



*Via regulations.gov*

Paul Lewis, Director  
Food Disclosure and Labeling Division  
Fair Trade Practices Program, Agricultural Marketing Services  
U.S. Department of Agriculture  
c/o Docket Clerk  
1400 Independence Ave, SW  
Room 2069-South  
Washington, DC 20250

September 20, 2022

**Re: Agricultural Marketing Service, National Bioengineered Food Disclosure Standard: Annual Updates to the List of Bioengineered Foods, Docket no. AMS-FTPP-20-0057**

Dear Mr. Lewis,

Thank you for the opportunity to comment on the Agricultural Marketing Service's (AMS's) proposed rule to update the List of Bioengineered Foods (the List) under the National Bioengineered Food Disclosure Standard (the Standard or NBFDS). As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at [www.FMI.org](http://www.FMI.org).

**Executive Summary**

FMI recognizes the evolving landscape of bioengineered foods (BE foods) and the need for AMS to routinely evaluate the List to ensure it is accurate and up to date. In the proposed rule, AMS proposes to add to the List "Sugarcane (Bt insect-resistant varieties)" and to revise the description for the existing entry for "Squash (summer)" by changing it to "Squash (summer, mosaic virus-resistant varieties)." AMS is required to consider two specific criteria in making this determination:<sup>1</sup> (1) whether the food has been authorized for commercial production somewhere in the world; and (2) whether the food is currently in legal production for human food somewhere in the world. However, the assessment does not end there. The regulations go on to state that AMS will modify the List if AMS determines that such an update is

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<sup>1</sup> 97 CFR § 66.7(a)(4).



appropriate “following its review of *all relevant information provided*.”<sup>2</sup> As described in more detail below, we believe that a review of all relevant information would call into question whether Sugarcane (Bt insect-resistant varieties) should be added to the List.

Currently, Bt insect resistant varieties of sugarcane are authorized for commercial production only in Brazil. Even then, the majority of Bt insect resistant varieties of sugarcane produced in Brazil is not for human consumption. The varieties are not in legal production in the United States, nor in the other countries from which sugarcane is frequently sourced, and there is a miniscule likelihood BT insect-resistant varieties of sugarcane from Brazil would be imported into the United States. AMS explained in the preamble to the proposed rule that whether a product is likely to end up in the United States is not a factor that AMS is required to consider. While this particular factor is not enumerated as a required consideration, the likelihood of whether a product will end up in the United States, as well as other considerations discussed in more detail below, are indeed relevant in conducting the cost-benefit analysis of making an update to the List, and should be considered by AMS as relevant information.

To that end, FMI is submitting comments on three primary issues:

- First, FMI encourages AMS to reconsider its proposal to add sugarcane (Bt insect-resistant varieties) to the List, as doing so would result in outsized administrative burdens on regulated entities without material benefit to consumers, given the very small amount of imported sugarcane that could potentially be from BE varieties, and that fact that virtually all sugarcane would be processed in a way that renders any modified genetic material non-detectable such that it is not considered a BE food.
- In the alternative, in the event AMS adds Bt insect resistant varieties of sugarcane to the List, in order to account for the current supply chain challenges and in an effort to reduce the administrative burden that would be imposed by this change, FMI requests that AMS:
  - Exercise enforcement discretion related to the BE recordkeeping requirements for sugarcane (BT insect resistant varieties) unless and until there is confirmation that this crop or foods derived from this crop are being imported to the United States for human consumption;
  - Confirm in the preamble to the final rule that no additional recordkeeping is required if a regulated entity has documentation stating that the Sugarcane originated from a country that does not produce BE sugarcane varieties (i.e., any country other than Brazil); and/or
  - Exercise enforcement discretion related to the compliance date for recordkeeping requirements related to sugarcane until 24 months following the effective date of the updated List. This action is justified based on the fact that virtually all

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<sup>2</sup> *Id. at* § 66.7(a)(5) (emphasis added).

products derived from BE varieties of sugarcane will not contain detectable modified genetic material, so the enforcement discretion would relate only to the recordkeeping requirements and would not delay any BE disclosures that otherwise would be made.

- Finally, we encourage AMS to create updated crop summary pages on its website for Squash (summer) and Sugarcane (Bt insect resistant varieties) (if it is added to the List), as well as all other foods on the List, to ensure there is up to date information on how BE varieties are labeled throughout the supply chain, which would help regulated entities comply with the rule.

We address these, and other considerations, in the comments that follow.

