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

RE: Biotechnology Notification File No. BNF 000173

Dear Dr. Allen:

This letter addresses Bayer Crop Science 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) on genetically engineered corn, MON 87429. According to information Bayer has provided, MON 87429 corn is genetically engineered to express 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)[2] for tolerance to aryloxyphenoxypropionate acetyl coenzyme A carboxylase inhibitors (so-called "FOPs" herbicides such as quizalofop) and 2,4-dichlorophenoxyacetic acid (2,4-D) herbicides; and CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) for tolerance to glyphosate herbicide and for glyphosate-inducible male sterility. The administrative record for this consultation has been placed in a file designated BNF 000173. 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 the MON 87429 corn, which FDA received on February 5, 2019. Bayer submitted additional information, received by FDA on August 7, 2019, June 4, 2020 and May 18, 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 87429 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 87429 corn does not raise issues that would require premarket review or approval by FDA.

[1] Monsanto Company submitted the notice for BNF No. 000173. 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.
[2] Bayer refers to the modified RpdA as FT_T.

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 87429 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. Producers, distributors, and marketers of MON 87429 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 87429 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 000173 and copies of FDA's memoranda summarizing the information in BNF 000173 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: 2022.07.07 10:22:06 -04'00'

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