NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

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

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR Part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of an extension request (APHIS Number 15-124-01p) by Syngenta Seeds, Inc. of Research Triangle Park, NC, USA (hereafter referred to as Syngenta) for their transgenic corn, event MZHG0JG (hereafter referred to as MZHG0JG corn), which is resistant[1] to the herbicides glyphosate and glufosinate-ammonium. 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.

[1] "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. Throughout the EA, USDA-APHIS has used the terms "resistance" and "tolerance". It should be noted however, that different terms for the same concept may be used interchangeably in some instances. In its petition to USDA-APHIS, Syngenta references MZHG0JG corn as "herbicide-tolerant" and used the term "herbicide-tolerant" throughout its documentation to describe the corn event. This terminology can be considered synonymous with "herbicide-resistant" (HR), and has been used in the Environmental Assessment (EA) to reflect language in USDA petition 15-124-01p.

This EA has been prepared in order to specifically evaluate the impacts on the quality of the human environment[2] that may result from a determination of nonregulated status of MZHG0JG corn. The EA assesses alternatives to a determination of nonregulated status MZHG0JG corn and analyzes the potential environmental and socioeconomic impacts that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic mission of USDA-APHIS. USDA-APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (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 within the Executive Office of the President, 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.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA-APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

USDA-APHIS has authority to regulate GE organisms under the plant pest provisions in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq.*). APHIS regulates GE organisms to ensure that they do not pose a plant pest risk based on requirements in 7 CFR Part 340.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this

[2] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The EPA regulates pesticides and plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 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) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). 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.

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, are promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or under 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 pursuant to Part 340 when APHIS has reason to believe that the GE organism may be a plant pest.

APHIS' Response to an Extension Request for Nonregulated Status

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 Plant Pest Risk Similarity Assessment (PPRSA), APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk.

Syngenta submitted an extension request (APHIS Number 15-124-01p) to USDA-APHIS seeking a determination that MZHG0JG corn is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article pursuant to regulations at 7 CFR Part 340.

MZHG0JG corn

MZHG0JG corn is genetically engineered (GE) to be resistant to 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 resistance to glufosinate-ammonium in herbicide products.

GE corn varieties comprised of mEPSPS and PAT traits have been in commercial production since 1997. 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. Stacked-trait varieties with both insect-resistant (IR) and herbicide-resistant (HR) traits accounted for 76% of the 2014 U.S. corn crop. Upon commercialization, MZHG0JG corn is anticipated to support agricultural efficiency by making available another stacked-trait herbicide-resistant corn variety to corn producers.

MZHG0JG corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of MZHG0JG corn have been conducted under USDA-APHIS authorizations 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 request for extension for MZHG0JG corn (15-124-01p).

A determination of nonregulated status for MZHG0JG corn would include MZHG0JG corn, and any progeny derived from MZHG0JG corn through traditional breeding with other non-GE corn varieties and GE corn varieties that have been deregulated pursuant to Part 340 of the Plant Protection Act. 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* pests (e.g., beetles). This type of next-generation HR/IR stacked-trait corn variety could expand grower choice, and facilitate pest and weed management in commercial corn production.

Coordinated Framework Review

Food and Drug Administration

MZHG0JG corn falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (FDA 2006). In compliance with this policy, Syngenta submitted a compositional and nutritional assessment to the FDA to initiate a consultation on the safety of food and feed derived from MZHG0JG corn. The FDA will review the compositional and nutritional data and provide Syngenta and the public a decision on their food and feed safety evaluation for MZHG0JG corn.

Environmental Protection Agency
Under FIFRA (7 U.S.C. 136 *et seq.*), the EPA regulates the use of pesticides, and requires registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use. 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 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.

To ensure the continued safety of pesticides and public health, the EPA conducts pesticide registration reviews pursuant to the Food Quality Protection Act of 1996, 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 2015h). As part of the registration review program, both glyphosate and glufosinate are currently undergoing review with EPA (EPA 2015f, EPA 2015g). Both pesticides, when used in accordance with existing EPA label requirements, present negligible risk to human health (e.g., (EPA 2015a, EPA 2015b, TOXNET 2015a, TOXNET 2015b)).

Scope of the Environmental Analysis
Although a determination of nonregulated status of MZHG0JG corn would allow for new plantings of MZHG0JG corn to occur anywhere in the United States, USDA-APHIS limited the environmental analysis to those geographic areas that currently support corn production. A determination of nonregulated status of MZHG0JG corn is not expected to increase corn production in these areas, or result in an increase in the overall acreage used for corn production. 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 2014b). 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.

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 2014c, Westcott and Hansen 2015). This comprises approximately 25% of total U.S. cropland (~394 million acres) (USDA-NASS 2014b). The amount of 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). Subsection 2.1.1 in the EA, Acreage and Area of Corn Production, presents an overview of the areas and acreage utilized for corn production in the U.S.

The scope of analysis also includes the potential effects of the mEPSPS and PAT traits on the human environment; as stacked traits, and individually. In doing so, the EA considers the similarity of MZHG0JG corn to previously deregulated VCO-Ø1981-5 corn and DP-ØØ4114-3 corn events, described below. Because a determination of nonregulated status for MZHG0JG corn would include MZHG0JG corn, and any progeny derived from MZHG0JG corn through traditional breeding with other non-GE corn varieties, USDA-APHIS further considers the potential impacts of such other stacked-trait corn hybrids under the Cumulative Impacts section of the EA.

Relationship to Other Environmental Documents
Syngenta requested that USDA-APHIS consider the request for a determination of nonregulated status an extension to prior petition, 11-342-01p, based on the phenotypic similarities of MZHG0JG corn to the antecedent organism that is the subject of petition 11-342-01p; VCO-Ø1981-5 corn. Like VCO-Ø1981-5 corn, MZHG0JG corn is glyphosate-resistant. USDA-APHIS prepared a Final EA for the petition for nonregulated status of VCO-Ø1981-5 corn, and published a notice (78 FR 45169) advising the public of the preliminary determination of nonregulated status on July 26, 2013. USDA-APHIS issued a determination of nonregulated status for VCO-Ø1981-5 corn on September 25, 2013 (USDA-APHIS 2015).

Syngenta requested that USDA-APHIS also consider petition 11-244-01p (maize event DP-ØØ4114-3) for determination of nonregulated status of MZHG0JG corn, submitted by Pioneer Hi-Bred International, Inc. USDA-APHIS considered maize event DP-ØØ4114-3 in review of Syngenta's MZHG0JG corn extension request given the phenotypic and glufosinate-resistant trait similarities shared by DP-ØØ4114-3 and MZHG0JG corn. USDA-APHIS prepared a Final EA for the petition for nonregulated status of DP-ØØ4114-3 corn, and issued a determination of nonregulated status on June 11, 2013 (USDA-APHIS 2015).

Both of these antecedent organisms were considered in USDA-APHIS' Plant Pest Risk Similarity Assessment for MZHG0JG corn, and pertinent information available in the VCO-Ø1981-5 corn and DP-ØØ4114-3 corn EAs have been incorporated by reference into the MZHG0JG corn EA, and this decision document.

Public Involvement
APHIS published a notice in the Federal Register announcing its preliminary regulatory determination and the availability of the EA, PPRSA, preliminary FONSI, and preliminary determination for a 30-day public review period. No substantive information were received that would warrant substantial changes to the APHIS analysis or determination, and thus 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.

Major Issues Addressed in the EA

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
- 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 were also considered, potential impacts on threatened and endangered species (TES), as wells as adherence of the proposed action to Executive Orders, and environmental laws and regulations to which the action may be subject.

Alternatives that were Fully Analyzed

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. APHIS reviewed and analyzed the information submitted in the extension request by Syngenta (Davis, Jarrett et al. 2015), and has concluded that MZHG0JG corn is similar to the antecedent organisms VCO-Ø1981-5 corn (USDA-BRS 2013b) and DP-ØØ4114-3 corn, and therefore, based on the PPRAs for VCO-Ø1981-5 corn and DP-ØØ4114-3 corn (USDA-BRS 2013a)), APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk (*see* Appendix A). 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.

No Action: 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 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.

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 USDA-APHIS determined that MZHG0JG corn is unlikely to pose a plant pest risk. Permits issued or notifications acknowledged by USDA-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.

Alternatives Considered but Rejected from Further Consideration
USDA-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, USDA-APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

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, USDA-APHIS

considered prohibiting the release of MZHG0JG corn, including denying any permits associated with field testing. USDA-APHIS determined that this alternative is not appropriate given that USDA-APHIS has concluded that MZHG0JG corn is unlikely to pose a plant pest risk.

In enacting the Plant Protection Act, Congress found that (7 U.S. C. §7701(4)): "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, USDA-APHIS determined that MZHG0JG corn is unlikely to pose a plant pest risk. Accordingly, there is no basis for prohibiting the release of MZHG0JG corn.

Approve the extension request in part
The regulations at 7 CFR 340.6(d)(3)(i) state that USDA-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 USDA-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.

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, USDA-APHIS considered requiring an isolation distance separating MZHG0JG corn from conventional and specialty corn production. However, because USDA-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 USDA-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).

Requirement 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. USDA-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 the Agency's purpose and need to respond appropriately to the request for extension in accordance with USDA regulatory authorities.

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

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.	Unchanged from No Action Alternative
Agronomic Practices	Practices are expected to remain essentially the same as current, with	Unchanged from No Action Alternative

Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
	possible expansion of crop rotation and conservation tillage practices as part of integrated weed management strategies.	
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 in 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
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
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 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, pesticide use, and fertilizer application, and 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

Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
Climate Change	Primary GHG emissions from corn production are PM and N_2O, with lesser amounts of CO_2. GHG emissions have remained relatively steady over the last 20 years, a trend that would be expected to continue, with slight increases or reductions possible (EPA 2013a).	Unchanged from No Action Alternative
Biological Resources		
Animal Communities	Corn fields are host to many species, some of which may be controlled by the use of integrated pest management strategies. Currently available glufosinate-resistant and glyphosate-resistant crops do not substantially impact wildlife. EPA regulates herbicides applied to HT corn and determines uses that may pose unacceptable risk to non-target organisms.	Unchanged from No Action Alternative
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 plant communities.	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.
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 the 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	Unchanged from No Action Alternative

Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
	unmanaged habitats. Currently available glyphosate and glufosinate-tolerant corn cultivars are not known to have any substantial impact on biodiversity.	
Human and Animal Health		
Risk to Human Health	FDA regulates food and feed safety. 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 human health.	Unchanged from No Action Alternative
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 similar to other 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 2014).	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	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.

Summary of Issues of Potential Impacts and Consequences of Alternatives		
Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
	produced from GE-crops. Import of each specific GE-trait requires approval by the importing country.	
Other Regulatory Approvals [5]		
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

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

Context

The term "context" recognizes potentially affected resources, as well as the location and setting in which potential impacts could occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments, agricultural workers, human food and animal feed production systems, and foreign and domestic commodity markets.

