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

Genective Company
VCO-01981-5 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.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 11-342-01p) by Genective Company (hereafter referred to as Genective) for their genetically engineered VCO-01981-5 Corn that expresses an *epsps grg23ace5* gene that confers resistance to 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 petition seeking nonregulated status for VCO-01981-5 Corn. The EA assesses alternatives to a determination of nonregulated status of VCO-01981-5 Corn 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 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 Petition for 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 VCO-01981-5 Corn. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Genective has submitted a petition (APHIS Number 11-342-01p) to APHIS seeking a determination that their genetically engineered VCO-01981-5 Corn is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

VCO-01981-5 Corn

Genective SA of Chappes, France, with the Bayer Company of Research Triangle Park, North Carolina, submitted a petition (APHIS Number 11-342-01) to APHIS in 2011 for determination of nonregulated status for VCO-01981-5 Corn that expresses an *epsps grg23ace5* gene (Genective, 2012). This gene was transformed from the common soil bacterium, *Arthrobacter globiformis*, into corn for resistance to glyphosate. The protein expressed by the gene, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, EPSPS ACE5, confers resistance to the common herbicide glyphosate and has greater enzymatic half-life than the native protein, but somewhat less than the native enzyme from corn. The corn protein ACE5 EPSPS expressed in VCO-01981-5 Corn is similar to other EPSPS proteins in other glyphosate resistant soybean and corn hybrids including the CP4 EPSPS protein of glyphosate resistant (Roundup Resistant) soybean and corn. Genective SA 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 insert herbicide. APHIS used current glyphosate herbicide labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate.

Glyphosate (*N*-(phosphonomethyl) glycine) is a broad-spectrum systemic herbicide used to kill weeds. It is registered with the Environmental Protection Agency (EPA) for non-selective weed control for both non-food use and food use plants. Glyphosate's mode of action is to inhibit the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) involved in the synthesis of the aromatic amino acids: tyrosine, tryptophan and phenylalanine. Glyphosate functions due to its resemblance to the structure of the substrate for EPSPS enzyme and thereby competing with this substrate for the enzyme's active site, thus preventing the synthesis of aromatic amino acids and killing the plant.

In the event of a determination of nonregulated status, the nonregulated status for VCO-01981-5 Corn would include VCO-01981-5 Corn, any progeny derived from crosses between VC-01981-5 and conventional corn, and crosses of event VCO-01981-5 Corn with other biotechnology-derived corn that has been deregulated pursuant to Part 340 and the Plant Protection Act. If VCO-01981-5 Corn is deregulated, growers and corn seed suppliers would have another trait available for glyphosate resistance in weed management, and are expected to see benefits such as an alternative to the application of conventional insecticides and economic benefits, through increased crop yield, and increased marketplace competition for insect-protected seed products.

Event VCO-01981-5 Corn is currently regulated under 7 CFR part 340. Interstate movements and field trials of event VCO-01981-5 Corn have been conducted under permits issued or notifications acknowledged by APHIS since 2007 from Puerto Rico and since 2008 from Iowa. Data resulting from these field trials are described in the petition (Genective, 2012).

Coordinated Framework Review

Food and Drug Administration

VCO-01981-5 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. In June 2006, FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (US-FDA, 2011) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

Genective (predecessor organization, Athenix Corporation) initiated a consultation with the FDA by submitting an early food safety evaluation of the ACE5 epsps protein expressed in VCO-01981-5 Corn (NPC 000012: Agency Response Letter) on October 7, 2009. FDA completed its evaluation with no further questions on October 15, 2010, (US-FDA, 2010). Genective also submitted a safety and nutritional assessment of food and feed derived from VCO-01981-5 Corn to the FDA on March 5, 2012 (BNF-000137). FDA is presently evaluating this submission. No questions have been raised thus far (personal communication, I. Coats, Bayer, May 22, 2012) pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act.

Environmental Protection Agency

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011a). The latest reregistration decision for glyphosate was issued in 1993 and the reregistration review was started in July 2009 (US-EPA, 2009b); (US-EPA, 2009a). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount

of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011c). Glyphosate currently has established tolerances for residues, including established residue concentrations for glyphosate in field corn for forage, grain, and stover (US-EPA, 2011b). Pesticide tolerance levels for glyphosate have been established for corn and are published in the *Federal Register*, CFR, and the *Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities* (US-EPA, 2011b). The glyphosate tolerance level established for field corn intended for forage is 6.0 ppm and for grain corn is 5.0 ppm (40 CFR §180.364).

