



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 66

[Document No. **AMS-FTPP-20-0057**]

National Bioengineered Food Disclosure Standard; Updates to the List of Bioengineered Foods

ACTION: Request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) of the Department of Agriculture (USDA) is soliciting comments and feedback on recommendations to update the List of Bioengineered Foods (List) as it pertains to the National Bioengineered Food Disclosure Standard (Standard).

DATES: Comments are due by [Insert date 30 days after date of publication in the FEDERAL REGISTER], 2020.

ADDRESSES: We invite you to submit written comments via the internet at <http://www.regulations.gov>. All comments should refer to the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice, including the identity of individuals or entities submitting comments, will be made available to the public on the internet via <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Trevor Findley, Deputy Director, Food Disclosure and Labeling Division, Fair Trade Practices Program, Agricultural Marketing Service, U.S. Department of Agriculture, telephone (202) 690-3460, email trevor.findley@usda.gov.

SUPPLEMENTARY INFORMATION:

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 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, include the AMS List of Bioengineered Foods (the List), which currently includes: 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 NBFDS, 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 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. The regulations further provide that:

(1) Recommendations regarding additions to and subtractions from the List may be submitted to AMS at any time or as part of the annual review process.

(2) Recommendations should be accompanied by data and other information to support the recommended action.

(3) AMS will post public recommendations on its website, along with information about other revisions to the List that the agency may be considering, including input based on consultation with the government agencies responsible for oversight of the products of biotechnology: USDA's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA), and appropriate members of the Coordinated Framework for the Regulation of Biotechnology or a similar successor.

(4) AMS will consider whether foods proposed 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.

(5) If AMS determines that an update to the List is appropriate following its review of all relevant information provided, AMS will modify the List.

In addition to seeking public recommendations generally regarding the entries on the List, AMS is specifically seeking public comment on the recommendations listed below.

Additions to the List

As required by 7 CFR 66.7(a)(4), AMS will consider two criteria when identifying food to add to the List: (1) whether the food proposed for inclusion on the List has been authorized for commercial production somewhere in the world, and (2) whether that food is currently in legal commercial production for human food somewhere in the world.

For the first criterion, AMS considers a food to have been authorized for commercial production when it has cleared all the legal requirements necessary to be produced in that country. If multiple authorizations are required before a food can be commercially produced, AMS would not consider that food to have been authorized for commercial production until it has completed all such authorizations. For the second criterion, AMS will look to see if the food that has been authorized for commercial production actually is in legal commercial production for use as human food.

Based on publicly available information, AMS currently believes there is at least one crop that meets the dual criteria required by 7 CFR 66.7(a)(4). AMS believes that sugarcane is (1)

authorized for commercial production somewhere in the world and
(2) currently in legal commercial production for human food
somewhere in the world.

1. **Sugarcane:** AMS believes that Brazil approved
bioengineered sugarcane for commercial release and that
bioengineered sugar cane is currently in legal commercial
production.¹ The sugarcane was developed using recombinant DNA
technology to be insect-resistant to help control sugarcane
borer infestations. Brazil approved the bioengineered sugarcane
for commercial production in 2018 and planted approximately
4,000 hectares for commercial production in the 2018/2019 crop
year.² As a result, AMS believes that sugarcane should be added
to the List. Consistent with other items on the List, AMS would
initially propose that sugarcane include "(insect-resistant³)"
because there is currently only one bioengineered trait used in

¹Agricultural Biotechnology Annual - 2018, [Brazil- Agricultural
Biotechnology Report]
[https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportBy
FileName?fileName=Agricultural%20Biotechnology%20Annual Brasilia
Brazil 12-26-2018](https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual%20Brasilia%20Brazil%2012-26-2018)

²Agricultural Biotechnology Annual - 2019, [Brazil- Agricultural
Biotechnology Report]
[https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportBy
FileName?fileName=Agricultural%20Biotechnology%20Annual Brasilia
Brazil 10-20-2019](https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual%20Brasilia%20Brazil%2010-20-2019)

³Consultations on Food from New Plant Varieties,
[https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon&id=CTC17
5-A](https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon&id=CTC175-A)

sugarcane production. As stated in the preamble to the final rule,⁴ if other BE versions of listed foods are authorized and become legally available, AMS would revise the listing during the annual update process to be more generic. Therefore, AMS seeks comment on whether it should undertake rulemaking to add "Sugarcane (insect-resistant)" to the List.

Amendments to the List

1. **Squash (summer):** Squash (summer) is currently included on the List but AMS proposes to add an additional modifier to reflect that the only trait for bioengineered summer squash that is currently available is virus-resistance.⁵ Therefore, AMS would add "virus-resistant" to the existing modifier "summer," so that squash on the list would read "Squash (summer, virus-resistant)." This change would be consistent with the treatment of other items on the list, where modifiers are included when only one bioengineered trait is available, as is the case with eggplant, papaya, and pineapple. Therefore, AMS seeks comment on whether it should add "virus-resistant" as a modifier to the existing entry of "Squash (summer)."

⁴83 Fed. Reg. 65819

⁵Consultations on Food from New Plant Varieties, <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=SEM%2D0CZW3%2D2>, Consultations on Food from New Plant Varieties, <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&id=SEM%2D0ZW20%2D7>

Other foods considered for addition to the List

In its research, AMS identified several bioengineered foods that 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 bioengineered foods do not yet meet the criteria in 7 CFR 66.7(a)(4) to be added to the List, AMS is seeking public comment to determine if additional information is publicly available.

1. Cowpea: Nigeria recently authorized the commercial release of pod-borer resistant cowpea (Event - AAT709A), bioengineered for lepidopteran insect pest (*Maruca vitrata*) resistance.⁶ AMS seeks comment on whether cowpea is in legal commercial production for human food, or would be in legal commercial production for human food when AMS initiates the rulemaking process.⁷ If cowpea is added to the List, AMS also seeks comment on whether the addition should include any modifiers that would more accurately describe the type of cowpea

⁶Agricultural Biotechnology Annual - 2019, Nigeria Approves the Commercial Release of Bt. Pod-Borer Resistant Cowpea [https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual Lagos Nigeria 5-21-2019](https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual%20Lagos%20Nigeria%205-21-2019)

⁷Pod-borer Resistant Cowpea Project, <https://www.aatf-africa.org/wp-content/uploads/2019/06/Cowpea-Project.pdf>, Event Name AAT709A, <https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=543&Event=AAT709A>

that is bioengineered, such as pod-borer resistant cowpea or insect resistant cowpea.

2. Rice: AMS is aware that the Philippine Department of Agriculture approved the safety of bioengineered rice (Event-GR2E, Production of provitamin A carotenoids), also known as golden rice, for use as human food.⁸ While this approval has to do with the safety of the rice as human food, the rice is not yet authorized for commercial production. Because this rice has not yet been authorized for commercial release and is not in legal commercial production, it does not meet the criteria identified in 7 CFR 66.7(a)(4) and AMS is not recommending it be added to the List. AMS seeks comment on its understanding of the current status of this rice.

After completing its research, AMS has not identified any other foods that it believes would meet the criteria to be included on the List. AMS requests public comment on any other foods not mentioned above that it should consider for addition to the List.

Any comments not directly related to the addition, deletion or modification of the potential items for the List will not be considered nor will recommendations that are not accompanied by

⁸Philippines approves Golden Rice for direct use as food and feed, or for processing, <https://www.irri.org/news-and-events/news/philippines-approves-golden-rice-direct-use-food-and-feed-or-processing>

data and other information to support the recommended action. After reviewing the comments on this notice, AMS will determine whether it should initiate rulemaking to update the List. Any changes to the regulations would be reflected in an amendment to the regulations found at 7 CFR part 66. As stated at 7 CFR 66.7(b), regulated entities would 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 7 CFR part 66.

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

Bruce Summers,

Administrator,

Agricultural Marketing Service.

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