



Haeman Jang, Ph.D.
Global Regulatory Manager
Bayer U.S. – Crop Science
700 Chesterfield Parkway W
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000186

Dear Dr. Jang:

This letter addresses Bayer CropScience LP's (Bayer's) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)) on genetically engineered corn, MON 95275. According to information Bayer has provided, MON 95275 corn is genetically engineered to express: the *Brevibacillus laterosporus* Mpp75Aa1.1 protein, the *Bacillus thuringiensis* Vpb4Da2 protein, and the *DvSnf7.1* double stranded RNA derived from the western corn rootworm. These modifications are intended to confer resistance to targeted coleopteran insect pests, including western corn rootworm and northern corn rootworm. The administrative record for this consultation has been placed in a file designated BNF 000186. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Bayer submitted to FDA a summary of its safety and nutritional assessment of MON 95275 corn, which FDA received on November 4, 2021. Bayer submitted additional information, received by FDA on March 17 and 30, 2022, and December 2, 2022. These communications informed FDA of the steps taken by Bayer 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 Bayer has conducted, it is our understanding that Bayer has concluded that human and animal food from MON 95275 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 MON 95275 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. MON 95275 corn contains PIPs, which are within the purview of EPA. It is Bayer's responsibility to obtain all appropriate clearances, including those from the EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MON 95275 corn.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
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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 MON 95275 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Bayer has presented to FDA, we have no further questions concerning human or animal food derived from MON 95275 corn at this time. However, as you are aware, it is Bayer'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 000186 and copies of FDA's memoranda summarizing the information in BNF 000186 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

Kristi L. Muldoon Jacobs - S  Digitally signed by Kristi L. Muldoon Jacobs -S
Date: 2023.06.21 11:48:42 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
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