



March 31, 2025

Ed Allen, Ph.D.
Senior Global Regulatory Manager
Bayer U.S. - Crop Science
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000195

Dear Dr. Allen:

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 corn, MON 94804. According to information Bayer has provided, MON 94804 corn is genetically engineered to express GA20ox_SUP micro ribonucleic acid (miRNA) that suppresses the expression of plant hormone gibberellic acid (GA) biosynthetic genes *ZmGA20ox3* and *ZmGA20ox5*. Suppression of these biosynthetic genes leads to reduced levels of GA and shorter internode length, resulting in a short stature phenotype. The administrative record for this consultation has been placed in a file designated BNF 000195. 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 94804 corn, which FDA received on February 3, 2023. Bayer submitted additional information, received by FDA on February 17 and February 21, 2023; and May 30, August 7, and October 10, 2024. 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 94804 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 94804 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 94804 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 94804 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 94804 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 000195 and copies of FDA's memoranda summarizing the information in BNF 000195 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