

AMS Civil Rights Program
Civil Rights Impact Analysis: Fair Trade Practices Program
Proposed Rule; National Bioengineered Food Disclosure Standard (the Standard): Updates
to the List of Bioengineered Foods (the List)

Regulation
Civil Rights Impact Analysis

Agency: Agricultural Marketing Service
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Title of Action: Proposed Rule; National Bioengineered Food Disclosure Standard (the Standard): Updates to the List of Bioengineered Foods (the List)

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 bioengineered. In accordance with the amended Act, USDA published final regulations 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 bioengineered food is a food that, subject to certain factors, conditions, and limitations, contains detectable 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 7 CFR 66.6 regulations include the AMS List of Bioengineered Foods (the List), which currently are: 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), and sugarbeet.

As stated in the preamble to the final rule, at 83 FR 65852, the List “establishes a presumption about what foods might require disclosure under the Standard, but does not absolve regulated entities from the requirement to disclose the bioengineered 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 bioengineered.” As a result, if a regulated entity is using a food or ingredient produced from an item on the List, they must make a bioengineered food disclosure unless they have records demonstrating that the food or ingredient they are using is not bioengineered. Similarly even if a food is not on the List, a regulated entity must make a bioengineered food disclosure if they have actual knowledge a food or ingredient they are using is a bioengineered food or a bioengineered food ingredient.

As stated in 7 CFR 66.7(a), AMS will review and consider updates to the List on an annual basis and will solicit recommendations regarding updates to the List through notification in the Federal Register and on the AMS website.

On July 24, 2020, AMS published a Notice in the Federal Register seeking public comment on recommendations to update the List (85 FR 44791). In that Notice, AMS sought comments on adding one item to the List - “sugarcane (insect-resistant)” and amending one item currently on the List “squash (summer),” by adding “virus-resistant” after “summer,” making it “squash (summer, virus resistant).” AMS also sought comment on two other foods it considered for addition to the List: cowpea and rice.

The comment period for the Notice closed on August 24, 2020. AMS received a total of 17 comments. Based on the public comments, AMS is proceeding with this proposed rule to add sugarcane (insect-resistant) and amend squash (summer) to squash (summer, virus resistant). In the first notice seeking comments in 2020, AMS identified bioengineered versions of cowpea and golden rice are at various stages of authorization or have been authorized for commercial production but are not yet in legal commercial production for human food. Although AMS believes these foods do not yet meet the criteria in 7 CFR 66.7(a)(4) to be added to the List, AMS sought public comment to determine if additional information is publicly available. AMS did not receive any comments on cowpea or rice and is not proposing any action related to those two crops at this time.

AMS received comments that both supported and opposed adding sugarcane to the List. Those in favor of adding sugarcane to the List generally agreed that sugarcane met the dual criteria identified at 7 CFR 66.7(a)(4) to be added to the List: (1) authorized for commercial production somewhere in the world, and (2) currently in legal commercial production for human food somewhere in the world. In addition, several comments noted that adding sugarcane to the List would provide consumers with more information about their food.

AMS confirmed that sugarcane is both: (1) authorized for commercial production somewhere in the world, and (2) currently in legal commercial production for human food somewhere in the world. As a result, AMS is proposing that “sugarcane (insect-resistant)” be added to the List.

Commenters generally acknowledged that sugarcane is authorized for commercial production in Brazil and that commercial production is currently taking place. Those opposed to adding sugarcane to the List generally suggested that bioengineered sugarcane produced in Brazil is primarily used to bulk up seedling production at this time. While one commenter suggested that existing production is primarily for seedling bulk up, they did not suggest that is the exclusive use and did not indicate that no existing production will be used for human food.

Another commenter suggested that sugarcane produced in Brazil is unlikely to end up in the United States. Although this may be the case, whether a product is likely to end up in the United States is not a factor that AMS must consider under 7 CFR 66.7. The List reflects production of bioengineered foods on a global level and does not consider whether such foods are likely to end up in the United States. At present, some items on the List are not likely to be sold in the United

States but are still included on the List to reflect global production.

Last, some commenters suggest that because sugarcane is only turned into sugar, which is highly refined to the point that modified genetic material is no longer detectable, it therefore would not be considered a bioengineered food and should not be added to the List.

This assertion misstates the law. As stated above, the List establishes a presumption about which foods are or may be bioengineered. 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 bioengineered food. Rather, it establishes a presumption and means a regulated entity must make a bioengineered food disclosure unless they maintain records, in accordance with 7 CFR 66.9, to demonstrate that modified genetic material is not detectable.

Because the criteria identified in 7 CFR 66.7(a)(4) are met, AMS is proposing to update the List to include sugarcane (insect-resistant).

Commenters were generally supportive of adding an additional modifier to the existing entry for squash. One commenter noted that the additional information increases transparency and provides more information to consumers.

Another commenter asked that AMS consider additional specificity by further amending the entry for squash to include the specific trade name, Performance Series. As mentioned in the preamble to the Final Rule (83 FR 65819), AMS will, where practical, include specific trade names “to help distinguish bioengineered versions of those foods from their non-bioengineered counterparts.” Indeed, AMS included specific trade names for Arctic variety apples and AquAdvantage brand salmon. 7 CFR 66.6. In both instances, only one entity completed the premarket notification and/or approval process. Unlike apple or salmon, summer squash has had more than one entity complete the premarket notification and approval process. Similar to potato, which does not have a specific trade name on the List, summer squash has had more than one entity complete the premarket notification and approval process. As explained in the preamble to the Final Rule, items on the List will necessarily become more generic as more versions are available. 83 FR 65819. As a result, AMS is not proposing to add a specific trade name to summer squash. However, adding virus-resistant to the existing description will reduce the recordkeeping burden for regulated entities.

In summary, AMS is proposing to amend the List to be the following:

1. Alfalfa
2. Apple (Arctic™ varieties)
3. Canola
4. Corn
5. Cotton
6. Eggplant (BARI Bt Begun varieties)
7. Papaya (ringspot virus-resistant varieties)
8. Pineapple (pink flesh varieties)
9. Potato
10. Salmon (AquAdvantage®)

11. Soybean
12. Squash (summer virus-resistant varieties)
13. Sugarbeet
14. Sugarcane (insect-resistant)

The authority for this proposed rule is under the Administrator, Agricultural Marketing Service. AMS expects to publish this proposed rule updating the List in Spring, 2022. To assist the industry in complying with the new regulations for the List, the regulated entities will have 18 months following the effective date of the updated the List to revise food labels to reflect changes to the List in accordance with the disclosure requirements.

Analysis:

Data Analysis

AMS established baseline data using principal operators for all sectors in U.S. Population in 2012 and the impact rates of the groups were measured using data from the 2017 Annual Economic Survey for the United States.

Table 1. Program Participants Race/Ethnicity/Gender Data for Firms with or without paid employees

| Principal Operators in U.S.(Census 2012- 27,626,360) | | | | | | | |
|--|------------------------|---------------------------|-------------------|---|-----------------------------------|--------|--------|
| Hispanic or Latino | Non-Hispanic or Latino | | | | | Total | |
| | White | Black or African American | Asian American PI | Native Hawaiian or Other Pacific Islander | American Indian or Alaskan Native | M | F |
| 12.00% | 78.00% | 9.40% | 6.90% | 0.00% | 1.00% | 53.70% | 35.80% |
| Impacted (Census Data 2017 - 644,066) | | | | | | | |
| Hispanic or Latino | Non-Hispanic or Latino | | | | | Total | |
| | White | Black or African American | Asian American PI | Native Hawaiian or Other Pacific Islander | American Indian or Alaskan Native | M | F |
| 4.50% | 88.01% | 0.64% | 6.34% | 0.12% | 0.26% | 81.46% | 18.54% |

The data indicates that in 2012 of the 27,626,360 firms in the United States for all sectors; 53.70% are male, 35.80% are female, 78.00% are White, 12.00% are Hispanic/Latino, 1.00% are American Indians/Alaskan Natives, 6.90% are Asians, and 9.40% are Black or African Americans. The proposed rule impacts firms in the food, beverage, and chemical manufacturing sectors.

The data indicates that in 2017 of the 644,066 firms, there were 4.50% Hispanic/Latino, 88.01% White, 0.64% Black or African Americans, 6.34% Asians, 0.12% Native Hawaiian or Other Pacific Islanders, 0.26% American Indian/Alaska Natives, 81.46% males, and 8.54% females.

**DISPROPORTIONATE IMPACT – (10 PERCENT ANALYSIS)
FIRMS, WITH OR WITHOUT PAID EMPLOYEES**

We established a baseline using Principal Operators for all sectors in U.S. Population in 2012. We measured disparate impact using a 10% variance to determine disproportionate impact. We used a 10% variance to determine if the impact rates of the groups from the 2017 Annual Economic Survey for the United States were proportionate to their respective participation rate with census data from 2012.

Table 2. Program Participants for Firms, With or Without Paid Employees

| Group | Principal Operators in U.S. | Range (10% Variance) | Census Data 2012 Impact Rate | Proportionate or Disproportionate |
|-------------------------------------|------------------------------------|-----------------------------|-------------------------------------|--|
| Males | 53.70% | 48.33% - 59.07% | 81.46% | Disproportionately Higher |
| Females | 35.80% | 32.22% - 39.38% | 18.54% | Disproportionately Lower |
| Hispanic/Latino | 12.00% | 10.80% - 13.20% | 4.50% | Disproportionately Lower |
| White | 78.00% | 70.20% - 85.80% | 88.01% | Disproportionately Higher |
| Black or African Americans | 9.40% | 8.46% - 10.34% | 0.64% | Disproportionately Lower |
| Asian | 6.90% | 6.21% - 7.59% | 6.34% | Proportionate |
| Native Hawaiian or Pacific Islander | 0.00% | 0.00% - 0.00% | 0.12% | N/A |
| American Indian or Alaska Natives. | 1.00% | 0.90% - 1.10% | 0.26% | Disproportionately Lower |
| Persons with Disabilities | 0.00% | 0.00% - 0.00% | 0.00% | N/A |
| Per. with Targeted Disabilities | 0.00% | 0.00% - 0.00% | 0.00% | N/A |

The impact rate for Asians was proportionate with their respective participation rate for Principal Operators for all sectors in U.S. Population in 2012.

The impact rates for Females, Hispanics, Black or African Americans, and American Indian or Alaska Natives were disproportionately lower than the participation rate for these groups for Principal Operators for all sectors in U.S. Population in 2012.

The impact rates for Males and Whites were disproportionately higher than the participation rate for this group for Principal Operators for all sectors in U.S. Population in 2012. Information for Persons with Disabilities was not available.

**DISPARATE IMPACT (80/20 ANALYSIS) –
FIRMS, WITH OR WITHOUT PAID EMPLOYEES**

**Table 3. Program Participants Race/Ethnicity/Gender Data for Firms,
With or Without Paid Employees**

| Hispanic or Latino | White | Non-Hispanic or Latino | | | | Total | |
|--|---------|---------------------------------|---|---|--|---------|--------|
| | | Black or African American | Asian American/ Pacific Islander | Native Hawaiian or Other Pacific Islander | American Indian or Alaskan Native | M | F |
| Impacted (Census Data 2012 - 644,066) | | | | | | | |
| 4.50% | 88.01% | 0.64% | 6.34% | 0.12% | 0.26% | 81.46% | 18.54% |
| Principal Operators in U.S. = 27,626,360 | | | | | | | |
| 12.00% | 78.00% | 9.40% | 6.90% | 0.00% | 1.00% | 53.70% | 35.80% |
| Selection (Impact) Rates | | | | | | | |
| 37.50% | 112.83% | 6.81% | 91.88% | N/A | 26.00% | 151.69% | 51.79% |
| 80% Calculation | | | | | | | |
| 24.72% | 74.38% | 4.49% | 60.57% | N/A | 17.14% | 100.00% | 34.14% |

We established a baseline using Principal Operators for all sectors in U.S. Population in 2012. We assessed whether the impact rate for any group met the condition of adverse impact using the 80% Rule.

The impact rate for Males is above 80% and does not meet the condition for adverse impact.

The impact rates for Females, Hispanics, Whites, Black/African Americans, Asian and American Indian/Alaskan Natives falls below 80% and meets the condition for adverse impact.

Mitigation:

Individuals from the impacted groups (Black/African Americans, Hispanic/Latino, Asians, American Indian/Alaskan Native and women) who produce or manufacture food products using squash (summer virus resistant) or sugarcane (insect resistant) may have a harder time complying with the Standard. To help regulated entities with preparing for compliance, regulated entities will have 18 months following the effective date of the updated the List to revise food labels to reflect changes to the List in accordance with the disclosure requirements. If a regulated

entity from one of the impacted groups is using a food or ingredient produced from an item on the List, they must make a bioengineered food disclosure unless they have records demonstrating that the food or ingredient they are using is not bioengineered. Difficulties may arise in cases where information on the Standard is difficult to access or understand due to language barriers. Other challenges may occur when a small, regulated entity finds it difficult to provide the funds to change labels or test the products to comply with the disclosure regulation. As such, civil rights implications may occur.

AMS is committed to several strategies to mitigate the potential for civil rights implications on these and other affected groups, through: 1) exemptions, 2) multiple disclosure options, and 3) outreach activities for regulated entities:

Exempted Manufacturers and Businesses:

- Very small food manufacturers (any food manufacturer with annual receipts of less than \$2,500,000) are exempt from the Standard, thus mitigating any potential disparate impacts on the affected groups who belong to the very small food manufacturers category.
- Food served in a restaurant or similar retail food establishment (cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises) are exempt from the Standard as well, thus mitigating any potential disparate impacts on the affected groups who belong to the restaurant or similar retail food establishment category.

Multiple Disclosure Options:

According to the Final Rule on the Standard, four disclosure options are available to regulated entities, which may mitigate the costs associated with a new label. As mentioned in subpart B of the regulations, those four options are (1) on-package text, (2) the bioengineered (BE) symbol, (3) electronic or digital link, or (4) text message:

1. If a regulated entity chooses to use on-package text, as described at 7 CFR 66.102, the language must be "Bioengineered food," "Contains a bioengineered food ingredient," or if multiple bioengineered food ingredients are present, "Contains bioengineered food ingredients."
2. The BE symbol, described at 7 CFR 66.104, can be utilized [see <https://www.ams.usda.gov/rules-regulations/be/symbols>], and may be in either the black and white version or the version provided in color.
3. The electronic or digital link, explained at 7 CFR 66.106, requires an on-package statement that says: "Scan here for more food information" and "Call 1-000-000-0000 for more food information." When accessed, the electronic or digital link must include the bioengineered food disclosure in either text or symbol form, as described above.
4. The text message option, described at 7 CFR 66.108, requires an on-package statement that says "Text [command word] to [number] for bioengineered food information."

When used, the consumer must receive the bioengineered food disclosure using the same language allowed by on-package text, as noted above.

These four disclosure options allow flexibility for regulated entities of the impacted groups to select the disclosure option that best suits their product and funding availability. Small food manufacturers, defined at 7 CFR 66.1 (any food manufacturer with annual receipts of at least \$2,500,000, but less than \$10,000,000), have additional options for disclosure available to them as described at 7 CFR 66.110.

Education and Technical Assistance:

During Fiscal Year 2020 and 2021 AMS engaged with stakeholders through several venues and formats to provide technical assistance with validation and testing guidance and education on the Standard:

