



Julie Francois, Ph.D.  
Global Regulatory Manager  
Bayer CropScience LP  
700 Chesterfield Parkway West  
Chesterfield, Missouri 63017

RE: Biotechnology Notification File No. BNF 000204

Dear Dr. Francois:

This letter addresses Bayer CropScience LP's (Bayer) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered cotton, MON 96012. According to information Bayer has provided, MON 96012 cotton is genetically engineered to express CP4 EPSPS for tolerance to glyphosate herbicides, PAT (*pat*) for tolerance to glufosinate herbicides, DMO for tolerance to dicamba, TDO for tolerance to mesotrione, and *H\_N90 PPO* for tolerance to PPO-inhibiting herbicides. The administrative record for this consultation has been placed in a file designated BNF 000204. 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 96012 cotton, which FDA received on July 2, 2025. Bayer submitted additional information, received by FDA on January 7, 2026. 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 96012 cotton are not materially different in composition, safety, and other relevant parameters from other cotton-derived human and animal food currently on the market, and that genetically engineered MON 96012 cotton does not raise issues that would require premarket review or approval by FDA.

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 96012 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 96012 cotton at this time. However, as you are aware, it is Bayer's continuing responsibility to ensure that foods marketed by the company are safe,

wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000204 and copies of FDA's memoranda summarizing the information in BNF 000204 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