Andrew Olson, Ph.D.
U.S. Regulatory Manager
BASF Agricultural Solutions
2 TW Alexander Drive
Research Triangle Park, NC 27709

RE: Biotechnology Notification File No. BNF 000172

Dear Dr. Olson:

This letter addresses BASF Corporation's (BASF) 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, GMB151. According to information BASF has provided, GMB151 soybean is genetically engineered to express Cry14Ab-1 for protection against soybean cyst nematode and to express a 4-hydroxyphenyl-pyruvate dioxygenase protein (HPPD-4) for tolerance to HPPD-inhibitor herbicides and for use as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000172. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, BASF submitted to FDA a summary of its safety and nutritional assessment of GMB151 soybean, which FDA received on February 1, 2019. BASF submitted additional information, received by FDA on May 11, 2021. These communications informed FDA of the steps taken by BASF 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 BASF has conducted, it is our understanding that BASF has concluded that human and animal food from GMB151 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 GMB151 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 (PIP), which include both the active and inert ingredients. GMB151 soybean contains a PIP, which is within the purview of EPA.[1] It is BASF's responsibility to obtain all appropriate clearances, including those from EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from GMB151 soybean.

[1] EPA granted a permanent exemption from the requirement of a tolerance for Cry14Ab-1 when used as a PIP in soybean (40 CFR 174.540) and for HPPD-4 when used as a PIP inert ingredient in all food commodities (40 CFR 174.537).

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 GMB151 soybean are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information BASF has presented to FDA, we have no further questions concerning human or animal food derived from GMB151 soybean at this time. However, as you are aware, it is BASF'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 000172 and copies of FDA's memoranda summarizing the information in BNF 000172 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: 2022.04.27 17:18:15 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
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