The deregulation of MZHG0JG corn involves approximately 90 million acres of U.S. land. 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 2014b, Westcott and Hansen 2015). This comprises approximately 25% of total U.S. cropland (~394 million acres). 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. 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, USDA-ERS 2015b). By 2014, 89% of the 87.6-million-acre crop was produced from GE HT corn, and 80% from IR. Stacked-trait varieties with both IR and HR traits accounted for 76% of the 2014 crop. Only 13% contained a single HT trait, and 4% a single IR (Fernandez-Cornejo, Wechsler et al. 2014b, USDA-ERS 2015a). 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.

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 2014b). 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. Most of production of corn in the U.S. will continue to be centered in the Corn Belt. Subsection 2.1.1 - Acreage and Area of Corn Production, provides details on the locations in which corn is grown, and where potential environmental impacts could occur.

Corn is an economically important commodity and the most abundant crop planted and harvested in the U.S. Corn commodities are primary that of animal 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% of corn harvest is typically used for direct human consumption (USDA-NASS 2014a). Food and industrial uses of corn (other than ethanol production) are projected to rise at a moderate pace over the next decade. Domestic corn production is expected to increase from 173 to 185 bushels/acre by 2024/25, with net returns for growers increasing from $244/acre (2014) to $300/acre (2024/25) (Westcott and Hansen 2015). Ethanol production in the U.S., 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).

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). In general, corn grain exports represent a substantial 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.

MZHG0JG corn is a glyphosate- and glufosinate-resistant stacked-trait variety that, if adopted by growers, is expected to replace other GE corn varieties currently cultivated for commercial purposes, as opposed to augmenting current corn crops. MZHG0JG corn would be planted in the areas where commercial corn is produced in the U.S. Growers would adopt and continue use of MZHG0JG corn to the extent it met market demand, provided optimal crop yields, product quality, and net returns.

A determination of nonregulated status of MZHG0JG corn is not expected to require any increase in the acreage of U.S. corn production, or change in the areas where corn is produced. USDA market projections through 2024/25 on the acreage of planted corn, yield increases, and growth in net returns per acre, would not be altered by the determination of nonregulated status for MZHG0JG corn. Conventional and organic corn production systems, agricultural workers, human food and animal feed production systems, and foreign and domestic commodity markets, are note expected to be substantially impacted by the availability of MZHG0JG corn to the U.S. market.

Intensity

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

1. *Impacts that may be both beneficial and adverse.*

In the EA, USDA-APHIS analyzed the potential beneficial and adverse impacts that could potentially result from a determination of nonregulated status of MZHG0JG corn. Corn is a critical crop to the U.S. economy and provides vital sustenance for both humans and livestock, in the U.S., and abroad. However, in some instances the commercial production of corn can result in environmental impacts, both beneficial and adverse, relative to the wide range of agronomic practices and inputs used in the production corn. The potential beneficial and adverse impacts as identified in the EA are summarized below.

Water Quality: The EA describes potential adverse impacts from corn production on water resources through soil erosion and run-off of agricultural inputs into surface waters. The potential for fertilizer run-off, and to a lesser degree pesticides, is an ongoing potential impact for all crops utilizing these agricultural inputs, including corn crops. These potential impacts are mitigated through EPA pesticide use requirements and restrictions as provided on EPA approved pesticide labels, as well federal and state initiatives to reduce the entry of fertilizers into surface waters. To the extent that cultivation of MZHG0JG corn allows growers to adopt or expand conservation tillage practices, water quality improvements associated with these tillage practices would be expected to follow. There is evidence that adoption of herbicide-resistant crops can facilitate conservation tillage practices, due in part to the fact that herbicide-resistant crops tend to make weed control more effective and less costly (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. The EA determined that 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.

Air Quality: Agricultural practices have the potential to adversely impact air quality. Agricultural emission sources from corn production include smoke from agricultural burning (particulate matter [PM]); emissions of some of the National Ambient Air Quality Standards pollutants (NAQQS) criteria pollutants from tillage and harvest equipment burning fossil fuels (i.e., PM, CO_2, NOx, SOx emissions); soil particulates from tillage (PM); and soil nitrous oxide (N_2O) emissions from the use of fertilizers. To the extent that cultivation of MZHG0JG corn allows growers to adopt or expand conservation tillage practices, air quality improvements associated with these tillage practices would be expected to follow. Conservation tillage practices also reduce the use of fossil fuel burning equipment used for tillage, minimizing emissions of NAQQS pollutants. The EA determined that the potential impacts of determination of nonregulated status for MZHG0JG corn on air quality, both beneficial and adverse, would be the same as or similar to the No Action Alternative.

Biological Resources: The potential for pesticide run-off, drift, and volatilization to affect non-target species is an ongoing potential impact for all crops utilizing pesticides, including corn crops. The potential for pesticide run-off, drift, and volatilization to affect non-target species is mitigated through EPA pesticide use requirements and restrictions as provided on EPA approved pesticide labels. 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 and animal communities, and provides labeled use restrictions, inclusive of drift minimization guidance, intended to be protective of non-target species (EPA 2015d, EPA 2015h, EPA 2015e). There are no changes to glyphosate and glufosinate-ammonium application rates or label requirements for cultivation of MZHG0JG corn. When used in accordance with label requirements glyphosate and glufosinate are considered to pose only minimal risks to biological resources.

In general, relative to any undisturbed ecosystem, biodiversity will be less on intensively managed agricultural lands, such as commercial corn fields. 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 potentially reduce the impacts of agriculture on biodiversity through facilitating adoption of conservation tillage practices, potential reductions in pesticide use, use of more environmentally benign pesticides, and increased yields that can alleviate pressure to convert additional land into agricultural uses (Carpenter 2011).

The EA determined that the potential impacts of determination of nonregulated status for MZHG0JG corn on biological resources, both beneficial and adverse, would be the same as or similar to the No Action Alternative.

Weed Management: Because weedy plants can be responsible for substantial crop yield and financial losses, these species are of primary concern to commercial corn producers. 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 certain methods of herbicide use, namely the singular and chronic use of an herbicide with one mode of action, and has been well-studied since the 1960s (Holt 1992). 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 substantial 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). Development of GR weeds occurred as a result of the singular and continuous use of this herbicide on a variety of agricultural crops, such as corn, soy, and cotton.

In response to development of HR weeds, producers are diversifying weed management strategies in corn production to more effectively and sustainably control weeds. Growers in many areas of the U.S. are increasingly adopting integrated weed management (IWM) practices to control the development of weed resistance (Frisvold, Hurley et al. 2009, Owen 2011, Mortensen, Egan et al. 2012, Owen 2012). IWM practices utilizing herbicides with differing modes of action, in conjunction with diversified crop rotation and tillage practices to reduce weed selection pressures that can drive the evolution of resistant weeds, can be effective in manage weeds, to include minimizing selection pressures for the development of herbicide-resistance in weeds, as well as potentially reducing the seedbank of current HR weeds (Werth, Preston et al. 2008, Duke and Powles 2009, Weller, Owen et al. 2010, Weirich, Shaw et al. 2011, Vencill, Nichols et al. 2012, Garrison, Miller et al. 2014, 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).

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, as well as 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 reducing weed infestations while maintaining robust crop yield potential (Gibson, Young et al. 2015), however; it will likely take many years to affect the seedbank of GR weeds, including recruitment of weed species with a high risk for resistance to glyphosate (Gibson, Young et al. 2015).

The EA determined that the potential impacts of determination of nonregulated status for MZHG0JG corn are not anticipated to substantially change the structure of plant communities in or around corn fields, to include the development of GR weeds. As a stacked-trait herbicide-resistant corn variety, 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. USDA-APHIS assumes that growers will likely employ those IWM and diversified crop management 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, Wechsler et al. 2014b, Fernandez-Cornejo and Osteen 2015, Livingston, Fernandez-Cornejo et al. 2015).

Socioeconomics: Adoption rates of stacked-trait varieties, such as MZHG0JG corn, 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 can generate higher yields relative to conventional seeds, or seeds with only one GE trait (Fernandez-Cornejo, Wechsler et al. 2014a). By example, 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. 2014a). GE varieties incorporating three or four traits are now common.

MZHG0JG corn is similar to other GE and non-GE corn varieties in terms of growth habit, agronomic properties, nutrional composition, and environmental interactions, and cultivation practices required for MZHG0JG corn are indistinguishable from those of other corn varieties (Davis, Jarrett et al. 2015). 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-resistant corn that may provide more flexibility in weed management programs. Growers would adopt and continue use of this corn variety to the extent it met market demand, provided optimal crop yields, product quality, and net returns. MZHG0JG corn, if adopted by growers, would be expected to replace other GE corn varieties currently cultivated, to the extent it provide growers benefits.

The EA concluded that: Given the agronomic, compositional, and nutrional 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 MZHG0JG corn on domestic and international trade markets would be expected to be similar to or same as the No Action Alternative.

2. *The degree to which the proposed action affects public health or safety.*
Public health and safety concerns are related to (1) the introduced EPSPS and PAT genes and their protein products, and (2) pesticides used in corn production. The EA determined that there would be no adverse impacts on human health or worker safety that would derive from a determination of nonregulated status of MZHG0JG corn. MZHG0JG corn is compositionally and nutritionally equivalent to currently available non-GE corn on the U.S. and international market (Davis, Jarrett et al. 2015), and commercial GE corn expressing variations of EPSPS and PAT have been cultivated in the U.S. and other countries for more than a decade providing safe food and feed products for both humans and livestock.

Syngenta provided the FDA with information on the identity, function, and characteristics of the genes and gene products in MZHG0JG corn, as well safety and nutrional information. The FDA is reviewing the 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 data reviews, FDA will provide a decision on the uses of MZHG0JG corn for food and feed.

Prior FDA reviews of 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). 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 2007b, EPA 2007a). Both EPSP and PAT naturally occur in soil bacteria worldwide, and EPSPS also naturally occurs in plants (to include corn). Both have been well studied as to potential environmental impacts, and both are widely recognized as environmentally benign (ILSI-CERA 2011b, ILSI-CERA 2011a).

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 2015e) for glufosinate at 40 CFR §180.473, and glyphosate at 40 CFR §180.364, for both food and feed. If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

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, the EA concluded that a determination on nonregulated status for MZHG0JG corn would present no risk to consumer health.

There are no new risks to worker safety presented by a determination of nonregulated status for MZHG0JG corn. The EPSPS and PAT proteins in MZHG0JG corn 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. 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 indicated on the pesticide label.

Current labels for both glyphosate and glufosinate-ammonium include label use restrictions intended to protect workers, such as the 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-ammonium are expected to present negligible risks to human health or worker safety (e.g., (EPA 2009, EPA 2013b, EPA 2015a, EPA 2015b)).

The EA concluded that worker health and safety concerns associated with the cultivation of MZHG0JG corn would be no different than those under the No Action Alternative.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of MZHG0JG corn. The common agricultural practices that would be used in the commercial production of MZHG0JG corn would not cause major ground disturbance; the physical destruction of or damage to property; any new alterations of property; disturb wildlife habitat or landscapes outside of agricultural settings; and does not involve the sale, lease, or transfer of ownership of any property.

MZHG0JG corn will be grown on farmland currently used for production of corn and is not expected to increase the acreage of corn production. This action would not convert land use to nonagricultural uses and therefore would have no impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of corn would be used on farmlands planted to MZHG0JG corn, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MZHG0JG corn, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in proximity to commercial corn production sites.

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

There are no potential impacts associated with a determination of nonregulated status of MZHG0JG corn that are considered highly controversial. MZHG0JG corn is similar to other GE and non-GE corn varieties in terms of growth habit, agronomic properties, composition, nutrional qualities, and environmental interactions (Davis, Jarrett et al. 2015). The structure and function of the EPSPS and PAT genes and their products are well understood, and safety of these genes and their products has been established (i.e., (EPA 2007b, EPA 2007a, ILSI-CERA 2011b, ILSI-CERA 2011a, USDA-BRS 2015)).

As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to cause any increase in the area or acreage used for commercial corn

production, nor will the cultivation of MZHG0JG corn require any changes in the agronomic practices used in commercial corn production. There are no anticipated changes to the production and availability of GE and non-GE corn varieties, to include organic corn, nor the markets for these corn varieties. A determination of nonregulated status of MZHG0JG corn would provide another stacked-trait GE corn variety to growers and would have no effect on market demands for GE corn, non-GE corn, or corn produced using organic methods. The potential impacts of the commercial production of MZHG0JG corn on wildlife or biodiversity would be no different than that of other glyphosate- and glufosinate-resistant GE corn varieties, or non-GE corn cropping systems utilizing glyphosate and glufosinate.

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

As a result of the extensive experience that USDA-APHIS, stakeholders, and commercial corn growers have with the use of GE corn and non-GE corn for production of food, feed, fiber, and fuel, and the use of pesticides in the production of these crops, the potential impacts on the human environment that could result from the production of GE and non-GE corn varieties have been clearly identified, and are well understood. Consequently, those potential impacts associated with a determination of deregulation of MZHG0JG corn, and examined in the EA, do not involve impacts that possess a high degree of uncertainty, nor are there any unique or unknown risks associated with commercial production of MZHG0JG corn. The EA identified and evaluated potential impacts on: The acreage, area, and agronomic practices utilized for U.S. corn production; soil, water, and air quality; biological resources; the potential gene flow and weediness associated with corn; soil quality and microorganisms; human health and safety; and the economic aspects of corn production, including domestic and international trade markets. The EA also examined the potential cumulative impacts associated with deregulation of MZHG0JG corn, for each of these areas of concern.

As discussed in the EA, a determination of nonregulated status of MZHG0JG corn is not expected to directly cause an increase in the area or acreage devoted to corn production, nor in agronomic practices, including pesticide and fertilizer use. Syngenta conducted a compositional and nutrional analyses of MZHG0JG corn (Davis, Jarrett et al. 2015), which verified that MZHG0JG corn and corn products processed from raw MZHG0JG corn are nutritionally and compositionally comparable to raw and processed corn from conventional varieties. Consequently, MZHG0JG corn is expected to provide substantive nutrition as part of human diets as well as formulated diets for livestock.

Commercial HT-corn expressing variations of EPSPS and PAT have been cultivated in the U.S. and other countries for more than a decade, and the safety of EPSPS and PAT proteins 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. 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 (i.e., (FDA 2012, FDA 2013b,

FDA 2013a, FDA 2014)). 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 2007b, EPA 2007a).

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 2015e) for glufosinate at 40 CFR §180.473, and glyphosate at 40 CFR §180.364, for both food and feed.

Given the extensive experience that USDA-APHIS, stakeholders, and growers have with GE corn and corn products, and experience with glyphosate- and glufosinate-resistant corn varieties in particular (USDA-APHIS 2015), there are no substantial uncertainties, or unique or unknown risks, associated with MZHG0JG corn.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
A determination of nonregulated status of MZHG0JG corn would not establish a precedent for future actions with substantial impacts or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by USDA-APHIS, a determination of nonregulated status of a GE organism is based upon an independent determination of whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR Part 340 - Introduction of Organisms and Products Altered or Produced Through Genetic Engineering which are Plant Pests or which There is Reason to Believe are Plant Pests.

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.

Each request for extension that USDA-APHIS receives is for a specific GE organism and undergoes an independent review to determine if the regulated article should be subject to regulation. If USDA-APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and under 7 CFR Part 340.

USDA-APHIS regulations at 7 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 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 pursuant to Part 340 when USDA-APHIS has reason to believe that the GE organism may be a plant pest or USDA-APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk. The decision-making process used in either determining MZHG0JG corn is unlikely to pose a plant pest risk, or a decision to deny the request for extension for nonregulated status of MZHG0JG corn would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*
The EA discusses potential cumulative impacts on the various aspects of the human environment that were evaluated in Chapter 4 of the EA, and concluded that on determination of nonregulated status of MZHG0JG corn, cumulative impacts would not be substantial. A cumulative impacts analysis is provided in Chapter 5 of the EA. In the event USDA-APHIS approves Syngenta's extension request for nonregulated status of MZHG0JG corn, USDA-APHIS would no longer have regulatory authority over this corn variety. In considering a determination of nonregulated status of MZHG0JG corn, USDA-APHIS has not identified any substantial impact on the human environment that may result from a determination of nonregulated status of MZHG0JG corn when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*
A determination of nonregulated status of MZHG0JG corn is not expected to adversely affect cultural resources or tribal properties. Any farming activities that may be undertaken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of MZHG0JG corn is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. Standard agricultural practices for soil preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MZHG0JG corn, including the use of EPA registered pesticides. Grower and agricultural workers' adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment.

In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible 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 audible impacts on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other

mechanical equipment, are conducted 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 does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

A determination of nonregulated status of MZHG0JG corn would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of substantial scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MZHG0JG corn.

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

As described in Chapters 4 and 6 of the EA, USDA-APHIS analyzed the potential effects of a determination of nonregulated status of MZHG0JG corn on federally listed threatened and endangered species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, pursuant to Section 7 of the Endangered Species Act. USDA-APHIS concluded that a determination of nonregulated status of MZHG0JG corn would have no effect on federally listed threatened or endangered species and species proposed for listing, or habitat for listed or proposed species.

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

The proposed action would be in compliance with all Federal, State, and local laws. Because USDA-APHIS concluded through a Plant Pest Risk Assessment that MZHG0JG corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MZHG0JG corn is a response that would be consistent with the plant pest provisions of the PPA and regulations codified in 7 CFR Part 340.

MZHG0JG corn falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (FDA 2006). In compliance with FDA policy, Syngenta initiated a consultation with the FDA on the food and feed safety of MZHG0JG corn. FDA will review compositional and nutrional data submitted by Syngenta, and provide a determination on the safety of food and feed derived from MZHG0JG corn.

The EPA regulates pesticides under FIFRA and establishes pesticide use restrictions that are given on pesticide labels. 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 2015e). The EPA has established tolerance limits for glufosinate at 40 CFR §180.473, and glyphosate at 40 CFR §180.364. If pesticide residues are found above the tolerance limit, the commodity will be subject to seizure by the government.

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 2015g). As part of this program, both glyphosate and glufosinate are currently under registration review with (EPA 2015f, EPA 2015c). There are no other Federal, State, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and believe that the issues identified in the EA are best addressed by selecting the Preferred Alternative, a determination that MZHG0JG corn is no longer a regulated article. This alternative meets the USDA-APHIS purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows USDA-APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As USDA-APHIS has not identified any plant pest risks associated with MZHG0JG corn, the continued regulated status of MZHG0JG corn would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR Part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated in this document, I have determined that a determination of nonregulated status of MZHG0JG corn will not have any significant environmental impacts.

M. J. Firko

11/30/2015

Michael J. Firko, Ph.D.

Date:

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Literature Cited:

AOSCA (2015). Association of Official Seed Certifying Agencies (AOSCA). **2015**. http://www.aosca.org/

Baucom, R. S. and Holt, J. S. (2009). "Weeds of agricultural importance: bridging the gap between evolutionary ecology and crop and weed science." New Phytologist **184**(4): 741-743. http://dx.doi.org/10.1111/j.1469-8137.2009.03077.x

Carpenter, J. E. (2011). "Impact of GM crops on biodiversity." GM Crops **2**(1): 7-23. http://www.tandfonline.com/doi/abs/10.4161/gmcr.2.1.15086

Davis, K. P., Jarrett, S. G. and Juba, N. C. (2015). "Request for an Extension of Determination of Nonregulated Status for Herbicide-Tolerant Event MZHG0JG Corn. OECD Unique Identifier: SYN-ØØØJG-2." from http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

Duke, S. and Powles, S. D. (2009). "Glyphosate-Resistant Crops and Weeds: Now and in the Future." AgBioForum, 15(3), 231-241 **12**(3&4): 346-357. http://naldc.nal.usda.gov/download/40555/PDF

EPA. (2007a). "40 CFR §174.522 - Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance." Retrieved June 12, 2015, from http://www.gpo.gov/fdsys/granule/CFR-2012-title40-vol25/CFR-2012-title40-vol25-sec174-522.

EPA. (2007b). "40 CFR § 174.523 - CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSP) synthase in all plants; exemption from the requirement of a tolerance." Retrieved July 21, 2015, from http://www.gpo.gov/fdsys/granule/CFR-2010-title40-vol23/CFR-2010-title40-vol23-sec174-523/content-detail.html.

EPA. (2009). "Pesticides: Registration Review - Glyphosate." Retrieved July 21, 2015, from http://www.epa.gov/oppsrrd1/registration_review/glyphosate/index.htm.

EPA (2013a). Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2011. U.S. Environmental Protection Agency [EPA 430-R-15-004]. http://www.epa.gov/climatechange/Downloads/ghgemissions/US-GHG-Inventory-2013-Main-Text.pdf

EPA (2013b). "Memorandum: Glufosinate Ammonium. Human Health Risk Assessment for Registration Review. Decision No.: 471210. DP barcode: 0406360. CAS No.: 77182-82-2. 40 CFR: 180.437. USEPA Office of Chemical Safety and Pollution Prevention." http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0026.

EPA (2015a). Enlist Duo Herbicide Label, Ammended. EPA Registration Number: 62719-649. U.S. Environmental Protection Agency. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0195-3131

EPA. (2015b). "Glufosinate 280 Herbicide - Notice of Pesticide Registration, EPA Reg. Number: 33270-35. U.S. Environmental Protection Agency, Office of Pesticide Programs." Retrieved June 16, 2015, from http://www3.epa.gov/pesticides/chem_search/ppls/033270-00035-20150429.pdf.

EPA. (2015c). "Glyphosate Registration Review. U.S. Environmental Protection Agency." from http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0361.

EPA. (2015d). "Pesticide Product Label System (PPLS). U.S. Environmental Protection Agency." Retrieved June 3, 2015, from http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

EPA. (2015e). "Pesticide Tolerances. U.S. Environmental Protection Agency " Retrieved June 12, 2015, from http://www.epa.gov/opp00001/regulating/tolerances.htm.

EPA. (2015f). "Pesticides: Registration Review - Glufosinate Ammonium. U.S. Environmental Protection Agency." Retrieved June 2, 2015, from http://www.epa.gov/oppsrrd1/registration_review/glufosinate_ammonium/index.htm.

EPA. (2015g). "Pesticides: Registration Review - Glyphosate. U.S. Environmental Protection Agency." Retrieved July 14, 2015, from http://www.epa.gov/oppsrrd1/registration_review/glyphosate/.

EPA. (2015h). "Reevaluation: Review of Registered Pesticides. U.S. Environmental Protection Agency." Retrieved June 8, 2015, from http://www2.epa.gov/pesticide-reevaluation.

Evans, J. A., Tranel, P. J., Hager, A. G., Schutte, B., et al. (2015). "Managing the evolution of herbicide resistance." Pest Manag Sci(Mar 24)

FDA. (2006). "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use. U.S. Food and Drug Administration." from http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm.

FDA. (2012). "Biotechnology Notification File BNF No. 000106, HCEM485 maize, herbicide tolerant corn. U.S. Food and Drug Administration." Retrieved June 17, 2015, from http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

FDA. (2013a). "Biotechnology Consultation Note to the File BNF No. 000136, Event 4114 insect-resistant, herbicide-tolerant corn. U.S. Food and Drug Administration." Retrieved June 17, 2015, from http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

FDA. (2013b). "Biotechnology Notification File BNF No. 000137, Event VCO-Ø1981-5, glyphosate-tolerant corn. U.S. Food and Drug Administration." Retrieved June 17, 2015, from http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

FDA. (2014). "Biotechnology Notification File No. 000145, MON 87411, Corn Rootworm Protected and Glyphosate Tolerant Corn. U.S. Food and Drug Administration." Retrieved June 17, 2015, from http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

Fernandez-Cornejo, J., Hallahan, C., Nehring, R., Wechsler, S., et al. (2012). "Conservation Tillage, Herbicide Use, and Genetically Engineered Crops in the United States: The Case of

Soybeans." AgBioForum **15**(3): 231-241. http://www.agbioforum.org/v15n3/v15n3a01-fernandez-cornejo.htm

Fernandez-Cornejo, J. and Osteen, C. (2015). Managing Glyphosate Resistance May Sustain Its Efficacy and Increase Long-Term Returns to Corn and Soybean Production. Amber Waves. , U.S. Department of Agriculture, Economic Research Service. http://www.ers.usda.gov/amber-waves/2015-may/managing-glyphosate-resistance-may-sustain-its-efficacy-and-increase-long-term-returns-to-corn-and-soybean-production.aspx

Fernandez-Cornejo, J., Wechsler, S., Livingston, M. and Mitchell, L. (2014a). Genetically Engineered Crops in the United States. U.S. Department of Agriculture, Economic Research Service, Economic Research Report Number 162. http://www.ers.usda.gov/media/1282246/err162.pdf

Fernandez-Cornejo, J., Wechsler, S. J. and Livingston, M. (2014b). Adoption of Genetically Engineered Crops by U.S. Farmers Has Increased Steadily for Over 15 Years. U.S. Department of Agriculture, Economic Research Service Amber Waves, U.S. Department of Agriculture, Economic Research Service. http://www.ers.usda.gov/amber-waves/2014-march/adoption-of-genetically-engineered-crops-by-us-farmers-has-increased-steadily-for-over-15-years.aspx

Foreman, L. (2014). Characteristics and Production Costs of U.S. Corn Farms, Including Organic, 2010. United States Department of Agriculture, Economic Research Service, Economic Information Bulletin No. (EIB-128) 43 pp, September 2014. http://www.ers.usda.gov/publications/eib-economic-information-bulletin/eib-128.aspx

Frisvold, G. B., Hurley, T. M. and Mitchell, P. D. (2009). "Adoption of Best Management Practices to Control Weed Resistance by Corn, Cotton, and Soybean " AgBioForum **12**(3 & 4): 370-381. http://www.agbioforum.org/v12n34/v12n34a12-frisvold.htm

Garrison, A. J., Miller, A. D., Ryan, M. R., Roxburgh, S. H., et al. (2014). "Stacked Crop Rotations Exploit Weed-Weed Competition for Sustainable Weed Management." Weed Science **62**(1): 166-176. http://dx.doi.org/10.1614/WS-D-13-00037.1

Gibson, D. J., Young, B. G., Owen, M. D., Gage, K. L., et al. (2015). "Benchmark study on glyphosate-resistant cropping systems in the United States. Part 7: Effects of weed management strategy (grower practices versus academic recommendations) on the weed soil seedbank over 6 years." Pest Manag Sci. http://onlinelibrary.wiley.com/doi/10.1002/ps.4039/epdf

Heap, I. (2015). "The International Survey of Herbicide Resistant Weeds. Online. Internet. Tuesday, May 19, 2015 . Available www.weedscience.org "

Holt, J. S. (1992). "History of Identification of Herbicide-Resistant Weeds." Weed Technology **6**(3): 615-620. http://www.jstor.org/stable/3987222

ILSI-CERA (2011a). A review of the environmental safety of the CP4 EPSPS protein. International Life Sciences Institute, Center for Environmental Risk Assessment, Washington, D.C. . http://www.cera-gmc.org/files/cera/uploads/ebr_cp4epsps.pdf

ILSI-CERA (2011b). A review of the environmental safety of the PAT protein. International Life Sciences Institute, Center for Environmental Risk Assessment, Washington, D.C. . http://cera-gmc.org/docs/cera_publications/pub_05_2011.pdf

Livingston, M., Fernandez-Cornejo, J., Unger, J., Osteen, C., et al. (2015). The Economics of Glyphosate Resistance Management in Corn and Soybean Production. U.S. Department of Agriculture, Economic Research Service, Economic Research Report Number 184. http://www.ers.usda.gov/media/1832877/err184.pdf

Mortensen, D. A., Egan, J. F., Maxwell, B. D., Ryan, M. R., et al. (2012). "Navigating a Critical Juncture for Sustainable Weed Management." BioScience **62**(1): 75-84. http://bioscience.oxfordjournals.org/content/62/1/75.abstract

Owen, M. D. K. (2011). "Weed resistance development and management in herbicide-tolerant crops: Experiences from the USA " Journal of Consumer Protection and Food Safety **6**(1): 85-89. http://link.springer.com/article/10.1007/s00003-011-0679-2

Owen, M. D. K. (2012). 2013 Herbicide Guide for Iowa Corn and Soybean Production: Weed management update for 2013 (WC-94). Iowa State University Extension and Outreach. http://www.weeds.iastate.edu/reference/WC94%202013.pdf

TOXNET. (2015a). "Glufosinate-Ammonium, CASRN: 77182-82-2. TOXNET, Toxicology Data Network, National Library of Medicine." from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+6666.

TOXNET. (2015b). "Glyphosate, CASRN: 1071-83-6. Toxicology Data Network, National Library of Medicine." from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+3432.

USDA-AMS (2007). Pesticide Data Program: Annual Summary, Calendar Year 2010. U.S. Department of Agriculture, Agricultural Marketing Service, Science and Technology Programs. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074338

USDA-AMS (2013). "Pesticide Data Program: Annual Summary, Calendar Year 2010. U.S. Department of Agriculture, Agricultural Marketing Service, Science and Technology Programs." http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110007

USDA-APHIS. (2015). "Biotechnology: Petitions for Determination of Nonregulated Status " Retrieved June 17, 2015, from http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

USDA-BRS (2013a). "Plant Pest Risk Assessment for Pioneer 4114 Maize (DP-ØØ4114-3)." http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dpra.pdf

USDA-BRS (2013b). "Plant Pest Risk Assessment: Genective Petition (11-342-01p) for Determination of Non-regulated Status of Event VCO-Ø1981-5 Corn. OECD Unique Identifier: VCO-Ø1981-5." http://www.aphis.usda.gov/brs/aphisdocs/11_34201p_fpra.pdf

USDA-BRS (2015). "Syngenta Seeds Inc. Request (15-124-01p_a1) for Extension of Determination of Non-regulated Status of MZHG0JG corn: Plant Pest Risk Similarity Assessment. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Research Services (BRS) "

USDA-ERS. (2015a). "Adoption of Genetically Engineered Crops 2014. Department of Agriculture, Economic Research Service." from http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx.

USDA-ERS. (2015b). "Adoption of Genetically Engineered Crops in the U.S. U.S. Department of Agriculture, Economic Research Service." from http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx.

USDA-ERS. (2015c). "Corn: Background. United States Department of Agriculture, Economic Research Services." from http://www.ers.usda.gov/topics/crops/corn/background.aspx.

USDA-FAS (2015). Grain: World Markets and Trade. United States Department of Agriculture, Foreign Agricultural Service, May 2015. http://apps.fas.usda.gov/psdonline/circulars/grain.pdf

USDA-NASS (2014a). 2012 Census of Agriculture, Summary and State Data, Volume 1, Geographic Area Series. U.S. Department of Agriculture, National Agricultural Statistics Service.
http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf

USDA-NASS (2014b). 2012 Census of Agriculture: Farms and Farmland Numbers, Acreage, Ownership, and Use [ACH12-13/September 2014]. U.S. Department of Agriculture, National Agricultural Statistics Service.
http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Farms_and_Farmland/Highlights_Farms_and_Farmland.pdf

USDA-NASS (2014c). Crop Production, 2013 Summary.
http://usda.mannlib.cornell.edu/usda/nass/CropProdSu//2010s/2014/CropProdSu-01-10-2014.pdf

Vencill, W. K., Nichols, R. L., Webster, T. M., Soteres, J. K., et al. (2012). "Herbicide Resistance: Toward an Understanding of Resistance Development and the Impact of Herbicide-Resistant Crops." Weed Science 2012 Special Issue: 2-30.
http://www.wssajournals.org/doi/pdf/10.1614/WS-D-11-00206.1

Weirich, J. W., Shaw, D. R., Owen, M. D. K., Dixon, P. M., et al. (2011). "Benchmark study on glyphosate-resistant cropping systems in the United States. Part 5: Effects of glyphosate-based weed management programs on farm-level profitability." Pest Management Science **67**(7): 781-784. http://dx.doi.org/10.1002/ps.2177

Weller, S. C., Owen, M. D. K. and Johnson, W. G. (2010). Managing Glyphosate-Resistant Weeds and Population Shifts in Midwestern U.S. Cropping Systems. Glyphosate Resistance in Crops and Weeds: History, Development, and Management. V. K. Nandula, John Wiley & Sons, Inc.: 213-232.

Werth, J. A., Preston, C., Taylor, I. N., Charles, G. W., et al. (2008). "Managing the risk of glyphosate resistance in Australian glyphosate- resistant cotton production systems." Pest Manag Sci **64**(4): 417-421. http://onlinelibrary.wiley.com/doi/10.1002/ps.1508/abstract

Westcott, P. and Hansen, J. (2015). USDA Agricultural Projections to 2024,Long-term Projections Report OCE-2015-1. United States Department of Agriculture, Office of the Chief Economist, World Agricultural Outlook Board. http://www.ers.usda.gov/media/1776036/oce151.pdf