



Finding of No Significant Impact

Agrivida, Inc. Petition (19-176-01p) for the Determination of Nonregulated Status of Maize Event PY203: *Zea mays* Expressing a Phytase Gene Derived from *Escherichia coli* Strain K12

OECD Unique Identifier: AGV-PY203-4

This document discloses the rationale for the Finding of No Significant Impact and approval of the Agrivida petition for nonregulated status.

Agency: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services

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Overview

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Movement of Organisms Modified or Produced Through Genetic Engineering," regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.¹ APHIS recently revised 7 CFR part 340 and issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034);² however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR) process, which replaces the petition for determination of nonregulated status process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However, "Until RSR is available for a particular crop...APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6." (85 FR 29815).

In June 2019, Agrivida, Inc. (Agrivida) submitted a petition (19-176-01p) to APHIS requesting that PY203 maize (corn),³ which was developed using genetic engineering, no longer be considered regulated under 7 CFR part 340, because it is unlikely to pose a plant pest risk (Agrivida 2019). Agrivida's petition for a determination of nonregulated status subject of this FONSI is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020), as it was received by APHIS in June, 2019. Accordingly, APHIS must respond to Agrivida's petition with a regulatory status decision to either approve or deny the petition.

Corn is the primary livestock feed grain in the United States, accounting for around 70% to 90% of total feed grain use on an annual basis. Agrivida modified PY203 corn to improve dietary phosphorus assimilation in non-ruminant livestock by increasing expression of the enzyme phytase in PY203 corn (Agrivida 2019). Phytase is an enzyme that breaks down a storage form of phosphorus called phytate, which improves dietary phosphorus assimilation. Phytase naturally occurs in corn although expressed at low levels with commensurate low enzymatic activity (Rodehutschord et al. 2016; Ingelmann et al. 2018). Because PY203 corn has increased expression of phytase, the phytate in feeds utilizing PY203 corn can be more readily degraded to bioavailable forms of phosphorus during digestion. PY203 corn will be ground into a coarse meal (GRAINZYME® phytase) that will be used as a feed additive to facilitate dietary phosphorus assimilation in non-ruminant livestock. PY203 corn may also be used for silage.

As part of evaluation of Agrivida's petition APHIS developed an Environmental Assessment (EA) to consider the potential impacts of a determination of nonregulated status for PY203 corn on the human

¹ Genetic engineering in the context of 7 CFR part 340 refers to biotechnology-based techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome. Various terms are used in the lay and peer review literature in reference to new plant varieties that have been developed using modern molecular biology tools, these include "agricultural biotechnology", "genetically engineered", and "genetically modified". In this FONSI, the terms "genetic engineering" and "biotechnology" may be used interchangeably. The term "transgenic" may also be used when discussing or referring to a transgene introduced into the genome of a plant. The USDA does not regulate plants that could have been developed through traditional breeding techniques—to include chemical and radiation based mutagenesis—as long as they are not plant pests or developed using plant pests.

²To view the final rule, go to www.regulations.gov and enter APHIS-2018-0034 in the Search field.

³ Maize is the botanical term used globally for the cereal plant *Zea mays*. In the United States maize is commonly referred to as corn. For consistency with the common plant name and petition APHIS uses the term maize, but also refers to corn in certain instances, such as in reference to food products. Both terms are used interchangeably in this document.

environment (USDA-APHIS 2020a).⁴ The EA was prepared in compliance with the National Environmental Policy Act (NEPA, 42 U.S.C. § 4321 et seq.), the Council of Environmental Quality’s (CEQ) NEPA-implementing regulations (40 CFR parts 1500-1508), and USDA and APHIS NEPA-implementing regulations (7 CFR part 1b, and 7 CFR part 372).

Pursuant to 40 CFR § 1501.6 agencies are required to prepare a Finding of No Significant impact (FONSI) and make the FONSI available to the public for disclosure, if the agency determines, based on the EA, to not prepare an environmental impact statement (EIS) because the proposed action will not result in significant impacts on the human environment. Because the proposed action is not similar to one for which an EIS is normally prepared, nor is the nature of the proposed action without precedent, a 30-day public review of the FONSI, as described in 40 CFR § 1501.6(2), does not apply. This document describes the rationale for the FONSI and decision to approve of the petition. The EA in support of this FONSI is available online at www.regulations.gov [Docket No. APHIS–2019–0084], the APHIS website (Petition No. 19-176-01p (USDA-APHIS 2020b)), and is incorporated by reference in its entirety.

Public Involvement

On April 16, 2020, APHIS announced in the *Federal Register* that it was making Agrivida’s petition available for public review and comment to help identify potential environmental and interrelated economic issues and impacts that APHIS should consider in evaluation of the petition.⁵ APHIS accepted written comments on the petition for a period of 60 days. At the end of the comment period APHIS had received 13 comments on the petition. Two comments were in opposition to deregulation of Agrivida’s phytase corn, 11 comments were in favor of approval of the petition. No issues were raised in public comments that suggested potentially significant environmental impacts could occur as a result of cultivation of PY203 corn. Comments from academia, the agricultural industry, and farmers were in support of this corn variety entering the animal feed market. A full record of each comment received is available online at www.regulations.gov [Docket No. APHIS–2019–0084].

On June 24, 2021, APHIS announced in the *Federal Register* that it was making Agrivida’s draft EA, preliminary Finding of No Significant Impact (FONSI), draft plant pest risk assessment (PPRA), and preliminary regulatory status determination available for public review.⁶ APHIS accepted written comments on these documents for a period of 30 days, until midnight July 26, 2021. At the end of the comment period, APHIS had received 4 comments on the draft EA. Two comments were in opposition to deregulation of Agrivida’s phytase corn, 2 separate comments—received from the same individual, were in favor of approval of the petition. A full record of each comment received is available online at www.regulations.gov [Docket No. APHIS–2019–0084].

⁴ Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment (40 CFR § 1508.1(m)).

⁵ *Federal Register*, Vol. 85, No. 74 / Thursday, April 16, 2020, p. 21170 – Agrivida, Inc.; Availability of a Petition for Determination of Nonregulated Status for Maize Genetically Engineered for the Production of Phytase Enzyme [<https://www.govinfo.gov/content/pkg/FR-2020-04-16/pdf/2020-08065.pdf>]

⁶ *Federal Register*, Vol. 86, No. 119 / Thursday, June 24, 2021, p. 33209 – Agrivida, Inc.; Availability of a Draft Plant Pest Risk Assessment, Draft Environmental Assessment, Preliminary Determination, and Preliminary Finding of No Significant Impact for Determination of Nonregulated Status of Maize Developed Using Genetic Engineering for the Production of Phytase Enzyme: [<https://www.govinfo.gov/content/pkg/FR-2021-06-24/pdf/2021-13341.pdf>]

As discussed in the FR notice described above, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, or substantially change the analysis of impacts in the EA, the preliminary regulatory determination will become final and effective upon notification of the public through an announcement on APHIS' website. No further *Federal Register* notice will be published announcing the final regulatory status determination. There were no comments received that altered the analyses presented in the draft EA, nor preliminary FONSI.

Alternatives Evaluated

NEPA implementing regulations (40 C.F.R. 1500 – 1508) require agencies to evaluate alternative actions that would avoid or minimize adverse impacts, or enhance the quality of the human environment, while meeting the purpose and need for Agency action (in this case, a regulatory decision). Two alternatives were evaluated in the EA: (1) No Action, denial of the petition, which would result in the continued regulation of PY203 corn, and (2) Preferred Alternative, approval of the petition, which would result in a determination of nonregulated status for PY203 corn

No Action: Deny the Petition

APHIS considered a “No Action Alternative,” in the EA consistent with CEQ regulations (40 CFR § 1502.14). For APHIS, No Action in this context means no change in regulatory status. Under the No Action Alternative APHIS would deny the petition request for nonregulated status and PY203 corn would remain regulated under 7 CFR part 340.

Preferred Alternative: Approve the Petition for Nonregulated Status

Under this alternative APHIS would approve the petition request. PY203 corn and progeny derived from it would no longer be subject to APHIS regulation under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of PY203 corn.

Finding of No Significant Impact

APHIS developed a list of topics for consideration in the EA based on issues identified in public comments on the petition, public comments submitted on EAs and EISs evaluating other petitions for nonregulated status, prior EAs for biotechnology-derived corn varieties, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Zea* and *Tripsacum* species. The following subject areas comprise the scope of the impacts analysis in the EA (40 CFR § 1501.2 and § 1501.3).

