Tufts UNIVERSITY | Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy | FOOD & NUTRITION INNOVATION INSTITUTE

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via http://www.regulations.gov

Re: Docket No. FDA-2016-D-2335 for Proposed Rule on "Food Labeling: Nutrient Content Claims; Definition of Term Healthy"; Fed. Reg. 87 FR 59168 (September 29, 2022)

The Bioactives Working Group of the Food and Nutrition Innovation Institute at Tufts University appreciates the opportunity to comment on the docket regarding the Food and Drug Administration (FDA) proposed definition of "healthy." Hosted by the Friedman School of Nutrition Science and Policy, the Food and Nutrition Innovation Institute is dedicated to building a collaborative, robust, science-driven ecosystem of food and nutrition innovation and entrepreneurship. The Institute's Innovation Council is the largest academically convened food system innovation organization in the world and offers the opportunity for both small and large food and technology companies, healthcare and insurance companies, and community focused non-profits to collaborate on critical needs within national and global food systems.

The Bioactives multi-stakeholder working group aims to translate and advance decades of evidence-based research on dietary bioactive components ("bioactives") and associated health benefits into recommended daily intakes. These recommended intakes can be used to inform and educate healthcare professionals, key public health officials, community-based practices, and individuals; drive scientific research; advance food policy; and communicate the evidence in simple ways that foster individual, community, and corporate action. Our goal is to facilitate a dynamic system of cross-sector collaboration to accelerate the acknowledgment, acceptance, and implementation of bioactives into various food policies to address and improve public health.

We are pleased with FDA's intention to inform and empower consumers to make healthful dietary choices by updating the term "healthy" to reflect the latest scientific evidence. We also applaud FDA for wanting to address diet-related and preventable chronic diseases, such as cardiovascular disease and type 2 diabetes. Like the FDA, we support food labeling regulations that provide guidance at the point of purchase to consumers regarding healthy foods and beverages consistent with science-based evidence, including the Dietary Guidelines for Americans (DGA). However, we feel neither the current nor proposed definition of "healthy" sufficiently capture the role of bioactives, which have been shown to be important for health by improving the quality of life and reducing the incidence of major chronic diseases. We are

concerned the proposed definition of "healthy" will reduce or constrain daily intake of these critical components in the diet while limiting emerging food innovation by not allowing flexibility to deliver foods and beverages providing bioactives, particularly those outside the framework of food groups.

Bioactives have been defined as "constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs that are responsible for changes in health status."[1] Most bioactives are plant compounds with demonstrated health benefits and commonly found in berries, cocoa, coffee, herbs, tea, tisanes, tomatoes, spices, and other foods and beverages. The beneficial effects of bioactives have been described widely in the scientific literature with advances evident from recent guidelines developed on a daily recommended intake for flavan-3-ols, a sub-category of flavonoids.[2-10]

We appreciate FDA attempting to align the proposed definition of "healthy" to recommendations within the 2020-2025 DGA that provides a framework of recognized and scientifically substantiated food groups supporting healthy and well-balanced dietary patterns. Importantly, most of these food groups are under-consumed or paired with nutrients to limit (e.g., added sugars, saturated fats, sodium). The proposed definition excludes low-calorie and non-caloric beverages that contribute significant amounts of bioactives, such as carotenoids and flavonoids, to the intake of the US population. For example, unsweetened coffee and tea as well as some juices can substantially contribute to increasing the intake of these health-promoting compounds. However, unsweetened coffee and tea are not categorized in a food group but also provide hydration without calories or added sugars. Thus, to address the question put forth by FDA, we support the inclusion of unsweetened tea and coffee in the definition of "healthy." However, we request FDA re-examine the proposed definition and consider additional criteria to enable foods and beverages rich in bioactives to bear the claim of "healthy" without the food group requirement.

