August 24, 2020

Mr. Bruce Summers Administrator Agricultural Marketing Service, U.S. Department of Agriculture 1400 Independence Avenue, NW Washington, DC 20250 via Regulations.gov

Re: National Bioengineered Food Disclosure Standards; Updates to the List of Bioengineered Foods, 85 Fed. Reg. No. 143 (July 24, 2020)

Docket No. AMS-FTPP-20-0057

Dear Administrator Summers,

The Brazilian Sugarcane Industry Association ("UNICA") appreciates the opportunity to comment on the proposed rule entitled *National Bioengineered Food Disclosure Standards; Updates to the List of Bioengineered Foods*, 85 Fed. Reg. No. 143 (July 24, 2020) (hereinafter "Proposal").

UNICA is the leading trade association for the sugarcane industry in Brazil, representing about 55% of the country's sugarcane production and processing. UNICA serves as a source for credible scientific and economic data about the competitiveness of sugarcane biofuels. UNICA also works to encourage the continuous advancement of sustainability throughout the sugarcane industry and to promote the products of sugarcane domestically and internationally.

Brazil is the world's largest sugarcane and sugar producer in the world¹. In 2019, Brazil produced 29.6 million metric tons of sugar, 64% of which were exported to more than 100 countries worldwide. Brazil's use of sugarcane goes way beyond sugar production. Innovative use of ethanol in transportation and biomass for power cogeneration has made sugarcane a leading source not only of food but of renewable energy in Brazil, representing 18 percent of the country's total energy supply.² In 2019, ethanol consumption accounted for 48.4% of Brazilian Otto cycle consumption³.

¹The Sugar Series: The Top 5 Global Sugar Producers -. CZARNIKOW. https://www.czarnikow.com/ service/physical_trading/the-sugar-series-the-top-5-sugar-producers. Published March 31, 2020.

² Fed. Govt. of Brazil, Ministry of Mines & Energy, Energy Research Office, *Brazilian Energy Balance* (Base year 2019).

³ National Agency of Petroleum, Natural Gas and Biofuels (ANP)

In response to the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) Request for Comments (Document No. AMS-FTPP-20-0057), UNICA would like to respectfully submit the comment below.

In the Proposal, AMS requested comments on whether insect-resistant sugarcane should be added to its List of Bioengineered Foods. In the Federal Register, Vol. 85, No. 143, July 24, 2020, AMS specifies **two criteria** that determines whether a food should be added. **First**, whether the food has been authorized for commercial production somewhere in the world. **Second**, whether the food is currently in legal commercial production for human food somewhere in the world.⁴

We contend that nether criteria apply. The current and near-term cultivation of Centro de Tecnologia Canavieira's (CTC's) bioengineered insect-resistant sugarcane varieties are being cultivated primarily for seedling bulk up and not for human food production. Nonetheless, and more importantly, the sole human food produced from sugarcane industry in Brazil is sugar and AMS has already determined that sugar is not a Bioengineered Food.

The cultivation of bioengineered insect-resistant sugarcane in Brazil is focused on seedling bulk up since it was approved by Brazil's National Technical Commission of Biosafety (CTNBio) in 2017. This is because sugarcane is vegetatively propagated and its rate of hectare expansion is limited by the number of plants under cultivation. This contrasts with crops like maize and soybeans where seed production allows for rapid expansion. For instance, each sugarcane plant produces from four to ten new plants whereas each maize plant produces roughly one hundred fifty seeds. Consequently, the first four to five years of cultivation of any new sugarcane variety focus on plant propagation. Such is the case for CTC's bioengineered insect-resistant sugarcane varieties: available plants are currently used primarily to produce more plants for further cultivation, and not for sugarcane processing.

As AMS' Proposal noted, there were only about 4,000 hectares of insect-resistant sugarcane planted in Brazil in early 2019. According to the USDA's Foreign Agricultural Service GAIN Report, (2019)⁵, the estimated 2019 cultivation of sugarcane in Brazil was 9,900,000 ha. Current and near-term commercial cultivation of bioengineeredsugarcane plants, for the next two to three years, is focused on plant propagation and not for human food production.

It is also important to note that the developer of the bioengineered insect-resistant sugarcane, CTC, is a Brazilian sugarcane breeding and technology company focused entirely on improving the genetics of Brazilian sugarcane varieties. The company recently confirmed to UNICA that it does not currently intend to sell these insect-resistant varieties for commercial cultivation in any other country (see Appendix 1 -- correspondence from CTC dated August 10th, 2020). Therefore, CTC's bioengineered insect-resistant sugarcane varieties are intended to be produced solely for use by the Brazilian sugar-energy sector.

The sugar-energy sector in Brazil is a vertically organized industry and is a major producer of renewable energy in the form of ethanol fuel for transportation and

⁴ "National Bioengineered Food Disclosure Standard; Updates to the List of Bioengineered Foods." Federal Register, 24 July 2020, www.federalregister.gov/documents/2020/07/24/2020-14933/national-bioengineered-food-disclosure-standard-updates-to-the-list-of-bioengineered-foods.

⁵ USDA Foreign Agricultural Service Gain Report; Brazil Sugar Annual 2019; GAIN Report Number BR19005, April 15 2019, <u>https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?</u> filename=Sugar%20Annual_Sao%20Paulo%20ATO_Brazil_4-15-2019.pdf

electricity. Although this is a very diverse and dynamic industry, the only food product of the sector is sugar, in the form of raw and refined sugar. The traditional sugarcane processing by-products are consumed locally in the fermentation (molasses, juice) to produce ethanol. Another important by-product of sugarcane processing is vinasse. The liquid rich in water, potassium, calcium and magnesium is used as a natural fertilizer for sugarcane cultivation. Bagasse, the fibrous material left over after the crushing of the cane, is burned to generate steam for electricity production which currently represents an important source of energy in Brazil. In 2019 bioelectricity from sugarcane generated 36,827 GWh of power, 61% of which was exported to the national grid⁶. In the last 10 years the accumulated bioelectricity from sugarcane is equal to the annual energy consumption of Brazil's North, Southeast, and Center West regions combined. As described in the attached UNICA publications (Appendix 2), the production of the renewable energy sources is very important for Brazilian energy production, and its continued development is specifically noted in Brazil's Bioeconomy strategy and its' commitments for carbon emission reduction as part of the Paris Climate Agreement.

An evaluation of Brazilian export data since 2012 confirms that the only human food exported derived from Brazilian sugarcane processing is sugar (Appendix 3), a pattern that demonstrates that the evolution of the sector effectively eliminated the availability of traditional by-products for export. For example, in the last seven years (2012-2019), no exports of sugarcane plants, *in natura*, fresh or frozen were sent to the international market, including the United States. There were also no meaningful exports of minimally- processed sugarcane-derived products such as bagasse or molasses to the external market, including the United States. There has been a trivial export and erratic export to global markets of miniscule quantities, the purpose of which was to evaluate the low-carbon energy potential of the material (e.g., trivial use of bagasse pellets to evaluate low-carbon fuel for burning). Therefore, the future production and export of human food made from bioengineered insect-protected sugarcane plants grown in Brazil will be sugar, raw or refined.

Sugarcane is not a food *per se* and needs to be processed to produce human food. The processing of sugarcane plants, to produce raw and refined sugar, has been shown, in several studies, to denature and eliminate detectable modified genetic material in sugar (Joyce *et al.*, 2013; Cullis *et al.*, 2014; Cheavegatti-Gianotto *et al.*, 2018, 2019; Sereno *et al.*, 2020)⁷. For example, a recent detailed study by Sereno *et al.* (2019), using highly sensitive qPCR event-specific detection methods that probed for the presence of CTC's varieties in 12 distinct batches of raw sugar produced from the CTC varieties, found no detectable modified genetic material. Identical results were observed in studies of molasses and raw sugar studies (Joyce *et al.*, 2013; Cullis *et al.*, 2014; Cheavegatti-Gianotto *et al.*, 2018). Because raw and refined sugar are

⁶ Number compiled by UNICA based on data from Brazil's Ministry of Mines and Energy

⁷ Cheavegatti-Gianotto et al. (2019) The insect-protected CTC91087-6 sugarcane event expresses Cry1Ac protein preferentially in leaves and presents compositional equivalence to conventional sugarcane, GM Crops & Food, 10:4, 208-219.

Cheavegatti-Gianotto et al. (2018) Lack of Detection of Bt Sugarcane Cry1Ab and NptII DNA and Proteins in Sugarcane Processing Products Including Raw Sugar. Front. Bioeng. Biotechnol. 6:24.

Cullis et al. (2014) DNA and protein analysis throughout the industrial refining process of sugar cane. International Journal of Agricultural and Food Research, v. 3, n. 2, 2014.

