May 10, 2016

Via Electronic Submission

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

Re: Use of the Term "Natural" in the Labeling of Human Food Products: Request for Information and Comments; Docket No. FDA-2014-N-1207

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) submits the following comments addressing the Food and Drug Administration's (FDA) request for information and comments concerning "Use of the Term 'Natural' in the Labeling of Human Food Products."

Based in Washington, D.C., GMA is the trade organization representing the world's leading food, beverage and consumer products companies and associated partners. The U.S. food, beverage and consumer packaged goods industry has facilities in 30,000 communities, generates $1 trillion in sales annually, contributes $415 billion in added value to the economy every year and is the single largest U.S. manufacturing industry with 1.7 million manufacturing workers. Founded in 1908, GMA has a primary focus on product safety, science-based public policies and industry initiatives that seek to empower people with the tools and information they need to make informed choices and lead healthier lives.

I. Introduction and Executive Summary

The category of "natural" foods has emerged and is growing rapidly. More and more, consumers are seeking foods that are made without synthetic or artificial ingredients. Given the widespread interest in such products, it is important for the Food and Drug Administration (FDA) to address this issue in a deliberate and thoughtful way and to do so through 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 the food industry, ingredients, and manufacturing processes. The federal rulemaking process is the appropriate 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.

GMA appreciates the agency's efforts to assess the need for a regulatory definition for the term "natural" and to seek stakeholder input on an issue that is important to consumers and manufacturers. GMA believes that FDA should define the term "natural" to alleviate confusion for consumers and industry alike and to set a standard that will promote fair and consistent dealing among food and beverage manufactures. While consumer perception of the term "natural" is important, FDA should exercise its expertise and leadership and establish a definition that would provide clarity regarding the meaning of natural. When establishing a definition for the term "natural," we encourage FDA to balance the weight of consumer perception with the realities of current manufacturing practices, maintenance of food safety and public health, and consideration for future food processing technologies. We also urge FDA to establish a definition for natural that is distinct from "organic."

In our comments, GMA provides: 1) specific comments regarding how the term "natural" should be defined, in response to the questions posed by FDA[1]; and 2) as an alternative approach, a tiered system for "natural" claims that would distinguish between an "all natural" or "100% natural" claim, a "natural" claim, and a claim such as "made with natural ____" where specific ingredient(s) are highlighted as natural.

GMA believes that the criteria used to evaluate whether a food qualifies for a "natural" claim should chiefly focus on the nature of the ingredients (synthetic/artificial or natural) and the processing the ingredients undergo (with certain exceptions, such as for added vitamins and minerals), and not the function of the ingredients in the finished food. These same criteria should be used to evaluate colors, flavors, and preservatives. Moreover, the definition for "natural" should allow acceptable post-harvest processing and production methods. The definition should not consider the nutritional status of the ingredient or food. Furthermore, we strongly believe that the "natural" definition should permit ingredients that ensure food safety and the rational addition of nutrients in accordance with FDA's Fortification Policy or pursuant to a standard of identity for an enriched food regardless of the source of these ingredients.

II. **FDA Should Define the Term "Natural"**

GMA believes that FDA should define the term "natural." The key reasons to do so are to alleviate potential consumer confusion, to promote fair and consistent dealings among food manufacturers, and to provide a consistent and uniform regulation that can be relied upon by courts and regulatory bodies at both the state and federal levels. The lack of a regulatory definition has led to widespread industry and consumer confusion, and consumer mistrust. Given this confusion, GMA urges FDA to take a leadership role and establish a definition that is developed in a transparent, science-based manner. Such a definition would significantly reduce ambiguity for consumers and would establish a uniform set of enforceable requirements that would bring consistency to the claims made by companies.

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[1] Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69905 (Nov. 12, 2015).

We recognize the challenges that have confronted regulatory agencies in the past with defining the term, "natural." As the "natural" segment of the food market continues to be one of the fastest growing segments of the industry, it is becoming increasingly important for FDA to define the term, despite the difficulties FDA and other regulatory agencies have experienced in the past. 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.[2] 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 . . . ."[3]

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."[4] 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."[5] 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."[6]

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.'"[7] Thus, the agency chose to continue its policy of prohibiting artificial or synthetic substances in "natural" foods. Specifically, 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."[8] FDA has consistently maintained and implemented this policy now for more than 20 years. For example,

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[2] Food Labeling; Hearings, 43 Fed. Reg. 25296, 25296 (June 9, 1978). The FTC terminated its proposal to define the term "natural" and other terms used in advertising, stating "a fundamental problem exists by virtue of the fact that the context in which "natural" is used determines its meaning. It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream." 48 Fed. Reg. 23270, 23270 (May 24, 1983).

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

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

[5] *Id.*

[6] *Id.* at 60467.

[7] 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).

