



American Dietetic Association
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Leila G. Saldanha
Department of Health and Human Services
c/o Office of Dietary Supplements
6100 Executive Boulevard
Room 3B01
MSC 7517
Bethesda, Maryland 20892-7517

Dear Ms. Saldanha:

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well being. ADA commends the ad hoc Federal working group on its efforts to define the term "bioactive food component."

In May 2004, the ADA published a position paper, "Position of the American Dietetic Association: Functional Foods," which addresses physiologically active components in functional foods. This position states the following:

"... The Association supports research to define further the health benefits and risks of individual functional foods and their physiologically active components. Dietetic professionals will continue to work with the food industry, the government, the scientific community and the media to ensure that the public has accurate information regarding this emerging area of food and nutrition science."¹

ADA supports a hypothesis-driven approach to both the development and evaluation of the efficacy of bioactive food components that advances the science and understanding of bioactive foods. This evaluation must be completed using a scientifically valid risk-benefit model that clearly assesses all physiologic effects, both positive and negative. Review of the in vitro, animal, epidemiological and clinical data is essential before functional foods or bioactive food components are marketed to consumers as health-promoting products.

¹ Position of the American Dietetic Association: Functional foods. *J Am Diet Assoc.* 2004;104:814-826.

Specific Comments

1. Proposed definition:

The ad hoc Federal working group has recommended the definition, “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.”

ADA recommends that the working group consider the more comprehensive definition below. Since the basic dietary nutrients have health promoting, physiological activity, the definition below is more appropriate in guiding public health policy on how Americans may choose diets that promote good health.

Bioactive food components are physiologically active constituents in foods or dietary supplements derived from both animal and plant sources, including those needed to meet basic human nutrition needs, that have been demonstrated to have a role in health and to be safe for human consumption in intended food and dietary supplement uses.

2. Specific comments as requested that relate to the definition:

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

Any physiologically active component that is commonly consumed as food should be considered a bioactive food component. This includes all currently defined and characterized macronutrients and micronutrients.

Since bioactive components vary widely in chemical structure and function, they should be grouped accordingly, such as phenolic compounds and by their subcomponents such as the flavonoids. However, biological activity is affected within a chemical grouping by differences in chemical composition and structure, affecting bioavailability, distribution, metabolism and excretion of individual compounds. Therefore, each individual component within a group or subgroup should be fully characterized. Such differences already have been documented for the vitamins (i.e. vitamin E) and the omega-3 fatty acids.

- (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?

All potentially bioactive food components should be evaluated using a scientifically valid risk-benefit model that clearly assesses all physiologic effects, both positive and negative. Bioactive food components shown to be potentially toxic for the intended food or supplement use according to this analysis would not qualify. ADA recommends that the definition reflect the safety of bioactive food components.

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

Both essential and nonessential nutrients should be considered as bioactive food components based on the specific physiological function they impart, including characterization of their metabolic and physiological functions and associated targets, and biomarkers and confirmed by clinical trial.

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

Synthetically derived compounds possessing the physiochemical properties and biological equivalency of a naturally occurring bioactive food component should also be included in this definition. This definition should also apply to any processed naturally occurring bioactive food component, which might be extracted, concentrated or modified for the purposes of fortifying foods or other dietary supplements.

In addition, bioactive foods and components should be placed into any of the existing regulatory categories, including conventional foods, food additives, dietary supplements, medical foods or foods for special dietary use depending on how the manufacturer selectively positions and markets the product for its intended use and the specific claim associated with the food item.

We hope these comments are useful to the working group as it considers the definition for bioactive food components. Please do not hesitate to call Mary Hager at (202) 775-8277 with any questions or requests for additional information.

Sincerely,

Mary H. Hager, PhD, RD, FADA
Senior Manager for Regulatory Affairs
The American Dietetic Association