



INTERNATIONAL FORMULA COUNCIL

Formerly the Enteral Nutrition Council and Infant Formula Council

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

Re: Proposed Definition of Bioactive
Food Components

Dear Ms. Saldanha,

The International Formula Council ("IFC")¹, an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formula and adult nutritionals) whose members are predominately based in North America, is requesting an extension of the comment period for the Department of Health and Human Services' *Solicitation of Written Comments on Proposed Definition of Bioactive Food Components* [69 FR 55821, September 16, 2004]. The industry's experience and expertise provide a meaningful basis for evaluating the reasonableness of the proposed definition. In light of the importance of this proposal we believe an extension period of 90 days (i.e., to January 31, 2005) is necessary to permit its careful evaluation and ensure thorough comment.

We also request further clarification regarding the context in which this definition will be used, especially the extent to which it would impact the regulatory environment. 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 *Federal Register*. By definition, all nutrients are bioactive, whether or not they are components of food or dietary supplements. The current regulatory classification system, which differentiates foods, foods for special dietary use, dietary supplements, infant formulas, medical foods, and drugs, is adequate to differentiate all classes of nutrients, including those currently being considered as bioactive food components. Further, the current regulatory classification system is adequate to describe the safety of all classes of nutrients (e.g., infant formula safety is assured by major change requirements and novel ingredient requirements). However, the IFC would like to have the opportunity to comment further once we have the benefit of fully understanding the potential regulatory implications of the proposed definition

¹ International Formula Council members are Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division, Ross Products Division, Abbott Laboratories; Solus Products, and Wyeth Nutrition.

If however, after considering our requests you choose to proceed without providing the benefit of additional information and time, we now take this opportunity to address the proposed definition with our limited understanding as to how and in what context it would be used. As currently worded, the definition is not limiting, and may in fact create more confusion rather than guide and encourage future research with these components. A definition that defines bioactive food components as those constituents in food or dietary supplements “other than those needed to meet basic human nutritional needs,” does not acknowledge the basic premise of the field of nutrition, which is predicated on the understanding of the requirement of and role of dietary components in a globally sourced omnivore diet, and which evolves over time as more data are obtained. Currently there is growing evidence but rudimentary knowledge of the precise requirement for and the metabolic action of all the components from food groups; therefore, even the “basic human nutritional needs” are not all clearly defined. As scientists continue to unravel and understand “basic human nutritional needs,” this definition, as proposed, would continuously change to reflect that current knowledge and would not be definitive as is its purpose.

The International Formula Council appreciates the opportunity to comment and looks forward to providing additional comments should our request for an extension be granted.

Respectfully submitted,

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