



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

RE: Biotechnology Notification File No. BNF 000203

Dear Dr. Beyene:

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 94115. According to information Bayer has provided, MON 94115 soybean is genetically engineered to express protoporphyrinogen IX oxidase (PPO) protein that confers tolerance to PPO-inhibiting herbicides. The administrative record for this consultation has been placed in a file designated BNF 000203. 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 94115 soybean, which FDA received on June 30, 2025. Bayer submitted additional information on September 30, 2025. 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 94115 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 94115 soybean 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 (EPA) and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MON 94115 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, importers, and retailers of MON 94115 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 94115 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 000203 and copies of FDA's memoranda summarizing the information in BNF 000203 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