CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

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United States Department of Agriculture
Agricultural and Marketing Service

Submitted electronically to GMOlabeling@ams.usda.gov

Re: Comments on National Bioengineered Food Disclosure Standard

Herein, the Consumer Healthcare Products Association (CHPA), the 136-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements (chpa.org), provides comments on several questions from the U.S. Department of Agriculture's Agricultural Marketing Service regarding the establishment of a National Bioengineered Food Disclosure Standard.

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

Comments: CHPA suggests that "genetically modified" or "genetically engineered" be considered synonymous with "bioengineering" as these terms are familiar to consumers. AMS should strive to limit the amount of interchangeable terms as having too many could create consumer confusion.

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))

Comments: The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) 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. CHPA suggests that AMS consider that if highly refined and no residues (proteins) remain, these should be excluded from the definition. AMS should outline refining processes and the analytical methods utilized for these. AMS should also set a limit of quantification based on a threshold level that is both reliable and practical for industry to meet.

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))

Comments: CHPA believes that AMS should establish a reliable and practical threshold for considering whether a food contains bioengineered ingredients.

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

Comments: If dietary supplements are not excluded, we suggest that a threshold be established, below which companies would not have to disclose the presence of very small quantities of bioengineered

ingredients. We feel that the concept of creating multiple disclosure categories could work and suggest that at least one category exist for which label disclosure would not be required. For example, labeling requirements for FALCPA do not apply to major food allergens unintentionally added to a food as the result of cross-contact. A similar approach could be used for dietary ingredients containing genetically engineered material present due to cross contact (*i.e.*, unintentionally added).

10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))

Comments: See response to Question #8. CHPA believes that a threshold value should be established that is both reliably demonstrated and practical for industry to attain.

11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))

Comments: CHPA believes that AMS should exclude dietary supplements excluded from requiring disclosure as bioengineered foods, since dietary supplements are not defined nor consistently regulated as "foods". Per the FD&C Act – foods and supplements are defined differently. Foods are defined under 21 U.S.C. 321(f) and dietary supplements are defined under 21 U.S.C. 321(ff) and part of the definition of dietary supplements are that they can't be represented as a conventional food.

Dietary supplements are also exempt from certain aspects of the Food Safety Modernization Act (FSMA), while foods are not. FDA exempted dietary supplements from subpart C and G of the 21 CFR 117 if 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 does not include dietary supplements.[1] Lastly, the contribution to the diet of bioengineered ingredients in dietary supplements versus conventional foods is minimal.

Should dietary supplements/dietary ingredients be granted an exemption from federal law, we would support incorporation of language into the standard excluding both from regulation under state laws[2] and ask that communication of non-genetically-engineered (non-GMO) claims be allowed on product labels.

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))

Comments: CHPA is supportive of AMS allowing text disclosure to inform consumers of the presence of bioengineered ingredients in food. We support the use of consumer-friendly terms taking into account those demonstrated to be recognizable to the average consumer.[3]

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[1] CONSUMER PROTECTION – LABELING FOODS PRODUCED WITH GENETIC ENGINEERING: "Food" means (1) articles used for food or drink for humans, (2) chewing gum, and (3) articles used for components of any such article. Food does not include dietary supplements, as defined in 21 U.S.C. § 321(ff), or drugs, as defined in 21 U.S.C. § 321(g).

[2] In support of this, a recent comprehensive report by the National Academy of Sciences - Genetically Engineered Crops: Experiences and Prospects - concludes that genetically modified organisms are safe for both humans and animals.

[3] https://www.nongmoproject.org/

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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))

Comments: One possible option for disclosure is a letter display (*e.g.*, a stylized "***BE***"). CHPA suggests that relevant information be placed on the Nutrition Information panel below the mandatory labeling requirements, perhaps near the "Contains" statement). We do not support placement of this information on the Principal Display Panel (PDP) due to size restrictions and the current required inclusion of other pertinent information (*e.g.*, such as statement of identity, Net Quantity of Contents, name, *etc*.).

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))

Comments: AMS should align with FDA regulations in the treatment of very small and small packages for nutrition 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))

Comments: CHPA suggests that allowance of disclosure requirements for small packages be met by providing abbreviated text disclosure (*e.g.*, a stylized "***BE***") or a Web site address.

24. How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))

Comments: CHPA suggests that this information always be placed near FDA required labeling (Supplement Facts/ingredients/allergens).

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

Comments: CHPA suggests that record keeping requirements be aligned with dietary supplement GMP requirements.

27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))

Comments: Random testing of products that do not make any disclosure of genetically engineered ingredients coupled with use of results from Good Manufacturing Practice audits will allow AMS to adequately monitor compliance with the Standard.

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

Comments: CHPA believes that imported products/ingredients should be subject to the same requirements as those manufactured in the U.S.

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We appreciate the opportunity to comment on these questions. Please feel free to contact me should you have any questions.

Regards,

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