Aster Beyene, Ph.D.
Global Regulatory Manager
Bayer U.S. – Crop Science
700 Chesterfield Parkway West
Chesterfield, MO 63017

RE: Biotechnology Notification File No. BNF 000177

Dear Dr. Beyene:

This letter addresses Bayer CropScience LP's (Bayer)[1] 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 canola, MON 94100. According to information Bayer has provided, MON 94100 canola is genetically engineered to express dicamba mono-oxygenase (DMO) for tolerance to dicamba herbicide. The administrative record for this consultation has been placed in a file designated BNF 000177. 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 94100 canola, which FDA received on January 23, 2020. Bayer submitted additional information, received by FDA on July 16, 2021. 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 94100 canola are not materially different in composition, safety, and other relevant parameters from canola-derived human and animal food currently on the market, and that genetically engineered MON 94100 canola 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 94100 canola.

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 94100 canola are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

[1] Monsanto Company submitted the notice for BNF No. 000177. In a letter dated August 3, 2020, FDA was informed that Monsanto Company plant products "which were consulted on for food and feed safety and those still in the process" would be transferred to the legal entity Bayer CropScience LP, effective August 1, 2020.

Based on the information Bayer has presented to FDA, we have no further questions concerning human or animal food derived from MON 94100 canola 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 000177 and copies of FDA's memoranda summarizing the information in BNF 000177 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
Date: 2022.10.04 10:32:18 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition