

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION AND  
FINDING OF NO SIGNIFICANT IMPACT**

**Syngenta Seeds, Inc.**

**Request for Extension of Determination of Non-regulated Status for Insect-Resistant and  
Glufosinate-ammonium-Resistant MZIR098 Corn (15-218-01p)**

**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.

Syngenta Seeds, Inc. (hereafter referred to as Syngenta) submitted a request (APHIS Number 15-218-01p) to APHIS on July 14, 2015 for extension of a determination of nonregulated status Pursuant to 7 CFR 340 for their transgenic corn event MZIR098 (hereafter referred to as MZIR098 corn), which is genetically engineered (GE) for insect-resistant and resistance to the herbicide glufosinate-ammonium (Syngenta, 2015). A person may request that APHIS extend a determination of nonregulated status to other organisms pursuant to §340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the unregulated antecedent organism and the regulated articles. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act and the regulatory requirements of 7 CFR part 340 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 (Syngenta, 2015) and has concluded that MZIR098 is similar to the antecedent organism, Pioneer's genetically engineered DP-ØØ4114-3 corn deregulated in 2013 (76 FR 63279-63280). Based on its Plant Pest Risk Assessment for Pioneer's event DP ØØ 4114-3, APHIS has concluded that MZIR098 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2015).

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS completed an Environmental Assessment (EA) and FONSI that analyzed the potential impacts to the human environment from a determination on the regulated status of a petition request (APHIS-011-244-01p) by Pioneer for their genetically engineered DP-ØØ4114-3 corn in 2013 (76 FR 63279-63280). The EA assessed alternatives to a determination of nonregulated status pursuant to 7 CFR 340 for DP-ØØ4114-3 corn and analyzed the potential environmental impacts that result

from the proposed action and the alternatives. APHIS has carefully examined the existing NEPA documentation completed for DP-ØØ4114-3 corn, including comments received from the public involvement process on DP-ØØ4114-3 corn, and has concluded that the Syngenta extension request for a determination of nonregulated status of MZIR098 corn encompasses the same scope of environmental analysis and regulatory decision as DP-ØØ4114-3 corn. This conclusion is based on:

- MZIR098 corn expresses similar Cry proteins as DP-ØØ4114-3 corn.
- MZIR098 expresses similar resistance to coleopteran pests and resistance to herbicides formulations containing glufosinate-ammonium as DP-ØØ4114-3 corn.
- MZIR098 does not exhibit any additional traits beyond what is expressed in DP-ØØ4114-3 corn.
- the affected environment, issues and alternatives described and analyzed in the existing NEPA documentation for DP-ØØ4114-3 corn are applicable to the extension request of MZIR098 corn;
- no new alternatives have been identified that are relevant to this regulatory action;
- no substantive new issues and impacts on the human environment have been identified that are relevant to this regulatory action; and
- APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for MZIR098 corn, including the proposed action or analysis of impacts in the EA;

Based on its similarity to the antecedent organism event DP-ØØ4114-3 corn, the Syngenta extension request for MZIR098 corn has been subject to the previous NEPA review completed for DP-ØØ4114-3 corn. Therefore, the existing NEPA documentation completed for DP-ØØ4114-3 corn is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to Syngenta's extension request for a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn.

### **Regulatory Authority**

“Protecting American agriculture” is the basic mission of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (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 regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the

comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of 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’s APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

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

The FDA regulates GE organisms pursuant to the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). 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 pursuant to Federal food safety laws, FDA encourages them to participate in a voluntary 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). Pursuant to 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 foods.

The EPA regulates pesticides, including plant-incorporated protectants pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Specifically, EPA sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, pursuant to the Federal Food, Drug and Cosmetics Act (FFDCA) and regulates certain biological control organisms pursuant to 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 Services' (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, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, and further consolidated pursuant to the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA and 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 if the administrator has a reason to believe that the organism is 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 pursuant to §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 plant pest provisions of the PPA or the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk.

Syngenta submitted an extension request (APHIS Number 15-218-01p) to USDA-APHIS seeking a determination that MZIR098 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. APHIS reviewed and analyzed the information submitted in the extension request by Syngenta and has concluded that MZIR098 corn is similar to the antecedent organism, DP-ØØ4114-3 corn, and therefore, based on the Plant Pest Risk Similarity Assessment (PPRSA), APHIS has concluded that MZIR098 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2015).