While the FDA's proposed definition of "healthy" is aligned with current nutrition science and DGA-supported recommendations for dietary patterns, the current "healthy" definition allows the possibility to claim "healthy" for nutrient-dense foods with certain shortfall nutrients, including dietary fiber and select vitamins and minerals, that also deliver health-promoting bioactives. In the proposed definition, only the inclusion of identified food groups allows products to claim "healthy", which can potentially lead to reducing the intake of essential nutrients and bioactives in the diet and widening the gap of identified shortfall nutrients as well as consumption of bioactives. This condition limits the education and impact of nutrition labeling in driving consumers to purchase healthier options and thus not improving upon an overall healthy dietary pattern. The proposed definition should consider the inclusion of language that highlights the benefits of the eating of fruits and vegetables beyond the intake of essential nutrients, including the beneficial effects of consuming bioactives. Additionally, fruits and vegetables in more processed forms, such as tomato sauces and tomato ketchup, can also deliver highly bioavailable carotenoids in meaningful quantities.[7]

While scientific evidence has long supported the health properties of bioactives, there are recent approaches for guidance in determining how much we need to consume of a class of bioactives that can inform the FDA in the development of the definition of "healthy".[1,12,13] Recently, an expert panel of scientists convened by the Academy of Nutrition and Dietetics, funded through The Institute for the Advancement of Food and Nutrition Science, independently reviewed, developed, and published daily recommendations for flavan-3-ol consumption. This scientific panel followed a four-step framework

designed to develop evidence-based recommendations for safe and effective intakes of bioactives that have broader effects on promoting health rather than primarily preventing deficiency or decreasing chronic disease risk.[1] Based on the latest available data, Americans fail to consume sufficient levels of flavonoids, a prominent class of bioactives with well-established health benefits. Among all individuals aged 2 years and over, the mean estimated daily intake of total flavonoids is 185 mg, significantly lower than the new recommended daily intake of 400-600 mg based on the published guidelines for flavan-3-ols alone.[10,11] Recognizing and including bioactives in the definition of "healthy" will help Americans improve their diets and better meet these new recommendations while ultimately supporting their health

Previously, the FDA has acknowledged the benefits of bioactives, albeit in a limited capacity. For example, the consumption of certain cranberry products, including 27% cranberry juice containing bioactive flavonoids such as proanthocyanidins, was acknowledged by the FDA in a qualified health claim to contribute to an important health outcome, i.e., reducing the risk of recurrent urinary tract infections in healthy women. However, without the inclusion of bioactives in the proposed definition of "healthy", the same product could bear a qualified health claim but could not bear a "healthy" nutrient content claim under the current proposal without the equivalent fruit serving criteria. We recommend the FDA reconsider its position on the proposed definition of "healthy" to include those products that meet a qualified health claim.

In summary, we propose FDA expand the definition of "healthy" to include foods and beverages that deliver substantial amounts of bioactives as supported in the scientific literature as well as through recent guidelines published for their daily recommended intake. Recognition and inclusion of bioactives can help improve dietary patterns, contribute to a reduced risk of chronic disease, and improve the quality of life while providing healthy and safe food for the American population. We appreciate the opportunity to provide these comments. If you have any questions or would like to discuss further, please do not hesitate to contact us.

Sincerely,

[a]Katie Stebbins, Executive Director
Food & Nutrition Innovation Institute, Tufts University
[a]Correspondence to: Katie.Stebbins@tufts.edu; 150 Harrison Avenue, Boston, MA 02111

[b]Joy Dubost, PhD, RD, Head of Scientific Affairs & Nutrition
ekaterra
[b]Co-chair, Bioactives Working Group

[b]Christina Khoo, PhD, Director, Emerging Science, Nutrition & Regulatory Affairs
Ocean Spray
[b]Co-chair, Bioactives Working Group

[c]Jeffrey B. Blumberg, PhD, Research Professor
Friedman School of Nutrition Science and Policy, Tufts University
[c]Faculty Advisor, Food & Nutrition Innovation Institute

Signatories from Food and Nutrition Innovation Council:

Angel Santiago Colon, Chief Business Officer
Grupo Navis LLC

Colleen M. Zammer, Vice President of Varietal Solutions Growth & Innovation
Bay State Milling Company

Edwin O. Rogers, Chief Executive Officer
Bonumose, Inc.

Frank Jaksch, Chief Executive Officer
Ayana Bio

Hamed Faridi, Ph.D., Executive Director
McCormick Science Institute

Jan-Willem van Klinken, MD PhD MS FACN, SVP Medical, Scientific & Regulatory Affairs
Brightseed

Judy Seybold, MS, RD, LD, Chief Nutrition Officer
Sifter SP Inc.

Lynn Yu, PhD, RD, Nutrition Lead
The Kraft Heinz Company

Sean Harrington, Founder and General Manager
Notemeal

William W. Li, MD, CEO and Medical Director
The Angiogenesis Foundation

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