- Agricultural Production: Acreage and areas of corn production, agronomic practices and inputs
- Physical Environment: Soils, water resources, air quality
- Biological Resources: Soil biota, animal communities, plant communities, gene flow and weediness, biodiversity
- Public health and worker safety
- Food animal health and welfare

- Domestic economy and international trade
- Potential impacts on threatened and endangered species
- Compliance of the Agency’s regulatory status decision with Executive Orders, and environmental laws and regulations to which the action is subject.

In evaluating the significance of the potential impacts APHIS considered those requirements outlined in sections 102(2)(C)(ii),(iv), and (v) of NEPA, 40 CFR § 1502.16–Environmental consequences, 40 CFR § 1501.3–Determine the appropriate level of NEPA review, 40 CFR § 1502.24–Environmental review and consultation requirements, and 40 CFR § 1502.15–Affected environment, which are summarized below. The potential impacts/effects identified and discussed in the EA includes those that may be both beneficial and adverse. On balance, the Agency believes that the potential impacts of approval of the petition would be largely beneficial.

1. *Any adverse environmental effects that cannot be avoided should the proposal be implemented.*

Commercial crop production of any type, whether a conventional, organic, or biotechnology-derived cropping system always has some degree of impact on the environment, as discussed in the EA. Potential introduction of pesticides and fertilizers to surface water, soil erosion, and loss of biodiversity and habitats are examples of the potential impacts that can derive from crop production. These are issues that all farmers, not just those growing biotechnology-derived crops, work with in providing sufficient food, animal feed, fiber, fuel, and industrial products to meet societal needs. The degree of environmental impacts can be minor or noticeably adverse, depending on a variety of factors that include the type and quantity of agronomic inputs and practices employed, geography and proximity of surface waters to crops, local biota, weather, prevalence and diversity of insect pests and weeds, and crop type being produced. With around 360,000 corn farms comprising some 90 million acres of the land in the United States (USDA-NASS 2020), the scale of potential impacts, namely in an aggregate sense, requires integration of crop production with sustainability and conservation practices. While implementing such practices can often result in significant mitigation of environmental impacts, not all impacts can be fully attenuated, and some degree environmental trade-offs in meeting the market demand for corn-based food, feed, fuel, and industrial products are inevitable (Robertson and Swinton 2005).

On approval of the petition, and subsequent grower adoption of PY203 corn, the agronomic practices and inputs that would be used in the cultivation of PY203 corn, and any contribution of these practices and inputs to adverse effects on the physical environment (e.g., soils, water quality, or air quality) and biological resources is expected to be similar to that of other corn crops currently cultivated. Resources for the integration of sustainability and mitigation practices with PY203 corn production, summarized under item 9 below, would continue to be available. APHIS did not identify any significant changes to agronomic practices and inputs, nor in PY203 corn physiology, that would have effects on plant diseases and insect pests, or their management (USDA-APHIS 2020c).

To the extent that GRAINZYME® phytase is adopted for use in animal feed, and that manure derived from GRAINZYME® based feeds are utilized for fertilization of cropland, these uses

collectively could contribute, to some degree, to overall reductions in phosphorus runoff from agricultural facilities in the United States. Any contribution to reductions in total anthropogenic phosphorus inputs into surface waters would reduce the risks of eutrophication of surface waters, help improve the quality of impaired or threatened water bodies, and benefit aquatic ecosystems. Eutrophication has a major economic impact causing an estimated \$2.2 billion per year in damages related to recreational water usage, harmful algal blooms, fish kills, fish consumption warnings, waterfront real estate, and drinking water treatment (USDA-APHIS 2020a). Less reliance on inorganic phosphorus as a feed additive would also be expected to provide economic and environmental benefits. The majority of supplemented feed phosphate is derived from phosphate rock reserves that are a non-renewable resource and becoming increasingly scarce and expensive (Cordell and White 2011).

2. The relationship between short-term uses of man's environment and the maintenance and enhancement of long-term productivity.

Long-term agricultural productivity depends on the sustainable utilization of natural resources—namely topsoils, groundwater, populations of beneficial insects such as pollinators and plant pest predators, and the plants that support such insects. Cultivation of PY203 corn would occur on lands allocated/zoned for crop production, and utilize the same resources (e.g., groundwater, agronomic inputs) as all other corn production. The annual production of PY203 corn would present the same challenges to sustaining water and air quality, and top-soils and soil quality as other corn crops. Any groundwater use is expected to be similar to that of other dent corn varieties—there is no indication this variety utilizes more or less water during development.

3. Irreversible or irretrievable commitments of resources that would be involved in the proposal should it be implemented.

Corn production involves the irreversible consumption of nonrenewable petroleum-based products (e.g., fuels, cleaning agents, pesticide additives/adjuvants). Some crop production systems may utilize wind or solar energy sources—renewable sources. Topsoil is also considered nonrenewable, its erosional capacity can be affected by the types of tillage and irrigation systems employed on cropland. Materials such as aluminum, steel, wood, and plastics would be consumed as part of the process of crop production. Most of these materials are non-renewable and could be irreversibly utilized if not recycled (plastics, metals). Crop production inherently entails the irretrievable removal of natural habitat and associated wildlife from the landscape.

Renewable and nonrenewable resources utilized for PY203 corn production would differ little from that of other corn varieties. Any irreversible or irretrievable commitments of resources in PY203 corn production would be the same as or very similar to that of other corn cropping systems. Subtle variations in fossil fuel and energy use would occur relative to the frequency and duration of pesticide and fertilizer applications with this crop, and harvesting and facilities efficiencies, relative to other dent corn crops.

4. Whether the action would violate or conflict with federal or state laws, Executive Orders, or local requirements governing protection of the environment and environmental justice.

The EA found that approval of the petition would not lead to circumstances that resulted in non-compliance with any federal or state laws, local ordinances, or Executive Orders providing protections for environmental and public health. The Environmental Protection Agency (EPA) will regulate the use of pesticides on PY203 corn. Agrivida submitted a summary of its safety and nutritional assessment of PY203 corn to the FDA on June 19, 2018. On January 27, 2021, the FDA concluded consultation, stating that, based on the information Agrivida presented, the FDA had no further questions concerning the safety of human or animal food derived from PY203 corn (US-FDA 2021).

5. Possible conflicts between the proposed action and the objectives of federal, regional, state, tribal, and local land use plans, policies, and controls for the area concerned.

Approval of the petition could result in a minor increase in U.S. corn acreage, relative to market demand and the level of adoption of PY203 corn. Agrivida states that the area required to produce sufficient PY203 corn to meet the demands of the poultry and swine production markets is about 10,000 acres, the equivalent of around 0.01% of current U.S. corn acreage. PY203 corn would be produced on lands already allocated or zoned for crop production.

There are no conflicts with approval of the petition, and subsequent commercial production of PY203 corn with federal, state, tribal, or local government oversight of land uses and policies. Any cultivation of PY203 corn in the United States would require approval by a federal, state, or local government land management authority (e.g., local ordinance, zoning). Tribal entities are recognized as independent governments and agricultural activities on tribal lands would only be conducted if approved by the tribe. APHIS conducted outreach to tribal nations informing tribes of Agrivida's petition. APHIS received one reply from the Sac & Fox Tribe of the Mississippi in Iowa, stating they had no comments for APHIS on Agrivida's petition request.

6. Energy requirements and conservation potential of various alternatives and mitigation measures.

The energy requirements involved with the full life cycle of PY203 corn production and marketing would differ little from that of other commercial corn crops. USDA-NRCS provides guidance on energy management in crop production via practices such as integrated pest management, precision agriculture, irrigation water and nutrient management, and crop residue management (USDA-NRCS 2020). Energy conservation estimation tools are also provided to help growers estimate costs and saving associated with irrigation, nitrogen use, and tillage.

7. Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures.

There are no depletable resource requirements unique to the production and marketing of PY203 corn. Use of natural resources (e.g., irrigation water, soils, fertilizers) would be no different than that of other corn varieties. Natural resource conservation opportunities, whether USDA funded or otherwise implemented by growers or/and state agencies would be available to producers of PY203 corn. Available mitigation measures to curtail potential environmental impacts, such as those summarized below in item 9, would likewise not differ.

8. Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures.

Approval of the petition is not a decision that would directly or indirectly result in alteration of the character or use of historic properties protected under The National Historic Preservation Act, nor would it result in any loss or destruction of cultural or historical resources. PY203 corn production may occur in proximity to historic or cultural resources. There may be the potential for increased noise during the operation of machinery and other equipment, as with all corn crop production, however, these activities would have only temporary effects on historic sites in proximity to PY203 corn fields, with no consistent long-term effects on the enjoyment of a historical or cultural resources. The design of the built environment in relation to crop production activities would be resolved at the state and local levels of governance (e.g., city, county, and/or state departments governing land use).

9. Means to mitigate adverse environmental impacts.

There are a number of federal, state, and private sector collaborative initiatives to help farmers alleviate the collective impacts of crop production on the physical environment, as well as biological resources. Some of the USDA and partner programs supporting agricultural sustainability and natural resources conservation (e.g., National Water Quality Initiative, Natural Resources Conservation Programs) are discussed in the EA (USDA-APHIS 2020a). Each contribute in some way to environmental stewardship, long-term farm sustainability, and improved quality of life.

10. Economic and technical considerations, including the economic benefits of the proposed action.

The economic impacts associated with the introduction of PY203 corn into commerce would be considered potentially beneficial. GRAINZYME® phytase could reduce the need for the addition of microbial phytases and inorganic phosphorus to poultry and swine feed, and improve feed digestibility and animal performance, which could provide economic benefits for producers. PY203 corn and GRAINZYME® phytase will be produced using an identity preservation program (Agrivida 2020), which limits the likelihood of commingling with other feed corn commodities.

11. 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.

Based on APHIS' evaluation provided in Appendix 1 of the EA, a determination of nonregulated status of PY203 corn, and subsequent commercial production of this corn variety, would have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation.

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

Approval of the petition and subsequent availability of PY203 to commercial markets would not present any risks to public health or worker safety. It is unlikely that humans would have any dietary exposure to PY203 corn because its intended use is for animal feed. In the event of inadvertent human consumption of PY203 corn; phytase naturally occurs in cereals, legumes,

oilseeds, and nuts, and commonly consumed by humans. There are no health hazards presented by inadvertent consumption of the Phy02 phytase in PY203 corn (USDA-APHIS 2020a). Agrivida is consulting with the FDA as to the safety of feed derived from PY203 corn (US-FDA 2020a, b).

13. *Whether the affected environment includes reasonably foreseeable environmental trends and planned actions in the affected areas.*

Approval of the petition would provide for the commercial production of PY203 corn, subject to any EPA and state requirements. As of September 2021, APHIS has issued determinations of nonregulated status in response to 40 petitions for biotechnology-derived corn varieties. APHIS maintains a publicly available list of petitions and determinations of nonregulated status on its website (USDA-APHIS 2020b). Biotechnology-derived corn varieties were first commercially produced in the United States in late 1990s, with adoption rates increasing rapidly in the years that followed. Currently, over 90% of U.S. corn is produced using biotechnology-derived varieties. Annual production of corn comprises around 90 million acres.

Advances in biotechnologies are expected to refine the precision with which crop varieties will be developed, and lead to a greater diversity of commercial crop varieties (NAS 2016). While it is difficult to predict the scope of improved crop varieties that will emerge in the coming decades, beneficial traits likely to be utilized include improved tolerance to abiotic stresses such as drought and temperature extremes; increased efficiency in plant physiological processes such as photosynthesis and nitrogen use; resistance to fungal, bacterial, and viral diseases; and new types of herbicide resistance (NAS 2016).

For those biotechnology-derived plants that APHIS has determined are not subject to 7 CFR part 340, which were evaluated for potential plant pest risks, and potential environmental impacts via NEPA analyses: The available science provides little evidence that the cultivation of the presently commercialized biotechnology-derived corn plants have resulted in any adverse environmental impacts that are unique, or differ from conventional crops and cropping systems (e.g., (Sanvido et al. 2007; Brookes and Barfoot 2013; Klümper and Qaim 2014; NAS 2016) and others).

Generally, to date, biotechnology-derived crops, which undergo evaluation by USDA, the EPA, and FDA under the Coordinated Framework (ETIPCC 2017; USDA-APHIS 2020d), have been found to have no more or fewer adverse effects on the environment than conventionally bred crops (NRC 2010; NAS 2016).

NEPA Decision and Rationale

I have evaluated the information provided in the EA, compliance of approval and denial of the petition with applicable laws, regulations, and policy, and public comments on the petition. Based on this evaluation, as summarized above, I have not identified any significant impacts on the human environment that would derive from approval or denial of the petition. Because APHIS did not identify any plant pest risks associated with PY203 corn (USDA-APHIS 2020c), the regulation of PY203 corn 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 these reasons APHIS will implement the Preferred Alternative—approval of the petition. The Preferred Alternative is not a major

federal action significantly affecting the quality of the human environment under NEPA Section 102(2). Accordingly, an EIS is not required and environmental review pursuant to NEPA and CEQ implementing regulations is concluded with this FONSI.

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

Date

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