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The National Bioengineered Food Disclosure Standard: Overview and Select Considerations

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SUMMARY

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The National Bioengineered Food Disclosure Standard: Overview and Select Considerations

In July 2016, Congress enacted P.L. 114-216 (2016 Act), comprehensive legislation to govern the labeling of bioengineered foods. The 2016 Act required the U.S. Department of Agriculture (USDA) to establish the National Bioengineered Food Disclosure Standard. The Standard regulates labeling of bioengineered foods, a term defined in the 2016 Act. The act does not address or define other terms that some members of the public might associate with bioengineered foods, such as *genetically engineered* (GE), *genetically modified*, and *genetically modified organism* (GMO). The Standard guides the mandatory labeling of foods to indicate the presence of GE ingredients. As such, foods meeting requirements identified in the Standard must bear a bioengineered disclosure. Implementation began on January 1, 2020, and mandatory compliance begins on January 1, 2022.

The Standard provides details under the three key issues of applicability, disclosure options, and administrative provisions:

- *Applicability* discusses the definition of *bioengineered food* and the USDA-maintained List of Bioengineered Foods (List). The Standard applies to foods that are or may be derived from bioengineered ingredients, with some exclusions and exemptions. It does not apply to refined products, such as oils or sugars, that derive from GE plants but no longer contain detectable modified deoxyribonucleic acid (DNA). Many groups interpret the Standard as not applying to foods derived from gene editing and other new technologies that do not use recombinant DNA. The Standard exempts from disclosure foods served in restaurants. Some have endorsed such exclusions and exemptions, and others have criticized them.
- *Disclosure Options* outlines acceptable disclosure options for regulated entities, as well as additional options available for specific entities and types of food packages. Most regulated entities may disclose by text, symbol (pictured above), electronic or digital link, or text message. In some cases, a telephone number or website address may be acceptable. Some groups have praised the flexibility that this range of options provides regulated entities, while others have criticized these options as confusing.
- *Administrative Provisions* reviews compliance dates, recordkeeping requirements, and enforcement mechanisms, which include audits, examinations, hearings, and release of public findings. The 2016 Act provided few enforcement mechanisms to promote compliance. The Standard establishes how USDA may investigate accusations of non-compliance and how it may publicly release its findings.

The Standard does not affect how foods derived from biotechnology are regulated for safety and approval for human consumption. The *Coordinated Framework for Regulation of Biotechnology*, a policy the White House issued in 1986, continues to govern how federal agencies, including USDA, evaluate and approve products developed using modern biotechnology. More generally, USDA and the U.S. Food and Drug Administration (FDA) continue to ensure that foods sold in the United States are safe and properly labeled.

USDA's Agricultural Marketing Service (AMS) developed the Standard within a broader societal context. Before the 2016 Act, some members of the public had demanded *mandatory* labeling of the *presence* of GE ingredients in foods, based on the consumer's right to know. Other members of the public had opposed any GE labeling because of the scientific consensus that GE foods are safe to eat and concern that labeling may introduce unwarranted doubts about food safety. Before the 2016 Act, several states had enacted GE labeling laws, creating concerns among industry and consumer groups. In response, Congress debated this and other federal GE labeling legislation. GE labeling programs may be voluntary or mandatory and may indicate the presence or absence of GE ingredients. Several voluntary labeling programs predate the Standard's mandatory labeling requirements. Public and private programs for the *voluntary* labeling of foods continue to indicate the *absence* of GE ingredients in foods. These include the Non-GMO Project and the USDA National Organic Program.

Future considerations for Congress may include ongoing questions consumers may have concerning what it means for a food to be labeled as *bioengineered*, how regulated entities will respond to the Standard's new requirements, how USDA will implement its responsibilities under the Standard, potential market impacts as demand for GE versus non-GE foods may change, and how the Standard aligns with international labeling requirements. Congress may choose to monitor implementation of the new Standard in accordance with its oversight responsibilities.

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Introduction

The United States has been a global leader in developing advanced genetic technologies and applying them to crops and livestock.[1] Federal regulators first approved a genetically engineered (GE) food, the Flavr Savr tomato, for sale in 1994.[2] As additional GE crops gained federal approval, farmers rapidly adopted them. Today, about 90% of canola, corn, cotton, soybean, and sugarbeet acres in the United States are planted with GE varieties.[3] GE foods predominantly enter commerce as processed foods and food ingredients (e.g., soybean oil, corn syrup, and sugar).[4] Some members of the public seek to avoid consuming GE foods, as advances in biotechnology have outpaced their acceptance.

In July 2016, Congress enacted P.L. 114-216 (the 2016 Act), requiring the U.S. Department of Agriculture (USDA) to establish a National Bioengineered Food Disclosure Standard within two years.[5] The 2016 Act followed decades of societal debate about genetic engineering, and it marked the first time that the federal government would require the disclosure of GE foods to consumers. (The 2016 Act defined these as *bioengineered foods*.) With the 2016 Act, the United States joined more than 60 countries that require some form of GE labeling or on-package disclosure of GE foods or food ingredients.[6]

The Standard provides a mandatory national standard for disclosure of the presence of bioengineered foods and food ingredients to consumers. It details who is responsible for making disclosures, what they must look like, and when they are and are not required. The Standard provides U.S. food manufacturers, importers, and retailers with a voluntary compliance period and a mandatory compliance deadline. The more than 126,000 comments that USDA received during the rulemaking process demonstrate significant public interest in its formulation.[7] USDA released the final rule in December 2018, and phased implementation began in January 2020.[8]

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[1] For a history of the development of genetic engineering in agriculture and related regulatory policies, see National Academies of Science, Engineering, and Medicine (NASEM), *Genetically Engineered Crops: Experiences and Prospects*, 2016, pp. 65-96.

[2] The U.S. Food and Drug Administration (FDA) approved the Flavr Savr tomato, genetically engineered to stay firm after harvest, for sale in 1994.

[3] Daniel Hellerstein, Dennis Vilorio, and March Ribaudo, eds, *Agricultural Resources and Environmental Indicators, 2019*, U.S. Department of Agriculture (USDA), Economic Research Service (ERS), Economic Information Bulletin no. 208, May 2019, pp. 30-34.

[4] Gregory Jaffe, *Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions*, Center for Science in the Public Interest, 2015.

[5] P.L. 114-216, "An Act to Reauthorize and Amend the National Sea Grant College Program Act, and for Other Purposes," enacted July 29, 2016. Congress used the reauthorization of the National Sea Grant College Program Act as a legislative vehicle to enact GE labeling legislation. The 2016 Act amended the Agricultural Marketing Act of 1946 (7 U.S.C. §1621 et seq.) to add the Standard as a new subtitle.

[6] A *disclosure* may be a discrete statement or symbol, while a *label* may provide more comprehensive information about a product. This report may use *labeling* as a proxy for *disclosure*. For a summary of international laws, see Center for Food Safety (CFS), "International Labeling Laws," https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws. This CFS summary may not be comprehensive.

[7] USDA delegated development and implementation to the USDA Agricultural Marketing Service (AMS). In June 2017, AMS sought preliminary public input by issuing 30 questions related to the future standard. The public responded with more than 112,000 replies. In May 2018, AMS issued a Notice of Proposed Rulemaking in the *Federal Register*. AMS received approximately 14,000 comments on this proposed rule.

[8] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, December 21, 2018, p. 65835. The final rule adds the Standard as a new Part 66 of Title 7 of the *Code of Federal Regulations*.

