

SUMMARY OF COMMENTS RECEIVED IN RESPONSE TO THE *FEDERAL REGISTER* NOTICE¹ DEFINING BIOACTIVE FOOD COMPONENTS

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A *Federal Register* notice issued September 16, 2004, invited public comment on defining bioactive food components. Bioactive food components were defined in the notice, 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.” In addition to inviting comment on the proposed definition, comments were specifically requested on the following questions: (1) What categories/classes of compounds should be considered as bioactive food components? (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? (3) Should essential nutrients be included as bioactive food components? and (4) Should synthetically derived components used in fortified foods and dietary supplements be considered under this definition?

Seventeen written responses were received between September 16, 2004 and February 25, 2005. These responses were primarily from professional and trade groups, a few were from scientists in academia (see Attachment).

There were questions initially as to how the ad hoc Federal Working Group proposed to use the definition and the regulatory implications of the proposed definition. Most industry groups are opposed to the regulatory use of the definition. One group felt that the current regulatory classification system is adequate to describe the safety of all classes of nutrients. These groups subsequently provided written comments, given the intended use, which is, that these comments are being viewed by the ad hoc Federal Working Group as a first step toward developing approaches to assess the health effects of bioactive food components and in helping guide and encourage future research with these components.

Comments on the definition of bioactive food components.

Several alternate definitions of bioactive food components were provided; these are listed in the attachment. Some groups recommended using alternate terms such as “functional” or “physiologically-active” as the term bioactive was too broad, had regulatory implications, or is not consumer friendly. One group felt that the Working Group had begun to take a reductionist versus a more holistic approach to bioactive food components. A repeated comment was the inclusion of essential nutrients in the definition of bioactive food components. Another group strongly opposed the proposed definition, as it excluded essential nutrients. This group also saw no function in defining bioactive food components, as all or most food components are bioactive. Most comments did not distinguish between effects that are associated with and those that go beyond basic human nutrition or meeting basic human nutrition needs. While another group felt that the phrase “changes in health status” is vague and not necessarily positive. Another suggested arriving at a list of attributes, rather than defining the term per se. This group spent considerable time trying to define “functional food,” time in hindsight could have been spent on research.

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

¹ *Federal Register* Vol 69, No 179: Sept 16, 2004, pp 55821-55822

Inclusion of all physiologically active components found in foods, including probiotics, was almost unanimous; that is, there should be no limitations on the categories of compounds that may be considered as bioactive food components. The food industry groups stressed the inclusion of whole foods, functional foods, foods with multiple ingredients, and fortified and enriched foods. Further, that this DHHS effort be conducted in the context of the diet and in connection with patterns of dietary consumption of conventional foods with established history of use. These groups feel that whole foods are in themselves bioactive food components. One group suggested that all constituents considered under the definition of “dietary supplement” in DSHEA be considered, while another suggested including food additives. While another, suggested inclusion of dietary supplements containing natural products and food-based botanicals that provide physiological responses.

(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?

None, as most groups recommended inclusion of all known and potential bioactive components in foods. One group suggested that the definition should not characterize exclusions, but rather establish a set of flexible criteria to prioritize research, review, and evaluation. Pharmaceutical agents, compounds for which there is no history of use as human food, compounds that are not naturally part of a human diet (i.e., synthetic and racemic mixtures that are not chemically equivalent), and those with deleterious physiological response (i.e., contaminants, toxins, and pathogens) were among the list of compounds that should not be considered as bioactive food components. One group suggested excluding nutrients at levels required to meet essential nutritional needs. Another recommended that the definition reflect the safety of bioactive food components and that these components should be evaluated using a scientifically valid risk-benefit model that clearly assesses all physiological effects, both positive and negative.

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

The inclusion of essential nutrients was almost unanimous. A key scientific organization recommended that essential nutrients should be classified as bioactive food components when they have physiological effects at levels beyond those required to meet essential nutritional requirements. One group suggested that as evaluation of essential nutrients has been completed though the Food and Nutrition Board's DRI project focus should be placed on other bioactive food components, unless new benefits of essential nutrients emerged. Another commented that the definition of essential nutrients should be broadened beyond nutrients required for optimal health, as it is very likely in the near future that the definitions will merge. This group was concerned with classifying bioactive food components as something beyond essential nutrients, as “nutritive value” serves as an important regulatory anchor. This group also recommended limiting bioactive food components to those with the capacity to improve or maintain health.

