



INSTITUTE OF FOOD TECHNOLOGISTS

BARBARA BYRD KEENAN, CAE / *Executive Vice President*

December 13, 2004

Leila G. Saldanha
Department of Health and Human Services
Office of Dietary Supplements
6100 Executive Boulevard
Rm 3B01, MSC 7517
Bethesda, MD 20892

Dear Dr. Saldanha:

The Institute of Food Technologists would like to thank you for the opportunity to comment on the proposed definition of bioactive food component and applauds HHS for providing this opportunity for stakeholder input. We offer the following suggestions for your consideration.

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

We propose the following definition:

Bioactive food components are substances in foods, including dietary supplements that have biological activity that directly affect structure or function of the body.

This includes substances that have been defined as nutrients. It also includes components other than those required to meet basic nutritional needs, such as less refined components (e.g. bran, soy protein isolates, marigold powder), families of compounds (e.g. phytosterols, polyphenolics, flavanoids, proanthocyanadins), and specific chemical moieties (e.g. lutein, lycopene, DHA, EPA).

2. What categories/classes of compounds should not be considered as bioactive food components?

None, the objective is to advance health knowledge, through excellent and ethical research which requires supporting highly ranked research proposals on all classes and categories of bioactive food components.

3. Should essential nutrients be included as bioactive food components?
Yes, essential nutrients are covered in our definition. Research on bioactivity of nutrients should not be constrained by the existence of DRIs or limited tolerable upper level (TUL) data.

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

Yes, synthetically derived components used in fortified foods and dietary supplements are covered in our definition. The biological activity, efficacy and safety should be demonstrated for the substance regardless of source. The definition of bioactive food component should be based on physiological function not origin.

The Institute of Food Technologists advocates that attention be given to highly ranked research priorities for bioactive food components that can be added to the diet to directly affect structure and function of the body. We encourage research elucidating the mechanism(s) of action, efficacy, and safety of nutrients in quantities greater than those required to meet basic nutritional needs and of other compounds, including synthetically derived components, and optical and geometric isomers. Research should focus on plausible mechanism(s), specific target physiologic effects, identification of the active substances, and safety and efficacy across population segments (e.g. age, gender, etc.) Studies should also consider exposure based on typical consumption of foods and dietary supplements containing bioactive substances.

We cannot continue to expect that all bioactive food components will be safe or efficacious at all levels, for all people, at all ages. Commercial usage and promotion needs to be regulated by appropriate regulatory agencies, based in large part, on research results and to the degree efficacy and safety are established. We need to make bioactive components in foods and dietary supplements available to those who will benefit from their use while providing protection for those who may be adversely affected.

Founded in 1939, the Institute of Food Technologists is a nonprofit scientific society with 26,000 members working in food science, technology; and related professions in the food industry, academia, and government. As the society for food science and technology, IFT brings sound science to the public discussion of food issues.

We would be pleased to discuss our comments further if warranted. Please contact Fred Shank at (202) 466-5980 or me.

Sincerely,

A handwritten signature in cursive script that reads "Herbert Stone".

Herbert Stone, Ph.D.
President, IFT