Gregory Tilton, Ph.D.
Global Regulatory Manager
Bayer U.S. - Crop Science
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000193

Dear Dr. Tilton:

This letter addresses Bayer CropScience LP's (Bayer's) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)) on genetically engineered soybean, MON 94313. According to information Bayer has provided, MON 94313 soybean is genetically engineered to tolerate multiple herbicides by expressing dicamba mono-oxygenase (DMO) for tolerance to dicamba herbicide; phosphinothricin-N-acetyltransferase (PAT) for tolerance to glufosinate herbicide; a modified R-2,4-dichlorophenoxypropionate dioxygenase (RdpA) (referred to by Bayer as FT_T.1) for tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicide; and triketone dioxygenase (TDO) for tolerance to beta-triketone herbicides such as mesotrione. The administrative record for this consultation has been placed in a file designated BNF 000193. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Bayer submitted to FDA a summary of its safety and nutritional assessment of MON 94313 soybean, which FDA received on September 7, 2022. Bayer submitted additional information, received by FDA on January 24 and September 29, 2023; and January 11, February 14, and June 13, 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 94313 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 94313 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 and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MON 94313 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 94313 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 94313 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 000193 and copies of FDA's memoranda summarizing the information in BNF 000193 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

Kristi L. Muldoon Jacobs -S

Digitally signed by Kristi L. Muldoon Jacobs -S
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Kristi L. Muldoon Jacobs, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition