National Confectioners Association
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July 17, 2017

U.S. Department of Agriculture
Agricultural Marketing Service
Room 3071-S, Ag Stop 0201
1400 Independence Avenue, SW
Washington, DC 20250-0273

Submitted via email: GMOlabeling@ams.usda.gov

RE: NCA Comments on Proposed Rule Questions Under Consideration for Bioengineered Food Disclosure Rule

The National Confectioners Association (NCA) appreciates the opportunity to offer feedback on USDA's proposed rule questions for the bioengineered food disclosure rule.

NCA is the trade organization that advances, protects and promotes chocolate, candy, gum and mints, and the companies that make these special treats. As the leading association for the $35 billion U.S. confectionery industry, NCA educates the public to help ensure that people understand and appreciate the unique role that chocolate and candy can play in a happy, balanced lifestyle. The majority of our manufacturing member companies are small and medium-sized. Chocolate and candy are produced in all 50 states, employing approximately 55,000 workers in more than 1,000 manufacturing facilities across the country. More than 400,000 jobs in agriculture, retail, transportation and other industries rely in part on the sale of confections for their livelihood. In fact, for every one job that America's chocolate and candy companies create, another seven are supported in related industries.

Many NCA member companies use ingredients in their products that are derived from bioengineered crops. Likewise, a number of NCA member companies manufacture products geared towards consumers seeking non-GMO products. NCA supports a uniform federal standard on the labeling of food produced with bioengineering and thank AMS for their efforts in initiating the rulemaking process. NCA supports efforts that promote transparency, as well as science-based policies and regulations. Thank you for the opportunity to provide the following responses to the questions posed on USDA's website:

4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))

NCA supports requiring disclosures for food that contains highly refined ingredients such as oils or sugars from bioengineered crops. NCA is committed to transparency. In fact, America's leading chocolate and candy companies recently announced a major initiative to provide consumers more

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information, options, and support as they seek to manage their sugar intake and gain a better understanding of the ingredients in their favorite treats. Find more information at www.AlwaysATreat.com.

We are concerned that consumers may find it misleading if highly refined ingredients derived from crops produced with bioengineering are not disclosed. Amongst the concerns of consumers who are interested in gaining access to information about whether food is produced with bioengineering are those related the environment.[1] Consumer surveys have shown that these environmental concerns are linked to growing practices of these crops. Therefore, we believe these consumers would find the degree of refinement of these ingredients irrelevant to their interest. Furthermore, manufacturers are usually able to obtain the information from their suppliers about the status of these ingredients without relying on analytical detection. NCA supports providing consumers with full transparency about the source of these ingredients.

7. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))

NCA appreciates the addition of language in Sec.293(b)(2)(A)) of the Law pertaining to food products derived an animal that consumed feed produced from, containing, or consisting of a bioengineered substance, and thanks AMS for working to implement this provision. NCA supports USDA's thinking to consider regulatory language that is similar to the wording in the Law and encourages USDA to provide additional information when crafting the regulation to further clarify that food derived from any animal would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

Further, this position is consistent with the European Commission's Regulation No 1829/2003[2] which "does not require the labeling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products."

NCA encourages USDA to consider adopting similar language to that contained in the Law and to further clarify that all foods derived from any type of animal would not require disclosure as a bioengineered food.

[1] Pew Research Center, December, 2016, "The New Food Fights: U.S. Public Divides Over Food Science"
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829&from=en

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13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))

NCA supports the option of using a symbol to disclose a bioengineered food and considers this a practical approach for some confectionery products.

NCA agrees with USDA's thinking that the symbol should be scalable for different sized packages. As detailed in Question 17 of our comments, a majority of products in the confectionery industry are small and have limited space on packaging. Therefore, the ability to use scaling for a symbol on small packaging would be a sensible option for these types of products.

It is important that any symbol developed by USDA provide information to the consumer in a neutral manner and is not disparaging towards bioengineering. As major regulatory and science authorities, including the FDA, National Academy of Sciences and USDA have concluded that scientific evidence supports the safety of genetically engineered ingredients, it is crucial that the symbol not be misinterpreted by consumers as being a potential human health risk. To this end, NCA recommends that USDA conduct consumer testing on the proposed symbols to evaluate their effectiveness and ensure that they do not elicit a consumer response that is unfavorable towards bioengineering.

17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))

The confectionery industry is in a unique position to offer comments on small packages, since the majority of confectionery products are small and their packages have significant space limitations. Confectioners often face challenges fitting required labeling components on their packaging. As the new format of the nutrition facts panel is larger, many of NCA's member companies are currently working to redesign their packages to accommodate all necessary information.

NCA greatly appreciates this provision of the legislation and strongly supports AMS developing special disclosure options for small packages. These options have the potential to substantially alleviate regulatory burden on our industry.

NCA agrees with USDA's thinking of aligning with the FDA's definitions and regulations on small packages. As USDA notes, 21 CFR 101.9(j)(13)(i) defines "small packages" as those with less than 12 square inches of total surface area available to bear labeling. These products are exempt from nutrition labeling, unless a nutrition claim is made on the product. Likewise, per 21 CFR 101.9(j)(13)(ii) , FDA

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allows packages with less than 40 square inches of total surface space available to bear labeling the opportunity to use a modified format for the nutrition label. NCA encourages USDA to follow a similar approach, exempting products with less than 12 square inches of total surface area from the labeling requirement and providing modified requirements for those with less than 40 square inches.

Additionally, it is noteworthy that FDA does exempt certain very small candy products from all labeling requirements on the basis of their size. Per 21 CFR 1.24 (a)(4):

> Individually wrapped pieces of *penny candy* and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

NCA encourages USDA to align with FDA's regulations exempting individually wrapped chocolate and candy weighing less than one-half once from labeling.

18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))

NCA supports the option to provide manufacturers with flexibility to either provide a web address or telephone number to provide information. Since the companies producing these packages are already limited with space availability, more options would help manufacturers determine the disclosure with the smallest footprint. Different companies are better set up to staff phone lines to address consumer inquiries, while others may prefer to make this information available on a website. Another consideration related to this question is how AMS chooses to tackle Question 13. Symbols developed by AMS may have a significantly smaller footprint than text disclosures.

19. How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))

NCA is in a unique position to provide feedback on the definition of small food manufacturers because the vast majority of the association's member companies are small and mid-sized family owned businesses. Our entire industry is committed to transparency, but having an additional year to come into

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compliance with the bioengineered labeling requirements will help mitigate the regulatory burden and cost for these small businesses.

Small food manufacturers have fewer resources to dedicate to labeling and regulatory compliance and are already expending tremendous effort to implement the extensive new food regulations under the Food Safety Modernization Act and nutrition labeling requirements. NCA appreciates the additional time that was provided for these companies in the Law and thanks AMS for working to implement these provisions.

NCA recommends that AMS adopt the size standards developed by the Small Business Administration. The Small Businesses Act (Public Law 85-236, as amended) gives the Small Business Administration the authority to establish small business size standards for Federal government programs to encourage and strengthen their competiveness in the economy. The SBA considers a number of factors when determining these small businesses size standards for an industry, including the average and distribution of company sizes, the start-up costs/barriers to entry, and the degree of competition in a given industry. The definitions vary by type of industry in order to best reflect the unique needs of that particular sector. The standards are published in 21 CFR 121.201 and available on the SBA's website from: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

NCA also notes that for food manufacturing, the SBA's size standards are based on the number of employees. NCA strongly prefers the basis of the extension from this rulemaking to be on number of employees, versus sales of a given company. Sales are much more variable and outside of the control of a business than the decision to hire new employees. It may not be possible for a small company to predict their sales and thus adequately plan for compliance.

20. For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))

NCA supports USDA's consideration that the presence of a phone number on the packaging in conjunction with the language "Provides access to additional information" is sufficient for consumers to gain access to information on bioengineered ingredients. This proposed language is consistent with Sec. 293(b)(2)(F)(ii)(I)) of the Law. In keeping with the concerns related to space constraints on some packages, NCA also encourages USDA to consider more concise statements, perhaps something like: "Visit/call ___for more info".

NCA is looking forward to seeing the results from USDA's Study of Electronic or Digital Link Disclosure and believes that it will provide useful information as to the appropriate on-text information to accompany a phone number or website.

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22. How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))

It is NCA's position that in order to provide consumers with information about bioengineered food on the greatest number of products, as few companies as possible should be exempted on the basis of their size. NCA believes it is appropriate to require that any company that would be subject to nutrition labeling on the basis of its size to be subject to this requirement. FDA only exempts a narrow range of companies from nutrition labeling on the basis of their size. Per 21 CFR 101.9 (j), the following exemptions from nutrition labeling are established:

- 21CFR101.9(j)(1)(i) exempts businesses with less than $500,000 in annual gross sales
- 21CFR101.9(j)(18) exempts products made by companies with less than 100 full-time equivalent employees and annual sales of fewer than 100,000 units

NCA encourages AMS to consider adopting a similar approach to the definition of very small businesses, which would be exempt from the requirement to disclose information about bioengineering on the food label.

30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))

It is NCA's position that products imported into the United States should be subject to the same regulations as domestically produced products. NCA is committed to transparency and believes that consumers should have access to this information on all products, regardless of whether they were produced domestically or internationally.

This position is consistent with provisions under the Federal Meat Inspection Act[3] and the Poultry Products Inspections Act[4] which states that all imported meat and poultry products are subject to provisions under the Federal Food, Drug, and Cosmetic Act.

Per 21 U.S.C. §620(a):

[3] https://www.gpo.gov/fdsys/pkg/USCODE-2014-title21/html/USCODE-2014-title21-chap12-subchapI-sec620.htm
[4] https://www.gpo.gov/fdsys/pkg/USCODE-2014-title21/html/USCODE-2014-title21-chap10-sec466.htm

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All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]: *Provided*, That they shall be marked and labeled as required by such regulations for imported articles:

Per 21 U.S.C. §466(a):

All imported, slaughtered poultry, or parts or products thereof, shall after entry into the United States in compliance with such rules and regulations be deemed and treated as domestic slaughtered poultry, or parts or products thereof, within the meaning and subject to the provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and Acts amendatory of, supplemental to, or in substitution for such chapter and Act.

Additionally, NCA's position aligns with provisions contained in Section 801 of the U.S. Federal Food, Drug, and Cosmetic Act which requires imported food products to follow the same laws and regulations as food products produced domestically.

Importers of food products intended for introduction into the U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary, and labeling according to U.S. requirements.[5]

In conclusion, NCA is grateful for the opportunity to offer our positions on these questions and thanks AMS for considering our perspective. We look forward to working with AMS throughout the rulemaking process and would be happy to provide any additional input or information that may be helpful as the agency takes on the responsibility of drafting the proposed rule.

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Laura Shumow
Vice President, Scientific and Regulatory Affairs
202-534-1492
Laura.Shumow@CandyUSA.com

[5] https://www.fda.gov/food/guidanceregulation/importsexports/importing/default.htm