

January 31, 2005



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Dr. Leila Saldanha
Office of Dietary Supplements
National Institutes of Health
U.S. Department of Health and Human Services
6100 Executive Blvd., Room 3B01
Bethesda, MD 20892-7517

RE: Solicitation of Written Comments on Proposed Definition of Bioactive Food Components
69 *Federal Register* 55821, September 16, 2004.

Dear Dr. Saldanha:

The National Food Processors Association (NFPA) submits the following comments on the notice referenced above.

NFPA is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. **In 2005, NFPA will become the Food Products Association (FPA).**

NFPA appreciates this opportunity to comment on the work on bioactive food components by the Department of Health and Human Services and the Ad Hoc Federal Working Group on Bioactive Food Components (Working Group). These comments address the general NFPA position on the issue of bioactive food components, and respond to the proposed definition and four questions contained in the *Federal Register* notice.

In general, NFPA is supportive of the recent efforts of the Working Group to develop a framework for considering "bioactive food components." It is indisputable that the critical and fundamental human health requirement for food can be best understood by characterizing and exploring the interrelationships between human needs and the food environment, including the food attributes and components that serve human physiological needs.

Research regarding food and its components or substances helps explain the human health requirement for food and identifies factors that support both normal and optimal human physiology. We know exponentially more about diet, food, and its constituents from the past 20 years of research than was learned during the past century. The spectrum of understood health promotion and disease risk reduction benefits from food will continue to expand as science about diet, nutrition, and health continues to evolve.

NFPA supports the Working Group's desire to establish a definition for "bioactive food components" as a first step toward developing approaches that might be used to assess their health effects, as long as such a definition is not intended for use in any regulatory context. NFPA would object to any regulatory use of such a definition.

We concur that establishing a definition for bioactive food components, in the scientific context, may help in guiding and encouraging future research programs, and that establishing a definition for bioactive food components "may provide science-based information to help guide public health policy on how Americans may choose diets that promote good health."¹ The dietary dimension to the Working Group's efforts is critical.

The Working Group proposed the following definition of "bioactive food components":

*Bioactive food components are constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs, that are responsible for changes in health status.*²

NFPA proposes an alternate definition that we believe more accurately reflects the goals of the Working Group and the bioactive role of diet, food, and food components across the spectrum of normal nutrition and health promotion and chronic disease risk reduction:

Bioactive food components are those food substances that contribute beneficially to supporting health promotion and disease risk reduction in the context of the diet.

NFPA concurs that the broad definition of food should incorporate both conventional foods and dietary supplements.³ It should encompass items that have traditionally been added to foods, such as potentially probiotic organisms and nutrients used to fortify the food supply, whether synthetic or natural. The public health significance of specific "bioactive components" of dietary supplements and other foods that are currently part of

¹ 69 Federal Register 55822.

² 69 Federal Register 55822.

³ The Federal Food, Drug and Cosmetic Act defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article (21 U.S.C. 321(f)). Dietary supplements are defined as "food" as a matter of law by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(ff)).

the diet must be established appropriately. The expenditure of public resources should be targeted in a manner that can be translated and implemented through dietary practices that promise genuine and widespread benefit for public health. The opportunities for advancing public health from the study of “bioactive food components” should be a priority for foods, then food substances, then dietary supplements (food extracts or synthetic equivalents).

In order to be comprehensive, it is important that the definition includes dietary and food sources of bioactive components, and individual isolated components and synthetic substances. The exclusion of “basic human nutritional needs” in the currently proposed DHHS definition is unnecessarily limiting. We recommend its deletion given that the line between what is considered “basic” and what is considered “optimal” naturally evolves over time. Additionally, NFPA believes that “changes in health status” alone in the definition is vague and not necessarily positive. Thus, NFPA prefers a clearer phrase such as “contribute beneficially to supporting health promotion and disease risk reduction in the context of the diet.” As stated above, the alternate proposed definition better reflects the desire for the Working Group’s efforts to promote healthful diets that contribute beneficially to supporting, maintaining and promoting health and processes such as growth, maturation, performance, reproduction, aging, as well as disease risk reduction.

With regard to the specific questions contained in the *Federal Register* notice, NFPA offers the following responses and comments:

(1) What categories/classes of compounds should be considered as bioactive food components?

NFPA believes this DHHS effort should be conducted in the context of the diet and in connection with patterns of dietary consumption of conventional foods with established history of use. All foods are bioactive insofar as food, by its very nature, contributes beneficially to supporting human physiological needs that are essential for life, health, and wellness, including provision of components and substances that provide energy and support body structures and metabolic functions necessary for hydrating, nourishing, growing, maintaining, and repairing the body. This includes water, whole foods, foods made of multiple ingredients, enriched and fortified foods, and supplements to the diet.

A classical definition of nutritional “essentiality” does not encompass the full range of bioactive food components or substances. Bioactivity should be established from scientific evidence associated with benefits with respect to sustaining life, ensuring nutrition, and promoting growth, health, and wellness. For example, science is clear that diets rich in fruits, vegetables, whole grains, lower fat dairy products, and plant and

animal protein sources promote overall health and reduce disease risk.⁴ The contribution to health comes from both individual food components and total diet over time.

