

Preliminary Determination¹ of Nonregulated Status for Agrivida PY203 Maize

In response to petition 19-176-01p from Agrivida, Inc. (hereafter referred to as Agrivida), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that the new plant variety PY203 Maize (AGY-PY203-4) developed using genetic engineering for the production of phytase enzyme (*Zea mays*; hereafter referred to as PY203 maize) and progeny derived from it are not likely to pose a greater plant pest risk than the unmodified organism from which it was derived and are no longer to be considered regulated under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340)². Since APHIS has determined that PY203 maize is unlikely to pose a greater plant pest risk than unmodified organism from which it was derived, APHIS will approve the petition for nonregulated status of PY203 maize. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of PY203 maize and its progeny. Importation of PY203 maize seeds, other propagative material, or grain for consumption will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and Federal Seed Act Regulations at 7 CFR parts 201 and 361.

This Determination of nonregulated status for PY203 maize is based on APHIS' analyses of field and laboratory data submitted by Agrivida, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for PY203 maize.

The PPRA conducted on PY203 maize concluded that it is unlikely to pose greater plant pest risk than the unmodified organism from which it was derived and should no longer be subject to the regulations at 7 CFR part 340 for the following reasons:

- (1) No plant pest risk was identified from the transformation process, the insertion and/or expression of new genetic material, or from changes in metabolism in PY203 maize.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in PY203 maize compared to the control variety or other comparators in field trials conducted in growing regions representative of where PY203 maize is expected to be grown commercially. Observed agronomic traits also did not reveal any differences that would indirectly indicate that PY203 maize is more susceptible to pests or diseases. Therefore, no plant pest effects are expected on these or other agricultural products and no impacts are expected to APHIS pest control programs.
- (3) Exposure to and/or consumption of the PY203 maize is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of compositional, phenotypic, and agronomic data. PY203 maize is no more likely to become a weed

¹Determination is not effective until officially signed and published.

²The petition for nonregulated status described in this PPRA is being evaluated under the version of the regulations effective at the time that it was created. Animal and Plant Health Inspection Service (APHIS) issued a final rule published in the Federal Register on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034), revising 7 CFR part 340; however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR) process, which replaces 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, "[u]ntil 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). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on 6/25/2019.

than conventional maize varieties based on the observed agronomic characteristics of PY203 maize, the weediness potential of maize, and current management practices available to control maize as a weed.

- (4) PY203 is not likely to increase the weed risk potential of other species with which it can interbreed in the United States or its territories. Gene flow, hybridization, and/or introgression of inserted genes from PY203 maize to other sexually compatible relatives with which it can interbreed is not likely to occur.
- (5) Significant changes to agricultural or cultivation practices (e.g., pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of PY203 maize are not expected.
- (6) Horizontal gene transfer of the new genetic material inserted into PY203 maize to other organisms is highly unlikely and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

APHIS' analyses and conclusions in the PPRA regarding the plant pest risk of PY203 maize also apply to progeny such as any new varieties derived from PY203 maize.

Prior to this Determination of nonregulated status, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and has concluded that a determination of nonregulated status for PY203 maize and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened and endangered species, species proposed for listing, or their designated or proposed critical habitats.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the EA and the FONSI, and my knowledge and experience as the APHIS Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this Determination of nonregulated status for PY203 maize and progeny is the most scientifically sound and appropriate regulatory decision.

Bernadette Juarez

Date

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