U.S. FOOD & DRUG ADMINISTRATION

Patrick T. Garcia
U.S. Seeds Regulatory Affairs Leader
Corteva Agriscience
8325 NW 62nd Avenue
PO Box 7062
Johnston, IA 50131

RE: Biotechnology Notification File No. BNF 000200

Dear Mr. Garcia:

This letter addresses Pioneer Hi-Bred International, Inc.'s (Pioneer) consultation with the Food and Drug Administration (FDA, we) (Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)) on genetically engineered soybean COR23134. According to information Pioneer has provided, COR23134 soybean is genetically engineered to express proteins Cry1B.34.1, Cry1B.61.1, and IPD083Cb, conferring resistance against certain lepidopteran pests, as well as the protein GM-HRA, which confers tolerance to acetolactate synthase-inhibiting herbicides, for use as a selection marker. The administrative record for this consultation has been placed in a file designated BNF 000200. This file will be maintained in the Office of Food Chemical Safety, Dietary Supplements, and Innovation in HFP.

As part of this consultation, Pioneer submitted to FDA a summary of its safety and nutritional assessment of COR23134 soybean, which FDA received on February 13, 2024. Pioneer submitted additional information, received by FDA on April 12, 2024. These communications informed FDA of the steps taken by Pioneer 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 Pioneer has conducted, it is our understanding that Pioneer has concluded that human and animal food from COR23134 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 COR23134 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 (PIPs), which include both the active and inert ingredients. COR23134 soybean contains PIPs, which are within the purview of EPA. It is Pioneer's responsibility to obtain all appropriate clearances, including those from the EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from COR23134 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 COR23134 soybean are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Pioneer has presented to FDA, we have no further questions concerning human or animal food derived from COR23134 soybean at this time. However, as you are aware, it is Pioneer'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 000200 and copies of FDA's memoranda summarizing the information in BNF 000200 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: 2024.11.06 08:59:34 -05'00'

Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
Office of Food Chemical Safety,
Dietary Supplements, and Innovation
Human Foods Program