## **MZIR098 Corn**

Syngenta has developed MZIR098 corn (maize; *Zea mays* L.), a new cultivar that has been genetically modified to provide dual modes of action for control of corn rootworm (*Diabrotica* spp.) and resistance to herbicides formulations containing glufosinate-ammonium. MZIR098 corn and the antecedent organism, DP-ØØ4114-3 corn, as described in petition 011-244-01p (Pioneer, 2012), were generated through *Agrobacterium tumefaciens*-mediated transformation of conventional corn. MZIR098 corn plants contain the transgenes *ecry3.1Ab* and *mcry3A*, which encode the insecticidal proteins eCry3.1Ab and mCry3A, and the transgene *pat-08*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). The transformation plasmid

pSYN17629 was used to produce MZIR098 corn by *Agrobacterium*-mediated transformation of immature corn embryos (Negrotto, 2000). The DNA region between the left and right borders of the transformation plasmid included gene-expression cassettes for *ecry3.1Ab*, *mcry3A*, and *pat-08*.

GE corn varieties comprised of PAT and Cry traits have a long history of safe commercial production without adverse human health or environmental effects (Bravo, Gill, & Soberón, 2007; Mendelsohn, Kough, Vaituzis, & Matthews, 2003). Stacked-trait varieties such as MZIR098 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-tolerance (HT) traits accounted for 76% of the 2014 U.S. corn crop. Upon commercialization, MZIR098 corn is anticipated to support agricultural efficiency by combining two traits for resistance to coleopteran pest and herbicide formulations containing glufosinate-ammonium. MZIR098 corn is currently regulated pursuant to 7 CFR part 340. Interstate movements and field trials of MZIR098 corn have been conducted under APHIS authorizations since 2009. These field trials were conducted at eight U.S. locations in 2013 (Syngenta, 2015). Details regarding and data resulting from these field trials are described in the request for extension for MZIR098 corn (15-218-01p).

## **Coordinated Framework Review**

### *Food and Drug Administration*

MZIR098 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, in July 1, 2015 Syngenta submitted a compositional and nutritional assessment to the FDA to initiate a consultation on the safety of food and feed derived from MZIR098 corn. The FDA is currently reviewing the compositional and nutritional data and will provide Syngenta and the public a decision on their food and feed safety evaluation for MZIR098 corn when completed.

### *Environmental Protection Agency*

Pursuant to 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. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine through risk analysis 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, pursuant to 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 pursuant to the FFDCA, as amended by the Food Quality Protection Act of 1996. Relative to glufosinate-resistant MZIR098 corn; the EPA has established pesticide tolerance limits for 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 (US-EPA, 2015). The EPA received Syngenta's MZIR098 corn registration application on August 27, 2015. Since the EPA has previously evaluated the proteins present in MZIR098 corn (mCry3A, eCry3.1Ab, and PAT), no new protein specific data were provided. EPA previously evaluated mCry3A in context of MIR604 corn (EPA Registration No. 67979-4) and eCry3.1Ab in context of Syngenta's 5307 corn (EPA Registration No. 67979-22) (US-EPA, 2010a, 2010b, 2012a, 2012b). PAT has been previously evaluated in multiple corn events including Bt11 corn (EPA Registration No. 67979-1) (US-EPA, 2015). The protein sequences for these proteins are identical in MZIR098 corn. Since there is an existing registration for use of glufosinate ammonium on corn, Syngenta did not present any data and this information is not considered for the trait registration. In addition to previously reviewed safety information, Syngenta provided the EPA with a comprehensive event specific characterization (including the identity, function, and characterization of the genes) and an environmental safety assessment.

### **Scope of the Environmental Analysis**

Based on its similarity to the antecedent organism, event DP-ØØ4114-3corn, APHIS has concluded that the Syngenta extension request for a determination on the regulated status for MZIR098 encompasses the same scope of environmental analysis as DP-ØØ4114-3 corn. APHIS reviewed and analyzed the information submitted in the extension request by Syngenta (Syngenta, 2015) and has concluded that MZIR098 corn is similar to the antecedent organism, DP-ØØ4114-3 corn, and, therefore, based on its Plant Pest Risk Assessment (PPRA) for DP-ØØ4114-3 corn (USDA-APHIS, 2011b), APHIS has concluded that MZIR098 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2015). Although a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn would allow for new plantings of MZIR098 corn anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support corn production. Similar to the antecedent organism DP-ØØ4114-3 corn, a determination of nonregulated status of MZIR098 corn is not expected to increase corn production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE corn acreage. To determine areas of corn production, APHIS used data from the National Agricultural Statistics Service (USDA-NASS, 2014b) to determine where corn is

produced in the U.S. Corn is primarily produced throughout the Midwest U.S., with crop production concentrated in Illinois and Iowa (Commodities, 2013) .

## **Public Involvement**

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for DP-ØØ4114-3 corn, including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for DP-ØØ4114-3 corn. APHIS has not received any additional information or comments from the public specifically directed at the DP-ØØ4114-3 corn petition, PPRA or NEPA documentation since a determination of non-regulated status was announced on October 12, 2011 (76 FR 63279-63280).

In preparing this FONSI for MZIR098 corn, APHIS carefully reviewed and took into consideration all public input that was received during the public involvement process that was completed for Pioneer's petition 011-244-01p. On February 27, 2013, APHIS published a notice in the Federal Register (78 FR 13312-13313, Docket no. APHIS-2012-0026) announcing the availability of the Pioneer petition (011-244-01p), and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before April 29, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 573 comment were received during the comment period, of which 561 were form letters. Most commentors did not identify any substantive issues or disagreement with the APHIS analysis of DP-ØØ4114-3 corn, (Pioneer, 2012; USDA-APHIS, 2013b). Most comments stated general opposition to genetically modified organisms (GMOs) of GE crops. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. Response to substantive comments received by APHIS are included as an attachemnet to DP-ØØ4114-3 corn FONSI (USDA-APHIS, 2013a). Comment documents may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026>.

On February 17, 2016, APHIS published a notice in the Federal Register (FR 2016-03193, Docket no. APHIS-2016-0002) announcing the availability of the preliminary Syngenta Corn Extension Request Finding of No Significant Impact (FONSI) for a 30-day public review and comment period. Comments were required to be submitted by March 18, 2016. A total of five public comments were received subsequent to the preliminary FONSI publication. The commenters expressed disagreement with GE crops in general, but did not include any further information. There was no novel, substantive information received during the review periods for the petition, the preliminary FONSI, and preliminary PPRSA that warranted substantial changes to these analyses and APHIS' preliminary regulatory determination. Hence, APHIS developed its final EA and is issuing its FONSI for MZIR098 corn. The docket folder containing the comments may be located at: <https://www.regulations.gov/#!documentDetail;D=APHIS-2016-0002-0001>

## **Major Issues Addressed in the FONSI**

APHIS has concluded that the Syngenta extension request for a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn encompasses the same scope of environmental analysis as DP-ØØ4114-3 corn. APHIS is not aware of any substantive new issues that may impact the human environment associated with MZIR098 corn that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for DP-ØØ4114-3 corn. The potential impacts of insect-resistant and herbicide-resistant corn on agricultural production of corn, the physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species remain unchanged when compared to those presented in the Final EA and FONSI for DP-004114-3 corn. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for DP-ØØ4114-3 corn 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 by Syngenta for MZIR098 corn.

The issues considered in the DP-ØØ4114-3 corn analysis were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for DP-ØØ4114-3 corn. Issues discussed in the EA were developed by considering issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, issues raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods, and the environmental food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of MZIR098 corn.

The list of resource areas considered were developed by APHIS through experience in considering issues raised in public comments submitted for other EAs of GE organisms. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These same issues have been determined by APHIS to be relevant to APHIS' authority actions associated with DP-ØØ4114-3 corn. These resource areas can be categorized as follows:

**Agricultural Production Considerations:**

- Acreage and Areas of Corn Production
- Agronomic/Cropping Practices
- Corn Seed Production
- Organic Corn Production

**Environmental Considerations:**

- Water Resources
- Soil



- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow
- Microorganisms
- Biological Diversity

**Human Health Considerations:**

- Public Health
- Worker Safety

**Livestock Health Considerations:**

- Livestock Health/Animal Feed

**Socioeconomic Considerations:**

- Domestic Economic Environment
- Organic Farming
- Trade Economic Environment

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

**Alternatives that were analyzed**

APHIS has concluded that the Syngenta extension request for a determination of nonregulated status of MZIR098 corn encompasses the same scope of environmental analysis and regulatory decision as DP-ØØ4114-3 corn; that is, a determination of nonregulated status pursuant to 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by Syngenta (Syngenta, 2015) (Monsanto, 2013), and has concluded that MZIR098 corn is similar to the antecedent organism, DP-ØØ4114-3 corn, and therefore, based on its PPRA for DP-ØØ4114-3 corn (USDA-APHIS, 2011b), APHIS has concluded that MZIR098 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2015). The comparison of characteristics of MZIR098 corn to the antecedent organism, DP-ØØ4114-3 corn, indicates that MZIR098 corn expresses similar Cry proteins as DP-ØØ4114-3 corn, ; MZIR098 corn expresses the same resistance to corn rootworm (*Diabrotica* spp.) as DP-ØØ4114-3 corn, as well as resistance to herbicide formulations containing glufosinate-ammonium; and MZIR098 corn does not exhibit any additional traits beyond what is expressed in DP-ØØ4114-3 corn. Therefore, the proposed action

