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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 66

[Doc. No. AMS–FTPP–20–0057]

RIN 0581–AD95

#### National Bioengineered Food Disclosure Standard; List of Bioengineered Foods

**ACTION:** Final rule.

**SUMMARY:** This final rule updates the National Bioengineered Food Disclosure Standard’s (the Standard) List of Bioengineered (BE) Foods (the List) by adding “sugarcane (Bt insect-resistant varieties)” to the List and amending “squash (summer)” to “squash (summer, coat protein-mediated virus-resistant varieties).” In updating the List, this final rule provides consumers with information regarding foods that may be BE and aids regulated entities in determining whether they need to make a BE disclosure.

**DATES:**

*Effective Date:* This rule is effective December 29, 2023.

*Compliance Date:* June 23, 2025.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

#### I. Background

On July 29, 2016, Public Law 114–216 amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*) (amended Act) to require USDA to establish a national, mandatory standard for disclosing any food that is or may be BE. USDA published a final rule (2018 BE final rule) promulgating the regulations (7 CFR part 66) to implement the Standard on December 21, 2018 (83 FR 65814). The regulations became effective on February 19, 2019, with a mandatory compliance date of January 1, 2022. Under 7 CFR 66.1, a BE food is a food that, subject to certain factors, conditions, and limitations, contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

The regulations, at 7 CFR 66.6, contain the List, which currently includes: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ring-spot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet. As stated in the preamble to the 2018 BE final rule, at 83 FR 65852, the List establishes a presumption about what foods require disclosure under the Standard. However, a food or food ingredient’s absence from the List does not absolve regulated entities from the requirement to disclose the BE status of food and food ingredients produced with foods not on the List when the regulated entities have actual knowledge that such foods or food

ingredients are BE. If a regulated entity is using a food or ingredient produced from an item on the List, it must make a BE food disclosure unless it has records demonstrating that the food or ingredient it is using is not BE. Similarly, even if a food is not on the List, a regulated entity must make a BE food disclosure if it has actual knowledge that a food or a food ingredient being used is a BE food or a BE food ingredient. In accordance with 7 CFR 66.7(a)(5), this final rule updates the List.

On July 22, 2022, AMS published a proposed rule in the **Federal Register** seeking public comment on recommendations to update the List (87 FR 43751). In the proposed rule, AMS sought comments on adding “sugarcane (Bt insect-resistant varieties)” to the List and amending “squash (summer)” to “squash (summer, mosaic virus-resistant varieties).” Pursuant to 7 CFR 66.7(a)(3), AMS consulted with the government agencies responsible for oversight of the products of biotechnology, Animal and Plant Health Inspection Service (APHIS), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA), on the proposed updates to the List.

The comment period for the proposed rule closed on September 20, 2022. AMS received a total of 37 comments, out of which 36 comments were related to the proposed rule and one comment was unrelated. Commenters included individuals, consumer groups, companies, and organizations that represent different segments of the food industry. After reviewing the public comments, AMS is proceeding with this final rule to add “sugarcane (Bt insect-resistant varieties)” to the List and amend “squash (summer)” to “squash (summer, coat protein-mediated virus-resistant varieties).” Table 1 summarizes the final revisions to the List.

TABLE 1—UPDATES TO THE LIST

Crop	Regulation	Final rule action
Sugarcane .....	7 CFR 66.6 .....	Add to the List as “sugarcane (Bt insect-resistant varieties)”.
Squash (summer) ...	7 CFR 66.6 .....	Add additional modifier to the existing entry on the List to read “squash (summer, coat protein-mediated virus-resistant varieties)”.

#### II. Comments on the Proposed Rule

Most commenters supported the proposed rule overall, with many stating

that they thought that the two proposed List updates would provide the public with accurate information on the BE

status of foods. There was, however, opposition from two commenters about AMS’s proposal to add “sugarcane (Bt

insect-resistant varieties)” to the List. AMS has reviewed and considered the issues raised by commenters and provides its responses below.

#### 1. Addition to the List

AMS requested public comments on the proposed addition of “sugarcane (Bt insect-resistant varieties)” to the List.

*Comment:* Commenters both supported and opposed the addition of “sugarcane (Bt insect-resistant varieties)” to the List. Commenters in support of the addition of “sugarcane (Bt insect-resistant varieties)” expressed that it would provide more information to consumers. Commenters opposed to the addition of “sugarcane (Bt insect-resistant varieties)” expressed concern that this would place an undue burden on regulated industry for a product that was unlikely to be sold in the United States. Lastly, some commenters suggested that because sugar produced from “sugarcane (Bt insect-resistant varieties)” is highly refined, it does not contain detectable modified genetic material, it is not a BE food, and it should not be added to the List.