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

In general, responders supported the inclusion of synthetically derived components that are nature-identical synthetic forms, bio-equivalent, substantial equivalents to their natural counterparts, or meet FDA's “substantially equivalent” GRAS requirements. One group recommended excluding optical and geometric isomers that are not normally present in the food supply, given the lack of activity or potentially adverse effects of these components.

Alternate definitions of *bioactive food components* provided by groups/individuals that responded to the September 16, 2004 *Federal Register* notice.

	<u>GROUP/INDIVIDUAL</u>	<u>ALTERNATE DEFINITIONS</u>
1	American Dietetic Association (ADA)	<i>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.</i>
2	American Herbal Products Association (AHPA)	<i>Bioactive food components are constituents in foods or dietary supplements, other than those functioning to meet basic nutritional needs, that effect changes in health status or changes in the structure or function of the body.</i>
3	B. Sachou, Florham Park, NJ	Did not provide an alternate definition or comment on the definition <i>per se</i> .
4	Chris Hawkes, USDA/ARA Western Human Nutrition Center, University of California at Davis	Suggested including in the definition, “Any compound that occurs naturally in foods commonly consumed in the United States in quantities sufficient or likely to cause a detectable biological effect in humans.”
5	Consumer Healthcare Products Association (CHPA)	Instead of defining which compounds are or are not “bioactive,” the group should specify the types or categories of compounds or food components, that are of interest, perhaps by providing a more descriptive statement, such as food components, including essential nutrients, that may promote health and/or prevent disease. Essential nutrients should be included in any expository definitions developed.
6	Council for Responsible Nutrition (CRN)	It has been CRN's position that there is no need for a formal definition except when such a definition has regulatory or other practical implications.
7	Food Products Association (FPA, formerly, NFPA)	<i>Bioactive food components are those food substances that contribute beneficially to supporting health promotion and disease risk reduction in the context of the diet.</i>
8	Grocery Manufacturers of America (GMA)	<i>A bioactive food component is a nutrient, food, food component, or a combination of food components that affects the structure or function or imparts a physiological benefit in the body to improve health.</i> Suggests using the term “functional food component”

	<u>GROUP/INDIVIDUAL</u>	<u>ALTERNATE DEFINITIONS</u>
		instead of “bioactive food component” as it is more consumer friendly.
9	ILSI North America	<i>Physiologically-active food components: Food components demonstrated to result, directly or indirectly, in a consistent positive physiological response linked to health promotion, or reduction in risk of disease, as measured through utilizing appropriate methodology and biomarkers.</i>
10	Institute of Food Technologists (IFT)	<i>Bioactive food components are substances in foods, including dietary supplements that have biological activity that directly affect structure or function of the body.</i>
11	International Formula Council (IFC)	Based on the limited information that was provided in the request for comments, it is our initial position that a “bioactive food components” category will add no clarity to the existing regulatory language, and may even add more confusion unless the definition is very limiting, which is not the apparent intent as described in the <i>Federal Register</i> .
12	National Nutritional Foods Association (NNFA)	Consistent with FDA’s definition of “new dietary ingredients” as the term, in a sense, overlaps with “bioactive food components.”
13	National Yogurt Association	<i>Constituents in foods or dietary supplements, including those needed to meet basic nutritional needs, that are responsible for changes in health status beyond nutrition.</i>
14	Robert E Levin, University of Massachusetts	<i>Bioactive components of foods are individual chemical components that either influence the physiology and metabolism of the body directly, or have an indirect effect, by altering the metabolism of other chemical components in the diet. Such bioactive components of the diet being either detrimental or of benefit to the human body under otherwise normal conditions of dietary intake.</i>
15	Si-Quan Li, The Ohio State University	Did not provide an alternate definition or comment on the definition <i>per se</i> .
16	The American Society for Nutritional Sciences (ASNS); The American Society for Clinical Nutrition (ASCN)	<i>Bioactive food components are dietary constituents that elicit physiological effects beyond those associated with essential human nutrition.</i>
17	Wine Institute	Did not provide an alternate definition or comment on the definition <i>per se</i> .