

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

Stine Seed Farm, Inc.

Event HCEM485 Corn

**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. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

Stine Seed Farm, Inc. (hereafter referred to as Stine Seed) submitted a request to APHIS in 2009 for an extension of a determination of nonregulated status for a genetically engineered (GE) glyphosate resistant corn event HCEM485 ((hereafter referred to as HCEM485)). A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. 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 Stine Seed (Stine Seed, 2011) and has concluded that HCEM485 is similar to the antecedent organism, event GA21 and therefore, based on its Plant Pest Risk Assessment for HCEM485 (USDA-APHIS, 2012) APHIS has concluded that HCEM485 is unlikely to pose a plant pest risk.

The petition for Roundup Ready[®] corn Event GA21 (97-099-01p) received a determination of non-regulated status from APHIS on November 18, 1997 (62 FR 64350). GA21 corn contains a modified corn *epsps* gene which confers resistance to the herbicide glyphosate through the expression of a modified corn EPSPS protein. In accordance with § 340.6(e)(2), Stine Seed requests this determination of nonregulated status of Roundup Ready[®] corn Event GA21 from APHIS be extended to Event HCEM485 and any progeny derived from crosses of Event HCEM485 with conventional corn, and any progeny derived from crosses of Event HCEM485 with other GE corn varieties that have received a determination of nonregulated

status, no longer be considered regulated articles under 7 CFR Part 340. Event HCEM485 is currently regulated under 7 CFR part 340. Interstate movements and field trials of Event HCEM485 have been conducted under permits issued or notifications acknowledged by APHIS since 2005. Data resulting from these field trials are described in Stine Seed's application for extension (Stine Seed, 2011).

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 an extension of a determination of nonregulated status of a petition request (APHIS Number 09-063-01p) by Stine Seed Farm, Inc. (Stine Seed) for their genetically engineered Event HCEM485 Corn that expresses a modified corn *epsps* gene which confers resistance to the herbicide glyphosate. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the request for an extension of a determination of nonregulated status for HCEM485. The EA assesses alternatives to an extension of a determination of nonregulated status of HCEM485 and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge 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 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 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).

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000, as amended (7 USC §§ 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under 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 under 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). 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 foods.

The EPA regulates 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 Cosmetics 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 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 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 to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the Plant Protection Act or the regulations at 7 CFR part 340. The petitioner is required to provide information under §§340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Application for an Extension of Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as HCEM485. When a request for

an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined to be unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) of the antecedent organism that the genetically engineered organism identified in the extension request is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Stine Seed has submitted a request to APHIS for an extension of a determination of nonregulated status for a glyphosate resistant corn event HCEM485. In accordance with § 340.6(e)(2), Stine Seed requests APHIS' determination of nonregulated status for Roundup Ready® corn be extended to Event HCEM485 and any progeny derived from crosses of HCEM485 with conventional corn, and any progeny derived from crosses of HCEM485 with other GE corn varieties that have received a determination of nonregulated status, no longer be considered regulated articles under 7 CFR part 340. The antecedent organism identified in the extension request HCEM485 is Event GA21 (Stine Seed, 2011). The petition for Roundup Ready® corn Event GA21 (97-099-0lp) received a determination of non-regulated status from APHIS on November 18, 1997 (62 FR 64350).

HCEM485 Corn

HCEM485 corn has been genetically modified to express the EPSPS protein to convey resistance to the herbicide glyphosate. HCEM485 provides growers with an alternative to existing glyphosate-resistant corn products on the market today. HCEM485 will provide similar benefits to currently available glyphosate-resistant corn varieties by allowing post emergent applications of glyphosate to control weeds.

Coordinated Framework Review

Food and Drug Administration

Similar to the antecedent organism event GA21, HCEM485 Corn is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. Stine Seed initiated the consultation process with FDA for the commercial distribution of HCEM485 Corn and submitted a safety and nutritional assessment of food and feed derived from HCEM485 Corn to the FDA in December 2010 (Stine Seed, 2011). FDA completed the consultation with no further questions on July 31, 2012 (US-FDA, 2012).

Environmental Protection Agency

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants (PIPs) under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism.

EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. HCEM485 is similar to currently available glyphosate-resistant corn varieties. Stine Seed indicates that there will be no change in the use pattern for glyphosate on this glyphosate resistant variety and there will be no need to petition EPA for a change in the label for

glyphosate. APHIS used the current glyphosate labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate.

Scope of the Environmental Analysis

Based on the similarity to the antecedent organism event GA21, APHIS has concluded that the Stine Seed extension request for a determination on the regulated status for Event HCEM485 encompasses the same scope of environmental analysis as Roundup Ready[®] Corn. APHIS reviewed and analyzed the information submitted in the extension request by Stine Seed (Stine Seed, 2011) and has concluded that Event HCEM485 is similar to the antecedent organism, event GA21 and based on its Plant Pest Risk Assessment for HCEM485 corn (USDA-APHIS, 2012) APHIS has concluded that HCEM485 is unlikely to pose a plant pest risk. Although approving the request for an extension of nonregulated status of HCEM485 would allow for new plantings of Event HCEM485 to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support corn production. Similar to the antecedent organism event GA21, approving the request for an extension of nonregulated status of HCEM485 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 (NASS) to determine where corn is produced in the U.S. (UDA-NASS, 2012). Corn is primarily produced in an area of the U.S. commonly known as the Corn Belt, which includes Iowa, Illinois, Nebraska, and Minnesota, and parts of Indiana, South Dakota, Kansas, Ohio, Wisconsin, and Missouri. These ten states comprised approximately 73 percent of the nation's corn production in 2011 (USDA-NASS, 2012a; USDA-NASS, 2012b).

Public Involvement

APHIS published a notice on February 27, 2013, in the Federal Register (78 FR 13303-04, Docket no. APHIS-2012-0033) announcing the availability of the request for an extension of nonregulated status for genetically engineered corn event HCEM485 along with a PPRA and a preliminary (draft) determination response for a 30-day public review and comment period. Comments were required to be received on or before March 29, 2013. During the 30-day public comment period, three comments were received. Two comments stated a general opposition to GE crops, raised concerns about pollen drift and contamination of specialty crops, the human health concerns from the crop, and concerns about glyphosate persistence and safety in the environment. One comment raised concerns about the socioeconomic impacts on the export market from granting nonregulated status to HCEM485 corn. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. Responses to substantive comments are included as an attachment to this Finding of No Significant Impact. These comments¹ did not change the analysis in EA or PPRA for Event HCEM485.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant

¹ Comment documents may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0033>.

Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for HCEM485 Corn. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues 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 HCEM485 Corn.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

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

Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of an extension of a determination of nonregulated status to HCEM485 corn. To respond favorably to a request for an extension of nonregulated status, APHIS must determine that HCEM485 corn is similar to the antecedent organism, GA21 and is, therefore, unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2012), APHIS has concluded that HCEM485 corn is similar to GA21 and unlikely to pose a plant pest risk. Therefore, APHIS must determine that HCEM485 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) extension of a determination of nonregulated status to HCEM485 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 extension request. HCEM485 Corn and progeny derived from HCEM485 Corn would continue to be regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of HCEM485 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 that Maize Line HCEM485 is similar to the antecedent organism, GA21.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that HCEM485 Corn is similar to the antecedent organism, GA21 and unlikely to pose a plant pest risk (USDA-APHIS, 2012). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the extension request for nonregulated status.