Stakeholder reactions to the final Standard have been mixed. Several organizations immediately criticized the final rule, while others supported it. The Organic Trade Association (OTA), the Center for Food Safety (CFS), the Non-GMO Project, and the Institute for Agriculture and Trade Policy (IATP) each released statements with critical comments. OTA remarked that it is "deeply disappointed in the U.S. Department of Agriculture's final GMO labeling rule and calls on companies to voluntarily act on their own to provide full disclosures on their food products about GMO content."[9] CFS stated that "the USDA has betrayed the public trust by denying Americans the right to know how their food is produce[d]."[10] The Non-GMO Project commented that it "is disappointed by the content of the final rule, which jeopardizes GMO transparency for Americans."[11] IATP stated that "unfortunately, the final rule fails to fix the most egregious provisions of the draft rule and is practically useless in conveying accurate information about food ingredients to consumers while they are shopping."[12]

In contrast, the National Corn Growers Association (NCGA), the American Soybean Association (ASA), and the Food Marketing Institute (FMI) provided supportive comments. NCGA commented that "America's corn farmers need a consistent, transparent system to provide consumers with information without stigmatizing important, safe technology. Thus, we are pleased with the issuance of these rules and look forward to reviewing the details in the coming days."[13] ASA stated that "we believe that it allows transparency for consumers while following the intent of Congress that only food that contains modified genetic material be required to be labeled bioengineered under the law, with food companies having the option of providing additional information if they choose."[14] FMI stated that "the rule provides a consistent way to provide transparency regarding the foods we sell and allow[s] our customers across the country the means to learn more about grocery products containing bioengineered ingredients."[15]

This report provides background information on agricultural biotechnology; reviews major provisions of the Standard (related to applicability, disclosure options, and administrative provisions); and concludes with potential considerations for Congress. The **Appendix** provides definitions of select scientific and related terms used in this report.

Agricultural Biotechnology Background

People have been changing plants, animals, and other edible organisms since before agriculture began more than 10,000 years ago. Before people planted crops and raised farm animals, hunting and gathering changed the genetic composition of species. The pace of these changes accelerated with the onset of agriculture. Selective breeding helped create and improve agricultural varieties to meet farmer and consumer needs. Conventional (traditional) breeding created hybrid varieties with enhanced size, growth rate, and other valuable characteristics. Since the mid-20th century,

[9] OTA, "Position on GMO Labeling Standard: Response to the National Bioengineered Food Disclosure Standard," press release, December 20, 2018.

[10] CFS, "Long-Awaited Final Regulations for GMO Food Labeling Leave Millions of Americans in the Dark," press release, December 20, 2018.

[11] Non-GMO Project, "Americans Deserve Better Than the USDA's GMO Labeling Law," press release, December 20, 2018.

[12] IATP, "USDA's GMO Disclosure Rule Designed to Cover Up, Not Inform," press release, December 20, 2018.

[13] NCGA, "NCGA Pleased by USDA Issuing Bioengineered Food Disclosure Standard Labeling Rule," press release, December 20, 2018.

[14] ASA, "Soybean Growers Support USDA's Bioengineered Food Disclosure Rule," press release, December 20, 2018.

[15] FMI, "FMI Applauds Rule Establishing a Single Bioengineered Food Disclosure Standard," press release, December 20, 2018.

laboratory-based breeding techniques have further strengthened the ability to modify agricultural varieties. In recent decades, genetic engineering has allowed for increasingly specific genetic manipulation. These techniques can change plants and animals in ways that, with conventional breeding, would not be possible or could take decades to achieve.

The public has come to recognize plants and animals altered through modern biotechnology and genetic engineering as *genetically modified organisms (GMOs)*.[16] Scientific and federal government experts identify the term *genetically modified* as more general than *genetically engineered*, and as such *genetically modified* may include conventional breeding.[17] In this report, *genetic engineering* refers to genetic modification techniques other than conventional breeding.

The Standard addresses food labeling and does not change how foods derived from biotechnology are regulated for safety and approval for human or animal consumption. The federal government's 1986 *Coordinated Framework for Regulation of Biotechnology* governs how USDA, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) apply existing statutes to evaluate biotechnology products.[18] USDA regulates plants under the Plant Protection Act (7 U.S.C. §7701 et seq.). FDA regulates food, animal feed additives, and human and animal drugs, primarily under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) and the Public Health Service Act (42 U.S.C. §201 et seq.). EPA registers and approves the use of pesticides, including those incorporated into plants through biotechnology, under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. §136 et seq.). A key principle of the *Coordinated Framework* is to regulate products according to their characteristics and unique features rather than the processes used to develop them.

More generally, FDA and the USDA Animal and Plant Health Inspection Service (APHIS) have responsibilities for assuring that foods sold in the United States are safe, with respect to human and agricultural health, and properly labeled.[19] FDA released a policy statement on GE foods in 1992, indicating that in most cases they are "substantially similar" to non-GE foods and do not require additional regulation or labeling beyond what is required for comparable non-GE foods.[20] A legal decision in 2000 upheld this policy.[21] FDA requires labeling of GE foods that (1) have nutritional characteristics that differ from comparable non-GE foods, (2) contain GE material

[16] *Modern biotechnology* includes the tools of genetic engineering, in addition to other approaches (e.g., fusion of cells from different types of organisms to create new varieties). See Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, World Health Organization and Food and Agriculture Organization, 2003.

[17] FDA, "Questions and Answers on Food from Genetically Engineered Plants," January 4, 2018, https://www.fda.gov/food/food-new-plant-varieties/questions-answers-food-genetically-engineered-plants; NASEM, *Genetically Engineered Crops*; and Institute of Medicine and National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 2004.

[18] FDA, "Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting," 51 *Federal Register* 23302, June 26, 1986.

[19] For more information, see CRS In Focus IF10650, *Understanding Process Labels and Certification for Foods*.

[20] FDA, "Statement of Policy: Foods Derived from New Plant Varieties," 57 *Federal Register* 22984, May 29, 1992. Through this document, FDA permitted voluntary labeling to indicate that foods have or have not derived from genetically engineered plants or animals. See updated draft guidance documents: FDA, "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants," Regulations.gov, updated March 3, 2019; and FDA, "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon: Guidance for Industry," Regulations.gov, revised March 11, 2019.

[21] *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166 (D.D.C. 2000).

from known allergenic sources, or (3) have elevated levels of toxic compounds. This labeling is not required to indicate the GE status of the food.

APHIS reviews GE organisms on the basis of whether they pose plant pest risks to agriculture. In 2019, the agency issued a proposed rule to exempt several categories of GE plants from review, citing 30 years of evidence indicating that "genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk."[22] The proposed rule further stated that new GE technologies, such as gene editing, do not engage with plant pests in any way.[23]

The National Bioengineered Food Disclosure Standard

The Standard provides a mandatory national standard for disclosure of the presence of bioengineered foods and food ingredients to consumers. It provides U.S. food manufacturers, importers, and retailers with a voluntary compliance period and a mandatory compliance deadline.

Following enactment of the 2016 Act, USDA delegated development and implementation of the Standard to the USDA Agricultural Marketing Service (AMS), which oversees many other USDA food-labeling programs, including mandatory Country of Origin Labeling, the voluntary National Organic Program (NOP), and the voluntary Process Verified Program (PVP). AMS developed the Standard through federal rulemaking and issued the final rule in December 2018. The final rule defines key terms and interprets issues arising from the 2016 Act. The text box below includes terms defined in the Standard.

The Standard identifies *regulated entities* as the food manufacturers, importers, and retailers responsible for making disclosures under the Standard.[24] All regulated entities must comply with the Standard by January 1, 2022, although disclosures may begin during the voluntary compliance period, which started on January 1, 2020.

As required for economically significant regulations, AMS prepared and published a regulatory impact analysis (RIA) of the Standard.[25] The RIA estimates that implementation will cost between $570 million and $3.9 billion in the first year and between $52 million and $118 million in each following year. It attributes most first year costs to those incurred by manufacturers analyzing the applicability of the rule and their compliance with the rule ($401 million to $3.1 billion). After the first year, the RIA attributes most ongoing costs to regulated entities avoiding mandatory disclosures by verifying that foods are not subject to the Standard ($0 to $59 million) and replacing bioengineered ingredients with non-bioengineered ingredients ($41 million to $44 million). The RIA estimates annual financial benefits of $190 million to $565 million, mostly attributed to costs avoided: the costs of complying with a patchwork of state laws and by implementation of the federal Standard. The RIA does not anticipate that the new Standard will provide any benefits to human health or the environment.

[22] APHIS, "Movement of Certain Genetically Engineered Organisms," 84 *Federal Register* 26514, June 6, 2019.

[23] Under the proposed rule change, APHIS may evaluate new plant varieties created through gene editing for noxious weed risk.

[24] 7 C.F.R. §66.2.

[25] AMS, "Regulatory Impact Analysis," National Bioengineered Food Disclosure Standard, Regulations.gov, October 30, 2019.

Key provisions of the Standard, along with associated issues raised by stakeholders, are identified below within three categories: (1) applicability, (2) disclosure options, and (3) administrative provisions. Many components of the Standard remain controversial. Public reactions are discussed after each category.

Select Definitions from the National Bioengineered Food Disclosure Standard

The Standard (7 C.F.R. §66.1) defines the terms included in this list, as well as others that are not listed here.

Bioengineered food. "(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition: (i) 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; provided that (ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to §66.9. (2) A food that meets one of the following factors and conditions is not a bioengineered food. (i) An incidental additive that is present in food at an insignificant level and does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3)."

Bioengineered substance. "[S]ubstance 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."

Food. A "food (as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is intended for human consumption."

Information panel. A "part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g. irregular shape with one usable surface)."

Label. A "display of written, printed, or graphic matter upon the immediate container or outside wrapper of any retail package or article that is easily legible on or through the outside container or wrapper."

Principal display panel. The "part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale."

Regulated entity. The "food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures under §66.100(a)."

Similar retail food establishment. A "cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises."

Small food manufacturer. Any "food manufacturer with annual receipts of at least $2,500,000, but less than $10,000,000."

Very small food manufacturer. Any "food manufacturer with annual receipts of less than $2,500,000."

Small package. "[F]ood packages that have a total surface area of less than 40 square inches."

Very small package. "[F]ood packages that have a total surface area of less than 12 square inches."

Applicability

The Standard addresses its applicability to specific types of foods and types of entities involved in the manufacture, sale, and distribution of food.[26] These issues were debated in policy discussions about GE food labeling, and they range from how the Standard defines *bioengineered food* to which entities must comply with the Standard and which are exempt.

[26] AMS created an online decision tool to assist regulated entities in determining when they must comply with the Standard available at https://www.ams.usda.gov/rules-regulations/be/zingtree.

Bioengineered Food Definition and Exclusions

The 2016 Act defined *bioengineering*, with respect to food, as a food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."[27] It did not identify any specific technologies that would meet the definition of *bioengineering*.[28] The 2016 Act specified that *bioengineering* referred to foods "intended for human consumption," and the act left open the possibility that USDA could use additional similar terms in the Standard.[29]

When issuing the Standard, USDA added detail to some statutory definitions and did not provide explicit definition of some other terms. While the Standard builds on the definition of *bioengineering* by describing the applicability of term, it does not define component parts of the definition, including *conventional breeding* or *found in nature*. Nor does it specify whether foods developed through specific technologies, such as gene editing, require disclosure to consumers.[30] The Standard requires use of the term *bioengineering* rather than similar terms, such as *genetic engineering*, *genetically modified*, or *GMO*.

The final rule sets boundaries for the foods that require disclosure. Based on the definition of *bioengineering* in the 2016 Act, AMS determined that certain products that derive from GE sources do not require labeling. The Standard identifies these exclusions in its definition of *bioengineered food*. They include animal feed, which is not considered food because it is not intended for human consumption; foods in which modified DNA is not detectable (e.g., refined oils and sugars); and incidental additives, as described in Title 21, Section 101.100(a)(3), of the *Code of Federal Regulations*.[31] The Standard expressly exempts other foods and substances described below. The text box at the end of this section summarizes exclusions and exemptions from the Standard.

Exemptions

The Standard identifies five exemptions from disclosure.[32] The 2016 Act explicitly identified two of these: (1) food served at restaurants or similar retail food establishments and (2) food produced by very small food manufacturers. The act called for the Standard to set a third exemption: foods containing an amount of a bioengineered substance below a certain threshold. The final two exemptions are for foods derived from animals solely because they consumed bioengineered feed and food certified under NOP.

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[27] 7 U.S.C. §1639(1).

[28] For AMS's response to public comments calling for the final Standard to broadly interpret the statutory definition of *bioengineering* to include existing gene editing technologies, including its assertion that "AMS is not making a blanket statement regarding the scope of technologies that are covered by" the Standard, see USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65835.

[29] 7 U.S.C. §1639(2) and 7 U.S.C. §1639(1).

[30] *Gene editing* is defined as "a technique that allows researchers to alter the DNA of organisms to insert, delete, or modify a gene or gene sequences to silence, enhance, or otherwise change an organism's specific genetic characteristics," in NASEM, *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*, 2016, p. 182. For additional information on gene editing, see CRS Report R44824, *Advanced Gene Editing: CRISPR-Cas9*. In a personal communication with CRS on January 23, 2019, AMS stated that it intends to address gene editing, with respect to applicability of the Standard, on a case-by-case basis.

[31] 7 C.F.R. §66.1.

[32] 7 C.F.R. §66.5.

Food Served in a Restaurant or Similar Retail Food Establishment

The 2016 Act exempts from disclosure food served in a restaurant or *similar retail food establishment*.[33] The Standard defines this term as follows:

> A cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.[34]

Very Small Food Manufacturers

The 2016 Act exempts from disclosure food produced by a *very small food manufacturer*. The Standard defines this term as "any food manufacturer with annual receipts of less than $2,500,000."[35]

Foods with Unintentional Bioengineered Ingredients Under a Presence Threshold

The 2016 Act called for USDA to "determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food."[36] The Standard exempts "food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient."[37]

Foods Derived from Animals That Consumed Bioengineered Feed

The 2016 Act specified that the Standard should not consider food derived from animals to be *bioengineered food* solely because those animals consumed bioengineered feed.[38] The Standard exempts such foods. Food products such as meat, eggs, or milk derived from animals that consumed bioengineered feed do not require disclosure solely because the animals consumed bioengineered feed.[39]

Foods Certified Under NOP

The 2016 Act specified that NOP certification "shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as 'not bioengineered,' 'non-GMO,' or another similar claim."[40] The Standard explicitly exempts foods certified under NOP. NOP is a voluntary food labeling program managed by AMS and operated as a public-private partnership. NOP certifies that agricultural products have been produced using approved organic methods

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[33] 7 U.S.C. §1639b(b)(2)(G)(i).

[34] 7 C.F.R. §66.1.

[35] 7 C.F.R. §66.1.

[36] 7 U.S.C. §1639b(b)(2)(B).

[37] 7 C.F.R. §66.5(c).

[38] This is codified at 7 U.S.C. §1639b(b)(2)(A).

[39] A food derived from an animal that consumes bioengineered feed may not require disclosure on its own, but a multi-ingredient food containing such a food ingredient may require disclosure due to the presence of other bioengineered ingredients.

[40] This statement is codified at 7 U.S.C. §6524.

listed in statute.[41] Among NOP's diverse criteria, genetic engineering is an excluded method: NOP-certified products may not be produced or handled with genetic engineering. Thus, such products are not bioengineered and are exempted from the Standard.

Exclusions and Exemptions from the Standard

Exclusions: products that do not meet the definition of either *food* or *bioengineered food* and do not require disclosure (the Standard identifies exclusions at 7 C.F.R. §66.1)

- Animal feed (which is not food intended for human consumption)
- Foods in which modified DNA is not detectable (e.g., refined oils and sugars)
- Incidental additives[42]

Exemptions: products that may or may not meet the definition of *bioengineered food* and do not require disclosure (the Standard identifies exemptions at 7 C.F.R. §66.5)

- Food served in restaurants and similar retail food establishments
- Food from very small manufacturers (with annual receipts less than $2.5 million)
- Foods with up to 5% presence, per ingredient, of unintentional or technically unavoidable bioengineered substances
- Foods derived from animals based solely on the fact that the animal consumed bioengineered feed
- Foods certified under NOP

List of Bioengineered Foods

The 2016 Act directed USDA to establish "such requirements and procedures as the Secretary [of Agriculture] determines necessary to carry out the standard."[43] During rulemaking, AMS requested public comment on the utility of maintaining a list of potentially regulated foods for entities to consult when determining whether a food is subject to disclosure. The final Standard includes a List of Bioengineered Foods that identifies foods that are available in a bioengineered form.[44] While there are bioengineered and non-bioengineered versions of all foods on the List, only the bioengineered versions may require disclosure. The final rule details how AMS considered including on the List but ultimately did not include enzymes, yeasts, and other microorganisms produced in controlled environments. The rule states that regulated entities would need to make determinations on whether these substances require recordkeeping or disclosure on a case-by-case basis.[45]

AMS also publishes the List and associated details on its website.[46] Beginning in early 2020, AMS plans to update the List annually, with associated opportunities for public comment.[47] AMS

[41] 7 C.F.R. §205.105 and 7 C.F.R. §205.2. In 1990, Congress authorized USDA to establish NOP to enforce uniform national standards for organically produced agricultural products. It became operational in 2002, and AMS manages it. For more information, see CRS In Focus IF10278, *U.S. Farm Policy: Certified Organic Agricultural Production*.

[42] "As described in 21 CFR 101.100(a)(3), incidental additives that are present in food at an insignificant level and do not have any technical or functional effect in the food are exempt from certain labeling requirements under the FDCA." USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65821.

[43] 7 U.S.C. §1639b(a)(2).

[44] The current List is codified at 7 C.F.R. §66.6.

[45] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65839.

[46] AMS, "List of Bioengineered Foods," https://www.ams.usda.gov/rules-regulations/be/bioengineered-foods-list. This website links each food on the list to a summary document, which includes information on the crop or animal's *BE events* (specific approved bioengineered versions), production, safety reviews, and references.

[47] Processes related to updating the List are codified at 7 C.F.R. §66.7. In a personal communication with CRS on January 2, 2020, AMS stated that it anticipates publishing the first update in early 2020.

plans to notify the public of the review via the *Federal Register* and the AMS website. If needed, AMS plans to update the List through the federal rulemaking process. See the text box below for foods on the List as of January 2020.

Foods on the List of Bioengineered Foods (January 2020)

Alfalfa. Canada and the United States produce bioengineered alfalfa, with varieties including herbicide-tolerant and low-lignin (for improved digestibility by animals) traits. Alfalfa is primarily produced to feed animals, though people consume alfalfa sprouts, seeds, and leaves.

Apple (Arctic™ varieties). The United States produces bioengineered apples, with varieties including a non-browning trait.

Canola. Australia, Canada, and the United States produce bioengineered canola with herbicide-tolerant, high-laureate (for oil quality), pollination-control, reduced-phytate (for quality), and male-sterility (non-functional pollen) traits. People consume canola oil, and canola meal and protein are used in food and animal feed.

Corn. Fifteen countries, including the United States, produce bioengineered corn with traits for herbicide-tolerance, insect-resistance, increased-ear-biomass, alpha amylase (for quality), increased-lysine (for quality), male-sterility (non-functional pollen), pollination-control, and fertility-control.

Cotton. Twelve countries, including the United States, commercially produce bioengineered cotton with herbicide-tolerant and insect-resistant traits. People consume refined cottonseed oil, and animals consume cottonseed as a feed supplement.

Eggplant (BARI Bt Begun varieties). At present, only Bangladesh commercially produces bioengineered eggplant with an insect-resistant trait. APHIS does not currently admit fresh eggplant fruit from Bangladesh into the United States.

Papaya (ringspot virus-resistant varieties). The United States and China produce bioengineered papaya with ringspot virus-resistance traits.

Pineapple (pink flesh varieties). Costa Rica produces bioengineered pineapple with increased-carotenoid-level (yielding pink-colored flesh) and flowering-inhibition traits. Bioengineered pineapple is not currently available for sale in the United States, although it is approved for sale.

Potato. The United States and Canada produce bioengineered potatoes with traits that reduce bruising, free-asparagine levels, sugars, and traits that offer virus resistance and insect resistance.

Salmon (AquAdvantage®). Panama produces bioengineered salmon for sale to Canada with a trait that increases growth rates. As of 2019, bioengineered salmon is approved for food use in the United States but is not commercially available.

Soybean. Eight countries, including the United States, produce bioengineered soybean with traits for herbicide tolerance, insect resistance, altered oil-profiles, and altered growth-properties.

Squash (summer). The United States produces bioengineered summer squash with virus-resistant traits.

Sugarbeet. Canada and the United States produce bioengineered sugarbeet with traits for herbicide tolerance. Sugarbeets are refined into sucrose for use in foods and animal feeds.

Source: Compiled by CRS from 7 C.F.R. §66.6; USDA, "List of Bioengineered Foods," https://www.ams.usda.gov/rules-regulations/be/bioengineered-foods-list; and other sources.

Public Response to Applicability Provisions of the Standard

The Standard's definition of *bioengineered food*, and what it applies to, remains controversial. Some areas of disagreement among stakeholders include the use of *bioengineered* rather than alternative terms, the definition's treatment of gene editing and new genetic technologies, the definition's treatment of refined food products, and the disclosure threshold for inadvertent or technically unavoidable presence of GE ingredients. Some farmer and industry groups have praised the Standard, contending that it provides consumers and regulated entities with needed consistency and transparency.[48] Some advocates of stricter GE labeling argue that it is too

[48] Anna-Lisa Laca, "Ag Groups Praise National Bioengineered Food Disclosure Standard," *Ag Professional*, December

permissive because many foods they consider genetically engineered do not require disclosure.[49] These issues are addressed below.

Alternative terms. The terminology used in the Standard has been a point of contention. While USDA had statutory authority to use alternative terms to *bioengineered*, it did not do so. Some stakeholder groups argue that most consumers are unfamiliar with the term *bioengineered*. They assert that using other terms, such as *GMO*, *genetically modified organism*, or *genetically engineered* would be less confusing for consumers.[50] Other groups contend that the Standard's language is precise.[51]

Gene editing and new genetic technologies. The Standard's definition of *bioengineered food* does not identify specific technologies used to create such foods. AMS states that the Standard's definition "focuses primarily on the products of technology, not the technology itself."[52] During rulemaking, some stakeholders had called for the Standard to explicitly address the status of foods derived from new genetic technologies that may not meet the statutory definition of *bioengineering*.[53] For example, foods derived from gene editing may not meet the statutory definition of *bioengineering* if (a) they do not contain recombinant DNA or (b) AMS considers that that their modifications could be achieved through conventional breeding or found in nature. Other new genetic technologies may arise that do not meet the Standard's definition of *bioengineering* for these or other reasons.

Because the Standard does not address specific technologies, consumers and regulated entities may lack clarity about whether or not foods derived from new genetic technologies must be disclosed under the Standard. In the absence of this information, many have interpreted the bioengineering definition as broadly excluding foods derived from gene editing.[54] Under this interpretation, gene-edited foods would not require disclosure. Other interpretations of the Standard simply note that the final rule does not explicitly address gene editing or other new genetic technologies.[55] Advocates of stricter GE labeling requirements contend that even though gene-edited foods seem to be excluded from the Standard's definition of *bioengineering*, such foods meet the common understanding of *genetic engineering* and therefore should be required to bear disclosures.[56]

Refined foods exclusion. The Standard excludes refined food products that do not contain detectable amounts of modified DNA from required disclosure.[57] Food without detectable modified genetic material does not meet the statutory definition of *bioengineered*. Examples

20, 2018.