- Presentation at the 7th Annual Food & Beverage Exchange in Chicago, IL on 10/3/19 with 125 participants
- Presentation at the National American Association of Candy Technologists in Chicago, IL on 10/15/19 with 125 participants
- Presentation at the Enzyme Technical Association Board on 11/6/19 with 35 attendees
- Presentation at the American Agricultural Lawyers Association Annual Education Conference on 11/8/19 with 25 attendees
- Presentation at the American Bakers Association on 2/11/2020 with 60 attendees
- Presentation at the 7th Annual Food Labeling Regulatory Compliance Conference in February 2020 with approximately 60 attendees
- Presentation at Pacific Fisheries Technologists Conference on 3/1/2020 with 40 attendees
- Presentation at Q1 Production BE Food Labeling Webinar in June 2020 to 20 attendees
- Presentation at the Prime Label Annual Conference on 6/1/2020 to 200+ attendees
- 2 virtual presentations at the Institute of Food Technologists Annual Meeting on 7/13/2020
- Presentation to Association for Dressings and Sauces conference on 10/07/2020 with 25 attendees
- Presentation at The 8th Annual Food & Beverage Litigation, Compliance & Regulatory Exchange on 10/8/2020 with 150 attendees
- Presentation to University of Maryland Law students on 10/13/2020 with 15 attendees
- Presentation to AEIC on 10/14/2020 with 65 attendees
- Presentation to the SoCal Dietary Supplement Consortium on 10/19/2020 with 374 attendees
- Presentation to stakeholders from small and medium sized business on 12/01/2020 with 1,416 attendees
- Presentation to 8th Annual Food Labeling: Evolving Regulatory Compliance Conference on 02/04/2021 with 40 attendees
- Presentation to Quarterly Tribal Listening Session on 03/11/2021 with 40 attendees.
- Presentation to stakeholders from International Dairy Deli Bakery Association on 05/11/2021 with 100 attendees
- Presentation to Tortilla Industry Association on 07/09/2021 with 50 attendees

- 2 virtual presentations at the Institute of Food Technologists Annual Meeting on 7/19/2021
- Presentation to Quarterly Tribal Listening Session on 07/22/2021 with 40 attendees

Through a Notice to Trade, stakeholders of the Standard will be informed upon publication of the proposed rule. AMS also maintains a website with all current information regarding the List and the Standard. Interested persons, including regulated entities and consumers, can find information about the Standard.

AMS engages in outreach with stakeholders through webinars. On 12/01/2020, AMS hosted an informational webinar about the Standard in which 1416 stakeholders, a majority of them from small to medium sized businesses, attended. AMS plans to host other webinars in the future on specific topics of interest to the impacted groups such as recordkeeping, testing guidance, and validation guidance, in order to assist the impacted groups with compliance.

AMS responds on a continuous basis to questions and requests received through the email inbox at befooddisclosure@usda.gov. The majority of the questions received are from small to medium sized businesses asking for clarification on compliance. The average response time for fiscal year 2021 is 12 days.

AMS meets with stakeholders as requested and has accepted 100% of its customers' requested meeting invitations. For example, AMS met with commodity refiners on March 31, 2020, a Brazilian sugarcane trade group on October 19, 2020, the American Beverage Association on July 7, 2021, and held a listening session with members of the Food and Beverage Issue Alliance (FBIA) on Friday August 13, 2021. These trade groups represent the interests of many regulated entities who may be owned by the impacted individuals.

Conclusion:

The Agricultural Marketing Service proposes to publish a proposed rule to update the List of Bioengineered Foods (the List). Regulated entities using foods on the List must make a bioengineered food disclosure related to food ingredient(s). To assist the industry in complying with the new regulations for the List, the regulated entities will have 18 months following the effective date of the updated the List to revise food labels to reflect changes to the List in accordance with the disclosure requirements.

The proposed rule has potential to impose adverse and/or disproportionate impacts on protected groups ((Black/African American-, Hispanic/Latino-, Asian-, American Indian/Alaskan-, and men/women-owned businesses). AMS is committed to mitigating the potential impacts through the very small food manufacturer and restaurant/ready-to-eat-style business exemptions, multiple disclosure options, and training and technical assistance offered to regulated entities. Throughout the process of updating the List, AMS has and will engage industry stakeholders and consumers to ensure that the proposed rule accomplishes the objective without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the marketplace. AMS will also review and consider updates to the List annually and will solicit recommendations

regarding updates to the List through notification in the Federal Register and on the AMS website.

AMS expects to publish this proposed rule updating the List in Spring, 2022.