VIA USPS and Electronic Mail

December 5, 2013

Elizabeth H. Dickinson, Esq.
Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 31, Room 4536
Silver Spring, MD 20993

Re: "Natural" Labeling for Foods Containing Ingredients Derived from Biotechnology

Dear Ms. Dickinson:

I am writing on behalf of the Grocery Manufacturers Association (GMA) regarding the recent referrals by a number of United States District Courts to the Food and Drug Administration (FDA) for a determination of whether foods containing ingredients derived from biotechnology may be labeled "natural."[1] GMA believes that FDA should actively address this question through the rulemaking process: The agency has the authority and expertise to make this determination; federal regulation will bring uniformity and consistency to both consumers and food manufacturers; and our request is narrowly focused and consistent with longstanding agency policy. Accordingly, we want to alert you that GMA will be filing a Citizen Petition early in 2014 that asks FDA to issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled "natural."

Background

The GMA is the voice of more than 300 leading food, beverage, and consumer product companies around the world. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle.

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[1] *See, In re General Mills, Inc. Kix Cereal Litigation*, No. 12-249 (KM) (D. N.J. Nov. 1, 2013); *Barnes v. Campbell Soup Co.*, No. 12-cv-05185-JSW (N.D. Cal. July 25, 2013); *Cox v. Gruma Corp.*, 2013 U.S. Dist. LEXIS 97207 (N.D. Cal. July 11, 2013).

GMA's members have a strong interest in "natural" labeling for foods containing ingredients derived from biotechnology. Several of the most common ingredients derived from biotechnology are from crops such as soy, corn, canola, and sugar beets. There are 26 state legislatures considering whether foods containing ingredients derived from biotechnology should be labeled and whether they are permissible in "natural" foods. Moreover, there are approximately 65 class action lawsuits that have been filed against food manufacturers over whether foods with ingredients allegedly derived from biotechnology can be labeled "natural." Given the predominant use of crops derived from biotechnology in our economy as well as consumer and state interest in this issue, whether foods that contain ingredients derived from biotechnology can be labeled "natural" is an important matter to GMA members and is one that warrants FDA's involvement.

FDA Has the Authority and Expertise to Resolve This Matter

FDA is the agency with primary jurisdiction over whether foods that contain ingredients derived from biotechnology may be labeled "natural." The Federal Food, Drug and Cosmetic Act provides FDA with the statutory mandate to regulate food labeling claims, including the term "natural."[2] Further, the agency has the statutory authority to oversee foods derived from biotechnology – both their safety and labeling.[3] Indeed, foods and ingredients derived from biotechnology must meet the same safety and labeling requirements as foods and ingredients from traditionally bred crops.[4]

Furthermore, FDA has considerable experience and expertise with both foods derived from biotechnology and "natural" claims. FDA's Biotechnology Evaluation Team consults with developers of genetically engineered plants to ensure that new foods are safe and lawful.[5] In the past 20 years, FDA has completed nearly 100 such consultations.[6] The agency has published a Statement of Policy regarding foods derived from new plant varieties, including genetically engineered plants.[7] FDA also has issued draft guidance on voluntary labeling to indicate whether a food was derived from biotechnology.[8] Prior to issuing the draft guidance, FDA solicited public comment and held several public

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2 Federal Food, Drug and Cosmetic Act, § 403; 21 U.S.C. § 343.

3 FDA regulates food/crops derived from biotechnology in conjunction with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA).

4 Food and Drug Administration, Foods Derived from Genetically Engineered Plants (Apr. 8, 2013), http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm346858.htm.

5 Food and Drug Administration, Questions and Answers on Food from Genetically Engineered Plants (Last updated Apr. 7, 2013), http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm346030.htm.

6 *Id.*

7 Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992).

8 Food and Drug Administration, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance (Jan. 2001), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

meetings regarding the issue.[9] As such, FDA has substantial experience with foods derived from biotechnology and its scientists are highly knowledgeable in genetic engineering, toxicology, chemistry, nutrition, and other scientific areas needed to evaluate their safety and appropriate labeling.

With respect to "natural" claims, the agency has considered the meaning of the term, and whether a regulatory definition is appropriate, several times in the past 35 years. In the early 1990s, FDA declined to establish a regulatory definition but explained its "natural" claims policy.[10] As such, the agency has more than 20 years' experience applying this policy. FDA continues to enforce this policy by issuing Warning Letters to manufacturers whose products bear a "natural" or "all natural" claim and contain alleged artificial or synthetic ingredients, such as preservatives or flavors.[11] This significant experience considering the meaning of "natural" and its use in different contexts gives FDA the unique expertise needed to regulate use of the term on foods with ingredients developed from biotechnology.

Federal Regulation is Needed for Consistency and Uniformity

FDA's involvement in this issue is needed to ensure consistent and uniform rules for foods with "natural" claims and ingredients derived from biotechnology. Despite the agency's existing guidance, the nation's courts have been inundated with cases in which claims have been made concerning "natural" labeling and ingredients derived from biotechnology. Indeed, approximately 65 such class actions have been filed against food and beverage manufacturers. The issue may arise in many more cases. At the same

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[9] Food for human consumption: Food labeling- Foods derived from new plant varieties; policy statement, 58 Fed. Reg. 25837 (Apr. 28, 1993); Meetings: Biotechnology in Year 2000 and Beyond, 64 Fed. Reg. 57370 (Oct. 25, 1999).

