



Ms. Kyra Hjelle
Regulatory Affairs Manager
Hjelle Advisors, LLC
1100 Corporate Square Dr.
St. Louis, MO 63132

RE: Biotechnology Notification File No. BNF 000194

Dear Ms. Hjelle:

This letter addresses Helix Sementes e Biotecnologia Ltda.'s¹ (Helix'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, EH913. According to information Helix has provided, EH913 corn is genetically engineered to express the Cry1Da protein to confer resistance to certain lepidopteran insects, including fall armyworm and sugarcane borer, and the PAT protein to confer tolerance to glufosinate-ammonium herbicides. PAT was also used as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000194. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Helix submitted to FDA a summary of its safety and nutritional assessment of EH913 corn, which FDA received on October 27, 2022. Helix submitted additional information, received by FDA on May 1, 2023; May 9, 2023; September 27, 2023; November 28, 2023; December 15, 2023; and January 26, 2024. These communications informed FDA of the steps taken by Helix 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 Helix has conducted, it is our understanding that Helix has concluded that human and animal food from EH913 corn is 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 EH913 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. EH913 corn contains a PIP which is within the purview of EPA. It is Helix's responsibility to obtain all appropriate

¹ The developer informed FDA about its name change from "Helix Sementes e Mudás Ltda." to "Helix Sementes e Biotecnologia Ltda." on May 9, 2023.

clearances, including those from the EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from EH913 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. Food manufacturers, importers, and retailers of EH913 corn are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Helix has presented to FDA, we have no further questions concerning human or animal food derived from EH913 corn at this time. However, as you are aware, it is Helix'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 000194 and copies of FDA's memoranda summarizing the information in BNF 000194 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: 2024.05.22 10:26:15 -06'00'

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