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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION:
"NATURAL" STATEMENTS ON FOODS DERIVED FROM BIOTECHNOLOGY

The Grocery Manufacturers Association (GMA) submits this petition under 5 U.S.C. §553(e); 21 C.F.R. §§ 10.25 and 10.30; and, Sections 401, 403(a), 403(i), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to request the Commissioner of Food and Drugs to issue a regulation authorizing statements such as "natural" on foods that are or contain foods derived from biotechnology.

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.

For over 20 years, the Food and Drug Administration (FDA) has not wavered in its position that foods derived from biotechnology, as a class, are just as safe as their traditionally bred counterparts.[1] Furthermore, FDA has consistently recognized that biotechnology does not change the essential nature of a food. FDA also has consistently maintained that the method of plant breeding for a food, whether using a conventional technique (such as hybridization or chemical or radiation induced mutagenesis) or genetic engineering, is not material information for the purposes of labeling or advertising a food. Corn is corn regardless of the plant breeding technique.

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[1] The safety of foods derived from biotechnology is both well established and not relevant to the action requested here. Furthermore, the consultation process ensures that foods derived from biotechnology are as safe as their conventionally bred counterparts.

Based on FDA's own in depth analysis and findings concerning plants derived from biotechnology, it follows that a statement of "natural" or a similar statement would be neither false nor misleading on a food derived from such technology solely because of its heritage. Accordingly, GMA respectfully requests that FDA issue a regulation clarifying that statements such as "natural" may appear on a food if it is or contains a food derived from biotechnology. The regulation requested through this petition is a logical step for FDA to take to reinforce its longstanding position that there is no material difference between foods derived from biotechnology and their traditionally bred counterparts. Indeed, such a regulation would be fully consistent with the agency's clear, concise, and well-supported views about these foods.

As FDA is well aware, despite the agency's existing guidance, the nation's courts are considering numerous cases in which claims have been made concerning "natural" labeling and foods derived from biotechnology. At the same time, some state legislatures have passed legislation addressing this issue and several others are considering doing so. These forces could create a patchwork of rules that could not only be inconsistent with each other, but would be directly at odds with FDA's science-based policies on foods derived from biotechnology and the labeling of such foods. GMA is concerned that differing state laws and judicial decisions will inevitably confuse consumers, disrupt the free flow of goods in interstate commerce, and impose unnecessary costs on the food industry and, potentially, consumers.

Moreover, this is a complex scientific issue that deals with molecular biology, chemistry, and nutrition science. FDA has extensively developed agency expertise and agency resources that put it in the best position to address "natural" labeling for foods derived from biotechnology. The lack of an express regulation addressing this issue has led other interested parties to take it away from the one agency that has the scientific expertise and authority to resolve it. It's important for FDA to affirm that because the method of plant breeding (whether conventional or new) is not material information, it is irrelevant in a "natural" analysis.

Consumer interest in foods that are "natural" has increased in recent years. A whole category of "natural" foods has emerged and is growing rapidly. More and more, consumers are seeking foods that are made without synthetic ingredients or artificial preservatives. Given the widespread interest in such products, it is important for FDA to address this issue in a deliberate and thoughtful way and to do so in an open and transparent process that can ensure a voice to all interested stakeholders, while at the same time helping to educate the general public about biotechnology. The federal rulemaking process is the forum in which to do this: it ensures public participation and results in national, uniform standards. Consumers and the food industry would all benefit from uniform legal requirements and the consistent outcomes that result from federal regulations with preemptive effect.

Additionally, FDA's clarification that "natural" foods can contain ingredients derived from biotechnology can help ensure that consumers have a clear choice when they shop for foods and will continue to have access to affordable products that do not contain artificial or synthetic ingredients. Indeed, FDA's involvement in this issue is needed to ensure that the "natural" category of foods remains a distinct and vibrant category for those consumers who choose to avoid products with artificial or synthetic ingredients, but, for cost or other reasons, do not want to purchase "organic" foods. FDA can help the food industry meet consumer demand for "natural" foods by creating a national, uniform regulation that assures consumers that FDA has spoken on this issue.

While FDA has said repeatedly that it does not have the time or resources to undertake a comprehensive definition of "natural," FDA can and should take the narrower step to clarify that whether

a food has been derived through biotechnology is immaterial in a "natural" analysis. Whether foods derived from biotechnology can be labeled as "natural" is an important issue to consumers and the food industry and is one that warrants FDA immediate and direct involvement.

I. ACTION REQUESTED

GMA requests that FDA issue a regulation, consistent with FDA's longstanding views in this area, that it is neither false nor misleading to label a food as "natural" or similar terms solely because the food is or contains a food derived from biotechnology:

> 21 C.F.R. 102.58: Use of Natural on Foods Derived from Biotechnology.
> The term(s) "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" may accompany the common or usual name of a food or appear elsewhere on the label or in labeling. The food shall not be deemed to be misbranded solely because the food is or contains a food derived from biotechnology.
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> 21 C.F.R. 130.3(f): The term(s) "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" may accompany the name of a standardized food or appear elsewhere on the label or in labeling of the food. The food shall not be deemed to be misbranded solely because the food is or contains a food derived from biotechnology. [2]

II. STATEMENT OF GROUNDS

A. Executive Summary

As documented in detail below, the action requested through this petition is the next logical step for FDA to take to make its position explicit and ensure the regulations are consistent with the agency's clear, concise and well-supported view about foods derived from biotechnology. FDA has stated that:

- Foods developed from biotechnology do not differ from their traditional counterparts "in any meaningful or uniform way."
- New techniques involving biotechnology are simply "extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding."
- Biotechnology does "not change the essential nature of the plant."
- Foods derived from biotechnology do not, "as a class, exhibit attributes different from foods derived by other methods of plant breeding."
- The fact that a food has been developed from biotechnology "does not, in and of itself, mean there is a material difference in the food."

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[2] Alternatively, because a "natural" claim analysis is dependent on the ingredients in a product, it would be appropriate to amend the ingredient regulations as follows: 21 C.F.R. 101.4(i): A food bearing a claim that its ingredient or ingredients are "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" shall not be deemed misbranded solely because the ingredient or ingredients are derived from biotechnology.

These statements by FDA are longstanding, consistent and compelling. According to the agency's own conclusions, foods derived from biotechnology do not differ in any meaningful way from other foods. That is why FDA has repeatedly found it is not a "material fact" that a food was derived from biotechnology and why the same labeling requirements that apply to traditionally bred foods apply to foods derived from biotechnology.

FDA's equally longstanding "natural" policy focuses on the nature of the ingredients added to the food—whether anything artificial or synthetic or any color has been added to the product that would not normally be expected. In other words, whether a food is appropriately labeled "natural" depends on the attributes or objective characteristics of the food itself. The development of the plant from which a food is derived is not, however, an objective characteristic of the food itself. Simply put, because FDA has previously explained in depth that genetic engineering does not change the essential nature of the plant, plants derived from genetic engineering and plants derived from other breeding methods have the same objective attributes. Therefore, if a "natural" claim is appropriate for its traditional counterpart, it is equally appropriate for a food derived from biotechnology.

Moreover, FDA's natural policy focuses exclusively on the ingredients added to a food. Because the genes added to plants are not ingredients, they are outside the scope of the analysis conducted to determine whether a food may appropriately be labeled "natural." Also, foods produced from plants derived from biotechnology are neither artificial nor synthetic. Accordingly, it would be completely consistent with FDA's longstanding policies on foods derived from biotechnology and on "natural" claims to promulgate a regulation stating that a "natural" claim is not precluded solely by virtue of the food or its ingredient(s) having been derived from biotechnology. We petition FDA to do so.

Specifically, GMA petitions FDA to amend the common or usual name for nonstandardized foods regulations and the general regulations for standardized foods to allow "natural" and similar terms to accompany the name of a food or appear elsewhere on the label or in labeling and to state that the food shall not be deemed to be misbranded solely because the food is or contains a food derived from biotechnology. An amendment to the common or usual name for nonstandardized foods regulations and the general regulations for standardized foods will bring much needed uniformity and consistency to this issue by expressly preempting non-identical state and local requirements.

We believe FDA should address "natural" statements for foods derived from biotechnology through the rulemaking process and that it is in the public interest to do so. First, the agency has the authority and expertise to make this determination. Second, the rulemaking process has considerable benefits for the public and the agency. It allows for transparency and public participation. Third, a federal regulation is needed to preserve the "natural" category for consumers and ensure they have access to affordable foods made without artificial or synthetic ingredients. Finally, despite the agency's existing priorities and limited resources, we believe a narrowly focused rulemaking is possible and consistent with longstanding agency policy. We discuss all of these topics in greater detail below.

B. Legal and Factual Basis for the Proposed Regulation

1. FDA Has Repeatedly Found that Foods Derived from Biotechnology Do Not Differ from Other Foods

In 1992, FDA issued a detailed policy statement (still in place today) regarding new plant varieties created by bioengineering.[3] Significantly, FDA explained that a food's regulatory status "is dependent upon objective characteristics of the food and the intended use of the food (and its components)."[4] Although the method used to develop the food may shed light on its safety or nutrient characteristics, the important issue is the characteristics of the food.[5] It is the food, not the process, which matters. As a general matter, FDA concluded that it has no reason to believe "that foods derived by [biotechnology] differ from other foods in any meaningful or uniform way, or that, as a class, foods developed [by biotechnology] present any different or greater safety concerns than foods developed by traditional plant breeding."[6]

One year later, FDA requested data and information concerning the labeling of foods derived from biotechnology.[7] There, FDA provided a helpful overview of biotechnology, which FDA described "involves the presence in a plant chromosome of deoxyribonucleic acid (DNA) that was originally derived from an animal or microorganism but is now an inherent constituent of a plant."[8] FDA explained:

> When using recombinant DNA techniques, scientists do not infuse the plant with the original genes that were removed from the animal. The animal genes are used to produce copies in the laboratory. Once the copies are transferred to the plant, they become an integral part of its genetic information, just like thousands of other genes that are present in the plant chromosome. There is a scientific basis to conclude that such genetic alterations do not change the essential nature of the plant . . . .[9]

Significantly, FDA noted that "plant breeding methods are applied in the earliest stages of development of new plant varieties and are not processes applied to the finished food."[10] Thus, FDA reiterated its position that when genetic engineering is used to develop new plant varieties, it does not "result in foods which, as a class, exhibit attributes different from foods derived by other methods of plant breeding."[11]

FDA repeated its position again in 2001 when issuing a draft guidance document explaining how foods may be labeled regarding the presence or absence of genetic modification.[12] FDA restated it "has no

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

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] Food Labeling; Foods Derived from New Plant Varieties, 58 Fed. Reg. 25837 (Apr. 28, 1993).

[8] *Id.* at 25839.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] 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 [hereinafter *Draft Guidance*]. The draft guidance emphasizes that FDA "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

basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[13] Further, FDA noted it "has concluded that the use of or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food."[14]

FDA has echoed this basic conclusion in other forums. For example, in the agency's FDA Consumer Magazine, FDA Commissioner Jane Henney confirmed the agency's position stating "[i]t is important to know that bioengineering does not make a food inherently different from conventionally produced food."[15] Commissioner Henney also repeated that the agency is "not aware of any information that foods developed through genetic engineering differ as a class in quality, safety or any other attribute from foods developed through conventional means."[16] Finally, FDA's oversight of the use and marketing of foods produced from plants derived from biotechnology confirms that, as a class, these foods are not different from ingredients derived from traditionally bred plants in any way.[17] In sum, FDA has consistently taken the position that foods from plants derived from biotechnology are not categorically different from foods from traditionally bred plants.

2. Foods Derived from Biotechnology are Consistent with the Agency's Policy on "Natural" Claims

a. FDA's Natural Policy

GMA recognizes FDA's concerns that creating a comprehensive definition of the word "natural" in a regulation would be time consuming and use limited agency resources. Certainly, FDA has considered previously whether to define the term by regulation, and each time has declined to do so. Nonetheless, GMA is not proposing in this Citizen Petition that FDA comprehensively define the term "natural" in a

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ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act." *Id.* at 2.

13 *Id.* at 1.

14 *Id.* at 3.

15 Larry Thompson, *Are Bioengineered Foods Safe?*, FDA Consumer Magazine (Feb. 2000).

16 *Id.*

17 If a bioengineered food is sufficiently different from its conventionally bred counterpart—if, for example, there are nutritional changes or it causes allergies—it must be labeled to indicate that difference. For instance, when genetic modifications in varieties of soybeans changed the fatty acid composition of those plants, FDA agreed with the developer that "high oleic soybean oil" was the proper common or usual name for the food in order to distinguish it from traditional soybean oil. Letter from Mitchell Cheeseman, Acting Director, Office of Additive Safety, Food and Drug Administration to Dr. Cherian George, Regulatory Affairs Manager, Monsanto Company (Jan. 20, 2011) (regarding BNF No. 121). In contrast, FDA explained that the correct common or usual name for the FLAVR SAVR tomato is "tomato" because the genetically engineered variety is not significantly different from the range of commercial varieties referred to as "tomato." Food and Drug Administration, Agency Summary Memorandum Re: Consultation with Calgene, Inc. Concerning FLAVR SAVR Tomatoes (May 17, 1994) *available at*: http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm225043.htm (last visited Feb. 27, 2014). FDA also determined there are no safety or usage concerns to which consumers of FLAVR SAVR tomatoes need to be alerted by special labeling. *Id.*

regulation. Instead, GMA's proposal in this Citizen Petition is limited to a regulation authorizing use of the term "natural" on foods that are derived from biotechnology. As explained further below, this is consistent with FDA's longstanding policy on "natural" claims.

In June 1978, FDA, along with the Federal Trade Commission (FTC) and the U.S. Department of Agriculture (USDA), announced a series of public hearings to discuss several issues related to food labeling and advertising.[18] In 1979, the agencies issued "Tentative Positions" on the various issues. With respect to natural claims, FDA stated that the agency "does not attempt to restrict such claims because it believes that the development and enforcement of standards in this area would be difficult . . . ."[19]

Again in the early 1990s, when the agency conducted rulemaking to implement the Nutrition Labeling and Education Act, FDA considered defining "natural." In the 1991 proposed rule regarding nutrient content claims, FDA explained its longstanding "natural" policy: "In the past, FDA has not attempted to restrict use of the term 'natural' except for added color, synthetic substances, and flavors under § 101.22."[20] The agency further elaborated that it considers "'natural' to mean that nothing artificial or synthetic (including colors regardless of source) is included in or has been added to the product that would not normally be expected to be there."[21] FDA solicited comments on several issues related to "natural" claims, but acknowledged that "[b]ecause of the multiple and diverse meanings currently in use, establishing a definition for the term 'natural' that will be readily accepted and understood will be difficult."[22]

Although FDA received comments in response to its proposal, "none of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the word 'natural.'"[23] Thus, the agency chose to continue its policy of prohibiting artificial or synthetic substances in "natural" foods. Specially, FDA explained "natural" means "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."[24] FDA has consistently maintained and implemented this policy now for more than 20 years. For example, FDA has issued a multitude of warning letters to manufacturers whose products bear a "natural" or "all natural" claim and contain alleged artificial and synthetic ingredients, such as preservatives or flavors.[25]

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18 Food Labeling; Hearings, 43 Fed. Reg. 25296, 25296 (June 9, 1978).

19 Food Labeling; Tentative Positions of Agencies, 44 Fed. Reg. 75990, 76012 (Dec. 21, 1979).

20 Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60466 (Nov. 27, 1991).

21 *Id.*

22 *Id.* at 60467.

23 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).

24 *Id.*

25 *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 District Acting Director, Food and Drug Administration, to Matthew A. Pivnick, President, Key Ingredient Market (June 17, 2013); 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

In sum, FDA's natural policy focuses on two things: (1) what has been added to the food; and (2) whether those ingredients are artificial or synthetic. With respect to the first element, the natural policy focuses on ingredients in the food, not the process used to manufacture or otherwise develop the food. And with respect to the second element, FDA's sole focus has been on artificial or synthetic ingredients (or any color additives) that have been added to the finished food. FDA has generally interpreted "artificial or synthetic" to mean "chemical" ingredients. For example, FDA has issued Warning Letters to food manufacturers using chemical preservatives in foods labeled "natural,"[26] but does not consider common salt or vinegars to be "chemical preservatives."[27]

Moreover, despite the large number of "natural" claims on food products with ingredients that may be derived from biotechnology, we are not aware of a single instance in which FDA has issued a Warning Letter objecting to the use of a "natural" claim on a finished food solely by virtue of the food or one of its ingredients allegedly having been developed through biotechnology.[28] The "natural" policy—both in the way FDA articulated it over 20 years ago and in the manner that the agency has consistently applied it since then—has never contemplated that the breeding method used to produce the plant from which a food may be derived would have any bearing whatsoever on whether that food was "natural."

b. FDA's Natural Policy and Foods Derived from Biotechnology

Under Section 403(a)(1) of the FFDCA, a food is misbranded if its labeling is false or misleading in any particular.[29] Section 201(n) of the Act further defines misleading labeling. This section explains that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested, or with respect to consequences that may result from use of the food.[30] FDA has generally considered the scope of the materiality concept in Section 201 of the Act to be limited to information about the attributes of the food itself, not how it was produced.[31] Thus, "there must be something tangibly different about the food product – not the process by which it's made – for FDA to require labeling."[32]

Accordingly, the method of plant breeding used to develop foods and ingredients derived from those foods does not determine whether the finished food is "natural." The development of the plant from which a food is derived is not an objective characteristic of the finished food itself. As FDA has stated,

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Drug Administration, to Cyrus Teadolmanesh, President, Shemshad Food Products, Inc. (Mar. 11, 2011).

[26] *See, e.g.,* 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).

[27] 21 C.F.R. § 101.22(a)(5).

[28] We recognize that FDA inaction does not authoritatively establish the agency's policy position on any given issue. Nevertheless, it is noteworthy that FDA has had ample opportunity to challenge "natural" claims on products derived from biotechnology and has declined to do so.

[29] 21 U.S. C. § 343(a)(1).

[30] 21 U.S.C. § 321(n).

[31] 58 Fed. Reg. at 25838.

[32] Linda Bren, *How the FDA is Working to Meet the Challenges of Regulating Genetically Engineered Foods*, FDA Consumer Magazine (Nov. 2003).

"plant breeding methods are applied in the earliest stages of development of new plant varieties and are not processes applied to the finished food."[33] Stated another way, "genetic engineering is a technique used to produce, not process, a food."[34]

Moreover, how a plant was developed does not change its essential nature—it does not affect the objective attributes of the food derived from that plant. As FDA has previously explained, once the gene copies "are transferred to the plant, they become an integral part of its genetic information, just like thousands of other genes that are present in the plant chromosome. There is a scientific basis to conclude that such genetic alterations do not change the essential nature of the plant . . . ."[35] Because plants derived from biotechnology and plants derived from other breeding methods have the same objective attributes, foods derived from biotechnology may be labeled "natural" if that term would be suitable for their traditionally bred counterparts.

In addition, FDA has made clear that changes made through plant breeding are not treated as added ingredients to the plant or food derived from that plant.[36] More specifically,

> FDA does not consider those substances that are inherent components of a food to be ingredients . . . . A genetic substance introduced into a plant by breeding becomes an inherent part of the plant as well as all foods derived from the plant. Consistent with the agency's general approach on ingredient labeling, the agency has not treated as an ingredient a new constituent of a plant introduced by breeding, regardless of the method used to develop the variety.[37]

As an example, "most commercially produced tomatoes have introduced genetic traits derived from related weedy species, which traits are designed to combat fungal disease."[38] But tomatoes are not multi-ingredient foods. They are not fabricated from two or more ingredients, nor must they bear a label with the common or usual name of each ingredient. Because the genes added to plants are not ingredients, they are outside the scope of the analysis conducted to determine whether a food may appropriately be labeled "natural."

Furthermore, foods produced from plants derived from biotechnology are neither artificial nor synthetic. A plant that has had its genetic information altered remains a biological organism. It is no more artificial or synthetic than a plant which has had its genetic information altered by traditional breeding methods. An artificial or synthetic ingredient can be produced through a forced chemical reaction and is frequently derived from chemical sources rather than from a plant, animal, or other living organism. Foods derived from biotechnology have a natural origin. A FLAVR SAVR tomato is a natural tomato just like other

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33 58 Fed. Reg. at 25839.

34 Letter from Jeffrey Shuren, Assistant Commissioner for Policy, Food and Drug Administration, to Andrew Kimbrell, Executive Director, Center for Food Safety (Aug. 25, 2003).

35 58 Fed. Reg. at 25839.

36 58 Fed. Reg. at 25840 ("FDA has not previously considered new constituents of plants introduced via breeding to be ingredients.").

37 Food and Drug Administration, Agency Summary Memorandum Re: Consultation with Calgene, Inc. Concerning FLAVR SAVR Tomatoes (May 17, 1994) *available at*: http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm225043.htm (last visited Feb. 27, 2014).

38 58 Fed. Reg. at 25840.

tomatoes bred to combat fungal disease. Corn oil produced from corn derived from biotechnology is no more artificial or synthetic than corn oil produced from conventionally-bred corn.

Those who believe that foods derived from biotechnology should be precluded from bearing a "natural" claim assert that genetically engineered plants have been altered in a way that does not occur naturally, and, therefore, foods derived from such plants cannot be "natural."[39] Yet, these same advocates fail to consider that traditional breeding methods also may alter plants in ways that do not occur naturally. These techniques introduce new gene traits that the plant did not originally have. Traditional plant breeding also involves intentional mutagenesis and the use of irradiation to alter the plant's genetic material—processes that also require human intervention and do not occur readily in nature.[40] FDA has made clear that biotechnology simply is an "extension at the molecular level of traditional methods."[41] Thus, if the advocates have no objection to labeling foods that have been altered through traditional breeding methods as "natural," it would be inconsistent for them to oppose such labeling for foods derived from biotechnology.

