

Preliminary Determination¹ of Nonregulated Status for Pioneer DP202216 Maize

In response to petition 19-101-01p 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 enhanced grain yield potential and glufosinate resistant maize (*Zea mays*; hereafter referred to as DP202216 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 articles under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340). Since APHIS has determined that DP202216 maize is unlikely to pose a greater plant pest risk than the unmodified maize from which it was derived, APHIS will approve the petition for nonregulated status of DP202216 maize. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of DP202216 maize and its progeny. Importation of DP202216 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 DP202216 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 DP202216 maize.

The PPRA conducted on DP202216 maize concluded that it is unlikely to pose greater plant pest risk than the unmodified maize 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 DP202216 maize.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in DP202216 maize compared to the control variety or other comparators in field trials conducted in growing regions representative of where DP202216 maize is expected to be grown commercially. Observed agronomic traits also did not reveal any differences that would indirectly indicate that DP202216 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 DP202216 maize is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of compositional, phenotypic, and agronomic data.

- (4) DP202216 maize is no more likely to become a weed than conventional maize varieties based on its observed agronomic characteristics, the weediness potential of maize, and current management practices available to control maize as a weed.
- (5) DP202216 is not likely to increase the weed risk potential of other species with which it can interbreed in the United States or its territories. Even if sexually compatible relatives acquire transgenes through gene flow, the new phenotype(s) conferred by transgenes are not likely to increase the weediness of these compatible relatives or affect the current ability to control these relatives in situations where they are considered weedy or invasive.
- (6) Significant changes to agricultural or cultivation practices (e.g., pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of DP202216 maize were not identified and thus are not likely to increase plant diseases or pests or compromise their management.
- (7) Horizontal gene transfer of the new genetic material inserted into DP202216 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 DP202216 maize also apply to progeny such as any new varieties derived from DP202216 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 DP202216 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 DP202216 maize and progeny is the most scientifically sound and appropriate regulatory decision.

Bernadette Juarez

Date

APHIS Deputy Administrator
Biotechnology Regulatory Services
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