*AMS Response:* AMS has considered all the information provided to the agency related to the addition of “sugarcane (Bt insect-resistant varieties)” to the List. AMS has determined that the criteria identified in 7 CFR 66.7(a)(4) are met. “Sugarcane (Bt insect-resistant varieties)” has been authorized for commercial production in Brazil and is currently in legal commercial production for human food in Brazil.<sup>1</sup> There is no statutory or regulatory requirement that a BE food must be sold or grown in the United States for that food to be placed on the List. 7 CFR 66.7(a)(4) states that when determining if a food will be added to the List, “AMS will consider whether foods for inclusion on the List have been authorized for commercial production somewhere in the world, and whether the food is currently in legal commercial production for human food somewhere in the world.” AMS notes that the BE sugarcane grown in Brazil could be sold in the United States as an ingredient in single or multi-ingredient food products.

Additionally, AMS requested commenters provide any data and evidence that would suggest “sugarcane (Bt insect-resistant varieties)” is being used for seeding bulk up rather than

human consumption but did not receive any information in response to this request.

AMS does not believe that the addition of “sugarcane (Bt insect-resistant varieties)” constitutes an undue burden for regulated entities. AMS notes that regulated entities, both domestic and foreign, likely will have customary and reasonable records in accordance with the Standard if they are maintaining records in compliance with other laws and regulations associated with the food sector (83 FR 65830). Records are required to substantiate a decision not to label under 7 CFR 66.9. The Standard at 7 CFR 66.302(a)(4) includes a non-exhaustive list of records that could satisfy the recordkeeping requirements. That list includes, but is not limited to, supply chain records, bills of lading, invoices, supplier attestations, contracts, or brokers’ statements (such as those used to maintain compliance with the Perishable Agricultural Commodities Act); third party certifications (such as organic certifications provided by the USDA’s National Organic Program); laboratory testing results, and validated process verifications. These records could also include country of origin records that show a product or ingredient is from a country that has not authorized a BE variety of the crop for commercial production.

In response to some commenters’ statements that sugarcane is likely highly refined, AMS notes that the List establishes a presumption about what foods and food ingredients are or may be BE. Inclusion on the List does not affirmatively mean an item on the List, or a food produced from an item on the List, is a BE food. Rather, inclusion on the List establishes a presumption and requires a regulated entity to make a BE food disclosure unless it maintains records, in accordance with 7 CFR 66.9, to demonstrate genetic material is not detectable, or that the regulated entity or food qualifies for an exemption listed at 7 CFR 66.5.

*Comment:* One commenter opposed the addition of “sugarcane (Bt insect-resistant varieties)” to the List, noting that while the regulations require AMS to consider whether a food is authorized for commercial production somewhere in the world, and whether the food is currently in legal commercial production for human food somewhere in the world, AMS retains discretion as to its decision. Another commenter noted that in light of AMS’s regulatory requirement to consider “all relevant information,” sugarcane should not be added to the List at this time.

*AMS Response:* As stated in the 2018 BE final rule that established the Standard, the List captures BE crops or foods that meet the statutory definition of bioengineering, based on existing technology, and that could potentially be offered for sale in the United States.<sup>2</sup> In addition, Section 66.1 of the Standard defines the List as a list, maintained and updated by AMS and provided in 7 CFR 66.6, of foods for which BE versions have been developed. Commenters did not dispute that there is a BE version of sugarcane and that a BE version of sugarcane is currently authorized for commercial production and is currently in legal commercial production for human consumption in Brazil.

#### 2. Update to the List

AMS requested public comments on the proposed List update changing “squash (summer)” to “squash (summer, mosaic virus-resistant varieties).”

*Comment:* Most commenters supported updating “squash (summer)” on the List to include a modifier, and no commenters opposed the inclusion of a modifier. As with the addition of “sugarcane (Bt insect-resistant varieties),” commenters generally agreed that updating “squash (summer)” to include a modifier would provide additional information to consumers. Although no commenters were opposed to updating “squash (summer),” one commenter suggested revising the proposed modifier, which is discussed in the next comment discussion below. No commenters addressed AMS’s questions requesting information on the market share of BE and non-BE squash.

*AMS Response:* AMS proposed to update the List entry for “squash (summer)” to “squash (summer, mosaic virus-resistant varieties)” to provide additional descriptive information to stakeholders, including regulated entities and consumers. This change would be consistent with the treatment of other items on the List, where modifiers are included to describe a trait, as is the case with eggplant, papaya, and pineapple. AMS believes the further revised modifier for squash serves these goals as detailed below.

*Comment:* A commenter stated that the proposed “mosaic virus-resistant varieties” modifier is not specific enough to provide meaningful information to consumers. The commenter asked AMS to change the proposed “mosaic virus-resistant varieties” modifier to a more technical

<sup>2</sup> National Bioengineered Food Disclosure Standard, 83 FR 65818 (Dec. 21, 2018).

<sup>1</sup> USDA Foreign Agriculture Service. (2019). Gain Agricultural Information Network: Agricultural Biotechnology Annual Report—Brazil [https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual\\_Brasilia\\_Brazil\\_10-20-2019](https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Brasilia_Brazil_10-20-2019).

modifier to provide more meaningful information to consumers.

**AMS Response:** The goal in adding a modifier to the List entry for squash is to narrow the presumption of what type of squash is considered BE. The preamble to the 2018 BE final rule states, “Where practical, the List includes specific information about individual crops and foods, such as descriptions or trade names, to help distinguish bioengineered versions of those foods from their non-bioengineered counterparts, as requested by commenters.”<sup>3</sup> Amending the modifier for squash to include a more specific descriptor would be consistent with the treatment of other items on the List, where descriptive modifiers are included. A request for comments published July 24, 2020, sought to narrow the scope of the List entry for squash to serve this goal.<sup>4</sup> AMS received 22 comments on the request for comments, and later the proposed rule, supporting a modifier as it would provide additional information to consumers.

The proposed modifier in the request for comments was to amend “squash (summer)” to “squash (summer, virus-resistant varieties).” Comments on the request for comments suggested using a trade name; however, as explained in the proposed rule, the availability of two squash varieties in legal commercial production precludes this option.<sup>5 6</sup> Both varieties provide resistance to mosaic viruses, so the proposed modifier was updated to “mosaic virus-resistant varieties” in the proposed rule. Despite this further refinement, a commenter still noted the modifier was too broad in a comment on the proposed rule.

In response to the comment on the proposed rule, AMS researched whether the modifier was still too broad and if further refinement was indeed required. AMS concluded that further refinement was needed to provide more specific information to regulated entities and consumers on squash varieties requiring disclosure. As technology advances and

new squash varieties are developed, the modifier may need further refinement. The originally proposed modifier, “mosaic virus-resistant varieties”, covers the two BE squash varieties mentioned above, it would also cover squash varieties that are not BE. “Mosaic virus-resistance” specifies the result of the trait, namely that the squash is less susceptible to diseases caused by mosaic virus pathogens<sup>7</sup> “mosaic virus resistance” to describe both BE and non-BE squash that are resistant to mosaic viruses. The two BE squash varieties mentioned above are mosaic virus resistant.<sup>5 6</sup> Non-BE squash varieties could be more resistant to viruses naturally<sup>7</sup> or as a result of conventional breeding,<sup>8 9 10</sup> the result would be a mosaic virus-resistant squash that is not BE. AMS believes that it should refine the modifier to include all BE squash varieties and exclude all non-BE squash varieties.

AMS considered several options for a modifier that would accomplish the above goals and be narrower than “mosaic virus-resistant varieties.” Use of a trade name was not possible, as explained above, because of the availability of two BE squash varieties. The terms “transgenic virus resistance”<sup>11</sup> and “genetically engineered virus resistance”<sup>12</sup> would narrow the “mosaic virus-resistant varieties” modifier. These two modifiers describe the process used to achieve the virus resistance trait; however, the terms “transgenic” and “genetically engineered” are not defined in the Standard. AMS believes that using terms like “transgenic” or “genetically engineered” may create inconsistency with the Standard’s scope of disclosure.

“Pathogen-derived resistance”<sup>13</sup> has been used to describe the traits found in BE squash. However, this modifier is broad and could refer to bacterial or fungal resistance,<sup>14</sup> not just virus resistance. Therefore, it would not be wholly accurate and would not narrow the proposed modifier, “mosaic virus-resistant varieties”. “Coat protein-mediated protection”<sup>15</sup> and “coat protein-mediated virus resistance”<sup>16 17</sup> refer specifically to the trait found in BE squash varieties. Both these terms explain a subset of pathogen derived resistance in which a gene from a virus is added to a plant genome through biotechnology. The added viral coat protein gene then slows or prevents subsequent viral infection. AMS determined that “coat protein-mediated virus resistance” is the preferred terminology as it is more descriptive than “coat protein-mediated protection,” and it is used by academics and the industry. AMS believes the preferred term is more helpful to regulated entities and consumers. Both varieties of BE squash mentioned above use coat protein-mediated virus resistance to achieve mosaic virus resistance. Only BE squash is known to have coat protein-mediated virus resistance. The “coat protein-mediated virus-resistant varieties” modifier is more specific than “mosaic virus-resistant varieties” and currently pertains only to mosaic virus resistance achieved in BE squash varieties.<sup>18</sup>

<sup>13</sup> Baulcombe, D.C. (1996). Mechanisms of pathogen-derived resistance to viruses in transgenic plants. *The plant cell*, 8(10), 1833. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC161318/>.

<sup>14</sup> Canto-Pastor, A., Santos, B.A., Valli, A.A., Summers, W., Schornack, S., & Baulcombe, D.C. (2019). Enhanced resistance to bacterial and oomycete pathogens by short tandem target mimic RNAs in tomato. *Proceedings of the National Academy of Sciences*, 116(7), 2755–2760. <https://www.jstor.org/stable/26682958>.

<sup>15</sup> Gonsalves, D. & Slightom, J.L. (1993). Coat protein-mediated protection: analysis of transgenic plants for resistance in a variety of crops. *Seminars in Virology*, 4, 397–405. <https://doi.org/10.1006/smv.1993.1039>.

<sup>16</sup> Beachy, R.N., Loesch-Fries, S., & Tumer, N. (1990). Coat protein-mediated resistance against virus infection. *Annual Review of Phytopathology*, 28, 451–474. <https://doi.org/10.1146/annurev.py.28.090190.002315>.

<sup>17</sup> Lindbo, J.A., & Falk, B.W. (2017). The impact of “coat protein-mediated virus resistance” in applied plant pathology and basic research. *Phytopathology*, 107(6), 624–634. <https://doi.org/10.1094/phyto-12-16-0442-rvw>.

<sup>18</sup> Tricoll, D.M., Carney, K.J., Russell, P.F., McMaster, J.R., Groff, D.W., Hadden, K.C., Himmel, P., T., Hubbard, J.P., Boeshore, M.L., & Quemada, H.D. (1995). Field evaluation of transgenic squash containing single or multiple virus coat protein gene constructs for resistance to cucumber mosaic virus, watermelon mosaic virus 2, and zucchini yellow mosaic virus. *Bio/technology*, 13(12), 1458–1465. <https://doi.org/10.1038/nbt1295-1458>.

<sup>7</sup> Martín-Hernández, A.M., & Picó, B. (2020). Natural resistances to viruses in cucurbits. *Agronomy*, 11(1), 23. <https://doi.org/10.3390/agronomy11010023>.

<sup>8</sup> Schultheis, J.R., & Walters, S.A. (1998). Yield and virus resistance of summer squash cultivars and breeding lines in North Carolina. *HortTechnology*, 8(1), 31–39. <https://doi.org/10.21273/HORTTECH.8.1.31>.

<sup>9</sup> Harris Seeds Product Page. (n.d.). Squash Reward F1 Seed. Product number 11780-00-01-012. <https://www.harrisseed.com/products/11780-squash-reward-f1?variant=12427665539144>.

<sup>10</sup> Bayer Group. (2022). Agronomic Spotlight: Mosaic Virus Diseases of Squash. <https://www.vegetables.bayer.com/us/en-us/resources/growing-tips-and-innovation-articles/agronomic-spotlights/mosaic-virus-diseases-of-squash.html>.

<sup>11</sup> Mueller, E., Gilbert, J., Davenport, G., Brigneti, G., & Baulcombe, D.C. (1995). Homology-dependent resistance: transgenic virus resistance in plants related to homology-dependent gene silencing. *The Plant Journal*, 7(6), 1001–1013. <https://doi.org/10.1046/j.1365-3113x.1995.07061001.x>.

<sup>12</sup> Grumet, R. (1990). Genetically engineered plant virus resistance. *HortScience*, 25(5), 508–513. <https://doi.org/10.21273/HORTSCI.25.5.508>.

<sup>3</sup> National Bioengineered Food Disclosure Standard, 83 FR 65819 (Dec. 21, 2018).

<sup>4</sup> USDA-AMS (2022). Public Comments for Proposed Rule: National Bioengineered Food Disclosure Standard: Updates to the List of Bioengineered Foods (Docket AMS-FTPP-20-0057). <https://www.regulations.gov/document/AMS-FTPP-20-0057-0001>.

<sup>5</sup> U.S. FDA. (1997). Consultations on Food from New Plant Varieties. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=SEM%2D0CZW3%2D2>.

<sup>6</sup> U.S. FDA. (1994). Consultations on Food from New Plant Varieties. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=SEM%2D0CZW20%2D7>.

Therefore, the “coat protein-mediated virus-resistant varieties” modifier encompasses both BE varieties of squash without including any non-BE varieties. AMS believes that this modifier narrows the List entry for squash and will amend the List using this modifier. With the addition of the modifier, summer squash that is not a coat protein-mediated virus-resistant variety will no longer be presumed to be a BE food.

AMS consulted with the government agencies responsible for oversight of the products of biotechnology, APHIS, EPA, and FDA, regarding the two updates to the List, including the updated “coat protein-mediated virus-resistant varieties” modifier. Representatives from APHIS and FDA had no comments on the use of “coat protein-mediated virus-resistant varieties” for the modifier used on the List. EPA suggested adding “gene” to the modifier: “coat protein gene-mediated virus-resistant varieties.” EPA’s suggestion would clarify that “coat protein” is the name of the gene that encodes the coat protein of a virus and that it is the presence of the gene in BE squash that confers resistance to mosaic viruses, rather than the protein product of the gene. While EPA’s proposed modifier may provide more scientific clarity, AMS will use “coat protein-mediated virus-resistant varieties” without adding “gene.” AMS believes adding “gene” to the commonly used, AMS-preferred term would not provide any additional insight for consumers in identifying what foods are presumed to be a BE food.

### 3. Information Collection and Recordkeeping Comment

Commenters expressed that the proposed amendment would create burdens in connection with recordkeeping for sugarcane. They recommended that sources, trade names, and modifiers should be included on the List to minimize the recordkeeping burden of substantiating a determination not to disclose. One commenter stated that AMS’s economic analysis was flawed. The commenter stated that AMS miscalculated the costs associated with the use of sugarcane in products, underestimating the time and resources required to comply with the recordkeeping requirements. The commenter also stated that AMS calculated estimated costs by erroneously considering only Universal Product Codes (UPCs) that use cane sugar as an ingredient. The commenter contends that this analysis does not account for the costs incurred by regulated entities with those UPCs that contain other ingredients made from BE

foods and crops in addition to cane sugar. The commenter’s position is that these regulated entities would incur costs associated with their use of cane sugar regardless of whether the final product contains other BE ingredients or ingredients derived from BE sources.

*AMS Response:* AMS has considered all information provided to the agency related to the modifier for sugarcane and has determined “sugarcane (Bt insect-resistant varieties)” to be the most precise naming convention to minimize the recordkeeping burden. The List includes specific information about certain individual crops and foods, such as modifiers or trade names, to help distinguish BE versions of those foods from their non-BE counterparts. The specificity of the sugarcane modifier “Bt insect-resistant varieties” is intended to identify foods for which disclosure may be necessary, based on the regulated entities’ records. There would be no presumption that sugarcane or sugarcane-derived ingredients would be BE unless they were sourced from Bt insect-resistant varieties. Regulated entities may refer to the AMS website to obtain additional information regarding the associated BE events for crops or foods they are sourcing and determine whether they need to make a disclosure.

Products with potential BE ingredients (other than cane sugar) do not need to be added into the calculation for recordkeeping costs (since the recordkeeping costs associated with those ingredients are already included in the cost of the baseline program). Products that could use BE varieties of sugarcane, but list only “sugar” as an ingredient already require recordkeeping under the Standard and thus were not considered when estimating costs associated with this rule. If a regulated entity was already disclosing a BE food, their disclosure requirements would not change, nor would they incur additional costs.

Customary and reasonable records can be used to justify non-disclosure for sugarcane-containing products. For further details on the economic analysis, see Section III.D of this rule.

*Comment:* Commenters explained that recordkeeping for refined sugars typically does not follow standard recordkeeping specifications that track the sugar back to its source. Commenters further stated that generating records and coordinating with suppliers and laboratories for such records is a significant cost. Due to these obstacles, commenters requested a 24-month enforcement discretion period for recordkeeping of sugarcane.

*AMS Response:* The final rule at 7 CFR 66.7(b) states that, “regulated entities will have 18 months following the effective date of the updated List of Bioengineered Foods to revise food labels to reflect changes to the List in accordance with the disclosure requirements.” After considering input from commenters and other available information when drafting the 2018 BE final rule, AMS recognized that regulated entities should have sufficient time to transition their recordkeeping and labeling processes and procedures to implement the BE disclosure requirements. AMS continues to believe that regulated entities will have sufficient time to update recordkeeping procedures and to revise food labels to reflect changes to the List contained in this update within the 18-month compliance phase-in period.

### 4. Outreach and Education

*Comment:* Commenters requested increased outreach and education to consumers on BE foods to include definitions for the descriptions of resistant varieties.

*AMS Response:* AMS intends to update the List on its website consistent with this final rule. Any definitions for the modifiers of resistant varieties included in this final rule will be reflected on the AMS website. The AMS website provides consumers and regulated entities with additional information including FDA-reviewed BE events in the food supply, BE varieties, trade names, source, and traits (*e.g.*, non-browning, pesticide resistance, virus resistance, enhanced growth, etc.) for items on the List. While the List names each food known to have a BE variety, this additional information on the website seeks to enumerate each available BE variety. Regulated entities can use this information, to better understand if their products require a BE disclosure. Similarly, consumers can use this information to understand the types of BE products available. AMS will continue to update the website and corresponding outreach materials as new information becomes available.

## III. Required Regulatory Analyses

### A. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the information collection related to the Standard has previously been approved by OMB and assigned OMB No. 0581–0315—National Bioengineered Food Disclosure Standard. AMS estimates that changes in the recordkeeping burden due to the

proposed revisions to the List would be minimal.

Generally, the records necessary to substantiate the need for a disclosure are customary and reasonable, and maintained in the usual course of business. The same records would be required to substantiate a decision not to label under 7 CFR 66.9. Limiting reporting to specific varieties of summer squash does not impact recordkeeping. Entities may still be subject to an examination of customary or reasonable records for summer squash following a BE audit, as outlined in 7 CFR 66.402.