The EPA regulates plant-incorporated protectants (PIPs), although the *epsps grg23ace5* gene expressed in this corn is not a PIP, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 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.

As VCO-01981-5 Corn does not express any pesticidal properties, the EPA has no FIFRA review authority over this corn product. However, if VCO-01981-5 Corn provides for a change in use of registered herbicides, the EPA would review proposed label changes relating to these new herbicide uses. But Genective does not indicate any change in glyphosate use with the crop that would differ from that currently registered for other, similar glyphosate resistant crops.

Scope of the Environmental Analysis

Although approving the petition for nonregulated status of VCO-01981-5 Corn would allow for new plantings of VCO-01981-5 Corn anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that current support corn production. Approving the petition for nonregulated status of VCO-01981-5 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, 2010) to determine where corn is produced in the U.S. (USDA-NASS, 2010). 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, 2012b; USDA-NASS, 2012a) .

Public Involvement

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR 41353-41354, Docket no. APHIS-2012-0046) announcing the availability of the Genective petition for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 4,693 comments were received from individuals during the comment period, of which 4,601 were form letters. Comment documents may be viewed at: http://www.regulations.gov/#!searchResults;rpp=50;so=ASC;sb=docId;po=0;s=APHIS-2012-0046. . Most comments received were in form letters from individuals expressing an opinion of general opposition to GE food, the belief that GE crops harm the environment, or the belief that

GE crops are not beneficial to farmers. Many of the comments also objected to APHIS publishing multiple dockets for review on the same day.

Issues related to Genective VCO-01981-5 Corn which were raised in these comments are addressed in our EA; the issues raised included:

- Development of glyphosate resistant weeds.
- The fate of glyphosate in water.
- The effects of glyphosate use on biological organisms.
- Concern that cross-pollination between GE and organic or crops for GE-sensitive markets will affect sales for growers of these crops.
- Concerns that Genective VCO-01981-5 Corn is not approved in all export markets.

APHIS evaluated these issues raised in the comments and provided citations. A discussion of these issues is incorporated in the EA where appropriate.

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 Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for VCO-01981-5 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 VCO-01981-5 Corn.

The list of resource areas considered were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). 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

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of VCO-01981-5 Corn. To respond favorably to a petition for nonregulated status, APHIS must determine that VCO-01981-5 Corn is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2012a), APHIS has concluded that VCO-01981-5 Corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that VCO-01981-5 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 VCO-01981-5 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. VCO-01981-5 Corn and progeny derived from VCO-01981-5 Corn would continue to be regulated articles under the regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of VCO-01981-5 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 VCO-01981-5 Corn.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that VCO-01981-5 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012a). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

<u>Preferred Alternative</u>: Determination that VCO-01981-5 Corn is No Longer a Regulated Article

Under this alternative, VCO-01981-5 Corn and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. VCO-01981-5 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012(USDA-APHIS, 2012a)). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of VCO-01981-5 Corn and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of VCO-01981-5 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. This alternative best meets the 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 under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that VCO-01981-5 Corn is unlikely to pose a plant pest risk, a determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 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 VCO-01981-5 Corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. <u>Prohibit any VCO-01981-5 Corn from Being Released</u>

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of VCO-01981-5 Corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that VCO-01981-5 Corn is unlikely to pose a plant health risk (USDA-APHIS, 2012a).

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, 2012a), and the scientific data evaluated therein, APHIS concluded that VCO-01981-5 Corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of VCO-01981-5 Corn.

2. 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 a petition. Because APHIS has concluded that VCO-01981-5 Corn is unlikely to pose a plant pest risk, (USDA-APHIS, 2012a), there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3. Isolation Distance between VCO-01981-5 Corn and Non-GE Corn Production and Geographical Restrictions

However, because APHIS has concluded that VCO-01981-5 Corn is unlikely to pose a plant pest risk (USDA-APHIS, 2012a), 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.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating VCO-01981-5 Corn from conventional or specialty corn production. APHIS also considered geographically restricting the production of VCO-01981-5 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' plant pest risk assessment for VCO-01981-5 Corn, there are no geographic differences associated with any identifiable plant pest risks for VCO-01981-5 Corn (USDA-APHIS, 2012a). This alternative was rejected and not analyzed in detail because APHIS has concluded that VCO-01981-5 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 a petition 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 VCO-01981-5 Corn or to use isolation distances and other management practices to minimize gene movement between VCO-01981-5 Corn and non-GE corn fields. Information to assist growers in making informed management decisions for VCO-01981-5 Corn is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

4. Requirement of Testing for VCO-01981-5 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 VCO-01981-5 Corn does not pose a plant pest risk (USDA-APHIS, 2012a), 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 VCO-01981-5 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

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, 2012b)
Management Practices		
Acreage and Areas of Corn Production	Yearly fluctuation but no or small net increase of acreage and no new regions of corn planted	Unchanged from No Action Alternative
Agronomic Practices	Cropping practices will remain the same as current practices for commercial corn production	Unchanged from No Action Alternative
Pesticide Use	Herbicide use patterns are related to weed management strategies	Unchanged from No Action Alternative
Corn Seed Production	Fluctuates yearly somewhat; foreign seed production is used to respond to specific needs	Unchanged from No Action Alternative
Organic Corn Production	Yearly production not affected by conventional corn production	Unchanged from No Action Alternative
Environment		
Land Use	Corn acreage generally stable but fluctuates yearly	Unchanged from No Action Alternative
Water Resources	Herbicides in water fluctuate with weather, climate and	Unchanged from No Action Alternative

	usage	
Soil	Glyphosate in soil has a short half-life. Conservation tillage may be increasing slightly	Unchanged from No Action Alternative
Air Quality	Air quality (particulates) affected by tillage and weather	Unchanged from No Action Alternative
Climate Change	Climate changes affected by land use, tillage and greenhouse gases	Unchanged from No Action Alternative
Animals and Plants		
Animals	Vertebrates interact infrequently with corn agriculture; invertebrates not likely to have new impacts from corn production compared to any other agricultural production	Unchanged from No Action Alternative
Plants	Natural vegetation highly reduced near farms; herbicide resistant weeds increasing	Unchanged from No Action Alternative
Gene Movement	No gene flow to wild plants; gene flow to other corn easily controlled. Horizontal gene flow not observed	Unchanged from No Action Alternative
Soil Microorganisms	Microorganisms affected by tillage, agronomic activity and pesticides	Unchanged from No Action Alternative
Biological Diversity	Contemporary agriculture impacts diversity but new impacts not likely to be significant	Unchanged from No Action Alternative
Human and Animal Health		
Risk to Human Health	EPA rates glyphosate impacts from glyphosate resistant corn as having no reasonable certainty of harm	Unchanged from No Action Alternative
Risk to Animal Feed	Corn is a major feed protein for animal nutrition; quality is unchanging and adequate to animal needs	Unchanged from No Action Alternative
Socioeconomic		
Domestic and Economic Environment	Corn seed with various traits has a competitive market in the US, with four major seed suppliers, and over a hundred smaller ones	Unchanged from No Action Alternative

Trade Economic Environment	Corn export levels decreased by 23% from 2010 to 2012 in the US	Unchanged from No Action Alternative
Other Regulatory Approvals	Completed FDA early food safety consultation; final consultation in progress. EPA tolerance exemptions and conditional pesticide registrations granted	Completed FDA early food safety consultation, final consultation in progress. EPA tolerance exemptions and conditional pesticide registrations granted
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 2009, the U.S. produced 40% of the total world supply of corn (USDA-OCE, 2011). Corn is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2011). Approximately 15 to 20% of the U.S. corn production is exported (USDA-OCE, 2011).

Corn is the most widely cultivated feed grain, accounting for more than 95% of total value and production of feed grains (USDA-ERS, 2011b). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011a); (USDA-NASS, 2010). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011b). In the U.S. for the 2012 production year, corn was cultivated on over 96 million acres, a 5% increase in corn acreage from 2011 (USDA-NASS, 2012a). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2012b). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated $5.18 per bushel in 2010 and $6.20 in 2011 (USDA-NASS, 2012a), (USDA-NASS, 2012c). GE herbicide-resistant corn comprised approximately 21% of the total corn acreage in the U.S., insect-resistant varieties comprised 15% of the acreage, and stacked varieties comprising 52% of the total corn acreage (USDA-NASS, 2012a). The costs for GE corn seed are higher than that for conventional seed. Growers pay a premium for GE seed, with

growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010).

Approximately 88% of corn fields were planted with transgenic corn in 2011 (USDA-NASS, 2011). Introduction of herbicide-resistant corn varieties, in particular glyphosate-resistant corn, has not significantly affected corn acreage managed with total herbicide application. A determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 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.

Results of the agronomic and morphologic assessments conducted by Genective indicate that the introduced herbicide resistance trait does not confer any competitive advantage in terms of weediness (USDA-APHIS, 2012a). Genective asserts that VCO-01981-5 Corn will be a replacement product for other varieties of corn currently cultivated, so new acreage is not expected to accommodate the cultivation of VCO-01981-5 Corn (Genective, 2012). The glyphosate resistance trait, already in commercial use for fifteen years, is not expected to extend the range of cultivation for VCO-01981-5 Corn outside of existing cultivation areas (Genective, 2012).

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

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

   In the past 30 years, the public's consumption of corn-based products has more than doubled. Per capita consumption of corn products rose from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners increased from 35.3 pounds annually per capita to 69.2 pounds during that period (USCB, 2011). As of 2012, 88% of the corn cultivated is GE (USDA-NASS, 2012a). Public health concerns associated with the use of GE corn, such as VCO-01981-5 Corn, and GE corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities.

   A determination of nonregulated status of VCO-01981-5 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, a determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 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. A determination of nonregulated status of VCO-01981-5 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. GE and organic corn are planted on about 88% and 0.2% of corn acreage, respectively (USDA-ERS, 2010). As of 2008, the most recent year for which data are available, approximately 168,000 acres of certified organic corn were grown in the U.S. Based on the data provided by Genective for VCO-01981-5 Corn (Genective, 2012), APHIS has concluded that the availability of VCO-01981-5 Corn would not alter the

agronomic practices, locations, and seed production and quality characteristics of conventional and GE corn seed production (USDA-APHIS, 2011) . A determination of nonregulated status of VCO-01981-5 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.*

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. Under 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 VCO-01981-5 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 and 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). Genective has provided the FDA with information on the identity, function, and characterization of the genes for VCO-1981-5 Corn, including expression of the gene products. The FDA has completed its early food safety evaluation, but has not yet completed its food and nutrition Biotechnology Consultation.

A determination of nonregulated status of VCO-01981-5 Corn would have no significant impacts on human or animal health. VCO-01981-5 Corn is compositionally similar to currently available corn on the market with the exception of the *epsps grg23ace5* gene. Based on the FDA's consultation, laboratory data and scientific literature provided by Genective (Genective, 2012), APHIS has concluded that VCO-01981-5 Corn 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 adversely impacted by a determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 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 VCO-01981-5 Corn including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of VCO-01981-5 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 a determination of nonregulated status of VCO-01981-5 Corn are not highly controversial. Although APHIS received public comments opposed to a determination of nonregulated status of VCO-01981-5 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, 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 VCO-01981-5 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. It 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 VCO-01981-5 Corn on wildlife or biodiversity is not different than that of other glyphosate-resistant crops currently used in agriculture, or other GE or non-GE 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 EA, the possible effects on the human environment 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, a determination of nonregulated status of VCO-01981-5 Corn is not expected to directly cause an increase in agricultural acreage devoted to corn production, or those acres devoted to GE corn cultivation. A determination of nonregulated status of VCO-01981-5 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 effect of VCO-01981-5 Corn on wildlife or biodiversity is no different than that from other glyphosate-resistant crops currently used in agriculture, or other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter2

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), VCO-01981-5 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 2010) (USDA-NASS, 2012a). 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 VCO-01981-5 Corn. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE corn products and glyphosate-resistant agricultural crops, 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.*

   A determination of nonregulated status for VCO-01981-5 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 VCO-01981-5 Corn. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that the genetically engineered organism 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 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.*

   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 reaches a determination of nonregulated status of VCO-01981-5 Corn, APHIS would no longer have regulatory authority over this corn. In the event of a determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 Corn when added to past, present, and reasonably forseeable 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.*

   A determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 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 VCO-01981-5 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 VCO-01981-5 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 use and enjoyment of a historic property when 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 results 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 VCO-01981-5 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 a determination of nonregulated status of VCO-01981-5 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 a determination of nonregulated status of VCO-01981-5 Corn, APHIS has determined that a determination of nonregulated status of VCO-01981-5 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 VCO-01981-5 Corn is unlikely to pose a plant pest risk, a determination of nonregulated status of VCO-01981-5 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 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 VCO-01981-5 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 VCO-01981-5 Corn, the continued regulated status of VCO-01981-5 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 VCO-01981-5 Corn will not have any significant environmental effects.

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Michael C. Gregoire Date

Deputy Administrator

Biotechnology Regulatory Services

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