A diet composed of solely essential nutrients, consumed at recommended levels, is not sufficient to support optimal health promotion and reduced disease risk. In the future, while not all bioactive food factors may not fit the traditional definition of essentiality as nutrients in the diet, many likely will play important roles in health promotion and disease risk reduction. Thus, in the context of total diet, bioactive food components from foods will exhibit relationships to health in the absence of defined deficiency state.

We also know from history that dietary fiber was not initially identified as an essential nutrient to the diet. However, over time, consensus science demonstrated that dietary fiber is essential for health and wellness from whole food sources, as ingredients in foods, or as dietary supplements. Other examples of food sources of bioactive substances or components with significant roles in the diet, rather than in isolation, include tomatoes (e.g., lycopene), fatty fish (e.g., omega-3 fatty acids), whole grains (numerous substances), green tea (e.g., catechins), soybeans (e.g., phytosterols, isoflavones), fermented dairy products (e.g., probiotic organisms), broccoli (e.g., glucosinolates), or red grapes (e.g., resveratrol).⁵ Many other foods consumed as part of the diet or as ingredients in foods, such as probiotics and natural identical synthetic versions of essential nutrients, will provide significant sources of bioactive food components to support health promotion and reduce disease risk, with or without extraction or concentration.

(2) What categories/classes of compounds should not be considered as bioactive food components? How should the definition be modified to reflect exclusion of these compounds?

Realizing that federal resources are limited for research and evaluation, the Working Group should establish priorities for approaches to evaluate the health effects resulting from consuming foods and bioactive food components. NFPA believes that as the Working Group continues its internal discussion and obtains input from stakeholders, some categories or classes of compounds initially should be excluded as bioactive food components. Categories of food components or synthetic substances that should be excluded include toxins, pathogens, molds, and other contaminants associated with food-borne illness, and components of dietary supplements for which there is no history of use as human food. Additionally, the Working Group should not include items that are

⁴ U.S. Department of Health and Human Services and Department of Agriculture. Dietary Guidelines for Americans 2005. Accessed at <http://www.healthierus.gov/dietaryguidelines/>.

⁵ More detailed discussions of foods, food substances, and food components can be found in the following papers. Institute of Food Technologists. 2004. Functional Foods: Opportunities & Challenges. Report of the IFT Expert Panel on Functional Foods, Fergus Clydesdale, chair. *Food Technol.* 58(12):35-40. American Dietetic Association. 2004. Position of the American Dietetic Association: Functional Foods. *J Am Diet Assoc.* 2004;104:814-826.

considered bioactive only if consumed at levels inconsistent with normal dietary patterns, or do not focus on broad benefit for public health (i.e., one person in a million).

NFPA believes that the definition should not characterize exclusions. Apart from the items described above that we do not consider “bioactive food components,” a set of criteria should be developed by DHHS and the Working Group to help prioritize research, evaluation, and review of bioactive food components, substances, and factors. Although bioactive, the essential nutrients, energy-providing food components, dietary fiber, electrolytes, and water have been evaluated thoroughly as part of the Food and Nutrition Board, Institute of Medicine’s Dietary Reference Intakes (DRI) project.⁶ Criteria should help establish the scientific base and assist in defining research needs on foods, food groups, food substances and components, and probiotic organisms that may be included in or added to foods and beverages. However, since science is always evolving, criteria need to be flexible enough to allow new bioactive components or substances to be included in the prioritization process as they are discovered or become known.

(3) Should essential nutrients be included as bioactive food components?

Yes. NFPA believes that essential nutrients should be included as bioactive food components. However, as stated above, the evaluation of essential health effects of nutrients has been completed through the set of nutrient reports in the Food and Nutrition Board’s DRI project. Thus, food components defined as essential may not need further evaluation through the efforts of the Working Group. On the other hand, as new positive or beneficial health effects emerge regarding essential nutrients, their further study would not be ruled out by the alternate definition proposed by NFPA.

(4) Should synthetically derived components used in fortified foods and dietary supplements be considered under this definition?

Yes. NFPA believes that synthetically derived components used in food fortification and as dietary supplements should be considered under this definition. Our support for this is twofold. First, components in conventional food and synthetic versions of the same component merit inclusion (e.g., vitamin C) for comparative value of bio-equivalence. Second, nutrients required to be added to foods through required enrichment provide critical support for human health by preventing nutrient deficiency (e.g., B vitamins) or reducing disease risk (i.e., folic acid). In addition, as knowledge about bioactive food components evolves, new approaches to improve dietary consumption through foods for health and wellness may require expanding targeted fortification. As knowledge about nutrition and health expands, public health will benefit from a systematic approach to consideration of health promotion and disease risk reduction effects of food components not currently defined as essential nutrients.

⁶ Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes, general overview of project and list of reports. Accessed at <http://www.iom.edu/project.asp?id=4574>.

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Thank you for the opportunity to provide input on the proposed definition of bioactive food components. NFPA looks forward to contributing to the ongoing work of the Ad Hoc Federal Working Group on Bioactive Food Components through its conferences and other forums in 2005 and beyond.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Earl". The signature is fluid and cursive, with the first name "Robert" and last name "Earl" clearly distinguishable.

Robert Earl, MPH, RD
Senior Director for Nutrition Policy

cc: Jennifer Weber, Office of Disease Prevention and Health Promotion, DHHS