identified in the existing NEPA documentation completed for DP-ØØ4114-3 corn is being used to evaluate APHIS' action associated with a determination of nonregulated status of MZIR098 corn.

Based on the similarity to the antecedent organism event DP-ØØ4114-3 corn, APHIS has concluded that all the alternatives identified in the DP-ØØ4114-3 corn EA to be relevant to APHIS' regulatory actions associated with MZIR098 corn, and therefore, are being used in their entirety. APHIS is not aware of any new alternatives that are relevant to APHIS' decision on the regulatory status of MZIR098 corn that were not considered in the previous NEPA analysis for DP-ØØ4114-3 corn. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for DP-ØØ4114-3 corn to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status of MZIR098.

#### ***Alternatives described in existing DP-ØØ4114-3 Corn EA***

The EA analyzes the potential environmental consequences of a determination of nonregulated status of DP-ØØ4114-3 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2011b), APHIS has concluded that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that DP-ØØ4114-3 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of DP-ØØ4114-3 corn. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section of the EA.

#### **No Action: Continuation as a Regulated Article**

Under the No Action Alternative, APHIS would deny the petition. DP-ØØ4114-3 corn and progeny derived from DP-ØØ4114-3 corn would continue to be regulated articles pursuant to the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of DP-ØØ4114-3 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 DP-ØØ4114-3 corn.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011b) indicating this alternative would not satisfy the purpose and need for making a determination of plant pest risk status and responding to the petition for nonregulated status.

#### **Preferred Alternative: Determination that DP-ØØ4114-3 Corn is No Longer a Regulated Article**

Under this alternative, DP-ØØ4114-3 corn and progeny derived from them would no longer be regulated articles pursuant for the regulations at 7 CFR part 340. DP-ØØ4114-3 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011b). Authorizations issued by APHIS would no longer be required for introductions of DP-ØØ4114-3 corn and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of DP-ØØ4114-3 corn, is not expected to increase corn production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE corn. Potential impacts would be similar to the No Action Alternative. Because the agency has concluded that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of DP-ØØ4114-3 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.

### **Alternatives Considered but Rejected from Further Consideration**

APHIS assembled a list of alternatives that might be considered for DP-ØØ4114-3 Corn. The agency evaluated these alternatives, in light of the agency's authority pursuant to 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 DP-ØØ4114-3 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

#### Prohibit any DP-ØØ4114-3 Corn from Being Released

APHIS considered prohibiting the release of DP-ØØ4114-3 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that DP-ØØ4114-3 corn is unlikely to pose a plant health risk (USDA-APHIS, 2011b).

In enacting the Plant Protection Act, Congress found that

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

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 policies for oversight of emerging technologies (such as genetic engineering) at the agency level (76 FR 3821-3823, 2011). 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:

“[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency”

Based on the PPRA (USDA-APHIS, 2011b), and the scientific data evaluated therein, APHIS concluded that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DP-ØØ4114-3 corn.

#### Approve the Petition in Part

The regulations at 7 CFR 340.6(d) (3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in the extension request. Because APHIS has concluded that DP-ØØ4114-3 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011b), there is no regulatory basis pursuant to the plant pest provisions of the PPA for considering approval of the petition only in part.

#### Isolation Distance between DP-ØØ4114-3 Corn and Non-GE Corn Production and Geographical Restrictions

Because APHIS has concluded that DP-ØØ4114-3 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2011b), an alternative based on requiring isolation distances would be inconsistent with the statutory authority pursuant to the plant pest provisions of the PPA and regulations in 7 CFR part 340.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating DP-ØØ4114-3 corn from conventional or specialty corn production. APHIS also considered geographically restricting the production of DP-ØØ4114-3 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 APHIS’ PPRA for DP-ØØ4114-3 corn, there are no geographic differences associated with any identifiable plant pest risks for DP-ØØ4114-3 corn (USDA-APHIS, 2011b). This alternative was rejected and not analyzed in detail because APHIS has concluded that DP-ØØ4114-3 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS’ statutory authority pursuant to 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, the imposition of isolation distances or geographic restrictions would not meet APHIS’ purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency’s authority pursuant to the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from DP-ØØ4114-3 corn or to use isolation

distances and other management practices to minimize gene movement between DP-ØØ4114-3 corn and non-GE corn fields. Information to assist growers in making informed management decisions for DP-ØØ4114-3 corn is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

Requirement of Testing for DP-ØØ4114-3 Corn

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that 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 DP-ØØ4114-3 corn does not pose a plant pest risk (USDA-APHIS, 2011b), 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 DP-ØØ4114-3 corn would not meet APHIS’ purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

**Environmental Consequences of APHIS’ Selected Action**

Based on the similarity of the antecedent organism event DP-ØØ4114-3 corn to MZIR098 corn (USDA-APHIS, 2015), APHIS has concluded that the previous analysis of impacts completed for DP-ØØ4114-3 corn to be relevant to APHIS’ regulatory actions associated with responding to the Syngenta extension request for MZIR098 corn. The potential impacts of MZIR098 corn on agricultural production of corn, physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species are identical to those presented in the Final EA and FONSI for DP-ØØ4114-3 corn and therefore are being used in their entirety to evaluate APHIS’ action associated with a determination of nonregulated status of MZIR098 corn. The DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a) contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	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—risk assessment (reference)

<b>Management Practices</b>		
Acreage and Areas of Corn Production	Unlikely to change current production areas or acreage of corn planted.	Unchanged from No Action Alternative.
Agronomic Practices	Agronomic practices will remain the same as current practices for commercial corn production.	Unchanged from No Action Alternative.
Pesticide Use	Pesticide usage unlikely to change.	Unchanged from No Action Alternative.
Corn Seed Production	Unchanged.	Unchanged from No Action Alternative.
Organic Corn Production	Unchanged.	Unchanged from No Action Alternative.
<b>Environment</b>		
Land Use	Not expected to have any impact on land use.	Unchanged from No Action Alternative.
Water Resources	Not expected to have any impacts on water resources.	Unchanged from No Action Alternative.
Soil	Not expected to have any impacts on soil.	Unchanged from No Action Alternative.
Air Quality	Not expected to have any impacts on air quality.	Unchanged from No Action Alternative.
Climate Change	Not expected to have any impacts on climate change.	Unchanged from No Action Alternative.
<b>Animals and Plants</b>		
Animals	DP-ØØ4114-3 will remain regulated, and will not affect any organisms other than targeted insects.	Unchanged from No Action Alternative.
Plants	Not expected to have any impact on plants.	Unchanged from No Action Alternative.
Gene Movement	Not expected to have any impact on horizontal or vertical gene flow.	Unchanged from No Action Alternative.
Soil Microorganisms	Not expected to have any impact on soil organisms.	Unchanged from No Action Alternative.
Biological Diversity	Not expected to have any impact on biological diversity.	Unchanged from No Action Alternative.
<b>Human and Animal Health</b>		
Risk to Human Health	Not expected to have any impacts on human health.	Unchanged from No Action Alternative.
Risk to Animal Feed	Not expected to have any impacts on animal feed.	Unchanged from No Action Alternative.
<b>Socioeconomic</b>		
Domestic and Economic Environment	Unchanged.	Unchanged from No Action Alternative.
Trade Economic Environment	Unchanged.	Unchanged from No Action Alternative.
Other Regulatory Approvals	Unchanged for existing nonregulated GE organisms.	FDA consultation and EPA revision are ongoing.
<b>Compliance with Other Laws</b>		
CWA, CAA, Eos	Fully compliant	Fully compliant

## **Finding of No Significant Impact**

Based on the analysis of impacts in the final EA for DP-ØØ4114-3 corn (USDA-APHIS, 2011a) and the similarity of MZIR098 corn to the antecedent organism DP-ØØ4114-3 corn, a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn will not have a significant impact, individually or cumulatively, on the quality of the human environment. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

*Context* - The term “context” recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic corn production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

