

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION (ODPHP)  
OFFICE OF PUBLIC HEALTH AND SCIENCE

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON A PROPOSED DEFINITION OF "BIOACTIVE FOOD COMPONENTS"

November 1, 2004

The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

### **Background**

In a *Federal Register* notice of September 16, 2004, the Office of Disease Prevention and Health Promotion (ODPHP), Office of Public Health and Science, Department of Health and Human Services (HHS), acting on behalf of an ad hoc Federal working group, solicited written comments on a proposed definition of "bioactive food components." The proposed definition for this term provided in the above identified notice is as follows:

*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.*

In requesting comments on the proposed definition, ODPHP also posed a number of related questions for which comments were solicited. AHPA is providing here its responses to ODPHP's questions and specific recommendations for modifying the proposed definition.

### **Suggested modifications to the proposed definition**

AHPA and its members suggest two revisions, one addition, and one deletion to the proposed definition, such that AHPA recommends that the word "needed" be replaced with the word "functioning;" that the word "human" be deleted; that the words "are responsible for" be replaced with the word "effect;" and that the words "or changes in structure or function of the body" be added at the end of the definition. The following revised definition incorporates each of these suggestions:

*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.*

AHPA's rationale for deleting the word "human" from the proposed definition is that the federal definition of the word "food" includes "articles used for food or drink *for man or other animals*" (emphasis added). 21 U.S.C. 321 (f)(1). Another way to square this proposed definition with the existing federal definition for "food" is to add the word "human" in the proposed definition, such that the term to be defined would be "bioactive human food components."

The suggested replacement of "needed" with "functioning" is based on the fact that the same compound can have more than one function. It can function to meet basic nutritional needs to sustain life, or it can function to effect changes in health status or the body's structure or function. Therefore the distinction between "nutritional" and "bioactive" needs to hinge on the action (i.e., "function") of the compound rather than an assumed inherent nature of the compound. And the suggested replacement of "are responsible for" with "effect" is offered to simply to suggest an active rather than passive role.

*The American Heritage Dictionary of the English Language*, 3<sup>rd</sup> edition (1996) defines "bioactive" to mean "[O]f or relating to a substance that has an effect on living tissue." There is nothing in this definition that suggests that such effect is limited to one that is responsible for changes in health status. AHPA's rationale for proposing the additional words at the end of the proposed definition is to be more consistent with the normal meaning of the word "bioactive," and to recognize that the definition must be broad enough to include components that affect the structure or function of the body in ways that do not necessarily effect changes in health status. Also, dietary supplements, by definition, have effects that change the structure or function of the body.

### **Response to questions posed by ODPHP**

AHPA offers the following responses to the questions posed by ODPHP:

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

All categories and classes of compounds found in food should be considered as potentially bioactive food components themselves or as possible sources of bioactive food components.

The September 16<sup>th</sup> Notice provided several example of bioactive food components (e.g., lycopene, isoflavones, and resveratrol) that act through biochemical processes. Categories of compounds that effect changes in health status or on the structure or function of the body through purely physical mechanisms should also be considered as bioactive food components. For example the bulk laxative action of mucilage produced by marshmallow or psyllium seed husks and the absorptive nature of activated charcoal result from physical phenomena that may effect beneficial changes in health status albeit through a physical, not biochemical, mechanism.

Some food components serve both to meet basic human needs and to effect changes in health status or in the body's structure or function. For example some polysaccharides found in species of mushrooms have immunostimulating properties and may also serve as an energy source for the body; similarly, long-chain omega-3 fatty acids are biologically active beyond their caloric value. Such food components must also be considered as bioactive food components.

Finally, even food components that can potentially have a negative effect on health status should be considered to be bioactive food components and may be legitimate subjects for research. Toxic effects are related to dose and matrix, and so components that are known to be toxic in one context may, at different doses or in different matrices, be found to be beneficial.

- (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?*

No categories or classes of compounds that are found in foods should be excluded from the definition of bioactive food components; therefore no additional modifications to the proposed definition are required.

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

Essential nutrients should be included in the definition of bioactive food components when they contribute to changes in health status or changes in the structure or function of the body beyond basic life sustaining nutritional needs. Some essential nutrients may be responsible for positive changes in health status or help to maintain a healthy state, such as selenium's effect on cancer prevention, beyond their function as essential nutrients.

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

Synthetically derived components used in fortified foods and dietary supplements should be considered under this definition. Also, close synthetic analogs of bioactive food components, the ethyl ester of creatine for example, should be included under this definition.

**Additional comments**

AHPA requests that, as the definition of "bioactive food components" is revised and comes into use, it be recognized that each of these words, including the word "bioactive," may already be used in the marketplace to describe foods, including dietary supplements. No attempt should be made in developing a newly defined use for these words and the term "bioactive food components" to restrict the use of any of these words in a truthful and nonmisleading manner on the labeling of food or dietary supplement products.

In addition, AHPA notes that the September 16<sup>th</sup> notice concluded with a statement that comments received in this matter would be used not only to refine the proposed definition, but would also be reviewed "in future plans involving the use of this definition." AHPA further notes that one of the reasons provided for the need for the definition is to "help in guiding and encouraging future research with these components." With these two statements in mind, AHPA recommends that the primary focus of research for bioactive food components should be on the types of examples presented in the September 16<sup>th</sup> notice (e.g., lycopene, long-chain omega-3 fatty acids, EGCG, isoflavones, sulphorophane, and resveratrol) and other food components such as proanthocyanidins, carnosic acid, phytosterols, etc.

Research efforts should be directed toward an understanding of the potential beneficial health effects of such compounds and compound classes. AHPA also recommends that future research focus primarily on the naturally-occurring rather than synthetic bioactive food components.

Sincerely,

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