Joyce et al. (2013) Sugar from genetically modified sugarcane: tracking transgenes, transgene products and compositional analysis. International Sugar Journal, 115(1380), 864-867.

Sereno et al. (2020) Evaluation of the effects of sugarcane processing on the presence of GM DNA and protein in sugar, GM Crops & Food.

highly- refined, chemically- pure substances, the human food, sugar, is indistinguishable from sugar produced from conventional varieties. The same conclusion has been made regarding sugar produced from bioengineered sugar beets (Klein *et al.*, 1998; Oguchi *et al.*, 2008)⁸. The refined sugar produced from either bioengineered sugarcane and sugar beets are expected to meet all applicable national and CODEX Alimentarius specifications.

In accordance with this, both the US and Brazilian regulatory agencies, specifically the USDA and the CTNBio, responsible for the review, regulation and labeling of human food, have concluded that sugar produced from bioengineered sugarcane do not contain genetic material from the bioengineered plant and are, therefore, not bioengineered foods. The USDA AMS (Federal Register Vol 83, No 245, December 21, 2018 p. 65816) concluded, "AMS has chosen to adopt the definition of "bioengineered food" that hews closely to the plain language of the amended act. This definition references \$66.9 to explain how a regulated entity may demonstrate that a food, including a refined food ingredient, does not contain detectable modified genetic material. AMS has revised the proposed definition of "bioengineered food" to reflect its interpretation of the amended Act that foods with undetectable modified genetic material are not bioengineered foods. Whether a food or food ingredient contains modified generic material may vary depending on the refining process used to product the food. For refined foods that are derived from bioengineered crops, no disclosure is required if the food does not contain detectable modified genetic material." Therefore, per the AMS definition and Federal Register Notice, sugar, the only food product produced from sugarcane, is not a bioengineered food. Similarly, CTNBio, the regulatory and scientific body that reviews biotechnology products in Brazil, including bioengineered crops, has concluded that the highly-purified, chemically-defined human food sugar is not a bioengineered food that requires a safety review, per se, or food labeling (Brazil, 2018)⁹. Neither the US regulatory agency (the USDA AMS) nor the Brazilian CTNBio consider raw or refined sugar as a bioengineered food. Consequently, it is neither appropriate nor accurate to add insect-resistant sugarcane to the List of Bioengineered Foods because sugarcane itself is not a human food and sugar is not a bioengineered food.

In conclusion, the specific situation of the Brazilian insect-resistant sugarcane plants is unique compared with other bioengineered crops globally. But considering the specific situation, the bioengineered sugarcane produced by CTC, and processed by the Brazilian sugar-energy sector, results in the production of raw or refined sugar, a human food that has been determined not to be a bioengineered food. Other byproducts produced from sugarcane processing in Brazil are not exported and consequently do not enter the food and feed chain in the United States. As such, raw and refined sugar does not meet the criteria for Listing as a Bioengineered Foods by AMS.

⁸ Klein et al. (1998) Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets. J Biotech 60, 145–153.

Oguchi et al. (2008) Investigation of Residual DNAs in Sugar from Sugar Beet (Beta vulgaris L.). J. Food Hyg. Soc. Japan. 50:41–46

⁹ The opinion of CTNBio was published in the Brazilian Official Gazette through Technical Opinion No. 5.837/2018. Due to its clarity, it is transcribed (translated) as follows: "*The description of the product* "sugar" contained in the inquiry, allows for its qualification as a "[...] pure chemically defined substance" according to the paragraph 4, article 3, of Law 11,105/2005, since the absence of recombinant DNA and viable organism in the product was proven; As a consequence of this qualification, we concluded that this "sugar" product does not fall within the scope of the Biosafety Law, in its 1st article, and is not a GMO neither a GMO derivative, as set forth in its article 3. At its 210th ordinary meeting, CTNBio unanimously concluded that the product "sugar" produced from genetically modified substance is a "[...] pure, chemically defined substance" according to paragraph 2, article 3, of the Biosafety Law".

Inclusion of sugarcane in the List would only create a discriminatory and costly burden in our industry and a negative impact in the entire supply chain. Therefore, UNI-CA respectfully request AMS not to include sugarcane in the List, based on the specific practical, scientific and regulatory arguments noted above.

UNICA appreciates the opportunity to comment on the Proposal and stands ready to provide AMS with any additional information it needs

Sincerely,

Evandro Gussi

CEO

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