CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

July 3, 2018

VIA ELECTRONIC SUBMISSION

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: National Bioengineered Food Disclosure Standard; Proposed Rule; Request for Comments, 83 Fed. Reg. 19860 (May 4, 2018), Docket No. AMS-TM-17-0050

Herein, the Consumer Healthcare Products Association (CHPA), the 137-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements (chpa.org), provides feedback on the Agricultural Marketing Service (AMS) request for comments on a Proposed Rule to establish the national mandatory bioengineered food disclosure standard. Many of our member companies market dietary supplement products which will potentially be affected by this rule and thus we appreciate the opportunity to comment as the AMS determines the intent and scope of this provision.

Table of Contents

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

1. Applicability

In previous comments submitted to AMS on July 17, 2017, CHPA requested that dietary supplements be excluded from requiring disclosure as bioengineered foods, as they are not defined nor consistently regulated as "foods". In the current Proposed Rule, AMS did not include language exempting dietary supplements, despite using supplements as a potential example in the request for feedback from stakeholders in 2017.[1] Following discussion with our members in the dietary supplement industry CHPA has determined that a majority of members support the exclusion of dietary supplements from the National Bioengineered Food Disclosure Standard (for the reasons outlined below) while a minority of members do not support an exemption.

As per the Food Drug & Cosmetic Act, foods and dietary supplements are defined differently - foods under 21 U.S.C. 321(f) and dietary supplements under 21 U.S.C. 321(ff). Part of the definition of dietary supplements includes that these products are "not represented for use as a conventional food or as a sole item of a meal or the diet". Dietary supplements are also exempt from certain aspects of the Food Safety Modernization Act (FSMA), while foods are not. FDA has exempted dietary supplements from subpart C and G of 21 CFR 117 provided they are in compliance with 21 CFR 111 and adverse event reporting. In addition, the definition of "food" from the Vermont law on foods produced with genetic engineering[2] did not include dietary supplements. FDA also notes the distinction between liquid dietary supplements and beverages in a Guidance document[3], referencing that "the agency does not believe that Congress intended the overlap in composition between dietary supplements and conventional foods to be total."

Lastly, the contribution to the diet of bioengineered ingredients in dietary supplements versus conventional foods is expected to be minimal. We recognize, as noted by AMS in the proposed rule that disclosure of a bioengineered food or food ingredient does not convey any information "…about the health, safety, or environmental attributes of [bioengineered] food compared to non-[bioengineered] counterparts." Should dietary supplements/dietary ingredients be granted an exemption from federal law, we would support incorporation of language into the standard excluding

---

[1] USDA Agriculture and Marketing Service, Proposed Rule Questions Under Consideration June 28, 2017. Question 11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))
Context: AMS is considering if it could exclude certain food types such as medical food and ***dietary supplements***, among others from requiring disclosure as bioengineered. (emphasis added)

[2] Act 120, signed into law on May 8, 2014

[3] FDA Guidance for Industry Distinguishing Liquid Dietary Supplements from Beverages, January 2014

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

both from regulation under state laws, and ask that communication of non-bioengineered claims be allowed on product labels.

2. Definition of "Bioengineering" and "Bioengineered Food"

As proposed by AMS, the Act would define a bioengineered food as one "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". AMS has requested comment on what could be considered to constitute bioengineering and has provided two viewpoints regarding the statutory definition of this term. CHPA believes that products that are highly refined should not fall within the definition of "bioengineering" (Position 1) and thus should be exempt from the disclosure requirements of the standard. This aligns with the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which exempts certain foods from allergen labeling requirements. Under FALCPA, raw agricultural commodities (generally fresh fruits and vegetables) are exempt, as are highly refined oils derived from one of the eight major food allergens and any ingredient derived from such highly refined oil.

SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMATION REGARDING ALLERGENIC SUBSTANCES

``(qq) The term `major food allergen' means any of the following:

1. Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
2. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
   A. Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil. [underlined emphasis added]
   B. A food ingredient that is exempt under paragraph (6) or (7) of section 403(w)."

CHPA suggests that AMS adopt the position that highly refined foods with no remaining residues (proteins) should be excluded from the definition of a bioengineered food.[4] AMS should also outline refining processes and the analytical methods utilized to determine the absence of bioengineered material and set a limit of quantification based on a threshold level that is both reliable and practical for industry to meet.

[4] This is consistent with genetically modified food labeling in Australia and New Zealand (Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology).

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

3. Lists of Bioengineered Foods

AMS has requested comments on the development of specific lists of food that would be subject to disclosure of bioengineered ingredients, proposing a list of commercially available bioengineered foods that have a high adoption (or "the prevalence with which bioengineered cultivars of a food crop are planted or produced in the United States, relative to the number of non-bioengineered cultivars of the same crop in production") rate as well as a list of commercially available bioengineered foods that are not highly adopted. CHPA believes that the development of such lists would be of benefit to industry by providing a clear indication of which foods or products which would be subject to disclosure under the National Bioengineered Food Disclosure Standard. AMS may wish to consider the adoption of a single list of highly adopted bioengineered foods as confusion amongst both consumers and stakeholders (industry) may result from the establishment of both a 'highly adopted' and a 'not highly adopted' list, particularly if there are differing labeling disclosures and thresholds inherent within the two lists. Requiring industry to include the disclosure that a product "may contain a bioengineered ingredient" (from a food on the "Commercially Available BE Foods-Not Highly Adopted" list) would not be expected to be helpful to the average consumer.

AMS has proposed a list of foods to be considered "highly adopted" which would encompass commercially available bioengineered foods that have an adoption rate of eighty-five percent or more and would include canola, field corn, cotton, soybean and sugar beet. CHPA is supportive of the proposed cutoff value of 85%. Bioengineered foods considered to be "not highly adopted" would fall below the 85% threshold and would include apple (non-browning cultivars), sweet corn, papaya, potato, squash (summer varieties).

For the list of bioengineered foods proposed to be considered "highly adopted", we ask that AMS clarify that "[o]nly foods or products on either of those lists or made from foods on either of the lists would be subject to disclosure under the NBFDS." CHPA is supportive of these lists being reviewed and revised on an annual basis; however, we request additional clarity surrounding the timing associated with revision of the proposed lists and ask that AMS consider the complexity of global supply chain efforts when enacting any requirements regarding the timing of updates to the respective lists, in order to allow industry sufficient time to navigate possible formulation changes or updates to product labeling.

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

4. **Factors and Conditions**

a) Incidental Additives

By definition, incidental additives are present in food at an insignificant level and do not have any technical or functional effect.[5] CHPA supports AMS aligning with the applicable FDA regulations regarding disclosure for incidental additives and not adopting these ingredients as being included within the definition of bioengineered foods. Requiring incidental additives to be disclosed under the National Bioengineered Food Disclosure Standard, but not per food labeling regulations (*i.e.* 21 CFR 101.100 Exemptions from Food Labeling Requirements) would create inconsistency that could lead to consumer confusion.

b) Undetectable Recombinant DNA

If AMS were to decide that highly refined ingredients are included within the definition of "bioengineered food", the demonstrated absence of recombinant DNA is proposed as a means of potentially excluding products for which genetic material could not be detected. While CHPA is supportive of not including highly refined ingredients within the definition of bioengineered foods, should AMS decide to include highly refined ingredients within the definition, we would be supportive of allowing industry to demonstrate through recordkeeping that modified genetic material cannot be detected following testing by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines.

5. **Threshold**

AMS is seeking comment on three proposed alternative thresholds used to determine the amount of a bioengineered substance that may be present in food, in order for it to be considered a bioengineered food. CHPA believes that Alternative 1-C is most appropriate for adoption. This proposal would allow industry to use a small amount of bioengineered ingredients up to a certain threshold (*e.g.*, 5% of the total weight of the product) before being required to label a product as containing bioengineered ingredients. Adopting this approach would be consistent with regulations defined under the USDA National Organic Program for multi-ingredient or processed products which must contain at least 95% organic ingredients in order to be called "organic." This percentage is measured by weight (or fluid volume). Thus, up to 5% of the remaining ingredients may be

[5] Incidental additives are exempt from certain labeling requirements under the FDCA (see 21 CFR 101.100(a)(3)

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

nonorganic, but must be approved for use under 7 Code of Federal Regulations (CFR) 205.605[6] and 205.606[7], the National List of Allowed and Prohibited Substances. As with the other proposals in the proposed rule, this would be verified through company recordkeeping.

6. Disclosure

a) Responsibility of Disclosure

AMS is considering establishing recognition agreements with foreign governments that have established labeling standards for bioengineered food. CHPA is supportive of AMS establishing "mutual recognition agreements" with appropriate foreign government agencies that have established labeling standards for bioengineered food. Should AMS decide to adopt mutual recognition agreements with foreign governments, we recommend that this be established through public rulemaking and that these agreements not contradict any US laws and/or regulations.

b) Appearance and Placement of Disclosure

CHPA is supportive of AMS proposing several options for placement of the disclosure, including on the information panel, the principal display panel and on an alternate panel (should there not be sufficient space on the information panel or the principal display panel). CHPA expects that the majority of our members would include the disclosure on the information panel where consumers would be able to easily access the required disclosure information.

c) Disclosure options (text, symbol, electronic/digital link, text message)

CHPA is supportive of the flexibility provided by AMS in the allowable types of disclosure for providing information on the presence of bioengineered food or bioengineered food ingredients.

d) Small/Very Small Packages

CHPA member companies support the use of truncated statements for bioengineered food disclosure for small or very small packages as defined under 21 CFR 101.9(j)(17) and 21 CFR 101.9(j)(13)(B), respectively. The proposed statements for each of the three options – an electronic/digital link disclosure ("Scan for info"); text message ("Text for info"); and phone number

[6] Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
[7] Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

("Call for info") will allow consumers access to information and provide industry with sufficient flexibility to meet the requirements of disclosure.

7. Recordkeeping Requirements

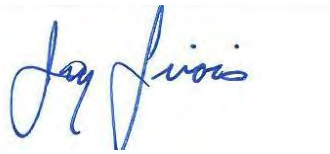
In order to ensure complete understanding of the disclosure requirements under the National Bioengineered Food Disclosure Standard, CHPA requests that AMS clarify that foods that are not on either of the lists[8] currently proposed by AMS would not be subject to the disclosure standard. We understand that the lists will be updated on an annual basis but seek clarification regarding the scope of the initial rulemaking.

Regarding the need for companies to verify the bioengineered status of a product bearing the disclosure 'contains a bioengineered ingredient', CHPA members believe that maintaining a record documenting the presence of such ingredients should be sufficient.

AMS has also requested comment on the proposed timeline for providing records following review during an audit or investigation. CHPA member companies believe that 5 business days is a reasonable amount of time for companies to produce records to AMS on the bioengineered status of a food/food ingredient.

CHPA and our member companies marketing dietary supplement products appreciate the opportunity to comment on this process. Should you have any questions, please do not hesitate to contact me.

Regards,



Jay Sirois, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

[8] 'Commercially Available BE Foods – Highly Adopted' or 'Commercially Available BE Foods – Not Highly Adopted'

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa