



December 21, 2004

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

Re: Comments to the Proposed Definition of Bioactive Food Component

Dear Dr. Saldanha:

The National Yogurt Association (“NYA”) is pleased to submit these comments to the Department of Health and Human Services (“HHS” or the “Department”) in response to the *Federal Register* notice, “Solicitation of Written Comments on Proposed Definition of Bioactive Food Components,” published on September 16, 2004.¹ Consistent with the purpose of the *Federal Register* notice, these comments respond solely to HHS’s proposed definition, and do not support or provide guidance on the regulation of bioactive food components.

NYA is the national nonprofit trade association representing the producers of Live and Active Culture (“LAC”) yogurt products as well as suppliers to the yogurt industry. NYA’s member companies are among the largest yogurt manufacturers in the United States. NYA sponsors scientific research regarding the health benefits associated with the consumption of yogurt with LAC and serves as an information resource to the American public about these attributes.

¹ 69 Fed Reg. 55821 (2004).



I. Importance of Defining “Bioactive Food Components”

In the past several years, there has been a great deal of research on the health effects of bioactive food components, functional foods, patterns of food consumption,² and models that can be used to measure the health effects of these foods on the gut and immune system.³ Bioactive components in foods are showing promise in reducing risks of certain chronic degenerative diseases and enhancing overall health. For example: (1) soy products are being consumed for their ability to lower cholesterol levels and prevent memory loss; (2) fish containing omega-3 fatty acids are being recommended for heart disease, stroke, memory loss, and depression prevention; (3) the carotenes in carrots are thought to lower risks of heart attacks and lung cancer; and (4) the benefits of probiotic-containing foods, and in particular LAC yogurt on intestinal health are being confirmed.⁴ The traditional foundations of nutrition science, which focused on individual nutrients, are no longer sufficient in light of this new information. As a result, HHS’s desire to formulate a working definition of “bioactive food components” and assess approaches for evaluating the health effects resulting from the consumption of these components is both timely and important.

II. The Definition of “Bioactive Food Components” is Partially Appropriate

HHS proposes to define “bioactive food components” as “constituents in foods or dietary supplements, other than those needed to meet basic nutritional needs, that are responsible for changes in health status.”⁵ NYA supports the attribute-based aspect of the definition as opposed to a conventional list. However, NYA notes that the proposed definition could be interpreted to exclude from the definition components that are “needed to meet basic nutritional needs” even if, in addition to their “nutritional

² Lori E. Hoolihan, “Individualization of Nutrient Recommendations and Food Choices, Diet and Behavior,” *Nutrition Today*, Nov. 1, 2003 at 225.

³ J.H. Cummings et al., “Passclaim – Gut Health and Immunity,” *Eur. J. Nutr.*, 43: II/118-173 (2004).

⁴ Hoolihan, *supra* note 2 at 225-227; Elizabeth Somer, “25 Ways to Make Food Healthier,” *Natural Health*, June 1, 2004 at 30.

⁵ 69 Fed Reg. at 55822.

properties” these components have other functional attributes that positively influence the health status of those who consume them.

The proposed definition determines whether a food component may be considered bioactive based on its functional properties and ensures that food ingredients that are able to demonstrate health benefits are included. A definition based on a “list” of specific bioactive food components would be unnecessarily restrictive and lead to premature exclusion of yet undiscovered components. Therefore, based on the above, NYA proposes to slightly modify the proposed definition of “bioactive food components” so it reads “constituents in foods or dietary supplements, including those needed to meet basic nutritional needs, that are responsible for changes in health status beyond nutrition.”

III. The LACs Found in Yogurt Are Properly Defined as “Bioactive Food Components”

LACs refer to living organisms, which may ferment a variety of food matrices. In the specific case where LACs are used to ferment milk they create “cultured dairy products.” One of the most traditional “cultured dairy products” is the standardized food “yogurt.” Under current standards of identity⁶ established by the Food and Drug Administration (“FDA”), “yogurt is the food produced by culturing . . . dairy ingredients . . . with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*.” Many yogurt products contain other LACs as well.

As provided in the next section, available scientific evidence demonstrates that the LACs found in yogurt, as well as other LACs with demonstrated beneficial properties, are properly defined as bioactive food components because of the health benefits that are derived from these food ingredients beyond basic nutritional needs. Specifically, those LACs that should be considered to be bioactive components are those that meet the definition of “probiotics.” A definition of “probiotics” recognized by the National Yogurt Association is:

⁶ 21 CFR §§ 131.200, 131.203, 131.206.

“Probiotics are living microorganisms, which upon ingestion in sufficient numbers, exert health benefits beyond basic nutrition.”

Thus, from the above it is quite clear that probiotics are properly designated as bioactive components.

A. Scientific Research

Researchers have studied and documented the health benefits associated with LACs in yogurt and other probiotic-containing food products. These studies suggest that certain LACs play an active role in preventing gastrointestinal infections,⁷ fighting certain types of cancer,⁸ boosting the body’s immune system,⁹ reducing nasal allergies,¹⁰ and partially breaking down the lactose contained in milk thus allowing those who are lactose intolerant or suffer from lactose malabsorption to enjoy the nutritional benefits of dairy products, namely yogurt without or with limited side effects like bloating and diarrhea.¹¹

Studies on the possible health benefits of yogurt on gut-associated diseases substantiate the belief that consuming yogurt and other fermented milk products with specific probiotic LACs provide various health benefits.¹² Research addressing the issue of yogurt and gut health suggested that yogurt and/or its cultures reduced the duration of diarrheal

⁷ “Getting to Know Yogurt,” *Food Management*, July 1, 2004 at 65; M. Freitas et al., “Host-pathogens Cross-talk. Indigenous Bacteria and Probiotics Also Play the Game,” *Biol. Cell*, 95: 503-6 (2003).

⁸ RK Peters et al., “Diet and Colon Cancer in Los Angeles County,” *Cancer Causes Control*, 3(5): 457-473 (1992) (Results from a study of over 1,400 subjects with colon cancer that sought to determine which foods were associated with a reduced risk of colon cancer indicated that yogurt intake is associated with a significantly decreased risk of colon cancer); O. Adolfsson et al., “Yogurt and Gut Function,” *American Journal of Clinical Nutrition*, 80(2): 245-56 (2004); J. Saikali et al., “Fermented Milks, Probiotic Cultures, and Colon Cancer,” *Nutrition and Cancer*, 49(1): 14-24 (2004).

⁹ M. Piaia et al., “Assessment of the Benefits of Live Yogurt: Methods and Markers for in vivo Studies of the Physiological Effects of Yogurt Cultures,” *Microb. Ecol. Health Dis.*, 15: 79-87, 82 (2003).

¹⁰ *Id.*

¹¹ *Id.* at 80; Adolfsson et al., “Yogurt and Gut Function” at 245-56.

¹² Adolfsson et al., “Yogurt and Gut Function” at 245-56.

diseases in children and had a beneficial effect on lactose digestion by those suffering from lactose intolerance. The article also highlighted: (1) the preventative and/or therapeutic effects of yogurt and its cultures on inflammatory bowel disease (“IBD”) and colon cancer as suggested by epidemiological evidence and animal studies; and the (2) possible beneficial effects of yogurt cultures in increasing the eradication rate of *Helicobacter pylori* (“*H. pylori*”)¹³ as indicated by in vitro and preliminary human studies.¹⁴

Indeed, the *absence* of live cultures is found to significantly affect the beneficial qualities of yogurt. Another recent review article documented the physiological effects associated with the consumption of yogurt containing LACs, and the consequences of heat treatment after fermentation (which destroys the cultures).¹⁵ The review paper concluded that the beneficial effects of live yogurt on the gut equilibrium, immune system, infections, lactose maldigestion, allergies, and mutagenesis and carcinogenesis are destroyed or diminished by heat-treatment.¹⁶ These results show that from a nutritional and functional perspective heat treatment dramatically alters some intrinsic beneficial properties of yogurt.

Finally, it is important to note that yogurt cultures and other probiotic LACs have been shown to have beneficial effects on certain structure components or functions of the human body, including the composition of the gut flora, gut flora metabolisms, the gut epithelium and its barrier effect,¹⁷ the overall gut transit time,¹⁸ and on the body’s natural

¹³ Infection with *H. pylori* is known to play a role in peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and mucosa-associated lymphoid tissue.

¹⁴ Adolfsson et al., “Yogurt and Gut Function” at 245-56.

¹⁵ Piaia et al., “Assessment of the Benefits of Live Yogurt: Methods and Markers for in vivo Studies of the Physiological Effects of Yogurt Cultures” at 79-87.

¹⁶ *Id.* at 86.

