August 7, 2017

Re: Stakeholder Input on the Agricultural Marketing Service's "Proposed Rule Questions Under Consideration."

The Independent Bakers Association ("IBA") submits the following input to the US Department of Agriculture's Agricultural Marketing Service ("AMS") as a stakeholder affected by the National Bioengineered Food Disclosure Standard legislation, ("the disclosure legislation" or "the legislation") and its implementing regulations. IBA is a Washington, DC-based national trade association of over 250 mostly family-owned, small to midsize wholesale bakeries and allied businesses that span the supply-chain. IBA was founded in 1968 to protect and serve the interests of independent wholesale bakers. We appreciate the opportunity to submit the following preliminary responses to AMS's "Proposed Rule Questions Under Consideration."[1]

1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

IBA recommends AMS consider "genetic engineering, "GE," "biotechnology," and "BE" to be interchangeable with bioengineering. We recommend AMS not consider "GMO" or "genetically modified" to be interchangeable with bioengineering because it is perceived to include processes that can occur in nature (e.g. hybrid breeding techniques). FDA has guidance outlining the larger scope of the term "genetically modified" and concludes it is not synonymous.[2] We recommend aligning the interchangeable terms of "bioengineering" with the FDA guidance.

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))

In the National Bioengineered Food Disclosure Standard legislation, the definition of "bioengineering" refers to food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." Highly-refined ingredients that are derived from bioengineered crops, but do not contain genetic material from those crops, are not within the scope of the

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1 U.S. Dept. of Ag., *Proposed Rule Questions Under Consideration* (June 28, 2017), *available at* https://www.ams.usda.gov/rules-regulations/gmo-questions.

2 Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants; Guidance for Industry, 80 Fed. Reg. 73194 (Nov. 24, 2015).

statutory definition of "bioengineered food." Further, a requirement to disclose highly refined ingredients as being derived from bioengineered crops could cause consumers to falsely believe that such ingredients do indeed contain modified genetic material. Therefore, AMS should not consider them "bioengineered food" for purposes of the regulatory framework and should not require disclosure.

8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))

IBA recommends using a disclosure threshold determined by the percentage of total bioengineered ingredients (i.e., those containing genetic material that has been modified through in vitro recombinant DNA technologies) in the product rather than by the proximity of a bioengineered ingredient to the top of the ingredient list. We recommend exempting the disclosure requirement when the cumulative amount of bioengineered ingredients makes up less than 5% of the total ingredients in the product. We also encourage FNS to exclude all processing aids and incidental ingredients from the disclosure requirement.

The 5% threshold and exemption for incidental ingredients and processing aids provides a reasonable, attainable standard for food manufacturers, while still allowing the disclosure scheme to provide clear and useful information to consumers. It eases the burden of a food manufacturer having to account for minute amounts of bioengineered ingredients to a pain-staking degree and throughout the entire supply chain. The 5% cumulative ingredient threshold also aligns with current standards around the world, including Canada's voluntary labeling policy and Japan's mandatory labeling law.

9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))

As specified in the National Bioengineered Food Disclosure Standard legislation, AMS should provide disclosure options that allow food manufacturers to label that a product *does* contain or *may* contain bioengineered food. This will ensure that a company isn't mislabeling or violating the disclosure standard simply because ingredient sources change to and from bioengineered foods based on seasonal availability or price concerns.

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

IBA recommends implementing only one phrase for each category of disclosure, rather than interchangeable options, unless they differ only because of a different allowed interchangeable term for "bioengineering" (see IBA response to question #1). However, in the interest of flexibility and efficiency, IBA would be supportive of AMS allowing current labels to remain for a finite period of time so they can be phased out.

We advise AMS against implementing the Vermont phrase as the text disclosure option, even though some companies currently use it voluntarily. IBA is aware that several parts of the phrase tested the poorest out of many options in consumer research conducted by food manufacturers in recent years, although we do not have access to that study data at this time. In the Vermont phrases, "partially" is unclear because it doesn't specific what part or what ingredient. "Produced" is misleading because it is overly broad and could encompass manufacturing processes like cooking, baking, melting, refining, packaging, etc.

In addition, IBA recommends that the clearest on-pack text disclosure option would include a "per ingredient" designation in the ingredient list (i.e. an asterisk after each ingredient subject to the regulation) along with one explanatory phrase in the information panel. We recommend the phrases "bioengineered ingredient" and "ingredient may be bioengineered."

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))

We recommend the symbol be located on the information panel and not required to be on the front of packaging. We recommend the symbol be consistent with the requirements for color scheme and size of the "USDA Organic" seal within 7 CFR §205.311.

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))

IBA recommends the small package disclosure provisions should align with FDA's definition of small packages for nutrition labeling, meaning those with less than 12 square inches of total surface area which can bear 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))

IBA recommends AMS should allow disclosure on small and very small packages via website address or toll-free telephone number.

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

AMS should define small food manufacturers in a way that aligns with other current USDA policy. We recommend the definition align with the FSIS small business definition of 500 or fewer employees. We recommend tethering the definition of small business to employees rather than sales or production because the latter measurements vary more drastically than employee force from year to year.

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))

IBA recommends AMS use "Call for more food information" as stated in the legislation. AMS should align the language as much as possible with the explanatory language required for the digital link disclosure option.

26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

IBA recommends aligning the record-keeping requirement to those in the current FSIS regulations mentioned in the "context" section for this question, which require no more than a 2-year period for retention.

Additional Recommendations from IBA:

QR Code "Patent Troll" Litigation

IBA is monitoring several active and previous instances of private litigation brought by "patent trolls" relating to the use of QR code technology in the past several years. At least four companies with various patents for the code generation, scanning and transmission software have filed lawsuits against companies ranging from fast food franchises to healthcare labs. The majority of these settle out of court with the plaintiff affording a license to the defendant to use the patent—often without a formal determination of whether or not the patent was actually infringed. Now, some companies who develop and maintain QR code software are offering "patent-troll protection" as part of their services to food manufacturers as they seek to implement the digital link disclosure option. Many of the most affordable servicers, however, do not offer any protections or guarantees of this type with their software packages.

The US Trademark and Patent Office addressed this issue in 2014 with a series of formal and informal actions aimed to tamp down frivolous litigation by narrowing the breadth of claims that can be brought based on software patents and by giving consumers and businesses more tools to defend against baseless claims. In spite of these actions, QR code "patent trolls" continue to target companies that elected to do business with a software company unwilling to assist in would-be litigation defense.

IBA is appreciative that AMS seeks to ensure the disclosure regulation is flexible for small businesses by crafting language that allows for each business to determine the most practical and cost-effective compliance option for itself. We ask that AMS recognize that the threat of baseless, costly patent litigation is a consideration that, while outside the scope of the plain language of the legislation, seriously affects a food manufacturer's considerations when electing a compliance option. We further request that USDA take all actions within its authority to provide effective protection in the form of express release or exemption from liability, joint action with USPTO, administrative guidance, or other channel to food manufacturers choosing to comply with the disclosure requirement via a digital link.