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

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

Dear Sir or Madam:

The Institute of Food Technologists (IFT) appreciates the opportunity to provide comments on the “Use of the Term “Natural” in the Labeling of Human Food Products.” Founded in 1939, the Institute of Food Technologists is committed to advancing the science of food. Our non-profit scientific society—more than 17,000 members from more than 95 countries—brings together food scientists, technologists and related professionals from academia, government, and industry.

IFT offers the following comments for the agency’s consideration.

Recommendations:

- To reduce or prevent consumer confusion and misinterpretation of the term “natural” on food packages, the Food and Drug Administration (FDA) should consider either clearly defining or prohibiting the use of the term “natural” on food labels. Should the agency decide to define the term “natural” for use on food labels, then, IFT recommends that the agency:
 - consider setting standards or guidelines for use of the term
 - seek to harmonize the definition and standards or guidelines among all federal agencies (for example, U.S. Department of Agriculture (USDA), FDA, and Federal Trade Commission (FTC))
 - engage in consumer education about:
 - definition of the term “natural,” and standards or guidelines
 - how specific foods and ingredients with or without the “natural” label fit into their dietary patterns
 - the meaning of the absence of the term “natural” on food labels, and that its absence does not necessarily mean that the food is unsafe or unhealthy
 - provide a brief explanatory label descriptor to accompany the term, regarding what is meant by the use of the term “natural”
 - carefully consider whether modern genetic modification techniques should be included or excluded in the definition of “natural”
 - carefully consider the critical roles (for example, food safety, preservation, nutritional quality, convenience, availability) of various food processing technologies.

Responses to questions raised by the FDA:**Q1) Should we define, through rule making, the term “natural?” Why or why not?**

The label on food packages is valuable to consumers if it provides science-based information about the food they are eating and helps them in making informed purchasing decisions. There is an increasing demand for foods and beverages labeled “natural;” however, as discussed below, the lack of clear definition and/or standards or guidelines has led to consumer confusion, misinterpretation, and misuse of the term.

The term “natural” is being interpreted differently by different people. The current policy related to the use of the term “natural” on food labels is vague and leads to misinterpretation, confusion, and misuse of the term, and can lead consumers to make judgements that are not scientifically accurate. For example, the 2015 Consumer Reports’ National Research Center survey reported that consumers think that “natural” labeling on food means that no toxic pesticides (63%), no artificial materials or chemicals (62%), no artificial ingredients or colors (61%), and no GMOs (60%) were used; and that the “natural” claim is verified (45%), whereas that may not be the case. Further, a greater percentage of consumers believe that the “natural” label should mean that no toxic pesticides (84%), no artificial materials or chemicals (85%), no artificial ingredients or colors (84%), and no GMOs (82%) were used in producing the food. Furthermore, those consumers (62%) who buy food labeled “natural” are even willing to pay more if the food labeled “natural” meets their expectations (87%), and three-fourths of the 38% of consumers who currently do not buy food labeled “natural” would do so if the label meets their expectations (Consumer Reports National Research Center 2015).

According to the Food & Health Surveys by the International Food Information Council (IFIC) there is a slight increase in the number of consumers (40% in 2015 vs. 37% in 2014) purchasing foods and beverages because they are advertised as “natural” on the label (IFIC 2014, 2015).

Consumers are skeptical of the term “natural” on a label, however, they still look for it and find value in it. For example, about two-thirds of consumers believe “when I see products labeled as ‘all natural,’ I think it’s healthy.” While this statement may or may not be accurate, it is important to acknowledge that consumers believe that “natural” and “healthy” are largely linked (Dornblaser 2013). Another survey found that 63% of consumers thought that sugars that are naturally found in food and beverages are more healthful than other sugars (IFIC 2015). Use of the term “natural” then should not mislead consumers into thinking that these foods are superior in some manner when in reality they are comparable in health and safety to other foods not bearing the term “natural.” It is important that any rulemaking be science-based and clarifying, and not perpetuate inaccurate consumer perceptions.

To reduce or prevent consumer confusion and misinterpretation of the term “natural” on food packages, the FDA should consider either clearly defining or prohibiting the use of the term “natural” on food labels. Should the agency decide to define the term “natural” for use on food labels, then, IFT recommends the following:

- in addition to defining the term “natural,” consider setting standards or guidelines, as USDA has developed for the term “organic,” which lay out criteria for food to be included or excluded from the potential to bear a “natural” label, and to clarify if one, more, or all criteria are needed for a product to be labeled as “natural”
- seek harmonization of the definition and standards or guidelines across all federal agencies (for example, USDA, FDA, and FTC) who regulate labeling of food and

- beverage products sold and consumed in the United States. Inconsistency will result in consumer confusion, misinterpretation, and misuse of the “natural” label
- engage in consumer education about:
 - the definition of the term “natural” and standards or guidelines to avoid confusion, misinterpretation, and misuse of the term “natural” on the food label
 - how specific foods and ingredients with or without the “natural” label fit into their dietary patterns
 - the meaning of the absence of “natural” label on foods, and that its absence does not necessarily mean that the food is unsafe or unhealthy
 - provide a brief explanatory label descriptor to accompany the term, regarding what is meant by the use of the term “natural.”