¹⁷ Adolfsson et al., “Yogurt and Gut Function” at 245-56.

¹⁸ M. Bouvier, et al., “Effects of Consumption of a Milk Fermented by the Probiotic Bifidobacterium Animalis DN 173 010 on Colonic Transit Time in Healthy Humans,” *Bioscience and Microflora*, 20(2): 43-48 (2001); P. Marteau, et al., “Bifidobacterium Animalis, Souche DN173 010 Shortens the Colonic Transit Time in Healthy Women. A Double Blind Randomized Controlled Study,” *Aliment Pharmacol. Ther.*, 16: 587-593 (2002); S. Meance, et al., “A Fermented Milk with Bifidobacterium Probiotic Strain DN-173 010 Shortened Oro-fecal Gut Transit Time in

defenses.¹⁹ Since the digestive tract is frequently the object of functional and health claims, researchers have also explored models to measure intestinal well being and define the limits of normal digestive and immune function.²⁰

B. Opinion of the Medical Community

The medical community recognizes the health benefits of consuming yogurt. The “Live Active Culture (LAC) Yogurt Survey,” polled 565 physicians across the country to assess whether they believed there are health benefits associated with the regular consumption of active cultures.²¹ The survey found that two out of three doctors who counsel their patients on nutritional issues recommend LAC yogurt for: (1) its overall nutritional health benefits; (2) finding it helpful in maintaining a healthy intestinal system; and (3) as a tolerable source of dairy calcium for those who are lactose intolerant.²²

Research suggests that LACs provide unique beneficial health effects. In light of this research and current medical opinion, LACs are properly defined as bioactive food components.

Elderly,” *Microb. Ecol. Health Dis.*, 13: 217-222 (2001); S. Meance, et al., “Recent Advance in the Use of Functional Foods: Effect of the Commercial Fermented Milk With Bifidobacterium Animalis Strain DN-173 010 and Yogurt Strains on Gut Transit Time in the Elderly,” *Microb. Ecol. Health Dis.*, 15: 15-22 (2003).

¹⁹ N. Borruel, et al., “Effects of Non Pathogenic Bacteria on Cytokine Secretion by Human Intestinal Mucosa,” *Am. J. Gastro.*, 98(4): 865-870 (2003).

²⁰ J.H. Cummings, et al., “PassClaim – Gut Health and Immunity” at 118-173.

²¹ “Nutrition: Doctors Who Discuss Nutrition With Their Patients Often Recommend Yogurt,” *Obesity, Fitness & Wellness Week via NewsRx.com and NewsRx.net* (December 29, 2001 – January 5, 2002) (This article was prepared by Obesity, Fitness & Wellness Week editors from staff and other reports).

²² *Id.*

IV. Inclusion of LACs in the Definition of “Bioactive Food Components” Will Help Foster Additional Research and a Greater Understanding of Their Health Effects.

Although scientific studies have been able to reveal some information about the health benefits of LACs, additional research to fully understand the attributes of yogurt is necessary. NYA understands the definition of bioactive food components will be used, among other things, to guide future research funding decisions. By including LACs in the definition, it will recognize LACs as an important food component with potentially unique health benefits that should be further explored through adequate research and funding.

As previously stated, NYA has funded research on a number of issues concerning the benefits of LAC. While current science clearly establishes the beneficial nature of certain LACs beyond their nutritive value, more research is necessary to develop reliable methods and measures for evaluating gut health and explore additional avenues by which LACs provide health benefits.

Future studies on LACs should consider issues such as: (1) substantiate and/or extend present findings using animal models and clinical trials; (2) further evaluate if effects are age-specific or can be observed across all age groups; and (3) further investigate the mechanisms through which yogurt exerts its effects.²³ Studies focused on determining the characteristics of a healthy gut would also be helpful in evaluating the effect of yogurt on “gut health.”²⁴

Because of their association with healthful properties and an emerging body of scientific research, LAC yogurt and other probiotics continue to interest scientists around the world.

²³ Adolfsson et al., “Yogurt and Gut Function” at 245-56.

²⁴ *Id.*

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V. Conclusion

Based on the foregoing, NYA agrees with the proposed definition for bioactive food components, with the slight modification as noted above, and believes that LACs are properly defined as bioactive food components. As previously stated, the purpose of these comments is to provide information about scientific matters related to LACs and, in no way, suggests any regulatory framework for bioactive food components.

Respectfully submitted,

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