CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

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July 3, 2018

VIA ELECTRONIC FILING

Mr. Arthur Neal
Deputy Administrator, Transportation and Marketing
Agricultural Marketing Service
U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

RE: National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19,860 (May 4, 2018); Docket No. AMS-TM-17-0050

Dear Mr. Neal:

The U.S. Chamber of Commerce submits these comments in support of the Agricultural Marketing Service's (AMS or Service) proposal to establish the national mandatory bioengineered food disclosure standard (NBFDS or Standard).[1] Chamber members operate at all stages of the nation's food supply chain and many food products marketed today contain bioengineered (BE) ingredients. It is imperative that AMS promulgates a standard that provides regulatory certainty for the food supply chain, allows consumers to obtain more information if they want it, and protects the biotechnology industry from harmful and stigmatizing mandatory warning labels.

I. Background

The Chamber has long supported a common sense BE food disclosure standard to create regulatory certainty for all those operating along the nation's food supply chain. On July 29, 2016, President Obama signed Public Law 114-216 into law to amend the Agricultural Marketing Act of 1946 (amended Statute), establish a national standard requiring the disclosure of certain BE foods, and create uniformity to preempt a state-by-state patchwork of laws.[2] The amended Statute tasks the U.S. Department of Agriculture (USDA) with promulgating regulations to implement the NBFDS, which it delegated to AMS, as well as conduct a study to identify potential technological

[1] National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19,860 (May 4, 2018) (to be codified at 7 C.F.R. 66).
[2] Pub. L. 114-216, Subtitle E, 130 Stat. 834 (2016) (codified as amended 7 U.S.C. § 1621 *et seq*.).

challenges associated with electronic and digital disclosure methods.[3] AMS completed that study and published the results on its website in September 2017.[4]

At the onset of the rulemaking process, AMS posted 30 questions on its website regarding the proposed NBFDS to solicit public input on the Standard.[5] AMS received over 112,000 responses from stakeholders representing a number of different industries, governments, and other interest groups, and posted those responses on its website.[6] A number of Chamber members weighed in on the questions in written submissions.

On May 4, 2018, AMS proposed regulations to implement the NBFDS with the intent to "provide for [the] disclosure of foods that are or may be bioengineered in the interest of consumers"…and "minimize implementation and compliance costs for the food industry – costs that could be passed on to consumers."[7] The proposal includes a number of notable requirements spread across three major sections:

1. Applicability Provisions;
2. Disclosure Provisions; and
3. Administrative Provisions

The Chamber supports AMS' efforts to promulgate regulations for the NBFDS that provide uniform information to consumers about bioengineered food ingredients while reducing compliance costs for the food industry. The Chamber, however, believes that the final NBFDS regulations should be clear and straightforward, and incorporate flexibility where needed. The proposal takes the definition of "bioengineering" straight from the amended Statute without any additional explanation or guidance on the term's meaning. To ensure that the final NBFDS rule provides for regulatory certainty, AMS should make it clear in either the preamble or final rule itself that foods developed using certain genetic engineering processes will be excluded from the regulatory definition of "bioengineered food."

With that said, the Chamber offers the following comments, as discussed in further detail below, regarding certain provisions included in the proposed NBFDS regulations:

1. Applicability Provisions
    a. Position 1, which would exclude highly refined ingredients and products from the definition of "bioengineered food;"

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[3] *Id.*
[4] Deloitte, Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure, U.S.D.A., (July 2017), *available at* https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf.
[5] Proposed Rule Questions Under Consideration, U.S.D.A. (June 28, 2017), *available at* https://www.ams.usda.gov/rules-regulations/gmo-questions.
[6] Public Input on Bioengineered Food Disclosure Questions, U.S.D.A., *available at* https://www.ams.usda.gov/rules-regulations/public-input-bioengineered-food-disclosure-questions.
[7] 83 Fed. Reg. 19,861.

b. The Chamber supports AMS' 2-List approach for identifying products subject to disclosure under the Standard;
c. The Chamber supports AMS' proposed petition process for determining BE factors and conditions;
d. The Chamber supports AMS' approach to identifying an appropriate BE substance disclosure threshold level; and
e. The Chamber supports the proposed NBFDS exemptions, but believes AMS should expand them.

2. Disclosure Provisions
   a. The Chamber supports the use of text messaging as an option for disclosure under the Standard and the use of new technologies as they develop;
   b. The Chamber supports the voluntary disclosure option for regulated entities.

3. Administrative Provisions
   a. The Chamber supports the proposed compliance dates for the NBFDS; and
   b. The Chamber encourages AMS to use more recognizable terminology when labeling products.

II. Applicability Provisions

The Chamber finds that AMS has included transparent applicability provisions in the proposed NBFDS regulations that will allow stakeholders to identify accurately and effectively those foods that may be subject to disclosure under the Standard. AMS proposes to have the NBFDS apply to foods covered under the Federal Food, Drug, and Cosmetic Act (FDCA),[8] as well as those covered, with certain conditions, by the Federal Meat Inspection Act (FMIA),[9] Poultry Products Inspection Act (FPIA),[10] and Egg Products Inspection Act (EPIA).[11]

In regards to the proposed NBFDS provisions, the Chamber supports:

1. Excluding "highly refined ingredients/products" from the definition of "bioengineered food;"
2. AMS' 2-list approach to identifying what products may need to be disclosed under the Standard, provided it includes a streamlined process allowing stakeholders to determine early on whether a product is considered "BE;"
3. The proposed petition process for requesting a determination by AMS regarding additional factors and conditions under which a food is considered a BE food;
4. AMS' approach to identifying a threshold level for the amount of BE substance for determining whether food must bear a BE disclosure; and
5. The four exemptions to the NBFDS provided for in the proposal.

[8] 21 U.S.C. § 301 *et seq.*
[9] 21 U.S.C. § 601 *et seq.*
[10] 21 U.S.C. § 451 *et seq.*
[11] 21 U.S.C. § 1031 *et seq.*

To that end, the Chamber believes that AMS should consider expanding the exemptions to the NBFDS regarding "very small food manufacturers" and "animals fed with bioengineered feed and their products" to properly exempt other related stakeholders and products from certain disclosure requirements under the Standard.

a. AMS Should Adopt Position 1 in Regards to the Definition of "Bioengineered Food"

The Chamber appreciates the approach that AMS has taken to determine the definition of "bioengineered food" and consider whether "highly refined ingredients/products" should be included in that term.

The amended Statute provides the Secretary of the Department of Agriculture (Secretary) with the authority to define "bioengineered food," consistent with other provisions in the amended Statute, including "bioengineering."[12] The amended Statute defines "bioengineering," with respect to food, as a food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and for which the modification could not otherwise be obtained through conventional breeding or found in nature."[13] AMS proposes to directly incorporate the definition of "bioengineering" into "bioengineered food."

AMS has offered two positions in the proposal for defining "bioengineered food." These two positions take contrasting stances as to whether AMS should incorporate highly refined ingredients/products into that definition. Position 1 takes the stance that "highly refined products are not within the scope of 'bioengineering' because they do not 'contain…genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques,' and therefore do not require disclosure as 'bioengineered' under the NBFDS."[14] Position 2, on the other hand, takes the stance that the scope of the definition of "bioengineering" "includes all foods produced from bioengineering," including highly refined products.[15]

The Chamber encourages AMS to adopt Position 1. For purposes of the Standard, disclosure is limited to only those foods that meet the statutory definition of "bioengineering." Highly refined ingredients/products are typically subject to processes that remove genetic material to the extent that it can no longer be detected through common testing methods. In maintaining consistency with the statute, they no longer contain the genetic material necessary to fall within the scope of "bioengineering."

The Chamber finds that the proposal also offers regulated entities two process options, as later discussed in further detail, to provide for the alternative disclosure of certain highly refined ingredients in the future. First, AMS proposes to provide regulated entities with the option to later petition the Service to include specific factors or conditions not otherwise provided for in the definition of "bioengineered food." Second, AMS proposes to provide stakeholders with the

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[12] 83 Fed. Reg. 19,862.
[13] 7 U.S.C. § 1639(1); 83 Fed. Reg. 19,885.
[14] 83 Fed. Reg. 19,862.
[15] 83 Fed. Reg. 19,863.

freedom to disclose voluntarily additional ingredients/products as long as they are truthful and consistent with the NBFDS.

While it is imperative that the Service define "bioengineered food," highly refined ingredients and products should not be disclosed within the scope of the Standard. As such, the Chamber encourages AMS to adopt Position 1.

b. The Chamber Supports AMS' 2-List Approach for Identifying Products Subject to Disclosure Under the Standard

The Chamber supports AMS' decision to utilize a 2-list approach for identifying products subject to disclosure under the NBFDS. AMS proposes to create two BE food "lists" to assist consumers and regulated entities in determining whether a food item requires disclosure under the Standard.[16]

The first proposed list applies to those BE foods that are commercially available and have been adopted at a rate exceeding 85% in the United States.[17] These foods include canola, field corn, and soybean. The second proposed list includes foods that are "not highly adopted commercially available" BE foods. These foods include certain apples, sweet corn, and papaya. Notably, in terms of the proposal, "adoption" refers to U.S. plantings of those crops as "bioengineered cultivars."[18] The Chamber feels that this crop-based approach offers a flexible option for consumers and regulated entities to identify those foods requiring disclosure under the NBFDS.

However, the Chamber feels that AMS should develop and include in the regulations an explicit process whereby product developers can obtain a prior determination that a product is not BE. This process should mirror, or be similar to, that process carried out by the Biotechnology Regulatory Services of the Animal and Plant Health Inspection Service (APHIS) under the authority of the Plant Protection Act (PPA).[19] Inclusion of a regulatory determination process analogous to the BRS PPA process would provide product developers with the opportunity to obtain certainty as to whether a particular product would be subject to the requirements of the NBFDS.

Under this process, a producer may submit a letter to BRS containing certain specific information regarding a product's development and characteristics.[20] BRS will then assess the information provided in the letter and issue a written response to the producer.[21] That response will indicate whether a product is subject to regulation under the PPA.[22] Recent examples of such

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[16] 83 Fed. Reg. 19,864.
[17] *Id.*
[18] *Id.*
[19] Am I Regulated Under 7 CFR part 340?, U.S.D.A., *available at* https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated.
[20] *Id.*
[21] *Id.*
[22] *Id.*

determinations include those for "Corn with Increased Yield" and "Soybean Engineered for Transposon Mutagenesis."[23]

With that said, including a streamlined petition process in the final NBFDS would ensure that regulated entities are able to proactively engage AMS regarding the inclusion of their foods or products within the scope of the Service's two lists. The Chamber supports such a streamlined approach, and encourages AMS to explore the possibility of including one in the final rule.

c. The Chamber Supports AMS' Proposed Petition Process for Determining Additional BE Factors and Conditions

The Chamber finds that AMS' proposed petition process for determining additional factors and conditions for consideration in the definition of "bioengineered food" to be a transparent and flexible approach to identifying factors or conditions that may otherwise not initially be considered part of BE food. The amended Statute provides that the Secretary establish a process via regulation for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a BE food.[24] The amended Statute is silent on the specific process, and provides the Secretary with discretion as to setting up the process. The Chamber supports this, considering the breadth of expertise and knowledge of the subject matter of those promulgating the regulation at AMS.

Moreover, the Chamber believes that the Secretary should ultimately base his or her decision to include additional factors and conditions within the scope of BE food on the weight of the scientific evidence and best available scientific data. To that end, a petition process would provide the public with a transparent rulemaking process and the opportunity to participate in potentially limiting the scope of BE food and excluding certain products from disclosure. Additional limitations to the scope of the NBFDS would undoubtedly affect many Chamber members.

d. The Chamber Supports AMS' Approach to Identifying an Appropriate BE Substance Disclosure Threshold Level

The Chamber encourages AMS to adopt Alternative 1-A when determining an appropriate BE substance disclosure threshold, and supports the Service's decision to provide three alternative options for stakeholders to comment on. The amended Statute requires that the Secretary "determine the amounts of a bioengineered substance that may be present in food, as appropriate for the food to be a bioengineered food."[25] Based on responses from the initial 30 questions provided by the Service in last year's stakeholder survey, AMS has proposed three alternative thresholds in an effort to minimize costs for regulated entities after a final rule goes into effect:

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[23] Regulated Article Letters of Inquiry, U.S.D.A. (June 4, 2018), *available at* https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry.
[24] 7 U.S.C. § 1639b(b)(2)(c); 83 Fed. Reg. 19,865.
[25] 7 U.S.C. § 1639b(b)(2)(b); 83 Fed. Reg. 19,867.

1. **Alternative 1-A**: an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than ***five percent (5%) of the specific ingredient by weight***, would not be subject to disclosure as a result of that one ingredient;

2. **Alternative 1-B**: an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than ***nine-tenths percent (0.9%) of the specific ingredient by weight***, would not be subject to disclosure as a result of that one ingredient; and

3. **Alternative 1-C**: allow regulated entities to use a small amount of BE ingredients up to a certain threshold, ***such as 5% of the total weight of the product***, before being required to label a product with a BE disclosure.[26]

The Chamber believes Alternative 1-A offers the best disclosure threshold for regulated entities, and notes that it is important for the Service to recognize that the Standard is a marketing standard and not one based on health and safety.

Alternative 1-A provides regulated entities with the most flexibility and certainty when engaged in the food supply chain. For example, food manufacturers typically use the same manufacturing processes on both BE and non-BE crops. During those processes, trace or insignificant amounts of BE substances may transfer from BE crops to non-BE crops. Accordingly, the Senate Report for the amended Statute states that, "there is no difference in safety between a bioengineered food and its non-bioengineered counterpart."[27]

Moreover, Congress directed USDA to "minimize the impacts on all aspects of the domestic and international value chain" when determining the amounts of a BE substance that may be present in food.[28] A number of countries, including Canada, Indonesia, and Japan, incorporate a 5% threshold on either a mandatory or a voluntary basis.[29] It would be prudent to mirror that level to support regulatory certainty for the international food supply chain.

Lastly, Alternative 1-A would provide for consistency with USDA's National Organic Program (NOP) requirements. The amended Statute requires that USDA consider establishing consistency between the NOP requirements and the NBFDS requirements.[30] The amended Statute also specifies that foods certified under the NOP may be represented as non-BE foods.[31] To that end, when labeling products as "organic" under the NOP approach, that product must contain a minimum of 95% organic ingredients (excluding salt and water), and up to 5% of the ingredients may be nonorganic agricultural products that are not commercially available as organic and/or

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[26] 83 Fed. Reg. 19,868-9.
[27] Sen. Rep. No. 114–403, at 2 (Dec. 9, 2016).
[28] *Id.* at 4.
[29] *See* Stakeholder Input on Questions Regarding the Establishment of a National Bioengineered Food Disclosure Standard, Nat'l Corn Growers Ass'n (Aug. 25, 2017) (Footnotes 5 and 6), *available at* https://www.ams.usda.gov/sites/default/files/media/NationalCornGrowersAssocBE.pdf.
[30] 7 U.S.C. § 1639b(f); 83 Fed. Reg. 19,867.
[31] *Id.*

nonagricultural products that are on the National list.[32] The Chamber finds that Alternative 1-A provides for the most consistency with the NOP program.

Given the uncertainty of when and where these trace amounts may shift, and in an effort to adhere to Congressional intent and mirror USDA's NOP approach, the Chamber feels that Alternative 1-A provides for the most certain and cost-effective threshold in ensuring a safe, affordable, and sustainable food supply.

e. The Chamber Supports the Proposed NBFDS Exemptions, but Believes AMS Should Expand Them

The Chamber supports the exemptions to the NBFDS provided in the proposal. AMS should, as it has proposed, expressly exempt "food serviced in a restaurant or similar retail establishment" and "very small food manufacturers" from the scope of the NBFDS.[33] AMS also should exempt "animals fed with bioengineered feed and their products" and "food certified under the National Organic Program."[34]

The Chamber supports the exemption for "animals fed with bioengineered feed and their products," and urges AMS to extend this sensible exemption to include BE-derived substrates as well as processing agents. These substrates typically become feed stock for plants or microbes and would no longer qualify as "bioengineered" under the amended Statute." As such, it is necessary that this exemption include all foods or ingredients used in the production of BE feed, not just the final product.

III. Disclosure Provisions

The Chamber generally supports the disclosure provisions include in the proposed NBFDS regulations. AMS is proposing that food manufacturers, food importers, and, in certain situations, food retailers alike disclose the presence of BE food or BE food ingredients in the food that they process and/or sell via on-package text, on-package symbol, electronic or digital link, or through an additional text message option.

The Chamber supports the use of a text messaging option as a means of allowing consumers to identify if a product is a BE food or contains BE food ingredients. The Chamber also recommends that, as technologies continue to evolve, the AMS consider providing additional disclosure options that may be appropriate for consumers. For example, artificial intelligence technologies may provide additional opportunities for innovation with respect to food disclosure, and AMS should ensure that the final rule enables the Service to accommodate advances in these new and evolving technologies moving forward.

Moreover, the Chamber also supports the option for the voluntary disclosure of the presence of BE food or food ingredients for food that may not otherwise be subject to disclosure

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[32] 7 C.F.R. § 205.301.
[33] 83 Fed. Reg. 19,867.
[34] *Id.* at 19,869.

under the Standard.

a. The Chamber Supports the Use of Text Messaging as an Option for Disclosure under the Standard

The Chamber supports the addition of a text messaging disclosure option for consumers under the NBFDS. The amended Statute provides three alternative options for disclosure under the NBFDS – text, a symbol, or an electronic or digital link – for those BE foods that have successfully completed the pre-market Federal regulatory review process.[35] As previously noted, the amended Statute tasks the Secretary, through AMS, to conduct a study to identify potential technological challenges associated with electronic and digital disclosure methods.[36]

AMS completed that study and posted the results on its website in September 2017. The study focused on five factors: 1) the availability of wireless internet or cellular networks; 2) the availability of landline telephones in stores; 3) challenges facing small and rural retailers; 4) the efforts that retailers and other entities have taken to address potential technology and infrastructure challenges; and 5) the costs and benefits of installing in retail stores electronic or digital link scanners, or other evolving technology that provide bioengineering disclosure information.[37]

The study found a number of different things. Notably, it found that consumers might recognize digital links, but lack familiarity with scanning.[38] Additionally, the study found that 85% of consumers experienced technical challenges using certain mobile software applications for scanning digital links.[39] These factors, combined with the fact that some retailers, including those that are small or in rural areas, lack access to WIFI or cellular data networks, indicates that an electronic/digital method may not be the best option for some consumers.[40]

As a result, AMS has included a text messaging disclosure option in the NBFDS proposal. The Chamber feels that this option for disclosure is justified given that not all consumers have access to broadband internet or a smart phone. Additionally, the Chamber feels that this demonstrates AMS' willingness to go beyond the amended Statute's text when promulgating regulations for the NBFDS.

b. The Chamber Supports the Voluntary Disclosure Option for Regulated Entities

The Chamber supports AMS' decision to provide regulated entities with the option to voluntarily disclose foods and ingredients that may not otherwise be subject to disclosure under the NBFDS. According to the proposal, AMS recognizes that "some entities responsible for disclosure may want to provide a BE disclosure even though they are exempted."[41] For example, very small

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[35] *Id.* at 19,875-6.
[36] *Id.* at 19,875.
[37] *See supra* note 5.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] 83 Fed. Reg. 19,877.

food manufacturers that may want to provide information to their consumers regardless of the exemptions. The Chamber feels that voluntary disclosure may also provide regulated entities with the option to disclose BE information regarding ingredients, such as highly refined sugars or oils, which may otherwise not require disclosure under the Standard.

IV. Administrative Provisions

The Chamber believes that AMS has included certain provisions in the proposed NBFDS regulations that will provide for an efficient administration of the Standard. Indeed, the Chamber supports the proposed compliance dates, which indicate that AMS seeks regulatory coordination amongst Agencies and provide enough time for affected stakeholders to comply with the new regulations. The Chamber questions, however, AMS' decision to shift away from use of the term "GMO" (genetically modified organisms) in favor of the term "BE."

a. The Chamber Supports the Proposed Compliance Dates for the NBFDS

The Chamber supports AMS' proposal to align compliance dates for the NBFDS with the Food and Drug Administration's (FDA) compliance dates for its "Nutrition Facts and Supplemental Facts" label and "Serving Size" final rules.[42] FDA recently extending these compliance dates from July 26, 2018 to January 1, 2020 and January 1, 2021 for food manufacturers and small food manufacturers, respectively.[43] AMS proposes to use those same compliance dates for the NBFDS.

The Chamber believes that this course of action is appropriate and agrees with AMS in that the proposed compliance dates "provide a balance between the time industry will need to come into compliance with the new labeling requirements and the need for consumers to have the information in a timely manner."[44] Moreover, the Chamber believes that this encourages interagency coordination and cooperation in an effort to develop a proper product-labeling regime.

b. The Chamber Encourages AMS to Use Recognizable Terminology on Product Labels

The Chamber believes that terms used to disclose BE ingredients or foods should be simple, scientifically accurate, non-disparaging, and educational. AMS may want to consider using more recognizable terminology when disclosing BE ingredients on product labels. In issuing the NBFDS proposal, AMS has proposed using the term "BE" on product labels.

Nevertheless, the Chamber believes AMS should consider using a term more recognizable than "BE" on product labels. While the amended Statute and proposal use the terms "bioengineering" and "bioengineered food," AMS is not required to use those terms, or "BE" on product labels. Rather, it leaves the disclosure standard up to the discretion of the Secretary, in that

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[42] *Id.* at 19,879.
[43] Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates, 83 Fed. Reg. 19,619 (May 4, 2018).
[44] 83 Fed. Reg. 19,879.

a disclosure must be made in accordance with the NBFDS regulations promulgated by the Secretary.[45] Moreover, according to Congress, the only text required to accompany an electronic or digital link disclosure option is "scan here for more food information."[46] This statement gives no reference that AMS *must* use "BE" on product labels.

For example, according to a 2016 study conducted by one Chamber member, consumers want to see the word "GMOs" on labels, as technical terms are confusing, feel less transparent, and make food feel scientific. Additionally, the study found that consumers support the inclusion of phrases such as "The FDA considers GMO crops to be safe," as they are direct and to the point, and use language that consumers understand.

The use of the term "GMO" is consistent with existing FDA guidance for the labeling of foods derived from BE plants. Its use would provide for a coordinated degree of certainty among Federal agencies,[47] and AMS has already demonstrated a willingness to coordinate with FDA on compliance dates in the proposal. While the term "GMO" may not be as scientifically accurate as "BE" or "bioengineered," consumers are much more likely to recognize such a term when shopping for products and adding value to the food supply chain.

As such, the Chamber encourages AMS to consider these results and choose labeling language that best balances the need for scientific accuracy and consumer awareness.

V. Conclusion

The Chamber appreciates AMS' consideration of these comments and urges the Service to implement a commonsense national mandatory bioengineered food disclosure standard that ensures regulatory certainty for all those operating along the nation's food supply chain. If you have questions regarding these comments, please contact me at (202) 463-5558 or at kharbert@uschamber.com.

Sincerely,

Karen A. Harbert

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[45] 7 U.S.C. § 1639b(b)(1).
[46] Sen. Rep. No. 114–403, at 2.
[47] *See* Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry; Availability, 80 Fed. Reg. 73,194 (Nov. 24, 2015), *available at* https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm.