



GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

February 25, 2005

Dr. Leila Saldanha
Office of Dietary Supplements
National Institutes of Health
U.S. Department of Health and Human Services
6100 Executive Blvd., Room 3B01
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RE: Solicitation of Written Comments on the Proposed Definition of Bioactive Food Components. 69 Federal Register 55821, September 16, 2004.

The Grocery Manufacturers of America (GMA)¹ appreciates this opportunity to comment on the work of the bioactive food components by the Department of Health and Human Services and the Ad Hoc Federal Working Group on Bioactive Food Components (Working Group). These comments respond to the proposed definition and four questions contained in the *Federal Register* Notice.

Introduction:

The task of developing a definition of bioactive food components is significant and has not only scientific ramifications, but also potential regulatory and public health implications. Thus, GMA has some apprehension with the initial definitional approach taken by the Working Group. It would appear that the Working Group has begun to take a reductionist approach to bioactive food components versus a more holistic approach. GMA is concerned that the Working Group's narrow focus on food components is more limiting than it should be. Research may show that a single bioactive food component, or a combination of bioactive food components, ultimately provides the beneficial effect. We believe that we have the opportunity to accelerate government research spending on the health benefits of bioactive food components and foods to improve the health of Americans. Consumers want to feel empowered to change the course of their health through the foods and beverages, including alcoholic beverages, they choose to consume.

¹ The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage and consumer product companies. Led by a board of 42 Chief Executive Officers, GMA applies legal, scientific and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry. With U.S. sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

It would appear the Working Group's definition; "*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,*" hopes to channel new research dollars over and above research dollars funneled for the determination of nutrient requirement for optimal health.

GMA applauds this effort but believes the definition should frame the term "bioactive" in a broader sense than proposed by the Working Group. Thus, GMA proposes the following definition for a bioactive food component:

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.

GMA recognizes that NIH's mission is to focus on scientific research, but ultimately scientific findings are shared and communicated to the public. Communications about dietary components for health promotion hold promise to profoundly affect public knowledge, behavior, and well-being. GMA recommends the Working Group consider testing the term "bioactive food component" with consumers. The International Food Information Council (IFIC) has conducted consumer research on the acceptance of terminology among consumers and found the term "functional food component" was considered a consumer friendly term .

GMA is concerned, that "bioactive" component may not have a positive, or may have a mixed, connotation with the public. To ensure that Americans will embrace new research findings, we must be certain that we are using the most appropriate and clearly understood terminology.

The IFIC Website indicates a number of challenges unique to communications about bioactive food components, including:

- 1) Empowering consumers to view beneficial dietary components as one part of a healthful diet and lifestyle rather than as "magic bullets."
- 2) Balancing increased consumption of beneficial components within the proper caloric intake necessary to maintain healthful weight.
- 3) Communicating which segment(s) of the population would likely benefit from increased or decreased consumption of a given component.

We hope that the Working Group will take all of these factors into consideration.

Following are GMA's responses to specific questions posed by the Working Group:

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

GMA feels strongly that this initiative should not be just about exploring food components. We already know that foods have enormous health benefits, but we have yet to discover and identify the specific component and mechanism of action. This area of research will continue to advance, but we must not exclude the food itself as a bioactive entity.

GMA recommends that the categories/classes of compounds that should be considered as bioactive food components should include an individual food component or a combination of food components. Examples could include: macronutrients, vitamins & minerals, phytochemicals in blueberries, apples or cranberries, polyphenols, phytoestrogens, phytosterols, oligosaccharides, and bioactive peptides from whey protein and casein. Food components such as whole grains, fiber, carotenoids, omega-3 fatty acids, conjugated linolenic acid, curcumin, lactic acid bacteria and other prebiotic and probiotic components, including microorganisms should also be considered. Another example of a bioactive component that is a mineral is calcium. Calcium in dairy foods has shown a beneficial synergistic impact on weight loss in individuals.

We support the Working Group's interest in the identification of models to measure outcomes. Biomarkers have not been elucidated for many of these bioactive food components, making it difficult to establish efficacy of the bioactive food component. Yet, science evolves continuously and therefore there must be a dynamic approach to modeling to ensure inclusion of new scientific developments.

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

Pharmaceutical agents, that is, compounds that are intended for the cure, treatment and mitigation of a disease or condition, and are not naturally found in foods, should be excluded from the definition.

Similarly, the safety of a bioactive food component should be evaluated along with its benefits. After considerations of exposure and consumption, certain bioactive food components may need to be limited or excluded.

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

Yes. Essential nutrients found in foods and dietary supplements fulfill essential and beneficial physiological effects, and thus should be classified as bioactive food components. It is the very core of what makes a nutrient essential.

At the December 2004 meeting of the Food and Nutrition Board, there was wide agreement that the definition of essential nutrients should be broadened beyond nutrients required for optimal health. It is very likely in the near future that the two definitions will merge, and rightfully so, because the foremost objective is the advancement of public health. Otherwise, there would be a question as to where to draw the line between the level that is required to prevent a nutrient deficiency versus a higher level that is considered a bioactive food component because it reduces the risk of chronic disease. The two are one and the same.

Why should essential human nutrition be separate and not considered within the range of bioactive food components? If left separate, how does one deal with vitamin D? Vitamin D is produced in the body and also obtained from food. Higher nutrient requirements for vitamin D that are related to the reduction of chronic disease are just as important as essential human nutrition. The Dietary Reference Intake (DRI) for vitamin D is based on endocrine function in the body but, with the recent scientific advancements, the paradigm is shifting to include the autocrine function in the body. This shift is critical in the future deliberations of the Working Group.

GMA believes “bioactives” should, first and foremost, be limited to those with the capacity to improve or maintain health. The only difficulty with this approach is that something has to be defined as “bioactive” in order to become eligible for the research that will determine whether it has a positive impact. We need to be careful not to exclude large classes of compounds from NIH research simply because the regulatory bodies have not recognized biomarkers for those compounds that are associated with reduced risk of disease. GMA believes NIH should take the lead in supporting research to validate additional health biomarkers.

Furthermore, if we classify bioactive food components as something above and beyond the essential nutrients, it will be difficult to align this duality with the simpler and singular definition of “nutritive value.” “Nutritive value” serves as a very important regulatory anchor. The Working Group needs to consider the existing FDA regulatory framework particularly “nutritive value.” It is important the Working Group strikes a balance with FDA and other regulatory agencies to ensure harmonization to avoid conflicting regulatory and non-regulatory outcomes. GMA wants to be certain the Working Group consider the unintended consequences of a definition for bioactive food components that could negatively impact FDA regulations.

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

Yes, if they have the same bioactive effects. Synthetic vitamins are recognized as equivalent to their naturally-derived versions and have been used to enrich and fortify foods for decades. Synthetic ascorbic acid, as a source of vitamin C, is probably one of the most commonly added substances that has a bioactive characteristic. In some instances, the synthetic form of the vitamin is more bioavailable or more effective in

providing the benefit to the body (e.g., synthetic folic acid). Naturally-derived versions may be required for organic foods, but the organic foods standards² specify process requirements and are not concerned with bioactivity.

Thank you for the opportunity to provide input on the proposed definition of bioactive food components. GMA looks forward to contributing to the ongoing work of the Ad Hoc Federal Working Group on Bioactive Food Components through its conferences in 2005 and beyond.

Sincerely yours,

A handwritten signature in black ink that reads "Alison Kretser". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

Alison Kretser, MS, RD
Director, Scientific and Nutrition Policy

² 7 CFR 205 National Organic Program.