



Council for Responsible Nutrition

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<http://www.health.gov/dietaryguidelines/dga2015/comments/writeComments.aspx>

RE: Calcium and Vitamin D

Dear Dr. Olson and Ms. Rihane:

The Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement and functional food industry, appreciates the opportunity to provide additional comments to the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA).

Calcium and vitamin D supplements can be safely used to help Americans achieve adequate nutrient levels when recommended intakes cannot first be met through food, and can

contribute to bone health in certain populations. The DGAC designated vitamin D as a nutrient of public health concern for underconsumption (*Part D. Ch.1, page 13, lines 473-474*). Vitamin D, along with potassium, is a nutrient of public health concern not provided in recommended levels by the USDA Food Patterns (*Part D. Ch.1, page 21, lines 788-790*). An important implication is that meeting the needs for these nutrients may require careful attention to excellent natural sources, food enriched or fortified with the nutrients, or, in some cases, consideration of supplements (*Part D. Ch.1, page 21, lines 792-793*); when needed, supplementation can be considered to achieve RDA intakes of vitamin D (*Part D. Ch.1, page 25, lines 911-913*). CRN agrees with the DGAC and supports multiple national and international groups, including the American Academy of Pediatrics, the Endocrine Society and the National Osteoporosis Foundation who have recommended strategies to achieve the RDA or higher levels of vitamin D intake that include consumption of fortified foods, broadening the range of dairy products that are fortified, and consideration, in some cases, of the use of a vitamin D supplement or a multivitamin including vitamin D. Such a use is especially appropriate where sunshine exposure is more limited due to climate or sunblock use (*Part D. Ch.1, page 15, lines 537-543*).

The DGAC also classified calcium as a nutrient of public health concern and notes that calcium is an underconsumed nutrient of public health concern among pregnant women (*Part D. Ch.1, page 15, lines 555-557*). In addition to consumption of fortified foods, strategies to achieve RDA levels of calcium should include the use of dietary supplements. The DGAC stated that concerns about the safety of calcium supplements limit recommendations to use supplementation as a strategy to meet the RDA for calcium, compared to using fortified foods (*Part D. Ch.1, page 15, lines 563-565*). CRN is not aware of data that demonstrates that calcium intake from dietary supplements is physiologically different from intake from fortified foods and questions the scientific basis used by the DGAC to distinguish between these two sources. However, dietary supplements contribute significantly to helping Americans achieve their individual Dietary Reference Intakes for calcium¹. Evidence does not indicate overconsumption of calcium from the use of supplements, with only 2.4% of Americans 2 years and older exceeding the UL². Intakes of calcium above the UL remain low (6%) even when the population group only includes adult supplement users³. As stated in the Advisory Report, calcium supplements do not contribute to health concerns associated with overconsumption of calcium (*Part D. Ch.1, page 19, lines 704-705*).

Evidence does not support the hypothesis that calcium supplementation increases coronary heart disease or all-cause mortality risk. A reanalysis of the Women's Health Initiative (WHI), a double-blind, placebo-controlled clinical trial consisting of over 36,000 postmenopausal women, showed no significant increase in the risk of myocardial infarction, coronary heart disease, total heart disease, stroke, overall cardiovascular disease, or total mortality, either in the overall study population or in the subset who did not use calcium and vitamin D supplements at baseline⁴. Furthermore, a recent secondary analysis of WHI data illustrated that supplemental calcium (1,000 mg) and Vitamin D (400 IU) was beneficial for heart failure risk in a sub-cohort of postmenopausal women without major heart failure precursors⁵. In a prospective cohort study of more than 74,000 women in the Nurses' Health Study, calcium supplement intake, assessed every 4 years over 24 years of follow-up, was not associated with increased risk of incident coronary heart disease or stroke⁶. Results of the prospective Canadian Multicentre Osteoporosis Study of over 9,000 community-dwelling men and women showed that supplementation with up to 1,000 mg calcium per day was associated with reduced all-cause mortality in women over a 10-year follow-up⁷. No consistent effects on mortality were observed in men.

In a review of calcium supplement use and cardiovascular disease risk, researchers stated that little evidence exists to link calcium supplementation with adverse cardiovascular outcomes⁸. Further, a review of studies that served as the basis of the U.S. Preventive Services Task Force recommendations regarding the benefits and harms of vitamin and mineral supplementation for the prevention of cancer, CVD, and all-cause mortality concluded that the available data are insufficiently consistent to support the conclusion that supplementation with calcium is harmful⁹. A recent meta-analysis of 18 studies reaffirmed that calcium supplementation with or without vitamin D did not increase coronary heart disease or all-cause mortality in elderly women¹⁰.

Further, evidence shows that calcium supplements have health benefits, particularly for bone health in older populations. The reanalysis of the WHI clinical trial data showed, among a large subgroup of over 15,000 women not taking personal calcium or vitamin D supplements at baseline, a reduction in the risk of hip fracture in post-menopausal women who received calcium

and vitamin D supplements for at least 5 years compared to placebo⁴. This association was strengthened in combined analyses of clinical trial and observational data.

CRN agrees with current clinical guidelines for preventing osteoporosis and believes they should be reinforced by the 2015 Dietary Guidelines so that Americans receive clear, consistent messages about the health benefits of calcium. The Dietary Guidelines should advise that Americans consume diets that provide the recommended total calcium intake (1,000 mg/day for men 50 to 70 years; 1,200 mg/day for women 51 and older and men 71 and older), incorporating dietary supplements if foods sources of calcium are insufficient¹¹.

Consumers understand that calcium and vitamin D supplements can help support bone health when adequate calcium and vitamin D are not consumed through food sources. CRN supported a survey which was fielded in October 2014 to measure consumer attitudes about the role of multivitamins, calcium and/or vitamin D supplements, and other supplements in improving dietary intakes. Results of the survey show that nearly 90% of U.S. adults agree that calcium and vitamin D supplements can help support bone health when adequate calcium and vitamin D are not consumed through food sources. The statement, “*Americans who do not consume the recommended amounts of calcium and vitamin D through food sources should consider a calcium and vitamin D supplement to help support bone health*” was considered easy to understand by nearly 90% of consumers and a relevant and an important reminder for health by nearly 75% of consumers.

For the 2015 Dietary Guidelines for Americans (DGA), CRN recommends modified language from the 2010 DGA on calcium and vitamin D¹²: In the United States, most dietary **calcium and** vitamin D is obtained from **dairy, fortified foods, and dietary supplements**. Some other foods and beverages, such as breakfast cereals, orange juice, and soy beverages, also are commonly fortified with these nutrients. Natural sources of vitamin D include some kinds of fish (e.g., salmon, herring, mackerel, and tuna) and egg yolks, which have smaller amounts. **Calcium and vitamin D are** available in the form of dietary supplements. **Americans who do not consume the recommended 3 servings of low/non-fat dairy per day should consume 300 mg of supplemental calcium for each absent serving. In addition, Americans who do not consume the recommended 600-800 IU of vitamin D per day from food should consider supplemental vitamin D to ensure optimal bone health.**

Thank you for the opportunity to provide comments. We would be happy to provide further information or clarification if needed.

Regards,

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

Douglas MacKay, N.D.
Senior Vice President, Scientific & Regulatory Affairs

A handwritten signature in black ink, appearing to read "Andrea Wong", with a large, stylized flourish at the end.

Andrea Wong, Ph.D.
Vice President, Scientific & Regulatory Affairs

A handwritten signature in black ink, appearing to read "Haiuyen Nguyen", with a long, sweeping flourish at the end.

Haiuyen Nguyen
Associate Director, Scientific & Regulatory Affairs

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