Preferred Alternative: Approve the Request for an Extension of a Determination of Nonregulated Status to HCEM485 Corn from Corn Event GA21

Under this alternative, HCEM485 Corn and progeny derived from HCEM485 Corn would no longer be regulated articles under the regulations at 7 CFR part 340. HCEM485 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of HCEM485 Corn and progeny derived from this event. The preferred alternative best meets the purpose and need to respond appropriately to a request for an extension of nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that HCEM485 Corn is similar to the antecedent organism, GA21 and is unlikely to pose a plant pest risk, an extension of a determination of nonregulated status to HCEM485 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 HCEM485 corn. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, 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 HCEM485 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. Prohibit any HCEM485 Corn from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of HCEM485 Corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that HCEM485 Corn is similar to the antecedent organism, GA21 and is unlikely to pose a plant pest risk (USDA-APHIS, 2012).

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. 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, 2012), and the scientific data evaluated therein, APHIS concluded that HCEM485 Corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of HCEM485 Corn.

2. Isolation Distance between HCEM485 Corn and Non-GE Corn Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating HCEM485 Corn from conventional or specialty corn production. However, because APHIS has concluded that HCEM485 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of HCEM485 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 HCEM485 Corn, there are no geographic differences associated with any identifiable plant pest risks for HCEM485 Corn (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because APHIS has concluded that HCEM485 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 under the plant pest

provisions of the Plant Protection Act and regulations in 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 an extension request for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from HCEM485 Corn or to use isolation distances and other management practices to minimize gene movement between cornfields. Information to assist growers in making informed management decisions for HCEM485 Corn is available from AOSCA(AOSCA, 2010).

3. Requirement of Testing for HCEM485 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 HCEM485 Corn does not pose a plant pest risk (USDA-APHIS, 2012), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for HCEM485 Corn would not meet APHIS' purpose and need to respond appropriately to the request in accordance with its 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.

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 (USDA-APHIS, 2012)
Management Practices		
Acreage and Areas of Corn Production	88% of all corn produced in US is GE. 23% are herbicide-resistant varieties that are not combined with other GE traits. Corn yields are expected to continue to increase, but total acreage is likely to vary by about 2% during this decade.	Unchanged from No Action Alternative
Agronomic Practices	Crop rotation can reduce selection pressure for weed resistance to herbicides. Reduced or conservation	Unchanged from No Action Alternative.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	tillage has largely replaced conventional tillage.	
Pesticide Use	EPA-approved uses of glyphosate on corn have been reviewed since the introduction of glyphosate resistant varieties, and have remained unchanged.	Unchanged from No Action Alternative
Other Specialty Corn Production Systems	Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops	Unchanged from No Action Alternative
Organic Corn Production	Certified organic com acreage is a small but increasing percentage of overall com production.	Unchanged from No Action Alternative
Environment		
Land Use	Current trends in the acreage and areas of production are likely to continue to be driven by market conditions (i.e., increased demand for US corn and corn products for animal feed, ethanol, etc.) and federal policy	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff	Unchanged from No Action Alternative
Soil	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing corn	Unchanged from No Action Alternative
Air Quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of insecticides may impact	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	
Climate Change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production)	Unchanged from No Action Alternative
Animals and Plants		
Animals	Invertebrates that feed on corn are typically considered pests and may be controlled by the use of insecticides or other production practices. The toxicity of glyphosate to animal species from registered uses poses minimal risks to animals.	Unchanged from No Action Alternative
Plants	Corn fields can be bordered by other agricultural fields (including other corn varieties), woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Corn growers use production practices to manage weeds in and around fields	Unchanged from No Action Alternative
Gene Movement	Cultivated corn varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative
Soil Microorganisms	APHIS has previously examined potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils.	Unchanged from No Action Alternative
Biological Diversity	HR crops, such as corn, have been correlated with an increase in conservation tillage in U.S. crop	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	<p>production, which promotes biodiversity by allowing the establishment of other plants, and the accumulation of more plant residue that increases soil organic matter, food, and cover for wildlife. Effects of GE crops have been associated with positive impacts on biodiversity because of increased yields, fewer applications of less toxic pesticides, and facilitation of conservation tillage.</p>	
<p>Human and Animal Health</p>		
<p>Risk to Human Health</p>	<p>EPSPS proteins pose no potential for toxicity or allergenicity for humans. Agricultural workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. The EPA's Worker Protection Standard (WPS) (US-EPA, 1992); 40 CFR Part 170.1, <i>Scope and Purpose</i>) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.</p>	<p>Unchanged from No Action Alternative. A comprehensive assessment of the safety of EPSPS demonstrated that the protein is nontoxic to mammals and unlikely to be a food allergen. US-EPA-registered pesticides that are currently used for corn production would continue to be used by growers under the Preferred Alternative. Agricultural production with HCEM485 corn does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional corn. Therefore, worker safety issues associated with the agricultural production of HCEM485 corn would remain the same as those under the No Action Alternative.</p>
<p>Risk to Animal Feed</p>	<p>EPSPS proteins are not expected to be allergenic, toxic, or pathogenic in mammals or poultry. The maximum tolerance level for glyphosate in field corn is 5.0 ppm for grain and is 6.0 ppm for forage.</p>	<p>A compositional analysis concluded that forage and grain from HCEM485 corn hybrids are considered similar in composition to forage and grain from both the non- GE comparator and conventional corn hybrids. Therefore this is unchanged from No Action Alternative</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic		
Domestic and Economic Environment	The widespread adoption of herbicide-resistant corn has been attributed to the cost savings for production, among other non-monetary benefits.	Unchanged from No Action Alternative
Trade Economic Environment	The primary US corn export destinations are also the largest world importers of corn and do not have major barriers for importing food or feed commodities produced from GE crops, including those with herbicide resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country	The trade economic impacts associated with Approving the request for an extension of nonregulated status to HCEM485 corn are anticipated to be similar to the No Action alternative because the U.S. and other countries already have access to other glyphosate-resistant corn cultivars.
Other Regulatory Approvals	FDA completed consultations, EPA tolerance exemptions and pesticide registrations granted	FDA completed consultations,
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. I agree with this conclusion and therefore find that an EIS need not be prepared. 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.

In 2011, corn was grown on 91.9 million acres in the United States (USDA-NASS, 2011; USDA-NASS, 2012). Approximately 88% of corn fields were planted with GE corn in 2011 (USDA-NASS, 2012). Approving the request for an extension of nonregulated status to HCEM485 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 HCEM485 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.

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.*

Approving the request for an extension of nonregulated status to HCEM485 Corn will have no significant environmental impact in relation to the availability of GE, conventional, and organic corn varieties. As discussed in Chapter 4 of the EA, approving the request for an extension of nonregulated status to HCEM485 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 HCEM485 Corn will not change the cultivation areas for corn production in the U.S., and there are no anticipated changes in the availability of GE and non-GE corn varieties on the market. Approving the request for an extension of nonregulated status to HCEM485 Corn could add another GE corn variety to the conventional corn market, but is not expected to change the market demands for GE corn or corn produced using organic methods. GE and organic corn are planted on about 88% and 0.2% of corn acreage, respectively (USDA-NASS, 2012; USDA-ERS, 2010). As of 2008, approximately 168,000 acres of certified organic corn were grown in the U.S. Based on the data provided by Stine Seed for HCEM485 Corn (Stine Seed, 2011), APHIS has concluded that the availability of HCEM485 Corn would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE corn seed production (USDA-APHIS, 2012). Approving the request for an extension of nonregulated status to HCEM485 Corn will not require a change to seed production practices, nor current production practices. The introduction of HCEM485 Corn provides an alternative corn variety with glyphosate resistance.

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

Approving the request for an extension of nonregulated status to HCEM485 Corn would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that HCEM485 Corn is compositionally similar to other commercially available corn (Stine Seed, 2011). Stine Seed initiated the consultation process with FDA for the commercial distribution of HCEM485 Corn and submitted a safety and nutritional assessment of food and feed derived from HCEM485 to the FDA in December 2010. Based on the information Syngenta submitted, and as of July 31, 2012, FDA has no further questions regarding HCEM485 Corn (US- FDA, 2012). Based on the FDA's consultation, laboratory data and scientific literature provided by Stine Seed (Stine Seed, 2011), and safety data available on other herbicide-resistant products, APHIS has concluded that HCEM485 would have no significant impacts on human or animal health.

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 approving the request for an extension of nonregulated status to HCEM485 Corn. Similar to the antecedent organism GA21, 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 approving the request for an extension of nonregulated status to HCEM485 Corn. Similar to the antecedent organism GA21, 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 HCEM485 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 approving the request for an extension of nonregulated status to HCEM485 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 effects on the quality of the human environment from approving the request for an extension of nonregulated status to HCEM485 Corn are not highly controversial. Although there is some opposition to approving the request for an extension of nonregulated status to HCEM485 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 EA, extending 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 HCEM485 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. Approving the request for an extension of nonregulated status to HCEM485 Corn could add another GE corn variety to the corn market and is not expected to change the market demands for GE corn or corn produced using organic methods. Approving the request for an extension of nonregulated status to HCEM485 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 effect of HCEM485 Corn on wildlife or biodiversity is not different than that of other herbicide-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing approving the request for an extension of nonregulated status to HCEM485 Corn. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. APHIS has addressed substantive comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

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 EA and its similarity to the antecedent organism event GA21, the possible effects on the human environment from approving the request for an extension of nonregulated status to HCEM485 are well understood. The effects 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 EA and its similarity to the antecedent organism GA21, approving the request for an extension of nonregulated status to HCEM485 Corn is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those acres devoted to GE corn cultivation. Similar to the antecedent organism GA21, approving the request for an extension of nonregulated status to HCEM485 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. Similar to the antecedent organism GA21, the effect of HCEM485 Corn on wildlife or biodiversity is no different than that from other herbicide-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, 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 (GE and non-GE varieties), HCEM485 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. Additionally, GE corn currently is planted on the majority of corn acres (88% of acreage in 2011) (USDA-NASS, 2012). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without approving the request for an extension of nonregulated status to HCEM485 Corn. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE corn products, the possible effects to the human environment from the release of an additional GE corn product are already well known and understood. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

Extending a determination of nonregulated status to HCEM485 Corn would not establish a precedent for future actions with significant effects 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. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as HCEM485 Corn. When a request for extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously

been determined to be unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment, that the genetically engineered organism identified in the extension request is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A person may also request that APHIS extend a determination of nonregulated status to other organisms under §340.6(e)(2). 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.

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

Based on the similarity of the antecedent organism GA 21 to HCEM485, no significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on corn management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS approves the request for an extension of nonregulated status to 5307 Corn, APHIS would no longer have regulatory authority over this corn. APHIS has not identified any significant impact on the environment which may result from the incremental impact of approving the request for an extension of nonregulated status to HCEM485 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 analysis documented in the EA and its similarity to the antecedent organism event GA21, Approving the request for an extension of nonregulated status to HCEM485 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. Similar to the antecedent organism GA21, Approving the request for an extension of nonregulated status to HCEM485 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 approving the request for an extension of nonregulated status to HCEM485 Corn. Similar to the antecedent organism GA21, 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. Approving the request for an extension of nonregulated status to HCEM485 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. 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 effects on the character or use of historic properties. For example, there is potential for audible effects 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 effects 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 HCEM485 Corn does not inherently change any of these agronomic practices so as to give rise to an impact under 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 EA, APHIS has analyzed the potential for effects from approving the request for an extension of nonregulated status to HCEM485 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 under Section 7 of the Endangered Species Act. After reviewing possible effects of approving the request for an extension of nonregulated status to HCEM485 Corn, APHIS has concluded that approving the request for an extension of nonregulated status to HCEM485 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 HCEM485 Corn is unlikely to pose a plant pest risk, approving the request for an extension of nonregulated status to HCEM485 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. Stine Seed initiated

the consultation process with FDA for the commercial distribution of HCEM485 Corn and submitted a safety and nutritional assessment of food and feed derived from HCEM485 Corn to the FDA to on December 9, 2010 (Stine Seed, 2011). Based on the information Stine Seed submitted, and as of July 31, 2012, FDA has no further questions regarding HCEM485 Corn (US-FDA, 2012). 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 the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that HCEM485 Corn is No Longer a Regulated Article). This alternative meets 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, Alternative 2 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 HCEM485 Corn, the continued regulated status of HCEM485 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 approving the request for an extension of nonregulated status to HCEM485 Corn will not have any significant environmental effects.

Michael C. Gregoire

Michael C. Gregoire

Deputy Administrator

Biotechnology Regulatory Services

April 8, 2013

Date

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Response to Public Comments on Stine Seed HCEM485 Corn:

On February 27, 2013, APHIS published a notice in the Federal Register (78 FR 13303-13304, Docket no. APHIS-2012-0033) announcing the availability of the petitioners request for an extension of a determination of nonregulated status for genetically engineered corn event HCEM485 along with a PPRA and a preliminary (draft) determination response for a 30-day public review and comment period. Comments were required to be received on or before March 29, 2013.

APHIS received a total of three comments on the HCEM485 corn petition (hereafter referred to as HCEM485 Corn), PPRA, and draft EA. Two comments opposed the development of genetically engineered foods and/or HCEM485 Corn. These two comments raised concerns about pollen drift and a lack of consideration regarding specialty corn production systems, the perceived negative effects on human health, the public right to choose non-GE containing food products, concerns about glyphosate persistence and safety in the environment. The third comment raised concerns about the socioeconomic impacts on the export market from granting nonregulated status to HCEM485 corn. These public comments did not explain or identify elements in the HCEM485 Corn PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims. Several specific issues related to the HCEM485 Corn EA were, however, identified in these three public comments. These were organized into categories and addressed below.

Issue 1: “I am deeply concerned about the ongoing destructive contamination by this genetically engineered maize of our maize heirloom diversity. According to Baker Creek Seed Companies own tests, half of our heirloom maize varieties are now contaminated by contact with GMO pollen. Arkansas red corn is gone. These biotech products should not be planted in open fields where the pollen can blow for hundreds of miles into other farmers crops.”

APHIS response:

Potential gene flow issues associated with the proposed action, including potential cross-pollination between GE corn and other corn, including organic, as well as maintaining seed and crop purity are thoroughly discussed in Sections 2.1.3 and 4.2.3 – Corn Seed Production, 2.1.4 and 4.2.4 – Organic Corn Production, and 2.3.3 and 4.4.3 Gene Flow and Weediness of the EA.

Issue 2: “I ask you to please look with good eyes at the effects of the present unlabeled crops which are indeed not substantially equivalent to the heirloom crops that they have destroyed. Putting these into our food supply unlabeled does not allow the effects to be tracked.”

APHIS response:

As stated in the EA (Purpose and Need: Regulatory Authority), the United States government regulates 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 explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest authorities in the Plant Protection Act of 2000, as amended (7 USC § 7701 et seq.) to ensure that they do not pose a plant pest risk to the environment. 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 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 FDA has concluded that GE agricultural products are not inherently different from other foods in any meaningful or uniform way and that GE products do not present any different or greater safety concerns relative to foods developed by conventional plant breeding methods (USHHS-FDA, 2001). However, FDA guidance indicates that foods, including bioengineered foods, that (1) exhibit significantly different nutritional qualities; (2) contain an allergen that consumers would not expect to be present; (3) present issues due to how the food is used or consequences of its use; or (4) are significantly different than a traditional counterpart should be labeled to indicate the difference or issue (USHHS-FDA, 2001; Byrne, 2010).

References:

Byrne, P. (2010). Labeling of Genetically Engineered Foods. Retrieved, April 13, 2011, from: <http://www.ext.colostate.edu/pubs/foodnut/09371.html>.

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Issue 3: "Roundup is a chelator, which removes minerals from the soil as it degrades. The resulting food crop is demineralized, causing miscarriages due to Manganese deficiencies, for instance."

APHIS response:

Potential soil quality issues associated with the proposed action, including potential manganese deficiencies from glyphosate use are thoroughly discussed in Section 2.2.1 and 4.3.1 – Soil Quality of the EA.

Issue 4: “Roundup-ready crops undoubtedly cause many other deleterious health effects, which are not considered in its approval for human consumption.”

APHIS response:

The EA has reported on the safety of the use of glyphosate in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health.

The EPSPS protein used in HCEM485 Corn confers tolerance to glyphosate. This protein is structurally homologous and similar functionally to endogenous plant EPSPS enzymes and is similar to the EPSPSs in other Roundup Ready® crops, including Roundup Ready® corn (GA21), Roundup Ready® soybean, Roundup Ready® canola, Roundup Ready® sugar beet, and Roundup Ready® cotton

(http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). The first generation of Roundup Ready® corn (GA21) was determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act in 1997

(http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). The *epsps* gene has been assessed extensively in the last 16 years. The safety of EPSPS protein present in biotechnology derived crops has been evaluated as part of comprehensive reviews of the safety of glyphosate exposure and ingestion (Harrison et al., 1996; see also Hammond et al., 1996; Padgett et al., 1996). The FDA has reviewed the safety of human consumption of the EPSPS protein in HCEM485 Corn, and concluded that this protein presents negligible risk to human health from consumption (US-FDA, 2012).

The EPA has also reviewed the safety of the EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The EPSPS protein expressed in HCEM485 Corn is the same as that previously reviewed by the EPA. Accordingly, HCEM485 Corn is anticipated to be safe for human and animal consumption with regard to the *epsps* gene.

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. During agricultural production of soybean, agricultural workers and

pesticide applicators may be exposed to a variety of EPA registered pesticides (see, e.g., <http://www.cdc.gov/niosh/topics/pesticides/>). Such chemicals would be expected to include those products currently used for insect pest and plant pest management in both GE and non-GE soybean cultivation, including the use of glyphosate. Worker safety is taken into consideration when a pesticide label is developed during the registration process. When use is consistent with the label, pesticides including the glyphosate to be used with HCEM485 Corn present minimal risk to the worker.

References:

Hammond, B. G., Vicini, J. L., Hartnell, G. F., Naylor, M. W., Knight, C. D., Robinson, E. H., Padgett, S. R (1996). The feeding value of soybeans fed to rats, chickens, catfish and dairy cattle is not altered by genetic incorporation of glyphosate tolerance. *The Journal of Nutrition*, 126(3), 717-727.

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Issue 5: “The herbicide Roundup was originally patented as a chelator, it removes minerals from the soil as it degrades. If the minerals are not present, the glyphosate half life can be as long as 26 years. It builds up season to season in the water and soil. Glyphosate has been detected in the rain in the Midwest.”

APHIS response:

Potential issues associated with glyphosate use and fate in soil and water under the proposed action are thoroughly discussed in Sections 2.2.1 and 4.3.1 – Soil Quality, 2.2.2 and 4.3.2 – Water Quality, and 2.2.3 – Air Quality of the EA.

Under the PPA, APHIS has no regulatory authority to restrict the use of herbicides on crops, whether they are GE or non-GE crops. The EPA is responsible for the regulation of pesticides, including herbicides; in this case, the safe use of glyphosate (EPA, 1993) has been established by the EPA through their registration for use on corn and the setting of tolerances. Glyphosate, when used according to the label, has been shown not to have unreasonable adverse effects on plants, animals, humans, and the environment. To make such determinations, EPA reviews a large number of scientific studies and tests conducted by applicants (EPA, 2009). Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA does this by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may pose to non-target species. In considering whether to register a pesticide, EPA reviews data from ecological, dietary, and exposure experiments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered by EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate poses no unreasonable risks to humans, wildlife, and the environment (EPA, 2008).

References:

EPA. 1993. Reregistration Eligibility Decision (RED) – Glyphosate (738-R-93-014).

Office of Prevention, Pesticides and Toxic Substances. United States Environmental Protection Agency, Washington, D. C.

(http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf).

EPA. 2009. Pesticides: Regulating Pesticides. United States Environmental Protection Agency, Washington, D.C. (<http://www.epa.gov/pesticides/regulating/>). Accessed on March 16, 2009.

Issue 6: “Corn also includes the ability to manufacture the pesticide bacillus thurengensis this. This was detected in over 80% of the blood of pregnant women and the cord blood of babies. The only logical way for this to be in the blood itself is if the mothers' intestinal bacteria had become manufacturers of the pesticide itself.”

APHIS response:

Bt is not produced by HCEM485 corn and therefore this comment is outside the scope of this EA.

Issue 7: “I am indeed troubled by the patenting of these seeds and the refusal of these companies to give seeds for independent testing or of the FDA to test these themselves.”

APHIS response:

APHIS has no regulatory authority over the patenting of intellectual property including seeds. Please refer to <http://www.uspto.gov/> for more information on the patent process.

APHIS is responsible for regulating GE organisms and plants under the plant pest authorities in the Plant Protection Act of 2000, as amended (7 USC § 7701 et seq.) to ensure that they do not pose a plant pest risk to the environment. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. There is no regulatory requirement that information submitted by petitioners to APHIS must be peer reviewed by a scientific panel.

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) (see 7 U.S.C. §7701(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 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:

“[D]ecisions 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.”

To assist APHIS in their scientific technical review of a petition request, in accordance with APHIS regulatory requirements set forth in 7 CFR part 340, APHIS makes each complete petition available for a 60 day public comment period. Petitions submitted by developers are announced in a Federal Register Notice and made publicly available on the APHIS website*. Petitions submitted by developers are made available to the public and include the methods used for experiments along with the subsequent observations and results. APHIS typically receives and fully considers responses from scientists made on the methodology used and the results summarized in the petition. These inputs allow APHIS to make an informed decision on the petition request, benefitting from external scientific expertise. APHIS may also directly consult with experts and scientists on specific issues to assure adequate analysis of possible environmental impacts

* http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml

Issue 8: One commenter asserted that Stine Seed has not thus far been successful in obtaining sufficient authorizations to import HCEM485 corn. The commenter states that failure to obtain the authorizations in key markets within the world would create a risk of significant economic losses to U.S. grain and oilseed producers and markets.

APHIS response:

The trade economic environment would not be affected as a direct or indirect result of approving the request for an extension of nonregulated status to HCEM485 Corn. Worldwide market conditions and destination country approval of GE crop commodities would continue to be factors for international corn prices, without regard to the presence or absence of HCEM485 Corn on the market.

To avoid adversely affecting international trade in corn commodities exported from the US, Stine Seed is currently developing agreements with other collaborators for the eventual marketing of varieties containing HCEM485 Corn. Any such collaborations would include seeking approvals in other countries prior to launch. According to the company, no marketing of HCEM485 Corn will take place until the approvals are granted. When international acceptance of a specific event has not been attained, US elevators and grain buyers may either refuse to purchase the grain, or may require that it be diverted to elevators that are solely designated as sources for domestic grain sale (Reuters, 2011).

Reference:

Reuters. US Edition (2011). Cargill bars Syngenta corn variety at US wet mills. Thursday, September 1, 2011. <http://www.reuters.com/article/2011/09/01/cargill-corn-idUSN1E78017Q20110901>