



Jerry J. Hjelle, Ph.D.
Hjelle Advisors LLC
252 Gay Avenue
St. Louis, MO 63105

RE: Biotechnology Notification File No. BNF 000169

Dear Dr. Hjelle:

This letter addresses Centro de Tecnologia Canavieira's (CTC) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on raw and refined sugar from genetically engineered sugarcane, event CTC91087-6. According to information CTC has provided, CTC91087-6 sugarcane is genetically engineered to express the Cry1Ac protein from *Bacillus thuringiensis* to help control sugarcane borer infestations and the phosphinothricin-N-acetyl-transferase (PAT) protein as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000169. This file will be maintained in the Office of Food Additive Safety in CFSAN. In its submission, CTC notes that it does not intend for CTC91087-6 sugarcane to be grown in the United States and that the food products intended for marketing in the United States would be raw and refined sugar.

As part of bringing this consultation to closure, CTC submitted to FDA a summary of its safety and compositional assessment of the CTC91087-6 sugarcane, which FDA received on October 1, 2018. CTC submitted additional information, received by FDA on March 27, 2019, May 7, 2020 and July 16, 2020. These communications informed FDA of the steps taken by CTC 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 CTC has conducted, it is our understanding that CTC has concluded that raw and refined sugar from CTC91087-6 sugarcane is not materially different in composition, safety, and other relevant parameters from raw and refined sugar currently on the market, and that raw or refined sugar from genetically engineered CTC91087-6 sugarcane 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. CTC91087-6 sugarcane contains a PIP, which is within the purview of EPA. CTC consulted with EPA, which concluded that the Cry1Ac protein and PAT protein in CTC91087-6 sugarcane fall under the tolerance exemptions in 40 CFR 174.510 and 174.522, respectively. It is CTC'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 CTC91087-6 sugarcane in the United States.

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,

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distributors, and marketers of raw and refined sugar from CTC91087-6 sugarcane are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information CTC has presented to FDA, we have no further questions concerning raw and refined sugar from CTC91087-6 sugarcane in human or animal food at this time. However, as you are aware, it is CTC'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 000169 and copies of FDA's memoranda summarizing the information in BNF 000169, are available to the public at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.
Keefe -S**  Digitally signed by
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Date: 2020.08.25
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Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition