U.S. FOOD & DRUG ADMINISTRATION

Heather Anderson, M.S.
Senior Global Regulatory Manager
Bayer CropScience LLC
700 Chesterfield Parkway West
Chesterfield, Missouri 63017

RE: Biotechnology Notification File No. BNF 000208

Dear Ms. Anderson:

This letter addresses Bayer CropScience LLC (Bayer)'s consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered corn, MON 80616. According to information Bayer has provided, MON 80616 corn is genetically engineered to express protoporphyrinogen IX oxidase (PPO) to confer tolerance to PPO-inhibiting herbicides. The administrative record for this consultation has been placed in a file designated BNF 000208. 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 80616 corn, which FDA received on January 20, 2026. This communication 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 80616 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 80616 corn does not raise issues that would require premarket review or approval by FDA.

It is Bayer's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MON 80616 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 80616 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 80616 corn 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 000208 and copies of FDA's memoranda summarizing the information in BNF 000208 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

MARK A. HARTMAN -S

Digitally signed by MARK A. HARTMAN -S
Date: 2026.07.29 13:26:11 -04'00'

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