

## MEMORANDUM

**From:** Martin J. Hahn  
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**Date:** December 21, 2018

**Re:** **USDA's AMS Issues Final Rule on National Bioengineered Food Disclosure Standard**

Yesterday the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) released its final rule implementing the National Bioengineered Food Disclosure Standard (NBFDS) passed by Congress in July 2016. In this memorandum we summarize the top ten key highlights of the final rule.

- 1. Compliance Date.** The final rule establishes an implementation date of January 1, 2020 for regulated entities other than small businesses, a voluntary compliance period until December 31, 2021, and a mandatory compliance date of January 1, 2022. Companies with at least \$2.5 million but less than \$10 million in annual receipts will need to begin implementing the rule on Jan. 1, 2021. <sup>1/</sup> USDA refers to the period ending Dec. 31, 2021 as a "voluntary compliance period." USDA states in the preamble that beginning January 1, 2022, "all regulated entities must comply with the requirements."
- 2. Refined Ingredients Derived from Bioengineered Sources.** For refined foods or ingredients that are derived from bioengineered (BE) sources (e.g., corn syrup derived from BE corn), no disclosure is required if the food does not contain detectable modified genetic material. The final rule sets forth the procedures to demonstrate that modified genetic material is not detectable. <sup>2/</sup>
- 3. Voluntary Disclosure.** Relatedly, AMS recognizes that regulated entities may make voluntary disclosures that a food is derived from a bioengineered source, including when

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<sup>1/</sup> The implementation date refers to the date that "Regulated entities should begin implementing the NBFDS... by identifying the foods that will need to bear a BE disclosure, the records necessary to meet the recordkeeping requirements, and the type of BE disclosure they will use on their products."

<sup>2/</sup> A regulated entity can demonstrate that modified genetic material is not detectable through (1) records verifying that the food is sourced from a non-bioengineered crop or other food source, such as non-bioengineered salmon; (2) records verifying that the food has been subject to a refinement process "validated" to render modified genetic material undetectable; or (3) certificates of analysis or other testing records appropriate to the specific food tested that confirm the absence of modified genetic material. AMS has established performance standards in the final rule related to detectability analysis.

modified genetic material is not detectable in the food. 3/ Note, the voluntary disclosure is limited to foods or food ingredients that:

- a. do not meet paragraph (1) of the definition of bioengineered food in § 66.1 (which requires detectable modified DNA);
- b. do not qualify as a factor or condition under paragraph (2) of the definition of bioengineered food in § 66.1 (which includes incidental additives);
- c. are not exempt from disclosure under § 66.5 (i.e., foods sold in restaurants or similar retail food establishments, or by very small manufacturers; foods with no more than 5 percent adventitious BE presence per ingredient; foods derived from an animal that consumed BE feed; or foods certified as organic); and
- d. are derived from a food on the AMS “List of Bioengineered Foods.”

The voluntary disclosure must use one of the same methods of disclosure as provided in the rule for the mandatory disclosure 4/ but must use distinct terminology. Specifically, it must use the statements, “derived from bioengineering” or “ingredient(s) derived from a bioengineered source.” The word “ingredient(s)” may be replaced with the name of the specific crop(s) or food ingredient(s). AMS also has established a unique symbol that can be used on foods derived from bioengineering, set forth below.



4. **List of Bioengineered Foods.** The rule contains a non-exhaustive list of BE foods:

alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet.

The final rule contains a single list, rather than two separate lists based on the degree of adoption, and the list has been expanded to include BE crops and foods produced in other countries. Even if a food is not on the list, however, companies with actual knowledge that a food they are selling is bioengineered are subject to the disclosure requirements. Additionally, simply because a crop or food is on the list does not necessarily mean it requires disclosure; if, for example, the regulated entity maintains records that they are using a non-bioengineered version of the food. AMS will review the list of BE foods annually, and update it as needed via rulemaking. The final rule provides an 18-month compliance period from the effective date of any revisions for regulated entities to revise labels.

5. **Factors and Conditions; Incidental Additives.** The final rule establishes a process for submitting a request or petition to limit the scope of the definition of bioengineered food

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3/ Additionally, entities that are exempt from disclosure – very small food manufacturers, restaurants, and similar retail food establishments – may voluntarily provide the disclosure using the mandatory disclosure format.

4/ That is, the text, a symbol, an electronic or digital link, a text message, or as appropriate, the options for small manufacturers and small and very small package disclosure options.

based on other “factors or conditions.” AMS also listed one “factor or condition” in the final rule; for incidental additives. Under the final rule, incidental additives – i.e., those that are present in food at an insignificant level and that do not have any technical or functional effect in the food – are not considered BE foods.

With respect to treatment of yeasts, enzymes, or any other microorganisms, AMS explains that if they qualify as incidental additives that are not required to be labeled as ingredients on a food label, then they do not require disclosure as BE foods. If they do not meet the incidental additive definition, these substances may require disclosure unless they are otherwise exempt (e.g., if the modified genetic material is not detectable). The final rule does not include a categorical exemption for microorganisms, but AMS states that such an exemption could be considered through the factors and conditions process if a petition or request is submitted.

6. **Threshold for Disclosure.** The final rule establishes a threshold for the inadvertent or technically unavoidable presence of BE substances of up to five percent (5%) for each ingredient, provided that no ingredients are intentionally used in the food that contain a BE substance. There is no threshold for intentionally added BE ingredients unless the ingredient qualifies as an incidental additive. The 5% threshold is intended to account for comingling among BE and non-BE crops.
7. **Disclosure Options.** For foods that require a disclosure, companies would have the option to choose any one of the following four disclosure options. Regardless of the format chosen for the disclosure, the disclosure must be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions. With respect to placement, the on-pack statement must appear either (1) on the information panel, directly adjacent to the statement identifying the name and location of the manufacturer, distributor, packer, or similar information, (2) anywhere on the principal display panel (PDP), or (3) if there is insufficient space on the information panel or PDP, on an alternate panel.
  - a. **On-Pack Text Disclosure.** The specific text of the disclosure would read either (a) “**Bioengineered food**” for a raw agricultural commodity that is a BE food, or a processed food that contains only BE food ingredients; or (b) “**Contains a bioengineered food ingredient**” for a multi-ingredient food that contains one or more BE ingredients, but does not fall into category (a) above. Note that the plural forms of “foods” or “ingredients” may be used if applicable. The rule does not permit use of a “may contain” statement.
  - b. **On-Pack Symbol Disclosure.** AMS adopted the following symbol, which notably uses the term “bioengineered.” The symbol may be in black or white or in color, using the specific colors required in the regulation. A color version is available on the AMS website. 5/

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5/ See <https://www.ams.usda.gov/rules-regulations/be>.



- c. Electronic or Digital Link. In addition to the electronic or digital link that would appear on the label (e.g., a Quick Response (QR) code), this disclosure option is comprised of three additional elements:
- i. *Disclosure on the “first screen to appear”*. The electronic or digital link must provide the BE food disclosure on the “the product information page,” which “must be the first screen to appear on an electronic or digital device after the link is access as directed” and must exclude marketing and promotional information. The disclosure on the product information page must conform to the requirements for either the text disclosure or the symbol disclosure.
  - ii. *On-pack “Scan here” statement*. The electronic or digital link on the label must be accompanied by, and be placed directly above or below, the statement “Scan here for more food information,” or equivalent language that reflects technological changes. <sup>6/</sup>
  - iii. *On-pack telephone number*. When the electronic or digital disclosure is chosen, the disclosure must also be accompanied by a telephone number that provides access to the disclosure. The disclosure must be available regardless of the time of day, and the telephone number must be located in close proximity to the electronic or digital link, and be accompanied by the statement “Call \_\_\_\_\_ for more food information.”
- d. Text Message Disclosure. Under this option, companies would include a statement on the package that instructs consumers to “Text [command word] to [number] for bioengineered food information,” where the number would be a telephone number or short code that immediately responds with the disclosure using the disclosure text discussed above.

## 8. Disclosure Options for Small Packages and Small Food Manufacturers.

- a. For small packages with a total surface area less than 40 square inches, and very small packages with a total surface area of less than 12 square inches, a shortened version of the accompanying text could be used. That is: “Scan for info” (for the digital or electronic link), “Text for info” (for the text message disclosure), or “Call for info” (for the telephone disclosure). Additionally, for very small packages only, if the preexisting label includes a website URL or telephone number that a person can use to obtain other food information, that website or telephone number may also be used for the BE disclosure.

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<sup>6/</sup> AMS lists the examples “Scan anywhere on package for more food information,” and “Scan icon for more food information” as appropriate statements to accommodate various technologies.

