October 24, 2008

Ms. Carole Davis, Nutrition Promotion Staff Director
Co-Executive Secretary of the Dietary Guidelines Advisory Committee
Center for Nutrition Policy and Promotion
U.S. Department of Agriculture
3101 Park Center Drive, Room 1034
Alexandria, VA 22302
http://www.cnpp.usda.gov/dietaryguidelines.htm

Dear Ms. Davis:

The Soyfoods Association of North America (SANA) represents the interests of small and large soyfood manufacturers, soy processors, suppliers, soybean farmers, and other industry stakeholders. SANA appreciates the opportunity to provide comments to the 2010 Dietary Guidelines Advisory Committee.

Focus on Food Environments, Behavior Change, and Eating Patterns
SANA recognizes the importance of the 2010 Dietary Guidelines Advisory Committee in deciding whether the guidelines for all Americans over the age of two need to be revised using the preponderance of current scientific and medical knowledge that focuses on health promotion and disease risk reduction. At this point in time, the Advisory Committee should focus more on strategies and research that assure adoption of the Dietary Guidelines by a very diverse American population than on bodies of research that will slightly tweak the recommendations. Research over the past five years does not appear to justify overhauling the 2005 Dietary Guidelines that have now formed the basis for reforms in the WIC food package and anticipated reforms to the school meal patterns. The American food supply, food environments, food preferences, and food consumption patterns will continue to change more before 2010, whereas research on any specific dietary guideline or nutrient will likely remain relatively consistent.

Because of the growing diversity in the population, the multitude of eating patterns Americans follow, the economic limitations many face, and the variety of food environments in which food is offered and consumed, the Dietary Guidelines Advisory Committee should translate science into recommendations suitable to all Americans. The Guidelines should also address major public health concerns and be able to be met by Americans within the current economic conditions and food supply. It is also important to examine research on the health benefits related to dietary patterns that include alternatives to traditional animal-based foods, such as plant-based diets.

Although a vast majority of individuals report, "Healthy eating habits are very important to me" (95 percent) and "I am actively trying to eat a healthy diet" (90 percent); their dietary choices fall far short of the desirable intakes of whole grains, milk products, fruits and vegetables, and avoidance of saturated fat, trans fat, cholesterol, carbohydrates, sodium and sugar revealed mixed adherence to attitudes and intentions," according to the Office of Disease Prevention and Health Promotion (ODPHP) and U.S. Food & Drug Administration (FDA) Health and Diet Survey: Dietary Guidelines Supplement¹, conducted from November 14, 2005 to February 6, 2006. The report also identified the

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Soyfoods Are Nutrient Rich Substitutes for Those Who Want a Plant-based Alternative

The 2005 Dietary Guidelines recommended increasing consumption of more high fiber foods such as 5 to 13 servings of fruits and vegetables and at least 3 servings of whole grains. In addition, advice about eating foods lower in saturated fat, cholesterol and sodium continues was joined by new messages to select foods higher in potassium, calcium, magnesium, and healthier omega-3 fatty acids.

Soyfoods go a long way to meeting all of these recommendations and fitting into each of the major food groups highlighted in the Dietary Guidelines, except fruit. Whole soybeans, as fresh edamame, roasted soy nuts, or canned, cooked soybeans are rich in fiber, potassium, folic acid, iron, and other minerals and vitamins. Fortified soymilk, one of the most popular soyfoods, makes a great alternative for those who do not drink milk because it is a rich source of calcium and other key nutrients, such as magnesium, potassium, and vitamin A. Soyfoods, such as tofu and soy meat alternatives are good sources of high quality protein without saturated fat and cholesterol. Soy protein added to meat products reduces calories as well as saturated fat and cholesterol content, while adding soy flour to baked goods enriches the dietary fiber content, iron, vitamin B and potassium.

Soy-based foods, which are consumed by a fast growing number of Americans, provide a protein of comparable quality to eggs, milk, and other animal proteins, evaluated and in calculations using the PDCAAS pattern for use in children two years of age and above and in all other older age groups. The Food and Nutrition Board (FBN), in its discussion of the Daily Reference Intakes (DRIs) for protein, reaffirms that the nutritional quality of different proteins should be evaluated using the protein digestibility corrected amino acid score (PDCAAS) as proposed by FAO/WHO in 1991. FDA has also adopted PDCAAS as an appropriate method for measuring protein quality.

Besides high quality protein, ounce for ounce soyfoods provide nutrient rich alternatives for animal based foods to add variety to the diet and meet ethnic, religious, and cultural preferences. For example, soyfoods provide alternatives for individuals who do not consume animal-based products as part of their diet. Soyfoods also provide alternatives for those with peanut, milk, or other common allergies as well as lactose intolerance or other gastrointestinal problems. A study of food allergic children found that of offending foods identified in 34 of 41 cases, cow’s milk was the most frequently reported cause (32%), followed by peanuts (29%), eggs (18%), tree nuts (6%) and soy (1%). These foods provide calcium, fiber, potassium, iron, phosphorus, magnesium and other important nutrients without increasing cholesterol and saturated fat content of diets.

The array of soy products begins with the whole soybean (i.e., Edamame, soy flour and soy nuts) and products made from the whole bean such as soymilk, soymilk-based yogurts, cheeses, and frozen desserts, tofu, soy nut butter, tempeh, and miso. Many other soyfoods that include meat and dairy alternatives, energy bars, cereals, snacks, and baked goods are made from soy protein, derived from the

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3 Institute of Medicine: Food and Nutrition Board. WIC Food Packages: Time for a Change, 2005; p 689.
whole soybean. Soyfoods are generally lower in fat and calories than animal alternatives. It is also important to note that in 2007, when the Canadian Office of Nutrition Policy and Promotion released their revised version of Canada’s Food Guide, they included “fortified soy beverage” as an alternative to milk.\(^8\)

Fortified soymilk contains high quality protein, calcium, vitamin A, vitamin D, riboflavin, vitamin B\(_6\) and phosphorus, nearly comparable to cow’s milk. Fortified soymilk has been shown in a study in the *Journal of the American Dietetic Association* to be readily acceptable by children in school and to provide readily bio-available calcium.\(^9\) That study also showed that children drinking fortified soymilk received more calcium per gram of saturated fat than those children consuming fluid milk, because of the low saturated fat content of soymilk. A recent study\(^{10}\) published in the *Journal of Nutrition* compared the calcium bioavailability of cow’s milk and soymilk fortified with calcium and found that, whether fortified with calcium carbonate (CC) or tri-calcium phosphate (TCP), the calcium-fortified soymilk provided more absorbable calcium than equal amounts of cow’s milk. A 1994 study in the *American Journal of Clinical Nutrition* showed that there is only a 32 percent calcium absorption rate from cow’s milk, whereas fortified soymilk, tofu, and tempeh calcium absorption rate has been shown to be “excellent.”\(^{11}\) Other studies concerning calcium availability and bioavailability in fortified soymilks have used questionable sample methods and analytical methods that are not representative of the entire soymilk category.\(^{12}\) SANA believes that current industry testing of fortified soymilk ensures that there is a reliable amount of calcium availability and bioavailability in fortified soymilks and that fortified soymilk is an excellent source of calcium for people who suffer from lactose malabsorption, have milk allergies, or avoid milk for cultural, religious, or other personal reasons.

Finally, SANA would like to recommend that the Dietary Guidelines Advisory Committee consider changing the terminology used when recommending the consumption of legumes and dried beans. These terms are not well-understood by or commonly used among the American public, making the important dietary recommendations for increasing consumption of these foods difficult to understand and follow. We believe that it would be more useful to refer to legumes and dried beans as “beans” or by providing specific names of beans, such as soybeans, edamame, kidney beans, black beans, or chickpeas and products from these beans.

**Soyfoods Promote Heart Health and Weight Management.**

SANA would like to inform the Advisory Committee about the following research that may be important to consider during its review:

- **Soy protein remains an important dietary factor in cholesterol reduction** - Three recent comprehensive reviews of human intervention studies show that the totality of scientific evidence continues to support the Food and Drug Administration’s health claim for 25 grams of soy protein and LDL cholesterol lowering. Harland and Haffner from the United Kingdom recently conducted a meta-analysis as well as two other reviews conducted by Dr. James W. Anderson, Professor Emeritus at the University of Kentucky Medical School (Lexington, KY) and Dr. Arline McDonald, Clinical Research Scientist, Radiant\(^(\text{®})\) Development Research (Chicago, IL) that were submitted to FDA in June 2008.

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\(^{10}\) Zhao Y, Martin BR, Weaver CM. Calcium bioavailability of calcium carbonate fortified soymilk is equivalent to cow’s milk in young women. *J Nutr*. 2005 Oct;135(10):2379-82.


Harland and Haffner\textsuperscript{13} analyzed thirty studies containing 42 treatment arms with an average daily soy protein intake of 26.9g from the scientific literature from 1998 through October 2007. Their analysis found when soy protein was included in the diet of adults, statistically significant reductions in total and LDL cholesterol occurred. Average intake of soy protein of 24.3g/day led to reductions in LDL, total cholesterol and blood triglycerides of 9.7 mg/dL; P<0.0001, 9.7 mg/dL; P<0.0001 and 11.5 mg/dL; P=0.003, respectively. Total/HDL ratio was significantly lower and HDL cholesterol was marginally increased. All data were tested for heterogeneity and none were identified. The authors concluded that achievable daily-intake of soy protein, particularly when used in association with other dietary measures, can make a useful contribution to blood cholesterol management.