AMS requested comments with data or information on market share or proportion of squash of virus-resistant varieties and the number of entities that might be impacted by this change as part of the proposed rule during the 60-day comment period. While AMS received two comments during the open comment period for the Information Collection renewal request published in 2022,<sup>19</sup> those comments were not substantive and did not include any data or comments on market share or proportion of virus-resistant varieties of squash.

#### B. Civil Rights Review

AMS has considered the potential civil rights implications of this final rule on minorities, women, or persons with disabilities to ensure that no person or group shall be discriminated against based on race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities that are subject to these regulations.

The 2018 BE final rule offers several distinct avenues of compliance for regulated entities that can be tailored to the needs of their consumers. This final rule to update the List of BE Foods does not alter those options. No persons or groups are denied the benefits of the program nor are any persons or groups subjected to discrimination by making amendments to the List. The amended Act is a federal law that established a national, mandatory standard for disclosing any food that is or may be BE. The law applies generally to all persons conducting business subject to the Standard. Congress declared in the amended Act that “a sound, efficient, and privately operated system for distributing and marketing agricultural

products is essential to a prosperous agriculture and is indispensable to the maintenance of full employment and to the welfare, prosperity, and health of the Nation”.<sup>20</sup>

USDA, AMS’ Food Disclosure and Labeling Division administers and enforces the Standard and its regulations and is responsible for establishing new rules as needed. This final rule updates the List of BE Foods at 7 CFR 66.6 by adding “sugarcane (Bt insect-resistant varieties)” to the List and amending “squash (summer)” to “squash (summer, coat protein-mediated virus-resistant varieties)” under the Standard. Regulated entities, subject to this final rule, and consumers who benefit from the rule, would not be required to apply to any program or opt-in to participate. This final rule is not intended to: (1) opt-in any stakeholder to participation under the AMS final rule; and/or (2) recruit any stakeholder including consumers, retailers, manufacturers, or importers. The regulation acts as a federal law that would establish the requirement for BE food disclosure to consumers; and regulated entities that fail to disclose would be subject to an investigation and results reported on the AMS website.

#### C. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175—Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This final rule may impact individual members of Indian Tribes that operate as food manufacturers or retailers; however, AMS has determined that this final rule does not have a direct effect on Tribes or the relationship or distribution of power and responsibilities between the Federal Government and Indian Tribes that would require consultation. AMS continues to engage with Tribes on such changes, including through teleconference calls on March 11, 2021,

and July 22, 2021, where AMS provided Tribal representatives with an overview of the upcoming proposed rule that would add “sugarcane (Bt insect-resistant varieties)” to the List, amend “squash (summer)” to include the modifier “mosaic virus-resistant varieties” and extended the opportunity for questions and requests for additional information. At that time, AMS received no questions or requests from Tribal representatives.

On September 20, 2022, the comment period for the proposed rule closed. Only one comment out of 37 comments received on the proposed rule was identified as being submitted from a Tribal representative. The commenter acknowledged the proposed rule provides transparency to the consumer about BE foods and stated that the Tribal groups have not yet seen if certain groups will be affected, but the exemptions seem to offer such groups with a cushion. AMS will continue to extend outreach to ensure Tribe members are aware of the requirements and benefits under this final rule once effective. Where Tribes request consultation on relevant matters that are not required under legislation, AMS will collaborate with the Office of Tribal Relations to ensure meaningful consultation is provided.

#### D. Executive Orders 12866, 14094 and 13563

USDA is issuing this final rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, which include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This rule has been designated “Significant” under Executive Order 12866 as amended by Executive Order 14094. To provide sufficient time to help mitigate impacts to regulated entities, pursuant to 7 CFR 66.7(b), regulated entities have 18 months following the effective date of the updated List of Bioengineered Foods to revise food labels to reflect changes to the List in accordance with the disclosure requirements of this part.

<sup>19</sup> USDA–AMS. (2022). Public Comments for the National Bioengineered Food Disclosure Standard Information Collection Renewal (Docket AMS–22–0005–0001). <https://www.regulations.gov/document/AMS-AMS-22-0005-0001>.

<sup>20</sup> Agricultural Marketing Act of 1946”. Sec 202. [7 U.S.C. 1621 note] <https://www.govinfo.gov/content/pkg/COMPS-10259/pdf/COMPS-10259.pdf>.

AMS identified three benefits of this rule. First it fulfills the regulatory responsibility to update the List according to 7 CFR 66.7. Sugarcane has satisfied the criteria for inclusion, as does the amendment to squash; in addition, the amendment to squash was initiated by a comment from the stakeholder. The updates in this final rule inform consumers whether certain products are BE, and aid regulated entities in determining if their product requires disclosure. Second, this rule provides specific information to consumers about the types of BE foods that are or could become available for retail sale. Third, this rule removes the presumption that all summer squash is BE and now only “coat protein-mediated virus-resistant varieties” will be presumed to be BE.