[49] See for example, IATP, "USDA's GMO Disclosure Rule;" CFS, "Long-Awaited Final Regulations;" and Non-GMO Project, "Americans Deserve Better."

[50] See, for example, CFS, "Long-Awaited Final Regulations;" and OTA, "Position on GMO Labeling Standard."

[51] See, for example, FMI, "FMI Applauds Rule."

[52] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65835.

[53] For AMS's discussion of comments on including gene editing in the definition of *bioengineered food*, see USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65835.

[54] For interpretations of how the Standard treats gene edited foods, see, for example, Russ LaMotte, Alan Sachs, and Matt Schneider, "USDA Issues Final Bioengineered Food Disclosure Standard," Beveridge and Diamond, January 3, 2019; and see OTA, "Position on GMO Labeling Standard;" and Non-GMO Project, "Americans Deserve Better."

[55] See, for example, Melvin S. Drozen, Evangelia C. Pelonis, and Samuel D. Jockel, "USDA AMS National Bioengineered (BE) Food Disclosure Standard Final Rule," *National Law Review*, December 28, 2018.

[56] See, for example, OTA, "Position on GMO Labeling Standard."

[57] 7 C.F.R. §66.5.

include soybean oil, canola oil, and refined sugar. The Standard does not require regulated entities to test every product for the presence of detectable modified genetic material. Rather, manufacturers, importers, and retailers can demonstrate the absence of modified genetic material with records of a validated refining process.[58] Some groups that favor a more expansive definition of *bioengineered foods* argue that consumers want to know whether the foods they eat derive from GE plants and animals, and thus the Standard should have required disclosures for these refined foods.[59] In contrast, some industry groups, including the Consumer Brands Association (formerly the Grocery Manufacturers Association), commended the Standard for providing regulated entities with the option to voluntarily disclose such foods if desired.[60]

Disclosure threshold. The Standard does not require disclosures for foods with up to 5% presence, per ingredient, of unintentional or technically unavoidable bioengineered substances. In comparison, the European Union applies a threshold of 0.9% per ingredient, and Australia and New Zealand use a threshold of 1% per ingredient.[61] Foods in Japan must be labeled if a GE ingredient is among the top three ingredients and accounts for more 5% of the total product by weight.[62] AMS selected the 5% threshold for the Standard to "appropriately balance providing disclosure to consumers with the realities of the food supply chain."[63] Some advocates of stricter GE labeling, such as OTA, argue that the threshold in the Standard is too high and is "inconsistent with accepted private standards, most of our major global trading partners and unacceptable to consumers."[64]

Disclosure Options

The Standard identifies permissible options for on-package disclosure of bioengineered foods. All disclosures 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."[65] Regulated entities must place the disclosure in one of three places: within the information panel close to details about the manufacturer, on the principle display panel, or on another panel the consumer is likely to see. In most cases, only one form of disclosure is required per package. Some disclosure options are available to all regulated entities for required disclosures (text, symbol, electronic or digital link, and/or text message), while others are

[58] The Standard outlines validated refining processes and standards of performance for detectability testing at 7 C.F.R. §66.9(b)-(c). USDA issued public notice of draft instructions for the validation of refining processes in USDA, "National Bioengineered Food Disclosure Standard; Validation of Refining Processes," 84 *Federal Register* 68815, December 17, 2019.

[59] The final rule (USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814) discusses different views at length on pages 65833-65834. See also OTA, "Position on GMO Labeling Standard;" and CFS, "Long-Awaited Final Regulations."

[60] Elaine Watson, "Final GMO Labeling Rule Does Not Require Labeling of Highly Refined Ingredients from GM Crops, if No Modified Genetic Material Is Detectable," Food Navigator, December 20, 2018. The Grocery Manufacturers Association changed its name to the Consumer Brands Association effective January 2020.

[61] See European Union, "Traceability and Labeling," https://ec.europa.eu/food/plant/gmo/traceability_labelling_en; and Food Standards Australia New Zealand, "Genetically Modified (GM) Food Labeling," https://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx.

[62] Japan's regulation is currently under review with a proposal to reduce this threshold. Kazuhito Yamashita, "The U.S. Approaches Japan in Regulations on GM Foods—Mistake to Think That the TPP Lowers Food Safety Standards," Canon Institute for Global Studies, November 5, 2018.

[63] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65824.

[64] OTA, "Position on GMO Labeling Standard."

[65] 7 C.F.R. §66.100(c).

available only to small food manufacturers (telephone number or website address) or in cases of voluntary disclosure (voluntary version of the BE disclosure symbol). Each option is described below.

Standard Disclosure Options

The 2016 Act specified that the Standard should provide several types of disclosure options.[66] The final rule gives additional detail to their implementation.

Text.[67] "Bioengineered food" is the required text to disclose foods for which all ingredients either meet the definition of *bioengineered food* or lack records that indicate whether or not they are bioengineered. "Contains a bioengineered food ingredient" is the text required to disclose multi-ingredient foods for which some ingredients are not bioengineered while others are bioengineered or are of undetermined status. For foods distributed solely within a U.S. territory where the predominant language is not English, the appropriate text disclosure may be displayed in the territory's predominant language.

Symbol.[68] Regulated entities may use color or black-and-white versions of the disclosure symbols shown in **Figure 1**. The symbol that incorporates the word *bioengineered* is for products that require disclosure. The symbol that incorporates the phrase *derived from bioengineering* may be placed voluntarily on packages of food that do not meet the bioengineered food definition but contain food that is derived from bioengineered food (such as refined foods without detectable modified DNA). Disclosures must not be false or misleading. Entities that are exempt from mandatory disclosure (e.g., very small food manufacturers and restaurants) may make voluntary disclosures using the appropriate symbol.

Figure 1. Disclosure Symbols for the Standard

Source: CRS from USDA, "BE Symbols," https://www.ams.usda.gov/rules-regulations/be/symbols.

Notes: Foods that meet criteria in the Standard must display the "bioengineered" symbol. The "derived from bioengineering" symbol may be displayed on foods that do not meet the bioengineered food definition yet derive from bioengineered food (e.g., refined foods that do not contain detectable modified deoxyribonucleic acid). Entities may use the appropriate symbol in color or in black and white (not shown). Entities exempt from disclosure (e.g., very small food manufacturers and restaurants) may make voluntary disclosures using the appropriate symbol.

[66] 7 U.S.C. 1639b(b)(2)(D).

[67] 7 C.F.R. §66.102.

[68] 7 C.F.R. §66.104.

Electronic or digital link.[69] Entities may disclose bioengineered food via electronic or digital links, which are codes that consumers can scan to access more information. Current examples include Quick Response codes and digital watermarks that consumers may scan with a smart phone or in-store scanner. The code may embed product information or a link to a website with this information presented on the first webpage. The 2016 Act and the Standard require that any electronic or digital link disclosure on a package must be accompanied by the text "Scan here for more food information" or equivalent language consistent with technological changes. They also require that such disclosures be accompanied by a telephone number that consumers may call to receive additional information.

Providing disclosure via these technologies was among the most controversial aspects of the 2016 Act. In the 2016 Act, Congress required USDA to solicit public comment and conduct a study to determine if electronic or digital links would provide consumers with sufficient access to information while shopping. If USDA were to determine that these disclosure methods were insufficient in this regard, then the Standard would need to provide additional disclosure options.

AMS contracted with Deloitte Consulting to conduct the study. The resulting report identified several challenges that would need to be overcome for consumers to access information through digital or electronic link disclosures.[70] AMS determined that the Deloitte study indicated that electronic and digital links would not provide consumers with sufficient access to this information.[71]

Text message.[72] In response to public comments and the results of the Deloitte study, the Standard adopts disclosure by text message as an option in addition to those identified in the 2016 Act. Regulated entities choosing this option must include a clear statement on the food package describing how to receive a text message.

Disclosure Options for Small Food Manufacturers

The Standard defines a *small food manufacturer* as one with annual receipts of between $2.5 million and $10 million. As directed in the 2016 Act, the Standard allows small food manufacturers to select from additional disclosure options. These consist of providing a telephone number or an internet website address to allow consumers to access more information.[73] Such disclosures must be accompanied by the text "Call [number] for more food information" or "Visit [Uniform Resource Locator of the website] for more food information."

Alternative Disclosure Options for Specific Circumstances

The Standard specifies additional considerations for small and very small packages as well as food sold in bulk containers. The additional disclosure options for small packages mirror the standard options but allow for abbreviated on-package text: "Scan for info," "Text [number] for info," and "Call [number] for info."[74] For very small packages, regulated entities may use a label's preexisting telephone number or website address in lieu of other disclosures. Retailers are

[69] 7 C.F.R. §66.106.

[70] Deloitte Consulting, *Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure*, USDA, July 2017.

[71] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 65828.

[72] 7 C.F.R. §66.108.

[73] 7 C.F.R. §66.110.

[74] 7 C.F.R. §66.112.

responsible for disclosures for food sold in bulk containers (e.g., display case, bin, carton, and barrel), and they must use the primary disclosure options.

Voluntary Disclosure

The Standard allows for voluntary disclosure in some cases.[75] Exempt entities (very small food manufacturers and restaurants and similar retail food establishments) may voluntarily disclose bioengineered foods and food ingredients using any of the options provided. Additionally, the Standard permits both regulated and exempt entities to voluntarily disclose foods that do not require mandatory disclosure. Such foods include refined foods that derive from bioengineered foods but do not have detectable modified DNA. Voluntary disclosures should indicate that ingredients are "derived from bioengineering" rather than "bioengineered." The Standard does not permit voluntary disclosure in most other circumstances.

Public Response to Disclosure Options of the Standard

During the rulemaking process for the Standard, some advocates for strict GE labeling provisions were seeking a single, easily identifiable, on-package disclosure. These respondents have criticized the disclosure options in the Standard as confusing and uninformative. In contrast, some other groups sought flexible disclosure options that regulated entities could adapt easily to different circumstances. Such industry groups have supported the disclosure options in the Standard as informative and flexible enough for manufacturers to meet.

Among critics, OTA argued that the Standard does not provide for meaningful disclosure. It stated that the Standard "allows for the option of digital/electronic disclosures rather than requiring on-pack plain English text disclosure" and that the "stylized GMO symbol with a four-pointed starburst does not reflect a neutral symbol as Congress intended and is misleading."[76] CFS found that "both disclosure methods [electronic and digital disclosure], as well as 800 numbers, are unwieldy, time-consuming, and clearly designed to inhibit rather than facilitate access to GE content information."[77]

The International Dairy Foods Association (IDFA) provided a mixed reaction, approving of some aspects of the Standard while further stating that "the rule does not provide the level of transparency IDFA and consumers were hoping for."[78] Among other perceived limitations, IDFA added that the Standard does not require disclosure of highly refined ingredients deriving from GE foods, although it allows for voluntary disclosure of these products.

Among supporters of the Standard, FMI and the NCGA welcomed the disclosure consistency that the Standard provides.[79]

The Standard's inclusion of a voluntary disclosure option elicited mixed responses. While the Consumer Brands Association praised this option, the Center for Science in the Public Interest commented that voluntary disclosure could introduce confusion.[80] It identified the potential for

[75] 7 C.F.R. §66.116.

[76] OTA, "Position on GMO Labeling Standard."

[77] CFS, "Long-Awaited Final Regulations."

[78] IDFA, "USDA Releases National Bioengineered Food Disclosure Standard," press release, December 20, 2018.

[79] FMI, "FMI Applauds Rule;" and NCGA, "NCGA Pleased."

[80] Elaine Watson, "Final GMO Labeling Rule Does Not Require Labeling of Highly Refined Ingredients from GM Crops, if No Modified Genetic Material Is Detectable," Food Navigator, December 20, 2018.

consumers to encounter a single type of product, derived from bioengineering, that one company chose to voluntarily disclose and another company did not. OTA called on food companies to voluntarily disclose all foods produced with genetic engineering.[81]

Administrative Provisions

Stakeholders have also focused on the administrative provisions of the Standard. Key administrative issues include the speed at which regulated entities must comply with the Standard, recordkeeping requirements and burdens, and the enforceability of the Standard. These topics are addressed below.

Compliance Deadline

The 2016 Act did not specify compliance dates for the Standard. The final rule allows for phased implementation before requiring all regulated entities to comply with the Standard (see **Table 1**). It sets January 1, 2020, as the date on which most regulated entities may begin implementation. Small food manufacturers have an additional year to begin implementation, with a start date of January 1, 2021.[82] All regulated entities must fully comply with the Standard by January 1, 2022.

Table 1. National Bioengineered Food Disclosure Standard Implementation Dates

Milestone	Date	Comments
Effective date	February 19, 2019	This is 60 days after publication of the final rule.[83]
Implementation (other than small food manufacturers)	January 1, 2020	Regulated entities, other than small food manufacturers, *may* begin disclosure.
Implementation (small food manufacturers)	January 1, 2021	Small food manufacturers *may* begin disclosure.
Voluntary compliance period	*Until* December 31, 2021	Regulated entities *may* meet disclosure standards.
Mandatory compliance	January 1, 2022	Regulated entities *must* meet disclosure standards.

Source: CRS, from U.S. Department of Agriculture, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, December 21, 2018.

Recordkeeping

In the RIA, AMS commented that it provides the List to "simplify and minimize analysis and recordkeeping burden on regulated entities."[84] The Standard requires regulated entities that sell foods on the List, including both bioengineered and non-bioengineered versions, to maintain records documenting whether or not those foods or their ingredients are bioengineered. The Standard does not require potentially regulated entities to maintain records for foods that are not on the List unless they know that a food is bioengineered. This situation could occur if AMS has not yet identified the food as commercially available and has not yet added the food to the List. In such cases, the entity must disclose the food and must maintain records.

[81] OTA, "Position on GMO Labeling Standard."

[82] As required by the 2016 Act, at 7 U.S.C. §1639b(b)(2)(F)(i).

[83] This date is consistent with Congressional Review Act requirements for a major rule (5 U.S.C. §801 et seq.).

[84] AMS, "Regulatory Impact Analysis," p. 15.

Regulated entities may determine what records to keep and how to manage them so long as they contain sufficient detail for AMS to understand and audit them under the Standard. Entities must maintain these records for two years after sale or distribution of the food.

Enforcement

Failure to make a required disclosure is prohibited under the 2016 Act.[85] However, the act limited the scope of potential enforcement mechanisms and remained silent on others. The 2016 Act explicitly prohibited USDA from recalling food for known or suspected violations of the Standard.[86] It did not address or authorize potential civil penalties for violations. The act allowed USDA to enforce compliance through records audits, examinations, hearings, and public disclosure of findings.

The Standard identifies procedures for carrying out these enforcement mechanisms. AMS does not continuously and proactively verify compliance with the Standard. Rather, the Standard creates a mechanism for the public to file statements or complaints to the AMS administrator about possible violations of the Standard, and it outlines how AMS may respond to these written statements or complaints. If AMS determines that a complaint warrants further investigation, AMS may audit or examine the records of the entity responsible for disclosure and make its findings available to the entity. The entity may then request a hearing if it objects to the findings. The Standard allows for AMS to revise the findings if warranted and provides that AMS will make the final results of the investigation publicly available.

Public Response to Administrative Provisions of the Standard

While most stakeholder responses to the final Standard have focused on applicability and disclosure options, some interested groups have commented on its administrative provisions. Before release of the Standard, advocates of strict GE labeling had called for an early start to the mandatory compliance period.[87] However, some industry groups supported the delay of mandatory compliance, citing the need to allow sufficient time for regulated entities to adjust labels and recordkeeping procedures.[88] Echoing comments that AMS received during the federal rulemaking process, some critics of the Standard have continued to assert that its enforcement mechanisms are weak.[89]

Other GE Labeling Approaches

The Standard was developed within a broader societal context. State-level approaches to GE labeling predated the federal 2016 Act. These were driven by public interest in knowing the GE status of their foods. In addition, some private and federal voluntary labeling programs that

[85] 7 U.S.C. §1639b(g)(1).

[86] 7 U.S.C. §1639b(g)(4).

[87] See public comments on the proposed rule at Regulations.gov, for example, IATP, July 10, 2018, https://www.regulations.gov/document?D=AMS-TM-17-0050-8837.

[88] See public comments on the proposed rule at Regulations.gov, for example, GMA, July 3, 2018, https://www.regulations.gov/document?D=AMS-TM-17-0050-12345; and see IDFA, "USDA Releases National Bioengineered Food Disclosure Standard."

[89] For example, Non-GMO Project, "Americans Deserve Better."

provide information on the GE status of foods are expected to continue after implementation of the Standard.

Public Opinion and State-Level GE Labeling Before the Standard

When foods containing GE ingredients were first introduced in the 1990s, some members of the public called for banning them based on concerns about potential harm to human health.[90] Research has repeatedly found no difference between foods developed with and without GE in terms of the health and safety of the people consuming them.[91]

Even so, some consumers remain concerned about GE, citing health, personal preference, religious, economic system, and other objections.[92] Moving on from calls to ban GE foods for human health reasons, many consumers began to demand a government role in making GE foods easily identifiable via GE labeling. Before establishment of the Standard, some surveys reported that the majority of consumers wanted GE foods to be labeled.[93] Various proposed GE labeling laws and initiatives at the state and federal levels provided for *mandatory* or *voluntary* labeling. Mandatory labeling requires companies to disclose the presence of GE ingredients. Voluntary labeling can allow companies to certify the absence of GE ingredients (as discussed in "Continuing Voluntary Labeling Programs and GE-Absence Claims") or to disclose the presence of GE ingredients.

The 2016 Act preempted state laws and initiatives and instituted mandatory labeling of the presence of GE ingredients in foods.[94] In the years preceding the introduction and passage of the 2016 Act, state laws and ballot initiatives on GE labeling began to proliferate.[95] In 2014, Vermont became the first state to enact a mandatory GE labeling law with an effective date of July 1, 2016. Other states enacted similar laws, while others still considered similar legislation or voted on state ballot initiatives. Michigan and North Dakota enacted legislation urging the U.S. Congress to pass a uniform GE labeling standard.

Most GE labeling proponents strongly supported mandatory labeling standards, citing consumers' right to know, even if safety were not an issue.[96] Some GE labeling opponents argued that no

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[90] Bloomberg BNA, "Group Encourages Consumer Support for U.S. Ban on Genetically Altered Food," *Daily Report for Executives (BNA)*, August 31, 1999; and Alan Yonan Jr., "Environmentalists Escalate Fight Against Altered Crops," Dow Jones, August 24, 1999.

[91] See FDA, "Questions and Answers on Food from Genetically Engineered Plants," January 4, 2018; NASEM, *Genetically Engineered Crops*; and Institute of Medicine and National Research Council, *Safety of Genetically Engineered Foods*.

[92] For reviews of some of these concerns, see Emmanuel B. Omobowale, Peter A. Singer, and Abdallah S. Daar, "The Three Main Monotheistic Religions and GM Food Technology: An Overview of Perspectives," *BMC International Health and Human Rights*, vol. 9, no. 18 (August 2009); and Stefaan Blacke, "Why People Oppose GMOs Even Though Science Says They Are Safe," *Scientific American*, August 18, 2015. See also Non-GMO Project, "GMO Facts," https://www.nongmoproject.org/gmo-facts/.

[93] For example, Consumer Reports National Research Center, "Consumer Support for Standardization and Labeling of Genetically Engineered Food: 2014 Nationally-Representative Phone Survey," 2014, https://advocacy.consumerreports.org/wp-content/uploads/2014/06/2014_GMO_survey_report.pdf.

[94] 7 U.S.C. §1639i.

[95] For an overview of GE labeling legislation in 2016, see CRS In Focus IF10376, *Labeling Genetically Engineered Foods: Current Legislation*. See also an overview of state laws enacted in 2015 at National Conference of State Legislators, *State Legislation Addressing Genetically Modified Organisms*, July 7, 2015.

[96] CFS, "About GE Food Labeling," https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/about-ge-labeling.

scientific basis existed for requiring mandatory GE labeling, and that such labeling may unnecessarily introduce doubt about the quality or safety of labeled foods and could cause costly and unnecessary market disruption.[97] Before the 2016 Act, some GE labeling proponents and opponents called for a federal law to preempt development of an uncertain and confusing patchwork of state laws with different GE labeling requirements.[98]

In the absence of federal legislation in 2015, USDA experimented with adapting an existing voluntary USDA labeling program to meet consumer and producer interests in GE labeling. That year, AMS used its PVP to certify the absence of GE ingredients in food products from a single company, which had requested this service.[99] Some anticipated that this would lead to a voluntary USDA program to certify the absence of GE ingredients in foods.[100] GE-labeling proponents responded that, although this would be a step in the right direction, a voluntary program would fail to meet consumer demands, and only mandatory labeling would do so.[101] This application of PVP to certify the absence of GE ingredients in foods did not expand beyond a single company.

Continuing Voluntary Labeling Programs and GE-Absence Claims

Voluntary labeling programs that identify the absence of GE ingredients predate legislation to require mandatory labels on foods that contain GE ingredients. On-package symbols from these private and public-private programs indicate to consumers that foods do not contain GE ingredients. They may either make a direct GE-absence claim (certifying that the food does not contain GE ingredients) or indicate that the food was produced with processes that do not include GE (e.g., certified organic production methods). Food producers and manufacturers may choose to opt into these programs and to bear associated costs.

One example is the Non-GMO Project, which a nonprofit organization manages to provide third-party verification for processed foods that do not contain GE ingredients.[102] Companies sign agreements with the Non-GMO Project to have their processes reviewed and to have any high-risk products tested by third-party laboratories. Once the Non-GMO Project verifies a company's processes and products, the company can display the Non-GMO Project Verified symbol on its food packaging. This symbol on food packaging makes a GE-absence claim.

Another example is NOP, a public-private program for voluntary labeling that, among other things, indicates the absence of GE ingredients. NOP, which is administered by AMS, certifies that agricultural products have been produced using approved organic methods listed in statute.[103]

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[97] *Scientific American*, "Labels for GMO Foods Are a Bad Idea," September 1, 2013.

[98] Elaine Watson, "NPA Calls for National GMO Labeling Standard as State-Level Initiatives Proliferate," Food Navigator, March 19, 2013; and Grocery Manufacturers Association, "Vermont GMO Labeling Bill Critically Flawed and Bad for Consumers," press release, April 23, 2014.

[99] Tom Vilsack, Secretary of Agriculture, letter to USDA employees, May 1, 2015, https://www.faegrebd.com/webfiles/Vilsack-Letter.pdf.

[100] Mary Clare Jalonick, "USDA Develops New Government Label for GMO-Free Products," *Washington Post*, May 14, 2015.

[101] Just Label It, "Statement from Gary Hirshberg on USDA Plan to Create Voluntary Certification System," press release, May 14, 2015; and CFS, "Center for Food Safety Statement on New USDA GMO-Free Label," press release, May 15, 2015.

[102] This program considers GE presence of less than 0.9% to be below its "action threshold"—that is, products with GE content below this threshold are compliant with the program.

[103] These methods are codified in regulation at 7 C.F.R. §205.105 and 7 C.F.R. §205.2. In 1990, Congress authorized USDA to establish NOP to enforce uniform national standards for organically produced agricultural products. For more information, see CRS In Focus IF10278, *U.S. Farm Policy: Certified Organic Agricultural Production*.

Genetic engineering is an excluded method: NOP-certified products may not be produced or handled with genetic engineering. The NOP symbol indicates that a food meets diverse criteria, including production methods that exclude genetic engineering.

These *voluntary labeling programs* are expected to continue after implementation of the Standard. They differ from the Standard's *voluntary disclosure option*, which permits voluntary disclosure of foods that derive from bioengineering yet no longer have the characteristics of bioengineered foods, and it is discussed in this report's section on "Voluntary Disclosure." The voluntary labeling programs provide opportunities to identify foods that affirmatively do not derive from bioengineering. The Standard does not address GE-absence claims, and the final rule states that FDA (and the USDA Food Safety and Inspection Service, depending on the food at issue) "retain authority over absence claims."[104]

Select Considerations for Congress

Implementation of the Standard over the next two years and beyond will affect consumers, regulated entities, and AMS. Many potential issues arising from the Standard will become clear only as implementation continues. The below text summarizes potential and stated concerns related to applicability, disclosure options, administrative provisions, and other issues. Congress may choose to monitor the new Standard's implementation in accordance with its oversight responsibilities.

A key question for Congress is whether AMS's implementation of the 2016 Act meets congressional intent regarding the scope of applicability and the degree of disclosure required. In the final rule, AMS asserted that it balanced flexibility for regulated entities and information to consumers regarding the bioengineered status of their foods. Stakeholders who question AMS's decisions in the rulemaking process, as described above, may question the extent to which AMS's implementation aligns with congressional intent.

Applicability. Groups that have criticized the definition of *bioengineered* in the 2016 Act may call on Congress to amend the definition to include highly refined products derived from GE organisms and/or include products that do not meet the current definition, such as those derived from gene editing and other new technologies. Other interested groups may continue to advocate for a definition that restricts the number and types of foods to which the definition applies.

AMS has committed to maintaining and updating the List through annual public reviews and on an interim basis as needed. Such reviews can provide opportunities to add to the List any bioengineered food products that have entered commerce. Additionally, during these reviews, stakeholders with differing views may encourage the agency to adopt either a more expansive or a more restrictive listing of bioengineered foods.

Disclosure. Another issue in the context of disclosure is the degree of familiarity with the required labels that consumers may have. Consumers unfamiliar with the term *bioengineered* may have questions about what this means on foods bearing disclosure. Public reaction to implementation of the various types of disclosure may generate calls for these options to be revised based on their success or failure to provide consumers with easily accessible and useful information.

Administrative provisions. An issue for potential consideration is the extent to which additional federal resources will be required to implement the Standard in both the voluntary and mandatory

[104] USDA, "National Bioengineered Food Disclosure Standard," 83 *Federal Register* 65814, p. 6544. See also FDA, "Guidance for Industry."

compliance periods. In its RIA, AMS broadly estimated that it may need $2 million annually to implement the Standard, without differentiating potential expenses during the voluntary and mandatory compliance periods. AMS proposed that it would use such funds to update the List; conduct audits and hearings; manage complaints and inquiries; and provide training, education, outreach and programmatic support.[105]

AMS may need to assign staff and develop new processes to implement the Standard's provisions related to audits, examinations, hearings, and publications of findings. Congress may be asked to consider allocating new resources to support continued implementation of the new Standard.

In addition, Congress may assess the cost and administrative overhead that regulated entities expend to identify and maintain records on foods subject to disclosure and to adjust labels on food packaging. Estimates for administrative costs to regulated entities, which AMS presents in its RIA, range from a lower bound of $459 million to an upper bound of nearly $3.6 billion for the first year.[106] AMS anticipates that these costs will greatly reduce in subsequent years as potentially regulated entities replace bioengineered ingredients with non-bioengineered ingredients.

Regarding enforcement, the rule largely relies on a public notification mechanism to influence the compliance of regulated entities and correct violations of the Standard. Stakeholders may or may not view this mechanism as successful depending on the extent and frequency of any such violations. Interested parties may petition Congress to strengthen existing enforcement mechanisms or identify new ones to enhance compliance with the new Standard.

Market demand for bioengineered versus non-bioengineered products. In the RIA, AMS indicates that it cannot accurately predict how consumers will react to bioengineered disclosures on food labels.[107] Consumers may avoid foods labeled as bioengineered, they may prefer them, or such labels may make no difference to consumer purchasing behaviors. In the RIA, AMS assumes that manufactures will avoid labeling 20% of their products as bioengineered by replacing bioengineered with non-bioengineered ingredients due to potential consumer reactions. AMS selected 20% for purposes of estimating costs and benefits in the RIA following consideration of existing studies and surveys of consumer behavior and consideration of the requirements of the Standard. Depending on how consumers respond, implementation of the Standard may influence manufacturer and retailer demand for bioengineered and non-bioengineered foods. Congress may respond to stakeholder concerns about any market shifts resulting from the Standard.

Interactions with international trade. Unexpected issues may arise as implementation begins. For example, AMS states that it does not expect the Standard to impact foreign trade.[108] However, it also notes that the USDA Foreign Agriculture Service is prepared to work closely with foreign countries that export food and agricultural products to the United States to facilitate their understanding of the Standard. If trade issues arise, Congress may choose to address harmonization of labeling requirements with foreign trading partners by amending applicability, disclosure, or administrative requirements in the 2016 Act or by other means.

[105] AMS, "Regulatory Impact Analysis," p. 38.

[106] AMS, "Regulatory Impact Analysis," Table 14, p. 30.

[107] AMS, "Regulatory Impact Analysis," pp. 30-32.

[108] AMS, "BE Frequently Asked Questions—General," https://www.ams.usda.gov/rules-regulations/be/faq/general. See also 7 U.S.C. §1639c(a), a provision in the act that states, "This subchapter shall be applied in a manner consistent with United States obligations under international agreements."

Appendix. Glossary of Select Scientific and Related Terms

Many terms are used when describing human alterations of plants and animals over time. Unless otherwise noted, the definitions in this glossary derive from USDA's online *Agricultural Biotechnology Glossary* and are used for the purposes of this report.[109]

Agricultural biotechnology. A range of tools, including traditional breeding techniques, that alter living organisms or parts of organisms to make or modify products, improve plants or animals, or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering.

Conventional breeding. Undefined in USDA's *Agricultural Biotechnology Glossary*. USDA defines a similar term, *traditional breeding*, as "modification of plants and animals through selective breeding. Practices used in traditional plant breeding may include aspects of biotechnology such as tissue culture and mutational breeding."

Gene editing. A technique that allows researchers to alter the DNA of organisms to insert, delete, or modify a gene or gene sequences to silence, enhance, or otherwise change an organism's specific genetic characteristics.[110]

GE labeling. On-package disclosure of genetically engineered foods or food ingredients.[111]

Genetically engineered. Produced through genetic engineering.[112]

Genetic engineering. Manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

Genetic modification. The production of heritable improvements in plants or animals for specific uses via either genetic engineering or other more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering.

Genetically modified organism. An organism produced through genetic modification.

Recombinant DNA. A molecule of DNA formed by joining different DNA segments using recombinant DNA technology.

Recombinant DNA technology. Procedures used to join together DNA segments in a cell-free system (e.g., in a test tube outside living cells or organisms). Under appropriate conditions, a recombinant DNA molecule can be introduced into a cell and copy itself (replicate) either as an independent entity (autonomously) or as an integral part of a cellular chromosome.

Selective breeding. Making deliberate crosses or matings of organisms so the offspring will have particular desired characteristics derived from one or both of the parents.

Transgenic organism. An organism resulting from the insertion of genetic material from another organism using recombinant DNA techniques.

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[109] Available at https://www.usda.gov/topics/biotechnology/biotechnology-glossary.

[110] NASEM, *Gene Drives on the Horizon*, p. 182.

[111] CRS.

[112] CRS.

Variety. A subdivision of a species for taxonomic classification, also referred to as a "cultivar." A variety is a group of individual plants that is uniform, stable, and genetically distinct from other groups of individuals in the same species.

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