Dr. Anderson’s analysis\textsuperscript{14} showed that the mean change in low-density lipoprotein cholesterol (LDL-C) from baseline from all 64 interventions (1,839 subjects) was -0.26 mmol/l (-6.4%) and the net change (difference between the soy intervention and control group) was -0.19 mmol/l (-4.6%, p<0.05). Analogous data weighted by the number of subjects in the study groups were -0.26 mmol/l (-6.3%) and -0.18 mmol/l (-4.6%, p<0.05), respectively. Analysis of the 21 high quality studies (882 subjects) revealed that unweighted and weighted changes in LDL-C from baseline were -0.025 mmol/l (-5.3%) and -0.22 mmol/l (-4.9%), respectively while those for net changes were -0.19 mmol/l (-4.6%) and -0.16 (-4.0%, p<0.05), respectively. Of the 21 high-quality studies, 17 (81.0%) reported statistically significant differences between the soy intervention(s) and the control diet whereas this finding was the case for 56.3% of all studies. Finally, the data show that the net decrease in LDL-C from baseline as well as the net change in this parameter due to soy protein consumption was highest among subjects with elevated baseline LDL-C concentrations.

Dr. McDonald’s analysis\textsuperscript{15} summarizes results from 35 studies published between 1998 and 2008 which examined the effects of soy protein on total cholesterol (TC) and LDL-C or non-high-density lipoprotein cholesterol (non-HDL-C) concentrations among subjects who consumed a fat-modified diet (≤30 of energy as fat and <12% as saturated fat) (n=17 studies) or an Average American Diet (AAD) (>30% of energy from fat and ≥12% as saturated fat) (n=18). This analysis showed that 13 of 17 studies (76%) in which soy protein was consumed as part of a fat-modified diet achieved statistically significant reductions in plasma LDL-C or non-HDL-C. Most studies reported reductions of between 4 and 6 percent. In addition, 50% (9/18 studies) of the studies involving subjects who were consuming an AAD reported statistically significant effects of soy protein on these measures. These reductions ranged from 1-12% for LDL-C and from 2-10% for TC. Of the 15 high-quality studies, 11 (73.3%) reported statistically significant differences between the soy intervention(s) and the control diet whereas this was the case for 20/35 (57.1%) of all studies.

- **Soyfoods have a role equal to dairy foods in weight and adiposity reduction** - An evidence-based review by Dr. David Allison and Dr. Mark Cope at the University of Alabama at Birmingham, and Dr. John Erdman at the University of Illinois at Champagne-Urbana, finds soyfoods are equal to other protein sources, such as dairy or meat, in helping to battle weight


\textsuperscript{14} Anders, James W. Soy Protein Effects on Serum Lipoproteins: A Quality Assessment and Weighted Analysis of Randomized, Controlled Studies. Submitted by the Soy Nutrition Institute to the FDA in response to comments for Docket No. 2007N-0464 on June 18, 2008.

by promoting fat loss. This comprehensive review\textsuperscript{16} of current research on animals, human populations, and clinical trials sought to determine the strength of the evidence on four proposed mechanisms by which soy may aid weight control: 1) soy increases weight loss when consumed at an equal calorie level as other foods, 2) soy aids weight and fat loss by decreasing caloric intake, 3) certain soyfoods benefit glucose control and heart health during weight loss, and 4) certain soyfoods will minimize the loss of bone mass during weight loss. The review, including results from eight human studies, finds that individuals lost equivalent amounts of weight and, in some cases, equal inches of fat around the waist, using soy protein, dairy milk meal replacements, beef or pork at equal calorie levels. Findings also support the possibility that soy protein decreases short-term appetite and calorie intake. Limited animal trials and human studies suggest soy-based diets and isoflavones may lower blood glucose and insulin levels. Researchers confirmed soy-based diets, compared to other low calorie diets, reduce LDL (bad) cholesterol and triglycerides and raise HDL (good) cholesterol. Findings indicate soy may reduce bone loss in women, but additional clinical trials on soy and bone loss are needed.

- **Effects of Soyfoods on Mineral Status in Women of Childbearing Age** - In a recent presentation\textsuperscript{17}, Dr. Lee Alekel and Manju Reddy from Iowa State University reported preliminary findings a controlled feeding study with 63 female subjects 18-28 years randomly assigned to consume two servings of soy foods (~20 g protein) or all meat daily for 10 weeks. The soy group was instructed not to consume additional soyfoods and control group not to consume more than one serving of animal foods per day. After treatment, authors observed no significant change in serum ferritin, iron, zinc, hemoglobin, or bone turnover markers between groups. The preliminary results indicated that incorporating 2-3 servings/d of soy foods containing ~20 g protein had no detrimental effect on bone turnover markers, iron status, or zinc status in women at-risk for these mineral deficiencies.

The 2010 Dietary Guidelines Advisory Committee can take a bold step to acknowledge that the new scientific evidence does not support significant changes in the Dietary Guidelines. Rather new evidence in food environments, food consumption patterns, and behavior change indicate the need for the Committee to focus on how to translate the recommendations in such a way that all Americans with their tremendously diverse eating patterns and economic means can adopt the Guidelines into their daily lifestyle.

Best regards,

\[\text{Nancy Chapman, M.P.H., R.D.}\]

Executive Director


\textsuperscript{17} Reddy MB, Zhou Y, and Alekel DL. Foods Do Not Negatively Impact Mineral Balance or Bone Turnover in Young Women. Presented at the 8\textsuperscript{th} International Symposium on the Role of Soy in Health Promotion and Chronic Disease, Tokyo, Japan, November 12, 2008.