



November 27, 2024

Jessica Fernandez
Global Regulatory Manager
Bayer CropScience LP
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000199

Dear Ms. Fernandez:

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 soybean, MON 94637. According to information Bayer has provided, MON 94637 soybean is genetically engineered to express the Cry1A.2 and Cry1B.2 proteins to confer resistance to susceptible lepidopteran insects. The administrative record for this consultation has been placed in a file designated BNF 000199. 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 94637 soybean, which FDA received on August 4, 2023. Bayer submitted additional information, received by FDA on February 16, 2024; June 19, 2024; and July 8, 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 94637 soybean are not materially different in composition, safety, and other relevant parameters from soybean-derived human and animal food currently on the market, and that genetically engineered MON 94637 soybean 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 94637 soybean 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 94637 soybean.

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 94637 soybean 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 94637 soybean 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 000199 and copies of FDA's memoranda summarizing the information in BNF 000199 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

Kristi L. Muldoon Jacobs
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Digitally signed by Kristi L. Muldoon
Jacobs -S
Date: 2024.11.27 09:43:17 -05'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
Office of Food Chemical Safety,
Dietary Supplements, and Innovation
Human Foods Program