1250 H Street NW, Suite 900
Washington, DC 20005
P: 202.737.4332 | F: 202.331.7820
WWW.IDFA.ORG

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Submitted via email to GMOlabeling@ams.usda.gov

Mr. Bruce Summers
Acting Administrator
Agricultural Marketing Service
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

RE: Proposed Rule Questions under Consideration for the National Bioengineered Food Disclosure Standard

Dear Mr. Summers:

The International Dairy Foods Association ("IDFA") respectfully offers these comments to the U.S. Department of Agriculture ("USDA" or "Department") regarding the Department's request for input on the implementation of the National Bioengineered Food Disclosure Standard ("the Standard").

IDFA, Washington, DC, represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of nearly 525 companies within a $125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation, the National Cheese Institute, and the International Ice Cream Association. IDFA's nearly 200 dairy processing members operate more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream, and frozen desserts produced and marketed in the U.S.

IDFA supports USDA's efforts to solicit public input on the Standard. In the comments that follow, we explain the need for legally defensible and scientifically based disclosure of bioengineered content of foods, and suggest criteria for development of the Standard.

1. USDA Should Recognize That the Standard Is a Marketing Program and That Bioengineering Is a Safe, Proven Technology.

In order to stop a patchwork of contradictory state labeling laws, Congress worked for over a year to create a national, uniform standard for identifying bioengineered foods. That work culminated in the passage the National Bioengineered Food Disclosure Standard Act ("the Act")[1] in July 2016. Under its marketing authority, USDA is required to establish a new standard that will require bioengineered foods to bear a text, symbol, or digital or electronic link that provides consumers information about the bioengineered content of a food.

Bioengineered agricultural products have undergone comprehensive scientific reviews that have shown them to be as nutritionally beneficial and safe as their non-bioengineered counterparts, and there are no potential adverse health effects of bioengineered foods as compared to non-bioengineered foods.[2] Additionally, countless preeminent scientific and technical organizations have reviewed the safety data on bioengineered foods and have found them to be safe including: the American Medical Association, the World Health Organization, the U.S.'s National Academy of Sciences, the Royal Society of Medicine in the United Kingdom, the American Association for the Advancement of Science, the European Commission, the Union of German Academics of Sciences and Humanities, the French Academy of Science, and Food Standards Australia and New Zealand.[3] Prior to reaching the market, bioengineered agricultural products and foods go through a rigorous scientific review by multiple federal agencies including the Food and Drug Administration ("FDA"), USDA, and Environmental Protection Agency.[4]

Congress was so confident in the safety of bioengineering that the Act requires that "a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering."[5] Additionally, it was recognized that the "mandatory disclosure requirement is designed solely to address marketing matters, not based on any concerns with respect to safety of bioengineered foods or ingredient."[6]

As such, IDFA is supportive of providing consumers with accurate and truthful information about the bioengineered content of their food and ensuring that the Standard is not disparaging to bioengineering nor does it stifle innovation of future bioengineering techniques.

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[1] National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (to be codified at 7 U.S.C. §§ 1639−1639c, 1639i, 1639j, 6524).
[2] The National Academes of Sciences, Engineering and Medicine, Genetically Engineered Crops: Experiences and Prospects (2016).
[3] National Research Council and Institute of Medicine, Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Heath Effects (2004); Statement, American Association for the Advancement of Science, Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods (2012).
[4] Executive Office of the President, Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology (Jan. 5, 2017), *available at* https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf.
[5] 7 U.S.C. § 1639b(b)(3).
[6] S. Rep. No. 114–403, at 4 (2016).

2. USDA Should Clearly Define the Scope of the Standard By Establishing Criteria for What Foods Require Disclosure.

Definition of Bioengineering

Under the Act, the term "bioengineering" when referring to food applications means "(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."[7] Congress has directed USDA to interpret this definition and establish a mandatory marketing program that is "technologically neutral and reflect technological changes over time."[8] IDFA encourages USDA not to develop a static list of techniques that represent "conventional breeding" as such a list may limit the development of future technologies and a list of technologies could lead to a false impression by consumers that some techniques are safer than others. The Standard should not limit new advances in technology in the creation of safe and readily available food in a growing global market. However, when interpreting "found in nature," it may be appropriate for USDA to recognize certain naturally occurring genetic changes or mutations that occur independent of human intervention so the scope of the Standard is clear.

IDFA urges to USDA to use clear and plain English when defining terms related to the definition of bioengineering. As bioengineering techniques represent complex technology, consumers may not understand that it is safe for use in food when overly technical and scientific language is used. If USDA uses language that is not easily understandable, consumers may begin to fear continued use of bioengineering in food, which is stigmatizing to the technology, may suppress continued innovation, and limit adoption in the food system. Using plain English will ensure that consumers understand what bioengineering is and that it is a safe, proven technology for use in food.

We encourage USDA to define conventional and non-conventional breeding consistently with the definitions set forth in the National Organic Program.[9] As such, conventional breeding includes "traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."[10] Non-conventional breeding methods include "cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology)."[11] Harmonizing with these definitions will create consistency in the marketplace and promote consumer understanding of bioengineering.

Food Products Requiring Disclosure

While Congress provided a precise definition for "bioengineering," the Act does not set forth the requirements for foods that must bear disclosure of bioengineered content. Additionally, USDA

[7] 7 U.S.C. § 1639.
[8] S. Rep. No. 114-403, at 4.
[9] 7 U.S.C. § 6501−24.
[10] 7 C.F.R. § 205.2
[11] *Id.*

was directed to "establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food."[12]As such, IDFA believes that USDA should establish criteria for what is a "bioengineered food" such that disclosure of refined ingredients that come from a bioengineered source, such as sugar from sugar beets or oil from corn, is mandatory. The disclosure requirement would be triggered even if the ingredient does not contain any detectable recombinant DNA in the ingredient. Including refined ingredients as part of the mandatory disclosure aligns this marketing program with consumers' expectations of the law. Additionally, requiring the disclosure of these ingredients aligns the Standard with the disclosure required under Vermont's Act 120[13] and Consumer Protection Rule 121,[14] which many food companies had already complied with prior to passage of the Act.

When developing these criteria, USDA should exclude certain ingredients from requiring mandatory disclosure. According to the bipartisan Senate Report for the Act, "Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered."[15] The Report noted examples of exemptions provided by various states to their labeling mandates, including for food products that may include enzymes, additives, and processing aids, and foods that have medicinal and supplementary applications.[16] We suggest that USDA exempt the following items:

- Incidental additives[17] that are bioengineered or derived from a bioengineered crop or source;
- Foods and ingredients derived from animals that have been treated with drugs and pharmaceuticals produced from, containing, or consisting of a bioengineered substance;
- Ingredients that are produced through fermentation, including when the fermentation organism and the feedstock or media are, or are derived from, products of bioengineering, such as enzymes, amino acids, citric acid, vinegar, and vitamins; and
- Ingredients that are produced through the chemical transformation of a bioengineered food or ingredient and substantially transformed into a new ingredient, such as caramel flavoring and color, polydextrose, vitamin C, and sugar alcohols. For such ingredients, the bioengineered source is typically not present or readily traceable in the supply chain.

However, USDA should not use this language to expand the definition of bioengineered and apply it to technologies that do not fit under the definition provided in the Act. USDA must make it clear in the regulation what technology is covered by the regulation and ensure that it does not stifle the use of new and innovative gene editing and gene silencing techniques that are being developed. Any criteria that the Department creates under this authority, as well as the evaluation process, must be transparent and scientifically justified. USDA should consider providing information on its website to help the public and developers of bioengineered food or ingredients understand if their products require disclosure under the Standard.

[12] 7 U.S.C. § 1639b(b)(2)(c).
[13] 9 V.S.A. §§ 3041−3048.
[14] 6-121 Vt. Code R. §121.01−121.06.
[15] S. Rep. No. 114–403, at 9.
[16] *Id.* at 3.
[17] USDA should adopt FDA's definition for incidental additives. 21 C.F.R. § 101.100(3).

Animal Feed

Under the Act, USDA is prohibited from considering an animal derived food is bioengineered solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.[18] As such, USDA should acknowledge the clear statutory intent that food is not subject to the disclosure requirements solely because it is from animals fed bioengineered substances, such as corn silage or soybean meal. According to the bipartisan Senate Report, "it is the intent of Congress that the mandatory disclosure provisions not apply to animal feed, pet food, or ingredients used in animal feed or pet food. The language prohibits the Secretary from considering any food product derived from an animal to be bioengineered solely because the animal may have eaten bioengineered feed."[19] IDFA suggests that USDA adopt in the regulation the same language provided in the Act related to animal feed in the regulation. Additionally, USDA should explain in the preamble of the regulation that the animal feed exemption applies to potential adventitious presence of bioengineered material in an animal product and would apply to apply to animal products such as honey, in addition to milk, meat, and eggs.

Threshold

The Act also directs 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,"[20] also known as establishing a threshold that would trigger mandatory disclosure under the Standard. IDFA believes that USDA should establish a threshold for the marketing Standard. When establishing a threshold for the disclosure of the bioengineered content of food, USDA should ensure that it does not stigmatize minor use of bioengineering in the food production process, which is consistent with language in the Act.[21] IDFA believes that the threshold level should be set at an amount that supports the continued use of bioengineered ingredients or substances and recognizes their contribution to a safe, affordable, and sustainable food supply.

When determining the amount of bioengineered substance in a food, Congress directed the Department to "minimize the impacts on all aspects of the domestic and international value chain."[22] Globally, countries with bioengineering disclosure requirements have different thresholds for disclosures, varying from five percent[23] to 0.9 percent[24] to total bans.[25] USDA should evaluate thresholds established by international trading partners that require similar bioengineering disclosure to ensure that the threshold does not act as a non-tariff trade barrier for imported products and is consistent with our obligations under the World Trade Organization.

[18] 7 U.S.C. § 1639b(b)(2)(A).
[19] *Id.*
[20] *Id.* § 1639b(b)(2)(B).
[21] *Id.* § 1639b(b)(3) ("a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.").
[22] S. Rep. No. 114–403, at 4.
[23] *E.g.* Consumer Protection Act of 2009 § 24(6) (S. Afr.).
[24] *E.g.* 2003 J.O. (L 268) 24.
[25] *E.g.* The Biosafety (Labeling) Regulation (2012) Kenya Gazette Supplement No. 48 §§ 3, 4.

USDA should additionally evaluate the standards currently used by industry such as the Vermont Consumer Protection Rule 121.[26] When reviewing these international and domestic marketplace standards, we also suggest that USDA recognize and explain the differences between the Standard and definitions and the scope used in international and domestic standards to ensure that whatever threshold is determined is easily understood by food manufacturers and consumers.

Additionally, to ease determinations of a food's threshold, USDA should recognize that the threshold would be calculated based on the finished product as presented to the consumer and not require the exclusion of salt or water from the calculation. The Department should also recognize that the adventitious presence of bioengineered content should not be included in the calculation for threshold amounts because in many instances this level may fluctuate depending upon the season and can be incalculable. Including those accommodations will ease the burden of compliance and recordkeeping when companies are determining the bioengineered content of their foods.

3. USDA Should Create a Truthful and Not Misleading Disclosure Requirement That Does Not Disparage the Use of Bioengineering.

A core tenant of food labeling law in the U.S. is that companies must provide information that is truthful and not misleading to consumers. As such, IDFA suggests that USDA use these as the guideposts while writing and implementing the Standard. To do this, USDA should ensure that the Standard and the mandatory disclosures on foods are not disparaging to the use of bioengineering.[27] Additionally, USDA should ensure that there are no implications that a bioengineered food is safer, or not as safe, as a non-bioengineered food.[28] USDA should create a simple, easy to manage disclosure system that provides consumer with accurate and understandable information about the bioengineered content of the foods they purchase. The below information and criteria is proposed by IDFA with these tenants in mind.

<u>Language and Terminology in the Disclosure</u>

IDFA suggests that USDA conduct consumer research in order to determine what bioengineering terminology is most appropriate for the Standard's disclosure text (i.e. "bioengineering" or "genetic engineering"). While we understand the short timeframe USDA has to complete the Standard, it is essential that USDA have the most up-to-date information about how consumer perceive and comprehend the wide variety of terms used to describe bioengineering. Ensuing that consumers understand the terminology used in the disclosure will increase consumer confidence in the Standard and help inform any consumer education about the Standard. During this research, USDA should also inquire about abbreviated bioengineering terms such as "GE" or "BE" to evaluate their effectiveness as part of the disclosure as well. Additionally, USDA should make clear that regardless of the disclosure terminology required by the Standard that potential use of the term "genetic engineering" in the disclosure required under section 293 has no impact

[26] 6-121 Vt. Code R. §121.03(e).
[27] S. Rep. No. 114–403, at 2, 4.
[28] 7 U.S.C. § 1639b(b)(3); S. Rep. No. 114–403, at 4.

on the definition or meaning of the term "genetic engineering" used in the broader preemption language in section 295 of the Act, which is consistent with Congressional intent.[29]

IDFA highly discourages USDA from using the term "GMO" in the Standard or requiring it as part of the disclosure. In most instances, foods do not contain an entire organism. Additionally, FDA discourages companies from using the term when making presence or absence claims on food products due to its potential to confuse consumers.[30]

Whatever terminology USDA chooses for the disclosure, USDA should also recognize that companies might want to provide additional clarifying information about the bioengineered content of their foods that put the mandatory disclosure into proper context or about bioengineering in general. These additional, voluntary disclosures would be provided outside of the confines of the Standard. As such, food manufacturers should be allowed to use any term commonly associated with bioengineering such as "genetically modified," "genetically engineered," or "genetic engineering."

Location of the Disclosure

USDA should provide flexibility in the regulation about where any disclosure is placed on a food label. In IDFA's view, USDA should at most require prominent and conspicuous placement of the text, symbol, or digital link and allow a food company the flexibility to choose where the disclosure should be placed. The Department should recognize that placement of any of the disclosure options anywhere on the label information panel[31] would satisfy a "prominent and conspicuous" requirement.

Definitions

The Act left several important terms undefined. As such, USDA should use their discretion to define these terms leaving no ambiguity as to the applicability of the Standard. Because a majority of the products regulated under the Standard fall under FDA's regulations for the majority of labeling issues, USDA should follow, where appropriate, the existing FDA labeling definitions for these terms as those definitions are familiar to the dairy foods industry.

The Department should define small and very small food manufacturers in alignment with the FDA Food Safety Modernization Act ("FSMA") definitions of small and very small businesses. These regulations define "small food manufacturers" as businesses employing 500 or fewer full-

[29] *Id.* at 6 ("Congress selected the term 'genetically engineered' food or seed, rather than 'bioengineering,' because it is the intent for the provision to broadly preempt state, tribal, and local requirements regarding genetically engineered foods or seed regardless of whether the technology used to develop the food or seed falls within the definition of bioengineering. The intended goal is national uniformity and avoiding [] confusion. . . .").
[30] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (2015), *available at* https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.
[31] *See* 21 C.F.R. § 101.2.

time employees.[32] When determining how to calculate full-time equivalent employees, food manufacturers follow the Small Business Administration's guidelines.[33] Correspondingly, "very small food manufacturers" would be defined as businesses averaging less than $1 million per year (adjust for inflation) in annual sales of human food and the market value of human food manufactured, processed, packed, or held without sale.[34] Using these definitions for the Standard would create consistency across the industry and ease compliance with the Standard.[35]

IDFA recommends that if a food manufacturer meets the small food manufacturer definition, provided above, USDA should make the following accommodations as required by the Act.[36] USDA should allow small food manufacturers to label consistent with the small package disclosure requirements described below and recognized in the Act (i.e. calling for more information or visiting a website for more information).[37] USDA should provide guidelines to communicate what information is required to be shared when a phone number is called or a website is visited. This information should be consistent with the information that would need to be available on the webpage of the electronic disclosure requirement to ensure that consistent information is shared with consumers about the bioengineered content of their foods.

USDA should define small and very small food packages using some of the principles that FDA applies when determining the appropriate format for nutrition labeling information or to determine that available labeling space is too small to accommodate nutrition facts information. Although FDA does not have a definition for very small package, small packages are defined as "having a total surface area available to bear labeling of less than 12 square inches. . . ."[38] IDFA believes that USDA should use the criteria of a package with less than 12 square inches of available labeling space should be considered a "very small package." FDA has also recognized that food packages with more than 12 square inches, but less than 40 square inches of available labeling space require smaller modified "tabular format" for nutrition facts information. It would be appropriate for USDA to use size of more than 12 square inches but less than 40 square inches of available labeling space for the definition of "small packages."

IDFA recommends that if a package meets the small package or very small package definition proposed above, that the following accommodations should be made. USDA should provide additional flexibility for the form of disclosure on small packages. Small packages should have options on the size of the disclosure, as the space available will determine the size of the text or symbol that can be placed on the label. Additionally, manufacturers of food in small packages should be allowed to list a phone number with language such as "For nutrition information or other food facts, call 1-800-XXX-XXXX" or "For nutrition information or [bioengineering terminology abbreviation] food facts, call 1-800-XXX-XXXX" so that consumers have access to

[32] Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908, 55965 (Sept. 17, 2015).
[33] 13 C.F.R. § 121.106.
[34] 80 Fed. Reg. at 55965.
[35] 21 C.F.R. §§ 117.3; 121.2; 1.904.
[36] 7 U.S.C. § 1639b(b)(2)(F) (requiring USDA to provide an additional year of compliance and providing disclosure through a phone number or website).
[37] *Id.*
[38] 21 C.F.R. § 101.9(j)(13)(i)(A).

the disclosure information. Alternatively, small packages should be provided additional flexibility and be allowed to only provide a web address maintained by the manufacturer that provides information consistent with the electronic disclosure requirements about the bioengineered content of the food. Due to the extremely limited labeling space on very small packages, USDA should not require disclosure on very small packages.

If USDA determines that bulk items are subject to the disclosure requirements, the Department should clarify that these requirements only apply to bulk items intended for retail sale. Bulk foods sold at retail store should only require a disclosure when nutrition information is required under FDA regulations.[39] Disclosures on these bulk foods would be provided via a counter card, sign, or through other appropriate means. Similarly, USDA should clarify that bulk foods shipped for further processing or packaging before retail sale[40] should not require a label on the food itself or the vehicle transporting the food, for example bulk sugar shipped via tanker truck. The bioengineered information for bulk unpackaged foods not intended for retail sale may be shared through a specifications sheet, bill of material, or other documentation.

Regarding food products purchased online and in vending machines, USDA should not require additional disclosure requirements for those foods. The disclosures mandated on these foods should be similar to those for foods sold in a brick-and-mortar retail store. The Standard should be solely based on the accurate labeling not how the food is purchased. Labeling food products based on the form of purchase, for example through a vending machine, and requiring visible disclosure at the point of purchase is impractical and adds a level of complexity to the Standard that is unnecessary. Additionally, the Act does not require that consumers be provided disclosure information prior to purchase, as did FDA's vending calorie labeling rule.[41] Therefore, labeling required under this Act should be sufficient disclosure for items sold through vending and online.

Additionally, USDA should consider excluding certain foods from the disclosure requirements. IDFA supports not requiring disclosure on medical foods,[42] exempt infant formulas,[43] or dietary supplements[44] intended for retail sale as these foods were exempt from the Vermont disclosure

[39] *Id.* § 101.9(a).
[40] FDA defines these foods as "Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed." *Id.* § 101.9(j)(9)
[41] *See id.* § 101.8.
[42] The Orphan Drug Act defines medical foods as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. § 360ee(b)(3).
[43] FDA defines an exempt infant formula as "an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems." *See* 21 C.F.R. §107.3; FDA, Exempt Infant Formulas Marketed in the United States By Manufacturer and Category (2017), *avilable at* https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm106456.htm.
[44] A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to or supplement the diet. A "dietary ingredient" may be one, or any combination, of the following substances: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by people to supplement the diet. 21 U.S.C. § 321(ff).

law.[45] USDA should also recognize that labeling of certain foods is impractical and should also be excluded from the disclosure requirements. For example, the FDA has provided exemptions from traditional nutrition facts labeling under its regulations.[46] IDFA suggests that USDA similarly recognize that foods exempt from traditional labeling under FDA requirements should also be exempt from the bioengineered disclosure requirements.

Predominance of Ingredients

To determine whether a multi-ingredient food is subject to the disclosure requirements of the Standard, USDA should use the ingredient declaration on the product label to evaluate predominance of ingredient. As described in FDA and Food Safety Inspection Service ("FSIS") regulations and related guidance,[47] the ingredients are required to be declared on the label of a food by common or usual name in descending order of predominance by weight. As food manufacturers already determine predominance using this method, USDA should follow those regulations.

Text Disclosure

When a manufacturer chooses to declare the bioengineered content of its food on-package through text, USDA should require one of the following declarations:

- "Produced with [bioengineering terminology]"
- "Occasionally produced with [bioengineering terminology]"

These simple disclosures would provide consumers with truthful and not misleading information about the source of the bioengineered content of their foods. Additionally, these disclosures options are very similar to those under the Vermont's Consumer Protection Rule 121,[48] which consumers are already used to seeing on many foods. As described above, IDFA suggests that USDA conduct consumer research to determine what the most appropriate bioengineered terminology should be used in the disclosure.

Further, USDA should permit companies to use the "occasionally" language in the second bullet point to reflect instances where companies use both bioengineered and non-bioengineered ingredients in the same product throughout the year. This would provide flexibility for products that have a variable ingredient base that depends upon changing ingredient availability and may include a substitute ingredient produced with bioengineering.

USDA should consider including language in the regulation stating the text disclosure "shall appear prominently and conspicuously, but in no case may the letters be less than one-sixteenth inch in height" as this text size would require the information to be noticeable, but not make the declaration more prominent than other information provided on the label.[49]

[45] 9 V.S.A. §§ 3041−3048.
[46] 21 C.F.R. § 101.9 (10).
[47] 21 C.F.R. § 101.4(a); 9 C.F.R. §§ 317.2(f)(1), 381.118(a).
[48] 6-121 Vt. Code R. §121.01−121.06.
[49] *See* 21 C.F.R. § 101.2(c).

Additionally, the Department should establish a compliance date that provides sufficient time for those companies currently using other on-package statements, such as the disclosure statement previously required by the state of Vermont to revise their labels to comply with the new requirements. USDA should also consider harmonizing the compliance date for the Standard with other relevant labeling changes required by new regulations to reduce the regulatory burden on food manufacturers.

Disclosure through Use of a Symbol

When designing the symbol disclosure option, USDA must ensure that the symbol is in no way, shape, or form, disparaging to bioengineering. To accomplish this, USDA should avoid any shape, symbol, or color that is commonly associated to risk, warnings, or danger. Shapes that USDA should avoid include triangles, diamonds, or octagons, as these shapes are all used universally to connote warning. Symbols that USDA should avoid include exclamation points and skull-and-crossbones, as these symbols universally depict danger and death. USDA should also avoid using colors universally associated with warnings and danger such as red, orange, and yellow. Along with the previously stated, USDA should avoid using solely capitalized text, unless used for an acronym, as completely capitalized text can also imply danger or warning. IDFA also recommends that USDA be sure that the symbol they design is not comparable to any symbol describing hazards in the Globally Harmonized System of Classification and Labelling of Chemicals ("GHS").[50]

Electronic or Digital Link Disclosure

When establishing the requirements for the electronic or digital link disclosure option, USDA should ensure that the requirements are flexible and able to evolve with changes in technology. USDA should not require that companies only use a specific type of electronic or digital link, such as a QR code, but recognize that the link must include a Uniform Resource Locator (URL) that can be scanned and provide consumers with the mandatory disclosure information. This will provide companies the flexibility to choose any electronic or digital link like QR codes, DataMatrix, DataBar, RFID, and some forms of Digital Watermarking to meet this requirement and allow for technological advances in the future. Additionally, USDA should require that the electronic or digital link be easily and effectively scanned or read by a device through the camera function on the devices or other functions that allow consumers to gain access to the information.

On the food label next to the electronic or digital link, USDA should require language such as "Scan here for more food information" to indicate to consumers what to do with the link. At this time, "scan" is the most appropriate verb to be used as most technologies available require scanning of the embedded link. If another technology is developed and it is readily apparent that the term "scan" is no longer an appropriate verb to describe how a consumer may know to access information from that technology then USDA should provide companies with the option to use different terminology.

[50] U.N. Econ. Commission for Eur., Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (6th rev. 2015).

When scanned, the mandatory text on the online page should be the same as that required for the on-package text disclosure option described above. In addition to the required text, USDA should make it clear that nothing in the Act or the regulations prohibit companies from communicating additional truthful and not misleading information via electronic means about the bioengineered content of the food or bioengineering in general.

4. USDA Should Ensure That Recordkeeping, Records Inspection, and Hearing Requirements Reflect Standard Industry Practices.

When crafting the recordkeeping requirements for the Standard, USDA should assume if an ingredient could be sourced from a bioengineered crop or source, the ingredient is assumptively bioengineered unless document supports that the ingredient is non-bioengineered. Correspondingly, if no bioengineered source for that ingredient is commercially available or is otherwise exempt from the Standard, USDA should recognize that the ingredient would not require labeling or records to verify that the food is not bioengineered. This assumption reflects that the safe and proven technology of bioengineering has been overwhelmingly adopted in U.S. agricultural and food production[51] and will ease documentation management to demonstrate compliance with the Standard. Focusing recordkeeping requirements on the very small percentage of non-GE crops is a reasonable approach, especially as conventional and organic producers are already following identify preserved requirements throughout the chain of custody for a non-bioengineered ingredient.

Records

In order to demonstrate compliance with the Standard, USDA is authorized to require companies to maintain and make available records that are "customary and reasonable in the food industry."[52] As such, IDFA suggests that companies should only be required to maintain documents that contain information about the bioengineered content of the food or ingredient such as a bill of material, specification sheet, or other supplier documentation stating the bioengineered content consistent with the Standard. IDFA suggests that these records should only be maintained by a company for one year after the shelf-life of the product.

With respect to place and maintenance of records, USDA should recognize that many companies choose to manage labeling records at the corporate level and not at the processing facility. Thus, USDA should allow companies to store records offsite as long at those records can be retrieved and provided to USDA within a reasonable time following an oral or written request to inspect the records. Generally, FDA provides companies four to six weeks to allow companies to demonstrate compliance with certain labeling requirements and this timeframe would be appropriate for compliance with the Standard. If USDA determines that onsite maintenance of records at a processing facility is required, electronic records should be considered onsite if they are accessible from an onsite location. These requirements would mirror similar requirements

[51] According to USDA's Economic Research Service, "over 90 percent of U.S. corn, upland cotton, soybeans, canola, and sugarbeets [sic] are produced using GE varieties." USDA Econ. Res. Service, *Biotechnology: Overview* (Jul.12, 2017), *available at* https://www.ers.usda.gov/topics/farm-practices-management/biotechnology.aspx.
[52] 7 U.S.C. § 1369b(g)(2).

food facilities comply with under FDA's FSMA regulations.[53] Additionally, USDA should make it clear in the regulation that when reviewing records the Department does not have access to proprietary information such as recipes, nor does it have authority of make copies of such records as the Act did not grant this authority.

Audits and Opportunity for Hearing

IDFA supports USDA initiating an audit only after the Department conducts a review of food labels. An inquiry should only be initiated if the food is generally believed to be a source of bioengineered content and the product is believed to not be appropriately labeled. USDA should also conduct a review of other similar foods and their labeling to verify if those products are labeled instead of being requesting materials from companies prior to initiating an audit.

If USDA determines a company is not in compliance with the Standard, IDFA suggests that USDA issue a written notification of noncompliance to the food manufacturer listed on the label. The notification should provide:

1. A description of each noncompliance;
2. The facts upon which the notification of noncompliance is based; and
3. The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

USDA should then allow the food manufacturer 45 days to respond with supporting documentation establishing compliance with the Standard or corrective actions taken to address the non-compliance. USDA should allow a food manufacturer to request a meeting with USDA during this 45-day period to discuss the alleged non-compliance.

A company's failure to include corrective actions for both labeling and recordkeeping in a timely manner would result in the facility or supplier remaining non-compliant, and may result in further action by USDA. USDA would review the response provided from the food manufacturer that addresses the finding of non-compliance. If USDA is not satisfied with the response it receives, USDA would determine if further administrative or regulatory actions are necessary. If USDA is satisfied with the response, then USDA would issue a close out letter notifying the company of company's compliance with the Standard or the acceptability of the corrective actions. These procedures are similar to the Country of Origin Labeling ("COOL")[54] and FDA labeling[55] hearing procedures and are familiar to the food industry.

Additional, the Act does not provide USDA the authority to conduct inspections. Therefore, USDA should not attempt to extend its authority to inspect manufacturing facilities. USDA's audit authority should be limited to requesting and inspecting records of the entity required to label the food under the Standard.

[53] 21 C.F.R. § 117.315.
[54] USDA Agric. Marketing Service, Country of Origin Labeling Compliance and Enforcement Requirements 9 (2016).
[55] FDA, Regulatory Procedures Manual: 4-1Warning Letters (2016).

When making public the summary of the audits, USDA provide a preliminary announcement of compliance actions taken as well as the total number of audits performed without listing the details of the audits performed. This procedure would be similar to how USDA provides information about compliance under the COOL regulations.[56] Presumably, if an entity is found to be out of compliance it should be afforded the opportunity and time to work with USDA to address the issue to achieve compliance following the above proposed procedures. If USDA determined a company is still out of compliance after the above outlined procedures are followed, USDA should make public a simple declaration of an entity being out of compliance on its website for a period of six months. USDA does not need to provide a detailed summary of the outcome of its records examination as this could potentially involve the public release of confidential business information.

5. Imported Foods Should Not Receive Preferential Treatment under the Standard.

Under the Standard, imported foods should be subject to the same labeling disclosure and recordkeeping requirements as food produced and sold domestically, otherwise U.S. companies will be at a profound disadvantage to international food companies. Other countries with mandatory disclosures, such as the European Union,[57] China,[58] and Brazil,[59] require U.S. products to follow the same testing, labeling, and recordkeeping requirements as their domestic counterparts. Additionally, just as U.S. companies are required to do in other markets, imported foods should be labeled with the appropriate disclosure prior to import. This would have the added benefit of reducing liability risk to entities further down the distribution chain if the imported food is inaccurately labeled.

Further, USDA should apply the disclosure and recordkeeping requirements in a nondiscriminatory way to ensure that the Standard is consistent with U.S. obligations under the World Trade Organization and does not become a non-tariff barrier to trade. As described above, there is not internationally recognized standard for the acceptable presence of bioengineered content in a food to require labeling. Thus, USDA should establish a threshold level that is consistent with other trading partners and help facilitate free flow of goods.

[56] USDA Agric. Marketing Service, *Country of Origin Labeling Fiscal Year 2016 Retail Compliance Data* (Apr. 2017), *available at* https://www.ams.usda.gov/sites/default/files/media/2016RetailComplianceData.pdf.
[57] 2003 J.O. (L 268) 24.
[58] 中华人民共和国食品安全法 [Food Safety Law of the People's Republic of China] (order of the President of the People's Republic of China, Apr. 24, 2015), arts. 33, 69.
[59] Lei No. 11.105, de 24 de Março de 2005, art. 1 (Brz.).

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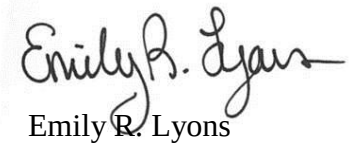
IDFA appreciates the opportunity to provide the Department feedback on how to create a legally defensible and scientifically based disclosure system for bioengineered foods. Please do not hesitate to contact us if we may be of further assistance.

Respectfully submitted,



Emily R. Lyons
Director, Regulatory Affairs and Counsel
International Dairy Foods Association