



## Council for Responsible Nutrition

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November 1, 2004

Leila G. Saldanha, Ph.D.  
Office of Dietary Supplements  
6100 Executive Boulevard  
Room 3B01, MSC 7517  
Bethesda, MD 20892-7517

Dear Dr. Saldanha:

CRN is pleased to submit these comments on the subject of a proposed definition of “bioactive food components,” as requested in the Federal Register of September 16, 2004.

It is self-evident that foods contain a vast array of bioactive food components, many of which are naturally-occurring constituents of food and many of which are added as ingredients to conventional foods and dietary supplements. The category of conventional foods is broad and includes many specialty products sometimes referred to by terms such as “nutraceuticals” or “functional foods.” There have periodically been efforts to define these categories of foods, simply because these terms are in common use. 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. Since the regulatory definitions applicable to conventional foods and food ingredients are sufficient to cover nutraceuticals or functional foods, there has been no need to develop a unique definition for these food categories.

CRN takes a similar position with regard to any potential definition of bioactive food components. It is obvious that such components exist, and the components are adequately described by existing technical and nutritional terminology. There is no need for any effort to create some new umbrella term encompassing such components, unless there is a clear need to distinguish them from other food components for some practical reason. No such reason is specified in the Federal Register notice.

CRN strongly opposes the definition suggested in the Federal Register notice, namely: “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.” Any definition of bioactive components that specifically excludes essential nutrients is ludicrous on its face, since essential nutrients are among the most fundamental bioactive components.

If there were any reason to define bioactive food components, any such definition should include all such components, including essential nutrients, and should include any relevant form of the component, ranging from its naturally-occurring form to a nature-identical synthetic form to other modified forms with equivalent or improved functional qualities. It is difficult to comprehend what food components might be excluded from the definition, since our understanding of the role of food constituents is continually evolving. For example, food fiber, once thought to be relatively inert, is now known to encompass various distinct types of fiber having substantial health benefits for differing health conditions.

Evidence suggests that all or most food components are bioactive. Given this assumption, CRN sees no function to be served by a definition of “bioactive food components.” It would either be all-encompassing and therefore unnecessary or it would create distinctions where none logically exist. Pending further clarification of the purpose of such a definition and its practical applications, CRN is opposed to this initiative.

Sincerely,

A handwritten signature in black ink that reads "Annette Dickinson". The signature is written in a cursive style. To the right of the signature is a vertical red line.

Annette Dickinson, Ph.D.  
President