SINCE 1985 Organic trade association

April 25, 2017

U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket: FDA-2016-D-2335

RE: Use of the Term "Healthy" in the Labeling of Human Food Products

Thank you for this opportunity to provide comment on the use of the term "healthy" in the labeling of human food products.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, health practitioners, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The U.S. Food and Drug Administration (FDA) plays a key role in ensuring that consumers have the information they need to achieve a healthy diet. Therefore, OTA is pleased to see FDA taking steps towards updating its "healthy" regulation through a public comment opportunity.

FDA is requesting feedback on the following question:

> Is the term "healthy" most appropriately categorized as a claim based only on nutrient content? If not, what other criteria (*e.g.*, inclusion of foods from specific food categories) would be appropriate to consider in defining the term "healthy" for use in food labeling?

OTA encourages FDA to consider additional criteria to help shape an updated definition for "healthy." We agree with many other stakeholders that the criteria for healthy should go beyond the nutrient content of a food product alone and take into consideration nutrient-dense whole foods and healthy eating patterns in accordance with the 2015-2020 *Dietary Guidelines for Americans*. We also believe that food production systems ultimately impact the quality and characteristics of food, and accordingly, it would be appropriate to consider such factors when defining the term "healthy" in food labeling.

The organic food industry in the United States has grown in annual sales from $3 billion in 2001 to nearly $40 billion in 2015. A niche industry in the huge food sector just a decade ago, organic food now accounts for nearly 5% of the $807 billion annual food sales in the United States. The growth rate of organic food sales, which has averaged just over 12% per year since 2005, has dwarfed the average annual growth of 3.5% in total food sales during that same period. Consumer demand for organic products continues to show double-digit growth with no signs of slowing. Consumers are not just eating organic; they are incorporating organic into their lifestyle.

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While the potential health benefits of organic food are not specifically raised as a question in FDA's notice for public comment, OTA believes it will become increasingly important to consider such criteria in future discussions, especially as the demand for organic grows and more scientific research on the attributes of organic food production becomes available.

For example, a broad, recent study[1] published in the *British Journal of Nutrition* found that organic produce has up to 69% higher antioxidant levels than their conventional counterparts. Studies have also shown that organic production of dairy and meat results in a more nutritious fatty acid profile than their conventional counterparts. Last year, two papers were published showing that organic milk[2] and meat[3] contain about 50% higher levels of beneficial omega-3 fatty acids than conventionally produced products. They also show that organic meat had lower concentrations of two saturated fats, and that organic milk and dairy products contain 40% more of the heart-healthy conjugated linoleic acid (CLA) than their conventional counterparts. Despite marginally lower iodine levels, organic milk had several beneficial increases in nutritional minerals and antioxidants, such as higher concentrations of iron, vitamin E, selenium, and carotenoids

A growing body of research also provides evidence that avoiding pesticide residues in your diet is critical for reducing health risks. Significantly, in 2010, the President's Cancer Panel, originally established by law in 1971 when the National Cancer Act was signed by President Richard Nixon, produced a report[4] with advice on ways to reduce environmental cancer risk. The panel, appointed by President George W. Bush, found that "[e]xposure to pesticides can be decreased by choosing, to the extent possible, food grown without pesticides or chemical fertilizers…. Similarly, exposure to antibiotics, growth hormones, and toxic run-off from livestock feed lots can be minimized by eating free-range meat raised without these medications." These attributes describe required practices in USDA certified organic agricultural production.

Emerging research continues to show the role that production practices – particularly organic practices – play in ultimate nutritional outcomes and human health. At the same time, American consumers are increasingly interested in the benefits of organic food production systems and how their consumption habits affect human health. As a result, they seek guidance on complicated decisions regarding the confluence between diet, nutrition, and food production practices.

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[1] Barański, M., et al., *Higher antioxidant and lower cadmium concentrations and lower incidence of pesticide residues in organically grown crops: a systematic literature review and meta-analyses.* British Journal of Nutrition, 2014. **112**(5): p. 794-811.

[2] Srednicka-Tober, D., et al., *Composition differences between organic and conventional meat: a systematic literature review and meta-analysis.* Br J Nutr, 2016. **115**(6): p. 994-1011.

[3] Średnicka-Tober, D., et al., *Higher PUFA and n-3 PUFA, conjugated linoleic acid, α-tocopherol and iron, but lower iodine and selenium concentrations in organic milk: a systematic literature review and meta- and redundancy analyses.* British Journal of Nutrition, 2016. **115**(6): p. 1043-1060.

[4] "Reducing Environmental Cancer Risk: What We Can Do Now," submitted to President Obama by Dr. LaSalle Leffall Jr., an oncologist and professor of surgery at Howard University, and Dr. Margaret L. Kripke, an immunologist at the M.D. Anderson Cancer Center in Houston.

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Going forward, OTA would like to encourage FDA to consider ways to incorporate the contribution of organic production practices and their impact on the quality and characteristics of food into your discussions on the use of the term "healthy" in the labeling of food products. Emerging evidence continues to support the connection between food production practices and our diets, and consumers are becoming more and more interested in the food-to-table movement with an aim to know where their food comes from and how it is produced. We believe that a commitment to organic agriculture is a commitment to the nutrition of American eaters, and that organic agriculture can be a key tool as you focus on the health of the American public.

On behalf of our members across the supply chain and the country, OTA again thanks FDA for the opportunity to comment on this important topic. We fully support FDA's efforts in ensuring that its nutrition labeling regulations reflect current federal dietary recommendations and enable shoppers to make choices that support healthy eating decisions and food choices. OTA, and the organic sector in general, look forward to being a partner with you as you update definitions and develop guidance to ensure the health of American families.

Respectfully submitted,

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cc: Laura Batcha
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