields, such as Canada geese (*Branta canadensis*), snow geese (*Chen caerulescens*), sandhill cranes (*Grus canadensis*), and various other species (Taft and Elphick 2007, Sherfy, Anteau et al. 2011).

A variety of mammals forage on corn at various stages of production. For the most part, herbivorous and omnivorous mammals feed on the ear at different stages of growth. Large- to medium-sized mammals that are common foragers of cornfields include (Flehart and Navo 1983, ODNR 2001):

- White-tailed deer (*Odocoileus virginianus*)
- Raccoon (*Procyon lotor*)

- Wild boar (*Sus scrofa*)
- Woodchuck (*Marmota monax*)

The most notable of these is the white-tailed deer which often inhabit woodlots adjacent to cornfields and frequent these fields for both food and cover especially in mid-summer. Agricultural crops, particularly corn and soybean, comprise a major portion of deer diets in Midwestern agricultural regions, and deer are considered responsible for more corn damage than any other wildlife species (MacGowan, Humberg et al. 2006). Cornfields are vulnerable to deer damage from emergence through harvest, although damage to corn at the tasseling stage most directly impacts yield (Stewart, McShea et al. 2007). Losses to crop yield from feeding by raccoons have also been documented (Beasley and Rhodes Jr. 2008). Mature corn has been shown to constitute up to 65% of the diet of raccoons in some areas prior to harvest (MacGowan, Humberg et al. 2006).

As with larger mammals, small mammal use of cornfields for shelter and forage also varies regionally. Some of the more common small mammals common to corn fields are (USDA-NRCS 1999, U-Illinois-Ext 2000, Sterner, Petersen et al. 2003).

- Deer mouse (*Peromyscus maniculatus*)
- House mouse (*Mus musculus*)
- Meadow vole (*Microtus pennsylvanicus*)
- Thirteen-lined ground squirrel (*Spermophilus tridecemlineatus*)

Invertebrates

Invertebrate communities in cornfields represent a diverse assemblage of feeding strategies including herbivores, predators, crop-feeders, saprophages, parasites, pollinators, gall formers, and polyphages (Stevenson, Anderson et al. 2002). Numerous insects and related arthropods perform valuable functions; they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Although many arthropods in agricultural settings are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and the corn rootworm (*Diabrotica* spp.), there are many beneficial arthropods which are natural enemies of both weeds and insect pests (Landis, Menalled et al. 2005). Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles, the caterpillar parasitoids (e.g., *Macrocentrus cingulum*), and the predatory mite (*Phytoseiulus persimilis*), (Landis, Menalled et al. 2005, Shelton 2011). Earthworms, termites, ants, beetles, and millipedes contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz, Lavelle et al. 2008).

The most agronomically-relevant invertebrates in corn production fields are those arthropods that feed on corn plants and adversely affect grain yield. These include Lepidoptera species that feed on the corn ear or stalk and coleopteran species that feed on other corn vegetative structures. Major Lepidoptera and Coleoptera insect pests in the United States include European corn borer and western corn rootworm, respectively. The European corn borer is present in every corn growing state except Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington (ISU 2012). Western corn rootworm has been reported as active in every corn growing state, with the exceptions of California, Florida, Louisiana, Nevada, Oregon and Washington (CABI 2015). In

the United States, monetary losses and expenses related to European corn borer and corn rootworm exceed \$1 billion/year for each pest (USDA 2013). The advent of GE *Bt* corn targeting these major insect pests has enabled a reduction in input costs by decreasing the number and volume of broad-spectrum insecticide application in U.S. corn cultivation (Brookes and Barfoot 2010, Benbrook 2012).

2.3.2 Plant Communities

Vegetation Associated with Cornfields

Non-crop vegetation within cornfields is limited by the extensive cultivation and weed control practices employed by corn farmers. Non-crop vegetation in cornfields is consequently generally associated with vegetative communities adjacent to these fields. Cornfields may be bordered by other field crops or by woodlands, hedgerows, rangelands, pasture and grassland areas. These plant communities may occur naturally, or they may be managed for the control of soil and wind erosion.

Members of the plant communities in and around cornfields that adversely affect corn cultivation are generally characterized as weeds, and weed control programs are fundamental components of crop production in maximizing crop yield and quality. The types of weeds in and around a cornfield vary according to the region in which the corn is planted, although some of the most common weeds in U.S. cornfields include (U-Missouri 2009):

- Giant foxtail (*Setaria faberi*);
- Giant ragweed (*Ambrosia trifida*);
- Velvetleaf (*Abutilon theophrasti*);
- Common lambsquarters (*Chenopodium album*);
- Common ragweed (*Ambrosia artemisiifolia*);
- Common cocklebur (*Xanthium pensylvanicum*);
- Canada thistle (*Cirsium arvense*);
- Johnsongrass (*Sorghum halepense*);
- Fall panicum (*Panicum dichotomiflorum*); and
- Maretail (*Conyza canadensis*).

In addition to the more common weed species listed above, the following species are also noted as problematic in corn growing regions of the U.S. (ISU-Ext 2003, USDA-NRCS 2015a):

- Cressleaf groundsel (*Senecio glabellus*);
- Purple deadnettle (*Lamium purpureum*);
- Biennial wormwood (*Artemisia biennis*);
- Asiatic dayflower (*Commelina communis*);
- Hophornbeam copperleaf (*Acalypha ostryfolia*);
- Burcucumber (*Sicyos angulatus*);
- Wild buckwheat (*Polygonum convolvulus*);
- Kochia (*Kochia scoparia*);
- Waterhemp (*Amaranthus rudis*);

- Palmer amaranth (*Amaranthus palmeri*);
- Star-of-Bethlehem (*Ornithogalum umbellatum*);
- White campion (*Silene latifolia*);
- Wild four o' clock (*Mirabilis nyctaginea*); and
- Pokeweed (*Phytolacca americana*).

Weed populations among corn fields change in response to agricultural management decisions. New weeds emerge as cropping practices change and when growers may fail to recognize or properly identify a plant as a weed. Collectively, management decisions will impart selection pressures⁶ on the weed communities, that can result in shifts of weed species on a local level (i.e., field level) (Owen 2011, Owen 2012, Vencill, Nichols et al. 2012). Weed shifts are generally most pronounced when a single or small group of weeds increases in abundance relative to other weed populations. Herbicide resistance in weeds naturally evolves when a plant survives and reproduces after exposure to a dose of herbicide, usually lethal to the wild type, passing this ability on to future generations of the plant.

Overreliance on a single weed management strategy, for example, a single mode of action (MOA) herbicide, can cause intense selection pressure on weed populations. In this context, selection pressure is the extent to which plants possessing a particular characteristic are either eliminated or favored by environmental conditions (Vencill, Nichols et al. 2012). This strong selection pressure can and has resulted in the evolution of herbicide-resistant weed biotypes (Wilson, Hooker et al. 2009, Shaw, Owen et al. 2011, Vencill, Nichols et al. 2012).

Weed resistance to herbicides can be a particular problem in crop production, and management of weed resistance is a primary aspect of corn cultivation (e.g., see (FAO 2015)). When a crop like corn is cultivated year after year in the same fields, using the same cultivation practices, the likelihood is high that weed and pest species will increase in these fields and that agronomic inputs may need additional attention (Owen 2011, Shaw, Owen et al. 2011). In particular, when only one herbicide is used year after year as the primary means of weed control, herbicide-resistant plants can quickly reproduce and spread to dominate the plant (weed) population and seed bank. With no change in weed control strategies, in time, the weed population will be selected for those species naturally resistant to an herbicide.

Weeds with evolved resistance to glyphosate have increased since the commercial introduction of the Roundup Ready® glyphosate-resistant crops in 1996 (Owen 2011, Heap 2015). Currently, there are 14 glyphosate-resistant (GR) weed species that have been documented in U.S. crop-production areas (Fernandez-Cornejo and Osteen 2015, Heap 2015). There is only one reported weed resistant to glufosinate in the U.S. weed (Heap 2015).

Many of the glyphosate-resistant weeds are agronomically important and dominant members of weed communities. For example, glyphosate-resistant Palmer pigweed (amaranth) is a major

⁶ Selection pressure may be defined as any event or activity that reduces the reproductive likelihood of an individual in proportion to the rest of the population of that one individual. In agriculture, selection pressure may be imparted by any facet of management in the production of a crop, including the type of crop cultivated, strategy of pest management, or when and how a crop is planted or harvested.

economic problem in the Southeast U.S., while glyphosate-resistant waterhemp is an economically important weed in Midwestern states (Culpepper, Grey et al. 2006, Owen 2008). Other glyphosate-resistant weeds of importance include giant ragweed, common lambsquarters, and horseweed (Owen 2011, Heap 2015).

Given that some weeds have evolved multiple resistance to several herbicide mechanisms of action, it is important that growers choose herbicides with diverse mechanisms of action to avoid intense selection from only one or a few herbicides. Current practices in managing weeds involve an integrated weed management (IWM) approach that diversifies weed management tactics and includes timely herbicide applications, use of herbicides with multiple modes of action, crop rotation, various tillage practices, and weed surveillance (Buhler 2002, Owen 2011, Brookes 2014, Garrison, Miller et al. 2014, CLI 2015b). To assist growers in managing weeds, individual states, typically through state agricultural extension services, track the prevalent weeds in crops in their area and the most effective means for their management (see, e.g., (IPM 2015)).

The key consideration to managing herbicide-resistant weeds is to ensure that the herbicides used continue to have efficacy on the target weeds. Weed scientists recommend the use of an IWM systems approach including science-based crop improvement and farm management tools developed over the last 60 years, as well as providing producers reasonable and attractive alternatives for effective weed (e.g., (Weller, Owen et al. 2010, Owen 2011, Owen 2012, Vencill, Nichols et al. 2012, Heap 2015)). In general, weed population densities can be decreased in continuous glyphosate-resistant (GR) cropping systems incorporating IWM strategies, although shifts in the density of high-risk weed species may take from two of six years and under continuous GR maize (Gibson, Young et al. 2015). Where academic recommendations that promote IWM to deter glyphosate resistance are successful in the short term for reducing weed infestations while maintaining crop yield potential, they may take many years to affect the weed seedbank, particularly for those species with a high risk for resistance to glyphosate, and cropping systems utilizing a single-trait glyphosate-tolerant crop variety (Gibson, Young et al. 2015).

2.3.3 Gene Flow and Weediness of Corn

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles, and evolution of new plant genotypes. Gene flow to and from an agro-ecosystem can occur both horizontally (asexual), and vertically (sexual reproduction). In general, plant pollen tends to represent the major reproductive method for moving across areas, while both seed and vegetative propagation tend to promote the movement of genes across time and space.

Vertical gene flow (i.e., sexual reproduction) generally involves the movement of alleles from parents to offspring. In corn, sexual reproduction may occur between domesticated corn varieties or from corn to sexually-compatible relatives. Vertical gene flow includes the possibility of pollen transfer between different varieties of corn. Various plant properties and environmental conditions can affect movement of genes between corn cultivars. For gene flow to occur between corn varieties, viable pollen must reach a receptive tassel. This requires that flowering times must overlap, viable pollen transfer between the varieties must occur, embryo/seeds must develop, and hybrid seed must disperse and establish. Spatial and temporal isolation can be one

of the most effective barriers to gene exchange between corn crop cultivars (Mallory-Smith and Zapiola 2008, Mallory-Smith and Sanchez Olguin 2011). Current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99% genetic purity, though higher instances of out-crossing can occur (Ireland, Wilson et al. 2006). These practices for maintaining varietal purity are also discussed in Subsection 2.1.3, Organic Corn Production.

The closest relative of *Zea* is the genus *Tripsacum* (OECD 2003). All of the *Tripsacum* species are perennial and are mostly found in Central America (OECD 2003). However, three species have been identified in the United States: *T. dactyloides*, Eastern gamagrass, is known to occur in the eastern half of the United States, *T. lanceolatum*, Mexican gamagrass, occurs in the southwest of the United States, and *T. floridanum*, Florida gamagrass, is native to South Florida and Cuba (Wozniak 2002, OECD 2003). *T. dactyloides* is the only *Tripsacum* species of widespread occurrence and agricultural importance in the United States, and commonly is grown as a forage grass (Wozniak 2002).

The potential for pollen-directed gene flow from corn to Eastern gamagrass is remote (Wozniak 2002). Although hybridization of *Tripsacum* and *Z. mays* has been accomplished in the laboratory using special techniques under highly controlled conditions, these hybrids have not been observed in the field (Wozniak 2002). Additionally, *Tripsacum* does not represent any species considered a serious or pernicious weed in the United States or its territories. Any introgression of corn genes into this species as a result of cross fertilization is not expected to result in a species that is weedy or difficult to control (Wozniak 2002). Hybrids between *Z. mays* and the teosinte subspecies *Z. mays* subsp. *mexicana* are known to occur when the two are sympatric in Mexico (CEC 2004, Ellstrand, Garner et al. 2007). Many species of *Tripsacum* can cross with *Zea*, or at least some accessions of each species can cross, but only with difficulty and the resulting hybrids are primarily male and female sterile (Wozniak 2002). The rate at which crop genes enter teosinte populations may be limited by genetic barriers, phenological differences, and subsequently by the relative fitness of the hybrids (CEC 2004, Ellstrand, Garner et al. 2007).

Horizontal gene flow is movement of genes across species through asexual mechanisms (i.e., bacterial transformation or conjugation) and consequent expression of (DNA) from another species. Horizontal gene flow among bacteria is common, although gene flow from plants to bacteria is rare (Bertolla and Simonet 1999, CAST 2007, Chandler and Dunwell 2008, Bock 2010, Nielsen, Bøhn et al. 2013, Arber 2014). Many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko, Nakamura et al. 2000, Wood, Setubal et al. 2001, Kaneko, Nakamura et al. 2002), and evidence that these organisms contain genes derived from plants is lacking. In cases where the review of sequence data implied that horizontal gene transfer occurred, these events were inferred to occur on an evolutionary time scale on the order of millions of years (Brown 2003). Much of the work that's been done indicates that the rate of horizontal gene transfer from plants to bacteria is very low, and poses negligible risks to human health or the environment (Keese 2008, Rizzi, Raddadi et al. 2012).

Corn as a Weed or Volunteer

In the United States, corn is not listed as a weed, nor is it present in the Federal Noxious Weed List (7 CFR part 360) (USDA-NRCS 2015a). Furthermore, corn is grown throughout the world without any report that it is a serious weed or that it forms persistent feral populations. However, corn periodically occurs as a volunteer when corn seeds remain in the field after harvest and successfully germinates (e.g., see (Deen, Hamill et al. 2006, Stahl, Potter et al. 2013)). Post-harvest seed residues in fields can be a result of harvester inefficiency, bird dispersal or seed drop, with the seed ending up beyond the field margins or remaining as residues in the field after the harvest. This can be a particular problem if late season weather causes ears to drop leaving ears on the ground with seeds that germinate the following year. When seeds survive to the next growing season, volunteer plants may develop within subsequent crops rotated with corn, or outside of the cropped area. GE corn may be a problematic volunteer the year after harvest in field crops grown in rotation with corn, especially soybean, dry beans, sugar beets, as well as subsequent corn crops.

The potential for corn, including GE corn to establish as a volunteer has been the subject of recent research, with a particular attention on yield impact and management of herbicide-resistant corn as a volunteer in subsequent crops (Deen, Hamill et al. 2006, Marquardt, Krupke et al. 2012, Stahl, Potter et al. 2013). The effect of volunteer corn on the yields of the intended crop depends on the density of the volunteer corn (Bernards, Sandell et al. 2010). In controlled agronomic studies, volunteer corn densities ranging from 800 to 13,000 plants per acre resulted in yield losses of 0 to 54% in soybean and 0 to 13% in corn (Stahl, Potter et al. 2013). Similarly, soybean yield reductions have been found to range from 10 to 41% where early-emerging volunteer corn densities ranged from 0.5 to 16 plants m², although no soybean yield loss occurred with the late-emerging cohort of volunteer corn (Marquardt, Krupke et al. 2012).

Successful control of corn volunteers, including HT varieties, is accomplished with the use of various combinations of cultivation practices and herbicides with differing modes of action (Beckie 2006, Jeschke and Doerge 2010, Owen 2011, Owen 2012). Volunteer corn is less of a concern in no-till fields than in fall-tilled fields because of the lower probability that corn seed will survive and germinate the following growing season (Bernards, Sandell et al. 2010). In no-till fields, the fallen corn is frequently predated by wildlife and also is subject to winter weather conditions (Bernards, Sandell et al. 2010). In fall tillage systems, corn seed may be buried in the soil and overwinter and germinate. This overwintering volunteer corn seed requires control with spring tillage or with an application of herbicides (Bernards, Sandell et al. 2010).

2.3.4 Microorganisms

Soil biota (i.e., earthworms, nematodes, fungi, bacteria) play a key role in soil structure formation, decomposition of organic matter, biodegradation of anthropogenic substances (e.g., pesticides), nutrient cycling, suppression of plant diseases, promotion of plant growth, and most biochemical soil processes (Parikh and James 2012). Some microorganisms can also cause plant diseases, which can result in substantial economic losses in crop production. These include fungal corn rusts, corn leaf blights, ear smuts, ear and kernel rot fungi, and maize mosaic viruses.

The main factors affecting soil biota populations and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop

rotation, tillage, herbicide and fertilizer application, and irrigation (Garbeva, van Veen et al. 2004, Gupta, Neate et al. 2007). Climate, particularly the water and heat content of soil, is a principal determinant of soil biological activity.

Potential changes to the soil microbial community as a result of cultivating genetically modified crops has been of much research interest in recent years (Lynch, Benedetti et al. 2004, Motavalli, Kremer et al. 2004, Locke, Zablutowicz et al. 2008). Potential direct impacts could possibly include changes to the structural and functional community near the roots of GE plants due to altered root exudation or the transfer of novel proteins into soil, or a change in microbial populations due to the changes in agronomic practices used to produce GE crops (e.g., pesticides, fertilizers, and tillage practices).

Findings from studies on the impact of GE crops on soil microbial communities are somewhat mixed. A review of those investigations examining the impact of GE plants on microbial soil communities completed by Kowalchuk et al. found that much of the research looking at distinctive microbial traits concluded there were minor or no non-target effects; only a few studies found induced targeted alterations to the composition of the microbial community that usually resulted in the inhibition of plant pathogenic organisms (Kowalchuk, Bruinsma et al. 2003). A similar review by Motavalli et al. found no conclusive evidence that GE plants resulted in any substantial impacts on microbe-mediated soil nutrient transformations, although it was asserted that further consideration of the effects of a wide range of soil properties, including the amount of clay and its mineralogy, pH, soil structure, and soil organic matter, and variations in climatic conditions, under which transgenic crops may be grown, is needed in evaluating the potential impact of transgenic crops on soil nutrient transformations (Motavalli, Kremer et al. 2004). Hart et al. found that neither crop type (transgenic or conventional) nor herbicide (glyphosate or conventional) examined had a significant effect on denitrifying or fungal communities. Their findings, instead, suggested that seasonality was a primary determinant of abundance and diversity of soil microbial communities (Hart, Powell et al. 2009).

In general, where some studies have shown that glyphosate-tolerant cropping systems may affect soil microbial populations, many studies have found only minor, transient effects. For example, Haney et al. report that glyphosate is mineralized by microorganisms that leads to an increase in their population and activity (Haney, Senseman et al. 2002), while Busse et al. and Weaver et al. found little evidence of changes to soil microorganism's population and activity, and any declines recorded were small and not consistent throughout the season (Busse, Ratcliff et al. 2001, Weaver, Krutz et al. 2007). In a comparison of fields planted with glyphosate-tolerant and conventional corn and cotton, Locke et al. found that glyphosate-tolerant crops exhibited subtle and dynamic differences in soil microbial populations when compared to non-glyphosate-resistant crops (Locke, Zablutowicz et al. 2008). The authors surmise that the decreased disturbance of the soil and increased level of residue as a result of reduced tillage on the glyphosate-tolerant crops allowed for a more diverse microbial population.

It also has been reported that the use of glyphosate increases the colonization of soil-born fungal pathogens such as *Fusarium* (Kremer and Means 2009). Similarly, research by Camberato et al. found that some weeds treated with glyphosate and other herbicides had increased incidence of fungal infection, suggesting that some soil fungi are more able to infect a weed after it has been weakened by glyphosate (Camberato, Casteel et al. 2011). They point out, however, that plant

pathologists have not observed widespread increases in plant diseases in glyphosate-tolerant corn and soybean (Camberato, Casteel et al. 2011). In a review of recent studies investigating a potential link between the use of glyphosate and outbreaks of fungal disease, Powell and Swanton did not find sufficient evidence from field trials demonstrating whether a causative relationship exists (Powell and Swanton 2008). Additionally, they found that observed links may be context dependent, as they were found only under controlled laboratory conditions. The authors suggest that to adequately address the effect of glyphosate on fungal diseases, future investigations should consider additional interactive factors, such as inoculum level, weed abundance and community composition, fertility, cultural practices, climate, and soil properties.

Glufosinate applications may impact soil microbial communities, although the reported research has yielded differing results (see, e.g., (Bartsch and Tebbe 1989, Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010)). For example, Sessitsch et al. concluded that rhizosphere bacteria associated with glufosinate tolerant oilseed rape were affected by the genetic modification of the plant; however, the effects were considered minor as compared to the influence of the plant growth stage (Sessitsch, Gyamfi et al. 2005). Gyamfi et al (2002) suggest that some of the observed microbial population shifts associated with glufosinate may be caused by an increase in herbicide-degrading soil microbes following application, due to use of glufosinate by microbes as a source of nitrogen (Bartsch and Tebbe 1989). Other research suggests that glufosinate may beneficially inhibit the activity of crop pathogens such as bacterial blight (Pline 1999) and grapevine downy mildew (Kortekamp 2011). Glufosinate has also been suggested to inhibit glutamine synthetase activity in pathogenic fungi or fungal like organisms, similar to inhibition of glutamine synthetase in plants (Kortekamp 2011). In general, glufosinate applied at recommended rates is not recognized as have having significant or consistent adverse effects on soil microbial diversity (e.g., see (Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010)).

In most cases, crop and soil management practices that increase soil organic matter and plant residues, such as conservation tillage, impart attributes to the soil environment that enhance microbial degradation of herbicides (Locke and Zablotowicz 2004, Locke, Zablotowicz et al. 2008), and hinder herbicide movement into surface and groundwater.

2.3.5 Biodiversity

Biodiversity concerns the variety and abundance of biota, and their roles ecosystem dynamics, including both managed and unmanaged ecosystems. It is the foundation of ecosystem goods and services to which human well-being is intimately linked (Díaz, Fargione et al. 2006). In an agricultural setting, biodiversity refers to the ability of a highly managed ecosystem, such as a cornfield, to support species that are important components of the biological landscape conducive to crop production (i.e., non-pest species). Such species include those affecting pollination (e.g., bees, butterflies), species that control insect pests and disease, important avian species (e.g., songbirds), small mammals, and members of the plant community. Biodiversity also serves functions that affect biogeochemical cycling, soil structure, and local hydrological processes. A loss of biodiversity in agricultural setting can result in the need for costly external inputs in order to provide these types of functions to a crop (Altieri 1999).

As a highly managed landscape utilized for intensive production of food, feed, fiber, and fuel, the impacts of commercial corn production on biodiversity are due largely to the loss of habitat, caused by conversion of an undisturbed/unmanaged environment to cropland. The degree of biodiversity in an agro-ecosystem depends on four primary characteristics: 1) the diversity of vegetation within and around the agro-ecosystem; 2) the permanence of various crops within the system; 3) the intensity of management; and 4) the extent of isolation of the agro-ecosystem from natural areas of native vegetation (Altieri 1999).

Where some crop production practices such as planting of monoculture crops, pesticide and fertilizer use, and harvest, limit habitat and thereby decrease the diversity of biota, other practices can be used to foster habitat preservation and biodiversity (Scherr and McNeely 2008). Conservation tillage practices can have a positive impact on wildlife through decreased soil erosion, improved water quality, retention of ground cover, availability of waste grain on the soil surface for feed, and increased populations of predaceous invertebrates as well as invertebrates as a food source (Altieri 1999, Landis, Menalled et al. 2005, Sharpe 2010, Towery and Werblow 2010). Crop rotations can reduce the likelihood of crop disease, and insect and weed pests, thereby reducing the need for pesticides, which can be beneficial to biodiversity by limiting the potential exposure of biota to pesticides. Crop rotations can also result in preservation of wildlife habitat; crop rotations with legumes and small grains have been shown to provide nesting cover, food, and brood-rearing habitat (Sharpe 2010). By example, allowing field edges to harbor non-crop vegetation can provide nesting and brood habitat for birds, support beneficial arthropods that suppress herbivore insect pests, and provide food and habitat for natural predators of crop pests (Sharpe 2010).

In general, relative to any undisturbed ecosystem, species abundance and variety will be less in intensively managed agro-ecosystems, such as commercial corn fields. However, practices as summarized above can foster greater diversity and abundance of biota. Where the potential impact of GE crops on biodiversity, in particular, has been a topic of general interest, a recent review suggests that commercial GE crops can reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, potential reductions of pesticide use, use of more environmentally benign pesticides, and increased yields that can alleviate pressure to convert additional land into agricultural uses (Carpenter 2011).

2.4 Human Health

2.4.1 Consumer Health

Food and Nutritional Safety

Public health considerations are those related to (1) the safety and nutritional value of GE corn to consumers, and (2) the potential health effects of pesticides that may be used in association with the GE corn. As for food safety, consumer health concerns are in regard to the potential toxicity or allergenicity of the introduced genes/proteins, possibly altered levels of existing allergens in plants, or the expression of new antigenic proteins. Consumers may also be concerned about potential consumption of pesticides used on food crops.

In the U.S., GE plants are regulated and evaluated for public health and environmental safety under the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302; 57 FR 22984) described in Section 1.3. The Coordinated Framework defines the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: (1) APHIS, (2) the EPA, and (3) the FDA. The safety assessment of crops derived through biotechnology, described following, includes characterization of the physicochemical and functional properties of the protein(s) produced from the inserted DNA, determination of the safety of the protein(s), and potential environmental impacts of the GE crop.

Under the Federal Food Drug and Cosmetics Act (FFDCA) and Food Safety Modernization Act (FSMA) food and feed manufacturers are required to ensure that the products they introduce into commerce are safe for human consumption. Food and feed derived from GE crops must be in compliance with the FFDCA, FSMA, and all other applicable legal and regulatory requirements. GE plants that will be used for food or feed purposes undergo a voluntary consultation process with the FDA prior to release of the food or feed into commerce. The FDA established this voluntary consultation process to review the safety of foods and feeds derived from GE crops.

In such a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use of the protein in food (Hammond and Jez 2011). The FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require.

Although a voluntary process, thus far all applicants who have wanted to commercialize a GE product that would be included in the food or feed supply have completed a consultation with the FDA. Syngenta has initiated the FDA consultation process by submitting a safety and nutritional assessment for MZHG0JG corn. Syngenta provided the FDA with information on the identity, function, and characterization of the genes for MZHG0JG corn, which contains the gene *mepsps-02* that encodes the enzyme modified 5-enol pyruvylshikimate-3-phosphate synthase (mEPSPS), a variant of the native EPSPS from *Z. mays*, and the gene *pat-09* that encodes the enzyme phosphinothricin acetyltransferase (PAT) derived from the soil bacterium *Streptomyces viridochromogenes*.

In addition, foods derived from genetically modified plants undergo a comprehensive safety evaluation among international agencies before entering the market, including reviews under the CODEX Alimentarius, the European Food Safety Agency (EFSA), the Australia and New Zealand Food Standards Agency (ANZFS), and the World Health Organization (e.g., see (FAO 2009, Hammond and Jez 2011)). Food safety reviews will frequently compare the compositional characteristics of the GE crop with non-GE varieties of that crop. Syngenta has also submitted a safety and nutritional assessments for MZHG0JG corn to FSANZ, to seek approval for food derived from MZHG0JG corn (FSANZ 2015).

The EPSPS and PAT proteins in MZHG0JG corn have well-understood biological activities. The EPSPS family of enzymes occurs naturally in plants (i.e., corn) and microorganisms, and PAT proteins occur naturally in *Streptomyces* spp. (bacteria) (ILSI-CERA 2011a, ILSI-CERA 2011b); humans and animals are potentially exposed to both proteins through environmental sources on a daily basis, worldwide.

Previous evaluations of EPSPS and PAT have shown they do not share amino acid sequence similarity to known toxins and are unlikely to be human allergens (ILSI-CERA 2011a, ILSI-CERA 2011b). The EPSP and PAT proteins in MZHG0JG corn have a history of safe use in several commercially available corn products that have been previously reviewed by the FDA and USDA, and approved for commercial use. These prior reviews of the EPSP and PAT proteins have concluded that their consumption poses no risk to human health (e.g., see (FDA 2012, FDA 2013b, FDA 2013a, FDA 2014)). Due to the negligible risk these proteins pose to human health, the EPA has issued permanent exemptions from food and feed tolerance limits for CP4 EPSPS and PAT proteins in all crops in the United States (EPA 2007c, EPA 2007b).

Food safety reviews frequently compare the compositional characteristics of the GE crop with non-transgenic, conventional varieties of that crop. Compositional characteristics evaluated in these comparative tests typically include constituents such as protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and anti-nutrients. Syngenta performed characterization analyses of the mEPSPS and PAT genes and proteins, safety assessments of these proteins, compositional analyses of MZHG0JG corn grain and forage, and safety and nutritional assessments of MZHG0JG corn and corn derived products (Davis, Jarrett et al. 2015). The data and information presented by Syngenta make evident that MZHG0JG corn is compositionally and nutritionally comparable to and as safe as conventional corn, and that no adverse health effects would result from exposure to either the mEPSPS or PAT present in MZHG0JG corn.

Syngenta has initiated consultation with the FDA on the potential commercial introduction of MZHG0JG corn by submitting to FDA the compositional and nutritional assessments, as well characterization data on the EPSPS and PAT genes and protein products for MZHG0JG corn. The FDA will evaluate the information submitted by Syngenta and provide a decision on the nutritional qualities and safety of food and feed derived from MZHG0JG corn.

Pesticide Safety

Both glyphosate and glufosinate may be used on MZHG0JG corn during production, and members of the general public may be concerned about exposure to residues of these herbicides via consumption of corn and corn products from MZHG0JG corn. Before a pesticide can be used on a food crop, the EPA, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) and Food Quality Protection Act of 1996 (FQPA), establishes tolerance limits, which is the amount of pesticide residue allowed to remain in or on each treated food commodity (21 U.S. Code § 346a - Tolerances and exemptions for pesticide chemical residues). Pesticide tolerance limits established by the EPA are to ensure the safety of foods and feed for human and animal consumption (EPA 2015l). If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

The EPA has established tolerance limits for glufosinate at 40 CFR §180.473, and glyphosate at 40 CFR §180.364. Both the FDA and USDA monitor foods for pesticide residues to enforce these tolerance limits, and ensure protection of human health (e.g., see (USDA-AMS 2015a)). By example, the USDA Pesticide Data Program (PDP) collects data on pesticides residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children (USDA-AMS 2015b). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the FQPA. Pesticide tolerance levels for glyphosate and glufosinate have been established for a wide variety of commodities, including field corn for grain and forage, as described in 40 CFR §180.364, and 40 CFR §180.473, respectively (EPA 2015h).

To ensure the continued safety of pesticides and public health, the EPA conducts pesticide registration reviews so that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects (EPA 2015q). As part of this program, both glyphosate and glufosinate are currently under registration review with EPA (EPA 2015m, EPA 2015n). Both pesticides, when used in accordance with existing EPA label requirements, present negligible risk to human health (e.g., see (EPA 2015m, EPA 2015n, TOXNET 2015a, TOXNET 2015b)).

If MZHG0JG corn provides for a change in use of these or other registered pesticides, the EPA would review proposed label changes and approve such changes before any new uses could be legally implemented. Syngenta does not indicate any change in glyphosate or glufosinate use with MZHG0JG corn that would differ from those current uses as indicated on EPA approved labels.

2.4.2 Worker Safety

Agriculture is considered one of the most hazardous industries in the U.S. Worker hazards common to all types of agricultural production include those associated with the operation of farm machinery, vehicles, and pesticide application.

Agricultural operations are covered by several Occupational Safety and Health standards including Agriculture (29 CFR 1928), General Industry (29 CFR 1910), and the General Duty Clause. Further protections are provided through the National Institute of Occupational Safety and Health (NIOSH), which in 1990 began development of an extensive agricultural safety and health program to address the high risks of injuries and illnesses experienced by workers and families in agriculture.

In consideration of the risk of pesticide exposure to field workers, the EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was issued in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment (PPE), restricted entry intervals (REI) following pesticide application, decontamination supplies, and emergency medical assistance. The Occupational Safety and Health Administration (OSHA) also requires employers to protect their employees from hazards associated with pesticides and herbicides.

On February 20, 2014, the EPA announced proposed changes to the agricultural WPS to increase protections from pesticide exposure for agricultural workers and their families. The EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication materials, use of personal protective equipment, and decontamination supplies. The proposed changes to the current WPS requirements, specifically will improve training on reducing pesticide residues brought from the treated area to the home on workers' and handlers' clothing and bodies. It will also establish a minimum age for handlers and early entry workers, other than those covered by the immediate family exemption to mitigate the potential for children to be exposed to pesticides directly and indirectly. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations; child farmworkers and farmworker families; the general public.

All pesticides labeled for use on crops in the U.S. must be evaluated for safety and registered by the EPA. The EPA pesticide registration process includes the development of use restrictions that, when followed, have been determined to be protective of worker health. Farmworkers are required to use pesticides consistent with the instructions provided on the EPA-approved pesticide labels, which may include instruction on personal protective equipment, specific handling requirements, pesticide equipment application specifications, and field reentry procedures.

2.5 Animal Feed

Corn is the most widely cultivated feed grain in the U.S., accounting for around 95% of feed grain production (USDA 2014), and a primary feed source for beef cattle, poultry, hogs, and dairy cattle. Animal feed derived from corn comes not only from the unprocessed grain, but also from silage (the above-ground portions of the corn plant), stalk residues in fields that might be grazed, and residuals derived from corn refining and milling, such as corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids.

Similar to the regulatory oversight for human consumption of corn under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they introduce into commerce are safe for animal consumption. Feed derived from GE corn must comply with all applicable legal and regulatory requirements, and, as described under consumer health consideration, may undergo a voluntary consultation process with FDA before being released to the market. Syngenta initiated the FDA consultation process by submitting a safety and nutritional assessment for MZHG0JG corn to the FDA. The FDA will review the information submitted by Syngenta and provide a decision on MZHG0JG corn prior to commercial cultivation of this variety for food and feed.

As described for consumer health, before a pesticide can be used on a food or feed crop, the EPA establishes tolerance limits under Section 408 of the FFDCA and Section 405 of FQPA, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (EPA 2015). Glyphosate and glufosinate currently have established tolerance limits for field corn for forage, grain, and stover. The EPA has established tolerance limits for glyphosate are at 40 CFR §180.364, and glufosinate at 40 CFR §180.473.

2.6 Socioeconomics

2.6.1 Domestic Economic Environment

U.S. Corn Supply and Demand

Corn is the most abundant crop planted and harvested in the U.S., primarily used for feed grain and fuel ethanol, which account for approximately 40% and 35% of use, respectively (USDA-ERS 2015c). The remainder of harvested corn is processed into a variety of food and industrial products such as starch, sweeteners, corn oil, and beverage and industrial alcohol (Figure 10).

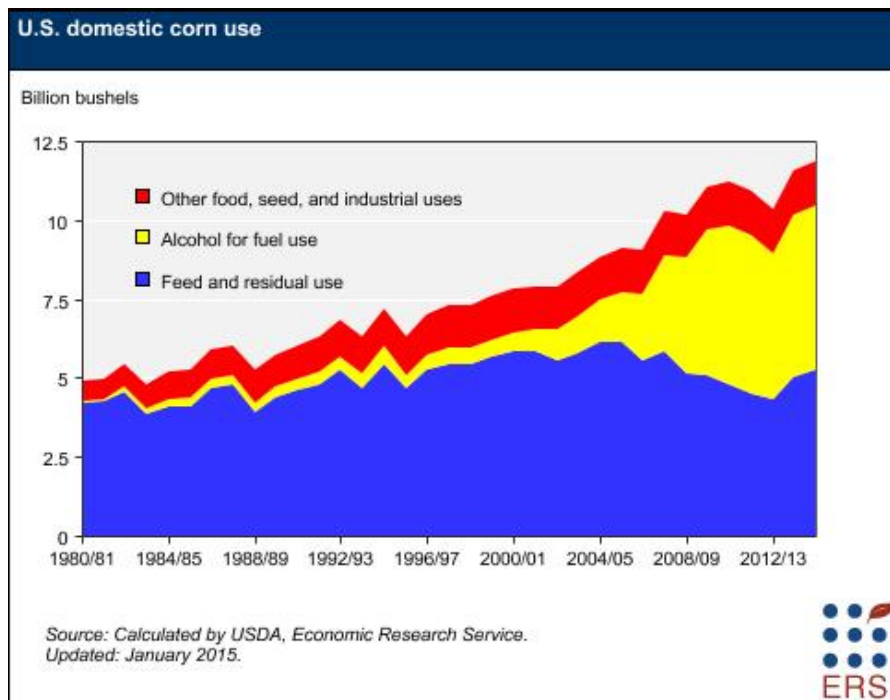


Figure 10. Uses of Corn in the U.S., 1980 – 2014

U.S. corn production has increased over time following technological improvements in seed varieties, pesticides, machinery, and production practices such as tillage, irrigation, crop rotations, and plant pest management systems (USDA-ERS 2015c). In 2014, 91.6 million acres (37.4 million hectares) were planted at a market value of \$52.3 billion (USDA-NASS 2015d) (Figure 11). Where this represents the lowest planted corn acreage since 2010, it is the fifth largest corn acreage planted in the U.S. since 1944 (USDA-NASS 2014e). The increase in acreage has involved all varieties of corn and is occurring throughout corn growing areas in the U.S.

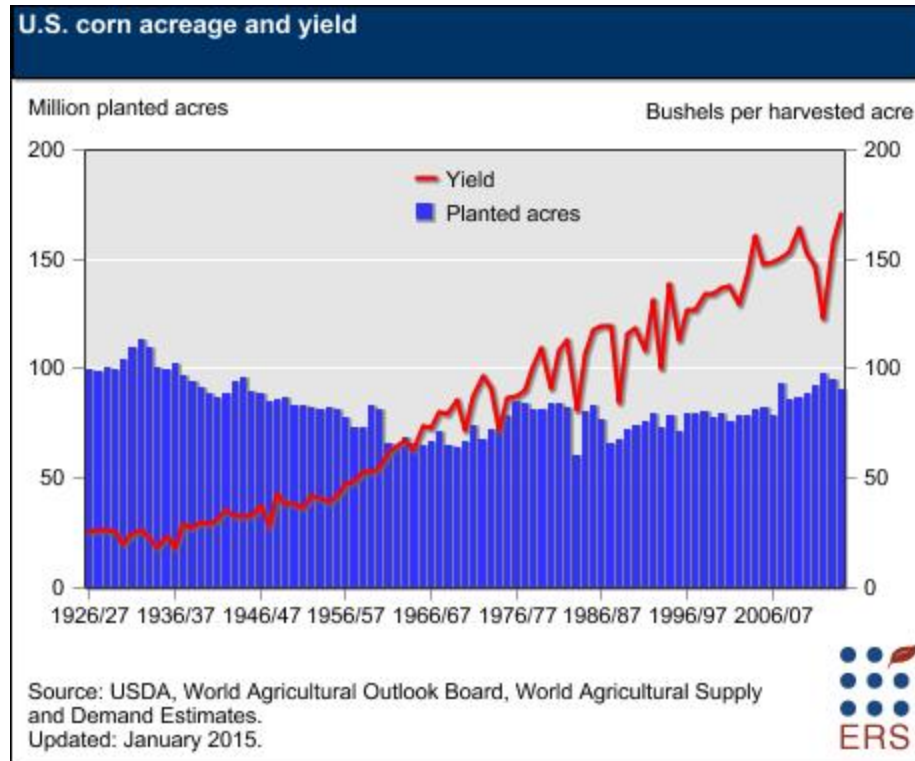


Figure 11. Corn Acreage and Yield from 1926 - 2014

Strong demand for ethanol production has resulted in generally higher market prices in recent years, and consequently, the incentive to increase corn acreage (USDA-ERS 2015c). In many cases, farmers have increased corn acreage by adjusting crop rotations between corn and soybeans, resulting in a decrease in soybean plantings. Other sources of land for increased corn plantings include cropland used as pasture, reduced fallow, acreage returning to production from expiring Conservation Reserve Program contracts, and shifts from other crops, such as cotton. In general, since 2006, U.S. corn planted acreage has increased as market prices have favored the planting of corn over alternative crops. However, ethanol production in the U.S., and demand for corn for ethanol (e.g., 35% of production), is projected to remain fairly steady through 2024/25, with most production using corn as the feedstock (Westcott and Hansen 2015).

Planting of GE corn has increased since the introduction of these varieties in the mid-1990s, accounting for over 89% of planted corn acres in the U.S. in 2013; a trend that is expected to continue (USDA 2015a). Rapid adoption of new GE corn varieties in the U.S. agricultural sector, and sustained production of these varieties, has resulted from several factors. When farmers adopt a new technology, they typically expect benefits such as increased farm net returns, time savings (by making corn production less intensive), or reduced exposure to chemicals (Fernandez-Cornejo, Klotz-Ingram et al. 2000) (Figure 12). Net benefits are a function of farm characteristics and location, output and input prices, existing production systems, and farmer abilities and preferences (Fernandez-Cornejo, Wechsler et al. 2014). Based on the 2010 Agricultural Resource Management Survey, farmers indicate that they adopted GE corn primarily to increase yields (71% surveyed), to save management time to facilitate other production practices (such as crop rotation and conservation tillage) (13%), and to reduce

pesticide input costs (7%)(Fernandez-Cornejo, Wechsler et al. 2014). The profitability of GE seeds for individual farmers depends largely on the value of the yield losses mitigated and the associated pesticide and seed costs.

Farmers' reasons for adopting genetically engineered crops

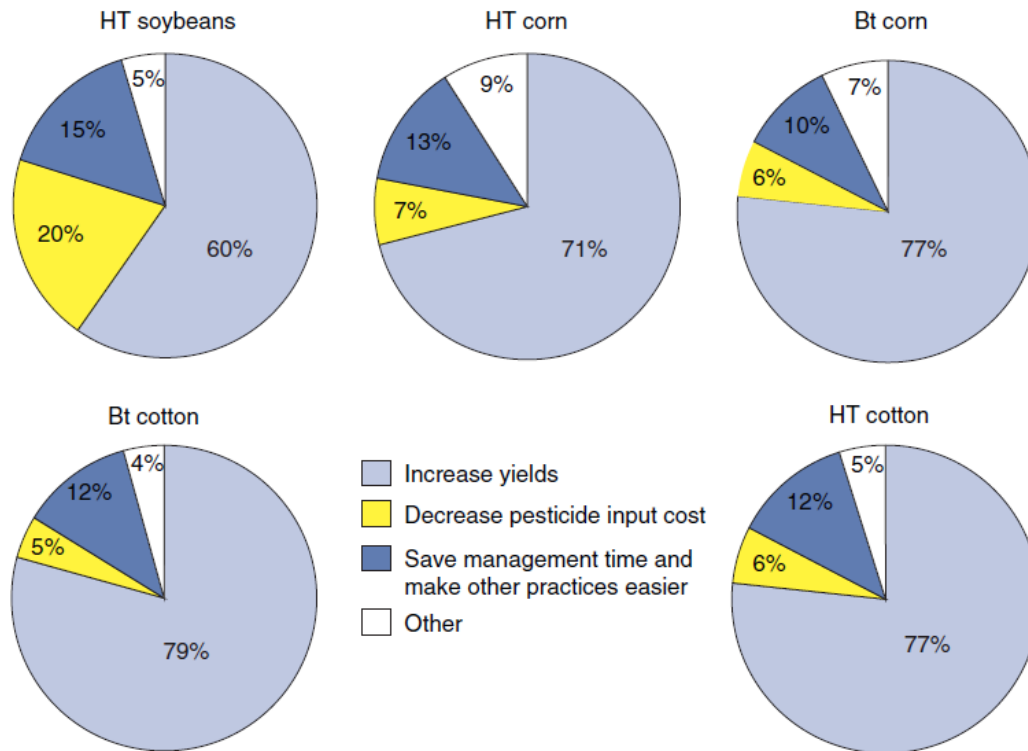


Figure 12. Common Reasons Growers Adopt GE Corn Varieties

Sources: (Fernandez-Cornejo, Wechsler et al. 2014); USDA Economic Research Service, USDA Agricultural Resource Management Survey (ARMS) Phase II surveys: 2010 for corn, 2007 for cotton, and 2006 for soybean.

The most widely and rapidly adopted bioengineered crops in the U.S. are those with herbicide-tolerant traits. These crops were developed to survive the application of specific herbicides that previously would have destroyed the crop along with the targeted weeds, and provide farmers a broader variety of herbicide options for effective weed control (Fernandez-Cornejo, Wechsler et al. 2014). Producers who plant HT crops expect to achieve at least the same yield while lowering weed control costs (e.g., chemicals and mechanical methods), and minimizing the need for weed scouting. In return, producers pay more for HT seeds. The price of GE soybean and corn seeds grew by about 50% in real terms (adjusted for inflation) between 2001 and 2010. (Fernandez-Cornejo, Wechsler et al. 2014).

In the absence of pests, commercially available GE seeds do not increase maximum crop yields. However, while the evidence of the impact of HT crops (for corn, cotton, and soybeans) on net returns has been somewhat mixed, the benefits appear to largely outweigh costs. The adoption of GE corn in the U.S. has generally reduced costs and improved profitability levels on the farm (Brookes and Barfoot 2013, Fernandez-Cornejo, Wechsler et al. 2014). These cost reductions

have been the result of reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs. The positive financial impact of adoption may also be due to seed companies setting lower premiums for herbicide-tolerant corn relative to conventional varieties in an attempt to expand market share. Other benefits to the grower from adoption of GE crops have included (Carpenter, Felsot et al. 2002, Brookes and Barfoot 2010):

- Reduced harvesting costs;
- Higher quality harvested crop;
- An improvement in soil quality as growers expand practices of limited tillage; and
- Overall improvements in human health costs associated with use of less toxic pesticides.

Relative to MZHG0JG corn, stacked-trait seeds have higher yields than conventional seeds or seeds with only one GE trait (Fernandez-Cornejo, Wechsler et al. 2014). USDA data indicate that conventional corn seeds had an average yield of 134 bushels per acre, while seeds with two types of herbicide tolerance (glyphosate and glufosinate) and three types of insect resistance (corn borer, corn rootworm, and corn earworm) had an average yield of 171 bushels per acre (Fernandez-Cornejo, Wechsler et al. 2014). Adoption rates of stacked-trait varieties have increased in recent years, with stacked-trait corn expanding from < 1% of planted acres in 2000, to 76% in 2014. GE varieties incorporating three or four traits are now common.

Weed Control Costs and Stacked Traits

Approximately 97% of U.S. acreage devoted to major crops was treated with herbicides in 2014 (USDA-NASS 2014d). Historically, adoption of a GE HT weed control system has reduced grower costs and increased profitability; however, an important concern currently facing U.S. farmers, including corn farmers, is the emergence of herbicide-resistant weeds; a result of the repeated, wide spread, and sometimes exclusive use of a single pesticide on corn, cotton, and soybean crops resistant to the pesticide, primarily glyphosate.

As of 2014, there were 14 different weed species with glyphosate-resistant populations, and 1 species resistant to glufosinate (Heap 2015). Stacked trait crops are planted to combat weed resistance, and stacked seeds are more costly. The extent to which HT adoption affects net returns is mixed and depends primarily on how much weed control costs are reduced and seed costs are increased. It may be possible that employment of management strategies utilizing crop rotation and stacked trait corn as a tool to manage weed density, could potentially decrease management costs and environmental impacts, and improve overall cropping system sustainability (Dunn 2009, Garrison, Miller et al. 2014).

Other recent analyses suggest that where weed management costs are higher with more intensive management with herbicides, reduced weed pressure resulted in a trend toward higher crop yields, which offset the higher weed management costs. It has also been noted that managing glyphosate resistance is more cost effective than ignoring it, and after about 2 years, the cumulative impact of the returns received is higher when managing instead of ignoring weed resistance (Livingston, Fernandez-Cornejo et al. 2015). Similarly, Weirich et al. investigated the effect of grower adoption of alternative glyphosate weed resistance management programs, finding weed resistance best management practices (BMPs) more costly, but provided similar

yields and economic returns (Weirich, Shaw et al. 2011). Findings from the study suggest that implementing weed resistance BMP systems net returns will be equivalent in the short run, and, in the long term, weed resistance BMP systems can result in substantial savings.

Despite the mixed but relatively minor effect HT crop adoption has had on overall herbicide usage, most researchers agree that the main effect of HT crop adoption has been the substitution of glyphosate for more traditional herbicides (NRC 2010, Fernandez-Cornejo, Wechsler et al. 2014). Because glyphosate is less toxic than many of the more traditional herbicides, the net impact of HT crop adoption has been an improvement in environmental quality and a reduction in the health risks associated with herbicide use. However, glyphosate resistance among weed populations in recent years may have induced farmers to raise application rates. Thus, weed resistance to glyphosate may be offsetting some of the economic and environmental advantages of HT crop adoption regarding herbicide use (NRC 2010, Fernandez-Cornejo, Wechsler et al. 2014, Fernandez-Cornejo and Osteen 2015).

Organic Corn Production

Growers can choose from a large number of conventional and organic corn hybrids produced from traditional breeding. As summarized previously, GE varieties of corn have been widely adopted during the past decade, and USDA recognizes that producers of non-GE corn, particularly producers who sell their products to markets sensitive to GE traits (e.g., organic or some export markets), desire to maintain the genetic purity of the crop product.

Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity. Insects, and farmers themselves, can also cause this type of cross-pollination. Either instance may result in economic losses to conventional or organic farmers. According to a Food and Water Watch survey, one third of surveyed organic farmers had dealt with contamination on their farms, and of those, over half had product rejected by their buyers for that reason (FWW 2014).

Practices to prevent contamination of non-GE corn include isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal cooperative communications between neighboring farms to ensure crop protection (Baier 2008, Roth 2011). These practices follow the same system utilized for the cultivation of Certified seed under the Association of Official Seed Certifying Agencies (AOSCA) procedures. During the cultivation period, cross-pollination is managed by recognizing corn pollen dispersal patterns and maintaining adequate distances and controls between fields (Mallory-Smith and Sanchez Olguin 2011).

Organic systems are usually certified organic according to USDA National Organic Program standards (USDA-AMS 2015c). In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic". Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. The NOP requires organic production operations to have a management plan approved by an accredited certifying agent, which may include measures such as distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations also must develop and maintain an organic production system plan approved by their accredited certifying agent to prevent genetic commingling due to pollen flow, as well as post-harvest commingling. Plans under the approved operating system enable the production operator to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. In NOP organic systems, the use of GE crops is excluded.

Organic corn in particular carries a price premium. While organic corn accounted for only 0.3% of total 2011 corn acres, acres planted to organic corn nearly tripled between 2001 and 2010. In contrast, total corn acres increased only 11% during the same period. The growth in organic corn acres was likely the result of high returns to organic corn production, but its share in total corn acres remains low possibly due to fixed costs and 3 years of time needed to convert land from conventional to organic production. Data from USDA-ERS and the 2010 Agriculture Management Resource Survey (ARMS) were used to compare costs and production practices for organic and conventional producers planting at least 1 acre of corn with the intent of harvesting it for grain. Producers saw average returns of \$307 per acre for conventional corn compared with \$557 per acre for organic corn in 2010. The gross value of production per acre from organic corn exceeded that from conventional corn in 2010, due primarily to higher organic corn prices that outweighed the effects of lower yields (Foreman 2014a).

Although organic yields tend to be lower than conventional corn yields, around some 80% (de Ponti, Rijk et al. 2012, Ponisio, M'Gonigle et al. 2015), net returns from organic acres continue to be greater than that from conventional acres, with a around a 60% premium received for organic corn growers reported in 2010 (USDA-ERS 2015e).

Similar to the production of conventional seed, industry quality standards for specialty crop products have led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops. Common practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen (NCAT 2003).

Considering producers of non-GE corn have available production and handling strategies in place to ensure that their product meets standards specified either in the USDA NOP regulations or through contracts, as relevant, USDA assumes that producers of non-GE corn will use practices to protect their crop from GE pollen and seed in order to maintain certification and price premium.

2.6.2 Trade Economic Environment

Corn is the dominant feed grain traded internationally, and in 2014, the U.S. produced approximately 36% of the total world corn supply (USDA-FAS 2015). Corn exports in recent

years have accounted for about 20% of U.S. production, although corn is expected to gain an increasing share of world coarse grain trade, with its market share of global trade projected to grow to almost 45% by 2024/25 (Westcott and Hansen 2015). Trade competition from Argentina, Brazil, and the former Soviet Union, as well as continued use of corn for ethanol production in the U.S. are anticipated to combine to hold the U.S. trade share below its 1970-2000 average of 71% (Westcott and Hansen 2015).

As the global demand for meat increases, so does the demand for livestock feed. The projected increase in U.S. corn exports over the next decade is largely due to a strong global demand for feed grains in support of meat production, particularly in those countries where climate and geography restrict local production of these feed materials. Almost no growth is projected for corn-based ethanol production over the next 10 years, with food and industrial demand for corn projected to rise at a moderate pace (Westcott and Hansen 2015).

In general, corn grain exports represent a principal source of demand for U.S. producers and make the largest net contribution to the U.S. agricultural trade balance of all the agricultural commodities, reflective of the importance of corn exports to the U.S. economy.

Identity protection is important in international trade. The low level presence (LLP) and adventitious presence (AP) of GE corn in internationally traded conventional or organic food and feed crops are important considerations in the trade of corn. Asynchronous Approvals (AA) and zero tolerance policy can result in the diversion of trade by some of exporters, and rejection or market withdrawals by importers of corn (e.g., see (FOEU , Frisvold 2015, WTO 2015)). Consequently, incidents of LLP or AP can lead to income loss for exporters and consequently for producers, and consumers in importing countries can potentially face higher domestic corn prices when import is deterred or directed to another trading partner (Atici 2014).

The challenges associated with maintaining variety identity in international trade can increase costs, as well as the premiums paid, for some GE crops. GE corn is excluded by some countries sensitive to the importation of GE crops, and other countries may lag approval of new GE corn varieties. In general, LLP or compromise of corn identity can cause disruptions in international trade when GE corn is inadvertently incorporated into food or feed grain shipments, or specialty corn fractions such as corn gluten. As such, GE crop producing countries are required to take those measures necessary in the production, harvesting, transportation, storage, and marketing of GE crops to avoid the potential for LLP in conventional or organic crops.

Syngenta initiated the FDA consultation process for use of MZHG0JG corn as food and feed in U.S. commerce in 2015, and additional regulatory approvals that facilitate global trade of MZHG0JG corn commodities will be sought on an as-needed basis.

3 ALTERNATIVES

To respond favorably to Syngenta's request for extension of nonregulated status to MZHG0JG corn, APHIS must determine that MZHG0JG corn is unlikely to pose a plant pest risk. Based on the PPRSA, USDA-APHIS has reviewed and analyzed the information submitted in the extension request by Syngenta (Davis et al., 2015), and has concluded that MZHG0JG corn is unlikely to pose a plant pest risk. Before the Agency can conclude that MZHG0JG corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA, it must also analyze the potential environmental consequences resulting from a determination of nonregulated status of MZHG0JG corn, which is the purpose of this EA.

Two alternatives are evaluated in this EA: (1) No Action, which is continuation of MZHG0JG corn as a regulated article; and (2) extension of nonregulated status for MZHG0JG corn. APHIS has assessed the potential for environmental impacts for each alternative in Section 4 - Environmental Consequences.

Syngenta has indicated its intention to develop stacked-trait hybrid corn varieties with MZHG0JG corn through conventional breeding techniques (Davis, Jarrett et al. 2015). In this process, the HT traits in MZHG0JG corn would be combined with the traits from other corn varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. APHIS does not have authority under the PPA and 7 CFR part 340 to review such stacked-trait hybrids developed using nonregulated articles and conventional hybridization techniques if there is no evidence of a plant pest risk. Therefore, this EA focuses on the commercial production of MZHG0JG corn for food, feed, fiber, and fuel. Relevant issues related to impacts that might be associated with stacking traits are reviewed in the cumulative impacts analyses of this EA (Section 5).

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the request for extension. MZHG0JG corn and progeny derived from MZHG0JG corn would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MZHG0JG corn and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MZHG0JG corn. This alternative is not the Preferred Alternative because APHIS has concluded through a PPRSA that MZHG0JG corn is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the request to extend determination for nonregulated status.

3.2 Preferred Alternative: Determination that MZHG0JG Corn is No Longer a Regulated Article

Under this alternative, MZHG0JG corn and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340 because APHIS determined that

MZHG0JG corn is unlikely to pose a plant pest risk. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MZHG0JG corn and progeny derived from it.

This alternative best meets the purpose and need to respond appropriately to a request for extension for nonregulated status when there is a determination of no pest risk. Because the agency has determined that MZHG0JG corn is unlikely to pose a plant pest risk, a decision of nonregulated status for MZHG0JG corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to MZHG0JG corn and progeny derived from this event if the developer decides to commercialize MZHG0JG corn.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MZHG0JG corn. The agency evaluated these alternatives, in light of the Agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MZHG0JG corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MZHG0JG Corn from Being Released

In response to public comments for other petitions requesting a determination of nonregulated status stating a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MZHG0JG corn, including denying any permits associated with field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk.

In enacting the PPA, Congress included findings that directed (§402(4); 7 U.S. C. §7701(4)) that: “decisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science;...”

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

“Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency;...”

Based on the PPRSA and the scientific data evaluated therein, APHIS determined that MZHG0JG corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MZHG0JG corn.

3.3.2 Approve the Request for Extension in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a request. Because APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the request for extension only in part.

3.3.3 Isolation Distance between MZHG0JG Corn and Non-GE Corn Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MZHG0JG corn from conventional and specialty corn production. However, because APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk, an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of MZHG0JG corn based on the location of production of non-GE corn in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in the Agency's PPRSA for MZHG0JG corn, there are no geographic differences associated with any identifiable plant pest risks for MZHG0JG corn. This alternative was rejected and is not analyzed in detail because APHIS has determined that MZHG0JG corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with the Agency's statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing factors, the imposition of isolation distances or geographic restrictions would not meet the Agency's purpose and need to respond appropriately to a request for extension based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from MZHG0JG corn or to use isolation distances and other management practices to minimize gene movement between corn fields. Similarly, growers of MZHG0JG corn may choose to implement crop isolation measures in production of MZHG0JG corn. Information to assist growers in making informed management decisions for MZHG0JG corn is available from the Association of Official Seed Certifying Agencies (AOSCA 2015).

3.3.4 Requirements of Testing for MZHG0JG corn

During comment periods for other petitions requesting a determination of nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because MZHG0JG corn does not pose a plant pest risk, the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MZHG0JG corn would not meet APHIS' purpose and need to respond appropriately to the request for extension in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 6 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 6. Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials.	Satisfied by plant pest risk similarity assessment
Management Practices		
Acreage and Areas of Corn Production	Minor yearly fluctuations with little increase or decrease in acreage currently used, no new regions of planted corn are expected (Westcott and Hansen 2015).	Unchanged from No Action Alternative
Agronomic Practices	Practices are expected to remain essentially the same as current, with possible expansion of crop rotation and conservation tillage practices as part of increased implementation of integrated weed management strategies.	Unchanged from No Action Alternative
Pesticide Use	Herbicide use patterns are unlikely to substantially change, though minor shifts in use of current herbicides may occur as required for grower needs. EPA approves and labels uses of herbicides on corn.	No substantial differences as compared to the No Action Alternative. An increased use of glufosinate may result with MZHG0JG corn commensurate with grower adoption of this cultivar.
Corn Seed Production	Will fluctuate annually to meet grower and market demand.	Unchanged from No Action Alternative

Table 6. Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Organic Corn Production	Production of organic corn is not expected to substantially change; increases or decrease will be commensurate with market demand.	Unchanged from No Action Alternative
Physical Environment		
Soil Quality	Growers will continue or adopt management practices, such as crop rotation, tillage, and pest and weed management strategies, to address their specific needs in maximizing crop yield and quality.	Unchanged from No Action Alternative, MZHGOJG corn is not expected to have any effect on soil quality
Water Resources	The primary source of agricultural NPS pollution is soil erosion, which can introduce sediments, fertilizer, and pesticides to aquatic ecosystems. It is expected that growers will adopt management practices to conserve water and soil, and mitigate soil erosion and run-off, with associated reductions in potential impacts on water quality.	Unchanged from No Action Alternative
Air Quality	Agricultural activities such as burning, tilling, spraying pesticides, and fertilizing, including emissions from farm equipment, can adversely affect air quality. In EPA designated nonattainment areas, there will be pressures to attain regional air quality standards. Increased efficiencies in use of pesticides and fertilizers, and conservation tillage practices, would mitigate impacts on air quality.	Unchanged from No Action Alternative
Climate Change	Primary GHG emissions from corn production are PM and N ₂ O, with lesser amounts of CO ₂ . GHG emissions have remained relatively steady over the last 20 years, a trend that would be expected to remain constant, with slight increases or reductions possible (EPA 2013b).	Unchanged from No Action Alternative
Biological Resources		
Animal Communities	Corn fields are host to many species, some of which may be controlled by	Unchanged from No Action Alternative

Table 6. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	the use of integrated pest management strategies. Currently available glufosinate-tolerant and glyphosate-tolerant crops do not have substantial impacts on impact wildlife. EPA regulates herbicides applied to HT corn and determines uses that do not pose unacceptable risk to non-target organisms.	
Plant Communities	Non-crop plants in corn fields are considered weeds and growers use production practices to manage weeds in and around fields. EPA regulates and determines use requirements for herbicides that are expected to be protective of non-target species. Current EPSPS and PAT trait crops pose negligible risk to plants.	Unchanged from No Action Alternative
Gene Flow and Weediness	Cultivated corn varieties can cross pollinate. Growers and seed-corn producers use various management practices to eliminate undesired cross pollination. Corn plants present negligible risk for weediness.	Unchanged from No Action Alternative. MZHG0JG corn would not be expected to have any effect on horizontal or vertical gene flow.
Microorganisms	Microorganisms are not substantially affected by corn production practices. EPA regulates herbicides applied to HT corn and determines whether the herbicides, including those subject of this EA, pose an unacceptable risk or impact on non-target organisms, including soil microorganisms.	Unchanged from No Action Alternative
Biodiversity	Commercial corn fields are highly managed and as such, biological diversity is generally lower than in unmanaged habitats. Currently available glyphosate and glufosinate-tolerant corn cultivars are not known to have any substantial affect biodiversity.	Unchanged from No Action Alternative
Human and Animal Health		
Risk to Human Health	FDA regulates food and feed safety.	Unchanged from No Action Alternative

Table 6. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	EPA regulates use of glyphosate and glufosinate; both herbicides have been determined to present no risk to human health when used according to EPA requirements. EPSPS and PAT proteins have histories of safe use, and present no risks to humans.	
Worker Safety	EPA regulates use of glyphosate and glufosinate. When used consistent with label requirements, these herbicides have been determined to present minimal risk to the health and safety of workers.	Unchanged from No Action Alternative
Risk to Animal Feed	Corn is a primary feed and protein source for animal nutrition, and expected to remain to as such. Neither the EPSP nor PAT proteins currently used in GE corn based feed are harmful to animals.	A compositional analysis concluded that MZHG0JG corn is compositionally similar to non-GE comparator corn hybrids. MZHG0JG corn presents no changes to animal nutrition as compared to other corn.
Socioeconomic		
Domestic Economic Environment	U.S. demand and supply of corn, GE-corn and non-GE corn, is not expected to substantially change over the next decade (Westcott and Hansen 2015). Returns from organic corn have exceeded those for conventional corn (inclusive of GE-corn) in recent years. If returns from organic corn production continue to remain high, further expansion in organic corn acres could occur in future years (Foreman 2014a).	MZHG0JG corn would present a stacked-trait herbicide-tolerant corn option to growers, and could potentially replace other corn varieties, where economically beneficial to do so. The domestic economic environment would be unchanged on introduction of MZHG0JG corn.
Trade Economic Environment	U.S. corn and corn products will continue to play a major role in global corn production and supply. The primary U.S. corn export destinations are also the largest world importers of corn and do not have major barriers for importing food or feed commodities produced from GE-crops. Import of each specific GE-trait requires approval by the importing country.	U.S. trade associated with a determination of nonregulated status of MZHG0JG corn would be expected to be unchanged as compared to the No Action alternative. Syngenta will seek international regulatory approvals that facilitate global trade of MZHG0JG corn on an as-needed basis.

Table 6. Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Other Regulatory Approvals		
U.S.	FDA consultations for MZHG0JG corn initiated in 2015. EPA tolerance exemptions for EPSPS and PAT granted in 2007. Herbicides with label use restrictions for glyphosate and glufosinate are registered with EPA.	Unchanged from the No Action Alternative
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 Environmental Consequences

Analysis of potential environmental consequences addresses the potential impacts to the human environment that may derive from the alternatives considered in this EA, namely; taking no action, and a determination by the agency that MZHG0JG corn does not pose a plant pest risk (Preferred Alternative).

An impact would be any change, beneficial or adverse, from the existing (baseline) conditions described in Section 2 - Affected Environment. Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples could include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples could include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from a change in herbicide use. Potential cumulative impacts are described in Section 5.

4.1 Scope of Analysis

The primary focus of analysis reported in this section is on the possible environmental impacts that may derive from the stacked GE traits in MZHG0JG corn, i.e., expression of mEPSPS and PAT proteins, which confer tolerance to glyphosate and glufosinate, respectively. In considering potential environmental consequences, it is noted that MZHG0JG corn contains traits from GE corn varieties that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. APHIS utilizes data and information submitted by Syngenta, in addition to current literature, to determine if MZHG0JG corn is any more likely than currently unregulated corn varieties to present risks to the human environment. APHIS considers VCO-Ø1981-5 corn, GA21 corn (OECD Unique Identifier MON-ØØØ21-9), Pioneer 4114 maize (OECD Unique Identifier DP-ØØ4114-3), and Bt11 corn (OECD Unique Identifier SYN-BTØ11-1), all of which were previously reviewed by USDA, and found not to pose a plant pest or other environmental risks, and currently unregulated corn varieties (described in Subsection 1.1 – Background).

By example, the mEPSPS produced in MZHG0JG corn is identical to the mEPSPS produced in GA21 corn (OECD Unique Identifier MON-ØØØ21-9), which was first introduced to the market in 1998 and has a history of safe use. GA21 corn was the subject of APHIS Petition No. 97-099-01p for determination of nonregulated status, which was granted November 18, 1997. Event Bt11 corn was the subject of APHIS Petition No. 95-195-01p for the determination of nonregulated status, which was granted July 18, 1996. The PAT produced in MZHG0JG corn is identical to the PAT produced in Event Bt11 corn (OECD Unique Identifier SYN-BTØ11-1), which was first introduced to the market in 1997. Both of these traits have been combined into stacked varieties of GE corn that APHIS has previously analyzed and determined not to have impacts on the human environment (USDA-APHIS 2007, USDA-APHIS 2013, USDA-APHIS 2015). A list of commercially available nonregulated U.S. corn products containing the mEPSPS and PAT proteins can be found in the CropLife International BioTradeStatus Database (CLI 2015a), as well as at the APHIS Biotechnology website (USDA-APHIS 2015).

Accordingly, this EA considers the potential environmental impacts of MZHG0JG corn in the context of previously considered GE corn varieties sharing the mEPSPS and PAT traits, and that have been in commercial production since the late 1990s. For the discussion of potential environmental consequences, the following principal areas of potential concern are addressed:

- Agricultural Production of Corn
- Physical Environment
- Biological Resources
- Human Health and Worker Safety
- Animal Feed
- Socioeconomics

The potential environmental consequences of both the No Action and Preferred Alternative are analyzed under the assumption that the geographic distribution of corn-growing regions of the U.S. will not change, and that farmers who produce conventional corn, specialty corn, organically certified corn and/or MZHG0JG corn will use currently accepted best management practices in the production of corn.

4.2 Agricultural Production of Corn

Over the years, corn production has resulted in well-established management practices used in the cultivation of both organic and conventional corn varieties, including GE corn varieties. Factors in crop production include planting dates; seeding rates; harvest times; soil type and fertility; soil management; weed and pest management; type of corn hybrid produced; market prices for corn; and agronomic input costs.

Growers may utilize various resources providing current management and market information for the efficient production of corn, such as those provided through local Cooperative Extension Service offices and their respective websites, the USDA Regional Integrated Pest Management (IPM) Centers Information Network, Association of Official Seed Certifying Agencies (AOSCA), National Corn Growers Association, and similar bodies assisting in the sustainable production of corn.

4.2.1 Acreage and Area of Corn Production

Corn is an economically important commodity and the most abundant crop planted and harvested in the U.S. In 2012, approximately 915 million acres of U.S. land was farmland, which comprised just over 40% of all U.S. land (USDA-NASS 2014c). Of the 915 million acres: 45.4% was permanent pasture, 42.6% was cropland, and 8.4% was woodland. The remaining 3.6% was land in farmsteads, buildings, livestock facilities, etc. (USDA-NASS 2014c). Over the last seven years, around 85 to 95 million acres of corn have been harvested in the U.S. on an annual basis, a trend that is expected to continue through 2024/25 (USDA-NASS 2014f, Westcott and Hansen 2015).

No Action Alternative: Acreage and Area of Corn Production

Under the No Action Alternative, MZHG0JG corn would only be grown in APHIS regulated field trials. Existing trends in U.S. corn production would be unaffected by this alternative. Corn will continue to be commercially cultivated in the U.S., most of production continuing to be centered in the Corn Belt. USDA projections for corn acreage and production through 2024/25 would be the expected conditions under the No-Action Alternative (Westcott and Hansen 2015): a decision to continue to regulate MZHG0JG corn would have no impact on USDA projections for the area and acreage required for of U.S. corn production over the next decade.

Preferred Alternative: Acreage and Area of Corn Production

Under the Preferred Alternative, nonregulated status of MZHG0JG corn is not expected to require an increase the area of U.S. corn production relative to the No Action Alternative. MZHG0JG corn, which is tolerant of the herbicides glyphosate and glufosinate-ammonium, would be expected to expand currently available options and strategies in the production of GE corn. Upon introduction of MZHG0JG corn, this variety could be combined, through traditional breeding methods, with insecticidal or herbicide-tolerant traits in other deregulated corn varieties that could protect against yield loss from lepidopteran and/or coleopteran pests, and facilitate weed control. These next-generation stacked-trait corn products may offer the ability to improve production efficiency, enhance grower choice, and manage pests and weeds.

Cultivation practices required for MZHG0JG corn are indistinguishable from those of other corn varieties (Davis, Jarrett et al. 2015), and MZHG0JG corn, if adopted by growers, would be expected to replace other corn varieties currently cultivated, as opposed to augmenting current corn crops. Under the Preferred Alternative, there would be no changes in the agronomic production of MZHG0JG corn, nor an increase corn acreage, or the area where corn is cultivated in the U.S. In terms of potential impacts on the areas and acreage of corn production in the U.S., there would be no difference between the Preferred Alternative and No Action Alternative.

4.2.2 Agronomic Practices

As summarized in Subsection 2.1.2, agronomic practices such as tillage, crop rotation, and fertilizer and pesticide inputs have substantial effects on the yield and quality of corn crops. These practices can also have environmental impacts, such as on air and water quality, and biological resources. The agronomic practices employed by corn crop producer are dependent on factors such as trends in climate; weed, insect, and disease pressures; worker safety; potential for crop injury; ease and flexibility of the production system; cost of agronomic inputs; market pricing for corn commodities; and potential net returns on crop production.

No Acton Alternative: Agronomic Practices

Under the No Action Alternative, practices used the commercial production of GE and non-GE crop varieties such as tillage, crop rotations, agronomic inputs, and other practices described in Section 2 of this EA would continue along current trends, unaffected by this alternative. A decision to deny the MZHG0JG corn extension request for nonregulated status would have no impact on grower choices in managing the commercial production of corn in the U.S.

Corn growers will continue to select pesticide types based on weed, insect, and disease pressures; potential for crop injury; efficacy of the pesticide; costs of pesticide inputs; worker safety; and ease and flexibility in management of pests and weeds. Based on current data, herbicide use is expected to remain constant and insecticide use is anticipated to decline as more IR varieties are cultivated (Fernandez-Cornejo, Nehring et al. 2014a). Fungicide use, for both seed and crop treatment, could continue to increase (Robertson and Mueller 2007, Robertson 2007, Wise and Mueller 2011). The vast majority of corn acreage is treated with fertilizer. Since 1975, some 95% to 97% of acreage has been treated with nitrogen, with the rate of application increasing from around 110 to 140 lbs/acre from 1975 to 2014. Phosphate use has remained steady over this period, at ~ 80-85% of acreage, at a rate of 60 lbs/acre. The acreage treated with potash slightly declined since 1975 to currently around 60% of acres, where there application rate has remained steady at ~ 80 lbs/acre (USDA-ERS 2015d). These inputs would be unaffected by a decision to deny Syngenta's extension request.

Trends related to tillage and crop rotations are likely to continue as currently practiced. In general, since 2000, corn acreage under conservation tillage, particularly no-till, has increased, as well as continuous corn and corn-inclusive rotations (Fernandez-Cornejo, Nehring et al. 2014a). In 2012, farmers applied tillage practices on 278.8 million acres; this included no-till on 96.5 million acres, conservation tillage on 76.6 million acres, and conventional tillage on 105.7 million acres (USDA 2012). Market demand and commodity pricing will continue to influence crop rotation practices (e.g., corn to corn, or corn to soybean). Currently, around 84% of corn is farmed using alternate crop rotations, and 16% using continuous corn (corn-to-corn rotations) rotations.

Growers in many areas of the U.S. will likely encounter the continued emergence of glyphosate-resistant weeds, requiring implementation of integrated weed management (IWM) practices for adequate control (Weller, Owen et al. 2010, Owen 2011, Vencill, Nichols et al. 2012), described in Subsections 2.1.2 -Agronomic Practices: Tillage, Crop Rotation, and Agronomic Inputs, and 2.3.2 - Plant Communities. These practices involve techniques such as utilization of herbicides with differing modes of action, alternating annual application of the types of herbicides used, selecting and deploying herbicide mixtures, rotating crops, and using mechanical means to manage weeds (e.g., tillage).

Any potential for adverse environmental effects associated with crop rotation, tillage, pesticide and fertilizer use, in the agricultural production of seed corn and commercial corn will remain unchanged under the No Action Alternative.

Preferred Alternative: Agronomic Practices

Because MZHG0JG corn is similar to other GE and non-GE corn varieties in terms of growth habit, agronomic properties, composition, and environmental interactions (Davis, Jarrett et al. 2015), agronomic practices would not be substantially affected by determination of nonregulated status for MZHG0JG corn.

Growers employ production practices to maximize crop yield, quality, and net returns, and would alter these practices in response to the need to maintain maximum yield and net returns in corn production, and reduce the potential for environmental impacts. A determination of nonregulated

status for MZHG0JG corn would make available to growers a stacked-trait corn variety tolerant of glyphosate and glufosinate. MZHG0JG corn would offer growers an additional cultivar of herbicide-tolerant corn that may provide more flexibility in weed management programs. Growers would adopt and continue use of this corn variety to the extent it provided optimal crop yields, product quality, and net returns.

Any changes in agronomic practices related to MZHG0JG corn would be related to the rates, quantities, and types of herbicides used. Increases in the annual use of glufosinate may occur in production of MZHG0JG corn, relative to adoption rates, with use volumes and restrictions regulated by the EPA. A determination of nonregulated status for MZHG0JG corn is unlikely to result in an increase in glyphosate use in U.S. corn production because MZHG0JG corn would be used to replace other GR corn varieties (namely single-trait); there are no proposed label changes for glyphosate use associated with MZHG0JG corn; and, as described above, there are no anticipated increases in the acreage for U.S. corn production over the next 10 years (Westcott and Hansen 2015).

Stacked-trait varieties such as MZHG0JG corn have become the dominant corn crops in the U.S., largely due to the broader range of weed management strategies provided by these varieties. Trends related to the development, management, and mitigation of GR-resistant weed populations are not anticipated to be substantially different under the Preferred Alternative. In the long-term, trends in the development of GR weeds may decrease under use of stacked-trait corn varieties such as MZHG0JG corn utilizing herbicides with differing modes of action, in conjunction with implementation of IWM strategies (Gibson, Young et al. 2015).

4.2.3 Organic Corn Production

While organic corn accounted for less than 1% of total 2010 corn acres, acres planted to organic corn nearly tripled between 2001 and 2010. In contrast, total U.S. corn acres increased only 11% during the same period (Foreman 2014b). Where current certified organic corn acreage in the U.S. is substantially less than that of conventional and GE corn acreage, approximately 234,000 acres or 0.25% of corn acres planted for grain in 2011 (USDA-NASS, 2012a), and organic corn yields (i.e., bushels per acre) tend to be less than conventional or GE crops, the profit per acre of organic corn can be substantially greater, due to the price premium organic growers receive for their products in the U.S. market.

Over 25,000 farmers, ranchers, and other businesses derive many benefits from USDA organic certification. Many receive premium prices for their products through the growing \$35 billion U.S. organic retail market (U-Minn 2010, USDA-ERS 2015e). Most operations that grow, handle, or process organic products, and want to market their products as organic, must be USDA certified (USDA 2015c).

Cross-pollination of corn can occur naturally among all varieties of corn in commercial production. The natural cross-pollination of GE corn with organic corn is a concern for some organic growers, particularly those with USDA certification in proximity to GE cropping systems. Organic production plans prepared pursuant to the National Organic Program (NOP) require practical methods to protect organically-produced crops from accidental contamination with GE materials (USDA-AMS 2015c, USDA 2015c). Typically, organic growers use more

than one method to maintain the genetic identity of their crop, including: isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal communications between neighboring farms (NCAT 2003, Roth 2011, USDA-AMS 2015c). These types of practices are also utilized for the cultivation of Certified corn seed under AOSCA (AOSCA 2015).

No Action Alternative: Organic Corn Production

Under the No Action Alternative, MZHG0JG corn can only be grown in USDA-APHIS regulated field trials, and existing trends in organic corn would be unaffected. Farmers and consumers would have continued access to current nonregulated GE corn, conventional corn, and organic corn varieties, and organic corn production and consumption would be expected to continue along current trends. Organic corn producers would continue to be able to use a variety of measures to manage crop identity, preserve the integrity of their production systems, and maintain organic certification (NCAT 2003, AOSCA 2015, USDA-AMS 2015c, USDA 2015c). This would not alter under the No Action Alternative.

Production of GE, non-GE, and organic corn and corn products would continue to fluctuate with market demands, and GE and conventional corn production will likely follow USDA projections through 2024/25 (Westcott and Hansen 2015). Organic corn production may increase, if trends in market price premiums sustain or increase (de Ponti, Rijk et al. 2012, Ponisio, M'Gonigle et al. 2015, USDA-ERS 2015e). Denial of the extension request for nonregulated status of MZHG0JG corn would have no reasonably foreseeable impact on organic corn production.

Preferred Alternative: Organic Corn Production

Under the Preferred Alternative, the trend in the cultivation of GE corn, non-GE, and organic corn varieties, as described previously, and the corresponding production practices to maintain varietal integrity, would be expected to remain the same as those under the No Action Alternative. MZHG0JG corn has been determined to be similar in its composition, growth habits, and cultural requirements to its comparators and other nonregulated corn varieties (Davis, Jarrett et al. 2015). Based on compositional analyses and the agronomic similarity, MZHG0JG corn would be expected to present no greater risk of cross-pollination with organic and other non-GE or GE corn cultivars currently in commercial production.

Considering producers of non-GE corn, and GE corn, have available production and handling methods to ensure that their product meets standards specified either in the USDA NOP, AOSCA (NCAT 2003, AOSCA 2015, USDA-AMS 2015c, USDA 2015c), or through contracts, as relevant, APHIS assumes that producers of GE and non-GE corn will use these practices to protect their crops from pollen and seed in order to maintain crop identity and certification as applicable, to ensure the sustainability of their production system, and price premiums in the market. MZHG0JG corn would have no impact on these practices, nor present a greater risk of cross-pollination than any other commercial corn variety. Accordingly, a determination of nonregulated status of MZHG0JG corn would not substantially differ from that of the No Action Alternative in regard to organic corn production.

Specialty Corn Production

No-Action Alternative: Specialty Corn Production

Specialty corn growers employ practices and standards for seed production, cultivation, product handling and processing similar to those for organic corn production to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford 2006). These management practices include maintaining isolation distances to prevent pollen movement from other corn crops, planting border or barrier rows to intercept pollen, changing planting schedules to ensure flowering at different times, and employing natural barriers to pollen (Wozniak 2002, Bradford 2006, Iowa-State 2013, AOSCA 2015). Denial of the extension request for nonregulated status of MZHG0JG corn would have no impact on the cultivation of specialty corn crops.

Preferred Alternative: Specialty Corn Production

No changes in the production or cultivation of specialty corn are required to accommodate MZHG0JG corn, as it is phenotypically and agronomically similar to conventional corn, and GE-corn varieties currently in commerce (Davis, Hill et al. 2012). Consequently, the risk of cross-pollination from MZHG0JG corn is expected to be similar to, or same as, existing corn cultivars, both GE and non-GE corn varieties. Standard management practices and procedures, as described previously for corn and corn seed production, identity protection, and organic corn farming, are in place to protect and maintain the genetic identity of corn crops. Corn growers have and are expected to use these methods to effectively meet the standards for the production of specialty crop seed. Therefore, selection of the Preferred Alternative would not substantially differ in affect from that of the No Action Alternative, and no change in the availability and genetic purity of seed for specialty corn varieties would be expected.

4.3 Physical Environment

4.3.1 Soil Quality

Maintaining soil fertility is a principal component of sustainable corn production, and major determinant of crop yield and product quality. Fertilizer and pesticide inputs, tillage, and irrigation practices, can potentially affect soil quality, and in turn air and water quality. Tillage practices in particular, along with fallow and crop rotation practices, can affect the erosional capacity of soils. Beneficial microorganisms, which are major determinants of soil fertility, can also be affected by agronomic practices. Potential impacts on soil microorganisms are discussed in Subsection 4.4.4 –Microorganisms.

No Action Alternative: Soil Quality

Current agronomic practices associated with corn production including tillage, crop rotations, applications of pesticides and fertilizers, and irrigation are not expected to substantially change under the No Action Alternative. Consequently, potential impacts on soil quality, both beneficial and adverse, would be expected to continue under current trends, and unaffected by denial of the extension request.

As for current trends: IWM practices can sustain or improve soil quality through efficient use of fertilizers and pesticides; use of cover crops to limit the time soil is exposed to weathering; crop rotations; and conservation tillage practices (USDA-NRCS 2006b). However, if herbicide-resistant weeds become problematic to the production of a corn crop, and other strategies are not effective, growers may have to consider more aggressive tillage practices, which can potentially impact soil quality and erosional capacity (Owen 2008, Owen 2011, Vencill, Nichols et al. 2012, USDA-NRCS 2015d).

The development of glyphosate-resistant (GR) weeds is likely to increase in some areas of the U.S. (Livingston, Fernandez-Cornejo et al. 2015). GR weeds are expected to continue to be a concern in the Southeast region (e.g., (Hollis 2015)), and the expansion of resistance into the Great Plains, Northern Crescent, and Heartland regions would require modifications of crop management practices to address GR weeds, which can affect soils (Owen 2011). These practices may include diversifying application of herbicides with different modes of action, making adjustments to crop rotation and tillage practices, and utilizing integrated weed management (IWM) strategies (Weirich, Shaw et al. 2011, Harker and O'Donovan 2013, Garrison, Miller et al. 2014). There are currently 14 glyphosate-resistant weed species have been documented in U.S. crop-production areas, and glufosinate has one known resistant weed species (Heap 2015).

The total acreage that could be impacted by an increase in tillage would be based on the extent of resistant weeds that occur in corn production systems, and the weed management strategies utilized by various growers. The particular mix of weed management tactics selected by an individual producer would be dependent upon a variety of factors, including the local ecology, the extent and type of problem weed, crop production costs, and other agronomic practices required to maximize crop yield. Currently, most corn growing states have between 7 to 26 different species of weeds that are herbicide resistant (Heap 2015).

Where expansion of GR weeds may result in impacts to soils, it is also possible expansion of GR weed biotypes, the range of GR weeds, may be mitigated through IWM practices and diversifying cropping systems (e.g., (Davis, Hill et al. 2012, Gibson, Young et al. 2015)).

Preferred Alternative: Soil Quality

Approving the extension request for a determination of nonregulated status of MZHG0JG corn, soil quality in U.S. corn fields is unlikely to be substantially affected where MZHG0JG corn is grown. MZHG0JG corn is compositionally, agronomically, and phenotypically equivalent to commercially cultivated corn, and the environmental interactions of MZHG0JG corn are same as or similar to conventional corn (Davis, Jarrett et al. 2015). Consequently, no changes to agronomic practices typically applied in the production of corn are required for MZHG0JG corn, and potential impacts on soil quality are not expected to change with the commercial cultivation of MZHG0JG corn.

As discussed above, weed management will continue to be an important aspect of corn production for farmers across the U.S. MZHG0JG corn could provide growers with alternatives to currently available single-trait glyphosate-tolerant corn varieties, which may expand the weed-management options available to growers. These additional options for weed control could

facilitate use of more diverse integrated weed management strategies employing crop rotations and conservation tillage, which can help preserve soil quality and reduce erosional capacity (Behrens, Mutlu et al. 2007, Harker and O'Donovan 2013, Garrison, Miller et al. 2014, Livingston, Fernandez-Cornejo et al. 2015).

MZHG0JG corn would likely replace other commercially available glyphosate-tolerant corn cultivars, primarily single-trait varieties. Stacked corn varieties reached 76% of corn plantings in 2014, and this trend is expected to continue as part of expansion of integrated weed management strategies in U.S. corn production systems (Brookes 2014, CLI 2015b, Westcott and Hansen 2015). Where the trend in stacked-trait corn varieties is increasing, the area and acreage of corn production potentially impacting soil quality is not expected change as a result of a determination of nonregulated status of MZHG0JG corn (Westcott and Hansen 2015).

Under the Preferred Alternative the EPSPS and PAT nucleic acids and proteins associated with MZHG0JG corn would be present in the environment. However, these nucleic acids and their protein products are naturally occurring in soil bacteria, worldwide. Both of these nucleic acids and their protein products have been cultivated in commercial GE corn varieties for over a decade, with no effect on soil quality, and are well recognized as environmentally benign (ILSI-CERA 2011a, ILSI-CERA 2011b). Consequently, MZHG0JG corn derived EPSPS and PAT would not be expected to adversely affect soil quality.

Glyphosate and glufosinate are currently registered and labeled for use as preplant and post-emergence herbicides in corn production. Use of these herbicides on MZHG0JG corn would be regulated by EPA pursuant to FIFRA, the FFDCA, and FQPA, and these use restrictions would not substantially differ from those of the No Action Alternative.

4.3.2 Water Resources

Corn is a water-sensitive crop with a low tolerance for drought, and many areas where corn is grown, primarily in the Midwest, require irrigation to sustain crop yield and quality. As discussed in Subsection 2.2.2, Water Resources, agricultural run-off and the introduction of soil sediment, nutrients, and pesticides into surface waters can adversely impact water quality and a concern in many areas of the U.S. Of these, sediments and nutrient loading are the principal concerns in corn production, although pesticides will always remain a monitored agronomic input due to potential adverse effects on both aquatic and terrestrial biota.

In 2010, fertilizer (primarily nitrogen) was applied to 97% of corn acres, and herbicides applied to 98% of planted corn (USDA-NASS 2011a, USDA-NASS 2011b), with glyphosate being the most commonly applied herbicide. Conversely, glufosinate use decreased, from approximately 1.2 million pounds in 2008, to 0.6 million pounds in 2012 (EPA 2015j).

Agricultural nutrient losses to streams are a primary concern in the U.S. Corn Belt (Ribaudó, Delgado et al. 2011), particularly in relation to the adverse effects of nutrient loads on hypoxia in the Gulf of Mexico (Wiebe and Gollehon 2006). In total, agricultural sources contribute more than 70% of the nitrogen and phosphorus delivered to the Gulf, versus only 9 to 12% from urban sources (Alexander, Smith et al. 2008). Corn accounts for 45% of U.S. crop acreage receiving manure and 65% of the 8.7 million tons of nitrogen applied by farmers each year (Ribaudó,

Delgado et al. 2011). Nitrogen run-off from cornfields, in particular, is the single largest source of nutrient pollution to the Gulf of Mexico's "dead zone" (Ribaud, Delgado et al. 2011).

As for the environmental transport, fate, and effects of glyphosate and glufosinate: Most observed environmental concentrations of glyphosate, and its degradation product aminomethylphosphonic acid (AMPA), have been well below existing health benchmarks and levels of concern for humans or wildlife, and rarely exceed the EPA's Maximum Contaminant Level (MCL) of 700 µg/l or Canadian short-term (27,000 µg/l) and long-term (800 µg/l) freshwater aquatic life standards (Scribner, Battaglin et al. 2007, Battaglin, Meyer et al. 2014). By example, median concentrations of glyphosate detected in U.S. rivers, streams, lakes, and ponds, have been below 0.2 µg/l (or 0.2 parts per billion [ppb]) (Battaglin, Meyer et al. 2014); some three orders of magnitude below the EPA MCL of 700 ppb. Glufosinate is seldom found in environmental samples, and when detected, has been at concentrations below levels of concern for humans or wildlife (Scribner, Battaglin et al. 2007). Both herbicides, used according to EPA label restrictions, are expected to pose only minimal risk to aquatic and terrestrial wildlife (EPA 2008b, EPA 2009b, TOXNET 2015a, TOXNET 2015b).

As discussed under Section 2.2.2, Water Resources, various National and regional efforts are underway to reduce NPS contaminants in agricultural run-off, and run-off itself. These efforts, and others, are expected to continue, and to help reduce the potential impacts of agriculture on water quality (EPA 2008c, EPA 2015c, EPA 2015s, USDA-NRCS 2015c, USDA-NRCS 2015d, USDA-NRCS 2015b, USDA 2015b). By example, in 2012, the USDA Natural Resources Conservation Service (NRCS) launched the National Water Quality Initiative (NWQI), in collaboration with the EPA and state water quality agencies, to reduce nonpoint sources of nutrients, sediment, and pathogens related to agriculture in small high-priority watersheds in each state (EPA 2015b).

No Action Alternative: Water Resources

Under the No Action Alternative, current trends in acreage used for corn and agronomic practices associated with U.S. corn production would not be expected to change. U.S. growers will continue to cultivate the same corn varieties and use the same agronomic practices and inputs associated with those varieties. These include current use of glyphosate and glufosinate in conjunction with both GE corn and non-GE varieties. Consequently, no substantial changes to water quality or use beyond current trends, and normal variation, associated with U.S. corn production would be expected under the No Action Alternative.

As discussed in Subsection 4.3.1, Soil Quality, more diverse weed management tactics, potentially including more aggressive tillage practices that can affect soil erosion, could be needed to address the increasing emergence of glyphosate-resistant (GR) weeds. In some areas of the South in particular, conservation tillage acres are at risk of being converted to higher-tillage systems due to the prevalence of glyphosate-resistant weeds (Hollis 2015). Higher-intensity tillage facilitates the burial of weed seed as well as preplant incorporated herbicides for the control of problematic weeds. Other options for control of resistant weeds, and which growers may use, are high density cover crops, residual herbicides, and timely post-emergence herbicides.

In general, growers reported GR weed infestations on 5.6% of corn acres in 2010, and declines in glyphosate effectiveness in about 40% of soybean acres in 2012, with the majority of those acres in the Corn Belt and Northern Plains (Livingston, Fernandez-Cornejo et al. 2015). Hence, where pervasiveness of GR weeds is notably less in corn than soybean, it is possible that the adoption of more aggressive tillage practices in some corn production systems to control GR weeds could contribute to soil erosion and consequently increase sedimentation and residual NPS pollutant loading in surface waters from these particular cropping systems.

Growers do, however, have available to them IWM and diversified cropping strategies that can help effectively manage resistant weeds (Owen 2011, Davis, Hill et al. 2012, Gibson, Young et al. 2015), which can help reduce the need for intensive conventional tillage practices. The particular mix of weed management strategies that will be employed by an individual grower are dependent upon many factors such as the agro-ecological setting, the extent and type of problem weed, and economic aspects of production uniquely important to individual farmers.

Preferred Alternative: Water Resources

Because MZHG0JG corn is agronomically and phenotypically equivalent to currently-cultivated corn varieties (Davis, Jarrett et al. 2015), and would only replace other corn varieties in the event of adoption, MZHG0JG corn would not be expected to increase the total acreage of corn or range of corn growing regions within the U.S., require more or less irrigation, nor substantially alter agronomic practices affecting soil erosion or run-off. Determination of nonregulated status for MZHG0JG corn would present another stacked-trait variety of corn (glyphosate and glufosinate tolerant), and potentially expand current weed management options to growers.

The use patterns for glyphosate and glufosinate on MZHG0JG corn would likely vary across U.S. corn growing regions, according to variations in problematic weeds species present in given areas, and local environmental conditions. The use of glyphosate and glufosinate on MZHG0JG corn will be regulated by EPA under FIFRA, FFDCa, and FQPA. The EPA determines the use requirements for these herbicides, which are intended to be protective of water quality and human health. The EPA considers the potential impacts to water resources from the agricultural application of glyphosate and glufosinate-ammonium, and provides label use restrictions and guidance for product handling intended to prevent impacts to water. Label restrictions specific to water resources include, for example, prohibiting applications directly to water (except as allowed for rice) or to areas where surface water is present, managing proper disposal of equipment wash water, and adopting cultivation methods (e.g., no till) to limit runoff to surface water.

The EPSPS and PAT proteins (both naturally occurring in the environment) expressed by MZHG0JG corn are currently expressed in several commercial corn and soybean varieties used throughout the U.S.(and world) (CLI 2015a, USDA-APHIS 2015), and recognized as environmentally benign (ILSI-CERA 2011a, ILSI-CERA 2011b). In 2007, the EPA issued permanent exemptions from food and feed tolerances for both EPSPS and PAT proteins in all crops in the U.S. (EPA 2007c, EPA 2007b).

To the extent that cultivation of MZHG0JG corn allows the grower to adopt or expand conservation tillage practices under integrated weed management programs, water quality

improvement associated with these tillage practices would be expected to follow. There is evidence that adoption of herbicide-tolerant crops can facilitate conservation tillage practices, due in part to the fact that HT corn crops can make weed control more effective (Fernandez-Cornejo, Hallahan et al. 2012, Livingston, Fernandez-Cornejo et al. 2015), minimizing the need for conventional tillage (which can adversely affect water quality through an increased potential for soil erosion).

Considering the above factors, the potential impacts of determination of nonregulated status for MZHG0JG corn on water quality, both beneficial and adverse, would be the same as or similar to the No Action Alternative.

4.3.3 Air Quality

As discussed in Subsection 2.2.3 – Air Quality, agricultural practices have the potential to adversely impact air quality. Agricultural emission sources include smoke from the burning of crop residues, particulate matter from tillage, emissions of NAAQS criteria pollutants from equipment burning fossil fuels, and pesticide drift and volatilization.

No Action: Air Quality

Potential impacts to air quality associated with corn cultivation would not be affected by a decision to deny the extension request for nonregulated status of MZHG0JG corn. Air quality would continue to be affected along current trends, both beneficially or adversely, by current emission sources associated with the agronomic practices used in corn production. Some of the more modern agronomic practices have the potential to reduce several of these emission sources. For example, conservation tillage requires less plowing, which decreases dust (PM) and tractor exhaust emissions (e.g., NAAQS criteria pollutants). It also facilitates the accumulation of soil surface residues, which creates a physical barrier that protects soils from weathering. This can decrease airborne soil particulates, and drift of soil-borne pesticide residues in wind-eroded soils.

As previously described, the benefits of conservation tillage to air quality could decline in some areas if growers employ more aggressive tillage to control an increase in resistance of weeds to herbicides. By example, in some areas of the South, multi-herbicide resistant Palmer amaranth has forced growers to include or intensify tillage, which can indirectly affect air quality as particulate matter can increase with more aggressive tillage practices (Hollis 2015). More aggressive tillage practices can also use more fossil fuels than conservation tillage methods. Consequently, the benefits of no-till or conservation tillage, relative to NAAQS emissions, may be reduced in areas where growers must employ more aggressive tillage to control an increase in the resistance of weeds to glyphosate (e.g., (Hollis 2015)).

Weed management methods, however, would vary from farm to farm, dependent upon the agro-ecological setting, the type and extent of problem weed, and agronomic and economic factors determining weed control costs and net returns on corn production (Beckie 2006, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015).

Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of MZHG0JG corn is unlikely to substantially impact air quality as compared to the No Action Alternative. Because the phenotypic, agronomic, and environmental interactions of MZHG0JG corn are equivalent to currently cultivated corn varieties (Davis, Jarrett et al. 2015), no substantial changes to emission sources (i.e., type and timing of tillage, equipment use, the application of fertilizers or pesticides) associated with the agronomic practices used in corn production would be expected. Similarly, there would be no change in the total acreage for U.S. corn production, as MZHG0JG corn, if adopted, would replace other varieties of GE corn currently on the market.

The commercial use of glufosinate could increase relative to the adoption of the MZHG0JG corn variety. Because MZHG0JG corn could replace other glyphosate tolerant corn varieties, use of glyphosate would be expected to remain the same or potentially decline, albeit it moderately, over time (i.e., (Gibson, Young et al. 2015)). Use of these herbicides on MZHG0JG corn, and potential environmental impacts through drift and volatilization, would not be expected to be significantly different under the Preferred Alternative. Use of both herbicides on MZHG0JG corn would be subject to the same EPA requirements and use restrictions as applicable to all other commercially produced corn.

Recent initiatives by the EPA strive to reduce potential impacts of pesticides on air quality by improving label requirements to reduce pesticide drift, and training and education of applicators on spray drift management (EPA 2015a, EPA 2015o). The EPA-approved labels for glyphosate and glufosinate provide measures for minimizing drift and potential air quality impacts that may derive from their use. When used in accordance with label requirements glyphosate and glufosinate are considered to pose only minimal risks to air quality.

Considering the above factors, the potential impacts of the Preferred Alternative on air quality, potentially beneficial and adverse, would be the same as or similar to the No Action Alternative. To the extent that adoption of MZHG0JG corn facilitated conservation tillage practices, and reductions in the use of fossil fuel burning equipment in fertilizer and pesticide application, there could be commensurate benefits to regional air quality in production systems utilizing this variety; in terms of reductions in NAAQS pollutants (CO, NO_x, O₃, PM, SO_x).

4.3.4 Climate Change

Agriculture is responsible for an estimated 8% of total greenhouse gas (GHG) emissions in the U.S. (EPA 2013b). Methane and N₂O are the primary GHGs emitted by agricultural activities. Methane emissions from enteric fermentation and manure management represent approximately 26% of emissions from anthropogenic activities (EPA 2013b). Soil management practices such as fertilizer application are the largest source of N₂O emissions nationally, currently accounting for around 74% of U.S. emissions (EPA 2013b).

CO₂ is also a GHG associated with agricultural land uses and energy consumption. Where soil carbon (C) occurs in both organic and inorganic forms, soil organic carbon (SOC) is the main source and sink for atmospheric CO₂ in most soils. Agronomic practices such as clearing, tillage, planting, crop residue management, and fertilization modify soil organic matter and carbon cycling, and influence whether there is a net flux of C to or from the soil carbon pool (Brenner, Paustian et al. 2001, Abdalla, Osborne et al. 2013, Campbell, Chen et al. 2014, Mangalassery,

Sjogersten et al. 2014). U.S. cropland that has remained steadily in production sequestered approximately 23.4 million metric tons (MMT) of CO₂ Eq. (6.4 MMT C) in 2013 (EPA 2013b). This was around 49% less sequestered carbon than in 1990, which was largely due to the decline in annual cropland enrolled in the Conservation Reserve Program (CRP) that was initiated in 1985 (EPA 2013b). Liming of agricultural soils and urea fertilization is also a source of CO₂ emissions, which resulted in CO₂ emissions of 9.9 MMT CO₂ Eq. (9,936 kt) in 2013 (EPA 2013b).

U.S. agriculture can contribute to reductions in GHG emissions through increased use of conservation tillage, reducing the amount of nitrogen fertilizer applied to crops, changing livestock and manure management practices, and planting trees or grass (USDA-ERS 2010). To the extent that U.S. corn growers are able to implement conservation practices, GHG emissions from corn production systems could potentially decline. For example, the EPA has noted that adoption of conservation tillage resulted in increases in carbon sequestration in soils on those croplands utilizing this tillage practice (EPA 2013b). The highest rates of carbon sequestration in mineral soils occurred in the Midwest, which is the region with the largest area of cropland managed with conservation tillage (EPA 2013b). In contrast, the highest emission rates from organic soils were noted in the southeastern coastal region, the areas around the Great Lakes, and the central and northern agricultural areas along the West Coast (EPA 2013b). Farmers' adoption of such practices would depend on their potential costs and net returns in crop production, as well as other economic incentives.

No Action Alternative: Climate Change

Under the No Action Alternative, MZHG0JG corn would remain a regulated article and planting of MZHG0JG corn could continue under the APHIS notification and permitting process. This alternative would not alter the agricultural practices associated with commercial corn production in the U.S. (e.g., tillage, cultivation, irrigation, pesticide and fertilizer applications, mechanized agriculture equipment). Consequently, potential impacts on GHG emissions, carbon sequestration, and climate change, would not be affected, nor would the potential impacts of climate change on corn production.

To the extent that U.S. corn growers are able to implement conservation practices, reductions in GHG emissions could follow. Conservation tillage generally contributes lower volumes of soil PM and into the atmosphere, and can reduce CO₂ and CH₄ emissions (e.g., see (Abdalla, Osborne et al. 2013, Campbell, Chen et al. 2014)). However, soils under zero tillage can also increase potential N₂O emissions. Where potential increases in N₂O emissions can occur under conservation tillage, this can be potentially counterbalanced by substantial reductions in CO₂ and CH₄ emissions (Mangalassery, Sjogersten et al. 2014).

Preferred Alternative: Climate Change

As described previously, MZHG0JG corn is similar to other GE and non-GE corn cultivars in terms of agronomic characteristics, composition, and environmental interactions (Davis, Jarrett et al. 2015). Consequently, the agronomic practices required to cultivate MZHG0JG corn would be not be substantially different than those currently used to produce other GE and non-GE corn cultivars. The range of U.S. corn production is not likely to expand or diminish as a consequence

of approving the extension request for nonregulated status for MZHG0JG corn, through 2024/25 (Westcott and Hansen 2015). As such, no changes to corn production or agricultural practices that could significantly affect GHG emissions, carbon sequestration, and climate change, would be expected for a determination of nonregulated status for MZHG0JG corn. A determination of nonregulated status for MZHG0JG corn would not be expected to substantially differ from the No Action Alternative in respect to potential reductions or increases in GHG emissions from commercial corn production.

4.4 Biological Resources

4.4.1 Animal Communities

Corn production systems can be host to a variety of animal species. A number of insect pests as well as beneficial insects feed on corn plants or prey upon other insects inhabiting cornfields. As highly managed lands, cornfields are generally considered poor habitat for wildlife in comparison with uncultivated lands, although the use of cornfields by birds and mammals is not uncommon.

Crop plants (e.g., corn, soybean, cotton) genetically engineered to express EPSPS and PAT proteins have a history of safe use since the mid-1990s (Hammond and Jez 2011, ILSI-CERA 2011a, ILSI-CERA 2011b, Hammond, Kough et al. 2013). In 2013, herbicide tolerant crops occupied 99.4 million hectares or 57% of the 175.2 million hectares of biotech crops planted globally (ISSA 2014), the most common of which are glyphosate and glufosinate tolerant varieties (ISSA 2014). EPSPS, which confers resistance to glyphosate, occurs naturally in algae, higher plants, bacteria (*Agrobacterium spp.*), and fungi. PAT, which confers resistance to glufosinate, occurs in soil bacteria worldwide (*Streptomyces spp.*). Corn lines that express these proteins have been commercialized, globally, without deleterious impacts on the environment or wildlife (ILSI-CERA 2011a, ILSI-CERA 2011b).

No Action Alternative: Animal Communities

Under the No Action Alternative, MZHG0JG corn will remain a regulated article, and commercial corn varieties containing EPSPS and PAT proteins will continue to be cultivated for the U.S. corn market. As discussed previously, the EPSPS and PAT proteins are considered environmentally benign, and of no risk to wildlife (Robertson and Mueller 2007, Robertson 2007, ILSI-CERA 2011a, ILSI-CERA 2011b, Wise and Mueller 2011).

Most wildlife that occurs in cornfields, and that may feed on corn, does not nest or reside in corn fields during the growing season due to frequent disturbance from use of agricultural equipment, application of pesticides, and other practices. Spray drift may inadvertently impact non-target species transiting corn fields and plants and animals adjacent to corn fields, and run-off from corn fields carrying pesticides, excess soil nutrients, and sediments, may adversely impact aquatic wildlife/ecosystems. The EPA considers non-target animal exposure in the registration and review of pesticides under FIFRA, including glyphosate and glufosinate (EPA 2010c, EPA 2015r), and has evaluated environmental exposures to these herbicides to determine safe use of these pesticides in the environment (e.g., (EPA 1993, EPA 2008b, EPA 2008a, EPA 2009b,

EPA 2013c, EPA 2013a)). When used according to EPA label restrictions, glyphosate and glufosinate pose only minimal risk to animals.

Under the No Action Alternative, potential impacts of GE and non-GE corn production practices on non-target terrestrial and aquatic species would be unchanged. Pest species in corn production systems would continue to be managed utilizing current methodologies, as required

Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts to wildlife are not anticipated to be substantially different compared to the No Action Alternative. The EPSPS trait in MZHG0JG corn is based on naturally occurring EPSPS enzymes that are ubiquitous in plants and microorganisms (ILSI-CERA 2011a), and PAT is normally produced in *Streptomyces* bacteria, which commonly occur in soil., worldwide. Wildlife species have been exposed to mEPSPS via GA21 corn for many years, as well as similar EPSPS enzymes in commercially cultivated GE crops, and no adverse effects of exposure to mEPSPS enzymes at naturally occurring concentrations or from the cultivation of GA21 corn are known to occur. Thirty-eight GE cultivars expressing PAT, including several corn cultivars, are approved for environmental release in at least one country (ILSI-CERA 2011b). As described, corn lines that express these proteins have been commercialized, globally, without deleterious impacts on the environment or wildlife (ILSI-CERA 2011a, ILSI-CERA 2011b). Due to the relative safety of these proteins, the EPA has issued permanent exemptions from food and feed tolerances for CP4 EPSPS and PAT in all crops in the United States (EPA 2007c, EPA 2007b).

Syngenta conducted compositional analyses, as well as safety and nutritional assessments on MZHG0JG corn (Davis, Jarrett et al. 2015). These studies demonstrated MZHG0JG corn and corn products processed from raw MZHG0JG corn are nutritionally and compositionally equivalent to raw and processed corn from conventional corn varieties, and that MZHG0JG corn is expected to provide ample nutrition as part of human diets, as well as formulated diets delivered to growing livestock. Consequently, MZHG0JG corn would be expected to be a nutritional food source for wildlife that foraged on MZHG0JG corn.

The commercial use of glyphosate and glufosinate is not expected to substantially change if the extension request for nonregulated status of MZHG0JG corn is approved. No changes to the registered uses or labels for glyphosate and glufosinate are proposed or would be required to cultivate MZHG0JG corn. Current EPA label application rates and associated use restrictions for glyphosate and glufosinate are intended to minimize the potential impacts of these herbicides on non-target organisms. APHIS assumes that glyphosate and glufosinate will be used in accordance with these label restrictions. Consequently, there would be no difference in the potential for MZHG0JG corn cultivation to impact wildlife or habitat from that of other nonregulated corn varieties on which glyphosate and glufosinate are used.

Considering the above factors, impacts on individual animals and animal communities under the Preferred Alternative would be substantially the same as those under the No Action Alternative.

4.4.2 Plant Communities

Vegetative communities surrounding cornfields are widely varied, and include other crop fields, woodlands, rangelands, and/or pasture/grassland areas. The primary concern in regard to potential impacts on these communities are from pesticide drift or runoff.

Because weedy plants can be responsible for substantial crop yield and financial losses (i.e., average of 10% worldwide), these species are of primary concern to corn crop producers. There are over 10 primary weed types commonly encountered in corn production in the U.S.

The most common weed management strategy currently used in U.S. corn production is to use herbicides in combination with specific tillage and crop rotation practices. These practices can, in some instances, impart selection pressures on the weed community that can result in shifts in the relative abundance and species of specific weeds. For example, in aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds; whereas, in no-till fields, greater diversity of annual and perennial weed species may occur (Baucom and Holt 2009). Herbicide resistance (HR) can occur in plants when a plant survives the application of an herbicide, and passes on its resistance genotype to new generations. Development of HR weeds is not unique to GE crop varieties; it has been occurring as result of herbicide use and well-studied since the 1960s (Holt 1992).

As discussed, weed species resistant to glyphosate (GR) have become more prevalent in the U.S., and several GR weed species such as Palmer amaranth (pigweed) are considerable problems in the Southeast U.S., although increasingly present in the Corn Belt and Midwestern states (Heap 2015). As of 2014, there were 14 different weed species with glyphosate-resistant populations, and 1 species resistant to glufosinate (Heap 2015).

In response to development of HR weeds, producers are diversifying weed management strategies in corn production to include alternating crops resistant to different herbicide modes of action that are grown on the same field, alternating the herbicide modes of action used with the same crop, practicing more crop rotation, and increasing tillage in some areas to control pernicious GR weeds (e.g., see (Owen 2011, Owen 2012)). Weeds can also develop resistance to multiple herbicides, which requires commensurate adjustments to agronomic practices, to include crop rotation and tillage.

Where the EPA specifies label use restrictions for pesticides that are intended to be protective of non-target plant species, long-term, cost-effective, environmentally sound weed management will require diversified management practices that minimize selection for herbicide resistance traits (Owen 2011, Owen 2012, Evans, Tranel et al. 2015). Such weed management practices will require the combination of cost-effective chemical, cultural, physical, and biological tactics that effectively minimize weeds, while reducing reliance on herbicides (Evans, Tranel et al. 2015).

No Action Alternative: Plant Communities

Under the No Action Alternative cultivation of MZHG0JG corn would remain under APHIS regulation and planted in areas of controlled, limited acreage. Plant species (i.e., weeds) that inhabit commercial GE and non-GE corn production systems in the U.S. will continue to be

managed through the use of mechanical and chemical control methods, and increasingly, IWM strategies. Multiple herbicides, including the herbicides glyphosate and glufosinate, will continue to be used as part of weed management practices. Plant communities surrounding cornfields may be subject to off-site movement of pesticides through run off and spray drift.

The application of an herbicide in corn production has the potential to impact non-target plant communities through spray drift, volatilization (evaporation), its adsorption to soils incorporated in runoff, and cleaning and disposal of equipment used in herbicide application. Glyphosate and glufosinate are toxic to most terrestrial and aquatic plants, and the potential impacts of glyphosate and glufosinate on non-target organisms are minimized when growers follow EPA-approved label use restrictions and guidance, which provide detailed measures to manage spray drift, and limit over-application. These measures include applying only during optimal wind conditions, temperature, and humidity; adjusting spray droplet size and sprayer boom heights and including drift reduction additives; and judicious use of aerial spraying from aircraft (e.g., (EPA 2015d, EPA 2015f)).

As discussed in Section 2.3.2, Plant Communities, over-reliance on glyphosate use as a single technique for weed control has resulted in the selection of weeds resistant to the herbicide, and a well-recognized problem for corn producers across the U.S. (Owen 2008, Owen 2011, Weirich, Shaw et al. 2011, Livingston, Fernandez-Cornejo et al. 2015). Deterring development of glyphosate resistant weeds is a primary concern, and growers work with University extension staff, seed developers, and corn producer associations to address this problem (e.g., (Gunsolus 2008)). Growers in many areas of the U.S. are increasingly adopting integrated weed management (IWM) practices to control weeds and development of weed resistance (Frisvold, Hurley et al. 2009, Owen 2011, Mortensen, Egan et al. 2012, Owen 2012). IWM employs strategies such as crop rotation, cover crops, competitive crop cultivars, judicious tillage practices, and targeted herbicide application, to reduce weed selection pressures that can drive the evolution of resistant weeds.

For risks of weed resistance to glyphosate, USDA in its various units is funding programs aimed at understanding weed resistance development, and managing crops to avoid resistance. By example, the USDA's Natural Resource Conservation Service (NRCS) offers financial assistance under its Environmental Quality Incentives Program (EQIP) for herbicide resistant weed control practices that utilize Integrated Pest Management plans and practices. The NRCS will also be soliciting proposals under the Conservation Innovation Grants (CIG) Program for innovative conservation systems that address herbicide resistant weeds. APHIS actively promotes use of best management practices (BMPs) in design protocols for regulated authorized releases of genetically engineered (GE) crops and will include recommendations for BMPs with the authorization of field trials of HR crops. USDA also partners with the Weed Science Society of America (WSSA) and provides funds for education and outreach in the management of herbicide-resistant weeds.

By example, the Weed Science Society of America provides training for certified crop protection specialists and others titled (e.g., “Current Status of Herbicide Resistance in Weeds” (<https://www.pentonag.com/courses/wssa-wrm>)), and seed technology developers such as Monsanto offer courses for certified pesticide applicators (e.g., “Weed Resistance Management (WRM) in Agronomic Row Crops & Trees, Nuts & Vines”

(<https://www.pentonag.com/courses/wrm>)). Similarly, organizations such as the National Corn Growers Association offer online training to assist growers in the prevention of development of weed resistance (<http://ncga.adayana.com/>).

While GR weeds are current problem in U.S. corn production systems, GR weed population densities can be decreased utilizing IWM practices, even in continuous glyphosate-tolerant cropping systems, although recent studies indicate shifts in the density of high-risk weed species may take from around two of six years and under continuous GR corn cultivation (e.g., see (Gibson, Young et al. 2015)). Where academic recommendations that promote IWM to deter glyphosate resistance are successful in the short term for reducing weed infestations, IWM practices may take many years to affect the weed seedbank in problem areas, particularly for those species with a high risk for resistance to glyphosate, and cropping systems utilizing a single-trait glyphosate-tolerant crop variety (Gibson, Young et al. 2015).

In summary, under the No Action Alternative, natural selection, and the selection pressure exerted through the use of herbicides and other agronomic practices, impacts plants communities by either inducing plant death, selecting for weedy characteristics, inducing shifts in the composition of the plant community, and in some cases, contributing to the development of herbicide-resistant weeds. Non-crop plant species (i.e., weeds) that typically inhabit GE and non-GE corn production systems will continue to be managed through the use of mechanical and chemical control methods, as currently practiced, including IWM strategies. Multiple herbicides, including the herbicides glyphosate and glufosinate, will continue to be used on corn, and it assumed will be used according to EPA labeled use requirements and recommendations.

Under the No Action Alternative, any potential impacts, beneficial or adverse, on plant communities associated with corn production systems will continue under the current trends as described.

Preferred Alternative: Plant Communities

A determination of nonregulated status of MZHG0JG corn would not be expected to affect plant communities adjacent to or within corn production systems that would differ from that of currently cultivated conventional and GE corn varieties. As discussed in Subsection 4.2., Agricultural Production of Corn, the agronomic and phenotypic characteristics of MZHG0JG corn have been evaluated in field trials and determined to be similar to comparator corn cultivars (Davis, Jarrett et al. 2015). Consequently, MZHG0JG corn would be cultivated as are other GE and non-GE corn varieties, utilizing the same agronomic practices, and present potential impacts on plant communities similar to those described under the No Action Alternative.

Because MZHG0JG corn is tolerant of applied glyphosate and glufosinate-ammonium, growers would select these herbicides for use in production of MZHG0JG corn. On average, glyphosate is currently used on ~ 73% of corn acreage annually, while over 84% of corn acres is treated with herbicides other than or in addition to glyphosate (Livingston, Fernandez-Cornejo et al. 2015). In recent years an average of 5% and a maximum of 10% of corn acres have been treated with glufosinate (EPA 2013a).

As discussed under the No Action Alternative, herbicide spray drift and run-off is a concern in regard to non-target plants growing proximate to fields where herbicides are used. The risk of off-target glyphosate and glufosinate herbicide drift is recognized by the EPA, and any use of glyphosate and glufosinate-ammonium with MZHG0JG corn would remain consistent with the per-application and per-year rates, as well as methodologies, approved by EPA. As part of the registration of glyphosate and glufosinate use on corn, EPA considers the impact on non-target plant communities, and provides labeled use restrictions, inclusive of drift minimization guidance, intended to be protective of non-target plant species (EPA 2015k, EPA 2015p, EPA 2015l). There are no changes to the application rates or label required to cultivate MZHG0JG corn. Accordingly, the potential impacts to non-target plants associated with off-site herbicide movement under the Preferred Alternative are the same as the No Action Alternative.

Potential impacts of determination of nonregulated status of MZHG0JG corn on the development of weeds resistant to glyphosate and glufosinate would be no different than under the No Action Alternative, other than MZHG0JG corn may improve the ability of corn growers to manage the potential development of resistant weed populations through implementation of IWM practices. MZHG0JG corn is expected to provide an additional cultivar option for herbicide-tolerant corn that would serve as a substitute or alternative to existing glyphosate-tolerant varieties.

In managing GR weeds, glufosinate is recognized as an additional herbicide that may be used to control GR weeds, though other herbicides are also available for use in corn. Table 7 illustrates the comparative control of glyphosate-resistant and hard to control weeds, and the potential use of glufosinate for control of some of these GR weeds.

Weed Species	Hard to Control	Glyphosate-resistant	ALS-resistant	Glufosinate controlled
<i>Abutilon theophrasti</i> (Velvetleaf)	X			
<i>Amaranthus palmeri</i> (Palmer amaranth) ¹	X	X	X	
<i>Amaranthus rudis</i> (Tall or common waterhemp)	X	X	X	
<i>Ambrosia artemisiifolia</i> (Common ragweed)	X	X	X	
<i>Ambrosia trifida</i> (Giant ragweed)	X	X	X	
<i>Chenopodium album</i> (common lambsquarters)	X		X	
<i>Conyza canadensis</i> (Marestail)	X	X	X	
<i>Eleusine indica</i> (Goosegrass)	X	X		X ³
<i>Ipomoea sp.</i> (Morningglory species)	X			
<i>Lolium multiflorum</i> (Italian ryegrass)	X	X ²	X	X ²
<i>Lolium perenne</i> (Perennial ryegrass)	X	X	X	X
<i>Lolium rigidum</i> (Rigid ryegrass)	X	X	X	X
<i>Poa annua</i> (Annual bluegrass)	X	X		X
<i>Sida spinosa</i> (Prickly sida, Teaweed)	X		X	
<i>Solanum ptycanthum</i> (Eastern black nightshade)	X		X	
<i>Sorghum halepense</i> (Johnsongrass)	X	X	X	

Sources: (Heap 2015, IPM 2015)

Notes: 1. Requires a broader management plan; 2. Reported in Heap as exhibiting resistance to both herbicides in Oregon; 3. Resistance to glufosinate reported in Malaysia.

To the extent that growers may cultivate MZHG0JG corn in lieu of currently-available corn hybrids with identical traits (i.e. glyphosate and glufosinate-tolerance), the total volume of herbicides used is not expected to substantially change, other than increases in use of glufosinate, which would be subject to EPA requirements.

Considering the above factors, under the Preferred Alternative, a determination of nonregulated status of MZHG0JG corn is not anticipated to substantially change the structure of plant communities in or around corn fields, to include the development of GR weeds.

4.4.3 Gene Flow and Weediness

Two forms of gene flow are considered in evaluating the potential environmental impacts of GE corn: Vertical and horizontal gene flow. Vertical gene flow involves sexual reproduction, and subsequent hybridization and introgression of genes into other plants. Horizontal gene flow involves mechanisms outside of sexual reproduction, generally to sexually incompatible species.

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative MZHG0JG corn would be grown under APHIS regulatory authority. Any potential for gene flow from MZHG0JG corn permitted testing sites, and currently available commercially grown GE cultivars to non-GE corn cultivars would remain unchanged from current conditions. In the United States, corn is not listed as a weed, nor on the Federal Noxious Weed List (7 CFR part 360) (USDA-NRCS 2015a). Corn has been cultivated throughout the U.S. without any evidence it forms persistent feral populations. As described in Subsection 2.3.3 - Gene Flow and Weediness of Corn, the establishment of corn as a weed is unlikely.

Preferred Alternative: Gene Flow and Weediness

An important environmental consideration with a GE-corn variety is how cross-pollination may affect the environment. Gene exchange through vertical pathways between MZHG0JG corn and other cultivated corn varieties could occur where such lines are cultivated in close proximity (Chilcutt and Tabashnik 2004, Messeguer, Penas et al. 2006, Mallory-Smith and Zapiola 2008, Ryffel 2014). Cultivated corn (*Zea mays* L. subsp. *mays*) is sexually compatible with other members of the genus *Zea*, and to a lesser degree with members of the genus *Tripsacum*.

The potential for corn to hybridize with wild and feral relatives of sexually compatible plants in the U.S. is very low, due to the fact that there are few biologically plausible avenues for gene flow to other sexually compatible plants to occur (e.g., see (Wozniak 2002)), and due to the rare occurrence of wild members of the genus *Zea* or *Tripsacum* in or around corn fields. As described in Section 2.1.3, Organic Corn Production, producers of GE, non-GE, and organic corn, utilize agronomic stewardship practices that deter or preclude the potential for cross-pollination, as it is desirable for growers to protect crop identity and maintain economic returns in crop production. Ample guidance on agronomic practices as provided by AOSCA and the NOP provide crop protection measures that sufficiently protect against potential gene flow (NCAT 2003, AOSCA 2015, USDA-AMS 2015c).

Horizontal gene transfer (HGT) of the EPSPS and PAT nucleotides in MZHG0JG corn to other biota is highly unlikely. Horizontal gene flow among bacteria is common, although horizontal gene flow from one plant to another, or other phyla (e.g., species of bacteria), would be considered an extremely rare event (Bertolla and Simonet 1999, CAST 2007, Chandler and Dunwell 2008, Bock 2010, Nielsen, Bøhn et al. 2013, Arber 2014). This event would require relocation of the complete, intact gene sequence from the transgenic plant to another species, including not only the genes that code for the production of specific proteins, but also those portions of the genome that regulate the expression and activity of those genes (i.e., regulatory elements) (Keese 2008).

There are no known naturally occurring vectors (such as plasmids, phages, or transposable elements) that could provide for inter-domain gene transfer, and there is little evidence that eukaryotic cells are naturally capable of stably incorporating genes from GE corn into their genome (Brown 2003). Although viruses can and do move genetic material across species, viruses that infect higher plants have relatively small ribonucleic acid (RNA) or DNA genomes, commonly with fewer than 20 that encode for proteins (Keese 2008). As such, viruses are constrained as to the type and size of novel genetic material that can be acquired and relocated via horizontal gene transfer (Keese 2008). Based on the current body of knowledge, HGT from GE corn is considered to pose negligible risks to the environment (Keese 2008, Rizzi, Raddadi et al. 2012). Consequently, there are no differences among the Preferred Alternative and No Action Alternative relative to potential horizontal gene flow.

Where corn presents little risk for weediness outside of cultivated areas, it can however overwinter and germinate in a subsequent crop as a “volunteer” weed. For example, corn is a common volunteer in soybean fields, and GE corn varieties, like any other non-GE or GE corn variety, possess the potential to become volunteers. Where volunteer corn occurs, GE corn varieties, like non-GE corn varieties, are controlled by mechanical cultivation, crop rotation practices, and readily available herbicides or other graminicides (e.g., (Marquardt, Krupke et al. 2012, Marquardt, Terry et al. 2013, Chahal, Kruger et al. 2014)). For example, common herbicides recommended for control of volunteer corn are the ACCase inhibitors and certain ALS inhibitors (Hager 2010, Stahl, Potter et al. 2013). These well-established and broadly used agricultural protocols to control volunteer corn (e.g., (Deen, Hamill et al. 2006, Jeschke and Doerge 2010, Marquardt, Terry et al. 2013, Stahl, Potter et al. 2013, Soltani, Shropshire et al. 2014)) are expected to be equally applicable to MZHG0JG corn under the Preferred Alternative.

Considering the above factors, and given MZHG0JG corn is similar to other GE and non-GE corn varieties in terms of growth habit, agronomic properties, composition, and environmental interactions (Davis, Jarrett et al. 2015), the potential for gene flow and weediness from MZHG0JG corn would be no different from that of other corn varieties, both GE and non-GE, currently cultivated. Consequently, the Preferred Alternative is not expected to substantially differ from the No Action Alternative with respect to the potential environmental impacts associated with gene flow and weediness.

4.4.4 Microorganisms

Soil microorganisms are important in soil structure formation, the decomposition of organic matter, toxin/toxicant degradation, nutrient cycling, soil-borne plant disease suppression, and most

biochemical soil processes. In the cultivation of corn, potential impacts to soil microorganisms can arise from the agronomic practices employed in the cultivation of corn (e.g., crop rotation, tillage, pesticide and fertilizer application, and irrigation), and from exposure to the introduced gene(s) and protein(s) if it is a GE-corn variety, (Dunfield and Germida 2004, Garbeva, van Veen et al. 2004, Gupta, Neate et al. 2007, Locke, Zablutowicz et al. 2008, Roger-Estrade, Anger et al. 2010, Kremer 2014). Plant roots, including those of corn, also release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere.

In general, cultivation of GE crops has not been found to present any substantive risks to soil microbial populations (Vencill, Nichols et al. 2012). The diversity of microbial populations may be affected by these corn varieties, but the effects reported to date have been of a transient and minor nature (Dunfield and Germida 2004, Vencill, Nichols et al. 2012). As described in Subsection 2.3.4 –Microorganisms, a number of studies have investigated whether soil microorganisms are affected by glyphosate. Results from these studies have had mixed findings, and are ongoing, although no substantive adverse impacts on soil microbiota have been identified (e.g., (Dunfield and Germida 2004, Widmer 2007, Kremer 2010, Camberato, Casteel et al. 2011, Kremer 2014), and others). Similarly, where some studies have noted transient changes in soil microbial populations associated with glufosinate use, substantial impacts on soil microbial communities have not been identified (see, e.g., (Bartsch and Tebbe 1989, Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010)).

Fundamentally, the primary pathway for glyphosate and glufosinate environmental degradation is through soil microbial catabolism. Glufosinate is readily degraded by soil microbiota to carbon dioxide and natural phosphorus compounds (TOXNET 2015a). The aerobic half-life in soil is typically 3-11 days, anaerobic half-life 5-10 days, and field dissipation half-lives around 6-20 days (avg. 13 days) (TOXNET 2015a). The median half-life of glyphosate in soil has been widely studied, with reported ranges between 2 and 197 days, relative to soil type and environmental conditions (NPIC 2010, TOXNET 2015b). The primary byproduct of glyphosate degradation is aminomethylphosphonic acid (AMPA), which is further broken down to carbon dioxide and inorganic phosphate (NPIC 2010, TOXNET 2015b). In many cases, crop and soil management practices that increase soil organic matter and plant residues, such as conservation tillage, impart attributes to soil that can enhance microbial degradation of pesticides, and hinder movements of pesticides to water and air (Locke and Zablutowicz 2004, Locke, Zablutowicz et al. 2008).

No Action Alternative: Microorganisms

Under the No Action Alternative, MZHG0JG corn may continue confined trials under APHIS authority. Limited production of MZHG0JG corn in field trials as a regulated article is not expected to have any substantive adverse effect on soil microbes. As described, soil microorganisms are not adversely affected by the EPSPS and PAT proteins that occur in MZHG0JG corn (and naturally occur soil bacteria) (ILSI-CERA 2011a, ILSI-CERA 2011b). Use of glyphosate and glufosinate on MZHG0JG corn would be no different than that currently occurring in commercial crops under EPA authority. Current agronomic practices associated with commercial corn production such as tillage and applications of pesticides and fertilizers are not expected to change. Consequently, potential impacts to soil microorganisms associated with commercial corn production, beneficial and adverse, would continue along current trends.

Preferred Alternative: Microorganisms

Under the Preferred Alternative, soil microorganisms are unlikely to be substantially affected by a determination of nonregulated status of MZHG0JG corn compared to the No Action Alternative. As discussed, MZHG0JG corn is phenotypically and agronomically similar to currently cultivated corn varieties (Davis, Jarrett et al. 2015, USDA-APHIS 2015). Accordingly, soil microorganisms are currently exposed to agronomic practices that would be employed in the cultivation of MZHG0JG corn, as well as the introduced mEPSPS and PAT proteins, which are considered environmentally benign (ILSI-CERA 2011a, ILSI-CERA 2011b, Davis, Jarrett et al. 2015).

Growers will have the option to include glufosinate along with glyphosate in their weed control strategies if they adopt MZHG0JG corn. Both are currently used in cultivation of corn, as well as soybean and cotton varieties (USDA-APHIS 2015). Hence, soil microorganisms are currently exposed to both glyphosate and glufosinate. Consequently, a determination of nonregulated status of MZHG0JG corn is not expected to substantially change soil microorganism exposure to these herbicides as compared to the No Action Alternative.

Considering the above factors, changes in potential impacts on soil microorganisms on deregulation of MZHG0JG corn are unlikely to occur. The herbicides glyphosate and glufosinate are currently EPA registered, labeled, and used in cultivation of GE-corn varieties, and the mEPSPS and PAT traits expressed by MZHG0JG corn have been safely cultivated in other GE corn varieties since 1997. Consequently, there are no substantial differences between the No Action Alternative and the Preferred Alternative with regard to potential impacts on soil microbial populations and associated biogeochemical processes governing soil fertility.

4.4.5 Biodiversity

Various studies over the last 10 years have investigated the differences in the biological diversity among GE and non-GE crop fields, particularly those GE crops that are resistant to insects (e.g., *Bt* crops) or herbicides (e.g., glyphosate- or glufosinate ammonium-resistant). Some studies have found negligible to modest decreases in biological diversity or abundance attributed to GE crops that are insect-resistant or herbicide-tolerant, where other studies have found no effects (e.g., see (Collier and Mullins 2010, NRC 2010, Carpenter 2011, Lauren M. Schwartz, David J. Gibson et al. 2015)).

A recent review by Carpenter (2011) of over 360 research articles on this topic suggests that, overall, currently commercialized GE crops have likely reduced the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, reduction of insecticide use, use of more environmentally benign herbicides, and increased yields that alleviate the pressure to convert additional land into agricultural uses (Carpenter 2011).

One of the most recent studies looking 156 different field sites with a minimum 3-year history of production of glyphosate-tolerant (GT) corn, cotton, or soybean found that agronomic practices alone were but one factor determining the biodiversity in an agricultural setting (Lauren M. Schwartz, David J. Gibson et al. 2015). The findings from this particular study suggests that diversification of the weed (plant) community, both in the seedbank and above ground, is

reflective of the geographic region of the cropping system and crop rotation, but not the frequency of the use for the glyphosate-tolerant trait. The plant community diversity under specific crops (i.e., cotton, corn, and soybean), where at least two-thirds of the crop include the GT trait, is not determined solely by GT trait status. Rather, the agronomic practices used in crop production (varying cultural and mechanical weed management tactics; diversity of herbicide modes of action, application timings, and frequency of glyphosate use; rotation of crops or the GT crop trait) along with other tactics determines the diversity of agricultural plants, and their prevalence in the soil seedbank (Lauren M. Schwartz, David J. Gibson et al. 2015).