The National Agricultural Statistics Service objective yield surveys in 10 corn producing States during 2014 indicated the highest number of ears per acre on record for the combined 10 objective yield States (Iowa, Illinois, Indiana, Kansas, Minnesota, Missouri, Nebraska, Ohio, South Dakota, and Wisconsin) (USDA-NASS, 2015). In 2014 approximately 90.6 million acres of corn were planted in the U. S. and 83.1 million of those acres were harvested, producing 14.2 billion bushels of corn (171.0 bushels/acre) with a value of \$51.9 billion (\$3.65/bushel) (USDA-NASS, 2014b). Total U.S. corn production was 10.8 billion bushels in the drought year of 2012, 12.3 billion bushels in 2011, and 12.5 billion bushels in 2010 (Thiesse, 2014; USDA-NASS, 2014a). The 2014 national average corn yield was well above recent U.S. corn yields of 158.8 bushels per acre in 2013, 123.4 bushels per acre in 2012, and 147.2 bushels per acre in 2011. The previous record U.S. average corn yield was 164.7 bushels per acre in 2009. Despite a late winter season delay in planting, more favorable spring conditions arrived allowing quick planting and largely favorable growing conditions that encouraged the record high production forecast.

Over the past 60 years, corn yield per unit area has almost tripled (Soyatech, 2008). This increase is attributed to the introduction of improved corn germplasm, development of new varieties, the availability of better field equipment, and the use of herbicide and other pesticides that have greatly reduced crop losses caused by weeds and pests (Soyatech, 2008).

The U.S. is the largest producer of corns in the world, followed by Brazil, Argentina, China, India, Paraguay and Canada, and these countries account for approximately 95% of all corn production worldwide (Association, 2012; Commodities, 2013).

A determination of nonregulated status of MZIR098 Corn is not expected to directly cause an increase in agricultural acreage devoted to corn production. The availability of MZIR098 corn will not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE corn varieties on the market. Although corn production data

has changed since the analyses were done for the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a), the changes remain consistent with the findings of that EA.

*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.*

A determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty corn varieties. Based on the discussions in Chapter 4 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a) and its similarity to the antecedent organism event, a determination of nonregulated status of Event MZIR098 corn is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those corn acres devoted to GE corn cultivation. The availability of MZIR098 corn will not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market. A determination of nonregulated status of MZIR098 corn could add another GE corn variety to the conventional corn market and is not expected to change the market demands for GE corn or corn produced using organic methods or specialty systems.

Based on data provided by Syngenta for MZIR098 corn (Syngenta, 2015), APHIS has concluded that the availability of MZIR098 corn would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE corn seed production. A determination of nonregulated status of MZIR098 corn will not require a change to seed production practices, nor current production practices.

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

A determination of nonregulated status of MZIR098 corn would have no significant impacts on human or animal health. As discussed in Chapter 4 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a), similar products are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340 beginning in 1996 with the introduction of *Bt* products. In each case, FDA and EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts.

Public health concerns associated with the use of GE corn, such as MZIR098 corn, and GE corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. Non-GE corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release in the market. Pursuant to the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they



market are safe and labeled properly. As a GE product, however, food and feed derived from MZIR098 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use in food (Hammond & Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Syngenta provided the FDA with a comprehensive event specific information on the identity, function, and characterization of the genes for MZIR098 corn on August 27, 2015. The FDA is currently reviewing Syngenta's submission.

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 pursuant to 7 CFR 340 of MZIR098 corn. Similar to the antecedent organism DP-ØØ4114-3 corn, the common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MZIR098 corn. The product will be deployed on agricultural land currently suitable for production of corn, will replace existing varieties, and is not expected to increase the acreage of corn production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MZIR098 corn, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential significant impacts to the human environment. In the event of a determination of nonregulated status of MZIR098 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 close proximity to corn production sites.

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

The impacts on the quality of the human environment from a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn are not highly controversial. Although there is some opposition to a determination of nonregulated status of MZIR098 corn, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a), a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those acres devoted to GE corn cultivation. The availability of MZIR098 corn will not change cultivation areas for corn production in the U.S., and there are no anticipated changes to the availability of corn varieties on the market. A determination of nonregulated status of MZIR098 corn could add another corn variety to the corn market and is not expected to change the market demands for corns produced using organic methods. A determination of nonregulated status of MZIR098 corn will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. Management practices and seed standards for production of certified corn seed would not change. The impact of MZIR098 corn on wildlife or biodiversity is not different than that of crops currently used in agriculture, or other corn produced in conventional agriculture in the U.S.

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

Based on the analysis documented in the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a) and its similarity to the antecedent DP-ØØ4114-3 corn, the possible impacts on the human environment from a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn are well understood. The impacts of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a), a determination of nonregulated status of MZIR098 corn is not expected to directly cause an increase in agricultural acreage devoted to corn, or those acres devoted to GE corn cultivation. A determination of nonregulated status of MZIR098 corn will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified corn seed would not change. The impacts of MZIR098 corn on wildlife or biodiversity is no different than that from other crops currently used in agriculture, or other corn produced in conventional agriculture in the U.S. As described in Chapter 2 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a), well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in corn

production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional corn varieties, MZIR098 corn, or produce corn using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural corn production. Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MZIR098 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 for MZIR098 corn would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Pursuant to the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

Based on the similarity of the antecedent organism DP-ØØ4114-3 corn to MZIR098 corn, no significant cumulative impacts were identified through this assessment. The DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a) discussed cumulative impacts on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative impacts analysis is included for each environmental issue analyzed in Chapter 4 of the DP-ØØ4114-3 corn EA (USDA-APHIS, 2011a). In the event APHIS reaches a determination of nonregulated status of MZIR098 Corn, APHIS would no longer have regulatory authority over this corn. In the event of a determination of nonregulated status of MZIR098 corn, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of MZIR098 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 historic resources.*

Based on the similarity of the antecedent organism DP-ØØ4114-3 corn to MZIR098 corn, a determination of nonregulated status pursuant to 7 CFR 340 of MZIR098 corn will not adversely

impact cultural resources on tribal properties. Any farming activities that may be taken 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 MZIR098 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 significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of MZIR098 corn. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of MZIR098 corn is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected pursuant to the National Historic Preservation Act (NHPA). 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 use and enjoyment of a historic property when common agricultural activities take place. Additionally, cultivation practices are already being conducted throughout the corn production regions. The cultivation of MZIR098 corn does not inherently change any of these agronomic practices so as to give rise to an impact pursuant to the NHPA.

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

As described in Chapter 6 of the DP-ØØ4114-3 EA (USDA-APHIS, 2011a), APHIS has analyzed the potential for effects from a determination of nonregulated status pursuant to 7 CFR 340 of DP-ØØ4114-3 corn on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required pursuant to Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of MZIR098 corn, APHIS has determined that a determination of nonregulated status of MZIR098 corn would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

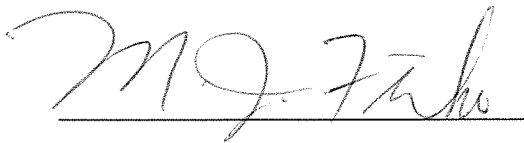
10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that MZIR098 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of MZIR098 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. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

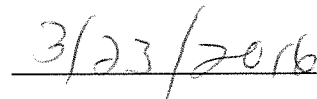
## NEPA Decision and Rationale

I have carefully reviewed the existing NEPA documentation completed for DP-ØØ4114-3 corn, including input from the public involvement process. Based on APHIS' conclusion that MZIR098 corn encompasses the same scope of environmental analysis and regulatory decision as DP-ØØ4114-3 corn; that is, a determination of nonregulated status pursuant to 7 CFR part 340, I conclude the issues identified and analyzed in the existing NEPA documentation for DP-ØØ4114-3 corn are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to MZIR098. This regulatory action meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the PPA and pursuant to 7 CFR 340.

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 (a determination of nonregulated status of MZIR098 corn) has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, this Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MZIR098 corn, the continued regulated status of MZIR098 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 above, I have determined that a determination of nonregulated status of MZIR098 corn will not have any significant environmental impacts.



Michael Firko, Ph.D.



Date

APHIS Deputy Administrator  
Biotechnology Regulatory Services  
U.S. Department of Agriculture