Q2) If we were to revise our policy regarding the use of the term “natural” or engage in rulemaking to establish a regulatory definition for “natural,” should certain production practices used in agriculture, for example, genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices, be a factor in defining “natural?” Why or why not?

The transfer and exchange of genetic material occurs in nature without human intervention. For centuries humans have shaped the development of new plants and animals by cross pollination and breeding for specific traits. In recent years, gene technology has enabled the transfer of specifically targeted traits from one organism to another, dramatically reducing their random nature, the time needed to express the improved trait, and the ability to identify a plant or animal with the desirable traits. Products in the marketplace that were made available through newer technologies have not been found to differ in safety from those produced using older methods (ILSI 2004; Preston 2005; Chassy and others 2007; Flachowsky and others 2007; Snell and others 2012; Zhu and others 2013; Biology Fortified, Inc.).

A survey conducted by IFIC found that the majority (66%) of consumers agree that the overall healthfulness of a food or beverage is more important than the use of biotechnology (genetic modification) (IFIC 2015). Only 6% disagree somewhat with this statement and 4% disagree strongly. Therefore, the healthfulness of the food is the most important consideration for the majority of consumers.

IFT recommends the agency carefully consider whether modern genetic modification techniques should be included or excluded in the definition of “natural.”

Q3) Should manufacturing processes be considered in determining when a food can bear the term “natural?” For example, should food manufacturing processes, such as drying, salting, marinating, curing, freezing, canning, fermenting, pasteurizing, irradiating, or hydrolysis, be a factor in defining “natural?”

The most common definition of natural found in dictionaries is “existing in nature and not caused by people.” As stated on the agency’s website “from a food science perspective, it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is no longer the product of the earth” (FDA 2016). Based on the above, very few foods and beverages that are currently consumed would qualify as “natural,” and would preclude all forms of processing, including those conducted at home by consumers such as washing, cleaning, cooking of raw foods

such as vegetables, grains, legumes, and meats. Given the importance that many consumers attach to the term “natural,” limiting the use of the term to such foods may lead in some instances to an unintended consequence of increased food safety risk.

Most foods such as grains, legumes, fresh meat, some vegetables and other foods at the least need to be cooked to make them safe for consumption, and to improve edibility, digestibility and palatability. Cooking—the original form of food processing—began about 2 million years ago with the discovery of fire (Wrangham 2009). Later, other methods such as fermenting, drying, preserving with salt, and other forms of food processing were developed. Humans first learned how to cook food, then how to transform, preserve, and store it safely. This experience-based technology led to modern food processing (Hall 1989; Floros 2008; IFT 2010). Processing of a food or beverage includes technologies and processes that transform raw food materials and ingredients into consumer food products. The purpose of food processing has evolved primarily from preservation and safety to address one or more of the following: quality, availability, convenience, innovation, health and wellness, sustainability, and post-harvest losses (IFT 2010).

A perception among some is that food processing that could be conducted in a home kitchen is more natural (and better for you) than other, presumed more complex, “industrial” food processing. Yet, the majority of food processing identified in this question can be conducted at home. The food industry implements ways to scale up home processing techniques to produce affordable foods in a safer environment. The chemical changes that occur through the use of these techniques are usually better controlled and hence better defined and often more limited than those that can arise in techniques used in the home.

The USDA/FSIS’s Food Standards and Labeling Policy (USDA/FSIS 2005) allows for foods to bear “natural” claims that are produced using “(a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices.” However, with advances in food science and technology, newer technologies (for example, microwave and ohmic heating, ultra-high pressure, pulsed electric fields, ultrasonic waves, and pulsed light) are used to achieve food safety (for example, high pressure processing to reduce pathogens), improve public health (for example, enzymolysis to reduce sugars, modified atmosphere to maintain nutrient content), meet the demands of efficiency and accessibility (for example, ultra-high temperature milk), and minimize cost (for example, spray drying) (IFT 2010). While the criteria to make food edible and/or safe are important and laudable, they can be highly complex when implemented on a large scale. Hence, limiting the term “natural” to a list of “traditional processes” similar to those in the USDA/FSIS Policy will create multiple anomalies and should be considered with caution.

Most of the above mentioned food manufacturing drivers of change (for example, enhancing food safety, increasing food availability and convenience, minimizing cost, and enhancing health and wellness) relate to consumer desires and demands, as well as marketplace forces relative to consumer food behavior. All of these drivers have to be equally considered in developing a regulated definition of the claim “natural.” Further, methods of food manufacturing are only one aspect of delivering food to consumers, an aspect that is inextricably linked to methods and technologies for growing, producing, harvesting, storing, processing, packaging, warehousing, and distributing foods. Any rationale to include or exclude food manufacturing processes in a regulatory definition of “natural” must not only consider the basis for using the technology or method, but also the steps in the chain

preceding and following the delivery of safe, nutritious, and affordable foods accessible to all consumers. Therefore, the degree of complexity that a definition would require to include food manufacturing processes as a component would make applying it almost insurmountable today. Furthermore, with the rate of advances in food manufacturing and technology methods, and ever-changing consumer demands and behaviors, applying a food manufacturing component in the definition would soon be outdated. Notwithstanding the complexity of factoring in food manufacturing processes in a definition, consumers are confused by the term “natural” (Consumer Reports National Research Center 2015) and could benefit from labeling on-package or off-package (for example, on websites) that states the manufacturing methods that make the food “natural” in the view of the manufacturer in an effort to be transparent.

IFT recommends the agency give careful consideration to the critical roles (such as food safety, preservation, nutritional quality, convenience, and availability) of various food processing technologies, should the agency decide to further examine and develop a definition and standards or guidelines related to processing technologies for “natural” labeling.

Q4) Should the term “natural” only apply to “unprocessed” foods? If so, how should “unprocessed” and “processed” be defined for purposes of bearing the claim? If the term natural should include some processing methods, what should those methods be? In making determinations related to processing, should one look at the process to make a single ingredient of a food, or does one evaluate the process done to the formulated finished food product (or both)?

This is a three part question and each part is addressed separately below.

Q4a) Should the term “natural” only apply to “unprocessed” foods? If so, how should “unprocessed” and “processed” be defined for purposes of bearing the claim?

Unprocessed is generally defined as “unaltered from an original or natural state; not processed” (Oxford Dictionaries 2016). Most foods are processed to some degree, sometimes using techniques which have been used for centuries. There is growing confusion surrounding processed foods. A scientific review by IFT describes processing as “one or more of a range of operations, including washing, grinding, mixing, cooling, storing, heating, freezing, filtering, fermenting, extracting, extruding, centrifuging, frying, drying, concentrating, pressurizing, irradiating, microwaving, and packaging” (IFT 2010). Efforts have been made to describe foods by differentiating them based on the level of processing, which has led to the terms such as “unprocessed” or “minimally processed” foods, “processed culinary ingredients.” However, it is important to recognize that all classification schemes are somewhat arbitrary, and that a subjective definition based on the extent of processing does not characterize foods in a helpful manner. Based on consumer focus group findings, IFIC has developed a set of definitions for processed foods on the basis of the level of processing (IFIC 2010; Weaver and others 2014).

IFIC’s categories of processed foods (IFIC 2010):

- Foods that require little processing or production (also called “minimally processed”), for example, washed and packaged fruit and vegetables, bagged salads, and roasted and ground nuts.
- Foods processed to help preserve and enhance nutrients and freshness of foods at their peak, for example, canned tuna, beans, and tomatoes, and frozen fruits and vegetables.

- Foods that combine ingredients such as sweeteners, spices, oils, flavors, colors, and preservatives to improve safety and taste and/or add visual appeal (does not include “ready-to-eat” foods), food example, packaged foods such as instant potato mix, cake mix, rice, and jarred tomato sauce.
- “Ready-to-eat” foods needing minimal or no preparation, for example, breakfast cereal, flavored oatmeal, crackers, jams and jellies, nut butters, ice cream, and yogurt.
- Foods packaged to stay fresh and save time, for example, prepared deli foods and frozen meals, and pot pies.

As can be noted from the above categorization, virtually all foods are processed to some degree, (for example, fresh produce may be washed and bagged, nuts may be shelled, and grains have outer coatings removed), thereby, leaving very few foods (for example, certain unrinsed produce) which would qualify as unprocessed based on the above definition. It will be very difficult to categorize foods as “natural” based on the degree of processing. If the definition of “natural” were limited to unprocessed foods, very few foods would be able to bear the “natural” label.

Q4b) If the term natural should include some processing methods, what should those methods be?

This is addressed above in Q3.

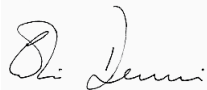
Q4c) In making determinations related to processing, should one look at the process to make a single ingredient of a food, or does one evaluate the process done to the formulated finished food product (or both)?

As discussed above in Q3, the purpose of food processing has evolved primarily from preservation and safety to address one or more of the following: quality, availability, convenience, innovation, health and wellness, sustainability, and post-harvest losses (IFT 2010).

IFT recommends the agency give careful consideration to the roles (such as food safety, preservation, and nutritional quality) of various processing technologies whether applied to a single ingredient or finished food product, should the agency decide to examine and develop a definition and standards or guidelines related to processing technologies for “natural” labeling.

Thank you for your consideration of IFT’s comments on the proposed rule. Please contact Farida Mohamedshah, Director, Food Health & Nutrition, (fmohamedshah@ift.org; 202-330-4986) if IFT may provide further assistance.

Sincerely,



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Executive Vice President & CEO

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