[8] *Id.*

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.[9]

In sum, FDA's natural policy focuses on three things: (1) what has been added to the food; (2) whether those ingredients are artificial or synthetic, and (3) whether consumers would normally expect the ingredient to be present in a food labeled as natural. With respect to the first element, the current 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 the presence of any **artificial or synthetic ingredients** (or any color additives) in the finished food. FDA has generally interpreted "artificial or synthetic" to mean "chemical" ingredients.[10] For example, FDA has issued Warning Letters to food manufacturers using chemical preservatives in foods labeled "natural,"[11] but does not consider common salt or vinegars to be "chemical preservatives."[12] With regard to the third element, the policy provides FDA with the discretion to consider whether consumers would expect an ingredient, regardless of its source, to be included in a food labeled as natural.

Since explaining its natural policy more than 20 years ago, the agency has been enforcing it. FDA's significant experience evaluating the meaning of "natural" and its use in different contexts gives the agency the unique experience needed to regulate the term. As such, GMA appreciates the agency efforts to engage with stakeholders on this issue and its request for comments.

GMA and its members have thoughtfully considered general parameters and principles for the use of the term "natural" and offer these comments to FDA for consideration as the agency explores defining the term.

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

[10] For purposes of these comments, GMA considers the terms "artificial" and "synthetic" to be synonymous and will use the term "synthetic" throughout the comments. GMA recommends that FDA define the terms "artificial," "synthetic" and "nature equivalent" in any regulations they may release.

[11] *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).

[12] 21 C.F.R. § 101.22(a)(5).

III. Proposed Guiding Principles for "Natural" Claim Criteria

In considering FDA's request for comment, GMA was guided by its own core principles: a commitment to consumers, responsible business practices, and science-based research, testing, and evaluation. GMA strongly believes consumer perception about the meaning of "natural" should be balanced with the current realities and scaleability of manufacturing practices, maintenance of a safe food supply, public health, and consideration of future food technologies to provide flexibility to industry – issues and concerns which largely do not enter into consumer perceptions.

In general, GMA believes that a primary consideration in whether an ingredient qualifies as "natural" is the **nature** (natural or synthetic/artificial) of the ingredient and the **processing** it undergoes. There are, however, certain exceptions to this principal, including synthetic vitamins, discussed in further detail below. We do not believe, however, that the ingredient's function should be fully determinative of whether it is "natural."

These principles should be used to evaluate whether ingredients that function as colors and preservatives can be included in "natural" foods. "Natural" should not just be limited to raw agricultural commodities, "unprocessed foods," or single ingredient foods (e.g., bottled water or bagged spinach) because this is far too restrictive. Multi-ingredient foods that consist entirely of materials derived from a natural source and that have undergone acceptable production or processing should be eligible to bear a "natural" claim.

We encourage FDA to provide clear definitions for the terms used in the "natural" claim criteria. Other existing definitions lack specificity, causing confusion among manufacturers, regulators, and consumers alike. GMA does not recommend the use of phrases such as "home kitchen" or "traditional food preparation" as they may be open to interpretation. These are not commonly understood terms and may limit the use of future technologies performed at a commercial scale.

Specifically, we encourage FDA to clearly identify the types of processes and ingredients that are appropriate for a food bearing a "natural" claim. The definition for "natural" should allow acceptable post-harvest processing and production methods. Furthermore, other aspects of sourcing, such as agricultural practices, use of biotech seeds, and animal husbandry (*e.g.*, attributes such as "free range," "fair trade," "grass fed"), should have no bearing on the "natural" status of an ingredient or food.[13] We believe that this is a key distinction between an organic claim, which is based on the use of organic farming, production, and handling methods; and

[13] USDA defines some of these terms (*See* FSIS, Food Safety Education, Meat and Poultry Labeling Terms http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms (accessed April 27, 2016)), and others are defined by third parties; *see, e.g.,* the Fair Trade and Non-GMO Project standards, http://fairtradeusa.org/# (accessed Apr. 27, 2016), and http://www.nongmoproject.org/ (accessed Apr. 27, 2016).

natural claims, which should be based on the natural status of the ingredients used to make the food and post-harvest processing of the ingredients.

While FDA does not limit natural claims under the existing policy to minimally processed ingredients, GMA would support a regulatory definition that incorporates the concept of allowing specific processes deemed by FDA to be appropriate for a "natural" food. Given GMA's and FDA's emphasis on food safety, we strongly believe the definition of "natural" should include processes that ensure food safety or that promote public health. In order to meet food safety and regulatory requirements and technical specifications, processes used to treat the food for food safety, such as pasteurization, or for reducing the formation of contaminants such as acrylamide (as described in FDA's guidance on this topic[14]), should be permitted on "natural" foods, provided that the primary chemical structure/s of the constituting components/s of the food ingredients are not altered.[15]

We also strongly believe a "natural" definition should permit the rational addition of nutrients to a food in accordance with FDA's Fortification Policy[16] or pursuant to a standard of identity for an enriched food without regard to the "natural" status of the vitamin or mineral. Standards of identity for enriched foods have served as a means to improve the overall nutritional quality of the food supply and meet demonstrated public health needs[17]. Consumers have long expected certain foods to contain added vitamins and minerals and therefore, fortification with mandated nutrients should not affect the ability for a food to be deemed "natural."

FDA requested comment on consumer perception of the term "natural" and the extent to which it should be considered in defining the term. We believe consumers have many different perceptions of what natural means,[18] and those perceptions should be considered in the way the definition is constructed. In particular, consumer understanding of "natural" claims is driven by the context in which the claim is made. For instance, the use of "natural cheese" as a product name would not be viewed in the same way as a "natural" claim on other foods. Consumers and regulatory agencies both have longstanding experience with treating "natural

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[14] FDA Guidance for Industry: Acrylamide in Foods (Mar. 2016), http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/UCM374534.pdf.

[15] The International Organization for Standardization (ISO) is also currently considering how to define natural, and in their February 3-4, 2016 meeting, the working group considered a proposal to include purifying processes to meet food safety and regulatory requirements. ISO/TC 34/WG 18, Natural food ingredients committee document dated January 8, 2016 (attached).

[16] 21 C.F.R. § 104.20

[17] FDA, "Questions and Answers on FDA's Fortification Policy," (November 2015) http://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm471087.pdf (accessed Apr. 27, 2016).

[18] *See, e.g.,* Consumer Reports Natural Food Labels Survey, http://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf.

cheese" as a distinct product category and as a term used to distinguish from processed cheese products, rather than as a "natural" claim.[19]

We encourage FDA to conduct research to understand consumers' perceptions of various terms and phrases related to natural. The results of such a survey may enable FDA to assist industry and consumers alike by "debundling" the various attributes that consumers may believe a natural product should provide (e.g., cage-free, no pesticides/herbicides, non-GMO, no antibiotic use). FDA may conclude that several claims may be necessary to clearly and simply communicate the desired attributes of a given product.

GMA strongly believes consumer perception should be balanced with the current realities and scaleability of manufacturing practices, maintenance of a safe food supply, public health, and consideration of future food technologies to provide flexibility to industry – issues and concerns which largely do not enter into consumer perceptions.

IV. Ingredient Considerations to Define the Term "Natural"

A. Ingredients Generally

1. Naturally-Sourced Ingredients

GMA strongly believes the nature of an ingredient (natural or synthetic/artificial) is a critical factor when determining whether a product qualifies as natural – not function. The functional purpose of the ingredient should not be an automatic disqualifying factor (e.g., colors, preservatives).

2. Synthetic or Artificial Ingredients

As a general rule, synthetic or artificial ingredients should not be allowed in products labeled as "natural," unless FDA specifically authorizes their use. Our recommendation is that FDA consider establishing a list of synthetics that would be authorized. Examples of synthetic or artificial inputs that should be authorized include: incidental additives, and vitamins and minerals that are added to food consistent with the Fortification Policy and any applicable FDA standard of identity. Both of these topics are discussed further below. There may also be synthetic or artificial ingredients added for food safety that FDA would deem appropriate for foods labeled as "natural."

[19] On this point, we refer to and incorporate the comments submitted to the agency by the International Dairy Foods Association (IDFA) on the meaning of "natural" claims.

B. Colors

1. Naturally-Sourced Colors

In broad terms, and as discussed at greater length below and throughout these comments, GMA believes FDA's definition of "natural" for use in the labeling of ingredients and foods should focus primarily on the nature and processing of the ingredients in the food, not on the functional use of those ingredients. GMA believes the same should hold true for colors.

GMA is aware of FDA's policy statement that "natural" means "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."[20] We believe, however, that consumers and industry would be better served by an overall approach to "natural" that eliminates exceptions based on the function of the ingredient. The simplicity of a definition that evaluates colors in the same way as every other category of ingredients should accelerate understanding of the term across the marketplace among both companies and consumers alike.

GMA also believes that some of the considerations that may have driven FDA's special treatment of colors for purposes of "natural" claims in the past may be less compelling today. For many years, colors have been added to provide visual appeal to products. Colors serve as a code to help consumer's identify on sight the flavor/taste profile of formulated, multi-ingredient products. In this way, colors add value to the consumer experience, and consumers reasonably expect their presence. Further, today's consumers appear to be drawing a distinction between the synthetically made "certified colors" and those colors derived from natural sources. The regulatory meaning of "natural" should reflect these developments in consumer understanding and expectations.

Finally, it is important to observe that this proposed approach, although a change from FDA's past policy on "natural," is not inconsistent with the agency's current color labeling regulations. Although the definition of artificial color at 21 C.F.R. § 101.22(a)(4) is expansive, encompassing non-certified colors extracted from materials that exist in nature, that definition speaks at the ingredient level, rather than the product level. The purpose of that definition is to help consumers identify colors that are not inherently found in a finished product; not to denote that the colors are not derived from a natural source.

The presence in a multi-ingredient food of an added color derived from sources that exist in nature using acceptable methods of processing is fully consistent with a "natural" characterization for the product as a whole. We note as well that FDA regulations permit manufacturers to declare non-certified colors derived from natural sources as "Colored with _____" (*e.g.*, colored with annatto) as an alternative to "artificial color" in the ingredient statement. The agency recognition in the ingredient labeling regulations that certain naturally derived colors do not need to be labeled as "artificial color" would be consistent with a regulation

[20] 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

that would allow a natural claim on products with colors from natural sources. In such instance, the ingredient statement of a product containing an added color from a natural source would be fully consistent with a "natural" label for the product as a whole and would not generate consumer confusion.

2. Certified and Synthetic Colors

Consistent with the current guidance, the use of synthetic FD&C colors should disqualify a food or ingredient from bearing the term "natural" because the source of the colors is not "natural".

C. Incidental Additives and Processing Aids

1. Defined

To better understand GMA's position, it is important to understand what incidental additives and processing aids are. Incidental additives are substances that are in a food at insignificant levels and do not have technical or functional effect in the food.[21] Examples of incidental additives are carriers used for a flavor that is used to produce a finished food product; or flow agents added to granular ingredients that are used to produce a finished product.

Processing aids are a type of incidental additive,[22] and are defined as follows:

> (*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.[23]
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> (*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.[24]
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> (*c*) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

2. "Natural" Pertains to Labeled Ingredients

GMA believes only *labeled* ingredients should be considered in evaluating whether a food qualifies for a natural claim. Claims about natural should be based on: (i) the natural status of the labeled ingredients, and (ii) type of processing used to produce the final product and each of its labeled ingredients. Incidental additives should not be included in the evaluation because they are, by definition, present in food at insignificant levels and do not have any technical or functional effect in food. FDA exempted incidental additives from the ingredient labeling

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[21] 21 C.F.R. § 101.100(a)(3).
[22] *Id. §* 101.100(a)(3)(ii)(a).
[23] *Id. §* 101.100(a)(3)(ii)(a).
[24] *Id. §* 101.100(a)(3)(i).

requirements precisely because the agency does not view their use as material information relative to the composition of the finished food. Evaluating each potential incidental additive for each labeled ingredient in foods throughout the total supply chain would not provide value-added information for the consumer.

Additionally, FDA has previously recognized that where a synthetic substance is removed during processing and is no longer present in the finished food, the use of that substance does not impact the "natural" status of the finished food. In the agency's 2008 letter to the Corn Refiners Association regarding the "natural" status of high fructose corn syrup (HFCS), FDA explained that the use of a synthetic fixing agent, glutaraldehyde, to fix to a column the enzyme used to make HFCS, does not preclude the use of a "natural" claim on the finished HFCS because any unreacted glutaraldehyde is removed by washing the column during the process. [25] FDA set the precedent for recognizing that incidental additives should not impact an assessment of whether a food is natural and should establish regulatory criteria for "natural" claims that would exempt any substances that fall within the FDA definition of incidental additive because these uses are not material to whether the finished food is "natural."

An excellent example of the principle that only labeled ingredients should be considered when considering whether a food is "natural" is sugar. Sugar is commonly understood to be natural and is a common ingredient in many foods. There are basic processing steps to produce sugar from sugar cane and principal processing aids typically used in each step, such as milk of lime (or sodium hydroxide).[26] However, because the processing aids have no technical or functional effect in refined sugar, the ingredient listing for the sugar ingredient will only list "sugar." As such, the processing aids would not be considered in evaluating the naturalness of the end product using that sugar.

D. Preservatives

1. Naturally-sourced

In broad terms, and as discussed at greater length throughout these comments, GMA believes FDA's definition of "natural" for use in the labeling of foods should be based on the nature (natural or synthetic/artificial) and processing of the ingredients in the food, not on the function played by those ingredients. GMA believes the same should hold true for naturally-sourced preservatives. A rosemary extract used to prevent oxidation of canola oil should be permitted for use in a natural food as long as the rosemary extract has only undergone processing permitted in FDA's definition of natural.

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[25] Letter to Audrae Erickson, President, Corn Refiners Association 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 (July 3, 2008).
[26] *See* The Sugar Association, "Refining and Processing Sugar," http://www.sugar.org/images/docs/refining-and-processing-sugar.pdf (accessed April 6, 2016).

2. Synthetic/Artificial

In general, the use of any synthetic preservative, except for incidental additives, should disqualify a food or ingredient from bearing the term "natural." As noted above, we ask that FDA establish a list of authorized synthetic/artificial ingredients in "natural" foods, such as synthetic vitamins, and that the agency consider whether there may also be synthetics added for food safety that FDA would deem appropriate for foods labeled as "natural."

E. Flavorings

GMA agrees with and supports maintaining FDA's current guidance that only natural flavor/flavorings, as defined in 21 C.F.R. § 101.22(a)(3) should be used in products bearing natural claims. The term "natural flavor" or "natural flavoring" is defined as follows.

> The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. . .

