

Regulation Civil Rights Impact Analysis

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Title of Action: **Final 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 that 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 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 to amend “squash (summer)” to “squash (summer, coat protein-mediated virus-resistant varieties).”

Most commenters supported the updates to the List put forward in the Proposed Rule. Of the 36 substantive comments received 72% supported adding “sugarcane (Bt insect-resistant varieties)” and 67% supported amending “squash (summer)” to “squash (summer, mosaic virus-resistant varieties)”. Only 6% were opposed to adding sugarcane, and no commenters were opposed to amending squash. Zero commenters addressed AMS questions on squash variety market share, or the Civil Rights Impact Analysis (CRIA). Commenters provided insight, questions, and suggestions on other topics including, pros and cons of the List Update, the potential burden on regulated entities, the timeliness of the List Update process, the AMS List website and supporting materials, education and outreach on biotechnology, and other concerns about biotechnology.

Of the commenters supporting the updates, many stated that the changes would help inform consumers and provide additional transparency. Most commenters (61%) spoke of the Update providing information in some form, and this belief aligned with support for the updates.

Of particular interest, four commenters identified that adding sugarcane to the List would present a burden on the sugar industry and regulated entities. Two of the four (6% of total) believed that this burden is high enough to oppose adding sugarcane to the List. These comments state many regulated entities using sugarcane or ingredients derived from sugarcane would be impacted, and that current recordkeeping practices would not be sufficient to satisfy the requirements of the Standard. In response, AMS does not believe that the addition of “sugarcane (Bt insect-resistant varieties)” constitutes an undue burden. 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. Records would be required to substantiate a decision not to label under 7 CFR 66.9. These records could include country of origin records that show a product or ingredient is from a country that has not approved a BE variety of the crop for commercial production.

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. In response to some commenters’ statements that sugarcane is likely highly refined, AMS notes that the List establishes a presumption about which 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 that modified genetic material is not detectable.

Additionally, one commenter asked that AMS use a more descriptive term for squash (summer) than “mosaic virus-resistant varieties,” as conventionally bred squash could presumably also be mosaic virus-resistant. In response, AMS is amending the List entry to “squash (coat protein-mediated virus-resistant varieties)” which provides 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. 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. 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.

In summary, AMS is amending 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 (coat protein-mediated virus-resistant varieties)
13. Sugarbeet
14. Sugarcane (Bt insect-resistant varieties)

The authority for this final rule is under the Administrator, Agricultural Marketing Service. AMS expects to publish this final rule updating the List in Summer, 2023. 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 List to revise food labels to reflect changes to the List in accordance with the disclosure requirements.

Analysis:

Race/Ethnicity/Gender Data

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.) (amended Act) is a federal law, that established a national, mandatory standard for disclosing any food that is or may be bioengineered. The law applies generally to all persons conducting business subject to the Standard. Congress declared in the amended Act (1621 et. seq.) that it is essential to have a sound, efficient, and privately operated system for distributing and marketing agricultural products to a prosperous agriculture and is indispensable to the maintenance of full employment and to the welfare, prosperity, and health of the Nation.

USDA, AMS' Food Disclosure and Labeling Division (FDLD) administers and enforces the mandatory National Bioengineered Food Disclosure Standard and its regulations and is responsible for establishing new rules as needed. This final rule will add "sugarcane (Bt insect-resistant varieties)" to the List and amend "squash (summer)" to "squash (summer, coat protein-mediated virus-resistant varieties). 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 bioengineered food disclosure to consumers; and regulated entities that fail to disclose would be subject to an investigation and results reported on the AMS website.

This final rule affects manufacturers, retailers, and importers. While completing these analyses, the US Census, Annual Business Survey 2018 was not designed for the user to select specific retailers and importers subject to the Standard such as food and beverage industries listed in the Industry Codes

(NAICS). If AMS included all retailers and importers in the data analyses, it may result in an inaccurate estimation of impacted groups and non-impacted groups. Therefore, AMS evaluated the data based only on the manufacturing sector.

The 2018 Annual Business Survey provides race, ethnicity, and gender (REG) data for principal operators in the US.¹ Table 1 shows the proportion of these groups in the manufacturing sector. The final rule does not alter the ability for manufacturer of any race, color, national origin, gender, religion, age, disability political beliefs, sexual orientation, or marital or family status to participate in the mandatory National Bioengineered Food Disclosure Standard or change their protections from discrimination. Any requirements for complying with the mandatory National Bioengineered Food Disclosure Standard as a manufacturer apply regardless of race, national origin, or gender. As previously mentioned, AMS has elected to use data from the manufacturers only to determine the adverse impact rates. The impacts of this final rule are predominantly due to required label changes to comply with bioengineered food disclosure laws.

Data Analysis

Table 1. Program Participants Race/Ethnicity/Gender Data for Firms With or Without Paid Employees as of 2018

Census Data 2018 for Principal Operators in U.S. (N = 35,499,980)							
Hispanic or Latino	Non-Hispanic or Latino					Total	
	White	Black or African American	Asian	Native Hawaiian or Other Pacific Islander	American Indian or Alaskan Native	Males	Females
4,228,625	25,219,883	3,239,551	2,651,835	46,653	113,433	17,796,959	12,001,410
11.91%	71.04%	9.13%	7.47%	0.13%	0.32%	50.13%	33.81%
Census Data 2018 Impacted Manufacturing Firms (n = 633,478)							
Hispanic or Latino	Non-Hispanic or Latino					Total	
	White	Black or African American	Asian	Native Hawaiian or Other Pacific Islander	American Indian or Alaskan Native	Males	Females
57,248	519,051	25,870	28,351	645	2,313	381,278	148,683
9.04%	81.94%	4.08%	4.48%	0.10%	0.37%	60.19%	23.47%

Note: “The total number of males and females above will not add up to the baseline or impacted totals, due to some principal operators not specifying a gender.”

¹ US Census ABS, 2018 Annual Business Survey, Statistics for Employer and Nonemployer Firms Demographics series. Available online at: [AB1800NESD05: Nonemployer ... - Census Bureau Table](#)

AMS established baseline data using principal operators for all sectors in U.S. Population in 2018 and the impact rates of the groups were measured using data from the 2018 Annual Business Survey for the United States.

The data shown in Table 1. indicates that in 2018 of the 633,478 impacted manufacturing firms, there were 60.19% Males, 23.47% Females, 9.04% Hispanic/Latino, 81.94% White, 4.08% Black or African Americans, 4.48% Asians, 0.10% Native Hawaiian or Other Pacific Islanders, and 0.37% American Indian/Alaska Natives.²

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

Group	Principal Operators in U.S.	Range (10% Variance)	Census Data 2018 Impact Rate	Proportionate or Disproportionate
Males	50.13%	45.12% - 55.15%	60.19%	Disproportionately Higher
Females	33.81%	30.43% - 37.19%	23.47%	Disproportionately Lower
Hispanic/Latino	11.91%	10.72% - 13.10%	9.04%	Disproportionately Lower
White	71.04%	63.94% - 78.15%	81.94%	Disproportionately Higher
Black or Black or African American	9.13%	8.21% - 10.04%	4.08%	Disproportionately Lower
Asian	7.47%	6.72% - 8.22%	4.48%	Disproportionately Lower
Native Hawaiian or Other Pacific Islander	0.13%	0.12% - 0.14%	0.10%	Disproportionately Lower
American Indian or Alaskan Native	0.32%	0.29% - 0.35%	0.37%	Disproportionately Higher

AMS established a baseline using Principal Operators for all sectors in U.S. Population in 2018. The Agency measured disparate impact using a 10% variance to determine disproportionate impact. A 10% variance was used to determine if the impact rates of the groups from the 2018 Annual Business Survey for the United States were proportionate to their respective participation rate with census data from 2018 shown in Table 2.

² US Census ABS, 2018 Annual Business Survey, Statistics for Employer and Nonemployer Firms Demographics series. Available online at: [AB1800NESD05: Nonemployer ... - Census Bureau Table](#)

According to Table 2, the impact rate for Females, Hispanics/Latino, Black or African Americans, and Asians, and Native Hawaiian or Pacific Islander were disproportionately lower than the participation rate for these groups for Principal Operators for all sectors in U.S. Population in 2018.

The impact rates for Males, Whites, and American Indian/Alaskan Natives were disproportionately higher than the participation rate for these groups for Principal Operators for all sectors in U.S. Population in 2018.

No data are available for Persons with Disabilities.

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

Hispanic or Latino	Non-Hispanic or Latino					Total	
	White	Black or African American	Asian	Native Hawaiian or Other Pacific Islander	American Indian or Alaskan Native	M	F
	Impacted (Census Data 2018 = 633,478)						
9.04%	81.94%	4.08%	4.48%	0.10%	0.37%	60.19%	23.47%
	Principal Operators in U.S. = 35,499,980						
11.91%	71.04%	9.13%	7.47%	0.13%	0.32%	50.13%	33.81%
	Selection (Impact) Rates						
75.87%	115.34%	44.75%	59.91%	77.48%	114.27%	120.06%	69.43%
	80% Calculation						
63.19%	96.07%	37.27%	49.90%	64.53%	95.18%	100.00%	57.83%

An adverse impact is an impact on employees, or a program beneficiary based on their membership in a protected group resulting from a regulatory change that meets the quantitative condition for adverse impact. An adverse impact is measured using the 80% Rule, 80/20 or “four-fifths” rule. The 80% rule is a test of proportions requiring the profile for the impacted group as well as the profile for the relevant baseline. Rates of 80% or higher do not meet the condition for having an adverse impact.³

A baseline was established using the demographics of Principal Operators for all sectors in U.S. Population in the United States from the 2018 Annual Business Survey. In Table 3, an assessment was made whether the impact rate for any group met the condition of adverse impact using the 80% Rule.

The impact rate for Whites, American Indians or Alaskan Natives, and Males are above 80% and does not meet the condition for adverse impact. The impact rates for Hispanics/Latinos, Black/African Americans, Asians, Native Hawaiians or Other Pacific Islanders, and Females, fall below 80% and meet the condition for adverse impact.

³ USDA Departmental Guidebook, Civil Rights Impact Analysis, Office of the Assistant Secretary for Civil Rights, 2020, Section 3 - Definitions, page 9.

Impacts on Regulated Entities

USDA 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 of adding sugarcane (Bt insect-resistant varieties) to the List would be between \$500,000 and \$3.5 million (annualized over 20 years using a seven percent discount rate). 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. 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.

The Standard is not expected to have any benefits to human health or the environment. Any benefits to consumers from the provision of reliable information about BE food products are difficult to measure. Under some, but not all, potentially informative analytic baselines, a more clear-cut benefit of the Standard is that it eliminates costly inefficiencies of a state-level approach to BE disclosure. AMS estimates the size of these benefits by focusing on the increased consumer access to bioengineered food disclosures. The rule is not considered to be economically significant under Executive Order 12866. Even considering only the first year (where all of the costs are expected to occur), the estimated costs do not exceed the \$200 million threshold to be considered economically significant.

Impacts on Protected Groups

Although the required analysis indicates a disproportionate impact for Hispanics/Latinos, Black/African Americans, Asians, Native Hawaiians or Other Pacific Islanders, and Females, because the new regulation impacts all industry participants equally, no individual or group would likely be adversely impacted differently.

Because the disparate impact analysis identified the potential impact rate for Hispanics/Latinos, Black/African Americans, Asians, Native Hawaiians or Other Pacific Islanders, and Females as having met the condition for adverse impacts, AMS will institute enhanced efforts to notify these groups as to the publication of the final rule.

Tribal Implications

AMS has assessed the impact of this final rule on Indian tribes and determined that this final rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, AMS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress. Throughout the rulemaking process, AMS will continue to develop and provide outreach and education for all regulated entities.

Barrier Analysis

Background

Barrier analyses are generally conducted to address a policy, procedure, or condition that may or may not limit the opportunity for members or participants of a particular race, ethnic group, or gender, or because of a disability. AMS conducted a barrier analysis for the final rule to assess potential barriers that may prevent any person or group affected by the rule from learning about the rule.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.) (amended Act) is a federal law that grants the Administrator the authority to promulgate regulations that establishes a consistent national, mandatory standard for disclosing any food that is or may be bioengineered. The USDA National Bioengineered Food Disclosure Standard (NBFDS) imposes labeling requirements for certain human foods that are bioengineered (BE) or contain BE food ingredients. The NBFDS covers foods (including dietary supplements) and food ingredients that contain genetic material (DNA) that has been modified through in vitro recombinant deoxyribonucleic acid techniques. Foods and food ingredients in which modified genetic material (rDNA) cannot be detected are excluded from the NBFDS. The law applies generally to all persons conducting business subject to the Standard (i.e., regulated entities – importers, manufacturers, and retailers). Manufacturers and importers have responsibility for applying the BE label on packaged food products. Retailers have responsibility for providing BE signage for food products such as fresh produce sold in bulk at grocery stores and similar establishments. The USDA NBFDS administers and enforces the Standard and its regulations and is responsible for establishing new rules as needed.

The USDA NBFDS label is a mandatory marketing standard for disclosing any food that is or may be bioengineered. The USDA NBFDS regulations and this final rule does not require all importers, manufacturers, and retailer operations to participate in the NBFDS program, nor does it seek to recruit all importers, manufacturers, and retailer operations into the NBFDS Program. This final rule will require regulated entities offering any food that is or may be bioengineered which are subject to the Standard and provide disclosure on the label. This action is aimed to better align with consumer expectations.

Findings

As discussed in the Analysis section of this document, there is evidence based on principle operator program participants that this final rule will have disproportionate adverse civil rights impact on manufacturers. This final rule, however, will not impose any requirements related to eligibility for benefits and services on protected classes, nor will the rule have the purpose or effect of treating classes of persons differently. This is a mandatory requirement for disclosing any food that is bioengineered.

Additionally, AMS's analysis of available data indicates that the impact rates for Hispanics/Latinos, Black/African Americans, Asians, Native Hawaiians or Other Pacific Islanders, and Females, fall below 80% and meet the condition for adverse impact. As such, AMS has re-evaluated its outreach strategy to address any potential invisible barrier preventing protected groups from learning about the final rule.

Potential Barriers

AMS has identified several potential barriers that may prevent certain groups or persons from learning about the final rule:

- **Disproportionate impact analysis.** A disproportionate impact analysis reveals that the impact rates for Females, Hispanics/Latino, Black or African Americans, and Asians, and Native Hawaiian or Pacific Islander were disproportionately lower than the participation rate for these groups for Principal Operators for all sectors in U.S. Population in 2018. AMS intends to address this barrier as part of its outreach and communication plan for the final rule (see more detail below).
- **Limited English proficiency.** While the final rule and information about it are approved to be provided in English, there may be a potential barrier that information about the rule is not translated for limited English-proficient (LEP) stakeholders. AMS would provide translated information about the final rule as requested. Translated information about the final rule would be posted on the AMS website.

Mitigation Strategies

AMS will address the potential barriers above as part of its outreach plan and monitoring mechanisms, described below in the Mitigation and Outreach section of this document. Specifically, the outreach plan is designed to maximize the reach of information about the final rule, including to persons and groups identified in this barrier analysis.

Mitigation:

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.) (amended Act) is a federal law, that established a national, mandatory standard for disclosing any food that is or may be bioengineered. The law applies generally to all persons conducting business subject to the Standard. Congress declared in the amended Act (1621 et. seq.) that it is essential to have a sound, efficient, and privately operated system for distributing and marketing agricultural products to a prosperous agriculture and is indispensable to the maintenance of full employment and to the welfare, prosperity, and health of the Nation.

USDA, AMS' Food Disclosure and Labeling Division administers and enforces the mandatory National Bioengineered Food Disclosure Standard and its regulations and is responsible for establishing new rules as needed. This final rule will add "sugarcane (Bt insect-resistant varieties)" to the List and amend "squash (summer)" to "squash (summer, coat protein-mediated virus-resistant varieties). 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 bioengineered food disclosure to consumers; and regulated entities that fail to disclose would be subject to an investigation and results reported on the AMS website.

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) 18-month implementation following the effective date of the rule to revise food labels, 2) exemptions, 3) multiple disclosure options, and 4) outreach activities for regulated entities:

18 Month Implementation to Revise Labels:

To help regulated entities with preparing for compliance, regulated entities will have 18 months following the effective date of the updated 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.

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 2018 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.

Outreach:

Education and Technical Assistance:

Through a Notice to Trade and a targeted email, stakeholders of the Standard will be informed upon publication of the final rule to the *Federal Register*. AMS also maintains a website at <https://www.ams.usda.gov/rules-regulations/be> with all current information regarding the List and the Standard. Interested persons, including regulated entities and consumers, can find information about the Standard. Upon publication of this rule, appropriate changes will be made to the List on the AMS Website. Additionally, AMS plans to continue presentations and other outreach as enumerated in the Prior Outreach Efforts section below.

AMS responds on a continuous basis to questions and requests received through the email inbox at befooddisclosure@usda.gov. Most questions received are from small to medium sized businesses asking for clarification on compliance. The average response time for fiscal year 2022 was 4 days.

Prior Outreach Efforts

During Fiscal Year 2022 AMS engaged with stakeholders through several venues and formats to provide technical assistance with validation and testing guidance and education on the Standard:

- Presentation on Bioengineered Overview for FAS Posts/Webinar on 1/19/2022, with unknown attendees
- Presentation on the Overview of the National Bioengineered Food Disclosure Standard for the Society of Flavor Chemist, West Coast Meeting on 1/27/2022, with 40 attendees
- Presentation on How Genetically Engineered Microbes are Regulated by the Standard for the Future of Micro-biotechnology: From Research to Regulation workshop on 2/3/2022, with unknown attendees
- Participation on a panel about Bioengineered for Registered Dietitians for the FDA’s Agricultural Biotechnology continuing professional education (CPE) on 2/22/2022, with unknown attendees
- Presentation on Overview of Bioengineered for the Q1 Productions 9th Annual Food Labeling: Evolving Regulatory Compliance Conference on 2/23/2022, with 75 attendees
- Presentation on Overview of The National Bioengineered Food Disclosure Standard for the Minnesota Department of Agriculture Specialty Crop Biotechnology Forum on 3/10/2022, with 35 attendees
- Presentation on Bioengineered Disclosure: Update and Enforcement #1 at Prime Label Consultants - Food Label Conference on 4/26/2022, with 200+ attendees
- Presentation on Bioengineered Disclosure: Update and Enforcement #2 at Prime Label Consultants - Food Label Conference on 4/26/2022, with 200+ attendees
- Presentation on Overview of The National Bioengineered Food Disclosure Standard to State Department - Foreign Service Institute on 7/21/2022, with 25 attendees
- Poster Presentation on Overview of Bioengineered program at Institute of Food Technologists Annual Meeting 2022 on 7/22/2022, with over 20,000 attendees
- Oral Presentation on Overview of Bioengineered program at Institute of Food Technologists Annual Meeting 2022 on 7/22/2022, with over 20,000 attendees
- Presentation on Bioengineered Regulations – specifically microbial products and import impacts to FAS - Turkish Cochran Fellows on 7/27/2022, with 15 attendees
- Presentation on Bioengineered Overview for Regulators to FAS - South American Regulators on 8/29/2022, with 15 attendees
- Presentation on the Bioengineered Consumer Complaint Process Overview at the American Bakers Association, Food Technical Regulatory Affairs Professional Group virtual meeting on 11/30/2022, with 50 attendees

Conclusion:

The Agricultural Marketing Service proposes to publish a final 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 final 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 final 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 final rule updating the List in Summer, 2023.