

## Determination of Nonregulated Status for Pioneer DP23211 Maize

In response to petition 20-203-01p from Pioneer Hi-Bred International, Inc. (hereafter referred to as Pioneer), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that the new plant variety DP23211 Maize (DP-Ø23211-2) developed using genetic engineering for resistance to western corn rootworm (WCR), and the herbicide active ingredient glufosinate-ammonium (*Zea mays*; hereafter referred to as DP23211 maize) and progeny derived from it are not likely to pose a greater plant pest risk than the unmodified maize 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)<sup>1</sup>. Since APHIS has determined that DP23211 maize is unlikely to pose a greater plant pest risk than unmodified maize from which it was derived, APHIS will approve the petition for nonregulated status of DP23211 maize. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of DP23211 maize and its progeny. Importation of DP23211 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 DP23211 maize is based on APHIS' analyses of field and laboratory data submitted by Pioneer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for DP23211 maize.

The PPRA conducted on DP23211 maize concluded that it is unlikely to pose a 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 changes in metabolism in DP23211 maize.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in DP23211 maize compared to the control variety or other comparators in field trials conducted in growing regions representative of where DP23211 maize is expected to be grown commercially. Observed agronomic traits also did not reveal any differences that would indirectly indicate that DP23211 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 DP23211 maize is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of compositional, phenotypic, and agronomic data. DP23211 maize is no more likely to become a weed than conventional maize varieties based on the observed agronomic characteristics of DP23211 maize, the weediness potential of maize, and current management practices available to control maize as a weed.
- (4) DP23211 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

<sup>1</sup>The 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 7/21/2020.

of inserted genes from DP23211 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 the adoption of DP23211 maize are not expected.
- (6) Horizontal gene transfer of the new genetic material inserted into DP23211 maize to other organisms is highly unlikely. It is not expected to lead directly or indirectly to disease, damage, injury, or harm to plants, creating new or more virulent pests, pathogens, or parasitic plants.

APHIS' analyses and conclusions in the PPRA regarding the plant pest risk of DP23211 maize also apply to progeny such as any new varieties derived from DP23211 maize.

Before 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 DP23211 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 DP23211 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