



Heather Anderson, M.Sc.
Senior Global Regulatory Manager
Bayer U.S. - Crop Science
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000179

Dear Ms. Anderson:

This letter addresses Bayer CropScience LP's (Bayer) 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 95379 corn. According to information Bayer has provided, MON 95379 corn is genetically engineered to express Cry1B.868 and Cry1Da_7 proteins for protection against targeted lepidopteran pests. The administrative record for this consultation has been placed in a file designated BNF 000179. 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 95379 corn, which FDA received on August 19, 2020. Bayer submitted additional information, received by FDA on April 26, 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 95379 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 95379 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 (PIP), which include both the active and inert ingredients. MON 95379 corn contains PIPs which are within the purview of EPA. It is Bayer'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 MON 95379 corn.

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 95379 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 95379 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 000179 and copies of FDA's memoranda summarizing the information in BNF 000179 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: 2022.12.05 09:04:39 -05'00'

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