NATIONAL ENVIRONMENTAL POLICY ACT

FINDING OF NO SIGNIFICANT IMPACT

Pioneer Hi-Bred International, Inc. Petition (19-101-01p) for Determination of Nonregulated Status for Enhanced Grain Yield and Glufosinate-Ammonium Resistant DP202216 Corn

OECD Unique Identifier: DP-2Ø2216-6

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 Finding of No Significant Impact (FONSI) to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) NEPA implementing regulations, and APHIS NEPA implementing procedures at Title 7 of the Code of Federal Regulations part 372 (7 CFR part 372). This FONSI sets forth APHIS' NEPA decision with respect to potential impacts on the human environment that could derive from a determination of nonregulated status for Pioneer enhanced grain yield and glufosinate-ammonium resistant DP202216 corn.

In April 2019, Pioneer Hi-Bred International, Inc. (Pioneer) submitted a petition (19-101-01p) to USDA-APHIS requesting that genetically engineered (GE) DP202216 corn, and any progeny derived from it, no longer be considered regulated under 7 CFR part 340. A GE organism is no longer subject to the requirements of 7 CFR part 340 if APHIS determines that it is unlikely to pose a plant pest risk. DP202216 corn is currently regulated by APHIS.

Pioneer genetically engineered DP202216 corn (hereafter referred to as DP202216 corn) for increased yield potential and resistance to the herbicide active ingredient (a.i.) glufosinate-ammonium.[1] Increased yield potential is conferred by modifying expression of the transcription factor ZMM28, which regulates plant inflorescence[2] and flower development. DP202216 corn contains a gene cassette with a constitutive corn promotor (*zm-gos2*), which drives expression of the *zmm28* gene (ZMM28 protein) at an earlier growth stage in the leaf, and for a longer period of time in grain (Anderson et al. 2019). Both *zm-gos2* and *zmm28* naturally occur in corn. The earlier and extended expression of the ZMM28 protein in DP202216 corn results in improved grain yield potential. Resistance to glufosinate-ammonium is conferred by introduction of a modified *pat* gene, derived from the soil bacterium *Streptomyces viridochromogenes.* The *pat*

[1] Note that "Resistance" to herbicides is defined by the Herbicide Resistance Action Committee (HRAC) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type. "Tolerance" is distinguished from resistance and defined by HRAC as the inherent ability of a plant to survive and reproduce following exposure to an herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant. In reference to GE crops, the terms "resistance" and "tolerance" are often used interchangeably. Throughout this EA, APHIS will use the term "resistance" and "resistant", and "herbicide-resistant" (HR), when referring to GE corn.

[2] A cluster of flowers on a branch or a system of branches.

gene encodes for expression of the enzyme phosphinothricin acetyl transferase (PAT), which acetylates and inactivates the herbicidal activity of glufosinate-ammonium. The introduction of improved yield potential and herbicide-resistance in DP202216 corn is intended to provide growers an additional corn variety to help meet market demand for feed, food, and fuel based corn products.

As part of evaluation of Pioneer's petition APHIS conducted an Environmental Assessment (EA) to help inform APHIS' decision regarding the regulatory status of DP202216 corn (USDA-APHIS 2019a). The EA evaluated the potential impacts of APHIS' regulatory decision on the quality of the human environment.[3] The EA did not identify any significant impacts that would derive from either approval or denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR part 1508.13. This FONSI provides a summary of the EA and the reasons why APHIS' decision to issue a determination of nonregulated status for DP202216 corn will not have a significant impact on the human environment.

APHIS Regulatory Authority and the Coordinated Framework

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products.[4] Since 1986, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and USDA have regulated GE organisms consistent with this framework. On January 4, 2017, the USDA, EPA, and FDA released a 2017 update to the Coordinated Framework (USDA-APHIS 2018), and an accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products (ETIPCC 2017). The authorities and regulatory roles for USDA–APHIS, the EPA, and FDA are briefly summarized below.

USDA-APHIS

Protecting animal and plant health is among APHIS' primary strategic goals. APHIS provides leadership in ensuring the health and care of plants and animals. The agency's strategic goals help improve agricultural productivity and competitiveness, and contributes to the national economy and the public health. The USDA asserts that all methods of agricultural production (conventional, organic, or the use of GE varieties) can provide benefits to the environment, consumers, and farm income.

APHIS regulates GE organisms to ensure that they do not pose a plant pest risk pursuant to the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 et seq.) and APHIS implementing regulations at 7 CFR part 340. APHIS regulations at 7 CFR part 340 govern the importation, interstate movement, and environmental release of GE organisms that may pose a plant pest risk. A GE organism is no longer subject to the PPA or to the requirements of 7 CFR part 340 when APHIS determines that a GE organism is unlikely to pose a plant pest risk.

[3] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

[4] An *Update to the Coordinated Framework for Regulation of Biotechnology* was released on January 4, 2017. See https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology

FDA

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. 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). Pursuant to this policy, the FDA uses what is termed a voluntary consultation process to ensure that human food and animal feed safety issues and other regulatory issues are resolved prior to commercial distribution of bioengineered foods. To help developers of food and feed derived from GE crops comply with their obligations pursuant under Federal food safety laws, the FDA encourages them to participate in a voluntary consultation process. Pioneer is consulting with the FDA in regard to the safety of food and feed products derived from DP202216 corn (Pioneer 2019).

EPA

The EPA regulates pesticide use, including plant-incorporated protectants pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Any pesticide used with DP202216 corn must comply with EPA labeled use and other requirements. The U.S. EPA also sets tolerance limits for residues of pesticides on and in food and animal feed or establishes an exemption from the requirement for a tolerance, pursuant to FFDCA. The EPA has established tolerance limits for glufosinate at 40 CFR §180.473. Pesticide tolerance levels for glufosinate have been established for a wide variety of commodities, including field corn for grain and forage, as described in 40 CFR §180.473 (US-EPA 2019a). Due to the negligible risk PAT poses to human health, the EPA has issued permanent exemptions from food and feed tolerance limits in all food commodities in the United States (US-EPA 2007).

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 govern the movement (e.g., transport, environmental release) of GE organisms that may pose a plant pest risk. A GE organism is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the PPA if APHIS determines through conduct of a Plant Pest Risk Assessment (PPRA) that it is unlikely to pose a plant pest risk.

Public Involvement

On July 25, 2019 APHIS announced in the *Federal Register* that it was making Pioneer's petition available for public review and comment to help identify potential environmental and interrelated economic issues that APHIS should consider in evaluation of the petition.[5] APHIS accepted written comments on the petition for a period of 60 days, until midnight September 23, 2019. At the end of the comment period APHIS had received 4 comments on the petition. Two were opposed to deregulating DP202216 corn, one commenter was in favor of deregulation, and on comment was unrelated to the petition. None of the comments provide any substantive

[5] Federal Register, / Vol. 84, No. 143 / Thursday, July 25, 2019, p. 35850 Pioneer Hi-Bred International, Inc.; Availability of Petition for Determination of Nonregulated Status for Enhanced Grain Yield Potential and Glufosinate-Ammonium Resistant DP202216 Maize [Docket No. APHIS–2019–0040]. Available at https://www.govinfo.gov/content/pkg/FR-2019-07-25/pdf/2019-15836.pdf

information that contributed to development of this draft EA. A full record of each comment received is available online at www.regualtions.gov [Docket No. APHIS–2019–0040].

On July 20, 2020, APHIS announced in the *Federal Register* it was making available the draft EA for a 30-day public review and comment period[6]. By the end of the comment period closed, APHIS received 2 public comments in favor of the approval of the petition. These were from the National Corn Growers Association, and one anonymous person. The comment from the National Corn Growers Association addressed that DP202216 corn variety can confer resistance to glufosinate-ammonium, and potential increased yield and yield stability. There was no comment received opposing the deregulation of the petition. No new information was presented to APHIS in the comments that contributed to or altered the analyses presented in the final EA. A full record of each comment received is available online at awww.regulations.gov, [Docket ID: APHIS-2019-0040].

The Environmental Assessment and Scope of Analysis

The EA was prepared consistent with CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing procedures (7 CFR part 372). APHIS developed a list of topics for consideration in the EA based on issues identified in public comments on prior EAs and EISs evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Zea* and *Tripsacum* species. The following topics were identified as relevant to the scope of analysis (40 CFR part 1508.25):

Agricultural Production

- Acreage and Areas of Corn Production
- Agronomic Practices and Inputs

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Soil Biota
- Animal and Plant Communities
- Herbicide Resistant Weeds
- Gene Flow and Weediness of Corn
- Biodiversity

Human Health

- Consumer Health and Worker Safety

Animal Health

- Animal Feed/Livestock Health

Socioeconomics

- Domestic Economic Environment and International Trade

[6] Federal Register / Vol. 85, No. 139 / Monday, July 20, 2020 / Notices / p. 43807: Pioneer Hi-Bred International; Availability of a Preliminary Pest Risk Assessment and Draft Environmental Assessment. Available at https://www.regulations.gov/document?D=APHIS-2019-0040

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

Alternatives Evaluated in the EA

NEPA implementing regulations (40 C.F.R. § 1502.14) require agencies to evaluate all alternatives that appear reasonable and appropriate to the purpose and need for the Agency's action (in this case, a regulatory decision). Two alternatives were evaluated in the EA for Pioneer's petition: (1) No Action, denial of the petition, which would result in the continued regulation of DP202216 corn, and (2) a determination of nonregulated status for DP202216 corn, approval of the petition, the Preferred Alternative.

No Action: Continuation as Regulated

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR part 1502.14. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and DP202216 corn would remain regulated under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would be required for the introduction of DP202216 corn. Because APHIS concluded in its draft PPRA that DP202216 corn is unlikely to pose plant pest risk (USDA-APHIS 2019b), this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the purpose and need for making a science based regulatory status decision pursuant to the requirements of 7 CFR part 340.

Preferred Alternative: Determination of Nonregulated Status for DP Corn

Under this alternative DP202216 corn and progeny derived from it would no longer be subject to regulation under 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, DP202216 corn is unlikely to pose a plant pest risk (USDA-APHIS 2019b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DP202216 corn. This alternative would best meet the purpose and need to respond appropriately to the petition for nonregulated status pursuant to the requirements of 7 CFR part 340.6, and the Agency's statutory authority under the PPA.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several other alternatives for consideration in the EA in light of the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed them from detailed analysis in the EA. The additional alternatives considered are summarized in the EA along with the reasons for dismissal from detailed analysis (USDA-APHIS 2019a).

Environmental Consequences of APHIS' Selected Action

The EA provides analyses of the alternatives APHIS considered, to which the reader is referred for specific details. Table 1 summarizes the potential environmental impacts of the No Action and Preferred Alternative.

Table 1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate DP Corn**	**Preferred Alternative: Approve the Petition for Nonregulated Status for DP Corn**
Meets Purpose and Need and Objectives	No	Yes
Unlikely to Pose a Plant Pest Risk	Determined via a Plant Pest Risk Assessment (USDA-APHIS 2019b).	(USDA-APHIS 2019b) Determined via a Plant Pest Risk Assessment (USDA-APHIS 2019b).
Management Practices		
Acreage and Areas of Corn Production	Denial of the petition would have no effect on the areas or acreage utilized for corn production. Fluctuations in production areas and acreage would be relative to pest and disease pressures, and market demand for corn commodities.	Approval of the petition is unlikely to have any effect on an increase or decrease in total U.S. corn acreage. DP202216 corn, if adopted by growers, would be expected to replace other corn varieties currently cultivated, as opposed to augmenting current corn crops.
Agronomic Practices and Inputs	Agronomic practices and inputs used in corn crop production would remain unchanged.	Studies evaluating the phenotypic and agronomic properties of DP202216 corn indicate agronomic practices and inputs would be the same as for other varieties of corn (Pioneer 2019).
Use of GE Corn	Approximately 80% of the U.S. corn crops are GE herbicide resistant (HR) varieties. Denial of the petition would have no effect on grower choice in the planting of GE and non-GE corn.	Approval of the petition would provide for cultivation of a GE corn resistant to glufosinate, and with potential increase in yield.
Physical Environment		
Soil Quality	Agronomic practices and inputs associated with corn production potentially impacting soils would be unaffected by denial of the petition..	The agronomic practices and inputs are the same for both DP202216 corn and existing corn varieties – potential impacts on soils would be unchanged.
Water Resources	Denial of the petition would have no effect on water resources in the United States.	Because the agronomic practices and inputs utilized for DP202216 corn production would be no different than currently used, sources of potential impacts on water resources, namely NPS pollutants in agricultural run-off, would not be expected to substantially differ. There are no novel impacts to water resources identified with cultivation of DP202216 corn. The EPA provides label use restrictions and guidance for pesticides, to include glufosinate based herbicides, that are intended to be protective of surface and groundwater.
Air Quality	Emission sources, namely tillage and machinery combusting fossil fuels, and the level of emissions associated with corn production, would be unaffected by denial of the petition.	Because the agronomic practices and inputs used for DP202216 corn production, as well as acreage, would remain unchanged, no changes to emission sources nor level of emissions are expected.
Biological Resources		

Table 1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate DP Corn**	**Preferred Alternative: Approve the Petition for Nonregulated Status for DP Corn**
Soil Biota	Potential impacts of corn production on soil biota would be unaffected by denial of the petition.	Commercial production of DP202216 corn or progeny is not expected to present any risks to soil biota. While DP202216 corn differs from non-GE corn varieties in the herbicide resistance and increased yield traits, these traits are not expected to have significant effects on soil biota or community structures. The introduced *zmm28* gene and ZMM28 protein product, which confers potentially increased yield, occurs naturally in corn and other plants. Glufosinate-ammonium resistance is conferred through introduction of a modified gene (*pat*) from *Streptomyces viridochromogenes*, a naturally occurring soil bacterium.
Animal Communities	Potential impacts on animal communities would be unaffected by denial of the petition.	Approval of the petition, and subsequent commercial production of DP202216 corn, would not be expected to affect animal communities adjacent to or within DP202216 corn cropping systems any differently from that of current corn cropping systems. Neither the PAT nor ZMM28 proteins present any risk to wildlife.
Plant Communities	Potential impacts on plant communities would be unaffected by denial of the petition.	Because the agronomic practices and inputs that will be used for DP202216 corn production are the same as for other corn varieties, potential impacts on plant communities would be the same as that for other corn varieties currently cultivated. The EPA regulates and determines the use of glufosinate. Pesticide use requirements are intended to be protective of non-target plant communities and other plants, such as those in adjacent fields.
Gene Flow and Weediness	*Tripsacum* species are the only sexually compatible plants found in the United States. The potential for corn (*Zea mays*) to hybridize with wild relatives of *Tripsacum* is low; hybridization and successful introgression of *Z. mays* genes into *Tripsacum* is rare (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995). While transient hybrids have been observed (e.g., 2 or 3 generations), successful introgression of *Zea mays* genes into *Tripsacum* populations, successful gene flow in	DP202216 corn, if grown for commercial purposes, would be cultivated as are current corn varieties and present the same potential risk for gene flow, specifically the propensity for and frequency of gene flow, as current corn varieties. In the unlikely event pollen flow from DP202216 corn to *Tripsacum* were to occur, it is unlikely the PAT trait extant in DP202216 corn would present any risk to communities of *Tripsacum* species in terms of plant fitness, or their ecological role in the communities of other plants. Conceptually, the ZMM28 increased yield trait could confer a fitness

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	this direction, has not been observed (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995).	advantage to *Tripsacum* species in the event gene flow occurred. This considered, it is unlikely that any hybrid *Tripsacum* populations with the ZMM28 trait gene would develop. Occurrence of *Tripsacum* in or around DP202216 corn fields is expected to be rare—it is highly unlikely DP202216 corn would be cultivated in proximity to *Tripsacum* for crop identity preservation purposes. In the event outcrossing occurred, successful introgression of *Zea mays* genes into *Tripsacum* populations, successful gene flow in this direction, has not been observed in the wild (de Wet and Harlan 1972; de Wet et al. 1978; Eubanks 1995)).
Biodiversity	Denial of the petition would have no effect on biodiversity in an around corn crops.	Commercial production of DP202216 corn would affect biodiversity in and around DP202216 corn crops no differently than other corn cropping systems. The ZMM28 and PAT trait proteins are unlikely to present any risks to plant, animal, fungal, or bacterial communities. The same or functionally similar ZMM28 proteins are ubiquitous among plants, and PAT among soil dwelling *Streptomyces* species. All pesticide use would be subject to EPA registration and use requirements.
Human and Animal Health		
Human Health and Worker Safety	Denial of the petition would have no effect on human health. DP202216 corn would remain a regulated article and would not be available for food or feed uses.	Approval of the petition would provide for the use of DP202216 corn products in the food and feed industries. As part of the FDA's voluntary biotechnology consultation program, Pioneer submitted a safety and nutritional assessment for DP202216 corn to the FDA's Center for Food Safety and Applied Nutrition (FDA CFSAN) in 2018 (Pioneer 2019). The EPA regulation of pesticides, and worker protection standards, would be no different than that of the No Action Alternative.
Animal Health and Welfare	Denial of the petition would have no effect on animal health and welfare.	DP202216 corn would provide for animal feed products. Pioneer is consulting with the FDA as to the safety of feed derived from DP202216 corn.
Socioeconomic		
Domestic Economic Environment	Denial of the petition would preclude DP202216 corn being available for	DP202216 corn may be cultivated to produce corn based food, feed, and fuel

Table 1. Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate DP Corn**	**Preferred Alternative: Approve the Petition for Nonregulated Status for DP Corn**
	food, feed, and fuel uses. This, however, would have no effect on domestic or international markets.	products. The selection and cultivation of corn varieties is based on market demand for corn commodities, and efficiencies in crop production. DP202216 corn may provide increased yields compared to other varietals, and as a glufosinate resistant variety is intended to facilitate the management of weeds, and herbicide resistant weeds and their development. Consequently, this variety may be competitive in grower selection of corn varietals. These factors considered, the impacts of DP202216 corn on domestic markets would be considered potentially beneficial. There are no adverse impacts associated with the introduction of DP202216 corn to commercial markets.
Trade Economic Environment	Denial of the petition would have no impacts on trade.	Approval of the petition is unlikely to have a substantial effect on the trade of U.S. corn commodities. As discussed above, DP202216 corn, a field corn variety, is expected to be used for provision standard corn based food, feed, and fuel products.
Cumulative Impacts		
Agriculture, Physical and Biological Resources, Public Health, Socioeconomic	There are no cumulative impacts on any aspect of the human environment evaluated identified with denial of the petition.	DP202216 corn production would entail the use of pesticides and fertilizers, and to some extent tillage, which will contribute to potential cumulative impacts on water, soil, and air quality, as does current corn production. If DP202216 corn is adopted by growers, no increase in acreage is expected, thus, no increase in level of total U.S. agricultural inputs or NAAQS emissions.
Coordinated Framework		
U.S. Regulatory Agencies	Denial of the petition would have no effect on the roles of the FDA and EPA in the oversight of DP202216 corn.	Pioneer is consulting with the FDA on the food and feed safety of DP202216 corn. Glufosinate and other pesticide use will be subject to EPA registration and label use requirements.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analyses in the EA indicate that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of a determination of nonregulated status for DP202216 corn. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA finding is based on the following context and intensity factors (40 CFR part 1508.27).

Context

The term "context" means identification of the locations and resources that could potentially be affected by the Agency's decision on the petition. Approval of the petition has the potential to affect GE, conventional, and organic corn cropping systems; environments adjacent to and downstream/downwind of DP202216 corn cropping systems; corn post-harvest processing systems; and domestic and foreign commodity markets.

Corn is grown in all states to some extent, although the majority of production occurs in the Corn Belt, generally defined as Illinois, Iowa, Indiana, southern and western Minnesota, eastern South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri. The leading corn-producing states of Illinois, Iowa, and Nebraska account for approximately 40 % of U.S. production. Substantial production also occurs in the Pacific Northwest, California's Central Valley, along the Mississippi River, and up the Eastern Seaboard from Georgia to Upstate New York.

Corn has food, feed, and industrial uses, although around 40% of harvest is used for feed grain and 35% for fuel ethanol production. The remainder of harvested corn is processed into a variety of food and industrial products such as starch, sweeteners, corn oil, and beverage and industrial alcohol. Corn grain exports represent a principal source of demand for U.S. producers and make the largest net contribution to the U.S. agricultural trade balance of all the agricultural commodities, reflective of the importance of corn exports to the U.S. economy. In 2017, among the 15 countries that exported the highest dollar value worth of animal feeds, the Netherlands ranked first at $2.1 billion (13.9% of exported animal feeds), and United States second at $1.6 billion (10.3%) (Workman 2019).

Intensity

Within the context discussed above, intensity means the degree or severity of potential impacts. As recommended by CEQ (40 CFR part 1508.27), the following were considered in evaluating intensity and making this NEPA determination.

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

   The EA evaluated the potential impacts of approval and denial of the petition, this included impacts that could be potentially adverse, as well as beneficial; these are summarized below.

   Potentially Beneficial: Approval of the petition could result in the market availability of a GE corn variety that can potentially increase yield, and is herbicide resistant (HR). GE HR corn varieties have proven effective in the management of weeds, and achieving optimal net returns (Fernandez-Cornejo et al. 2014). Glutamine synthetase inhibition (glufosinate mode of action) ranks among herbicide modes of action with the fewest

resistant weed populations; there are 4 reported glufosinate resistant weeds worldwide, and only one weed in the United States (Heap 2020). Considering the persistent risk of herbicide-resistance developing in weeds, it is possible that this glufosinate resistant corn variety, as part of an integrated weed management program, could serve as a useful tool for grower's in the management of weeds, and development of herbicide resistance in weeds (US-EPA 2016).

Potentially Adverse: The agronomic practices and inputs used for cultivation of DP202216 corn would be similar to/same as those used for other corn varieties. Thus, cultivation of DP202216 corn would have similar impacts on water, soil, and air quality as that of currently cultivated corn. The potential impacts of agricultural activities on air (i.e., emissions of pollutants), water (i.e., run-off of pesticides and fertilizers), and soil quality (i.e., tillage practices) are well understood and evaluated in the EA. Various ongoing federal and state cooperative initiatives to help mitigate these types of impacts are also discussed in the EA.

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

   Approval of the petition would not present any risks to public health or worker safety beyond those already associated with commercial corn production. As reviewed in the EA, the PAT and ZMM28 traits present negligible risks to human health. As part of the FDA voluntary consultation program, Pioneer submitted a safety and nutritional assessment for DP202216 corn to the FDA's Center for Food Safety and Applied Nutrition (FDA CFSAN) in 2018 (Pioneer 2019). Any use of pesticides would be subject to EPA as well as state requirements. The EPA has established tolerance limits for glufosinate at 40 CFR §180.473. Pesticide tolerance levels for glufosinate have been established for a wide variety of commodities, including field corn for grain and forage, as described in 40 CFR §180.473 (US-EPA 2019a). Due to the negligible risk PAT poses to human health, the EPA has issued permanent exemptions from food and feed tolerance limits in all food commodities in the United States (US-EPA 2007).

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.*

   It is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be affected by a determination of nonregulated status for DP202216 corn. Field corn (*Zea mays*) is a crop plant that was domesticated, bred for thousands of years, for large-scale food production. Domesticated corn does not possess any of the attributes commonly associated with weeds, such as persistence of the seeds in the soil, or having the ability to disperse, invade, or become a dominant species in areas outside of cultivation. As part of its PPRA, APHIS evaluated the potential weediness and invasiveness of DP202216 corn and concluded that it is unlikely that DP202216 corn will become weedy or invasive in areas where it is grown (USDA-APHIS 2019b). Corn has been grown throughout the world without any reports that it occurs as a serious weed.

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

   The agronomic practices and inputs that would be used for DP202216 corn production are no different than those utilized for production of current GE and non-GE corn varieties. Consequently, the potential sources of impacts, and the nature of potential impacts on physical and biological resources that could derive from DP202216 corn production are same as/similar to that of currently cultivated corn. The PAT and ZMM28 proteins present no risks to the physical environment or biological resources (USDA-APHIS 2019a). There are no impacts on the human environment of a highly controversial nature associated with cultivation of DP202216 corn, nor from food, feed, or fuel commodities derived from DP202216 corn. Glufosinate, registered for use on a variety of crops such as apples, berries, canola, citrus, and corn, would be subject to EPA use requirements.

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

   The potential impacts of corn production, and the PAT and ZMM28 proteins, on the human environment are well understood, thoroughly evaluated in the EA (USDA-APHIS 2019a), and summarized in this FONSI. There are no highly uncertain, nor unique or unknown risks associated with DP202216 corn. APHIS has reviewed and approved petitions for nonregulated status since 1992, to include 38 petitions for GE corn varieties. Currently, GE HR corn varieties comprise around 80% of U.S. corn acreage.

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.*

   Approval of Pioneer's petition would not establish a precedent for future actions, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether DP202216 corn poses a plant pest risk pursuant to 7 CFR part 340 (USDA-APHIS 2019b), and an environmental analysis consistent with NEPA and CEQ implementing regulations. All petitions received by APHIS are reviewed independent of the other, and determinations of regulatory status issued in part based on plant pest risk assessments and relevant NEPA analyses specific for the GE organism subject of the petition. Each petition that APHIS receives is for a particular GE organism-trait combination and undergoes an independent review to determine if the regulated organism may pose a plant pest risk. The requirements for petitions for nonregulated status, which include requirements for APHIS' response, are described in 7 CFR part 340.

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

   The potential cumulative impacts of commercial corn production on air, water, and soil quality are well recognized and evaluated in the EA (USDA-APHIS 2019a). Production of corn entails the use of pesticides and fertilizers, and to some extent tillage, which can contribute to potential cumulative impacts on water, soil, and air quality. DP202216 corn

would be no exception. The agronomic practices and inputs that would be used in the cultivation of DP202216 corn, and the potential cumulative impacts of the practices and inputs, would be no different than that of currently cultivated corn varieties.

There are various federal, state, and private sector collaborative initiatives–mitigating factors–to help alleviate the cumulative impacts of crop production on the physical environment, as well as biological resources. Examples include the USDA-NRCS National Water Quality Initiative (NWQI), which aims to reduce nonpoint sources of nutrients, sediment, and pathogens related to agriculture in high-priority watersheds (USDA-NRCS 2019a), the USDA funded Sustainable Agriculture Research and Education Program (SARE) (USDA-NIFA 2017; US-EPA 2019b)), and USDA-NRCS Conservation Stewardship Program, Landscape Initiatives, Environmental Quality Incentives Program, Landscape Planning, and other services that provide technical and financial support to growers to assist in managing the complex interaction of cropping systems and habitat (USDA-NRCS 2019b).

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

   The EA concluded that approval of the petition is not an action that would directly or indirectly affect the character or use of properties protected under the National Historic Preservation Act. It 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 cause any loss or destruction of significant scientific, cultural, or historic resources. DP202216 corn would be cultivated on lands zoned or allocated for agricultural uses. The crop production practices used in the cultivation of corn do not introduce significant visual impairments, or noise, in a manner that would impact the use and enjoyment of historic properties in areas proximate to corn fields. Any farming activities that may be undertaken on tribal lands are only conducted under the tribe's approval; tribes have control over any potential conflict with cultural resources on tribal properties.

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

   APHIS analyzed the potential effects of DP202216 corn on threatened and endangered species and critical habitat. APHIS concluded that approval of the petition for nonregulated status for DP202216 corn, and any subsequent commercial production of this corn variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are not required.

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

The EA evaluated federal, state, and local laws and regulations, executive orders, and policy related to APHIS' decision on Pioneer's petition. The EA concluded that approval of the petition would not lead to circumstances that resulted in non-compliance with federal, state, or local laws and regulations providing protections for environmental and human health. The EPA will regulate the use of pesticides on DP202216 corn. Pioneer is consulting with the FDA in regard to the safety of food and feed products derived from DP202216 corn.

NEPA Decision and Rationale

I have carefully reviewed the EA and determined that the analyses and conclusions support a Finding of No Significant Impact (FONSI) from the deregulation of DP202216 corn.

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." Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations pursuant to 7 CFR part 340. As APHIS has not identified any plant pest risks associated with DP202216 corn, the continued status of DP202216 corn as regulated would be inconsistent with the plant pest provisions of the PPA, APHIS regulations at 7 CFR part 340, and the biotechnology regulatory policies of the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of DP202216 corn will not have any significant impacts on the human environment.

BERNADETTE JUAREZ

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Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date

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