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Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine**

**Issued November 2015
Revised March 2019**

OMB Control No. 0910-0807

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Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

Manufacturers often voluntarily provide information on their labels beyond the information required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or FDA regulations. Their reasons for doing so may have to do with marketing or providing information of specific interest to their customers. This guidance addresses the voluntary labeling of plant-derived foods with information concerning whether the food was or was not produced using genetic engineering.² Some consumers are interested in knowing whether a food was produced using

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

² In July 2016, the National Bioengineered Food Disclosure Standard (NBFDS), PL 114-216, was signed into law. This law amended the Agricultural Marketing Act and charged the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) with developing a national mandatory standard for disclosing the presence of bioengineered material in human food. The term "bioengineered" as defined in that law includes products that are GE. The law primarily applies to human food derived from plants. Therefore, FDA no longer has authority over voluntary labeling to indicate the presence of GE content in human **foods including those derived from plants**. FDA retains jurisdiction over labeling statements to indicate the absence of GE content in human food. The NBFDS does not apply to animal food.

In light of the NBFDS and its implementing regulations issued on December 20, 2018, FDA is reviewing this draft guidance to consider what additional or new recommendations may be needed for the kinds of products or statements, including claims of non-GE content, that are not covered by the NBFDS.

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genetic engineering and some manufacturers want to respond to this consumer interest. FDA is providing this guidance to assist food and feed manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering. FDA's main concern within the context of this guidance is that such voluntary labeling be truthful and not misleading.

In this guidance, we use the terms "genetic engineering" and "bioengineering" to describe the use of modern biotechnology. Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection of plants (Ref. 1). The term "modern biotechnology" may alternatively be described as "recombinant DNA (rDNA) technology" (Ref. 2), "genetic engineering" (Ref. 3), or "bioengineering." These terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders and are used in this guidance to refer to foods derived from new plant varieties developed using modern biotechnology. The term "genetic modification" is also sometimes used to refer to the use of modern biotechnology (e.g., Ref. 4), although FDA's longstanding position, as discussed later in this guidance, is that such use of the term is less accurate because the term encompasses the broad spectrum of genetic alterations that can be made in plants (see, e.g., Ref. 5).

Because technically it is the plant that is genetically engineered rather than the food, for simplicity we use the term "food derived from genetically engineered plants" in this guidance to refer to products that are derived from genetically engineered plants. (For reasons discussed in more detail later in this guidance, FDA does not use the terms "genetically modified" or "genetically modified *organism*" (GMO) when referring to foods derived from genetically engineered plants.) Because section 201(f)(1) of the FD&C Act defines "food" in relevant part as "articles used for food or drink for man or other animals," the food derived from genetically engineered plants addressed in this guidance include plant-derived foods for animals as well as such foods for humans.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded. 21 U.S.C. § 331(a). Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. 21 U.S.C.

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§ 343(a)(1). Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n). In a 1992 “Statement of Policy: Foods Derived from New Plant Varieties” (1992 Policy) (Ref. 5) FDA explained its interpretation of the FD&C Act with respect to foods derived from new plant varieties, including varieties developed using bioengineering. In the 1992 Policy, FDA stated that it was not aware of any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding (Ref. 5). Further, FDA concluded that the method of development of a new plant variety (including the use of new techniques such as rDNA technology) is generally not material information within the meaning of section 201(n) of the FD&C Act, and would not usually be required to be disclosed in the labeling for the food. This determination was reviewed and upheld by the court in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178–79 (D.D.C. 2000) (finding that FDA’s determination that genetic engineering, alone, is not a material fact that warrants food labeling was entitled to deference) (Ref. 10). Labeling provided by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered as described in this guidance is acceptable to FDA, provided that such labeling is truthful and not misleading. Some consumers are interested in the information provided in such labeling.

The FD&C Act does not define the term “material” within the context of section 201(n) of the FD&C Act. Historically, the agency has interpreted the term, within the context of food, to mean information about the attributes of the food itself. For example, FDA has required special labeling in cases where the absence of such “material” information may: (1) pose special health risks (e.g., a warning statement on protein products used in very low calorie diets (21 CFR 101.17(d)) (Ref. 6), or a caution statement not to feed animal food products that contain animal-derived protein to cattle or other ruminants (21 CFR 589.2000(c)(1)(i)) (Ref. 7)); (2) mislead the consumer in light of other statements made on the labeling (e.g., a requirement for quantitative nutrient information when certain nutrient content claims are made about a product (21 CFR 101.13(j)) (Ref. 8)); or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic (e.g., taste, smell, or texture), or functional characteristics of the food it resembles when in fact it does not (e.g., a statement that reduced fat margarine is not suitable for frying (21 CFR 101.13(d)(1)) (Ref. 9). Further, section 403(i) of the FD&C Act and FDA regulations require that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term (21 U.S.C. § 343(i); 21 CFR 101.3, 501.3). For example, if oil from a genetically engineered canola plant has a significantly different amount of lauric acid such that the fatty acid composition of the oil is significantly changed compared to traditional canola oil, the term “canola oil” no longer adequately identifies or describes the nature of the oil or its characterizing properties, particularly

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since oils are distinguished by their fatty acid profiles.

Since the commercial introduction of bioengineered crops in the United States in 1996, the use of bioengineered crops has accelerated and such crops are now widely used (Ref. 11). In 2013, in the United States, bioengineered soybeans made up 93 percent of the acreage of planted soybeans, bioengineered cotton made up 90 percent of the acreage of planted cotton, and bioengineered corn varieties made up 90 percent of the acreage of planted corn (Ref. 11). In addition, bioengineered sugar beets accounted for 95 percent of the acreage of planted sugar beets in the 2009-2010 crop year (Ref. 11).

III. GUIDANCE

A. General principles

In determining whether a food is misbranded, FDA generally reviews labeling statements under sections 403 and 201(n) of the FD&C Act, and if applicable, other sections of the FD&C Act. Under section 403(a)(1) of the FD&C Act, a food is misbranded if its label or labeling is false or misleading in any particular. For example, the label on a chocolate bar may not declare that the chocolate contains ingredients, such as walnuts and coconut oil, if those ingredients are not actually present in the chocolate.

Under section 201(n) of the FD&C Act, both the presence and the absence of information are relevant to whether labeling is misleading. Put another way, food labeling may be misleading if it makes or suggests certain representations, or if it fails to disclose facts that are material in light of representations made or suggested about a food or facts that are material with respect to the consequences that may result from use of the food. In determining whether a labeling statement about a food is misleading under sections 201(n) and 403(a)(1) of the FD&C Act, FDA takes into account all labeling for that food, including the label on the food itself (e.g., all words used on the label including the brand name of the product, vignettes, logos or any of its containers or wrappers and other information accompanying the food, such as labeling for the food that is on the internet. Labeling means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. 321(m) (section 201(m) of the FD&C Act). Firms should be aware that “labeling” may extend to information beyond that included on containers or wrappers. For example, in certain circumstances, information that is disseminated over the internet by, or on behalf of, a regulated company meets the definition of labeling in section 201(m) of the FD&C Act and is subject to applicable requirements. See, e.g., Guidance for Industry and FDA: Dear Manufacturer letter Regarding Food Labeling, January 2007, available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053425.htm>. These general principles apply in evaluating a food labeling claim, including a statement about whether a food is or is not developed using modern plant biotechnology.

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B. Statements about foods that are not derived from genetically engineered plants

Food manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering, as long as such information is truthful and not misleading. In general, an accurate statement about whether a food was not produced using bioengineering is one that provides information in a context that clearly refers to bioengineering technology. Examples of such statements include:

- “Not bioengineered.”
- “Not genetically engineered.”
- “Not genetically modified through the use of modern biotechnology.”
- “We do not use ingredients that were produced using modern biotechnology.”
- “This oil is made from soybeans that were not genetically engineered.”
- “Our corn growers do not plant bioengineered seeds.”

Other terms are sometimes used by manufacturers in food labeling regarding whether a food was not derived from genetically engineered plants, including “not genetically modified” and claims using the acronym “GMO” (genetically modified organism). For the reasons discussed in the remaining paragraphs of this section, FDA recommends terms such as “not bioengineered,” “not genetically engineered,” and “not genetically modified through the use of modern biotechnology.” However, FDA does not intend to take enforcement action against a label using the acronym “GMO” in a statement indicating that the product (or an ingredient) was not produced through the use of modern biotechnology, as long as the food is, in fact, not derived from a genetically engineered plant and the food’s labeling is not otherwise false or misleading, as further discussed in this guidance. Similarly, we do not intend to take enforcement action against a label using the acronym “GMO” in a statement indicating that the product (or an ingredient) was produced through the use of modern biotechnology, as long as the statement was true and the food’s labeling is not otherwise false or misleading.

As stated, FDA encourages manufacturers to use labeling claims that state that a food product (or its ingredients, as appropriate) was not developed using bioengineering, genetic engineering, or modern biotechnology such as the claims included above.

“Not genetically modified” or “Non-genetically modified.” As noted above, the term “genetic modification” encompasses a broad range of methods that can be used to alter the genetic composition of a plant. FDA’s longstanding position has been that the term has traditionally been used broadly to signify the alteration of the genotype of a plant using any technique, new or traditional (See, for example, Refs. 5 and 12). The term “modification,” in this context means the alteration in the genetic composition of a plant that results from adding, deleting, or changing hereditary traits, irrespective of the method (Refs. 3, 5). Modifications may be minor, such as a

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single mutation that affects one gene, or major alterations of genetic material derived from conventional breeding (e.g., selection) that affect many genes. Because the term “genetically modified” can encompass any alteration to the genetic composition of a plant, including alterations achieved through traditional hybridization or breeding techniques, that term could apply to most cultivated food crops since most food crops are the product of selective breeding (Ref. 13). An example of a food that is derived from a plant that has not been subject to any form of selective breeding might be berries collected from wild plant varieties.

FDA encourages food manufacturers to ensure that labeling terminology concerning the use of modern biotechnology in the production of a food or its ingredients be accurate and consistent and that the integrity and meaning of scientific terminology be preserved to help ensure clear communication in food labeling. Thus, FDA encourages manufacturers to use labeling claims that state that a plant-derived food product or its ingredients, as appropriate, was not developed using bioengineering, genetic engineering, or modern biotechnology. Alternatively, FDA encourages that the terms bioengineering, genetic engineering, or modern biotechnology be used in conjunction with claims using the term “genetically modified” or “genetic modification” to indicate that a plant-derived food has not been genetically engineered or bioengineered (e.g., “not genetically modified through the use of modern biotechnology”).

“GMO free,” “GE free,” “does not contain GMOs,” “non-GMO,” and similar claims. The term “free” conveys zero or total absence unless a regulatory definition has been put in place in a specific situation (Refs. 14, 15). The potential challenges of substantiating a “free” claim are described in Section III.D of this guidance, and in light of these challenges FDA recommends that manufacturers not use food labeling claims that indicate that a food is “free” of ingredients derived through the use of biotechnology. Instead, FDA recommends that manufacturers consider the use of other types of statements to indicate that a plant-derived food has not been produced using bioengineering, as described above and below.

The “O” in the acronym “GMO” refers to the word “organism.” Most foods do not *contain* entire organisms (foods such as yogurt that contain microorganisms are exceptions); however, in some formulations this acronym may be read as meaning that the food was not *derived from* a genetically engineered organism, such as a plant that has been genetically engineered. In light of potential confusion regarding the meaning of the acronym “GMO,” FDA encourages manufacturers to consider the use of other types of statements to indicate that a plant-derived food has not been produced using bioengineering, as described above. For example, a statement that “our tomato growers do not plant bioengineered seeds” or “this oil is made from soybeans that were not genetically engineered” could be used.

Context. As noted above, under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Both the presence and absence of information on labeling can be misleading. Regarding the absence of information, section 201(n) of the FD&C Act provides in relevant part that labeling is misleading if it fails to reveal facts that are

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material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

An example of a statement that might by itself be truthful, but could be misleading when evaluated in the context of the entire labeling might be a statement that a particular ingredient in the food was not bioengineered, where there is another ingredient in the food that was bioengineered, about which the labeling is silent. For example, on a product made largely of flour derived from genetically engineered corn and a small amount of non-genetically engineered soybean oil, a claim that the product “does not contain bioengineered soybean oil” could be misleading if consumers believe that the entire product, or a larger portion of it than is actually the case, is free of bioengineered material. It may be necessary to carefully qualify the statement in order to ensure that consumers understand its significance.

Another example of a statement in food labeling that may be false or misleading could be the statement “None of the ingredients in this food is genetically engineered” on a food where some of the ingredients are incapable of being produced through genetic engineering (e.g., salt). It may be necessary to carefully qualify the statement where modern biotechnology is not used to produce a particular ingredient or type of food.

Further, a statement may be false or misleading if, when considered in the context of the entire label or labeling (as noted in Section IIIA. above), it suggests or implies that a food product or ingredient is safer, more nutritious, or otherwise has different attributes than other comparable foods because the food was not genetically engineered. For example, the labeling of a bag of specific type of frozen vegetables that states that they were “not produced through modern biotechnology” could be misleading if, in addition to this statement, the labeling contains statements or vignettes that suggest or imply that, as a result of not being produced through modern biotechnology, such vegetables are safer, more nutritious, or have different attributes than other foods solely because the food was not produced using modern biotechnology.

Common or usual name. Section 403(i)(2) of the FD&C Act requires that, for a food that is made from two or more ingredients, each ingredient must be declared on the food label by its common or usual name. Accordingly, FDA regulations require (among other things) that ingredients required to be declared on the label or labeling of a food must be listed on either the principal display panel or information panel of the food subject to certain exceptions. 21 CFR 101.4(a)(1). Further, FDA regulations provide that ingredients required to be declared on the label or in the labeling of food must be listed by their common or usual name and without intervening material. See 21 CFR 101.2(e), 101.4(a)(1), 501.2(e) and 501.4(a). In general, FDA has interpreted a term used to describe an ingredient in the list required by FDA’s regulations (typically in an ingredient statement) that is not part of the ingredient’s common or usual name (e.g., “pure,” “fresh,” “certified non-GE”) to be intervening material that violates FDA

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regulations (Ref. 16). However, elsewhere on the label, other than in the ingredient statement, terms that are not a part of the common or usual name of an ingredient may accompany the name of the ingredient provided it is done in a manner that is truthful and not misleading and otherwise in accordance with the FD&C Act and applicable regulations. For example, the principal display panel on a bottle of soybean oil made from soybeans that were not bioengineered could say “Made from certified non-GE soybeans,” provided that (1) the text does not obscure information required to be on the principal display panel, such as the statement of identity; and (2) the ingredient (i.e., soybean oil) is listed in the ingredient list by its common or usual name and without intervening material. This statement could also appear on the information panel of the food product, provided that it does not appear in the ingredient list. In this example, for the ingredient soybean oil, the ingredient list may only list such ingredient as “soybean oil” as that term is the common or usual name for the ingredient.

C. Statements about foods that are derived from genetically engineered plants

As explained in section III.A above, food labeling may be misleading if, among other things, it makes or suggests certain representations, or if it fails to disclose facts that are material in light of representations made or suggested in the labeling, or material with respect to the consequences that may result from use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. In general, an accurate statement about whether a food was produced using bioengineering is one that provides information in a context that refers to bioengineering technology. Examples of such statements include:

- “Genetically engineered” or “This product contains cornmeal from corn that was produced using modern biotechnology.”
- “Some of our growers plant soybean seeds that were developed through modern biotechnology to be drought tolerant.”

These kinds of simple statements that a food was developed using bioengineering are not likely to be misleading.

Multi-ingredient foods. Where a benefit from a bioengineered ingredient in a multi-ingredient food is voluntarily described in the labeling for a food, the statement should be worded so that it addresses the ingredient and not the food as a whole; for example, “This product contains laurate canola from bioengineered canola that may be used as an alternative to palm kernel oil.” In addition, the amount of the bioengineered ingredient in the food may be relevant to determine whether the statement is misleading. This would apply especially where the bioengineered difference is characterized as a functional improvement. For example, it may be misleading to make a statement about a functionally improved ingredient (e.g., in this example, that the oil may be used as an alternative to palm kernel oil in high temperature cooking applications) in a food that contains only a small amount of the ingredient, if such statement implies that the food’s

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overall functional quality is significantly improved when the amount of the ingredient present is not sufficient to confer the properties indicated. Research suggests that the presence of a statement on a product label regarding a specific benefit associated with the product can create a more favorable overall perception of a product. (Refs. 17, 18, and 19).

The labeling requirements that apply to foods generally, some of which are described above, also apply to food produced using genetic engineering. Foods from some genetically engineered crops, like food from non-genetically engineered crops, may have characteristics that are materially different from those of comparable foods. Such foods would require labeling under existing provisions to disclose such material differences.

Based on sections 403(a)(1), 201(n), and 403(i) of the FD&C Act:

- If a food derived from genetically engineered plants is significantly different from its traditional counterpart such that the common or usual name or existing statement of identity no longer adequately identifies or describes the new food, the name of the new food must be changed to a term that accurately identifies or describes the new food. For example, if oil from a genetically engineered plant has a significantly different amount of lauric acid such that the fatty acid composition of the oil is significantly changed compared to that of conventionally produced oil, the standard name for the oil no longer adequately identifies or describes the nature of the oil or its characterizing properties, particularly since oils are distinguished by their fatty acid profiles. See 21 CFR 102.5, 502.5. Under sections 403(a)(1), 201(n), and 403(i) of the FD&C Act, a word or phrase like “laurate” is required to appear as part of the new name to appropriately identify or describe the food. See also 21 CFR 101.3, 501.3.
- If a genetically engineered food or one of its constituents differs from its traditional counterpart regarding how the food is used or the consequences of its use (for example, if the genetically engineered food behaves differently than its traditional counterpart when used in a comparable way, such as in frying or canning), a statement must be made on the label to describe the difference(s) in use or the consequence(s) of its use. Therefore, in this case, under sections 403(a)(1) and 201(n) of the FD&C Act, the fact that such food behaves differently when canned or fried must be disclosed in the labeling for the food.
- If a food derived from genetically engineered plants has a significantly different nutritional property compared to its traditional counterpart, its label must describe such difference. For example, if (hypothetically) a vegetable has been bioengineered to contain vitamin B12, the fact that the vegetable contains vitamin B12 and that non-bioengineered versions of that vegetable do not contain vitamin B12 is material. Thus, in this instance, under sections 403(a)(1) and 201(n) of the FD&C Act, the fact that the vegetable contains vitamin B12 would have to be disclosed in the labeling for the vegetable.
- If a food derived from genetically engineered plants contains an allergen that consumers would not expect to be present in the food based on the name of the food, the presence of

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that allergen must be disclosed on the label. The presence of such allergen in the food would be material information. Under sections 403(a)(1), 201(n) and potentially, in some circumstances, section 403(w) of the FD&C Act, the labeling for such food is required to disclose the presence of such allergen.