Cost changes due to this action will be limited to the addition of “sugarcane (Bt insect-resistant varieties)” to the List because regulated entities have already incurred costs associated with the inclusion of summer squash on the List. More specifically, processors and retailers of summer squash are already required to keep records to justify their decision to label or not label their product. The addition of a new modifier to summer squash does not absolve regulated entities of the recordkeeping responsibility. The number of BE “squash (summer, coat protein-mediated virus-resistant varieties)” that must be labeled will remain the same as the number of BE “squash (summer)” that were required to be labelled pursuant to the original List in the 2018 BE final rule. All BE squash still must bear a disclosure. With the addition of the modifier, summer squash that is not a coat protein-mediated virus-resistant variety will no longer be presumed BE. The record keeping burden for regulated entities selling summer squash, or products with summer squash ingredients will also remain the same, since regulated entities are required to maintain records demonstrating that their product is not BE to satisfy the requirements of 7 CFR 66.302.

The addition of “sugarcane (Bt insect-resistant varieties)” to the List would not significantly increase the cost of compliance with, or enforcement of, the BE labeling requirements. To estimate the cost of this action, we used the Label Insight Database to determine the number of products that use sugarcane as an ingredient, and which have no other ingredients that would otherwise require labeling of the product as BE as described in the Regulatory Impact Analysis for the 2018 BE final rule on

page 19.<sup>21</sup> A total of 10,600 individual UPCs were identified using this criterion. Products that could use BE varieties of sugarcane, but list only “sugar” as an ingredient already require recordkeeping under the Standard and thus were not considered when estimating costs associated with this rule.

Increased costs associated with this rule are analytical costs and testing costs. Analytical costs represent the administrative costs of determining applicability of the Standard to products and compiling any records that may be required. Testing costs represent the costs that regulated entities would incur to test their products for detectable modified genetic material. The upper and lower bounds of the estimate were calculated by multiplying 10,600 UPCs by the unit cost for testing for detectability (unit cost range: \$153–\$431) and for analytical costs (unit cost range: \$376–\$3,084) as described in the Regulatory Impact Analysis for the 2018 BE final rule.<sup>22</sup> This is likely an overestimate of costs, as a test may be used to cover multiple UPCs. For example, different sizes of the same product would have different UPCs yet require only a single test for the product. AMS estimates that the costs associated with this action would range from \$6 million to \$37 million for the initial year, with no ongoing annual costs and no significant change in benefits. The annualized cost would be between \$500,000 and \$3.5 million (annualized over 20 years using a seven percent discount rate). Most of the estimated costs are related to a one-time deliberation and potential testing by food manufacturers to confirm the source of sugar used in their products and to comply with recordkeeping and labeling requirements.

#### *E. Final Regulatory Flexibility Analysis*

AMS has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of

the rule on small entities, consistent with statutory objectives. AMS has concluded that the rule will not have a significant economic impact on a substantial number of small entities.

The addition of “sugarcane (Bt insect-resistant varieties)” and amendment of “squash (summer)” to “squash (summer, coat protein-mediated virus-resistant varieties)” to the List would directly affect three industry sectors: manufacturers that process sugarcane, processed food manufacturers that use sugarcane or summer squash as ingredients, and grocery or other retailers that sell raw sugarcane or summer squash.

According to the 2017 Study of U.S. Business (SUSB) from the U.S. Census, there were 37 manufacturers that process sugarcane in the United States. Approximately 32 of these manufacturers would meet the Small Business Administration definition of small. Of the 32 small firms, 11 would also qualify as very small food manufacturers under the Standard and would be exempt from disclosure requirements. Accordingly, those 11 firms would incur no costs associated with the addition of “sugarcane (Bt insect-resistant varieties)” to the List. The remaining 21 small firms would not likely face significant costs as they only have one product and are likely to know where the cane for their sugar originates. At this time “sugarcane (Bt insect-resistant varieties)” is grown commercially only in Brazil. If “sugarcane (Bt insect-resistant varieties)” becomes more prevalent, manufacturers that process sugarcane may incur additional costs associated with substantiating non-disclosure (e.g., maintaining customary and reasonable records on the origin of the sugarcane processed into sugar, certification costs associated with demonstrating that the final product has no detectable modified genetic material). If the refinement of cane sugar, like beet sugar, would verifiably not contain detectable modified genetic material and therefore would not be BE, cane sugar producers would face minimal labeling costs.

Processed food manufacturers that use sugarcane as an ingredient will need to determine whether the sugar they use is BE—assuming sugar made from “sugarcane (Bt insect-resistant varieties)” makes it into the U.S. market. Most food manufacturers already face costs associated with determining whether their ingredients are BE and maintaining records to demonstrate that determination. The marginal cost associated with an additional ingredient is expected to be small. As noted in section III(D) of this rule, the costs

<sup>21</sup> USDA–AMS. (2019). Regulatory Impact Analysis for the Proposed Rule: National Bioengineered Food Disclosure Standard: Updates to the List of Bioengineered Foods (Docket AMS–TM–17–0050–14035). <https://www.regulations.gov/document/AMS-TM-17-0050-14035>.

<sup>22</sup> USDA–AMS. (2019). Regulatory Impact Analysis for the Proposed Rule: National Bioengineered Food Disclosure Standard: Updates to the List of Bioengineered Foods (Docket AMS–TM–17–0050–14035). <https://www.regulations.gov/document/AMS-TM-17-0050-14035>.

associated with this final rule will be limited to administrative costs to analyze applicability of the rule and compliance and validation testing to determine the presence of detectable modified genetic material in affected products. As with beet sugar, it is unlikely that refined sugarcane would contain detectable levels of modified genetic material. As a result, regulated entities may not have additional labeling costs due to the addition of “sugarcane (Bt insect-resistant varieties)” to the List.

Food manufacturers whose products contain summer squash and retailers that sell uncooked summer squash will see no change in costs as the amendment to the List would reduce the varieties of squash that are presumed to be a BE food. Food manufacturers whose products contain summer squash and retailers that sell uncooked summer squash are already maintaining records or labeling relevant products in accordance with the Standard.

Food manufacturers that use summer squash are likely concentrated in Fruit and Vegetable Preserving and Specialty Food Manufacturing (The North American Industry Classification System (NAICS) 3114). This industry sector had 1,540 firms listed in the 2017 Statistics of US Businesses. Of these, approximately 1,475 would be classified as small. Additionally, 904 firms would be classified as very small food manufacturers by the Standard and are therefore exempt. Food manufacturers already face the administrative costs associated with using a product on the List. The final rule would make it easier for regulated entities, who are already maintaining records in compliance with the Standard, to demonstrate that labeling is not required if they know they are not receiving BE varieties. Costs to small food manufacturers using summer squash therefore will remain unchanged by this proposal.

Retailers will not see a change in the number of labels required as a result of the change in the modifier of summer squash or by the addition of sugarcane. Summer squash that meets the requirement for disclosure under the 2018 BE final rule will also meet the requirement for disclosure under this amendment. The same number of labels are required under the two rules. Therefore, the cost to retailers will remain unchanged. Therefore, the costs to each of the three affected industry sectors would not be significant. For these reasons, AMS is certifying that this rule to add “sugarcane (Bt insect-resistant varieties)” to the List and limiting the varieties of squash listed as BE foods to “summer, coat protein-

mediated virus-resistant varieties” will not have a significant economic impact on a substantial number of small entities.

#### F. Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. The final rule is not intended to have retroactive effect. All labeling claims made in conjunction with this regulation must be consistent with other applicable Federal requirements. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

#### G. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), the Office of Information and Regulatory Affairs has determined that this action does not meet the criteria set forth in 5 U.S.C. 804(2).

#### List of Subjects in 7 CFR Part 66

Agricultural commodities, Food labeling, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Agricultural Marketing Service amends 7 CFR part 66 as set forth below:

### PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

- 1. The authority citation for part 66 continues to read as follows:

**Authority:** 7 U.S.C. 1621 *et seq.*

- 2. Revise § 66.6 to read as follows:

#### § 66.6 List of bioengineered foods.

The List of Bioengineered Foods consists of the following: Alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer, coat protein-mediated virus-resistant varieties), sugarbeet, and sugarcane (Bt insect-resistant varieties).

**Erin Morris,**

*Associate Administrator, Agricultural Marketing Service.*

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## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### 12 CFR Part 34

[Docket No. OCC–2023–0012]

RIN 1557–AF23

## FEDERAL RESERVE SYSTEM

#### 12 CFR Part 226

[Docket No. R–1819]

RIN 7100–AG19

## CONSUMER FINANCIAL PROTECTION BUREAU

#### 12 CFR Part 1026

### Appraisals for Higher-Priced Mortgage Loans Exemption Threshold

**AGENCY:** Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); and Consumer Financial Protection Bureau (Bureau).

**ACTION:** Final rules, official interpretations, and commentary.

**SUMMARY:** The OCC, the Board, and the Bureau are finalizing amendments to the official interpretations for their regulations that implement section 129H of the Truth in Lending Act (TILA). Section 129H of TILA establishes special appraisal requirements for “higher-risk mortgages,” termed “higher-priced mortgage loans” or “HPMLs” in the agencies’ regulations. The OCC, the Board, the Bureau, the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), and the Federal Housing Finance Agency (FHFA) (collectively, the Agencies) jointly issued final rules implementing these requirements, effective January 18, 2014. The Agencies’ rules exempted, among other loan types, transactions of \$25,000 or less, and required that this loan amount be adjusted annually based on any annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). If there is no annual percentage increase in the CPI–W, the OCC, the Board, and the Bureau will not adjust this exemption threshold from the prior year. Additionally, in years following a year in which the exemption threshold was not adjusted because the CPI–W decreased, the threshold is calculated by applying the annual percentage increase in the CPI–W to the dollar amount that