## Citations

- 76 FR 3821-3823. (2011). *Executive Order 13563 of January 18, 2011 Improving Regulation and Regulatory Review*.
- AOSCA. (2010). General IP Protocols Standards. Retrieved November 8, 2010, from <http://www.identitypreserved.com/handbook/aosca-general.htm>
- Association, A. S. (2012). Soy stats 2012. Retrieved August 26, 2013, from [http://www.soystats.com/2012/page\\_02.htm](http://www.soystats.com/2012/page_02.htm)
- Bravo, A., Gill, S. S., & Soberón, M. (2007). Mode of action of *Bacillus thuringiensis* Cry and Cyt toxins and their potential for insect control. *Toxicon*, 49(4), 423-435.
- Commodities, S. (2013). Soybeans-World Supply and Demand Summary. Retrieved March 13, 2014, 2014, from <http://www.spectrumcommodities.com/education/commodity/statistics/soybeans.html>
- Hammond, B. G., & Jez, J. M. (2011). Impact of food processing on the safety assessment for proteins introduced into biotechnology-derived soybean and corn crops. *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association*, 49(4), 711-721. doi: 10.1016/j.fct.2010.12.009
- Mendelsohn, M., Kough, J., Vaituzis, Z., & Matthews, K. (2003). Are Bt crops safe?
- Monsanto. (2013). Request for an Extension of Determination of Nonregulated Status for Lepidopteran-Protected Soybean (pp. 1-292): Monsanto Company
- Negrotto. (2000). <Negrotto 2000.pdf>.
- Petition for the Determination of Nonregulated Status for Insect-Resistant and Herbicide-Tolerant 4114 Maize (2012).
- Soyatech. (2008). *Statistics 2008 Soya and Oilseed Bluebook* (pp. 343-389). Southwest Harbor, Maine: Soyatech, Inc.
- Syngenta. (2015). Request For an Extension of Determination of Nonregulated Status For Insect-Resistant and Herbicide-Tolerant Event MZIR098 Corn.
- Thiesse, K. (2014). USDA projects record 2014 crop production. Retrieved October 23, 2015, from <http://cornandsoybeandigest.com/blog/usda-projects-record-2014-crop-production>
- US-EPA. (2010a). Biopesticides Registration Action Document: *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Material Necessary for Their Production (PHP17662 T-DNA) in Event DAS-59122-7 Corn (OECD Unique Identifier: DAS-59122-7). from [www.epa.gov/pesticides/biopesticides/pips/cry3435ab1-brad.pdf](http://www.epa.gov/pesticides/biopesticides/pips/cry3435ab1-brad.pdf)
- US-EPA. (2010b). Cry1Ab and Cry1F Bt Plant-Incorporated Protectants September 2010 Biopesticides Registration Action Document.
- US-EPA. (2012a). *Bacillus thuringiensis eCry3.1Ab protein in corn; exemption from the requirement of a tolerance. 40 CFR §174.532*.
- US-EPA. (2012b). *Current & Previously Registered Section 3 Plant-Incorporated Protectant (PIP) Registrations*. Retrieved from [http://www3.epa.gov/pesticides/chem\\_search/ppls/067979-00022-20120731.pdf](http://www3.epa.gov/pesticides/chem_search/ppls/067979-00022-20120731.pdf).
- US-EPA. (2015). Reevaluation: Review of Registered Pesticides. .
- US-EPA. (2015 ). *Non-PRIA (Pesticide Registration Improvement Act) Amendment – to extend the registration expiration date five years, amend the label ingredient statement and delete alternate brand names*. Retrieved from [http://www3.epa.gov/pesticides/chem\\_search/ppls/067979-00001-20150921.pdf](http://www3.epa.gov/pesticides/chem_search/ppls/067979-00001-20150921.pdf).

- USDA-APHIS. (2011a). Monsanto Company Petition (09-SY-194U) for Determination of Non-Regulated Status of Event MON 87701: Final Environmental Assessment (pp. 1-93): USDA-APHIS.
- USDA-APHIS. (2011b). Plant Pest Risk Assessment for Monsanto MON 87701 Soybeans (pp. 1-13): USDA-APHIS.
- USDA-APHIS. (2013a). *FONSI of DP-ØØ4114-3 corn*.
- USDA-APHIS. (2013b). Plant Pest Risk Assessment for Pioneer 4114 Maize.
- USDA-APHIS. (2015). *Plant Pest Risk Assessment for MZIR098 Corn (15-218-01p)*.
- USDA-NASS. (2014a). *Corn, US total*. Washington, D.C.: U.S. Department of Agriculture, National Agricultural Statistics Service.
- USDA-NASS. (2014b). *Quick stats: 2013 US total - Acreage, Yield, Production and Price for Soybeans*. Washington, D.C.: U.S. Department of Agriculture, National Agricultural Statistics Service Retrieved from [http://www.nass.usda.gov/Quick\\_Stats/Lite/result.php?9CF79235-C090-3838-8811-077B8BC4CA2F](http://www.nass.usda.gov/Quick_Stats/Lite/result.php?9CF79235-C090-3838-8811-077B8BC4CA2F).
- USDA-NASS. (2015). Crop Production 2014 Summary.