F. Fortificants

We also strongly believe a "natural" definition should permit the rational addition of nutrients to a food in accordance with FDA's Fortification Policy[27] or pursuant to a standard of identity for an enriched food without regard to the "natural" status of the vitamin or mineral. Standards of identity for enriched foods have served as a means to improve the overall nutritional quality of the food supply and meet demonstrated public health needs.[28]

Provisions in FDA's nutrition labeling regulations deem a food to be misbranded if its label or labeling represents, implies or suggests "that a natural vitamin in a food is superior to an added or synthetic vitamin."[29] Moreover, the addition of nutrients to food in accordance with FDA's Fortification Policy or pursuant to a standard of identity for an enriched food provides a great public health benefit. There are numerous studies that support the use of fortification as a means to improve the overall nutritional quality of the food supply and meet demonstrated public

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[27] 21 C.F.R. § 104.20.
[28] Questions and Answers on FDA's Fortification Policy: Guidance for Industry (Nov. 2015), available at http://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm471087.pdf. *See also* U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans, 8th Edition (Dec. 2015), *available at* http://health.gov/dietaryguidelines/2015/guidelines/.
[29] 21 C.F.R. § 101.9(k)(4).

health needs.[30,31,32] Also, the importance of fortification is recognized in the 2015-2020 Dietary Guidelines for Americans policy, "fortified foods and dietary supplements may be used in providing one or more nutrients that otherwise may be consumed in less than recommended amounts or that are of particular concern for specific population groups."[33]

Furthermore, while GMA recognizes that "organic" and "natural" are different, we did look to the National Organic Program (NOP),[34] as a resource, and under the NOP, nonagricultural, nonorganic substances, such as nutrient vitamins and minerals are allowed as ingredients in or on processed products labeled as "organic" or "made with organic." Restricting the addition of vitamins and minerals to foods labeled as "natural" would reduce consumers' options in purchasing "natural" ingredients and food particularly limiting those products that provide a public health benefit. There is clear benefit to not stigmatizing the addition of vitamins and minerals to foods in relation to the use of the term "natural" on a food or ingredient label. Therefore we assert that the addition of vitamins and minerals in accordance with the Fortification Policy or pursuant to a standard of identity provides a significant public health benefit and should not preclude an ingredient or food from bearing a "natural" claim.

It is well established that enriched and/or fortified food products and dietary supplements help improve dietary intake with little variation across age segments.[35] However, consumers increasingly seem to be substituting fortified foods with foods that are fresh or minimally processed (72%), naturally rich in nutrients (71%), made from all natural ingredients (68%) or organically grown (17%).[36] Additionally, there is a concerning trend toward de-fortification. [37] Unless natural and organic foods are fortified with vitamins, the prevalence of inadequate intakes in the context of overall dietary patterns will increase. An example of a very real public health benefit of fortification is folic acid fortification, which has resulted in decreased incidence of neural tube defects.[38] Essential nutrients that are added to fortify food, regardless of source, should be exempted from meeting any criteria for foods to bear the term "natural" on their labeling.

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[30] Fulgoni, V.L., Keast, D.R., Bailey, R.L., Dwyer, J. (2011). Foods, fortificants, and supplements: Where do Americans get their nutrients? *Journal of Nutrition. 141:1847-1854.*

[31] Berner, L.A., Keast, D.R., Bailey, R.L., Dwyer, J.T. (2014). Fortified foods are major contributors to nutrient intakes in diets of US children and adolescents. *Journal of the Academy of Nutrition and Dietetics. 114(7): 1009-1022.*

[32] Dwyer, J.T., Woteki, C., Bailey, R., Britten, P., Carriqulry, A., Gaine, P.C.,...Edge, M.S. (2014). Fortification: new findings and implications. *Nutrition Reviews. 72(2):127-141.*

[33] Accessed 4/6/2016, http://health.gov/dietaryguidelines/2015/guidelines/executive-summary/

[34] 7 C.F.R. § 205.605(b).

[35] Fulgoni, V.L., Keast, D.R., Bailey, R.L., Dwyer, J. (2011). Foods, fortificants, and supplements: Where do Americans get their nutrients? *Journal of Nutrition. 141:1847-1854.*

[36] *Id.*

[37] *Id.*

[38] Williams, J., Mai, C., Mulinare, J., et al. Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification – United States, 1995-2011. MMWR Morb Mortal Wkly Rep 2015;64:1-5.

We believe this position is consistent with the FDA's existing policy on "natural," which states that the food should not contain anything artificial or synthetic that would not "normally be expected to be there." This portion of the policy means that consumer expectations are key to whether a synthetic ingredient is permitted. If a synthetic ingredient would normally be expected in a "natural" food, its use is allowed. Although generally ingredients produced through chemical synthesis are inconsistent with expectations for "natural" foods, added vitamins are a notable exception. Consumers have eaten enriched foods for decades and are well aware that certain foods contain added ingredients for public health purposes, such as flours enriched with vitamins and minerals or dairy products fortified with vitamins A and/or D. Given these longstanding uses of added vitamins and minerals, we believe their use would be fully expected by consumers in a "natural" food.

