United States Department of Agriculture

Marketing and Regulatory Programs

Animal Plant Health Inspection Service

Biotechnology Regulatory Services

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Mark Zylstra, Director of Regulatory Affairs
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Ames, IA 50010

RSR number 23-179-01rsr

RE: Regulatory Status Review of maize developed using genetic engineering for production of the enzyme mannanase in the seed, and resistance to the herbicide glufosinate

Dear Mr. Zylstra

Thank you for your letter dated June 27, 2023, requesting a Regulatory Status Review (RSR) for maize developed using genetic engineering (modified maize). In your letter, you described that the maize was modified to impart seed-localized production of a mannan-degrading enzyme and glufosinate resistance via seed-specific expression of an endo-1,4-β-mannanase gene and expression of a phosphinothricin acetyl transferase gene.

The Plant Protection Act of 2000 (7 U.S.C. §§ 7701 et seq.) provides USDA authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect agriculture, environment, and the economy of the United States. USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates the "Movement of Organisms Modified or Produced through Genetic Engineering" as described in 7 CFR part 340.

Consistent with 7 CFR 340.4, APHIS reviewed your modified maize to determine whether it is subject to the regulations in 7 CFR part 340. Specifically, APHIS reviewed the modified maize to determine whether there is a plausible pathway by which the maize would pose an increased plant pest risk relative to the plant pest risk posed by an appropriate maize comparator. Based on information you provided, publicly available resources, and APHIS' familiarity with maize and knowledge of the trait, phenotype, and mechanism of action, APHIS considered the (1) biology of nonmodified maize and its sexually compatible relatives; (2) the trait and mechanism-of-action of the modification; and (3) the effect of the trait and mechanism-of-action on the (a) distribution, density, or development of the plant and its sexually compatible relatives, (b) production, creation, or enhancement of a plant pest or a reservoir for a plant pest, (c) harm to non-target organisms beneficial to agriculture, and (d) weedy impacts of the plant. APHIS did not identify any plausible pathway by which your modified maize would pose an increased plant pest risk relative to comparator maize plants. APHIS has determined your maize is unlikely to pose an increased plant pest risk relative to its comparators. Once APHIS determines that a plant product is unlikely to pose an increased plant pest risk relative to its comparator, and, thus, is not a plant pest or a plant that requires regulation because it is capable of introducing or disseminating a plant pest, APHIS has no authority to regulate it under 7 CFR part 340. Accordingly, your maize is not subject to the regulations under 7 CFR part 340. APHIS' determination that this modified plant is not subject to the regulations extends to any progeny of the modified plant that is derived from crosses with other non-modified plants or other modified plants that are also not subject to the regulations in 7 CFR part 340.

Please be advised that APHIS' decision applies to the maize developed using genetic engineering exactly as described in your letter. If at any time you become aware of any information that may affect our review of your modified maize, including, for example, new information that shows the trait, phenotype, or mechanism of action is different than described in your letter, you must contact APHIS for further review of the plant at RSRrequests@usda.gov.

Please be advised that your plant product, while not regulated under 7 CFR part 340, may be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, you may contact the PPQ general number for such inquiries at 877-770-5990. Your plant product may also be subject to other regulatory authorities such as the U.S. Environmental Protection

Agency (EPA) or the Food and Drug Administration (FDA). Please contact EPA and FDA to enquire about the regulatory status of your product.

Sincerely,

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

Date: November 14, 2023