NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

PIONEER HI-BRED INTERNATIONAL, INC.
SEED PRODUCTION TECHNOLOGY (SPT)
PROCESS DP-32138-1 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 08-338-01p) by Pioneer Hi-Bred International, Inc. (Pioneer) of Johnston, IA for their corn "Seed Production Technology" (SPT) maintainer event DP-32138-1. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from the deregulation of DP-32138-1 corn. The EA assesses alternatives to a determination of nonregulated status of DP-32138-1 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

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

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 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 EPA regulates plant-incorporated protectants 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.

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, 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 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 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.

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 DP-32138-1. 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 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.

Pioneer Hi-Bred International, Inc. (Pioneer) of Johnston, IA has submitted a petition to APHIS seeking a determination that their corn "Seed Production Technology" (SPT) maintainer event DP-32138-1 is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Pioneer 32138-1 Seed Production Technology (SPT) Maintainer

According to Pioneer, DP-32138-1 is engineered to produce male sterile female inbred plants for the generation of hybrid corn seed that is non-transgenic (Pioneer 2009). As detailed in the petition, the carefully controlled expression of a seed color marker gene and pollen fertility and sterility genes allows for the generation of red transgenic seed for seed increase of male sterile female inbred lines. The multistep process yields a non-transgenic male-sterile female parent. This non-transgenic material can then be used for hybrid seed production (Pioneer 2009). Typically, detasseling is needed in corn seed production, and confers substantial expense, lower seed yield and lower genetic purity. Use of DP-32138-1 would eliminate detasseling and lead to increased seed yield and higher genetic purity during seed increase operations. As detailed in the petition, the process predictably and reliably results in a commercial product which does not contain the DP-32138-1 transgenes (Pioneer 2009).

Coordinated Framework Review

DP-32138-1 is not designed for human and animal consumption. However, animals may inadvertently gain access to corn fields, to discarded corn seed or by-products and therefore may

also be subject to regulation by FDA. The DsRed2 protein is the only non-corn protein in DP-32138-1. A new protein consultation for the DsRed2 protein color marker was submitted to FDA on October 11, 2006 with the follow up letter of January 29, 2010 received from FDA. The FDA considers Pioneer's consultation on DsRed2 protein in DP-32138-1 to be complete (Appendix A of the EA). A new protein consultation for the ZM-AA1 protein, normally found in germinating corn seeds, was submitted to FDA on June 18, 2009. The FDA considers Pioneer's consultation on ZM-AA1 alpha-amylase protein to be complete (Appendix B of the EA). Because DP-32138-1 does not contain any GE pesticides or the genetic machinery necessary to produce them, or tolerance to herbicides, EPA consultation is not required.

Scope of the Environmental Analysis

The scope of possible impacts is limited in some ways by the relatively small area of potential use. DP-32138-1 lines containing transgenes only have utility in seed production and are not intended to be a commercial product to be used to plant conventional corn acres (Pioneer 2009). The total acreage of DP-32138-1 planted in the U.S. each year under close supervision is expected to be less than 5,000 acres (Pioneer 2009). If the DP-32138-1 is licensed to third parties and adopted across the entire U.S. seed industry, the total acreage is not expected to exceed 20,000 acres each year (Pioneer 2009).

Although a determination of nonregulated status of DP-32138-1 would allow for new plantings of DP-32138-1 to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support corn production. A determination of nonregulated status of DP-32138-1 is not expected to alter the range of corn cultivation as the new GE trait (DP-32138-1) does not change the growth habits compared to conventional varieties (USDA-APHIS 2010). Additionally, because DP-32138-1 is a technique for more efficiently producing seed that will be used to plant conventional corn production acres without introducing new transgenes to these production acres, even widespread use of DP-32138-1 will have no significant effect on increasing or decreasing the use of GE corn or on total corn production acreage.

To determine areas of corn production, APHIS used data from the National Agricultural Statistics Service (NASS) 2007 Census of Agriculture to determine where corn is produced in the United States (USDA-NASS 2010). Corn grain was produced in all US states except for Alaska.

Public Involvement

On January 3, 2011, APHIS published a notice in the Federal Register (76 FR 83-84, Docket no. 2010-0041) announcing the availability of the Pioneer Hi-Bred petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before March 3, 2011. A total of 52 comments were received from various groups and individuals during the comment period, with 8 comments providing support of the EA's preferred alternative; and 43 comments expressing general opposition to the development and use of genetically engineered foods. All comments were carefully analyzed to identify new issues, alternatives, or information. Responses to the comments are attached to this FONSI.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination to deregulate certain genetically engineered organisms, and for this particular EA, the specific deregulation of DP-32138-1. Issues discussed in the EA were developed by considering comments and information received from the public in response to publication of the draft EA, and the petition for deregulation and supporting materials submitted by Pioneer; 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 and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of DP-32138-1.

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):

Management Considerations:

- Acreage and Areas of Corn Production
- Cropping Practices
- Seed Production
- Organic Farming
- Specialty Corn Production

Environmental Considerations:

- Water Use
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Biological Diversity
- Gene Movement

Public Health Considerations:

- Human Health
- Worker Safety

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment
- Social Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of DP-32138-1 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that DP-32138-1 corn is unlikely to pose a plant pest risk. Based on its risk assessment (USDA-APHIS 2010) APHIS has concluded that DP-32138-1 corn is unlikely to pose a plant pest risk. Therefore APHIS must determine that DP-32138-1 corn is no longer

subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives are fully analyzed in the EA: (1) no action and (2) determination of nonregulated status of DP-32138-1 corn. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. DP-32138-1 corn and progeny derived from DP-32138-1 corn would continue to be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of DP-32138-1 corn and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of DP-32138-1 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2010) that DP-32138-1 corn is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination that DP-32138-1 is No Longer a Regulated Article

Under this alternative, DP-32138-1 corn and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. DP-32138-1 corn is unlikely to pose a plant pest risk (USDA-APHIS 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DP-32138-1 corn and progeny derived from this event. 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 DP-32138-1 corn are unlikely to pose a plant pest risk, a determination of nonregulated status of DP-32138-1 corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to DP-32138-1 corn and progeny derived from this event if the developer decides to commercialize DP-32138-1 corn.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for DP-32138-1 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 DP-32138-1 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any DP-32138-1 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 DP-32138-1, including denying any permits associated with the field testing. APHIS determined that this alternative is not

appropriate given that APHIS has concluded that DP-32138-1 is unlikely to pose a plant pest risk (USDA-APHIS 2010).