Although herbicide use potentially affects biodiversity, the application of pesticides in accordance with EPA label use requirements, and careful management of chemical spray drift minimizes the potential impacts on biodiversity. The EPA considers chemical spray drift in its herbicide registration and review process, and has established label use restrictions to minimize glyphosate and glufosinate drift (EPA 2009b, EPA 2013c, EPA 2015d, EPA 2015f).

Relative to MZHG0JG corn: Glufosinate is deemed non-toxic to birds, mammals, and insects; slightly non-toxic to freshwater fish; moderately toxic to estuarine/marine fish; moderately toxic to freshwater and estuarine/marine invertebrates; and toxic to terrestrial and aquatic plants (EPA 2008b). Glyphosate is practically non-toxic to birds, slightly toxic to practically non-toxic to freshwater fish, slightly toxic to practically non-toxic to freshwater invertebrates, and practically non-toxic to honeybees and arthropods (NPIC 2010).

No Action Alternative: Biodiversity

Under the No Action Alternative, MZHG0JG corn and its progeny would continue to be regulated by APHIS under 7 CFR part 340. Given the limited acreage and regulated plantings, no impacts to biodiversity are expected under this alternative.

Preferred Alternative: Biodiversity

A determination of nonregulated status of MZHG0JG corn would not change the agronomic practices or acreage required for the commercial production of corn. As described above, glyphosate and glufosinate use per EPA requirements are not expected to substantially affect biodiversity in or around cornfields, nor would the EPSPS and PAT proteins, which have a history of safe use (EPA 2007c, EPA 2007b). Consequently, approval of Syngenta's extension request would have no more potential beneficial or adverse effects on biodiversity than that of the No Action Alternative.

4.5 Human Health

Human health concerns surrounding GE products center on possible toxic, nutritional, or allergic effects. The assessment of potential human health effects from MZHG0JG corn considers two aspects of the crop: (1) the potential health effects associated with the introduced EPSPS and PAT nucleotides, and (2) herbicides used in crop production.

4.5.1 Consumer Health

No Action Alternative: Human Health

Under the No Action Alternative, MZHG0JG corn would remain a regulated article, could be cultivated in the U.S. under APHIS authority in field trials, and consumers would have no exposure to MZHG0JG corn. Commercial HT-corn containing the same mEPSPS and PAT expressed in MZHG0JG corn would continue to be cultivated for food, feed, fiber, and fuel (e.g., GA21-Corn [OECD unique identifier MON-ØØØ21-9]; and Bt11 corn [OECD Unique Identifier SYN-BTØ11-1]). As described in Subsection 2.4.1 - Consumer Health, the EPSPS and PAT proteins in currently cultivated GE corn varieties are not considered to present a risk to consumer health. The EPA would continue to regulate residues of glyphosate and glufosinate-ammonium in food and feed.

Preferred Alternative: Human Health

Under the Preferred Alternative, a determination of nonregulated status of MZHG0JG corn by APHIS would not be expected to result in any adverse impacts on human health compared to the No Action Alternative. MZHG0JG corn is compositionally equivalent to currently available corn on the U.S. and international market, and commercial HT-corn expressing variations of EPSPS and PAT have been cultivated in the U.S. and other countries for more than a decade.

APHIS considers the voluntary FDA consultation process in making its determination of the potential impacts of a determination on nonregulated status of the new agricultural product. Syngenta initiated the consultation process with FDA for the MZHG0JG corn and submitted a safety and nutritional assessment of food and feed derived from MZHG0JG corn to the FDA in 2015. The FDA is reviewing the safety data for the MZHG0JG corn event regarding: applications and uses; source, identity, and function of the introduced genetic materials; the intended effect of the modifications; and the compositional and nutritional equivalence of the MZHG0JG corn to non-GE counterparts. Following completion of the consultation processes and their data reviews, FDA will provide a decision on the uses of MZHG0JG corn for food and feed.

Prior FDA reviews of the EPSP and PAT proteins in currently cultivated GE corn varieties concluded that their consumption poses no risk to human and animal health (FDA 2012, FDA 2013b, FDA 2013a, FDA 2014). The FDA completed its biotechnology consultation for the antecedent organism VCO-Ø1981-5 corn in May 2013 (FDA 2013b). The FDA did not identify any safety or regulatory issues under the FFDCRA that would require further evaluation at that time, and considered Genective's consultation on corn VCO-Ø1981-5 to be complete. Due to the negligible risk EPSP and PAT proteins pose to human health, the EPA has issued permanent exemptions from food and feed tolerances for both CP4 EPSPS and PAT proteins in all crops in the United States (EPA 2007c, EPA 2007b).

Pesticide tolerance limits established by the EPA are intended to ensure the safety of foods and feed treated with pesticides, and are made following risk assessments that reflect real-world consumer and animal exposure scenarios. The EPA has established tolerance limits (EPA 20151) for glufosinate at 40 CFR §180.473, and glyphosate at 40 CFR §180.364, for both food and feed.

In USDA's 2013 annual pesticide data survey, USDA scientists detected pesticides on only 0.4% of the 261 sweet corn samples tested, the levels of which were well below the established EPA tolerance limits (e.g., an order of magnitude) (USDA-AMS 2013). The USDA tested 660 samples of corn grain in 2007 and found minimal pesticide residues. The percentage of total residue detections for corn grain was 0.8%, and all were below EPA tolerance limits (USDA-AMS 2007). In both surveys, over 99% of the products sampled through the USDA's Pesticide Data Program (PDP) had residues below the EPA tolerances.

Based on these factors and the compositional equivalency of MZHG0JG corn with conventional corn, a determination on nonregulated status for MZHG0JG corn would present no risk to human health or safety.

4.5.2 Worker Safety

No Action Alternative: Worker Safety

During the production of corn agricultural workers and pesticide applicators may be exposed to a variety of EPA-registered pesticides. As discussed, the EPA's registered pesticide labels establish use restrictions for pesticides, and growers are required to use pesticides such as glyphosate and glufosinate-ammonium consistent with the application instructions provided on the EPA-approved pesticide label. These EPA label restrictions are intended to mitigate or alleviate any potential impact on human health and the environment, and, once registered, a pesticide may not be legally used unless the use is consistent with the guidelines and application restrictions and precautions on the pesticide's label (i.e., (EPA 2009a, EPA 2015k, EPA 2015f)). The current labels for both glyphosate and glufosinate include label use restrictions intended to protect workers, including protective equipment to be worn during mixing, loading, applications and handling, equipment specifications to control pesticide application, and reentry periods establishing a safe duration between pesticide application and exposure to the pesticide in the field. Used in accordance with the label, glyphosate and glufosinate are expected to present negligible health risks to workers (e.g., (EPA 2009b, EPA 2013c, EPA 2015d, EPA 2015f)).

Preferred Alternative: Worker Safety

Under the Preferred Alternative, there are no new risks to worker safety presented by a determination of nonregulated status for MZHG0JG corn. As under the No Action Alternative, it is expected that EPA registered pesticides that are currently used for corn production will continue to be used by growers, including the use of glyphosate and glufosinate. MZHG0JG corn is not expected to change the application rates of glyphosate and glufosinate on corn; there are no proposed label changes for use of either herbicide on MZHG0JG corn. Worker exposure to glyphosate and glufosinate under the Preferred Alternative is not expected to differ from that under the No Action Alternative.

As described in Subsection 2.4 – Human Health, the EPA announced proposed changes to the EPA's Worker Protection Standard (WPS) (40 CFR Part 170) to increase protections from pesticide exposure for agricultural workers and their families. The EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification, communication

materials, use of personal protective equipment, and decontamination supplies. These changes are intended to provide further protections to those working with pesticides.

As discussed for the No Action Alternative, the mEPSPS and PAT proteins present no health risks to workers. Agricultural workers have been exposed to these proteins since 1997 without any concerns presented in regard to health and safety. Considering these factors, worker health and safety concerns under both alternatives are substantially the same.

4.6 Animal Feed

Corn accounts for around 95% of feed grain produced in the U.S. (USDA 2014), and is a primary feed for beef cattle, poultry, hogs, and dairy. Under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled, and GE corn based feed products typically undergo review by FDA before being introduced into commerce. Syngenta has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products in MZHG0JG corn. The FDA is evaluating the data submitted by Syngenta, and will provide a decision on the use of MZHG0JG corn as animal feed.

As part of consultation with FDA Syngenta conducted a compositional and nutritional analyses of MZHG0JG corn (Davis, Jarrett et al. 2015). These analyses demonstrate that MZHG0JG corn and corn products processed from raw MZHG0JG corn are nutritionally and compositionally comparable to raw and processed corn from conventional varieties, and that MZHG0JG corn is expected to provide adequate nutrition as part of human diets as well as formulated diets for livestock.

No Action Alternative: Animal Feed

Under the No Action Alternative, MZHG0JG corn will remain a regulated product, will not be available as an animal feed, and current corn based feed for livestock will remain unchanged.

Preferred Alternative: Animal Feed

A determination of nonregulated status of MZHG0JG corn will have no adverse effects on animal welfare. The safety of EPSPS and PAT proteins as expressed in currently available GE corn is well established (ILSI-CERA 2011a, ILSI-CERA 2011b). Deregulation of MZHG0JG corn would not result in any novel exposure of livestock to these proteins, given they are currently present in commercial GE-corn, and corn plant parts or products used for feed. MZHG0JG corn is compositionally and nutritionally equivalent to current feed (Davis, Jarrett et al. 2015), and there are no changes to current EPA established tolerance limits for pesticide residues in corn based feed. Under both the Preferred and No Action Alternative animal health and welfare would be expected to be sustained by corn based feed.

4.7 Socioeconomic Impacts

Food and industrial uses of corn (other than ethanol production) is projected to rise at a moderate pace over the next decade. Domestic production is expected to increase from 173 to 185 bushels/acre by 2024/25, with net returns increasing from \$244/acre (2014) to \$300/acre

(2024/25) (Westcott and Hansen 2015). U.S. corn exports are expected to increase over this time frame, in response to strong global demand for feed grains to support growth in meat production (Westcott and Hansen 2015). Ethanol production in the United States, which is based almost entirely on corn as stock material, is projected to remain fairly steady, with little to no growth in demand over the next 10 years (Westcott and Hansen 2015).

Adoption rates of stacked-trait corn varieties have increased in recent years, with stacked-trait corn expanding from 1% of planted acres in 2000, to 76% in 2014. The increase in adoption of stacked-trait GE varieties is due in part to the fact that stacked-trait varieties have generated higher yields relative to conventional seeds, or seeds with only one GE trait (Fernandez-Cornejo, Wechsler et al. 2014). USDA 2010 ARMS data indicate that conventional corn seeds had an average yield of 134 bushels per acre, while seeds with two types of herbicide tolerance (glyphosate and glufosinate) and three types of insect resistance (corn borer, corn rootworm, and corn earworm) had an average yield of 171 bushels per acre (Fernandez-Cornejo, Wechsler et al. 2014). GE varieties incorporating three or four traits are now common.

In general, corn grain exports represent a principal source of demand for U.S. producers and make the largest net contribution to the U.S. agricultural trade balance of all the agricultural commodities, reflective of the importance of corn exports to the U.S. economy.

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, MZHG0JG corn would continue to be regulated by APHIS and would not be produced for commercial uses. Accordingly, there would be no impact on the U.S. domestic economy on a decision to deny the extension request for nonregulated status of MZHG0JG corn. The demand and supply of corn, as well as projected corn values in bushels/acre, would likely follow USDA's ten year forecast through 2024/25 (Westcott and Hansen 2015).

Preferred Alternative: Domestic Economic Environment

Under this alternative, MZHG0JG corn, where adopted, would be expected to replace existing corn acres, commensurate with benefits this variety could provide to growers. The selection and cultivation of corn varieties, and the decision to cultivate corn (rather than soybeans or cotton, for example), is based on market demand for the crop, and efficiencies in crop yield; not the specific availability of a particular GE variety. In this respect, the potential domestic economic impacts associated with the introduction of MZHG0JG corn into commerce are no different than those currently observed for other corn varieties under the No Action Alternative.

As discussed in Subsection 4.4.2 - Plant Communities, farmers are broadening weed management strategies in some areas of the U.S. to control herbicide-resistant weeds, primarily glyphosate-resistant weeds, and weed management can increase the cost of production. However, these costs can be offset by increases in yields when weeds are effectively managed, with little negative impact on net returns (Weirich, Shaw et al. 2011, Brookes 2014, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). To the extent MZHG0JG corn, a

stack-trait glyphosate- and glufosinate-tolerant corn, may serve as part of a grower's integrated weed management program (Frisvold, Hurley et al. 2009, Owen 2011, Mortensen, Egan et al. 2012, Owen 2012), as described in 4.4.2 -Plant Communities, it could help minimize the cost of weed management, to include resistant weed biotypes (Livingston, Fernandez-Cornejo et al. 2015). In any event, the availability of MZHG0JG corn, in the context of weed management, would not be expected to increase production costs such that there were adverse impacts on U.S. producers, or the domestic economy. Growers would only adopt this variety to the extent it provided them economic benefit.

Given the agronomic and compositional equivalence of MZHG0JG corn to commercially available corn varieties (Davis, Jarrett et al. 2015), and considering USDA projections for corn acreage, yields, and net returns per acre through 2024/25 (Westcott and Hansen 2015), the economic impacts of a determination of non-regulated status of MZHG0JG corn on domestic markets would be expected to be similar to or same as the No Action Alternative.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

Under this alternative MZHG0JG corn would remain a regulated article by APHIS and no seed from MZHG0JG corn would be produced for export. There would be no impacts to trade under the No Action Alternative.

Preferred Alternative: Trade Economic Environment

Given the U.S. and other countries already have access to other herbicide-resistant corn cultivars, both single and stacked-trait varieties; that MZHG0JG corn is similar in composition, growth habits, and cultural requirements as compared to other nonregulated corn varieties (Davis, Jarrett et al. 2015); and it would have the same global uses as current GE and non-GE corn products; MZHG0JG corn would not be expected to affect the seed, feed, or food trade any differently than other nonregulated herbicide-tolerant corn varieties. MZHG0JG corn would be subject to the same international regulatory requirements as currently traded U.S. GE corn products, and, as another stacked-trait herbicide-tolerant corn that would be available to growers, MZHG0JG corn would be expected to replace other herbicide-tolerant cultivars only to the extent growers find economic gains in the international trade of MZHG0JG corn. Syngenta initiated the FDA consultation process for use of MZHG0JG corn as food and feed in U.S. commerce in 2015, and additional regulatory approvals that facilitate global trade of MZHG0JG corn commodities will be sought on an as-needed basis.

5 CUMULATIVE IMPACTS

Cumulative impacts are those that may result from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions, regardless of the agency (Federal or non-Federal) or person that undertakes such other actions. Cumulative impacts can result from individually minor, but collectively significant actions taking place over time (40 CFR part 1508, Section 1508.7, Cumulative impact). For example, the potential impacts associated with a determination of nonregulated status for a GE crop in combination with future crop production utilizing a variety of deregulated traits (i.e., “stacked” traits), including herbicide-tolerance and pest-resistance, would be those considered under cumulative impacts.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative impacts are evaluated for each aspect of the human environment assessed in Section 4, Environmental Consequences. In the Section 4 evaluations, if there are no direct or indirect impacts associated with those aspects of the human environment evaluated, then APHIS assumes there can be no reasonably foreseeable cumulative impacts. APHIS limits evaluation of cumulative impacts to those areas in the U.S. where corn is commercially produced.

Syngenta’s compositional analyses and field studies of MZHG0JG corn demonstrate that, apart from the intended phenotype of tolerance to glyphosate-based and glufosinate-ammonium based herbicides, MZHG0JG corn is no different than conventional corn with regard to phenotypic and agronomic properties (Davis, Jarrett et al. 2015). This implies, and APHIS assumes in evaluation of potential cumulative impacts, that farmers who will produce conventional or organic corn, and MZHG0JG corn, will continue to use those agronomic practices commonly applied in commercial corn production, as described in Section 2.1 - Agricultural Production of Corn. As glyphosate and glufosinate, in tandem with other pesticides, can be used in production of MZHG0JG corn, APHIS assumes that growers that adopt MZHG0JG corn will adhere to EPA-registered use and label requirements for all pesticides applied to this crop.

Corn varieties that contain more than one GE trait, or “stacked-trait” hybrids, are currently the most common varieties of commercial corn produced in the U.S. (USDA-ERS 2015b). If APHIS approves the extension request for nonregulated status of MZHG0JG corn, this variety could potentially be combined with non-GE and other GE corn cultivars through traditional breeding techniques, resulting in a corn variety that, for example, may be resistant to three or more herbicides or contain other insect-resistance traits that are no longer subject to the regulatory requirements of 7CFR Part 340. For example, MZHG0JG corn could be combined, through traditional breeding, with insecticidal traits in other deregulated corn varieties that protect against yield loss from lepidopteran and/or coleopteran pests.

APHIS assumes that next-generation stacked-trait corn products derived from MZHG0JG corn would likely be those conferring insect-resistance through breeding with nonregulated corn varieties containing the *Bacillus thuringiensis* (Bt) trait. APHIS further assumes that these stacked-trait varieties would be produced only in response to demand in expanding grower choice, and to the extent such a stacked-trait variety would offer the ability to improve production efficiency and control pests and weeds in large scale commercial corn production systems.

Stacking of nonregulated GE corn varieties using traditional breeding techniques is common practice, and not regulated under APHIS authority. Agency regulations at 7 CFR part 340 do not provide for Agency oversight of GE corn varieties that are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, unless it can be positively shown that such stacked varieties were likely to pose a plant pest risk. To date, none of the GE corn varieties that have been determined to no longer be regulated articles pursuant to Part 340 and the PPA, and used for commercial corn production or corn breeding programs, have been subsequently found to pose a plant pest risk.

The type of hybrid stack considered in this cumulative impacts analysis considers the combination of the MZHGOJG corn (glyphosate and glufosinate tolerant) with insect-resistance (Bt) from GE corn varieties no longer subject to the regulatory requirements at 7 CFR Part 340 or the plant pest provisions of the PPA. Stacked-trait corn varieties with tolerance to both glyphosate and glufosinate, and resistance to *Coleoptera* and *Lepidoptera* insect species are already in international commerce, some of which are summarized in Table 8. Recent commercial hybrids utilizing these stacked traits include the following products. Each of these varieties are approved for food and feed in the U.S. and E.U.

Table 8. Stacked-Trait GE Corn in International Commerce: Glyphosate- and Glufosinate Tolerant, Insect-Resistant					
OECD UID*	Species	Traits	Developers	E.U.	U.S.
DAS-Ø15Ø7-1	<i>Zea mays</i>	Lepidoptera resistance (Cry1F), Glufosinate tolerance (PAT)	DOW AgroSciences, DuPont	FF**	Commodity Cultivation
DAS-Ø15Ø7-1 x MON-88Ø17-3	<i>Zea mays</i>	Coleoptera resistance (Cry3Bb1), Lepidoptera resistance (Cry1F), Glufosinate tolerance (PAT), Glyphosate tolerance (CP4epsps)	DOW AgroSciences, Monsanto Company, DuPont	FF	Commodity Cultivation
DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	<i>Zea mays</i>	Lepidoptera resistance (Cry1F), Glufosinate tolerance (PAT), Glyphosate tolerance (CP4epsps)	DOW AgroSciences, Pioneer Hi-Bred International, Monsanto Company, Mycogen Seeds, DuPont	FF	Commodity Cultivation
DAS-59122-7	<i>Zea mays</i>	Coleoptera resistance (Cry34Ab1), Glufosinate tolerance (PAT)	DOW AgroSciences, DuPont	FF	Commodity Cultivation
DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	<i>Zea mays</i>	Coleoptera resistance (Cry34Ab1), Lepidoptera resistance (Cry1F), Glufosinate tolerance (PAT), Glyphosate tolerance (CP4epsps)	DOW AgroSciences, Pioneer Hi-Bred International, Monsanto Company, DuPont	FF	Commodity Cultivation

DAS-59122-7 x MON-ØØ6Ø3-6	<i>Zea mays</i>	Coleoptera resistance (Cry34Ab1), Glufosinate tolerance (PAT, Glyphosate tolerance (CP4epsps)	Pioneer Hi-Bred International, Monsanto Company, DuPont	FF	Commodity Cultivation
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* OECD UID: Organization for Cooperative Development Unique Identifier

** FF: Approved for Food and Feed in the European Union (E.U.)

Sources: (CLI 2015a); (Euginius 2015)

Whether MZHG0JG corn will be stacked with any particular nonregulated GE corn variety is unknown, as market demand, the economics of corn production, and seed company plans play a substantial role in the business of corn production, and generation of new corn hybrids. The adoption level of MZHG0JG corn would depend on the extent to which producers value the traits offered by stacked-trait versions of MZHG0JG corn over other available stacked-trait corn varieties, and comparative pricing and efficacy of stacked-trait MZHG0JG corn varieties relative to other corn varieties. However, for the purposes of evaluating cumulative impacts, USDA-APHIS assumes that MZHG0JG corn would likely be combined with commercially available herbicide-tolerant and insect-resistant corn varieties, and adopted in commercial corn production systems. APHIS further assumes that growers will likely employ those integrated weed management practices (described throughout this EA) that can reduce impacts to soil, water, and air quality, and help deter the development of herbicide resistant weeds (Owen 2011, Vencill, Nichols et al. 2012).

Since the commercialization of Bt crops, a substantial number of field studies required for EPA plant incorporated protectant (PIP) registration have demonstrated non-target invertebrates are generally more abundant in Bt corn fields than in non-transgenic fields managed with chemical insecticides (see (EPA 2010a)). These published and registrant-produced studies demonstrate that, not only have Bt crops not caused any unreasonable adverse environmental effects, but that arthropod prevalence and diversity is greater in Bt crop fields (EPA 2010a). Based on the body of knowledge accumulated on Bt based PIPs (e.g., see (EPA 2010b, EPA 2010a, USDA-ARS 2015)), several of these PIPs have been granted exemption from need for established tolerance limits in food and feed (Table 9), as described in 40 CFR §174, Procedures and Requirements for Plant-Incorporated Protectants.

Table 9. Tolerance Exemptions for <i>Bacillus thuringiensis</i> Modified Cry Proteins: 40 CFR §174	
§174.501	<i>Bacillus thuringiensis</i> Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.
§174.502	<i>Bacillus thuringiensis</i> Cry1A.105 protein; exemption from the requirement of a tolerance.
§174.504	<i>Bacillus thuringiensis</i> Cry1F protein; exemption from the requirement of a tolerance.
§174.505	<i>Bacillus thuringiensis</i> modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.
§174.506	<i>Bacillus thuringiensis</i> Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.
§174.507	Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.
§174.508	Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

§174.509	<i>Bacillus thuringiensis</i> Cry3A protein; exemption from the requirement of a tolerance.
§174.510	<i>Bacillus thuringiensis</i> Cry1Ac protein in all plants; exemption from the requirement of a tolerance.
§174.511	<i>Bacillus thuringiensis</i> Cry1Ab protein in all plants; exemption from the requirement of a tolerance.
§174.517	<i>Bacillus thuringiensis</i> Cry9C protein in corn; exemption from the requirement of a tolerance.
§174.518	<i>Bacillus thuringiensis</i> Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.
§174.519	<i>Bacillus thuringiensis</i> Cry2Ab2 protein; exemption from the requirement of a tolerance.
§174.521	Neomycin phosphotransferase II; exemption from the requirement of a tolerance.
§174.522	Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.
§174.529	<i>Bacillus thuringiensis</i> modified Cry1Ab protein as identified under OECD Unique Identifier SYN-IR67B-1 in cotton; exemption from the requirement of a tolerance.
§174.530	<i>Bacillus thuringiensis</i> Cry2Ae protein in cotton; exemption from the requirement of a tolerance.
§174.532	<i>Bacillus thuringiensis</i> eCry3.1Ab protein in corn; exemption from the requirement of a tolerance.

Future combinations of MZHG0JG corn with one or more of the deregulated PIP traits in Table 9 could be developed and commercially produced. An analysis of the cumulative impacts of such potential stacking is considered in the individual sections below.

A further consideration involving MZHG0JG corn, and stacked-trait progeny that could be derived from this variety, is the fact that U.S. growers cultivating Bt corn varieties are now required to adopt insect resistance management (IRM) strategies to delay the development of insect resistance as a result of continued exposure to Cry proteins. One of the key strategies required by the EPA involves the incorporation of refuges into their IRM practices (see, e.g., (EPA 2010a, EPA 2015i)). The refuge strategy is based on the concept that resistant insect pests will mate with susceptible pests from nearby refuges of host plants without Bt toxin, thus producing offspring that are susceptible to the Bt corn crop (Tabashnik and Gould 2012). Refuge strategies can include a field or a block or strip of non-Bt corn that does not contain a Bt trait. Recently, the EPA also has approved an integrated refuge strategy, named “refuge in a bag,” where non-Bt seeds are blended with the Bt corn products and planted randomly within the field to ensure that refuge requirements are followed.

Lastly, it is possible, as proposed by Syngenta, that MZHG0JG corn (not a future stacked-trait Bt variety) may facilitate grower compliance with EPA mandated refuge requirements for corn varieties with insecticidal traits. The EPA has authorized the use of seed blend products (“refuge in a bag”) to facilitate grower compliance with requirements to incorporate the appropriate proportion of non-insect-resistant refuge corn when planting corn varieties that produce EPA-registered PIPs. While many commercial stacked-trait insect-protected corn varieties are tolerant to herbicides containing glyphosate and glufosinate-ammonium, not all non-insect-resistant refuge seed varieties are tolerant to both herbicides. For this reason, MZHG0JG corn is also intended for use as the non-insect-resistant refuge component in seed blend products, offering growers the flexibility to use either glyphosate-based and/or glufosinate-ammonium-based herbicides, depending on their weed management needs and recommended control practices (Davis, Jarrett et al. 2015).

5.2 Cumulative Impacts: Acreage and Area of Corn Production

As discussed in Subsection 4.2.1 – Acreage and Area of Corn Production, a determination of nonregulated status of MZHG0JG corn is not expected to result in a substantial change in the acreage or area devoted to conventional or GE corn cultivation or corn grown for seed in the U.S.

