NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD RESOURCES TOOLKIT

Disclaimer: Please note that this toolkit is intended as an educational tool and should not be construed as legal advice regarding compliance with the National Bioengineered Food Disclosure Standard.

1.) SECTION 1: OVERVIEW

a. The aforementioned trade associations put together this resource toolkit for broad food industry distribution to ensure the supply chain has one comprehensive resource that contains key information regarding the National Bioengineered Food Disclosure Standard (NBFDS).

b. The date of compliance for the NBFDS is January 1, 2022, meaning foods labeled for retail sale entering commerce after this date will need to start including a bioengineered disclosure where required. USDA considers "entering commerce" to be the date the food is labeled for retail sale. Therefore, efforts to verify bioengineered status of ingredients should already be underway across the supply chain to ensure validation information on ingredients and foods are available so that manufacturers are able to comply with the NBFDS no later than January 1, 2022. All aspects of the supply chain must remain in close communication and coordination throughout this process in order for the compliance deadline to be met.

c. National trade associations have requested an extension of the compliance date and enforcement date, but these requests have been denied. Therefore, the final compliance and enforcement date is January 1, 2022, with no extension available.

2.) SECTION 2: BACKGROUND/TIMELINE

a. July 29, 2016: The National Bioengineered Food Disclosure Standard (NBFDS) was signed into law and established a national mandatory standard for disclosing foods that are or may be bioengineered.

   i. The NBFDS mandated that the U.S. Department of Agriculture (USDA) issue its regulation implementing the law within two years.

   ii. The NBFDS requirements do not apply to food served in a restaurant or similar retail food establishment, to very small food manufacturers, or to food certified under the National Organic Program.

   iii. The NBFDS law is available here.

b. December 20, 2018: USDA's Agricultural Marketing Service (AMS) issued its NBFDS regulation which defines bioengineered foods as those that contain detectable genetic material which has been modified through certain lab techniques (i.e., in vitro rDNA techniques) which could not otherwise be created through conventional breeding or found in nature. The regulation established:

i. The NBFDS regulations currently apply to the following bioengineered foods:
    1. Alfalfa, Arctic™ variety apples, canola, corn, cotton, BARI Bt Begun variety eggplant, papaya (ringspot virus-resistant varieties), pineapple (pink fleshed varieties), potato, AquAdvantage® salmon, soybean, summer squash, and sugarbeet.
    2. USDA will add foods to the bioengineered (BE) food list, as necessary, annually through rulemaking. For example, in a proposed rule released on July 24, 2020, USDA proposed to add insect-resistant sugarcane to this list. The USDA is currently considering public comments to determine whether to move forward with adding insect-resistant sugarcane to the list, and whether to make any other changes to the list (e.g., whether USDA should add the modifier "virus-resistant" to summer squash, whether USDA should consider additional information about cowpea or golden rice, and whether USDA should add any other foods to the list).
ii. A means of disclosure that a product is bioengineered or made with bioengineered ingredients (i.e., text disclosure, symbol disclosure, electronic or digital link disclosure, or text message).
iii. USDA clarified that highly refined foods or ingredients that do not contain detectable modified genetic material are not bioengineered foods. Therefore, foods made with refined ingredients which are produced from bioengineered sources, but which are refined in such a way that the modified genetic material is not detectable are not subject to mandatory disclosure. That said, finished food manufacturers may voluntarily disclose the BE source in these instances. The voluntary disclosure can be made using any of the disclosure methods available for mandatory disclosures enumerated above, and by using the phrase "derived from bioengineering" or "ingredient(s) derived from a bioengineered source;" USDA also permits a symbol including the text "derived from bioengineering" for this purpose.
iv. USDA explains in the preamble to the final rule and in guidance that incidental additives are excluded from the definition of a bioengineered food. For purposes of this exemption to USDA's BE disclosure requirements, an incidental additive is an ingredient present in food at an insignificant level that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3). In the preamble to the final rule, USDA writes, "Exempting incidental additives that are not required to be labeled under FDCA regulations is sensible, aligns the NBFDS with practices of trading partners, avoids consumer confusion that could otherwise result if a substance not appearing on a food label triggered the NBFDS disclosure requirement, and limits the burden on regulated entities without unduly limiting disclosure for consumers."
v. The NBFDS regulation is available here.

c. July 7, 2020: USDA AMS issued two guidance documents to provide more information on acceptable validation for a refining process and testing methods, which is further explained in Section 2.
    i. Guidance Document 1: Guidance on Validating a Refining Process
    ii. Guidance Document 2: Guidance on Testing Methods

d. January 1, 2022: USDA compliance date for all food manufacturers, meaning they must have bioengineered disclosure via text, symbol, or digital disclosure on all products entering commerce on or after this date which are subject to the rule. This also indicates enforcement may start on this date.

3.) SECTION 3: USDA AMS GUIDANCE DOCUMENTS ON REFINED INGREDIENTS

a. NBFDS Guidance to Facilitate Acceptable Validation of a Refining Process
   i. The NBFDS states there are three ways to show that modified genetic material is not detectable in a refined ingredient and therefore not subject to mandatory disclosure:
      1. Providing records to verify that the food is sourced from a non-bioengineered crop or source;
      2. Providing records to verify the food has been subjected to a refinement process validated to make modified genetic material in the food undetectable; and
      3. Providing certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.
   ii. This guidance provides general steps on how to validate a refinement process for manufacture of refined ingredients which are made from bioengineered sources, which permits end product testing as a means of validation of the refinement process.
   iii. As noted in the guidance, a process should be revalidated if there are significant changes in key manufacturing process steps. If significant changes are made in the manufacturing process, suppliers should advise customers and work to re-validate the refining process to determine there is no detectable modified genetic material.
   iv. Once validated, a process can be used at other facilities without requiring revalidation. Validation can be done in-house, and an entity can validate a process common to the production of multiple ingredients.
   v. Regulated entities should maintain "customary or reasonable" records verifying a validated process for at least two years to demonstrate compliance.

b. NBFDS Guidance on Testing Methods
   i. This guidance provides information regarding how to choose acceptable test methods which can be used to determine whether a food contains detectable modified genetic material.
   ii. The guidance includes information regarding general considerations for selecting a test method, including whether it is fit for purpose, DNA-based methods (e.g., polymerase chain reaction (PCR) testing), emerging technologies and other methods (e.g., DNA sequencing), general considerations in selecting a laboratory, and recordkeeping requirements to demonstrate compliance with the regulation.

4.) SECTION 4: QUESTIONS TO CONSIDER FOR DETERMINING BE STATUS

a. As suppliers look to determine the bioengineered status of their ingredients/products, they should consider the following questions which will help with providing information to customers:
   i. Is this ingredient/product derived from a bioengineered crop, as noted on the USDA BE List?

ii. Even if this food or its ingredients does not appear on USDA's BE List, do you have actual knowledge that the food or any of its ingredients are bioengineered? If so, please list any applicable food or ingredients.[1]
iii. If you answered YES to either of the above, do you have documentation showing that there is no detectable bioengineered material in the food or any ingredient?
iv. If the food or ingredient appears on USDA's BE List or if you suspect that it contains BE ingredients, is the food or ingredient otherwise exempt from USDA's bioengineered disclosure rule because (1) it is certified USDA organic; (2) the presence of the BE substance in the food or ingredient is unintentional and either inadvertent or technically unavoidable, and is present at equal to or less than 5% of the food or ingredient; or (3) the product contains meat, poultry, or egg listed as the first ingredient, or as the second ingredient where the first ingredient is water, broth, or a similar solution?
v. Is the ingredient an incidental additive as that term is defined in 21 CFR 101.100(a)(3)? The NBFDS Rule specifically excludes incidental additives from the definition of bioengineered foods.
vi. Does a validated, fit-for-purpose testing method, per AMS guidance, identify any detectable modified genetic material in the ingredient/product and are there records which show this?
vii. Has the manufacturing process for the ingredient/product been validated to demonstrate that the modified genetic material has been removed and is no longer detectable, and are there records which show this?

b. As an appendix (Appendix 1) to this toolkit, please find a supplier questionnaire developed by the Consumer Brands Association which could be viewed as a reference document for those questions suppliers should be prepared to answer regarding ingredients for NBFDS compliance.

5.) SECTION 5: OTHER USDA AMS RESOURCES

a. Slides from December 2020 Webinar on NBFDS
b. Decision Tool for Making Bioengineered Disclosure
c. NBFDS Fact Sheet
d. List of Bioengineered Foods
e. FAQs on Validation Testing Guidance (July 7, 2020)
f. FAQs on Testing Methods Guidance (July 7, 2020)
g. Additional FAQs:
    i. General
    ii. For Manufacturers
    iii. For Retailers and Importers
    iv. Disclosure and Voluntary Disclosure
    v. Compliance and Enforcement

6.) SECTION 6: QUESTIONS ON NBFDS

a. Suppliers and manufacturers are encouraged to share this information with their legal and compliance teams.

[1] As noted in Section 1, USDA reserves the right to add new foods to the list of BE commodities that are regulated under NBFDS. Once a new food is added, manufacturers will have 18 months to comply – for this reason, we ask you to disclose any ingredient you know is from a BE source.

b. Companies are encouraged to reach out directly to USDA AMS with their questions at befooddisclosure@usda.gov, or contact their national trade associations with questions as they arise who can also coordinate questions with USDA AMS.
c. The aforementioned trade associations will communicate regularly with each other and with USDA AMS to compare and share updates on NBFDS compliance progress.

APPENDIX 1: CONSUMER BRANDS ASSOCIATION SUPPLIER QUESTIONNAIRE

Introduction

The purpose of this questionnaire, developed in collaboration with the Corn Refiners Association and Institute of Shortening and Edible Oils, is to illustrate key questions related to the recordkeeping requirement of the National Bioengineered Food Disclosure Standard as described below which obligates food manufacturers, importers, and other regulated entities that label foods for retail sale to disclose the presence of bioengineered (BE) foods and BE food ingredients.

The questions outlined below should not be excerpted and should be presented in their entirety without editing, or paraphrasing. Companies should screen questions with their own internal and/or external legal counsel and should safeguard confidential or proprietary business information.

Once the responses have been received to the questionnaire, companies can also assess additional exclusions or exemptions found in the BE labeling rule, including those for:

- certain products subject to the labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act,
- foods served in a restaurant or similar retail food establishment,
- very small food manufacturers,
- foods derived from animals that consumed feed produced from, containing, or consisting of a BE substance, and
- incidental additives.

Standardized Supplier Questionnaire

The National Bioengineered Food Disclosure Standard (NBFDS) was published by the US Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) in December 2018. This rule defines bioengineered (BE) foods "as those that contain 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." USDA BE regulations, at 7 CFR 66.1, exclude from the BE definition incidental additives that are present in food at an insignificant level and that do not have any technical or functional effect in the food, as that term is defined at 21 CFR 101.100(a)(3).

Name of Supplier:
Product Description:
Product Code:

1. Is the food or are any of the product's labeled ingredients certified organic under the USDA National Organic Program?

□ Yes □ No

List the certified organic food or ingredient(s):

Additional Notes:

2. Other than certified organic ingredients, are any of the labeled ingredients listed in your product's ingredient statement either (a) derived from a commodity on the AMS List of Bioengineered Foods **or** (b) do you have actual knowledge that the ingredient(s) is bioengineered?

□ Yes, provide details below, then go to question 3 □ No, go to question 5

List bioengineered (BE) ingredient(s) and BE source:

Additional Notes:

3. Do any of the labeled ingredients contain detectable bioengineered genetic material or rDNA?

□ Yes, no further information needed □ No, go to question 4

Additional Notes:

4. If any of the BE-derived ingredient(s) do not contain detectable bioengineered genetic material or rDNA, how has this been demonstrated? Please answer for each declared ingredient that is derived from a BE commodity and does not contain modified genetic material.

□ Validation of the manufacturing process to verify that the ingredient is refined as to no longer contain detectable modified rDNA, consistent with the USDA guidance on validation
□ Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material, consistent with the USDA guidance on detectability testing

Additional Notes:

5. Are any of the ingredients listed in your product's ingredient statement derived from Non-BE commodities (e.g., source protected, identity preserved, or originate from a country where BE food is not commercially grown)?

□ Yes, provide details below, then go to question 6 □ No, no additional information needed

List Non-BE ingredient(s):

Additional Notes:

6. If yes, do you have an Identity Preservation Program and/or quality control measures in place that limit inadvertent or technically unavoidable presence of BE substances in each Non-BE ingredient to less than 5% (e.g., prevent cross-contamination with other BE substances in containers or equipment)?

□ Yes □ No

If yes, please describe:

Additional Notes:

□ In the event of any change that affects the information provided in this response, including the BE status of the food or the documentation provided, please confirm by checking this box that you will notify [Name of Company] prior to shipping the product, and provide updated documentation to reflect any changes.

□ I attest, to the best of my knowledge and belief, that all information provided in this questionnaire is accurate and complete.

_____

Name

_____

Title

_____

Signature