REGULATORY FOCUS

Disclosure under the national BE standard for dietary supplements

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With the approach of the 1 January 2022 mandatory compliance deadline for the National Bioengineered Food Disclosure Standard (BE standard), manufacturers and importers of dietary supplements should work to develop strategies for compliance and evaluating each product's bioengineered (BE) status if they have not already done so. This article reviews the requirements for disclosure under the BE standard.

Introduction

In May 2014, the Vermont legislature passed an act requiring "the labeling of food produced with genetic engineering."[1] That set off a flurry of federal legislative activity and advocacy that culminated in the passage of Public Law 114-216, which amended the Agricultural Marketing Act of 1946 to establish a BE standard.[2] The secretary of the US Department of Agriculture (USDA) was tasked with establishing the standard and the requirements and procedures for executing it,[2] and the agency's Agricultural Marketing Service (AMS) issued the final rule on 21 December 2018 (7 CFR Part 66).[3] The mandatory compliance date for all foods entering commerce is 1 January 2022 (§66.13(c)).

The mandatory disclosure requirement of the BE standard applies to human food, including dietary supplements, that is subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act, as well as some products under the jurisdiction of the USDA's Food Safety and Inspection Service. There are several express exemptions to the disclosure requirement in the regulations, including an exemption for very small manufacturers, a threshold for inadvertent or technically unavoidable presence of BE substances of up to 5% for each ingredient, and food and supplements certified under AMS's National Organic Program (§66.5(e)).

Who is regulated

The BE standard and the final rule incorporate the definition of "food" in the FDCA (section 201, 21 USC 321). This broad definition of food includes articles used for food or drink and articles used for components of any such article. Dietary supplements, dietary ingredients, and other ingredients (such as diluents, carriers, and processing aids), are included in this definition of "food." Entities regulated under the BE standard include manufacturers (unless they qualify as very small manufacturers), importers, and retailers (§66.5). If a food is packaged before receipt by the retailer, then the manufacturer or importer is responsible for disclosure. If a retailer packages or sells the food in bulk, then the retailer is responsible for disclosure.

Definition of 'bioengineered'

The BE standard defines "bioengineered food," in part, as "a food that 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" (7 USC 1639(1)). The regulations excluded certain items from the definition of bioengineered food and thus from the scope of the BE standard, including food that "does not contain modified genetic material." As discussed below, under the heading Detectability, a food does not contain genetic material if the genetic material is not "detectable" within the meaning of the regulation (§66.1; 66.9). Selection of test methods and validation of refining processes are addressed in AMS's guidance documents.[4,5] There is no affirmative requirement to identify the BE status of all ingredients in a product if a company has determined that a product must bear the disclosure based on some ingredients in the product.[6]

List of bioengineered foods

To aid companies considering whether they need to make a BE food disclosure, AMS developed a list of BE foods.[7] If a regulated entity uses a food or an ingredient produced from food that is on the list, the entity's records will determine whether the food must bear a BE food disclosure. The list is not exhaustive and will be updated as necessary. Entities are still required to disclose BE foods if they have actual knowledge that the food is BE, even if it is not on the list.[7]

Detectability

If the genetic material in a food or dietary supplement is not detectable, then, under AMS's regulations, the food or dietary supplement is not BE, and therefore disclosure is not required (§66.1). This concept may be especially important in determining whether some refined ingredients produced from those on the list of BE foods (e.g., high-fructose corn syrup, canola oil) are exempt from the disclosure requirement. There are three ways under the regulations to demonstrate modified genetic material is not detectable:
Records verify the food is sourced from a non-BE crop or source;
Records verify the food has been subjected to a refinement process "validated" to make modified genetic material undetectable; or
Testing records confirm the absence of modified genetic material (§66.9(a)).

The regulations also set out general standards of performance that must be followed if using analytical testing, including that the testing method used is fit for the purpose and testing validity ensures consistent accurate analytical performance (§66.9(b)).

AMS's guidance includes the following general steps to validate a refinement process:

- Identify raw materials, ingredients, and product-contact materials;
- Define characteristics and the intended use of the end product;
- Define the sequence and interaction of all processing steps used to arrive at the end product;
- Identify key steps in the refinement process that may influence the end product's characteristics and its ability to meet specified requirements;
- Assemble validation information that demonstrates the refinement process operates as intended to meet specific requirements (end-product characteristics), conducting studies as needed;
- Continually verify the refinement process is operating as validated;
- Revalidate the refinement process, as applicable, if significant changes are made to the process; and
- Maintain records of the validation and ongoing verification.[5]

AMS makes clear in its FAQs that validation of a refining process is not a requirement, nor is there a requirement to validate each step in a process."[8] It also:

- Indicates that testing of a finished ingredient for detectable genetic material can be done to validate a refining process;[8]
- Indicates that a process, once validated, may be used by different facilities, and that entities may validate common processes used to produce multiple ingredients;[8] and
- Reminds entities there is no specified threshold of minimal detection for rDNA, as test methodologies and technology continue to advance and detect increasingly minimal levels of rDNA.[8]

Exemptions

As already noted, there are several exemptions to the BE standard and the final rule (§66.5). Very small food manufacturers, defined as those with less than

$2,500,000 in annual receipts, are exempted from the disclosure requirements (§66.5(b)). Food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance (§66.5(d)). Food certified under the National Organic Program is exempt from the disclosure requirements (§66.5(e)). In addition, the Final Rule allows each ingredient to contain up to five percent of a BE substance, as long as it is inadvertent or technically unavoidable (§66.5(c)).

Factors and conditions

Because the technology of bioengineering is evolving, AMS created a petition process for requesting a determination by AMS regarding additional factors and conditions not otherwise considered in the definition of "bioengineered food." As already noted, AMS left open the possibility to adopt additional "factors and conditions" that might exclude products such as dietary supplements from the disclosure requirement, if requested (83 Fed. Reg. 65814, 65844; Dec. 21, 2018). AMS did adopt incidental additives as a factor or condition, discussed in section E.1 of the preamble of the final rule (83 Fed. Reg. at 65821, §66.1). Incidental additives, when used in accordance with 21 CFR 101.100(a)(3), are not bioengineered foods or ingredients and do not trigger the need for disclosure because they are present at an insignificant level and do not have any technical or functional effect (21 CFR 101.100(a)(3)).

Dietary supplements

AMS specifically addresses the application of the BE standard to dietary supplements in the preamble to the final rule and in FAQs on its website (83 Fed. Reg. at 65815). The FAQs state, "[t]he law does include dietary supplements in the definition of food covered under the standard, so manufacturers and importers of dietary supplements must comply with the disclosure requirements of the Standard."[3,9] This is consistent with the Dietary Supplement Health and Education Act (DSHEA) of 1994 (P.L. 103-417), which added a definition of "dietary supplement" to the Federal Food, Drug, and Cosmetic Act. In relevant part, that definition states: "Except for purposes of section 201(g) [which defines the term "drug"], a dietary supplement shall be deemed to be a food" within the meaning of the statute. In the preamble to the final rule, AMS acknowledged the receipt of comments requesting that dietary supplements be excluded from the definition of "bioengineered food," and stated that interested entities can petition AMS to adopt additional "factors and conditions" that might exclude such products (83 Fed. Reg. at 65844).

Labeling of bioengineered foods

Disclosure

USDA has provided flexibility in how a regulated entity discloses the BE status of a food on a package, and four options are provided for disclosure. There is not a requirement for foods sold online, in catalogs, or through other remote means to include a bioengineered food disclosure, other than what is required on the packaging itself.

The first option is on-package text, which must use the phrases "Bioengineered food," or "Contains a bioengineered food ingredient" (§66.102). While there is no font size requirement for the disclosure, it 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" (§66.100(c)).

The second option is to place a BE symbol on the packaging (§66.104). AMS designed two symbols – one for "Bioengineered" food and the other for voluntary disclosure of food "Derived from bioengineering." Both symbols are available in color and black and white.

The third option is the use of an electronic or digital link, and the link, such as a QR code, must include instructions to "Scan here for more food information" or similar language (§66.106). The language may only be changed to reflect technological changes, such as "Scan anywhere on package for more food information" for products with digital watermarks (§66.106(a)(1)). When it is accessed, the electronic or digital link must go directly to the product information page (§66.106(b)). The product information page must be the first screen to appear on an electronic or digital device and must include the bioengineered food disclosure in text or symbol form (§66.106(b)(1)). The electronic or digital disclosure must also be accompanied by a telephone number, in close proximity, that includes the statement "Call [1-000-000-0000] for more food information" (§66.106(a)(2)). AMS does allow for a combined statement indicating, "Scan here for more food information or call [1-000-000-0000]."[6] The phone number indicated must provide the BE food disclosure, regardless of time of day, and may be a recorded message. (§66.106(a)(2))Regulated entities are not allowed to collect information about the consumer or their devices when using this option (§66.106(b)(4)). It should be noted that the final rule does not allow for the use of a URL without embedding it in an electronic or digital link, except for disclosures made by small manufacturers and for disclosures on very small packages (see below, under the heading, Small manufacturers and packages; §66.100(e)).

The fourth option is to provide disclosure via text message (§66.108). Packaging must include the statement: "Text [command word] to [number] for bioengineered food information." The number must be a number, including a short code, that sends an immediate response to the consumer's mobile device (§66.108(a)).

Placement options

The final rule allows regulated entities to place disclosure on the information panel adjacent to the manufacturer/distributor information, or on the principal display panel (§66.100(d)(1)-(2)). If there is insufficient space on either the information panel or the principal display panel, the final rule allows for disclosure to be made on any other panel likely to be seen by a consumer under "ordinary shopping conditions" (§66.100d(3)).

Small manufacturers and packages

Small food manufacturers, with annual receipts of $2,500,000-$10,000,000, may use any of the four disclosure options or direct the consumer to "Call for more food information" or "Visit [URL of the website] for more food information" (§66.112). Such disclosures require an accompanying phone number or website URL. Small packages of less than 40 square inches may use a shortened version of the required on-package statement, including "Scan for info," "Text for info," or "Call for info." Very small packages of less than 12 square inches may use an existing URL for a website or phone number for disclosure (§66.112(d)).

Voluntary disclosure

AMS has allowed for limited voluntary disclosure. Entities that are exempt under §66.5 – very small manufacturer, restaurant, or similar retail establishment – may voluntarily disclose food on the list of BE foods (§66.116(a)). All entities may voluntarily disclose foods that do not contain detectable modified genetic material but are derived from bioengineering (i.e., highly refined ingredients in which the modified genetic material is no longer detectable, such as corn syrup originating from BE corn, and soybean oil).[6] Voluntary disclosure is not allowed for any other foods or ingredients. The AMS has provided examples of foods for which a voluntary disclosure is not permissible, including food produced from animals fed bioengineered feed; soups where the first ingredient is meat; and incidental additives (83 Fed. Reg. at 65830). Those choosing to voluntarily disclose may use any of the available disclosure options. However, the text must be "Derived from bioengineering" or "Ingredients derived from a bioengineered source" (§66.116(b)(1)). If the symbol is used to indicate the product is derived from bioengineering, it must comply with the disclosure requirements (size, location on package, etc.) for the chosen type of disclosure (83 Fed. Reg. at 65830). The symbol can be used in black and white or color.

Recordkeeping requirements

If a product contains a food on the list of BE foods that does not require disclosure – for example, corn syrup originating from BE corn with no detectable modified genetic material – then the entity must maintain records to validate that the food is not bioengineered or no longer contains detectable modified genetic material pursuant to §66.9 and §66.302(b). For a positive disclosure of foods on the list, those records would simply identify the food or ingredient (e.g., "Canola").[10] The final rule requires entities that make a mandatory or voluntary disclosure to keep sufficient records in any format to establish compliance with the rule (§66.302). The final rule does not require specific records or forms; customary or reasonable records that would be generated in the normal course of business may suffice (§66.302). Regulated entities may determine which records to maintain, provided they are sufficient to demonstrate compliance with the disclosure standard, and they may be stored at any business location. These records might include items such as invoices, bills of lading, supply chain records, organic certifications, and laboratory test results (§66.302(a)(4)). The records must be retained for at least 2 years after the food is sold or distributed for retail sale (§66.302(a)(3)). When requested by USDA, the records need to be produced within 5 business days, unless USDA

grants an extension. If on-site access is necessary, USDA will provide notice at least 3 business days in advance (§66.304).

Enforcement

While the BE standard states that failure to make a bioengineered food disclosure as required by the BE standard is prohibited (7 USC §1639b(g)(1)), USDA does not have the authority to issue a recall or impose civil penalties for violations of the BE standard (7 USC §1639b(g)5). However, the BE standard allows states to adopt identical requirements after the BE standard is implemented, and they may impose remedies for violations of their standards, such as monetary damages and injunctive relief (7 USC §1639b(e)). As an initial matter, complaints about possible violations of the BE standard can be made to AMS, who will determine whether further investigation is warranted (§66.400). AMS will then conduct a records audit, if necessary, and the regulated entity will be notified of the results of the audit. Those results can be appealed at a hearing (§66.404), and following any appeal, AMS will issue a final determination which will be posted to AMS's website (§66.406). If states adopt identical requirements that allow for civil penalties, litigation is a potential outcome when the final determinations are made public. Further, failure to provide a disclosure when required could trigger litigation under existing laws, such as those that prohibit deceptive practices.

Conclusion

As the 1 January 2022 mandatory compliance date for the BE standard approaches, manufacturers and importers of dietary supplements should work to develop a compliance strategy and evaluate each product's BE status if they have not already begun to do so. As part of the compliance strategy, a company should determine if existing records are sufficient, or whether additional records will be necessary. The company should also determine whether any testing or validation should occur, or if already completed, ensure that the testing comports with AMS guidance. If a food requires the disclosure, the company should determine the option of disclosure best suited to the company and its products. Finally, if a food does not require disclosure, the company should determine if a voluntary disclosure is available and appropriate. Making all of these determinations may require detailed communications and cooperation among various entities in the supply chain and could result in the need to revise existing manufacturing and supply agreements.

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