



Tianbo Xu, Ph.D.
Global Regulatory Manager
Bayer CropScience LP
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000202

Dear Dr. Xu:

This letter addresses Bayer CropScience LP's (Bayer's) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered cotton, MON 89151. According to information Bayer has provided, MON 89151 cotton is genetically engineered to express Cry1Da_7, Cry1B.3, and Vip3Cb1.1 proteins that are intended to protect cotton against feeding damage caused by lepidopteran pests. The administrative record for this consultation has been placed in a file designated BNF 000202. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Bayer submitted to FDA a summary of its safety and nutritional assessment of MON 89151 cotton, which FDA received on March 4, 2025. This document 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 89151 cotton are not materially different in composition, safety, and other relevant parameters from cotton-derived human and animal food currently on the market, and that genetically engineered MON 89151 cotton 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 89151 cotton 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 89151 cotton.

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,

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

importers, and retailers of MON 89151 cotton 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 89151 cotton 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 000202 and copies of FDA's memoranda summarizing the information in BNF 000202 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

MARK A.

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