May 10, 2016

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

The Biotechnology Innovation Organization (BIO) is pleased to submit these comments to FDA in response to FDA's request for information on the use of the term "natural" on food labeling (docket no. FDA-2014-N-1207). BIO is the world's largest biotechnology trade association, representing companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than thirty other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

SUMMARY

BIO respectively notes the following as a general matter:

First, we believe that the term "natural" may permissibly be used for food products irrespective of whether certain production practices, including genetic engineering and other modes of biotechnology, were used in some way that can be traced to the creation, development, production, or finishing of the products. The use of the term "natural" is appropriate in the labeling of food products that are genetically engineered, are derived in some way from genetically engineered organisms, or contain ingredients, additives, enzymes, or processing aids produced through the use of genetic engineering.

Second, we believe that if biotechnology, including a processing aid or enzyme derived from or utilizing biotechnology, was used in the production, processing, or sourcing of a food ingredient, that fact should not affect whether a food containing that ingredient may be labeled as "natural."

Finally, we offer a brief comment noting the broad scientific and regulatory consensus supporting the safety of foods improved through modern biotechnology, which FDA itself has recently and appropriately reaffirmed.

SPECIFIC QUESTIONS

FDA is soliciting comment on the following questions, among others, relating to the labeling of foods as "natural":

1. 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?

2. 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)?

3. The current policy regarding use of the term "natural" hinges in part on the presence or absence of synthetic ingredients. For example, under the current policy synthetic forms of Vitamin D would not be used in a food claiming to be "natural," whereas naturally sourced Vitamin D (e.g., from salmon or egg yolks) could be. Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as "natural?" Please explain your reasoning.

DISCUSSION

Addressing these questions insofar as they pertain to the use of biotechnology in agriculture or food production, we state that the term "natural" may permissibly be used for food products irrespective of whether certain production practices, including genetic engineering and other modes of biotechnology, were used in some way that can be traced to the creation, development, production, or finishing of the products. As further explained below, even the most traditional forms of agriculture and food production/processing have been deeply shaped by human action and human decisions. If natural means the absence of human influence, then no agricultural or food production activity is natural; all agriculture, and all human foods, bear the mark of human innovation, human intervention, or human choice. We thus perceive no sound legal or policy basis for forbidding certain food products from being labeled or described as "natural" simply because certain breeding methods or other production practices were used at some point in the process that resulted in those products. Accordingly, the use of the term ''natural'' is appropriate in the labeling of food products that are genetically engineered, are derived from genetically engineered organisms or their products, or contain ingredients, additives, enzymes, or processing aids produced through the use of genetic engineering.

Five considerations have particular weight in supporting this conclusion. First, modern biotechnology is a refinement of breeding techniques that have been used to improve plants and animals for thousands of years. The 20th century, in particular, saw the development and application of many new techniques based on advances in science to genetically improve crops, livestock, and microbes. For example, many plant varieties that are now common were developed decades ago through radiation and chemical

mutagenesis, which are methods directed by humans; indeed, plant varieties produced through these methods are used in organic food production. And many microorganisms used to ferment food, such as alcoholic beverages and cheese, were genetically improved in the decades before the advent of modern biotechnology. The same is true of many microorganisms that provide substances, such as processing aids and enzymes, that are used in food production and processing.

Second, looking further back in human history, all agriculture (including organic agriculture) has been fundamentally shaped and altered by human intervention, including the crops and livestock that farmers grow for food and the fruits, vegetables, and flowers that appear in our gardens. Humans – who, of course, are part of nature, in a fundamental sense –invented agriculture 10,000-12,000 years ago. Long ago, for example, early farmers crossed two unrelated species of grass to develop the species we now call wheat. Over the centuries, all agricultural plants and animals have been genetically changed intentionally through human intervention. The wild relatives that served as the forebears of our crop varieties and livestock breeds are natural, and they still persist in nature. Their descendants were bred and developed by humans. Conventional or otherwise, they are the result of humans modifying the genome of the plant or animal to accentuate a trait or impart a new trait by various methods, including hybridization, grafting, or, more recently, mutagenesis. In recent years, we have developed more precise and selective approaches to breeding for beneficial traits compared with earlier and more haphazard technologies, which imparted both negative and positive characteristics from which the breeder had to select or continue to rebreed; but the basic principles are the same. In a fundamental sense, humans did not "discover" our crops or livestock species; we invented them.

Third, many, if not most, of our existing agricultural crops, animals, and microorganisms cannot survive without human aid – precisely because the genetic changes that humans have deliberately guided and introduced in them over many centuries. Humans have created artificial environments that allow crop plants, animals, and microorganisms to survive and reproduce. They are dependent on humans for their survival and reproduction, as we depend on them.

Fourth, many of the tools used to genetically engineer plants and animals are tools that come from nature as defined in the most traditional sense. Many enzymes used to insert genes into plants, and vectors that plant breeders used to deliver genes into plants, are derived from nature, traditionally understood. And many organisms found in nature, such as certain bacteria and viruses, are capable of inserting their own genes into the genetic material of other organisms — a naturally-occurring process that humans have now learned to adapt for our own beneficial purposes, which is used in the development of many products of biotechnology.

Fifth, as FDA acknowledges in the request for information, FDA's longstanding policy concerning the use of the term "natural" was not intended to address production methods such as the use of genetic engineering or other forms of genetic modification,

nor did it explicitly address food processing or manufacturing methods. To depart now from FDA's settled policy would risk creating consumer confusion.[1]

In light of these considerations, the use of the term "natural" is appropriate in the labeling of food products that are genetically engineered, were produced by a genetically engineered organism or its products, or contain ingredients, additives, enzymes, or processing aids produced through the use of genetic engineering. In other words, a food or food product may bear the "natural" claim irrespective of whether it was derived from or developed using biotechnology or contains ingredients derived from products of biotechnology. The use of particular breeding techniques and methods to breed a plant or animal variety is not relevant to whether particular plants or animals, or food products derived from them or containing ingredients derived from such plants or animals, may be labeled as "natural." We thus agree with the citizen petition filed by the Grocery Manufacturers Association (GMA) requesting FDA to issue a regulation that would expressly allow the use of "natural" and similar terms for foods that are or contain foods derived from biotechnology.

For similar reasons, we believe that the term "natural" should not be limited to "unprocessed" foods. At minimum, the use of processing aids or enzymes in the production of a food should not disqualify the food from bearing the label "natural." And the specific manner in which an ingredient is produced or sourced does not necessarily affect whether a food containing that ingredient may be labeled as "natural." Many new or newly refined techniques used to produce or source food ingredients are deeply grounded in or reliant on natural phenomena and processes. And biotechnology methods, in particular, are often used to strengthen and benefit our natural environment.

A NOTE ON SCIENCE AND REGULATION

In considering this topic, it is important to note that there are hundreds of scientific studies supporting the safety of foods improved through biotechnology, including studies from the most credible scientific authorities in the world. The National Academies of Sciences, the United Nations Food and Agriculture Organization, the World Health Organization, the American Medical Association, and independent scientists and academicians – just to name a few – have concluded that foods that are genetically engineered, or that contain genetically engineered ingredients, are as safe to eat as any other foods.

- "[N]o effects on human health have been shown as a result of the consumption of [GM] foods by the general population in the countries where they have been approved." World Health Organization, *Frequently asked questions on genetically modified foods* 3 (May 2014), http://goo.gl/3QA0FZ.

[1] For this and other reasons, we think that the extreme option of simply prohibiting the use of the term "natural" in connection with food labeling (a possibility that FDA raises in its request for information) would be unwise and impractical, as well as highly controversial.

- "[E]very other respected organization [in addition to the EU] that has examined the evidence has come to the same conclusion: consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques. . . . GM crops are the most extensively tested crops ever added to our food supply." American Association for the Advancement of Science ("AAAS"), *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods* 1 (Oct. 20, 2012), http://goo.gl/82vY0A.

- "Foods derived from GM crops have been consumed by hundreds of millions of people across the world for more than 15 years, with no reported ill effects (or legal cases related to human health) despite many of the consumers coming from that most litigious of countries, the USA." Suzie Key et al., *Genetically Modified Plants and Human Health*, 101 J. of the Royal Soc. of Med. 290, 292–93 (2008), http://goo.gl/h7JAUD.

- "[N]o adverse health effects attributed to genetic engineering have been documented in the human population." National Academy of Sciences ("NAS") Report, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* 180 (2004), https://goo.gl/0a1nKO.

- In 2000, the National Research Council confirmed NAS's conclusion, outlined in a 1987 NAS white paper, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*, http://goo.gl/yqoL2a, that GE crops are as safe to grow as non-GE crops and, further, found no evidence that GE crops are unsafe to eat. *See* National Academy of Sciences, *Genetically Modified Pest-Protected Plants: Science and Regulation* 5–6, 8 (2000), http://goo.gl/J8sLFI.

- "[F]ood derived from GM plants approved in the EU and the US poses no risk greater than those from the corresponding 'conventional' food. On the contrary, in some cases food from GM plants appears to be superior with respect to health." Union of the German Academies of Science and Humanities, Commission Green Biotechnology, InterAcademy Panel Initiative on Genetically Modified Organisms, Group of the International Workshop Berlin 2006, *Are there health hazards for the consumer from eating genetically modified food*? 1, http://goo.gl/5z5CtN.

- "If we look at evidence from [more than] 15 years of growing and consuming GMO foods globally, then there is no substantiated case of any adverse impact on human health, animal health or environmental health, so that's pretty robust evidence, and I would be confident in saying that there is no more risk in eating GMO food than eating conventionally farmed food." Anne Glover, Chief Scientific Adviser, European Commission, *GE Food Poses No Risk*, Crop Biotech Update (Aug. 3, 2012), http://goo.gl/eCLypB.

- "The overwhelming evidence is that GM foods now on the market are as safe, or safer, than non-GM foods." Nina Fedoroff, Food in a future of 10 billion, 4 Agriculture & Food Security 5 (2015), http://goo.gl/Ru41d1.

These statements are supported by an abundance of scientific research, including a significant compilation funded by the European Union involving over 130 research projects, conducted over a 25-year period by more than 500 independent research groups.[2]

Moreover, extensive scientific studies have concluded that the use of genetically engineered crops is safe – and in most cases, even beneficial – for the environment. In fact, the National Academies of Sciences study, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, concluded that use of genetically engineered crops has resulted in "lower production costs, fewer pest problems, reduced use of pesticides, and better yields – compared with conventional crops."

Agricultural biotechnology products in the United States are regulated according to the Coordinated Framework, which includes oversight by as many as three different federal agencies:

- The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS)

- The FDA's Center for Food Safety and Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)

- The U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP)

The U.S. regulatory system employs rigorous scientific reviews within a transparent decision-making framework together with independent peer review of key science policy issues and regular opportunities for public participation. FDA assesses the safety of biotechnology-derived foods under the same high standards as any other food products and has consistently found biotechnology-derived foods to be as safe and nutritious as those produced through more conventional technologies. And genetically engineered plant varieties are subject to premarket field testing and review under the oversight of the USDA, EPA or both.

Once a biotechnology-derived food has been cleared for commercialization, federal officials are authorized to take action should any new information come to light indicating a potential safety issue. After over two decades of intensive regulatory, commercial, and academic oversight, there is no evidence to suggest that any

[2] JoAnna Wendel & Jon Entine, Genetic Literacy Project, *With 2000+ global studies affirming safety, GM foods among most analyzed subjects in science* (Oct. 8, 2013), http://goo.gl/VC4o2E; *see also* GENetic Engineering Risk Atlas (GENERA) Database, http://genera.biofortified.org/viewall.php; European Commission, *A Decade of EU-funded GMO research, 2001-2010*, http://goo.gl/Y3Q3bp.

biotechnology-derived foods on the market today have had any adverse effect on health, safety or the environment. Indeed, FDA very recently reaffirmed its longstanding, science-based position that FDA does not believe that foods produced through the use of genetic engineering differ from foods developed through traditional methods in any meaningful or uniform way. FDA does not believe that as a class, foods produced through the use of genetic engineering present any different or greater safety concern than foods developed through traditional methods.[3]

Thank you for your time and consideration.

Sincerely,

Brian Baenig
Executive Vice President, Food and Agriculture
Biotechnology Innovation Organization

[3] *See* FDA, *Statement of Policy: Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992); Letter from FDA Associate Commissioner Leslie Kux to Andrew Kimbrell, at 2, 6, 12, 26, 30-31 (Nov. 19, 2015) (denying citizen petition asking FDA to require labeling for GE foods and foods with GE ingredients) (http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0723-0788); *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (Nov. 2015) (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm).