U.S. FOOD & DRUG ADMINISTRATION

April 1, 2025

Dr. Shirong Zhang
U.S. Regulatory Affairs Manager
Syngenta Seeds, LLC
9 Davis Drive
Research Triangle Park, NC 27709

RE: Biotechnology Notification File No. BNF 000201

Dear Dr. Zhang:

This letter addresses Syngenta Seeds, LLC's (Syngenta's) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered corn, MZIR260. According to information Syngenta has provided, MZIR260 corn is genetically engineered to express the eCry1Gb.1Ig protein, conferring resistance to fall armyworm (*Spodoptera frugiperda*), as well as phosphomannose isomerase (PMI), an enzyme which permits growth of plant cells on mannose and was utilized as a selection marker. The administrative record for this consultation has been placed in a file designated BNF 000201. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Syngenta submitted to FDA a summary of its safety and nutritional assessment of MZIR260 corn, which FDA received on July 31, 2024. This communication informed FDA of the steps taken by Syngenta to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Syngenta has conducted, it is our understanding that Syngenta has concluded that human and animal food from MZIR260 corn are not materially different in composition, safety, and other relevant parameters from corn-derived human and animal food currently on the market, and that genetically engineered MZIR260 corn does not raise issues that would require premarket review or approval by FDA.

The United States Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIPs), which include both the active and inert ingredients. MZIR260 contains PIPs, which are within the purview of EPA. It is Syngenta's responsibility to obtain all appropriate clearances, including those from EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MZIR260 corn.

U.S. Food and Drug Administration
Human Foods Program
5001 Campus Drive
College Park, MD 20740
www.fda.gov

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the USDA's Agricultural Marketing Service with developing a national mandatory system for disclosing the presence of bioengineered material in human food. Food manufacturers, importers, and retailers of MZIR260 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Syngenta has presented to FDA, we have no further questions concerning human or animal food derived from MZIR260 at this time. However, as you are aware, it is Syngenta's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000201 and copies of FDA's memoranda summarizing the information in BNF 000201 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

MARK A. HARTMAN -S

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Mark A. Hartman
Director
Office of Food Chemical Safety,
Dietary Supplements, and Innovation
Human Foods Program