The majority of corn grown in the U.S. is GE herbicide-tolerant (USDA-ERS 2015b), and stacked-trait varieties represent an increasing proportion of commercially-available corn, with approximately 76% of the total corn acreage in 2014 cultivated with stacked-trait varieties (USDA-ERS 2015a). In general, single-trait GE corn varieties that are singularly HT or IR have been declining, and corn varieties stacked with both traits are planted more frequently than those varieties conferring resistance to a single trait, largely due to efficiencies in controlling weeds, to include glyphosate resistant weeds, and costs in pesticide management (Fernandez-Cornejo, Nehring et al. 2014a, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). The trend toward utilization of stacked-trait corn varieties combining insect-resistance and herbicide-tolerance (and potentially other traits) is likely to continue, as it may afford growers more options and efficiencies in the commercial production of corn.

There are multiple varieties of stacked trait glyphosate and glufosinate-tolerant corn currently in international commerce (e.g., see (CLI 2015a, Euginius 2015)). The EPSPS and PAT traits that are the foundation for MZHG0JG corn are already widespread in commercially produced corn, as are those Bt based traits with which MZHG0JG corn could be stacked (e.g., Table 9). MZHG0JG corn would simply provide another option for generating stacked-trait corn varieties utilizing currently deregulated GE corn varieties, and would only replace other corn varieties to the extent that growers found benefit in maximizing yield and net returns. Consequently, there are no reasonably foreseeable outcomes where the availability of MZHG0JG corn as a breeding stock to create future hybrid stacks would result in a change the areas or acreage required for commercial corn cultivation in the United States.

Both U.S. and global demand for corn and corn products determine the acreage required for corn production (e.g., see (Livingston, Fernandez-Cornejo et al. 2015, USDA-FAS 2015)). Relative to the particular variety of corn chosen for production: Based on the 2010 Agricultural Resource Management Survey (ARMS), farmers indicate that they adopted GE corn primarily to increase yields (71% surveyed), to save management time to facilitate other production practices (such as crop rotation and conservation tillage) (13%), and to reduce pesticide input costs (7%)(Fernandez-Cornejo, Wechsler et al. 2014).

It is assumed these would be driving factors in the adoption of any future MZHG0JG corn derived stacked-trait variety, and that growers would do so in response to market demand. Considering these factors, and that (1) MZHG0JG corn is agronomically and compositionally similar to other commercially available corn cultivars; (2) it is expected that MZHG0JG corn would replace other GE corn varieties, if adopted; and (3) USDA projections indicate planted corn will maintain around 89 million acres a year through 2024/25, about the same as the 91.6 million acres planted to corn in 2014 (USDA-NASS 2015f); the availability of MZHG0JG corn or stacked-trait progeny derived from conventional breeding would not likely have any substantial impact on the area or acreage of corn production.

5.3 Cumulative Impacts: Agronomic Practices

As discussed in Subsection 4.2.2 – Agronomic Practices, a determination of nonregulated status of MZHG0JG corn is not expected to result in any substantial changes to agronomic practices used in the production of corn. The agronomic characteristics evaluated for MZHG0JG corn in field trials encompassed the entire life cycle of the corn plant, and included seed germination and dormancy, growth habit, pollen viability and morphology, corn in ear height, plant height, and yield parameters. The compositional analyses included the major constituents (carbohydrates, protein, fat, and starch), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, and nutritional impact. These analyses confirm that MZHG0JG corn is agronomically and compositionally similar to other non-GE corn varieties (Davis, Jarrett et al. 2015). As a result, and as described in Section 4, Environmental Consequences, the potential direct and indirect impacts on agronomic practices under the Preferred Alternative would be same as or similar to those under the No Action Alternative.

As discussed in the introduction to this section, MZHG0JG corn may be combined with other HT and/or IR corn varieties to produce a conventionally bred corn with 3 or more traits. Weed management methods applied to MZHG0JG corn or its progeny would generally follow current practices for similar corn varieties currently utilized in commercial corn production (e.g., mEPSPS and PAT traits). Growers would continue using glyphosate and glufosinate for weed control, and/or glyphosate and glufosinate in combination with other herbicides on MZHG0JG corn progeny. The MZHG0JG corn or its progeny events could provide growers a broader range of choices for alternating the types of herbicides used annually, or within a given cropping season, as well as reducing insecticide use in the event this is bred with an IR GE corn variety (e.g., (EPA 2010a)).

Because the methods of application and use rate for pesticides that would be applied to MZHG0JG corn, or its progeny, would not change from those already approved by EPA for use on other nonregulated corn cultivars, the potential impacts from the use of herbicides under the Preferred Alternative would be the same as those of the No Action Alternative. The total amount of the mix of herbicides that could be applied to MZHG0JG corn, or its progeny, would be limited by the EPA authorized and registered uses of herbicides, and the annual application limits indicated on the labeled instructions for use (e.g., see (EPA 2015k)). As it is a violation of Federal law to use an herbicide in a manner inconsistent with its labeling, and considering the need for controlling the development of resistant weeds, it is expected that growers in coming years will use herbicides judiciously, and per EPA label use requirements, as part of IWM programs.

As described in Subsection 4.2.2 - Agronomic Practices, there are no changes to tillage, crop rotation, or agronomic inputs that would be required for MZHG0JG corn. In the event MZHG0JG corn is used to produce a stacked-trait IR corn variety; there are no reasonably foreseeable changes in agronomic practices that would be required for such progeny, as there are multiple examples of these types of HT/IR stacked-trait corn cultivars currently in commerce (e.g., (CLI 2015a, Euginius 2015) and Table 9).

Considering these factors, MZHG0JG corn and any hybrid progeny produced from it would not require substantially different crop production practices compared to other corn varieties that are

currently available to growers. Consequently, no significant cumulative impacts would be expected on U.S. corn production and yield, agronomic practices such as pesticide use, crop rotation, tillage, irrigation, disease management, or weed management.

5.4 Cumulative Impacts: Organic Corn Production

Based upon trends over the last decade, the adoption of GE corn varieties in commercial corn production is unrelated to the prosperity and market share of organic production systems (see Subsections 2.1.3 and 4.2.3, Organic Corn Production. U.S. consumer demand for organically produced goods has grown continuously since USDA established national standards for organic production and processing in 2002 (USDA-AMS 2015c). Domestic production of many organic crops and livestock specialties has also increased during this period. Between 2005 and 2011, certified organic cropland expanded nearly 80%, to 3.1 million acres (USDA-ERS 2015f). Organic livestock sectors have expanded at even greater rate. Together, certified organic cropland and pasture accounted for about 0.6% of the U.S. total farmland in 2011. Only a small percentage of the top U.S. field crops such as corn (0.3%), soybeans (0.2%), and wheat (0.6%), were grown under certified organic farming systems (USDA-ERS 2015f). This expansion of organic production occurred despite the concurrent increases in conventional and GE corn acreage (USDA-NASS 2014c).

Where certified organic corn acreage is substantially less than that of conventional and GE corn acreage (i.e., approximately 234,000 acres or 0.25% of corn acres planted for grain in 2011 (USDA-NASS, 2012a)), and organic corn yields tend to be less than conventional or GE crops (i.e., bushels per acre), the profit per acre of organic corn is greater because of the premium organic growers receive for their products in U.S. markets (U-Minn 2010, USDA-ERS 2015e).

Organic corn producers use a variety of measures to manage identity and preserve the integrity of their production systems (NCAT 2003, USDA-AMS 2015c), and this would not be affected by the Preferred Alternative. Conventional and GE-corn growers also use well established agricultural practices to reduce or limit cross pollination between corn varieties, which would not be expected to alter on introduction of MZHG0JG corn into commerce. Planting and production of GE, non-GE, and organic corn will continue to fluctuate with market demands, and GE and conventional corn production will likely follow USDA projections through 2024/25 (Westcott and Hansen 2015), pending any extreme, unforeseen weather events. In general, organic corn production may increase if trends in market premium sustain or increase.

Based on these trends, and the corresponding production systems already in place to maintain varietal integrity, described in Subsections 2.1.3 -Organic Corn Production, and 4.2.3 - Organic Corn Production, there are no reasonably foreseeable cumulative impacts to organic corn production that would follow a determination of nonregulated status for MZHG0JG corn.

5.5 Cumulative Impacts: Physical Environment

MZHG0JG corn is compositionally, agronomically, and phenotypically equivalent to commercially cultivated corn, and the environmental interactions of MZHG0JG corn are same as or similar to conventional corn (Davis, Jarrett et al. 2015). If MZHG0JG corn were bred for stacking, progeny would be similar to a number of stacked-trait HT/IR GE corn varieties also

currently in commerce (e.g., Table 9). In the event of adoption of MZHG0JG corn, it would replace other GE corn cultivars. As described above (Subsection 5.2), there are no reasonably foreseeable changes in the acreage or area of corn production that would be required for cultivation of MZHG0JG corn, or any stacked-trait progeny derived from it. Similarly, agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not be substantially altered, because MZHG0JG corn is agronomically similar to other GE HT corn and non-GE corn varieties (Davis, Jarrett et al. 2015). As described in Subsection 5.3, any stacked-trait progeny derived from MZHG0JG corn would likewise require no to little in change to standard agronomic practices applied to corn cultivation in the U.S., as these types of stacked-trait corn varieties (e.g., HT/IR) are already widely cultivated, worldwide.

If the extension request for nonregulated status for MZHG0JG corn is approved and it is stacked with other HT or IR traits, depending on the extent of its adoption, it may contribute to sustaining conservation tillage practices in U.S. corn production, which both directly and indirectly benefit water, soil, and air quality. Stacking MZHG0JG corn with other HT or IR traits would enable use of a combination of herbicides with different modes of action to be applied in integrated weed management (IWM) programs, which is widely recommended by academia and weed specialists to manage glyphosate-resistant weeds, and mitigate the future development of herbicide-resistant weeds (Owen 2011, Owen 2012, Vencill, Nichols et al. 2012, Evans, Tranel et al. 2015). Such IWM approaches may reduce the need for conventional tillage (Owen 2011, Owen 2012), thus benefiting soil, water, and air quality (Randall, Evans et al. 2002, Roger-Estrade, Anger et al. 2010, Fernandez-Cornejo, Hallahan et al. 2012, Roth 2015). Utilization of any MZHG0JG corn progeny stacked with IR traits could also facilitate reduction in insecticide use (EPA 2010b, EPA 2010a).

Considering MZHG0JG corn is similar to other GE and non-GE corn varieties in terms of growth habit, agronomic properties, composition, and environmental interactions (Davis, Jarrett et al. 2015); that any stacked-trait variety would likely be produced from an unregulated GE corn variety already in commerce (e.g., CLI 2015a, Euginius 2015), and Table 9); and that such stacked-trait varieties have been reviewed and approved as to potential adverse impacts on the physical environment; it is assumed that any progeny derived from MZHG0JG corn would not substantially differ in phenotype or environmental interactions from current commercial GE corn varieties. Any such progeny would likely replace other corn cultivars, to the extent that progeny provided efficiencies in the production of corn, and commensurate quality in corn and corn products. As such, a determination of nonregulated status of MZHG0JG corn is not anticipated to result in any significant cumulative impacts on water quality or use, soil or air quality, or on climate change, relative to the No Action Alternative, as MZHG0JG corn or its progeny, would replace currently cultivated GE corn varieties.

5.6 Cumulative Impacts: Biological Resources

A determination of nonregulated status of MZHG0JG corn is not anticipated to have any significant cumulative impacts on animals, plants, soil microorganisms, or biodiversity. As described in the previous section, MZHG0JG corn is both agronomically and compositionally similar to other nonregulated GE HT corn varieties (Davis, Jarrett et al. 2015), and any stacked-

trait MZHG0JG corn progeny is not expected to substantially differ from stacked-trait GE HT/IR corn varieties already in commerce.

Neither MZHG0JG corn nor its progeny would require any change in agronomic practices used to cultivate corn that could affect wildlife habitat or soil microbiota. The mEPSPS and PAT proteins expressed in MZHG0JG corn are environmentally benign (EPA 2007c, EPA 2007b, ILSI-CERA 2011a, ILSI-CERA 2011b, Davis, Jarrett et al. 2015), and any stacked-trait MZHG0JG corn progeny carrying Bt derived insect-resistant traits would not be expected to pose any risk to biological resources (e.g., see (EPA 2010b, EPA 2010a, USDA-ARS 2015)); there are currently multiple varieties of GE HT/IR corn cultivated worldwide, with negligible impacts on biological resources.

5.6.1 Mammals and Birds

As discussed in Subsection 4.4 – Biological Resources, cultivation of MZHG0JG corn, with the mEPSPS and PAT proteins providing herbicide resistance, is unlikely to have any adverse impacts on non-target organisms. The likelihood of cumulative impacts on non-target organisms as a consequence of exposure to these proteins following the introduction of MZHG0JG corn would be negligible (ILSI-CERA 2011a, ILSI-CERA 2011b, USDA-AMS 2015c). Likewise, any MZHG0JG corn stacked-trait progeny carrying Bt derived insect-resistant traits would not be expected to pose any cumulative risk to biological resources (e.g., see (EPA 2010b, EPA 2010a, USDA-ARS 2015)). As discussed, there are currently multiple varieties of GE HT/IR corn cultivated worldwide, with negligible impacts on biological resources, other than the fact that for all corn, GE and non-GE, cornfields have intrinsically less biodiversity, due to human disturbance of these environments.

The herbicides glyphosate and glufosinate are widely used in the commercial production of corn, and there are a variety of stacked-trait corn varieties commercially available that contain traits that confer tolerance to these herbicides (CLI 2015a, NCGA 2015). A hybrid based on MZHG0JG corn containing traits resistant to other herbicides or insects would provide growers with another corn varietal allowing the use of herbicides with multiple modes of action consistent with current recommended practices for effective management of weeds (Owen 2011, Vencill, Nichols et al. 2012). With regard to potential risk to mammals and birds from glyphosate and glufosinate exposure, various ecological risk assessments for glyphosate and glufosinate have been conducted (i.e., (TOXNET 2015a, TOXNET 2015b)), and these investigations have determined that there are minimal effects on birds and mammals, as well as fish and invertebrates (EPA 2008b, EPA 2013a, EPA 2015g, TOXNET 2015a, TOXNET 2015b). Any MZHG0JG corn stacked-trait progeny carrying Bt derived insect-resistant traits would not require any increase in the acreage required for commercial corn production, and the future use of any pesticide on MZHG0JG corn, or stacked-trait progeny, would be under those requirements specified by EPA. Consequently, there are no reasonably foreseeable cumulative impacts on mammals or birds that would derive from cultivation of a MZHG0JG corn, or its progeny.

5.6.2 Plant Communities

The primary potential cumulative impact to plant communities is the development of herbicide-resistant (HR) weeds, as described in Subsections 2.3.2 and 4.4.2 - Plant Communities. The use of glyphosate and glufosinate, or other herbicides, could potentially contribute to increased selection pressure for weed resistance, particularly if they are not used in a sound integrated weed management (IWM) system that includes use of herbicides with differing modes of action, and diversified weed management practices (Owen 2011, Gibson, Young et al. 2015).

The risk of herbicide-resistant weed development will be ever present where herbicides are used, however, current data indicate that IWM strategies can prolong the utility of the GE HT cultivars, and help reduce the seedbank of glyphosate-resistant weeds (Werth, Preston et al. 2008, Weirich, Shaw et al. 2011, Evans, Tranel et al. 2015, Gibson, Young et al. 2015). Proactive management of GR weed populations can also increase the long-term economic returns in corn production (Livingston, Fernandez-Cornejo et al. 2015). In general, it has been shown that academic recommendations, to include IWM practices, to deter glyphosate resistance can be successful in the short term for reducing weed infestations while maintaining robust crop yield potential (Gibson, Young et al. 2015), however; it will likely take many years, perhaps up to 10 years in some cropping systems, to affect the weed seedbank, including recruitment of weed species with a high risk for resistance to glyphosate (Gibson, Young et al. 2015).

Stacked-trait MZHG0JG corn and progeny hybrids would be expected to present growers with expanded weed management options for addressing hard to control weeds, to include options in IWM systems that can minimize potential impacts on biological resources. APHIS assumes that growers will likely employ those IWM practices widely recommended by academia and industry, which can help deter the development of herbicide resistant weeds, and potentially reduce the weed seedbank of GR weeds (Owen 2011, Vencill, Nichols et al. 2012, Gibson, Young et al. 2015) as there are both economic and practical incentives for doing so (Fernandez-Cornejo, Nehring et al. 2014b, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). APHIS further assumes that growers would adopt MZHG0JG corn, and any potential stacked-trait progeny, based on the efficiencies provided by this variety in maximizing crop yields, and managing weeds.

The availability of MZHG0JG corn to growers would not be expected to adversely affect the further development of glyphosate-resistant weeds, or deter the trend to broaden IWM strategies to control herbicide-resistant weeds. Growers are currently using both glyphosate and glufosinate to control weeds in similar stacked corn hybrids (see, e.g., (NCGA 2015)), and, as MZHG0JG corn is expected to replace other glyphosate-tolerant cultivars, there would be no increase in the acreage or area of corn production, or increase in the application rates of glyphosate (see Subsection 4.4.2, Plant Communities). On adoption of MZHG0JG corn, there would be a likely increase in the use of glufosinate. In the event MZHG0JG corn and or its progeny are adopted by growers, herbicides would be used according to EPA requirements, which would not change as a result of introduction of MZHG0JG corn into commerce. On approval of the extension request for nonregulated status of MZHG0JG corn, it is assumed that herbicides would be used according to EPA requirements, University extension programs recommended practices, academic and industry recommended IWM practices, as well as future recommendations that

may emerge in the management of weeds (e.g., (Evans, Tranel et al. 2015, Gibson, Young et al. 2015)).

Considering the factors described, there are no past, present, or reasonably foreseeable actions that would result in any significant cumulative impacts on plant communities as a result of determination of nonregulated status for MZHG0JG corn. Selection pressures to varying degrees for development of herbicide-resistant weeds will be ever present where herbicides are used, whether in commercial corn production or residential uses. However, the utilization of IWM and diversified weed management practices described, which are assumed will be employed in production of MZHG0JG corn and its progeny, can reduce selection pressure for resistant weed development. By necessity, growers of commercial corn will have to continuously adapt their weed management strategies and employ the best available science in management of weeds, to include development of HR weeds. It is unlikely that a determination of nonregulated status for MZHG0JG corn would adversely affect grower options or choices in the adaptive management of weeds in coming years.

5.6.3 Invertebrates

Use of MZHG0JG corn or stacked-trait hybrids combining the traits of MZHG0JG corn with nonregulated HT or IR varieties would allow the application of glyphosate and glufosinate, and potentially other pesticides, to MZHG0JG corn or progeny. As discussed in Subsections 2.3.4 and 4.4.4, Microorganisms, the current body of knowledge suggests that glyphosate has little long-term effect on soil microorganisms (USDA-FS 2003, Fernandez, Zentner et al. 2009, Kremer 2010, Duke, Lydon et al. 2012). Similarly, research on the influence of glufosinate on soil microbiota has yielded differing results, although long-term impacts have not been identified (see, e.g., (Bartsch and Tebbe 1989, Gyamfi, Pfeifer et al. 2002, Lupwayi, Harker et al. 2004, Wibawa, Mohamad et al. 2010). Any pesticides used in the commercial production of MZHG0JG corn or its progeny would be subject to EPA requirements for use of those pesticides. In many cases, crop and soil management practices that increase soil organic matter and plant residues, such as conservation tillage, impart attributes to soil that can enhance microbial populations and microbial pesticide degradation (Locke and Zablotowicz 2004, Zhao, Neher et al. 2013).

As discussed in Subsections 2.1.2 and 4.2.2, Agronomic Practices, there are no direct or indirect impacts on soil microbiota associated with the agronomic practices used in the commercial production of corn, nor have any potential impacts been identified for the commercial production of MZHG0JG corn. In the event MZHG0JG corn is used to produce a stacked-trait GE HT/IR corn variety that is introduced in to commerce, adverse impacts on invertebrates are unlikely. By example, various studies have demonstrated non-target invertebrates are generally more abundant in Bt corn fields than in non-transgenic fields managed with chemical insecticides (EPA 2010a).

Based on these factors, and those discussed in Section 4, there are no past, present, or reasonably foreseeable actions that would result in any cumulative impacts on invertebrate populations as a result of determination of nonregulated status for MZHG0JG corn.

5.6.4 Gene Flow and Weediness

APHIS has considered gene flow and weediness in its Plant Pest Risk Similarity Assessment and in Subsections 2.3.3 and 4.4.3 (Gene Flow and Weediness). APHIS concludes that introgression from cultivated corn to the wild relatives teosinte and *Tripsacum* is highly unlikely (Keese 2008). Only limited populations of compatible relatives of corn are found within the U.S., and the risk of gene movement between MZHG0JG corn, or stacked-trait progeny derived from this variety, and its wild relatives, is considered *de minimis*. Corn seed does not possess the characteristics for efficient seed-mediated gene flow, does not establish wild or feral populations, and is dependent on human cultivation for survival (OECD 2003, Doebley 2004). Various methods are available to control gene flow via vertical pathways. These include those to restrict pollen movement between cornfields through the use of isolation distances, border and barrier rows, the staggering of planting dates, detasseling and hand pollination, and various seed handling and transportation procedures (Wozniak 2002, NCAT 2003, Mallory-Smith and Zapiola 2008, Mallory-Smith and Sanchez Olguin 2011, AOSCA 2015).

As discussed in Subsection 4.4.3 - Gene Flow and Weediness, the horizontal movement of genes from corn to unrelated species through asexual pathways would be an event atypical of normal biological processes associated with corn plants, and highly unlikely event (Bertolla and Simonet 1999, CAST 2007, Chandler and Dunwell 2008, Bock 2010, Nielsen, Bøhn et al. 2013, Arber 2014). In considering horizontal gene transfer (HGT) relative to MZHG0JG corn, the relocation of an entire EPSPS or PAT transgene to an unrelated species, including the regulatory elements for expression of these genes, to other biota, is improbable (e.g., (Keese 2008)).

Considering best available science, including information in the Plant Pest Risk Similarity Assessment and in Subsections 2.3.3 and 4.4.3, there are no potential cumulative impacts associated with gene flow and weediness that would derive from a determination of nonregulated status for MZHG0JG corn, or its progeny.

5.7 Cumulative Impacts: Public Health and Animal Feed

5.7.1 Consumer Health

As described in Subsection 4.5 - Human Health, the EPSPS and PAT proteins expressed in MZHG0JG corn have a history of safe use and present negligible risk to human health and safety (EPA 2007c, EPA 2007b, ILSI-CERA 2011a, ILSI-CERA 2011b). Under present and expected use conditions, and when used in accordance with EPA label requirements, glyphosate and glufosinate do not pose risks that would compromise human health.. The EPA has established pesticide residue tolerance limits for glyphosate and glufosinate that include field corn for forage, grain, and stover. APHIS assumes that applications of glyphosate and glufosinate, and any other pesticide that may be used in conjunction with MZHG0JG corn stacked-trait progeny, will be done so consistent with EPA label requirements and pesticide residue tolerance limits (EPA 2015k, EPA 2015l).

Under the preferred alternative, MZHG0JG corn could be stacked with currently available nonregulated herbicide-tolerant or insect-resistant corn varieties. In accordance with 40 CFR part 174, all current nonregulated herbicide-tolerant and insect-resistant corn varieties have been

reviewed by USDA and FDA as to the safety of food and feed derived from these corn varieties. Any traits that may be developed in the future and stacked with MZHG0JG corn would be subject to APHIS, EPA, and FDA review and approval. Based on the body of knowledge accumulated on Bt based PIPs that may be stacked with MZHG0JG corn (e.g., see (EPA 2010b, EPA 2010a, USDA-ARS 2015)), several of these PIPs have been granted exemption from need for established tolerance limits in food and feed (e.g., Table 9), as described in 40 CFR §174, Procedures and Requirements for Plant-Incorporated Protectants.

As discussed in Subsection 4.5, Human Health, MZHG0JG corn would have no direct or indirect adverse impacts on human health, and there are no reasonably foreseeable potential cumulative impacts that would derive from a determination of nonregulated status for MZHG0JG corn.

5.7.2 Worker Safety

Worker safety issues related to agronomic practices and the use of pesticides in the production of corn would not change as a result deregulation of MZHG0JG corn. Those protective standards in place, such as the EPA's Worker Protection Standard (WPS) (40 CFR Part 170), are expected to remain in effect and unchanged by introduction MZHG0JG corn into commerce. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment (PPE), restricted entry intervals (REI) following pesticide application, decontamination supplies, and emergency medical assistance. The Occupational Safety and Health Administration (OSHA) also requires all employers to protect their employees from hazards associated with pesticides and herbicides.

Pesticide applicators are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. Worker safety precautions and use restrictions are clearly noted on pesticide registration labels (i.e., (EPA 2009a, EPA 2015k, EPA 2015f)). The current labels for both glyphosate and glufosinate include label use restrictions intended to protect humans, including protective equipment to be worn during mixing, loading, applications and handling, equipment specifications to control pesticide application, and reentry periods establishing a safe duration between pesticide application and exposure to the pesticide in the field. Based on those factors discussed in Subsections 2.4.2 and 4.5.2, Worker Safety, there are no reasonably foreseeable cumulative impacts on worker safety that would result from determination of nonregulated status of MZHG0JG corn, nor any stacked-trait progeny that would derive from MZHG0JG corn.

5.7.3 Animal Feed

Syngenta is currently, as of June 2015, in consult with the FDA on the food and feed safety of MZHG0JG corn. All varieties of GE corn with which MZHG0JG corn would be stacked have undergone, or are expected to undergo, this process to ensure their safety as food and feed products.

APHIS assumes that applications of glyphosate, glufosinate, and any other pesticide used in conjunction with MZHG0JG corn production or its stacked-trait progeny will be conducted consistent with EPA label and pesticide residue tolerance limits requirements. Syngenta has conducted biochemical analyses of MZHG0JG corn which have demonstrated that MZHG0JG

corn is compositionally and nutritionally equivalent to conventional corn varieties, and the EPA has exempted CP4 EPSPS and PAT from tolerance requirements due to lack of risk of these proteins to animal health (EPA 2007c, EPA 2007b). The FDA has also completed prior consultations with petitioners for the safety of EPSPS and PAT based corn, as discussed in Subsection 4.5.1 - Consumer Health. In these consultations, the FDA notes that the presences of the EPSPS and PAT proteins do not give rise to any animal feed concerns.

Under the preferred alternative, MZHG0JG corn could be stacked with insect-resistant corn varieties that express the Bt endotoxin. In accordance with 40 CFR part 174, all the currently nonregulated insect-resistant corn varieties that contain the Bt endotoxin are exempt from the requirement of tolerance in feed commodities. In the near future, any MZHG0JG corn stacked with insect-resistant (Bt) traits could replace other currently non-regulated GE corn varieties with herbicide and insect resistance. Any insect-resistance trait that may be developed in the future and stacked with MZHG0JG corn would be subject to APHIS, EPA, and FDA approval. The adoption of such a stacked MZHG0JG corn variety would be contingent on the extent to which growers see value in the traits expressed in comparison to other commercially available corn cultivars with similar herbicide- and insect-resistant traits.

In the near term, any additional GE traits that may be stacked with MZHG0JG corn have already been reviewed and deregulated. As previously discussed in Subsections 4.5 (Human Health) and 4.6 (Animal Feed), food and feed derived from GE corn must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market. All varieties of GE corn with which MZHG0JG corn would be stacked have undergone, or are expected to undergo, this process to ensure their safety as food and feed products.

Based on these factors, no potential cumulative impacts to animal feed or health have been identified related to the determination of nonregulated status of MZHG0JG corn.

5.8 Cumulative Impacts: Socioeconomics

5.8.1 Cumulative Impacts: Domestic Economic Environment

Upon a decision to deregulate MZHG0JG corn, it may be combined, through traditional breeding methods, with insecticidal-resistant or herbicide-tolerant traits in other deregulated corn to generate additional stacked-trait corn varieties. Similar stacked-trait varieties possessing glyphosate- and glufosinate-tolerance, and insect resistance, are already on the market; in the U.S. and internationally (CLI 2015a, Euginius 2015).

Adoption rates of stacked-trait corn varieties have increased in recent years, with stacked-trait corn expanding from 1% of planted acres in 2000, to 76% in 2014. Only 13% of corn acres contained a single HT trait, and 4% IR (USDA-ERS 2015c). The increase in adoption of stacked-trait GE varieties is due in part to the fact that stacked-trait varieties have generated higher yields relative to conventional seeds, or seeds with only one GE trait (Fernandez-Cornejo, Wechsler et al. 2014). USDA 2010 ARMS data indicate that conventional corn seeds had an average yield of 134 bushels per acre, while seeds with two types of herbicide tolerance (glyphosate and glufosinate) and three types of insect resistance (corn borer, corn rootworm, and

corn earworm) had an average yield of 171 bushels per acre (Fernandez-Cornejo, Wechsler et al. 2014). GE varieties incorporating three or four traits are now common.

The adoption of IWM strategies, incorporating several herbicides with alternative modes of action, may cost more initially than the conventional single-herbicide approach, but these costs can be offset by an increase in yields in those fields where the weed pressure has been (EPA 2007c, EPA 2007b, ILSI-CERA 2011a, ILSI-CERA 2011b, Weirich, Shaw et al. 2011, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015). There also is an inherent reduction in grower costs associated with a reduction in frequency of herbicide applications, and in the continued avoidance of tillage through careful herbicide applications.

By example, a USDA-ERS study estimated the average impact of GR weeds or reduced glyphosate effectiveness on yields, production costs, and returns. This study found that corn producers who reported GR weeds and soybean producers who reported reduced glyphosate effectiveness realized lower returns than similar corn and soybean producers who did not (Fernandez-Cornejo and Osteen 2015). Corn and soybean producers who used glyphosate alone received lower yields and returns than producers who used at least one other herbicide in combination with glyphosate (Fernandez-Cornejo and Osteen 2015). Although the crop producers using more than one herbicide had higher production costs, these additional costs were offset by higher crop yields (Fernandez-Cornejo and Osteen 2015). Hence, where stacked-trait varieties may incur more costs in some instances, use of integrated weed management practices can offset such costs through improvements in yields, and gains in net-returns (Livingston, Fernandez-Cornejo et al. 2015).

In general, stacked-trait HT/IR varieties have the potential to improve grower management strategies for control of glyphosate-resistant weeds through utilization of integrated weed management (IWM) practices, and are not expected adversely affect grower net-returns on crop production {Livingston, 2015 #53;Owen, 2011 #169;Owen, 2012 #192;Westcott, 2015 #65, and consequently, the agricultural industry and consumers.

The cultivation of a stacked-trait hybrid containing the traits from MZHG0JG corn and resistance to glyphosate, glufosinate, and other herbicides, is not likely to impact grower demands for stacked-trait products. Based on the 2010 Agricultural Resource Management Survey (ARMS), farmers indicate that they adopted GE corn primarily to increase yields (71% surveyed), to save management time to facilitate other production practices (such as crop rotation and conservation tillage) (13%), and to reduce pesticide input costs (7%)(Fernandez-Cornejo, Wechsler et al. 2014). The widespread adoption of GE seed varieties among corn farmers would be indicative of the fact that farmers have largely benefited from production of these crops.

Considering recent trends, it is expected that MZHG0JG corn would likely be stacked with insect-resistant traits and would have impacts on grower production costs and net returns similar to other such stacked-trait corn cultivars already on the market. APHIS assumes that growers will adopt the stacked-trait variety, and/or its progeny, to the extent that MZHG0JG corn and progeny provide benefits to the grower, namely in the way of yield potential, reductions in pest and weed management costs, and time saving crop management efficiencies. Adoption of MZHG0JG corn or progeny would be relative to market demand and grower preference, and have no impact on USDA market projections through 2024/25, which anticipate net returns on corn production increasing from \$244/acre in 2014 to \$300/acre by 2025 (Westcott and Hansen 2015). Based on

current data, APHIS has not identified any potential cumulative impacts on the economics of domestic corn production, or markets, associated with the cultivation of MZHG0JG corn.

5.8.2 Cumulative Impacts: Trade Economic Environment

Syngenta is pursuing regulatory approvals for MZHG0JG corn cultivation in the U.S. and Canada, and may seek cultivation approvals in other countries in the future. Whether MZHG0JG corn and/or hybrid progeny would be exported is unknown, as this variety is not yet approved for import in other countries as of the time of this assessment.

Global demand for agricultural products is projected to continue to rise from 2015 through 2024 (Westcott and Hansen 2015). Global production of agricultural products is also projected to increase more rapidly than world population, providing a marginal increase in average per capita use of most agricultural products (Westcott and Hansen 2015). U.S. corn exports are likewise expected to expand, increasing to 63.5 million tons/yr by 2024/25 (Westcott and Hansen 2015).

As described above for the domestic economic environment, current data indicates that stacked-trait corn technology has the potential to increase yield in corn production, at comparable or lower costs relative to conventional corn. This trend in increased yield per/acre (Fernandez-Cornejo, Wechsler et al. 2014), and gains in net-returns/acre {Fernandez-Cornejo, 2015 #66; Livingston, 2015 #53; Westcott, 2015 #65}, would be expected to at least sustain, and could enhance, the trade of U.S. corn in the global market.

Global demand for corn and corn products determine the acreage required for corn production (e.g., see (Livingston, Fernandez-Cornejo et al. 2015, USDA-FAS 2015)), as well as potential production efficiencies achieved with GE varieties of corn. The profitability of GE seeds for individual farmers depends largely on the value of the yield losses mitigated and the associated pesticide and seed costs. Considering that stacked-trait seeds have higher yields than conventional seeds or seeds with only one GE trait (described above) (Fernandez-Cornejo, Wechsler et al. 2014), and that farmers adopt GE corn primarily to (1) increase yields, (2) save management time to facilitate other production practices (such as crop rotation and conservation tillage), and (3) reduce pesticide input costs (Fernandez-Cornejo, Wechsler et al. 2014), it is assumed that farmers would adopt MZHG0JG corn and any stacked-trait progeny derived from it, only to the extent it provided growers an economic incentive to do so.

If MZHG0JG corn were approved as nonregulated in the U.S., yet not approved for import by other countries, this scenario would not likely affect the supply of U.S. corn eligible for import to other countries, nor U.S. trade of corn. Adverse impacts on exports under this scenario would be unlikely because most growers would likely hesitate to produce a crop with limited potential for international grain sales. Likewise, if it were approved both in the U.S. and for import by other countries, based on the similarity of MZHG0JG corn, as well as potential stacked-trait progeny, to other stacked-trait corn cultivars in commerce, and the likelihood it would replace other such cultivars without increasing the cost of corn production, MZHG0JG corn or progeny would be unlikely to affect the supply of U.S. corn available for export, as the same economic incentives for adopting these varieties would apply.

As discussed in Subsection 4.7.2 – Trade Economic Environment, a determination of nonregulated status of MZHG0JG corn would not likely affect the U.S. supply of corn such that

it may affect trade. Other countries are increasing their production of herbicide-tolerant corn, including glyphosate-resistant cultivars, and emerging as notable competitors in the international trade of corn trade (Westcott and Hansen 2015). Because the U.S. and other countries already have access to other herbicide-resistant corn cultivars, both single and stacked-trait varieties, and MZHG0JG corn and any progeny derived from it would present yet another option among stacked-trait corn varieties, its availability to U.S. producers would not be expected to impact U.S. trade. Growers will adopt MZHG0JG corn and its progeny to the extent this cultivar can meet global demands, and provide growers benefits in the way of yields and net-returns. Based on these factors, there are no reasonably foreseeable cumulative impacts on the U.S. trade of corn that could arise from a determination of nonregulated status for MZHG0JG corn.

6 Threatened and Endangered Species

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

6.1 Requirements for Federal Agencies

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the PPA (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

The APHIS regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). After completing a similarity assessment, if APHIS determines that MZHG0JG corn seeds, plants, or parts thereof do not pose a plant pest risk similar to its antecedents, then this article would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a

determination that this article is no longer regulated. As part of its EA analysis, APHIS analyzed the potential effects of MZHGOJG corn on the environment including any potential effects to threatened and endangered species (TES) and critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data related to the organism to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.
- Any other information that may inform the potential for an organism to pose a plant pest risk.

APHIS met with USFWS officials on June 15, 2011, to discuss and clarify whether APHIS has any obligations under the ESA regarding analyzing the effects on TES that may occur from use of pesticides associated with GE crops. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. APHIS has no statutory authority to authorize or regulate the use of pesticides by corn growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate MZHGOJG corn or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of pesticides on those organisms.

6.2 Potential Effects of MZHGOJG Corn on TES

Based on the information submitted by the applicant and reviewed by APHIS, MZHGOJG corn with the exception of tolerance to glyphosate and glufosinate-ammonium, is agronomically, phenotypically, and biochemically comparable to conventional corn (Davis, Jarrett et al. 2015). Syngenta has presented results of agronomic field trials for MZHGOJG corn. The results of these field trials demonstrate that there are no differences in agronomic practices between MZHGOJG corn and conventional corn (Davis, Jarrett et al. 2015). The common agricultural practices that would be carried out in the cultivation of MZHGOJG corn are not expected to deviate from current practices, including the use of EPA-registered pesticides. MZHGOJG corn is not expected to directly cause a measurable change in agricultural acreage or area devoted to corn in

the U.S. (see Subsection 4.2.1, Acreage and Area of Corn Production). Because MZHGOJG corn is agronomically and compositionally similar to other commercially available corn varieties (GE and non-GE), it is expected that MZHGOJG corn will replace other similar varieties without expanding the acreage or area of corn production.

Corn is cultivated in all 50 states within the U.S. Accordingly, the issues discussed herein focus on the potential environmental consequences of approving the extension request for nonregulated status of MZHGOJG corn on TES species and critical habitat in the areas where corn is currently cultivated. APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states where corn is produced from the USFWS Environmental Conservation Online System (USFWS 2015a).

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated article and corn varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on TES animals, APHIS focused on the implications of exposure to the modified 5-enol pyruvylshikimate-3-phosphate synthase (mEPSPS), and phosphinothricin acetyltransferase (PAT) proteins expressed in MZHGOJG corn as a result of the transformation (Davis, Jarrett et al. 2015), and the ability of the plants to serve as a host for a TES.

6.2.1 Threatened and Endangered Plant Species and Critical Habitat

The agronomic data provided by Syngenta were used in the APHIS analysis of the weediness potential for MZHGOJG corn, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by Syngenta tested the hypothesis that the weediness potential of MZHGOJG corn is unchanged with respect to conventional corn (Davis, Jarrett et al. 2015). No differences were detected between MZHGOJG corn and conventional corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tolerance to glyphosate and glufosinate-ammonium (Davis, Jarrett et al. 2015). Potential of corn weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart, Halfhill et al. 2003). Mature corn seeds have no innate dormancy, are sensitive to cold, and in colder climates, many do not survive in freezing winter conditions, although volunteers can be an issue in many locations. Corn has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations. Corn cannot survive in the majority of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops. APHIS has concluded that the determination of nonregulated status of MZHGOJG corn does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated corn varieties.

APHIS evaluated the potential of MZHGOJG corn to cross with a listed species. As discussed in Gene Movement and Weediness (Subsections 2.3.3 and 4.4.3), the potential for gene movement between MZHGOJG corn and related corn species is limited. There is a rare, sparsely dispersed feral population of teosinte, a relative of *Z. mays*, reported in Florida, however, this plant is not listed as a TES (USFWS 2015b). Moreover, where teosinte hybrids have been identified in the

field, they are found to exhibit low fitness and are unlikely to produce a second generation. None of the relatives of corn are Federally listed (or proposed) as endangered or threatened species (USFWS 2015b). Accordingly, a determination of nonregulated status of MZHGOJG corn will not result in movement of the inserted genetic material to any endangered or threatened species.

Based on agronomic field data, literature surveyed on corn weediness potential, and no sexually compatibility of any TES with corn, APHIS determined that MZHGOJG corn will have no effect on threatened or endangered plant species or on critical habitat.

6.2.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products from MZHGOJG corn would be those TES that inhabit corn fields and feed on MZHGOJG corn. As discussed further in Subsection 2.3.1 Affected Environment, Biological Resources, Animal Communities, cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands, but the use of cornfields by birds and mammals is not uncommon. Some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction. Most birds and mammals that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Few if any TES are likely to use corn fields because they do not provide suitable habitat. For birds, only whooping crane (*Grus americana*), Mississippi sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and Sprague's pipit (*Anthus spragueii*; a candidate species) occasionally feed in farmed sites (USFWS 2011). These bird species may visit corn fields during migration (Krapu, Brandt et al. 2004); (USFWS 2011). The whooping crane in particular spends the majority of its foraging time during migration in agricultural fields, although its diet during this time is not well understood (Canadian Wildlife Service and U.S. Fish and Wildlife Service 2007, ICF 2014). As discussed thoroughly in Section 2.3.1, Affected Environment, Biological Resources, Animal Communities, many mammals may feed on corn; especially white tailed deer, raccoons, mice, and voles. As for listed species, the Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas (USFWS 2015b), may occasionally forage on corn among other crops such as sugarcane, winter wheat, and soybean (MSU No Date).

APHIS considered the risks to threatened and endangered animals from consuming MZHGOJG corn. Syngenta has presented information on the food and feed safety of MZHGOJG corn, comparing the MZHGOJG corn variety with conventional varieties currently grown. There are no toxins or allergens associated with this plant (Davis, Jarrett et al. 2015). Compositionally, MZHGOJG corn was determined to be the same as conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (Davis, Jarrett et al. 2015). Results presented by Syngenta show that the introduced genetic material in MZHGOJG corn does not result in any compositional differences between MZHGOJG corn and the non-transgenic hybrid. A history of safe use demonstrate that the mEPSPS and PAT proteins present in MZHGOJG corn present no risk of harm to humans or livestock that consume corn products or to wildlife potentially exposed to MZHGOJG corn. EPSPS and PAT proteins are exempt by EPA from the requirement for food or feed tolerances in all crops (EPA 1997, EPA 2007c, EPA 2007b, EPA 2007a) and have a history of safe use in numerous transgenic crop

varieties that have been deregulated by the APHIS, and reviewed through the biotechnology consultation process with the U.S. Food and Drug Administration. Therefore, there is no expectation that exposure to the protein or the plant will have any effect on T&E animal species that may be exposed to MZHGOJG corn.

Syngenta conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MZHGOJG corn (Davis, Jarrett et al. 2015). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins. MZHGOJG corn protein was determined to have no amino acid sequence similar to known allergens, and lacked toxic potential to mammals (Davis, Jarrett et al. 2015). Syngenta has initiated a consultation with the FDA for the safety and nutritional assessment of food and feed derived from MZHGOJG corn (Davis, Jarrett et al. 2015).

APHIS considered the possibility that MZHGOJG corn could serve as a host plant for a threatened or endangered species (i.e., a listed insect or other organism that may use the corn plant to complete its lifecycle). A review of the species list reveals that there are no members of the genus *Zea* that serve as a host plant for any threatened or endangered species (USFWS 2015a).

Considering the compositional similarity between MZHGOJG corn and other varieties currently grown and the lack of toxicity and allergenicity of mEPSPS and PAT proteins, APHIS has concluded that exposure and consumption of MZHGOJG corn would have no effect on threatened or endangered animal species.

6.3 Summary

After reviewing the possible effects of allowing the environmental release of MZHGOJG corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of MZHGOJG corn on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur from the production of other corn varieties. Corn is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings. Corn is not sexually compatible with, nor serves as a host species for, any listed species or species proposed for listing. Consumption of MZHGOJG corn by any listed species or species proposed for listing will not result in a toxic or allergic reaction.

Based on these factors, APHIS has concluded that a determination of nonregulated status of MZHGOJG corn, and the corresponding environmental release of this corn variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Executive Orders Related to Domestic Issues

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- ***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.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898, EO 13045, and EO 13175. Neither alternative is expected to have a disproportionate adverse impacts on minorities, low-income populations, or children. Nor is either alternative expected to have potential Tribal implications.

The EPSPS and PAT proteins in MZHG0JG corn have a history of safe use and present negligible risks to humans (H erouet, Esdaile et al. 2005, ILSI-CERA 2011a, ILSI-CERA 2011b), inclusive of minorities, low income populations, and children who might be exposed to these proteins through agricultural production and/or processing.

As described in Section 4 (see Human Health), glyphosate and glufosinate would be used on MZHG0JG corn. These pesticides are registered by EPA under FIFRA, and EPA pesticide labels state use precautions and restrictions that are intended to be protective of workers and their families. It is assumed that pesticide applicators will adhere to these EPA pesticide use requirements, and that potential adverse impacts on human health would be *de minimis*.

Currently, the EPA is proposing to revise the existing Worker Protection Standard (WPS) at 40 CFR part 170 to reduce the incidence of occupational pesticide exposure and related illness among agricultural workers (workers) and pesticide handlers (handlers) covered by the rule. EPA is proposing to strengthen the protections provided to agricultural workers and handlers under the WPS by improving elements of the existing regulation, such as training, notification,

communication materials, use of personal protective equipment, and decontamination supplies. The EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public. This regulation, in combination with other components of EPA's pesticide regulatory program, is intended to prevent unreasonable adverse effects of pesticides among pesticide applicators, workers, handlers, the general public, and vulnerable groups, such as minority and low-income populations.

The following executive order requires consideration of the potential impacts of the Federal action on tribal lands.

EO 13175, (US-NARA 2010) (US-NARA 2010) "Consultation and Coordination with Indian Tribal Governments", pledges agency communication and collaboration with tribal officials when proposed Federal actions have potential tribal implications.

EO 13175 states that each Indian tribe has the opportunity to participate in policy development to the greatest extent practicable and permitted by law. Each tribe has the opportunity for timely and meaningful government-to-government consultation with APHIS in developing policies that may have tribal implications. Such policies that could have substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes. "Substantial direct effects" means positive, neutral, or negative effects and potential effects that APHIS or the tribes see as .

The APHIS proposed action, a determination of nonregulated status of MZHG0JG corn, is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, tribes would have control over any potential conflict with cultural and natural resources on tribal properties. The No Action and Preferred Alternatives have no impact on Indian tribal self-government and sovereignty, tribal treaties, or other rights, and consultation with tribal officials is not required.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

EO 1311, "Invasive Species," states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Field corn is not listed in the U.S. as a noxious weed species by the Federal government, nor is it listed as an invasive species by major invasive plant data bases (USDA-NRCS, 2010). As discussed in Subsections 2.3.3 and 4.4.3, Gene Flow and Weediness, cultivated corn seed does not have the ability to survive in the wild and requires human involvement for seed dispersion (OECD 2003). In addition, corn seed lacks dormancy, will not produce a persistent seed bank, and seed is not easily dispersed by wind, water, or wildlife, due the size and weight of the seed

(Mallory-Smith and Zapiola 2008, Mallory-Smith and Sanchez Olguin 2011). As such, the chance of corn becoming invasive as a result of seed dispersion is unlikely.

As discussed in Subsections 2.3.3 and 4.4.3, Gene Flow and Weediness, there are a few populations of closely related and sexually compatible subspecies of *Z. mays* within the U.S.; however, these populations are small and limited to collections in botanical gardens, some feral populations in some southeastern states, and small forage crops in some western states. While corn and various teosinte species are culturally and biologically similar, and gene exchange between these groups has been documented, no successful weedy species of corn has evolved and the potential for gene flow between *Z. mays* and sexually compatible wild relatives is not considered a substantial risk to agriculture or environmental (Wozniak 2002, OECD 2003, EPA 2010c). Non-GE corn, as well as other GE herbicide-resistant corn varieties, are widely grown in the U.S. Based on data submitted by Syngenta and reviewed by APHIS, MZHG0JG corn is similar in fitness characteristics to other corn varieties currently grown for commercial production, and is not considered a plant pest risk (Davis, Jarrett et al. 2015). Considering these factors, the potential for a weedy or invasive species of corn to develop as a result of outcrossing with MZHG0JG corn is considered highly unlikely.

The following executive order requires the protection of migratory bird populations:

EO 13186, “Responsibilities of Federal Agencies to Protect Migratory Birds,” states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

APHIS has in place a signed Memorandum of Understanding (MOU) with the U.S. Fish and Wildlife Service (FWS) for the protection of migratory birds and their habitats (USDA-FWS 2012). In accordance with this MOU, APHIS has considered the potential impacts of MZHG0JG corn on migratory birds.

As discussed in Subsections 2.4 and 4.5, Human Health, and 2.5 and 4.6, Animal Feed, data submitted by Syngenta has shown no substantial difference in compositional and nutritional quality of MZHG0JG corn compared with other non-GE corn, apart from the presence of the mEPSPS and PAT proteins. As previously discussed, the mEPSPS and PAT proteins expressed in MZHG0JG corn have been cultivated in a wide variety of commercial corn strains since 1995. The migratory birds that forage in cornfields are unlikely to be affected adversely by ingesting MZHG0JG corn and its products (Hérouet, Esdaile et al. 2005, ILSI-CERA 2011a, ILSI-CERA 2011b). Based on these factors, it is unlikely that the determination of nonregulated status of MZHG0JG corn will have any adverse impact on migratory bird populations.

7.2 Executive Orders related to International Issues

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 EO due consideration and does not expect a substantial environmental impact outside the U.S. in the event of a determination of nonregulated status for MZHG0JG corn. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new corn varieties internationally, apply equally to those covered by a APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of MZHG0JG corn subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC). The purpose of the IPPC “is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control” (IPPC 2015). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). 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 pest risk analysis for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD 2015) 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 still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated. 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.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the OECD. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO 2014).

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.

Syngenta is pursuing regulatory approvals for MZHG0JG corn cultivation in the U.S. and Canada. Additional regulatory approvals that facilitate global trade in corn commodities will be sought on an as-needed basis.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in corn production that may result from a determination of nonregulated status of MZHG0JG corn. As discussed in Subsections 2.1 and 4.2, Agricultural Production of Corn, cultivation of MZHG0JG corn is not expected to lead to the increased production of corn, or acreage of corn, in the U.S. As discussed in Subsections 2.2 and 4.3, Physical Environment, substantial changes in water use and quality, nor air quality, would be expected as a result of cultivation of MZHG0JG corn. Based on this review, APHIS concludes that the cultivation of MZHG0JG corn would be in compliance with the Clean Water Act and the Clean Air Act.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of MZHG0JG corn is not expected to impact the unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

Syngenta presented agronomic data on the field trials for MZHG0JG corn that demonstrate there are no substantial differences in agronomic practices required for MZHG0JG corn relative to current corn varieties in commerce. The common agricultural practices that would be carried out in the cultivation of MZHG0JG corn are not expected to deviate from current practices, nor will the use of the EPA-registered pesticides. MZHG0JG corn would be cultivated on agricultural land currently suitable for production of corn, would likely replace existing corn varieties, and would not increase the acreage or require different areas of corn production.

There are no proposed major ground disturbances; no new physical destructions or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sales, leases, or transfers of ownership of any property. This Preferred Alternative and No Action Alternative would not convert land use to non-agricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting,

irrigation, and harvesting of plants would be used on agricultural lands planted to MZHG0JG corn.

With regard to pesticide use, a determination of nonregulated status of MZHG0JG corn is not likely to result in substantial changes to the use of glyphosate and glufosinate on corn. USDA-APHIS assumes that growers who elect to cultivate MZHG0JG corn or varieties based on the MZHG0JG corn will adhere closely to the EPA label use restrictions for all pesticides applied to their crop.

Based on these considerations, a determination of nonregulated status of MZHG0JG corn is not expected to impact the unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act of 1966 as Amended

The National Historic Preservation Act (NHPA) of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

Neither the Preferred Alternative nor No Action Alternative is expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties. Neither Alternative would have an impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of scientific, cultural, or historical resources.

APHIS' Preferred Alternative is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in impacts on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary impacts on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of MZHG0JG corn is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

8 LIST OF PREPARERS

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Michael P. Blanchette <i>Senior Environmental Protection Specialist</i> Threatened and Endangered Species Analysis	<ul style="list-style-type: none"> ▪ B.S., Entomology, University of New Hampshire ▪ 22 years of professional experience as an Environmental Protection Specialist ▪ 8 years evaluating plant pest and environmental impacts of genetically engineered crops, including effects to threatened and endangered species and critical habitat.
Ron Hardman <i>Environmental Protection Specialist</i> Purpose and Need; Affected Environment; Alternatives; Environmental Consequences; Cumulative Impacts; Consideration of Executive Orders, Standards, and Treaties Relating to Environmental Impacts	<ul style="list-style-type: none"> ▪ Ph.D., Environment, Duke University ▪ M.S., Marine Science/Oceans and Human Health, University of North Carolina at Wilmington ▪ B.S., Biology, Adelphi University ▪ 13 years of experience in molecular and cellular biology ▪ 14 years of experience in environmental and human health risk assessment

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