### **Detailed Comments**

#### **1. Adding Sugarcane (Bt insect-resistant varieties) to the List would create an outsized administrative burden without material benefit to consumers**

FMI urges AMS to reconsider its proposal to add Sugarcane (Bt insect-resistant varieties) to the List, as doing so would result in overwhelming administrative burden on regulated entities without any material benefit to consumers. As discussed below, FMI is concerned that AMS has miscalculated the estimated costs in conducting its cost benefit analysis for the proposed rule.

- a. The administrative burdens of confirming the source of sugar and complying with the recordkeeping requirements in the Standard are significant.*

In the cost-benefit analysis in the preamble to the proposed rule, AMS notes that “most of the estimated costs are related to a one-time deliberation by food manufacturers to confirm the source of sugar used in their products and to comply with recordkeeping and labeling requirements.” This statement understates the time and resources required to comply with the recordkeeping requirements. Because the NBFDS does not define a regulated entity to include suppliers, food manufacturers commonly need to educate suppliers about the recordkeeping requirements for complying with the NBFDS because they are not familiar with them. Additionally, while the determination only needs to be made once, it may involve multiple outreach efforts to suppliers, who may in turn need to conduct outreach to their own suppliers; evaluation of the information provided; and potentially testing and related recordkeeping.

As an initial matter, all sugarcane products (of any variety) used in foods will be highly refined, and therefore will not contain detectable rDNA and will not require the BE disclosure. Once sugarcane has been refined, the specific sugarcane varietal used to manufacture the sugar (i.e., whether it is Bt insect-resistant) typically does not follow the specifications or other records of sugar shipments as it moves throughout the supply chain. Processed food manufacturers that use cane sugar as an ingredient cannot readily determine the source of the cane sugar based on existing records that are kept as a matter of course. To do so, manufacturers will be required to

coordinate throughout an already overwhelmed supply chain to trace back to the sugarcane source.

As AMS has recognized, it is unlikely that refined cane sugar would contain detectable levels of rDNA,<sup>3</sup> and therefore regulated entities may not have additional labeling costs. However, the costs associated with generating records to demonstrate a product is exempt from disclosure under 9 CFR § 66.9 are significant. Supply chains are currently disrupted due to shortages resulting from the COVID-19 pandemic, international conflicts, and other global crises. Additionally, laboratories are under-resourced and overwhelmed with requests. Therefore, obtaining the detectability test records from laboratories and/or from suppliers is time and resource intensive, a factor that is not contemplated in the AMS cost-benefit analysis.

Even more importantly, AMS calculated estimated costs by only considering UPCs that use cane sugar as an ingredient and that have no other ingredients that would otherwise require labeling of the product as bioengineered. The estimate omits the many UPCs that contain other ingredients derived from BE foods/crops in addition to cane sugar. This omission is significant because any regulated entity that uses cane sugar as an ingredient would be required to conduct the outreach, evaluation, testing, and recordkeeping detailed below, regardless of whether the products also contain other ingredients derived from a BE food in their product. Accordingly, the cost estimate discounts the vast number of products that contain both sugar cane and other ingredients derived from foods on the List, for which recordkeeping and other steps would be required.

*b. Because sugarcane (Bt insect-resistant varieties) is unlikely to be imported to the United States, and the refining process will make any rDNA undetectable, there is no meaningful benefit to consumers from listing this crop.*

Through the cost-benefit analysis, AMS is required to select regulatory approaches that maximize net benefits. However, there is no meaningful benefit to consumers that would justify the significant burdens discussed above. Indeed, it is highly unlikely that any genetically modified sugarcane would make it to U.S. markets and, if so, it would not contain detectable levels of genetic material to warrant disclosure.

Commercial production of genetically modified sugarcane is authorized only in Brazil. Based on the regional planting of sugarcane in Brazil, and import relationships with the United States, the possibility of genetically modified sugarcane intended for human consumption arriving in the United States is extremely low. There are two growing regions in Brazil that are thousands of miles apart: the North-northeastern region, which is responsible for 10% of cane production, and where no genetically modified sugarcane is planted; and the Center South region, which is responsible for 90% of cane production, of which a mere 0.5%-5% of sugarcane planted is estimated to be genetically modified. Moreover, only half of that 0.5-5% of BE sugarcane is planted for use as sugar for human consumption. The remaining half is used in ethanol and for

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<sup>3</sup> 83 Fed. Reg. 65,833-65,834 (Dec. 21, 2018).

seedling bulk up. Further, the United States sources Brazilian sugar predominantly—if not exclusively—from the North-northeast region where Bt insect resistant varieties are not produced. For example, the largest sugar refiners in the United States import sugarcane exclusively from the North-northeast region. Additionally, imports of raw sugar into the United States are governed by tariff-rate quotas (TRQ), and Brazil legislation guarantees that the North-northeast region maintains exclusivity to supply the raw sugar TRQ. Although it is theoretically possible that U.S. importers could import Center South sugars (i.e., either under the U.S. Re-Export Program or by paying a duty outside of the TRQ), it would only be a miniscule percentage.

Moreover, as briefly discussed above, all sugarcane products (of any variety) used in human foods will be highly refined, which eliminates detectable modified genetic material in sugar. Therefore, even if the minimal percentage of genetically modified sugarcane finds its way into the United States, any human food produced from the genetically modified sugarcane would be indistinguishable from sugar produced from conventional varieties and would not ultimately require a BE disclosure. The only difference in this instance would be the recordkeeping requirements triggered by the rule.

In sum, we note that while the regulations require the agency to “consider” the two factors of authorized and actual commercial production when determining updates to the List, the agency’s ultimate action is not bound by this “consideration.” AMS must also consider “all relevant information” and retains discretion as to its decision. We urge AMS to consider both the fact that BT insect-resistant varieties of sugarcane are unlikely to be imported to the United States, as well as the outsized administrative burden placed on regulated entities, without any corresponding benefit to consumers, in any conclusion it reaches.

## **2. In the alternative, FMI urges AMS to provide flexibility for compliance with the obligations under the BE Rule for sugarcane (BT insect resistant varieties)**

If AMS ultimately decides to add sugarcane (Bt insect resistant varieties) to the List, we urge the agency to account for the current supply chain challenges and reduce the outsized administrative burden that would be imposed by the change by offering regulatory flexibility. We have proposed three options that we ask the agency to consider individually or in combination.

First, we ask AMS to exercise enforcement discretion of the BE recordkeeping requirements for Bt insect resistant varieties of sugarcane unless and until there is confirmation that this crop or foods derived from this crop are being imported to the United States. If AMS intends for the List to reflect production of bioengineered foods “on a global level,” we urge the agency to consider limiting enforcement to those products that may directly impact United States consumers.

Second, we request that AMS confirm in the preamble to the final rule that no additional recordkeeping is required if a regulated entity has documentation stating that the sugarcane

originated from a country other than Brazil. This action would be consistent with the AMS guidance provided in the preamble to the final rule, where AMS stated, "If records demonstrate that a product originates from a country where BE food is not commercially grown, those records are sufficient to justify lack of disclosure and demonstrate compliance with the NBFDS."<sup>4</sup> Genetically modified sugarcane is currently grown only in Brazil. Therefore, sugarcane that is sourced from any other country would not be BE.

Finally, adding sugarcane to the List would trigger extensive coordination throughout an already overwhelmed supply chain. To allow for adequate time for regulated entities to determine and document the source of the sugar, conduct necessary detectability testing, and obtain records of such testing, we urge AMS to exercise enforcement discretion in the compliance date for sugarcane recordkeeping requirements to 24 months following the effective date of the updated List. Virtually all products derived from BE varieties of sugarcane will not contain detectable modified genetic material. Therefore, the requested enforcement discretion relates only to the recordkeeping requirements and would not delay any BE disclosures that otherwise would be made.

### **3. We encourage AMS to create updated crop summary pages for Squash, Sugarcane (if added to the List) and all foods on the List**

FMI believes the proposed updates to the List present an opportunity to update the Crop Summary pages available on the AMS website. Each food on the List has a dedicated "Crop Summary" that identifies the BE strain, includes information about its production, origin countries, food safety reviews, and references. These summaries are important tools that can help companies comply with the rule. As discussed above, the global supply chain can be long and convoluted, making it challenging for companies to be able to readily identify typical BE varieties of a food and how they are labeled by growers and suppliers. Although the summaries for some foods include comments such as the trade name for the BE food (e.g., "Pinkglow" for BE Pineapple (Pink Flesh) and "Rainbow and SunUp for Papaya), this is not available for all foods. We encourage AMS to update the Crop Summaries for Squash (summer), Sugarcane (Bt insect resistant varieties) (if added to the List), and all other foods on the List, to include more information about how BE varieties are identified throughout the supply chain. This labeling information, as well as up to date data with respect to production, safety, and producing countries, will help regulated entities to comply with the recordkeeping requirements and more readily determine whether a particular food is itself or is derived from a BE variety.

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<sup>4</sup> 83 FR 65814, 65831 (December 21, 2018).

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FMI thanks AMS for the opportunity to submit comments. Please do not hesitate to contact me with any questions.

Sincerely,



Dana Mullen Graber  
Senior Counsel, Legal and Regulatory Affairs