FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES
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July 17, 2017

Via Electronic Transmission

USDA-AMS
1400 Independence Ave. SW,
Washington, DC 20250-0268
GMOlabeling@ams.usda.gov

Re: Agricultural Marketing Service Request for Stakeholder Responses to Proposed Rule Questions Under Consideration Related to Implementation of the National Bioengineered Food Disclosure Standard

On behalf of the Flavor and Extract Manufacturers Association of the United States (FEMA), we appreciate the opportunity to submit comments in response to the Agricultural Market Service's (AMS) request for stakeholder comments to proposed rule questions related to the National Bioengineered Food Disclosure Standard.

Introduction

FEMA, founded in 1909, is the Washington, D.C. based national association of the U.S. flavor industry. FEMA's members include flavor manufacturers, flavor users, flavor ingredient suppliers and others interested in assuring the supply of safe flavoring materials. FEMA members manufacture and market more than 95% of all flavors sold in the United States and create flavors for use in a wide variety of food and beverage products. FEMA members also include a number of large-scale food and beverage manufacturers who include flavors in their products.

FEMA has a long history of working with food regulatory authorities, including the AMS. FEMA intends to participate in rulemaking related to AMS's implementation of the National Bioengineered Food Disclosure Standard. We are pleased to provide the following preliminary comments in response to questions the agency has related to implementing the National Bioengineered Food Disclosure Standard which are directly relevant to the flavor industry:

1. General Comments: FEMA suggests that any proposed and final rules implementing the National Bioengineered Food Disclosure Standard be consistent with established regulatory labeling schemes in other jurisdictions (i.e., Europe, Australia) so as not to erect difficult barriers to trade for American food and food ingredient industries.

2. Comments to Questions 4, 8 and 10: FEMA encourages AMS to consider disclosure exemptions for certain food products that contain highly refined products or a certain *de minimis* or adventitious amount of bioengineered material.

3. Comments to Questions 26 and 27: FEMA supports necessary record-keeping and information disclosure to ensure compliance with AMS rules implementing the National Bioengineered Disclosure Standard so long as those requirements are not arbitrary.

4. Comments to Question 9: AMS should further define and explain its intent regarding the establishment of multiple disclosure categories before FEMA can provide substantive comment.

General Comments: AMS final rules implementing the National Bioengineered Food Disclosure Standard must not erect international trade barriers

Any rule promulgated by AMS to implement the National Bioengineered Food Standard should adopt a scheme that would not impinge on global trade. FEMA suggests AMS carefully evaluate how bioengineered food disclosure requirements and related definitions have been established and enforced in other jurisdiction such as the European Union. Any AMS proposed or final rule should adopt a disclosure scheme that does not contradict what currently exists internationally. The European standard contains a distinction between food that is made with, and food that is made from, genetically modified material. AMS should keep this distinction in mind when crafting the regulations to implement the National Bioengineered Food Disclosure Standard.

In order to further our position, FEMA provides the following comments to the relevant AMS Proposed Rule Questions Under Consideration:

Comments to Questions 4, 8 and 10: FEMA encourages AMS to consider disclosure exemptions for certain food products that contain highly refined products or a certain *de minimis* or adventitious amount of bioengineered material

FEMA views questions 4, 8 and 10 together because they contemplate important issues related to limits of detection and the potential establishment of a *de minimis* threshold as an exemption to disclosure. FEMA agrees that AMS should consider both the establishment of a *de minimis* threshold and whether foods containing highly refined products, like highly refined oils, should require disclosure.

AMS should consider a disclosure exemption for foods containing a *de minimis* or adventitious amounts of bioengineered material. The U.S. food supply is increasingly global and complex. As a result, there exists opportunities for food to contain very small or adventitious amounts of genetically modified material. FDA's incidental additive labeling regulations (*see* 21 CFR 101.100(a)(3) and 101.22(h)(2)) provide good examples of common-sense regulations that appropriately exempt from labeling food ingredients present in food at such insignificant levels such that they do not have any technical or functional effect in the food. There are multiple examples of existing GM regulations around the world that recognize a reasonable *de minimis* threshold below which does not trigger disclosure. AMS should consider both FDA's incidental additive exemptions as well as other GM regulatory paradigms to help inform its construction of a *de minimis* threshold.

In the case of highly refined ingredients, such as highly refined oils, these ingredients contain undetectable levels of bioengineered material and therefore should not be subject to disclosure. The National Bioengineered Food Disclosure Standard amends the Agricultural Marketing Act of 1946 (7 U.S.C. 1621) and contemplates label disclosures only for food that meets the definition of "bioengineering." The statute explicitly states that a food is bioengineered only if it "contain(s) genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA techniques)." (7 U.S.C. 1621, §291). Therefore, food that contains ingredients like highly refined oils that do not or no longer contain genetically modified material would be exempt from labeling disclosure under the plain language of the statute. AMS should consider promulgating regulations that do not trigger disclosure for foods containing highly refined ingredients, such as highly refined oils, since these ingredients do not contain genetically modified material.

Comments to Questions 26 and 27: FEMA supports necessary record-keeping and information disclosure to ensure compliance with AMS rules implementing the National Bioengineered Food Disclosure Standard so long as those requirements are not arbitrary

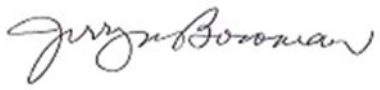
FEMA would support record keeping requirements that are no more onerous than current FSIS or NOP/AMS requirements. Any information necessary for verification of compliance must be limited and protective of confidential business information and must not be arbitrary.

Comments to Question 9: AMS should further define and explain its intent regarding the establishment of multiple disclosure categories before FEMA can provide substantive comment.

FEMA requests that AMS provide more details about what disclosure categories the agency contemplates and its rationale for differentiating between products that themselves are bioengineered and those that contain bioengineered ingredients before FEMA can provide further substantive comment. FEMA also requests that AMS explain how the agency will educate consumers about the distinctions between any proposed disclosure categories.

FEMA hopes that the direction and information provided for the AMS questions will help educate and encourage AMS regarding the international implications of a U.S. GM standard and the importance of harmonization. FEMA will have additional comments after the release of the Proposed Notice of Rule Making is released.

Sincerely,



Jerry Bowman
FEMA Executive Director