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"

Based on our Plant Pest Risk Assessment (USDA-APHIS 2010) and the scientific data evaluated therein, APHIS concluded that DP-32138-1 are unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DP-32138-1.

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 DP-32138-1 corn is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation Distance between DP-32138-1 and Non-GE Corn Production

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance of DP-32138-1 corn and non-GE corn production. However, because APHIS has concluded that DP-32138-1 corn is unlikely to pose a plant pest risk (USDA-APHIS 2010), an alternative based on requiring isolation distances would be inconsistent 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 DP-32138-1 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 DP-32138-1 corn, there are no geographic differences associated with any identifiable plant pest risks for DP-32138-1 corn (USDA-APHIS 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that DP-32138-1 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. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE corn production systems from DP-32138-1 corn or to use isolation distances and other management practices to minimize gene movement between corn fields. Information to assist growers in making informed management decisions for DP-32138-1 corn is available from Association of Official Seed Certifying Agencies (AOSCA 2010).

Requirement of Testing For Event 32138 Corn

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because DP-32138-1 corn does not pose a plant pest risk (USDA-APHIS 2010), 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 the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for DP-32138-1 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—plant pest risk assessment (USDA-APHIS 2010)
Management Practices		
Acreage and Areas of Corn Production	Unchanged	Unchanged
Cropping Practices	Unchanged	Unchanged
Pesticide Use	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Seed Corn Production	Unchanged	Minimal - may decrease need for seed corn acreage due to increased yields efficiency
Organic Farming	Unchanged	Unchanged
Impact to Specialty Corn	Unchanged	Unchanged
Environment		
Water use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Biological Diversity	Minimal	Minimal
Gene Movement	Minimal	Minimal
Human and Animal Health		
Public Health: Risk to Human Health	Unchanged	Unchanged
Public Health: Risk to Worker Safety	Minimal – detasseling carries some risk to workers	Minimal – fewer safety risks with less detasseling
Public Health: Risk to Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Minimal – seed producers save 4% of retail sales price; growers – possible small seed cost decrease Unchanged – immeasurably small impact on cost of commodity corn
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Minimal – fewer part time detasselers hired for summer work
Other Regulatory Approvals		
U. S.	Completed new protein consultations with FDA	Completed new protein consultations with FDA
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. As described in Chapter 4 of the EA, possible impacts from a determination of nonregulated status of DP-32138-1 is limited in some ways by the relatively small area of potential use. DP-32138-1 lines containing transgenes only have utility in seed production and are not intended to be a commercial product to be used to plant conventional corn acres (Pioneer 2009). The total acreage of DP-32138-1 planted in the U.S. each year under close supervision is expected to be less than 5,000 acres (Pioneer 2009). If the DP-32138-1 is licensed to third parties and adopted across the entire U.S. seed industry, the total acreage is not expected to exceed 20,000 acres each year (Pioneer 2009).

Although a determination of nonregulated status of DP-32138-1 would allow for new plantings of DP-32138-1 to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support corn production. A determination of nonregulated status of DP-32138-1 is not expected to alter the range of corn cultivation as the new GE trait (DP-32138-1) does not change the growth habits compared to conventional varieties (USDA-APHIS 2010). Additionally, because DP-32138-1 is a technique for more efficiently producing seed that will be used to plant conventional corn production acres without introducing new transgenes to these production acres, even widespread use of DP-32138-1 will have no significant effect on increasing or decreasing the use of GE corn or on total corn production acreage.

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

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

A determination of nonregulated status of DP-32138-1 corn will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty corn varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of DP-32138-1 corn will not directly cause an increase in agricultural acreage devoted to corn production (commercial and seed production), or those corn acres devoted to GE corn cultivation. Moreover, a determination of nonregulated status will not change cultivation areas for corn production in the U.S or corn production practices (i.e. crop rotation, tillage practices, and pesticide use). Additionally, there are no foreseeable changes to the availability of GE, conventional, organic or specialty corn varieties on the market. A determination of nonregulated status of DP-32138-1 corn would not change the use of presently available systems for seed corn production. DP-32138-1 will be produced in a manner similar to other seed corn inbreds and resulting

hybrids. As discussed in Chapter 4 of the EA, these inbreds and resulting hybrids are typically produced under identity preservation systems that include contracts with growers, traceability, product tracking, and process verification since Pioneer and other seed corn companies take precautions to insure that inbred parent lines are not misappropriated by third parties. These procedures greatly minimize any chances of commingling of the DP-32138-1 seed with other seed and, ultimately, commercial grain. The Pioneer Hi-Bred SPT process is designed to produce non-transgenic male-sterile female inbred parent plants for hybrid corn seed production without the need for tassel removal or bagging. The resulting hybrid seeds that would be used for commercial corn production would not contain the SPT transgene. As discussed in Chapter 4 of the EA, using DP-32138-1 in the increase of corn varieties could reduce the yield losses associated with detasseling and the consequence would be fewer acres of increase needed per variety. Additionally, there could be a decrease in the number of people required for detasseling resulting in reduced expenses and fewer safety hazards during the seed corn increase. The assumed maximum use of 20,000 acres industry wide for DP-32138-1 is only about 0.02% of the 80-90 million acres of annual corn production. The agronomic practices used for these seed production acres would be almost identical to the agronomic practices and locations currently being used, so no overall effects are anticipated.

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

A determination of nonregulated status of DP-32138-1 corn would have no significant impacts on human or animal health. The DsRed2 protein is the only non-corn protein in DP-32138-1. A new protein consultation for the DsRed2 protein color marker was submitted to FDA on October 11, 2006 with the follow up letter of January 29, 2010 received from FDA. The FDA considers Pioneer's consultation on DsRed2 protein in DP-32138-1 to be complete (Appendix A of the EA). A new protein consultation for the ZM-AA1 protein, normally found in germinating corn seeds, was submitted to FDA on June 18, 2009. The FDA considers Pioneer's consultation on ZM-AA1 alpha-amylase protein to be complete (Appendix B of the EA). Based on the assessment of laboratory data provided by Pioneer in the submitted petition and an analysis of the scientific literature (USDA-APHIS 2010), along with the completion of the consultation process with FDA, APHIS has concluded that a determination of nonregulated status of DP-32138-1 would have no significant impact 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 a determination of nonregulated status of DP-32138-1 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, do not cause any alterations of 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 DP-32138-1 corn. The product will be deployed on a limited number of acres of agricultural farm land used for corn seed production which may be focused in a small number of sites where Pioneer and future

potential licensees may produce seed corn. Potential for such production may exist where corn is grown in all US states, except Alaska. Progeny of this variety that express the identified traits of the DP-32138-1 corn will be retained by Pioneer or licensed users, while the resulting male sterile female inbred corn and its progeny will be predictably and reliably without transgenes. This action would not convert land use 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 DP-32138-1 corn including the use of EPA registered herbicides. 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 DP-32138-1 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 DP-32138-1 corn are not highly controversial. Although there is some opposition to a determination of nonregulated status of DP-32138-1, 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 of DP-32138-1 corn does not change the amount of corn production in the U.S. A determination of nonregulated status of DP-32138-1 corn will not change the agronomic and cultivation practices for producing GE or non-GE corn, including cropping practices and pesticide uses. The effect of DP-32138-1 corn on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. The Pioneer Hi-Bred SPT process is designed to produce non-transgenic male-sterile female inbred parent plants for hybrid corn seed production without the need for tassel removal or bagging. The assumed maximum use of 20,000 acres industry wide for DP-32138-1 is only about 0.02% of the 80-90 million acres of annual corn production. The resulting hybrid seeds that would be used for commercial corn production would not contain the SPT transgene. The agronomic practices used for these seed production acres would be almost identical to the agronomic practices and locations currently being used, so no overall effects are anticipated. A determination of nonregulated status of DP-32138-1 corn would not change the use of presently available systems for seed corn production. DP-32138-1 will be produced in a manner similar to other seed corn inbreds and resulting hybrids. As discussed in Chapter 4 of the EA, these inbreds and resulting hybrids are typically produced under identity preservation systems that include contracts with growers, traceability, product tracking, and process verification since Pioneer and other seed corn companies take precautions to insure that inbred parent lines are not misappropriated by third parties. These procedures greatly minimize any chances of commingling of the DP-32138-1 seed with other seed and, ultimately, commercial grain. During the public comment period, APHIS received comments opposing a determination of nonregulated status of DP-32138-1 corn. A majority of these individuals did not mention their specific disagreement with APHIS' analyses of DP-32138-1 corn detailed in the EA or the PPRA (USDA-APHIS 2011); rather, they expressed their general

opposition to genetically modified organisms (GMOs) or GE crops. Generally, people who expressed their opposition to deregulation did not provide any supporting evidence for their claims. APHIS has addressed these concerns 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 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. A determination of nonregulated status of DP-32138-1 corn does not change the amount of corn production in the U.S. DP-32138-1 corn will not change the agronomic and cultivation practices for producing GE or non-GE corn, including cropping practices, and pesticide uses. The effect of DP-32138-1 corn on wildlife or biodiversity is no different than that of other GE or non-GE corn produced in conventional agriculture in the U.S. As described in Chapter 4 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, DP-32138-1 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, most of the corn acreage (approximately 85%) in the U.S. is planted to GE varieties (USDA-NASS 2009), and 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 DP-32138-1. 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 a 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 of DP-32138-1 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 upon an independent determination 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 DP-32138-1. 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 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 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 included for each environmental issue analyzed in Chapter 4 of the EA. In the event of a determination of nonregulated status of DP-32138-1, DP-32138-1may be stacked (combined) with conventional varieties or other nonregulated GE corn varieties by traditional breeding techniques, resulting in hybrids that, for example, may also be resistant to herbicides or insects. The resulting hybrids would not contain the SPT transgene. There is no guarantee that DP-32138-1 will be stacked with any particular deregulated GE variety, as company plans and market demands play a significant role in those business decisions. Moreover, DP-32138-1 could even be combined with non-GE corn varieties. Thus, predicting all potential combinations of stacked varieties that could be created using both deregulated GE corn varieties and also non-GE corn varieties is hypothetical and purely speculative.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.*

A determination of nonregulated status of DP-32138-1 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 DP-32138-1 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 historical resources. This action is limited to a determination of non-regulated status of DP-32138-1 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 DP-32138-1 corn is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or 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 DP-32138-1 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 an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

As described in Chapter 4 of the EA, APHIS has analyzed the potential for effects from cultivation of DP-32138-1 and its progeny 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 DP-32138-1 corn, APHIS has reached a conclusion that the release of DP-32138-1 corn, following a determination of nonregulated status, would have no effect on federally listed threatened or endangered species or species proposed for listing, nor would it affect 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 DP-32138-1 corn are unlikely to pose a plant pest risk, a determination of nonregulated status of DP-32138-1 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. A new protein consultation for the DsRed2 protein color marker was submitted to FDA on October 11, 2006 with the follow up letter of January 29, 2010 received from FDA. The DsRed2 protein is the only non-corn protein in DP-32138-1. The FDA considers Pioneer's consultation on DsRed2 protein in DP-32138-1 to be complete (Appendix A of

the EA). A new protein consultation for the ZM-AA1 protein, normally found in germinating corn seeds, was submitted to FDA on June 18, 2009. The FDA considers Pioneer's consultation on ZM-AA1 alpha-amylase protein to be complete (Appendix B of the EA). Because DP-32138-1 does not contain any GE pesticides or the genetic machinery necessary to produce them, or tolerance to herbicides, EPA evaluation of the proteins is not required. 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 DP-32138-1 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 DP-32138-1 corn, the continued regulated status of DP-32138-1 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 DP-32138-1 corn will not have any significant environmental effects.

Michael C. Gregoire — 5/24/2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

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Attachment
Finding of No Significant Impact
Response to Comments
Petition 08-338-01p

Pioneer Hi-Bred International, Inc., has submitted a petition (APHIS No. 08-338-01p) to Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) seeking a determination that their genetically engineered (GE) corn "Seed Production Technology" (SPT) maintainer event (DP-32138-1) is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR part 340.

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 DP-32138-1 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 unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340. Based on its PPRA, APHIS has concluded that DP-32138-1 corn is unlikely to pose a plant pest risk (USDA-APHIS 2011). Therefore APHIS must determine that DP-32138-1 corn is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

APHIS has prepared an environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) regulations implementing NEPA (40 CFR Parts 1500-1508, 7 CFR 1b, and 7 CFR Part 372), and the USDA and APHIS NEPA implementing regulations and procedures. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[2] that may result from the deregulation of DP-32138-1 corn. As part of this process, APHIS routinely seeks public comment on draft EAs prepared in response to petitions to deregulate GE organisms. APHIS does this through a notice published in the Federal Register. Comments received by APHIS are reviewed and used to inform APHIS's determination decision and to assist APHIS in determining whether an Environmental Impact Statement is required prior to the determination decision. This document provides APHIS' response to these comments.

On January 3, 2011, APHIS published a notice in the Federal Register (76 FR 83-84, Docket no. 2010-0041) announcing the availability of the Pioneer Hi-Bred petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. This comment period ended on March 3, 2011. APHIS received a total of 52 comments from various groups and individuals. Eight comments supported deregulation, while 43 comments generally opposed the development and use of genetically engineered foods. One comment from an individual referred to their

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

personal blog on science and the natural environment and did not indicate any specific support or opposition to DP-32138-1 corn or genetically engineered foods.

Those supporting a determination of nonregulated status of DP-32138-1 corn included one academician, one individual from the agribusiness industry (the petitioner), one state government agency, three trade groups (grain and seed), and two growers associations (corn and alfalfa seed). These individuals cited several salient points regarding the SPT process and its benefits including: (1) the SPT process does not introduce a new transgenic gene or trait through commercial hybrid seed or grain production; (2) the SPT process is used to increase productivity and efficiency in seed corn production; and (3) the transgenic material is used two generations before hybrid seed production occurs or three times before commercial grain production.

Those opposing a determination of nonregulated status of DP-32138-1 corn included one Non Governmental Organization-(NGO) (supplied three comments, each with an attachment) and 40 individual consumers. A majority of these individuals did not mention their specific disagreement with APHIS' analyses of DP-32138-1 corn detailed in the EA or the PPRA (USDA-APHIS 2011); rather, they expressed their general opposition to genetically modified organisms (GMOs) or GE crops. Several individuals expressed their belief that GE corn pollen endangers all honeybees, other insects, and/or the whole ecosystem. Also, numerous individuals expressed their concern about genetic contamination of conventional and organic corn or wild relatives, as well as other crops, from GE corn. Others cite concerns for food and feed safety of GE corn. Several people maintained that scientific evidence supports the conclusion that GMOs are the cause of many deleterious health effects. Generally, people who expressed their opposition to deregulation did not provide any supporting evidence for their claims.

General Comments

1. Comment: Several commenters expressed a general disapproval of genetically engineered (GE) organisms and their deregulation.

Response: APHIS recognizes that some citizens are opposed to the concept of genetic engineering in general. As stated in the EA (Purpose and Need: Regulatory Authority), APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. "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 Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

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 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 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 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.

2. Comment: Several commenters asserted that genetically engineered (GE) commodities have been proven to have adverse affects on human health, while others stated that there is insufficient evidence that GE products are "not harmful and do not negatively impact human health" or stated that scientists have "no clue how GM crops affect the human body." One comment stated that "independent tests they have been shown to be incredibly toxic to human beings, as well as farm animals and other animals that ingest these substances." Two URLs were provided to support these statements, (Mothers for Natural Law, 2001; Fischer, 2010). Another comment cites a study that "proves three Monsanto GM corn varieties pose health hazards," which APHIS presumes cites the paper by deVendomois et al. (2009).

Response: DP-32138-1 is not intended for food or feed (EA, Purpose and Need: Other

Regulatory Approvals), and will not be a commercial product, nor will the 32138 SPT insertion be present in commercial seed sold to growers (EA, Purpose and Need: Purpose of the Product). DP-32138-1 does not express any proteins not approved for consumption by FDA, nor does it express any insecticidal or herbicide resistant traits (EA, Purpose and Need: Other Regulatory Approvals).

Although hybrid seed produced using DP-32138-1 technology will not contain any transgenic material, Pioneer submitted a new protein consultation for the DsRed2 color marker protein and the ZM-AA1 alpha-amylase protein to FDA. As part of this consultation, information on the identity, function, and characterization of the genes and gene products, toxicity and allergenicity information of the gene products, as well as the expression levels of the gene products, were submitted to FDA (Appendix A and B of the EA). Based on the information Pioneer presented to FDA, FDA had no further questions and considers the consultations on the ZM-AA1 and DsRed2 proteins to be complete. Because DP-32138-1 has successfully completed the new protein consultation process for the DsRed2 color marker protein with FDA, there are no human or animal health concerns if DP-32138-1 entered the food or feed supply. APHIS included information regarding Pioneer's completed new protein consultation with FDA in Appendix A (NPC00004) and Appendix B (NPC00011) of the EA.

Fischer (2010) presents allegations of possible hazards of genetically engineered (GE) foods, without references to scientific literature, or cites unpublished experiments, which cannot be subjected to scientific scrutiny over methods used or the results obtained. Mothers for Natural Law (2001) cites sources including popular magazines, books or allegations, none of which are given peer review before publishing. APHIS finds it difficult to respond to the commenters when there is no evidence of science based experiments or observations derived using sound science.

A second commenter cited a statistical analysis to assess effects of feeding trials conducted by Monsanto using GE corn derived from either herbicide resistant or lepidopteran resistant varieties. In this study, de Vendomois et al. (2009) concluded that several sex- and dose-dependent effects observed in rats were linked with GE corn consumption (NK603, MON810, and MON863); these effects included differences in organ weights or blood chemistry (Vendomois et al., 2009). Several independent scientific groups and regulatory agencies have reviewed and refuted this study, including the French High Council on Biotechnology (HCB), Food Standards Australia New Zealand (FSANZ), and the European Food Safety Authority (EFSA) (FSANZ, 2009; EFSA, 2010; HCB, 2010; Monsanto, 2010). The three scientific groups or regulatory agencies agreed that the conclusions presented by Vendomois et al. (2009) rely primarily on statistical analysis and fail to interpret these differences within a biological or toxicological context. Normal background variability between animals fed with different diets was ignored. Additionally, HCB, FSANZ, and EFSA concluded, based on the data published in Vendomois et al. (2009), that no new evidence was provided about the general safety of these GE plants, and that there was no reason to reconsider the safety assessments previously completed for NK603, MON810, and MON863 corn (EFSA, 2010; FSANZ, 2009; HCB, 2010; Monsanto, 2010).

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Mothers for Natural Law (2001). What are the dangers? http://www.safe-food.org/-issue/dangers.html

3. Comment: Several commenters expressed their support for requiring the labeling of genetically engineered (GE) foods.

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).

DP-32138-1 corn is intended to reduce yield loss in hybrid corn seed production and is not intended to enter commercial corn grain production systems (i.e., the food supply) in the U.S. (Pioneer 2009). Commercial seed produced using DP-32138-1 (SPT technology) does not contain any transgenes, although the seed used to begin the process contains the *Ms45*, *zm*-aa1, and *DsRed2* in expression cassettes. The petition (Pioneer 2009) and the EA (Purpose and Need: Other Regulatory Approvals, and Environmental Consequences: Seed Production) outline how these genes are eliminated from subsequent hybrid seed and checked to be free of any transgenes. Data submitted by the applicant has shown no difference in compositional and nutritional quality of DP-32138-1 compared to conventional corn (with the exception of the MS45, ZM-AA1, and DsRed2 proteins). Although the seed produced by the DP-32138-1 technology will not contain any transgenes, Pioneer Hi-Bred submitted a new protein consultation for the DsRed2 protein color marker to FDA on October 11, 2006, with a follow up letter dated January 9, 2010, received from FDA (see Appendix A of the EA). The DsRed2 protein is the only non-corn protein in DP-32138-1. A new protein consultation for the ZM-AA1 protein, normally found in germinating corn seeds, was submitted to FDA on June 18, 2009. The FDA considers Pioneer's consultation on ZM-AA1 alpha-amylase protein to be complete (see Appendix B of the EA).

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4. Comment: Several commenters expressed concern about cross-pollination of other corn varieties by DP-32138-1 and the resulting impact on organic and conventional corn products. Specifically, these comments collectively voiced general disapproval at the possible adventitious or unintended presence of DP-32138-1 corn material in organic and non-GE corn products.

Response: APHIS considered these comments as a whole because they are based upon concern for pollen-mediated gene flow from DP-32138-1 and its potential impact on organic and conventional corn agriculture.

As discussed in the EA (Environmental Consequences: Preferred Alternative, Animal Feed), DP-32138-1 is an integral component of the Pioneer Hi-Bred SPT process for the production of F1 commercial corn hybrid seed and is not to be used directly for commercial corn grain production, nor human or animal consumption. DP-32138-1 exhibits a non-viable transgenic pollen phenotype, meaning that any pollen that contains the transgenes is rendered non-viable, thus providing for a reliable bioconfinement system to prevent DP-32138-1 corn from pollinating any other variety. This corn is intended to eliminate the practice of tassel removal during female inbred seed scale up. The presence of SPT transgenes in the field (expressed by DP-32138) is a step two generations removed from commercial corn grain production. Seed from DP-32138-1 using the SPT process will be used for constructing nontransgenic male-sterile female inbred parents during F1 corn hybrid seed production. Male-sterile female inbred parent corn plants produced by DP-32138-1 and targeted for use in F1 corn hybrid seed production are highly unlikely to contain any transgenic elements due to mechanisms present during male-sterile inbred female parent scale up, including: 1) pollen from the DP-32138-1 parent that contains the SPT transgenic cassettes is aborted and sterile; 2) in the DP-32138 male pollen donor, the hemizygous DP-32138-1 event and the non-transgenic *ms45* mutation independently segregates in a Mendelian manner, so that seed produced in this cross results in female plants that are also male sterile and in which pollen development is prevented; and 3) two rounds of physical sorting follows crosses with a nonregulated male sterile female inbred parent line (Step II: see Figure 1 in the EA). Use of DP-32138-1 in the Pioneer Hi-Bred SPT system produces non-transgenic male-sterile female inbred parent plants with an efficiency of 99.9999995 percent, effectively assuring non-transgenic female inbred plants for F1 hybrid seed production and commercial corn grain that does not contain the DP-32138-1 event. The end result of the Pioneer Hi-Bred SPT process is that F1 corn hybrid seed planted for commercial grain production will not contain the DP-32138-1 event.

APHIS disagrees with the concern of the commenter that genes from DP-32138-1 will negatively impact organic corn grain production. As presented in the EA (Environmental Consequences: Agricultural Production of Corn, Organic Farming), it is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by APHIS' determination of nonregulated status of DP-32138-1 corn. In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced (Rogan, 2010). Organic production plans prepared pursuant to the NOP include practical methods to protect organically-produced crops from accidental contamination with genetically engineered materials. In accordance with NOP regulations, organic operators are required to manage the potential exposure of organic commodities with other substances not approved for use in organic production systems, whether from the non-organic portion of a split operation or from neighboring farms. The use of products of genetic engineering is also specifically prohibited in organic production and handling. The organic system plan, developed individually by a grower, must outline the steps taken to avoid contact or mixing, and organic producers are ultimately obligated to manage their operations to avoid unintentional contact with excluded methods and non-organic material. This was explicitly affirmed in response to public comment on the establishment of the National Organic Program (NOP) (Federal Register, Volume 65, p. 80556 - http://www.gpo.gov/fdsys/pkg/FR-2000-12-21/pdf/00-32257.pdf) and reaffirmed recently (USDA-NOP 2011). Implementation of procedures to maintain seed and commodity integrity within the context of an individual organic system plan required for NOP certification has proven effective in preventing the presence of excluded materials in certified organic products. Consistent increase in the numbers of certified organic corn acres between 2002 and 2007 (USDA-ERS, 2009) demonstrates the confidence of organic consumers in the present market, despite a concurrent increase in GE crop adoption (USDA-ERS, 2010) and the theoretically increased potential of admixture of GE corn traits into organic corn production .

As noted above, pollen carrying transgenes from DP-32138-1 plants is sterile and cannot fertilize organic or other corn. The non-transgenic F1 hybrids produced using DP-32138-1 technology will not contain the SPT transgenic cassettes and no gene flow from DP-32138-1 can occur. Because of the design of the SPT process, transgenes are confined to the female parent, and are not in viable pollen. In addition, any transgenic seeds produced on the female plants are red in color, allowing for their rapid and effective identification. Gene flow from transgenic DP-32138-1 maintainer plants used for male-sterile female inbred seed scale up is unlikely to be mixed with commercial organic grain production because organic seed producers and GE seed producers are separate entities with no common pathways or common equipment use. No mechanical mixing and, thus, no mechanically originated gene flow can occur between DP-32138-1 and commercial organic corn grain.

A single comment alluded to the possible biological breakdown of the mechanism for the male sterility trait and the transmission of transgenes through potentially viable pollen, negatively affecting subsequent generations of corn. Another comment recognized this potential and

suggested that DP-32138-1 should not be deregulated until it can be proven that the probability of DP-32138-1 genetic transmission is zero. While zero tolerance for any undesired component is difficult to attain for any agricultural commodity produced through GE or conventional methods, several redundant mechanisms in the DP-32138-1 sterility system that include both genetic and mechanical isolation procedures significantly mitigate this risk (Pioneer 2009). Firstly, commercial seed produced using DP-32138-1 technology can reliably and consistently be produced without any transgenic elements. This is due to both the non-viable transgenic pollen phenotype and the fact that transgenic seeds can be readily identified with the red color marker. Secondly, DP-32138-1 is unlikely to be planted on more than 5,000 acres in the U.S. (or not exceeding 20,000 acres if Pioneer Hi-Bred chooses to license out this technology to third parties). The anticipated acreage to be planted to DP-32138-1 would represent no more than approximately 0.006 percent of total planted U.S. corn acreage in 2009/10 (or 0.02 percent if Pioneer Hi-bred licenses out this technology), a small percentage of total corn cultivation area. Thirdly, Pioneer has strong financial reasons to retain direct control of this proprietary technology, and only allow selected seed producers to access the DP-32138-1 seed. Effective in-house quality control systems can be expected to continue to be effective in maintaining the genetic purity of other corn varieties grown concurrently with the DP-32138-1 maintainer line.

A single comment referred to an article describing the loss of Australian organic certification on a farm in Australia (comment number 2010-0041-0016). This article is not an accurate reflection of the situation in U.S. corn production, as it pertains to the inadvertent dispersal and growth of GE canola seeds on an organic oat farm in Australia and in the very different context of the Australian process for organic certification. As presented in the EA (Affected Environment: Agricultural Production of Corn, Organic Farming), in the U.S., standards for organic certification are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Organic Foods Protection Act and the National Organic Program regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of an excluded product does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation. This process-based approach does not exclude the end-market purchasers/distributers from maintaining their own testing standards for organic purity. In spite of specific end-market requirements, the vast majority of U.S. organic farmers (92 percent) have not incurred any direct additional costs or losses due to the proximity of GE crops grown near certified organic crops (Brookes and Barfoot, 2004).

APHIS concludes that any inadvertent pollination of commercial organic corn by use of the SPT process would be unlikely due to (1) the absence of the transgene in pollen of DP-32138 and absence of any transgenes in commercial F1 hybrid from DP-32138-1 plants, (2) the business and spatial separation between DP-32138-1 and commercial corn production, and (3) the adoption of successful reproductive isolation and other best management practices used to maintain genetic purity in corn seed and grain production.

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5. Comment: A single commenter stated that [this GE corn] "is a prime candidate for the death of the honeybee population as it currently stands".

Response: Honey bees (*Apis mellifera*), the only bee species commercially maintained in the U.S., function as vital pollinators of a variety of agricultural crops. First observed on the eastern U.S. coast in the second half of 2006, honey bee colony collapse disorder (CCD) accounted for a decline of approximately 36 percent of the honey bee population (Johnson, 2010). In contrast to other previous bee colony losses, CCD can be distinguished by several unusual attributes, including: 1) failure of adult worker bees to return to the hive, despite the presence of a brood and queen remaining in the hive; 2) relatively wide-spread and rapid colony loss throughout the entire year (i.e., not seasonal); and 3) that the mechanisms of the loss still remain unknown. Possible causes of CCD include pathogens, parasites, environmental stresses, and bee

management stresses (e.g., poor nutrition); however, recent evidence suggests that CCD may represent a syndrome caused by a suite of factors interacting synergistically to produce rapid and wide-spread colony collapse (USDA, 2009). Potential biotic and abiotic stresses correlated with CCD include, but may not be limited to: the single-celled parasite *Nosema ceranae*; Israeli acute paralysis virus (IAPV) and its potential vector, the *Varroa* mite; or neonicotinoids, synthetic insecticides that bind the insect nicotinic acetylcholine receptor (Matsuo et al., 1998). It is prudent to observe, however, that correlation does not equal causation; consequently, while several factors have been observed to be strongly correlated with CCD, it has not been experimentally demonstrated and thus it is not currently known with certainty that any one factor produces CCD.

Corn, including DP-32138-1, does not produce nectar. Thus, foraging honey bees and brood would only come into contact with DP-32138-1 pollen. DP-32138-1 pollen contains three expression cassettes, consisting of the pollen fertility restorer *Ms45*; an α-amylase, *zm-aa1*; and *DsRed2*, a red color marker. Both *Ms45* and *zm-aa1* represent modified versions of genes already present in corn. These modifications do not impact the catalytic capacity of these produced proteins, but rather the timing of gene expression or the specific spatial translocation of the protein. Bioinformatic queries demonstrated that both *Ms45* and *zm-aa1* do not match any known toxins, thus suggesting that the protein products of these genes are unlikely to elicit a toxic response in animals. Additionally, α-amylases like *zm-aa1* have a long history in food preparation and consumption without any detrimental effect (Pariza and Johnson, 2001). In regard to the DsRed2 protein, there was no evidence of toxicity in mice when fed 1860 mg of DsRed2 protein (equivalent to a 10 kg child or 60 kg adult consuming 45 kg and 270 kg of DsRed2, respectively), nor was there any evidence of protein similarity to known toxins (Pioneer 2009). DP-32138-1 does not produce any registered pesticidal compound (i.e., cry proteins) that can negatively affect arthropods. As a consequence of similarities in agronomic performance between DP-32138-1 and conventional corn, as well as similar responses to agricultural inputs, and a lack of differing pest susceptibility, pesticide application strategies are also likely to be similar. Taken in total, the demonstrated safety of DP-32138-1 pollen combined with unaltered agronomic practices between DP-32138-1 and conventional corn suggests that any potential impact of DP-32138-1 on the honey bee population will be unlikely.

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6. Comment: Several commenters expressed concern regarding the potentially negative environmental impact of DP-32138-1 on biodiversity, soil quality, and water quality due to its invasive potential and associated cropping practices. The majority of these comments, however, did not cite a specific source to support claims of potential negative environmental impacts.

Response: The impacts of DP-32138-1 corn on biodiversity, soil quality and water quality are discussed in the EA (Environmental Consequences: Animal and Plant Communities, Biological Diversity, and Physical Environment: Soil, and Physical Environment, Water Resources), respectively.

Biodiversity
Several comments alluded to the uncertain effect of DP-32138-1 on biodiversity, which may occur directly through an increased invasive potential or indirectly through altered susceptibility to disease and pests. In regard to the invasive potential, a PPRA prepared by APHIS concluded that DP-32138-1 is unlikely to pose a plant pest risk and that DP-32138-1 is unlikely to be any more invasive than conventional corn (USDA-APHIS, 2010). Commenters are referred to the APHIS PPRA for further discussion (http://www.aphis.usda.gov/brs/aphisdocs/ 08_33801p_dpra.pdf).

Pioneer Hi-Bred collected agronomic data with respect to germination/emergence, vegetative growth, reproductive parameters, yield, and ecological interactions on DP-32138-1 from 43 U.S. field trials conducted since 2005. The observations on naturally occurring insect and disease stressors showed no unexpected differences from inbred control maize (Pioneer 2009). No differences in phenotypic characteristics that might contribute to enhanced weediness were observed between DP-32138-1 and control lines for the wide range of phenotypic endpoints assessed in these field trials or in greenhouse or laboratory experiments (Pioneer 2009, Table 11). These indicators of potential invasiveness include germination, seedling vigor, plant height, ear height, stalk lodging, root lodging, final population, plant health, time to silking, time to pollen, pollen viability, and seed germination. APHIS assessed basic corn biology and the unique characteristics of DP-32138-1 under field conditions and concluded in its PPRA, that DP-32138-1 does not exhibit characteristics that would cause it to be weedier than the parental corn line (USDA-APHIS, 2010).

Additionally, through analysis of disease and pest data collected across six different locations (in 2007, representing likely DP-32138-1 agro-environments), APHIS concluded in its PPRA that no meaningful differences in diseases and pests exist between DP-32138-1 and conventional corn (USDA-APHIS, 2010). Diseases monitored included *Aspergillus* sp., *Aureobasidium zeae, Cercospora zeae-maydis, Colletotrichum graminicola, Exserohilum turcicum, Fusarium* spp.,

Gibberella zeae, Pantoea stewartii, Phytopthora spp., *Puccinia polysora, Puccinia sorghi* and *Ustilago zeae* (petition Appendix 13, table 2). Corn insects monitored included Aphididae, *Adoretus sinicus, Chaetocnema pulicaria, Cicadellidae,* Coleoptera, *Diabrotica* spp., *Glischrochilus quadrisignatus, Helicoverpa zea,* Lepidoptera, *Ostrinia nubilalis, Popillia japonica, Richia albicosta, Spodoptera frugiperda, Tetranychidae, Thripidae* (see Appendix 13, Table 1, Pioneer 2009). This lack of increased or altered disease and pest susceptibility resembles patterns previously observed in other currently nonregulated GE corn varieties (http://www.aphis.usda.gov/biotechnology/not_reg.html). Additionally, no impacts were observed on non-target, beneficial insects such as *Chrysoperla carnea* and *Syrphidae*.

Soil quality

Several commenters voiced concern for the potentially negative environmental impact of DP-32138-1 on soil quality. Direct effects could potentially include changes to tillage and crop rotation strategies and indirect effects may include runoff of pesticide residues and fertilizer into the environment.

Conventional tillage and the removal of plant residue from the soil are recognized as agronomic practices that generally facilitate the loss of soil organic carbon. Soil erosion and soil carbon cycling may be affected by these processes. However, after analysis of data from Pioneer Hi-Bred, APHIS concluded that DP-32138-1 does not differ from conventional corn in growth and development, except for the male sterility phenotype, and that it is unlikely that planting DP-32138-1 will change tillage practices used in the cultivation of seed corn (USDA-APHIS. 2010). Crop rotation also affects soil quality (Causarino et al., 2006) and these practices are also unlikely to change for DP-32138-1 (EA. Environmental Consequences: Agricultural Production of Corn, Preferred Alternative, Crop Rotation, Tillage, Production, and Pesticide Use). Crop rotation also serves a secondary function of maintaining genetic purity potentially compromised by volunteer corn which can be more easily identified and eliminated within the non-corn crop that follows corn. Lack of significant environmental impact on soil quality can also be expected because of the limited cultivation acreage of DP-32139-1. Intended to alleviate reductions in seed yield resulting from mechanical tassel removal during hybrid seed production, DP-32138-1 is not intended for commercial grain production. Accordingly, DP-32138-1 cultivation acreage is not projected to exceed 20,000 acres (Pioneer 2009), a value representing 0.02 percent of the 88.2 million acres planted in 2010 (USDA-ERS, 2011). Because of the minimal land area used for hybrid seed production, along with the continued practice of current tillage and rotation strategies, it is unlikely that DP-32138-1 will negatively impact soil quality in the agro-environment.

Water quality

Several comments also recorded concerns for potential impacts of DP-32138-1 on water quality. Both soil erosion and runoff containing fertilizers and pesticides into surface waters may potentially be increased by the agricultural management practices associated with new varieties. As discussed above, DP-32138-1 is unlikely to increase soil erosion relative to conventional corn varieties because similar cultivation practices between DP-32138-1 and the parental corn variety are likely. Conservation tillage, common in conventional corn production, will likely be practiced at a similar frequency in DP-32138-1 cultivation. DP-

32138-1 and its parental corn variety will likely require and respond to similar application rates of fertilizer and pesticide. Agricultural residue runoff is mediated by both soil erosion and rate of fertilizer or frequency of pesticide application, and is unlikely to be significantly different between conventional corn and DP-32138-1, as both require similar tillage and management strategies.

Thus, DP-32138-1 does not exhibit increased susceptibility to disease and pest, nor does it require different tillage, rotation, pesticide, or fertilizer strategies compared to conventional corn. Additionally, the projected maximum acreage for DP-32138-1 represents a small fraction of total corn cultivation area. Taken collectively, DP-32138-1 is similar to conventional corn in phenotype, with the exception of the male sterility trait, and is unlikely to impact the environment any more than conventional corn.

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7. Comment: Several commenters expressed concern with the introduction, inadvertent or intentional, of DP-32138-1 corn into animal feed channels via signed contractual agreements.

Response: Pioneer Hi-Bred submitted a comment to clarify some of the concerns voiced in public comments. Pioneer Hi-Bred maintains that DP-32138-1 will not enter animal feed channels, as it will not allow contractual growers the option to feed DP-32138-1 discard material to their own livestock animals (Hubbard, 2011).

As presented in the EA (Environmental Consequences: Threatened and Endangered Species), APHIS compared the composition and nutritional quality of DP-32138-1 corn with a non-genetically engineered control corn line and the natural variation found in two commercial corn inbred lines and concluded that DP-32138-1 is not biologically different from conventional corn. FDA in a new protein consultation had no questions about its safety for animals (Appendix A and B of the EA). As affirmed by Pioneer Hi-Bred, DP-32138-1 will not be used for animal feed, and if it were accidentally availed of by feeding animals, it would be unlikely for DP-32138-1 to have different effects on such animals than those of conventional corn.

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8. Comment: Several commenters expressed concern about the product interfering with seed saving by growers and the necessity to purchase new hybrid seed every growing season.

Response: DP-32138-1 is not intended to be commercially grown. Commercial corn grain growers will not have access to DP-32138-1 corn seed; only a limited number of Pioneer directed growers on a limited number of acres will be using DP-32128-1 corn. Thus, there will be limited exposure to DP-32138-1 within the environment. Although sterility systems are used with the SPT technology, several sterility systems are also used with conventional corn seed production. As with conventional sterility systems, male sterile plants produced using the SPT technology cannot outcross to neighboring fields because no pollen is produced. In addition, no escape of pollen bearing the SPT transgenic cassettes is possible from the maintainer line, since pollen containing the transgenes is not viable.

Grower use of hybrid corn seed is a well-established mechanism that obtains increased yield compared to inbred corn seed, and allows continuous improvements to yield and additional development of resistance to various insect and disease pests of corn. DP-32138-1 corn does not further increase the acceptance of hybrid seed in US agriculture, nor will it prevent growers who produce inbred corn from continuing to produce their seed and crops. DP-32138-1 will not lead to any introgression of transgenes, nor to additional admixture of undesired nontransgenic sterility genes that add appreciably to those which are already employed by the hybrid corn industry. Hybrid seed will continue to be a solution to grower needs and requirements, and

additional reliance by growers on hybrid seed production will not be caused by the marketing of any commercial product or by agronomic circumstances. DP-32138-1 will not discourage inbred seed production and use by those growers who desire this type of corn agriculture.

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9. Comment: Several comments indicate that deregulation of MON 87460 corn and other GE crops allows the creation of corporate food monopolies.

Response: APHIS acknowledges the comments. Although APHIS recognizes that new technologies developed and owned by a private firm have the potential to lead to increased market concentration when introduced in the market, introduction of new technologies or increased market concentration do not in themselves lead to unfair competition. Fair competition and business practices are enforced through United States anti-trust laws and institutions and are beyond the scope of this EA.