V. Production and Processing Considerations to Define the Term "natural"

A. Farming, Agricultural, and other Pre-Production Methods

GMA recommends that natural be defined in relation to "post-harvest" practices, rather than focusing on the pre-harvest agricultural practices used to produce and/or grow the plant, or in the case of animals, the practices prior to slaughter or the animal's production of the milk or eggs. Consideration of the farming or agricultural methods, including pesticide and herbicide use, use of biotech seeds, and animal husbandry practices, should be outside the scope of the "natural" definition.[39] We believe that this is a key distinction between an organic claim, which is based on the use of organic farming and production methods, and natural claims, which should be based on the natural/synthetic status (with certain exceptions, such as for added vitamins and minerals) and post-harvest processing of the ingredients.

There are process verification standards and claims available to manufacturers and consumers that provide criteria for the various pre-production processes and inputs, including the National Organic Program, Non-GMO Project, and standards for claims such as "cage-free" and "free-range". The use of the term "natural" can be combined with other certification and claim language, for example "Natural egg white from cage-free eggs."

We feel strongly that the use of biotech seeds should not preclude a finished product from bearing a "natural" claim. FDA has consistently recognized that biotechnology does not change the essential nature of a food.[40] FDA also has consistently maintained that the method of plant

[39] GMA's position here is consistent with its Citizen Petition submitted to the Food and Drug Administration, "'Natural' Statements on Foods Derived from Biotechnology," March 14, 2014.

[40] 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

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. 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. Therefore, if a "natural" claim is appropriate for its traditional counterpart, it is equally appropriate for a food derived from biotechnology.

In sum, the inclusion of agricultural practices into a definition of "natural" introduces – almost necessarily – the creation of a traceability and certification program for those practices to ensure that the specific standards are met. Under such an approach, there would be no meaningful distinction between "natural" and "organic." It would also require FDA to provide a detailed definition of when foods are considered to be produced with or without the use of genetic engineering. Ultimately we view "natural" as requiring consideration of post-harvest or post-slaughter processes, but as not extending to the pre-production practices that are better governed through the existing organic standards and other standards specific to animal husbandry and other practices.

B. Manufacturing Processes

GMA agrees with the principle established in the FSIS policy on "natural" claims that certain food manufacturing processes are appropriate for "natural" foods and that the term should not be reserved only for "unprocessed" foods. The existing FSIS definition, however, is not sufficiently detailed to address all processes used for FDA-regulated foods. GMA therefore recommends that FDA provide a specific list of acceptable processes for clarity and consistency in application of natural claims across the food industry, similar to that of the Canadian Food Inspection Agency.[41] As an alternative, FDA could offer guiding principles to assess acceptable current and future manufacturing processes, and consider a flow chart similar to that put forward by the ISO Natural Working group in its draft of February 3, 2016 (attached). GMA has given some thought to guiding principles that may be helpful to FDA in establishing a list of acceptable processes.

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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/geplants/submissions/ucm225043.htm (accessed April 27, 2016). 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.*

[41] CFIA, Method of Production Claims, Annex 1 – Minimum Processes, available at http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=7 (accessed April 27, 2016).

- Allow all processes that alter only the physical state of a food without the addition of synthetic materials (*e.g.*, chopping, pureeing).

- Allow processes that only minimally alter the ingredient and do not significantly alter the original chemical state of the ingredient or food, if they alter it at all (*e.g.*, cooking, baking).

- Allow some processes that may alter the chemical composition, but are "traditional" (for lack of a better term) (*e.g.*, fermentation and distillation).

- Allow processes that make food edible and promote food safety (*e.g.*, pasteurization, baking, steaming, and purification), and provide a list of such acceptable processes.

- Allow processes authorized for "natural flavors and natural flavorings" under 21 C.F.R. 101.22(a)(3).

While we embrace the concept of defining and creating a list of acceptable processes, we also feel that the term "minimal processing" does not provide sufficient clarity to the industry. We are concerned that use of descriptors that convey forms of "minimal processing" such as "home kitchen" and "traditional" may be misinterpreted and limit the use of current and future technology. For example, processes like milling and degerming are not typically done in home kitchens, but are done at the manufacturing level and, we believe, are acceptable processes that fit within the term "natural." We recommend focusing on the degree of processing that would occur post-harvest with a specific list of acceptable processes that would be updated with a regular cadence.

VI. Alternative Approach: Tiered Model

GMA believes all types of food should be allowed to bear the term "natural" provided they meet the criteria specified above in our comments. As an alternative to the specific suggestions above, we believe a tiered system for labeling different categories of natural products should be given serious consideration by FDA. For example, USDA's Agricultural Marketing Service (AMS) has a program that certifies products as "organic." The National Organic Program (NOP) has established standards for the production, handling, and labeling of organic products.

This program has been successful for consumers and industry and was developed through extensive discussions with government, academic, and industry stakeholders. Organic labeling regulations cover the wording allowed on both the front panel and the information panel of a packaged product and define three categories of labeling based on product composition. These categories represent different degrees of organic production and handling, and allow consumers to identify products that are organic, in entirety or in part, while still being truthful and not misleading. The experience gained through development and implementation of the NOP could inform the development of a similar set of definitions for "natural" products. GMA does not, however, recommend requiring third party certification for natural claims, because (1) this would

place an undue burden on both companies and the regulating authority in terms of time and resources, and (2) unlike for "organic" claims, food companies are well suited to assess themselves whether ingredients comply with the natural standard.

We propose the following three "tiers" for "natural" claims, followed by our justification for this alternative proposed framework.

Claim	Proposed Ingredient Sources	Proposed Chemical Alterations
Tier 1: "All Natural" or "100% Natural"	Plant, animal, mineral, microorganism, algae, fungi, and other naturally sourced ingredients, such as gases and water (including naturally carbonated water). Use of "natural" incidental additives and processing aids allowed. No added colors, regardless of source. Included ingredients: - Water from municipal water supplies - Salt	No chemical alteration, except for processes determined by FDA to be acceptable (e.g., cooking).
Tier 2: "Natural"	Same as Tier 1 ("All Natural" or "100% Natural") but criteria apply to labeled ingredients only; i.e., processing aids and incidental additives are not considered. Colors from natural sources are permitted. Allow for a threshold percentage by weight of the following ingredients: -Vitamins and minerals added for fortification -Synthetic ingredients to support food safety Ingredients that should be considered natural: - Carbonated water	No chemical alteration (same as above), except for: - Enzymatic reactions, assuming any residual enzymes are removed from or inactivated in the finished product. - Microbiological processing Purification processes (e.g., heating, removing pollen from honey) may be employed on foods and food ingredients, provided that the primary chemical structure/s of the constituting component/s of the food ingredients are only minimally altered.

Tier 3: "Made with Natural _____"	Individual ingredient(s) referred to as "natural" must meet Tier 2 criteria above for acceptable ingredient sources. The product would be required to contain a meaningful amount of natural ingredients, as potentially defined by FDA.	Individual ingredient(s) referred to as "natural" must meet Tier 2 ("Natural") criteria above for chemical alteration.

A. Tier 1: 100% Natural / All Natural

GMA recommends a first tier wherein 100% of ingredients within the formulation do not contain synthetic or artificial ingredients, and utilize only acceptable post-harvest manufacturing processes that do not alter the chemical structure of the food or the native color of the finished product. This would mean that the use of added colors, regardless of source, would preclude a "100% natural" or "all natural" claim. Use of this claim would include a review of the origin of any processing aids and/or incidental additives exempt from labeling[42] in the ingredient declaration, but would only require an inquiry that reaches one step back in the procurement process.

An example of a food that would qualify under this standard is a multi-ingredient food that consists entirely of materials that exist in nature and that have undergone acceptable processing like apple juice. Examples of additives which would not qualify for the "100% Natural" or "All Natural" claim are silicon dioxide, or BHA/BHT. Examples of products that would not qualify are onion powder with silicon dioxide (silicon dioxide not labeled in accordance with permitted labeling exemptions); apple sauce with citric acid (citric acid from synthetic source); pink lemonade; or a product that contains a natural flavor which is not processed using an acceptable process.

B. Tier 2: Natural

To qualify for the second tier, "Natural", the manufacturer only needs to ensure that the labeled ingredients meet the criteria set forth. Incidental additives or processing aids that are not labeled do not need to be considered. Additionally, colors from natural sources would be permitted in "natural" foods.

This tier would also allow for "natural" claims with the use of ingredients that are enriched pursuant to a standard of identity without regard to the "natural" status of the fortificants (e.g., the use of enriched flour in a product). We recommend that the presence of the added vitamin(s) and mineral(s) be disclosed using a qualifying statement such as "added," "plus," "fortified," or "enriched" in accordance 21 C.F.R. § 101.54(e).

[42] 21 C.F.R. § 101.100(a)(3).

- Examples of appropriate inputs or ingredients: Defoamer used in juice processing, where the defoamer is present at insignificant levels in the finished food and has no technical function or effect; a vegetable chili composed of natural ingredients as described in tier 2 but contains beet powder as a colorant.

- Example of an input that would preclude a "natural" claim: An ingredient with a synthetic acidifier which contributes to finished food pH.

GMA believes the definition of "Natural" for this tier should include criteria for qualified "natural" claims for circumstances where the vast majority of the ingredients in a finished food meet the criteria of the claim, but a limited number of ingredients do not. A threshold should be set during the rulemaking process to allow a certain amount of synthetic vitamins and minerals added for fortification, and synthetic or artificial ingredients to support food safety or promote public health.

C. Tier 3: "Made with Natural …"

This tier pertains to specific ingredients within a multi-component food. The qualifier, "made with ___" describes specific natural ingredients within a multi-component food where the finished product does not qualify for a "100% Natural," "All Natural" or "Natural" claim. The claims that can be made in this tier are, for example, "Made with 100% Natural [name(s) of ingredient(s)]" or "Made with Natural [name(s) of ingredient(s)]." As is the case for the "made with organic ____" labeling category, this tier would not permit the use of the claim "made with natural ingredients" without specifying which ingredients are considered natural.

We also propose that claims in this category could only be made where the food contains a meaningful amount of natural ingredients. FDA could outline a minimal threshold of natural ingredients required in order to qualify for this tier of claim. Alternatively, this tier could be regulated under the general false and misleading standard under section 403(a) of the Federal Food, Drug, and Cosmetic Act, without specifying a specific minimum percentage of natural ingredients. [43]

IV. Other "Natural" Definitions

GMA evaluated numerous definitions for the term "natural", including those of USDA's Food Safety and Inspection Service (FSIS),[44] ISO, the Canadian Food Inspection Agency (CFIA),[45]

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[43] 21 U.S.C. § 343(a).

[44] FSIS Food Standards & Labeling Policy Book (Aug. 2005), available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf ("A product shall not contain any artificial flavor or flavoring, FD&C (certified) colors or synthetically derived coloring ingredients, chemical preservative, or any artificial or synthetic ingredient, or [fortificant/enrichment] and the product and its ingredients are not more than minimally processed." OR "a food or ingredient derived solely from plant, animal, microbe or mined sources, either in its unprocessed state or having been subject to

the United Kingdom, Codex Alimentarius, Association of American Feed Control Officials (AAFCO),[46] and Australia's Competition & Consumer Commission.[47] We felt that all of these definitions would benefit from further clarification to ensure consistent application by manufacturers, and consistent understanding by consumers. We have incorporated specific parts of some of these definitions into our comments above; for example, the concept of the "source material consisting of plant, algae, fungi, animal, mineral or microorganism" is from the ISO draft. The processing guiding principles come in part from the CFIA definition.

VI. There Are No Public Health Benefits Associated with the Term "Natural"

GMA believes that "natural" is a term related to the processing of ingredients post-harvest and a finished product. It does not convey a nutrition or health benefit. Natural products are not necessarily nutritionally superior. A natural product, such as tortilla chips, could have an identical nutritional make up to a tortilla chip containing one or more synthetic or artificial ingredients.

VII. Recommendations to Ensure that Consumers Have a Consistent and Accurate Understanding of the Term "Natural" in Food Labeling

GMA believes that consumers would benefit from a clear definition of "natural" that could be applied across the industry. It is the responsibility of FDA and the food industry to clearly communicate this definition to consumers to allow them to make informed decisions about the products they purchase. FDA oversight of the "natural" criteria and consistent enforcement of these regulations, once finalized, would ensure consistency of the application of its definition across the industry.

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physical processing, heat processing, rendering, purification [non-chemical/solvent] extraction, hydrolysis, enzymolysis or fermentation, but not having been produced by or subject to a chemically synthetic process and not containing additives or processing aids that are chemically synthetic except in amounts as might occur unavoidably in good manufacturing practices.")

[45] CFIA, Food Labelling for Industry, Method of Production Claims: Nature, Natural, http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=2.

[46] "A food or ingredient derived solely from plant, animal, microbe or mined sources, either in its unprocessed state or having been subject to physical processing, heat processing, rendering, purification [non-chemical/solvent] extraction, hydrolysis, enzymolysis or fermentation, but not having been produced by or subject to a chemically synthetic process and not containing additives or processing aids that are chemically synthetic except in amounts as might occur unavoidably in good manufacturing practices."

[47] Australian Competition & Consumer Commission, Food and beverage industry: Food descriptors guideline to the Trade Practices Act (Nov. 2006), https://www.accc.gov.au/system/files/Food%20descriptors%20guidelines.pdf.

VIII. Recommended Compliance Provisions for FDA to Determine Whether Foods Labeled "Natural" Comply with Criteria for Bearing the Claim

To ensure compliance with a potential "natural" regulation, FDA should exercise post-market evaluation and conduct marketplace surveillance, similar to its evaluation of most other on-pack claims, such as "gluten-free" or "fresh." It would be reasonable to expect manufacturers to maintain records on ingredients and processes used to demonstrate the product meets criteria sufficient to bear the term "natural," including raw material dossiers from suppliers.

IX. Conclusion

GMA appreciates the agency's efforts to engage stakeholders on this issue and the opportunity to contribute to this effort. GMA has outlined general parameters and guiding principles on how the "natural" definition could be applied to ingredients and processing, as well as offered for consideration a tiered-approach for the application of "natural" claims on finished foods and beverages. We recognize the complexity of balancing consumer perception with the technical aspects of food safety and processing technologies that must be considered as the agency explores establishing a definition for the term "natural". GMA welcomes the opportunity and looks forward to working with the agency to address these matters utilizing the information provided in these comments and in other venues, as appropriate.

Thank you for the opportunity to comment on this very important issue.

Sincerely,

Karin F.R. Moore

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Grocery Manufacturers Association