



Patrick Garcia
US Registration Manager
Corteva Agriscience
8325 NW 62nd Avenue
Johnston, IA 50131

RE: Biotechnology Notification File No. BNF 000191

Dear Mr. Garcia:

This letter addresses Pioneer Hi-Bred International, Inc.'s (Pioneer'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 corn, DAS1131. According to information Pioneer has provided, DAS1131 corn is genetically engineered to express the Cry1Da2 protein to confer resistance to susceptible lepidopteran insects and DGT-28 EPSPS protein to confer tolerance to glyphosate herbicides. DGT-28 EPSPS was also used as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000191. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Pioneer submitted to FDA a summary of its safety and nutritional assessment of DAS1131 corn, which FDA received on January 26, 2022. Pioneer submitted additional information, received by FDA on May 03, 2023, May 24, 2023, September 05, 2023, and September 14, 2023. 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 DAS1131 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 DAS1131 corn 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. DAS1131 corn contains a PIP which is 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 DAS1131 corn.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

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 DAS1131 corn 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 DAS1131 corn 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 000191 and copies of FDA's memoranda summarizing the information in BNF 000191 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: 2023.12.27 09:25:49 -05'00'

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