Finally, we note that because FDA has found there is no material difference between foods derived from biotechnology and their traditional counterparts, there is no need to reach the issue of consumer perception.[42] As one district court has stated, "the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose material fact."[43] Again, FDA does not consider the methods used in the development of foods derived from biotechnology to be material information within the meaning of Section 201(n) of the FFDCA.[44] Therefore, as a general matter, FDA cannot require foods derived from biotechnology to be labeled differently than their traditional counterparts solely because of the method used to produce the plant from which the food is derived. By extension, to prohibit foods derived from biotechnology from bearing a "natural" claim but to allow such a claim for a traditionally bred counterpart (as class action plaintiffs, state legislators, and others propose) would be to treat products that are the same, differently. And such an approach would be inconsistent with the FFDCA. As the courts have explained, "'if . . . the product does not differ in any significant way from what it purports to be, then it

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39 *See, e.g.*, Letter from Andrew Kimbrell, Executive Director, Center for Food Safety, to Commissioner Margaret A. Hamburg, Food and Drug Administration (Nov. 4, 2013); Organic Consumers Association, *Tell the FDA: GMOs Aren't Natural*, http://salsa3.salsalabs.com/o/50865/p/dia/action3/common/public/?action_KEY=11779 (last visited Mar. 10, 2014).

40 *See* Miles McEvoy, Deputy Administrator, National Organic Program, *Policy Memorandum: Cell Fusion Techniques Used in Seed Production* 3 (Feb. 1, 2013).

41 57 Fed. Reg. at 22991.

42 Of significance, "it is doubtful whether the FDA would even have the power under the FDCA to require labeling in a particular situation where the sole justification for such a requirement is consumer demand." *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 179 (D.D.C. 2000) (citations omitted).

43 *Id.*

44 57 Fed. Reg. at 22991 ("FDA has not considered the methods used in the development of a new plant variety (such as hybridization, chemical or radiation-induced mutagenesis, protoplast fusion, embryo rescue, somaclonal variation, or any other method) to be material information within the meaning of section 201(n) of the act (21 U.S.C. 321(n)).").

would be misbranding to label the product as different, even if consumers misperceived the product as different.'"[45]

3. Appropriate Statements for Foods Derived from Biotechnology

GMA petitions FDA to amend the common or usual name for nonstandardized foods regulations and the general regulations for standardized foods. As set forth in the "Action Requested" section of this citizen petition, GMA requests that both regulations be amended to allow the term(s) "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" to accompany the name of a food or appear elsewhere on the label or in labeling and to state that the food shall not be deemed to be misbranded solely because the food is or contains a food derived from biotechnology.

Such statements are appropriate because FDA's regulations provide that the "common or usual name of a food . . . shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients."[46] The common or usual name also must be "uniform among all identical or similar products."[47] The "natural" foods category has become an established category of products with some retailers dedicating segments of their store for "natural foods." The foods in this category are considered "natural" regardless of whether that term appears as part of the statement of identity or as a separate statement on the principal display panel (PDP) or any other panel. The proposed common or usual name regulation recognizes this practice by allowing the "natural" term to appear either as part of the common or usual name or elsewhere on the label or in the labeling.

We believe that FDA's approach to the use of the term "organic" provides a useful precedent here. FDA does not object to the term "organic" appearing as part of the statement of identity, in the ingredient statement, or elsewhere on the label so long as the food meets the requirements of the U.S. Department of Agriculture's National Organic Program. Just as "organic" appropriately describes one category of foods, so, too, does "natural" (and similar terms) describe another category of foods. And like "organic," consumers view the term "natural" as part of the identity of the food.

Further, an amendment to the common or usual name for nonstandardized foods regulations and the general regulations for standardized foods will bring much needed uniformity and consistency to this issue. FDA's requirements for standardized foods, including the labeling of such foods, as well as its requirements regarding the labeling of the common or usual name of foods, expressly preempt non-identical state and local requirements.[48] The lack of a formal regulation has led to numerous class action lawsuits that assert that "natural" labeling on foods derived from biotechnology misleads consumers under state consumer fraud statutes. At the same time, some state legislatures have passed legislation addressing this issue and several others are considering doing so. Different results in

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45 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179 (quoting *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995)).

46 21 C.F.R. § 102.5(a).

47 *Id.*

48 FFDCA §§ 403A(a)(1) and (3); 21 U.S.C. §§ 343-1(a)(1) and (3). Likewise, FDA's requirements for ingredient labeling also preempt differing state and local requirements. FFDCA § 403A(a)(2); 21 U.S.C. § 343-1(a)(2). *See also* 21 C.F.R. § 100.1(c)(4) (a state requirement is "not identical" to a federal requirement for preemption purposes if it "imposes obligations or contains provisions concerning . . . the labeling of food" that "[a]re not imposed by" or "[d]iffer from those specifically imposed by" federal regulation).

lawsuits and varying laws enacted by state governing bodies are likely to be inconsistent with each other and directly at odds with FDA's stated policy on the labeling of foods derived from biotechnology. Consumers and the food industry would all benefit from uniform legal requirements and the consistent outcomes that result from federal regulations with preemptive effect. Accordingly, amending the common or usual name for nonstandardized foods regulations and the general regulations for standardized foods is the proper mechanism for regulating "natural" claims on foods derived from biotechnology.

4. Rulemaking Is in the Public Interest

Although FDA has declined, in the context of responding to private litigation,[49] to define "natural" with respect to food derived from biotechnology, it is nevertheless in the public interest for the agency to undertake that task through the rulemaking process.

a. FDA Is Best Positioned to Address this Issue

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."[50] Section 403(i) of the FFDCA requires that the food product as a whole, as well as each ingredient, with a few exceptions, be identified by its "common and usual name."[51] Also, the agency has the statutory authority to oversee foods derived from biotechnology—both their safety and labeling.[52] Indeed, foods and ingredients derived from biotechnology must meet the same safety and labeling requirements as foods and ingredients from traditionally bred crops.[53]

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.[54] In the past 20 years, FDA has completed nearly 100 such consultations.[55] The agency has published a Statement of Policy regarding foods derived from new plant varieties, including genetically engineered plants.[56] FDA also has issued draft guidance on voluntary labeling to indicate whether a food was derived from biotechnology.[57] Prior to issuing the draft guidance, FDA solicited public comment and held several

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[49] Letter from Leslie Kux, Assistant Commissioner for Policy, Food and Drug Administration, to the Honorable Yvonne Gonzalez Rogers, The Honorable Jeffrey S. White, The Honorable Kevin McNulty (Jan. 6, 2014).

[50] FFDCA § 403; 21 U.S.C. § 343.

[51] 21 U.S.C. § 343(i)(1), (2).

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

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

[54] 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.

[55] *Id.*

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

[57] Food and Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance* (Jan. 2001),

public meetings regarding the issue.[58] 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. Since explaining its "natural" policy more than 20 years ago, the agency has been actively enforcing it. 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.

In sum, FDA has extensively developed agency expertise and agency resources, making it best positioned to address "natural" labeling for foods derived from biotechnology. Federal rulemaking is needed so that this issue 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. Indeed, the parties who are behind the labeling initiatives at the state level and who are acting as plaintiffs in class action lawsuits take issue with FDA's conclusions regarding the safety and labeling of foods derived from biotechnology. Thus, it is FDA who should consider these views, and it should do so using the rulemaking process for the reasons described below.

b. The Rulemaking Process Confers Considerable Benefits

The rulemaking process, initiated through this petition, would confer considerable benefits to the public and the agency. Issuing a regulation through a proposal in the Federal Register is a public process. It allows for public participation. All stakeholders, including food manufacturers, scientists, farmers, consumers, wholesalers, retailers, and biotechnology companies, can comment and share their views with the agency. Indeed, the rulemaking process is the setting where all interested parties can be heard—a fact that is especially important for an issue of such wide-ranging public interest. Furthermore, issuing a proposed regulation would allow FDA to obtain additional data and information on this issue. It also allows the agency to share its preliminary views and solicit specific feedback. All comments received and other information that is part of the record (e.g., references) would be available for public review and further comment. Also, the rulemaking process is consistent with FDA's commitment to the principles of openness and transparency.[59]

c. Federal Regulation is Needed to Preserve the Natural Category for Consumers

FDA's involvement in this issue is needed to ensure that the "natural" category of foods remains a distinct and vibrant category. Consumer and retailer interest in foods that are "natural" or "organic" has dramatically increased sales of such products over the last several years.[60] More and more, consumers

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http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.

[58] Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25837 (Apr. 28, 1993); Biotechnology in Year 2000 and Beyond; Public Meetings, 64 Fed. Reg. 57470 (Oct. 25, 1999).

[59] *See* Food and Drug Administration, *FDA Transparency Initiative*, http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm (last visited Feb. 5, 2014); Memorandum of January 21, 2009 from Barack Obama on Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 26, 2009); Peter Orszag, Director, Office of Management and Budget, *Memorandum for the Heads of Executive Departments and Agencies M-10-06* (Dec. 8, 2009), http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf.

[60] Lisa Marshall, *Natural Industry Grows 10 Percent*, Natural Foods Merchandiser (May 31, 2013), http://newhope360.com/nfm-market-overview/natural-industry-grows-10-percent.

are seeking foods that are made without synthetic additives or artificial preservatives. The food industry has a vital interest in meeting this demand with nourishing, affordable foods.

But to best serve these consumers, "natural" must remain distinct from "organic." One difference between "natural" and "organic" is that "organic" foods may not contain any ingredients derived from biotechnology.[61] If, as a result of litigation or state legislation, food manufacturers are precluded from using the term "natural" on foods derived from biotechnology, the two categories would become blended, and consumers would not have a distinct choice between "natural" and "organic" foods. Those consumers who simply wish to avoid artificial and synthetic ingredients should be able to do so by choosing "natural" products. They should not be forced into choosing between conventional foods and "organic" foods. This is especially true considering one of the largest barriers to consumers purchasing organic foods is price.[62]

If the food industry were required to ensure that no ingredients in a "natural" product are derived from biotechnology, then the cost of "natural" foods would rise considerably. Food manufacturers would be required to source identity-preserved corn, soy, canola, and other ingredients. The process of creating and maintaining a separate supply of identity-preserved crops from farm to table would add significantly to the cost and availability of these ingredients. For example, participation in the Non GMO Project verification program can take several months[63] and requires ongoing traceability, testing, segregation and quality control standards.[64] If foods derived from biotechnology were precluded from use in "natural" foods, the price of such foods would invariably increase and the availability of such foods would likely decrease given the limited supply of identity-preserved foods and food ingredients. By continuing to allow foods derived from biotechnology in "natural foods," FDA will be ensuring the product category remains an affordable alternative to "organic" and conventional foods.

d. Our Proposal is Narrowly Focused and Consistent with Longstanding Agency Policy

GMA believes this proposal 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"[65] and that in previous rulemaking proceedings the agency has remarked that developing standards regarding the use of "natural" would be "difficult."[66] However, the present issue is significantly more narrow and straightforward. This request does not ask the agency to define "natural" for all types of food products. Instead, we are only asking FDA to issue a regulation authorizing foods

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61 7 C.F.R. 205.2 "Excluded methods." In contrast to "natural," "organic" refers not only to the food itself, but also to how it was produced (e.g., without synthetic pesticides). Foods labeled "organic" can contain up to five percent non-organic ingredients, including synthetic ingredients, listed on the National List of Allowed and Prohibited Substances.

62 Lisa Marshall, *Organic Continues Double-Digit Gains*, Natural Foods Merchandiser (May 31, 2013), http://newhope360.com/nfm-market-overview/organic-continues-double-digit-gains.

63 The Non GMO Project, *FAQs- Product Verification*, http://www.nongmoproject.org/product-verification/faqs/ (last visited Feb. 24, 2014).

64 The Non GMO Project, *Overview of the Standard*, http://www.nongmoproject.org/product-verification/non-gmo-project-standard/overview-of-the-standard/ (last visited Feb. 24, 2014).

65 Letter from Michael Landa, Acting Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, to the Honorable Jermone 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).

66 56 Fed. Reg. at 60467.

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.

GMA is mindful of FDA's acute resource issues and is well aware that the agency must prioritize its work carefully. For the reasons stated in this petition, the issue here is an important one—to the food industry (including farmers), consumers, and the states. And, because this Citizen Petition contains proposed regulatory language and the factual and legal basis for our request, we believe the agency has sufficient information to commence the rulemaking process.

C. Conclusion

For the reasons stated above, FDA should initiate rulemaking to allow the use of "natural" claims for foods with ingredients derived from biotechnology. Pursuant to 21 C.F.R. § 130.5(c), GMA is committed to substantiating the information in this petition by evidence in a public hearing, if such a hearing becomes necessary.

III. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. § 25.30(k) and § 25.32(a) and therefore does not require the preparation of an environmental assessment or environmental impact statement.

IV. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b)(3), a statement of the economic impact of the requested information is to be submitted only when requested by the Commissioner following a review of the petition.

V. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

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