D. Substantiation of labeling statements

A manufacturer that claims that a food product or its ingredients, including foods such as raw agricultural commodities, is bioengineered or is not bioengineered should substantiate that the claim is truthful and not misleading. We note that when selecting a method to substantiate a claim, a manufacturer should consider the specifics of the claim as one method might substantiate one kind of claim, but not another. The following methods may be used to substantiate that a claim, within this context, is truthful and not misleading:

- *Documentation of handling practices and procedures.* Manufacturers that have control over growing, harvesting, storing, and distribution should consider appropriate recordkeeping to document whether foods are or are not produced using bioengineering including segregation procedures, to ensure that a food's labeling is not false or misleading. Manufacturers not engaged in these activities may rely on certifications or affidavits from farmers, processors, and others in the food production and distribution chain to document whether foods are or are not produced using bioengineering. If a farmer, distributor, or manufacturer dealt only in plant-derived foods that were not bioengineered, they could have records attesting to this fact for all ingredients entering their distribution chain. For example, a farm could certify that it does not plant bioengineered seeds and keep records of handling practices for that crop to substantiate that the crop was not bioengineered. Similarly, a distributor could certify that it only purchases foods from farmers that do not plant bioengineered seeds and keep records to substantiate such certifications.
- *Use of certified organic food.* The Department of Agriculture's (USDA) Agricultural Marketing Service administers the National Organic Program, which enforces laws and regulations regarding certified organic foods. Foods that comply with 7 CFR part 205 (USDA organic regulations) would meet criteria to be labeled as not produced or handled using bioengineering. USDA regulations on organic food production and handling provide in relevant part that in order for a food to be sold or labeled as "100% organic," "organic" or "made with organic (specified ingredients or food group(s)), the food must be produced and handled without the use of such "excluded methods" as these methods are defined in 7 CFR 205.2. Compliance with USDA's requirements at 7 CFR 205.105 can therefore be used to support food labeling claims about the production of food without the use of bioengineering.³ Documentation of compliance with the USDA

³ USDA regulations cited in this section refer to the subject regulations as they existed as of the date of this guidance document.

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organic certification requirements and recordkeeping requirements for certified operations (7 CFR 205.100, 7 CFR 205.103 and 205.400 et seq.) would be sufficient to substantiate a food labeling claim that a food was not produced using bioengineering. (Ref. 20)

- *Use of validated test methods.* Validated analytical methods may be useful in confirming the presence of bioengineered material in food derived from genetically engineered plants or food ingredients. Where tests have been validated and shown to be reliable, they may be used to confirm the presence of bioengineered material in support of a claim that a food has been bioengineered. For many foods, however, particularly for highly processed foods such as oils, it may be difficult to differentiate, through validated analytical methods, between plant-derived food developed through bioengineering and plant-derived food developed using traditional breeding methods. Tests may be less useful in demonstrating the absence of bioengineered material in food derived from genetically engineered plants or food ingredients. It would be very difficult to identify all test methods that might be necessary to support an analysis-based statement that a particular food does not contain any material from each variety of bioengineered plant in the marketplace. In addition, the specific analytical methods necessary to detect bioengineered material likely will change as new bioengineered plant varieties are introduced to the marketplace, so firms may have to update tests and then routinely and methodically (e.g., shipment by shipment or lot by lot) analyze their ingredients or products for bioengineered material. If validated test methods are not available or reliable because of the way a plant-derived food is produced or processed, it may be more practical to substantiate a claim for such foods differently, such as documenting handling practices and procedures. For example, statements indicating that a food has not been produced using bioengineering could be substantiated through documentation of practices and handling procedures or documentation of compliance with USDA organic certification requirements (7 CFR 205.100 and 205.400 et seq.) and recordkeeping requirements for certified operations (7 CFR 205.103) as described above.

IV. PAPERWORK REDUCTION ACT OF 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501-3520). The collections of information have been approved under OMB control number 0910-0807.

V. REFERENCES

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through

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Friday; they are also available electronically at <https://regulations.gov>. References without asterisks are not on public display at <https://regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA had verified the website addresses, as of March 6, 2019, but websites are subject to changes over time.

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