[10] Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60466 (Nov. 27, 1991); Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms, Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

[11] *See, e.g.*, Letter from Roberta Wagner, Director, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, to John Stanger, Technical Manager, Waterwheel Premium Foods Pty Limited (July 26, 2013); Letter from Anne E. Johnson, Philadelphia DCalvin67istrict Acting Director, Food and Drug Administration, to Matthew A. Pivnick, President, Key Ingredient Market (June 17, 2013); Letter from Michael W. Roosevelt, Acting Director, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, to Alex Dzieduszycki, CEO/President, Alexia Foods, Inc. (Nov. 16, 2011); Letter from Alonza Cruse, Los Angeles District Director, Food and Drug Administration, to Garo Kurkjian, President, Lebanese Arak Corp. (Sept. 22, 2011); Letter from Gerald J. Berg, Minneapolis District Director, Food and Drug Administration, to Barry L. Berman, President/Owner, Bagels Forever, Inc. (July 22, 2011); Letter from Alonza Cruse, Los Angeles District Director, Food and Drug Administration, to Cyrus Teadolmanesh, President, Shemshad Food Products, Inc. (Mar. 11, 2011).

time, legislatures in 26 states have been considering whether ingredients derived from biotechnology should be labeled and whether they belong in "natural" foods.[12]

These forces are converging to create a patchwork of "state-by-state" laws that are not only inconsistent with each other, but are directly at odds with FDA's stated policy on the labeling of foods derived from biotechnology. GMA is concerned that differing state laws and judicial decisions will inevitably confuse consumers and impose unnecessary costs on the food industry.

In almost all areas of food labeling, Congress has concluded that a national, uniform framework is required.[13] Consumers and the food industry would all benefit from uniform legal requirements and the consistent outcomes that result from federal regulations, rather than state-by-state dictates through court decisions or state or local legislation. As such, federal rulemaking is needed here so that the issue of whether foods that contain ingredients derived from biotechnology can be labeled "natural" is removed from judicial or state interpretation and is resolved by the federal agency with the necessary expertise in foods derived from biotechnology and comprehensive legal authority over food labeling.

Our Request is Narrowly Focused and Consistent with Longstanding Agency Policy

GMA believes our request is narrowly focused and consistent with longstanding agency policy. As such, its resolution should be feasible within the agency's priorities and limited resources. We are certainly aware that FDA has previously declined to make an administrative determination on the meaning of "natural"[14] and that in previous rulemaking proceedings the agency has remarked that developing standards regarding the use of "natural" would be "difficult."[15] However, the present issue is significantly more narrow and straightforward. GMA does not intend in our Citizen Petition to ask the agency to define "natural" for all types of food products. Instead, GMA intends to file a Citizen Petition solely directed at asking FDA to issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled "natural."

This issue is technically precise, requires FDA's expertise, and can be resolved based on a review of the agency's existing guidance and precedent. Indeed, FDA has long held to a consistent position that foods derived from biotechnology are not materially different from their traditional counterparts. As FDA explained in its 1992 Statement of Policy: "FDA believes that the new techniques ["genetic engineering"] are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding. The agency is not aware of any information

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12 One such state law (Connecticut) has passed, and its effective date is contingent on similar laws being enacted in a certain number of states within specified geographical and population parameters.

13 Federal Food, Drug and Cosmetic Act §403A(a); 21 U.S.C. § 343-1(a).

14 Letter from Michael Landa, Acting Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, to the Honorable Jerome Simandle, U.S. District Judge (Sept. 16, 2010) (declining to provide an administrative determination of whether high fructose corn syrup qualifies as a "natural" ingredient).

15 56 Fed. Reg. at 60467.

showing that foods derived by these new methods differ from other foods in any meaningful or uniform way . . . ."[16] Accordingly, because there is no material difference between foods derived from biotechnology and their traditional counterparts — and they do not differ in "any meaningful . . . way" -- foods derived from biotechnology may be labeled as "natural" if that term would be suitable for their traditional counterparts. There is nothing "synthetic or artificial" about foods derived from biotechnology, as that term has been applied by the agency.[17]

GMA is mindful of FDA's acute resource issues and is well aware that the agency must prioritize its work carefully. The issue here, however, is an important one – to the food industry, consumers, and the states. It also is very specific, and straightforward: whether foods containing ingredients derived from biotechnology may be labeled "natural." We hope that by submitting a Citizen Petition that contains proposed regulatory language and the factual and legal basis for our request, we can assist the agency in commencing the rulemaking process. Our members and staff are ready to work with FDA so that clear and final regulations are issued.

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[16] 57 Fed. Reg. at 22991. FDA confirmed its position in the Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering stating "The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act." Food and Drug Administration, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (Jan. 2001), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

[17] 58 Fed. Reg. at 2407. FDA has explained that it considers "natural" to mean "that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." Moreover, FDA previously has advised that high fructose corn syrup is considered "natural" under the agency's policy when manufactured following a specific procedure. While FDA did not specifically address whether the "natural" claim is appropriate on corn that is derived from biotechnology, FDA surely must have realized that the overwhelming majority of corn in the United States is derived from biotechnology. Had the agency considered the manner in which the corn is derived a material fact in its natural analysis, the agency would likely have addressed it. Letter from Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA to Audrae Erickson, President, Corn Refiners Association, July 3, 2008, http://www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7-08.pdf

Thank you for your consideration. Please do not hesitate to contact me if you have any questions, or if GMA can provide any additional information to the agency.

Sincerely,

Karin F.R. Moore
Vice President & General Counsel

Cc: Michael Landa, Director, Center for Food Safety and Applied Nutrition