

September 2, 2004

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Director, Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Tarantino:

This letter is in support of the food additive petition for vitamin D₃ in cheese and cheese products by Kraft Foods Global, Inc. First, I will outline my qualifications for addressing this topic. I was a member of the Institute of Medicine panel that set the Dietary Reference Intakes (DRI) for calcium, vitamin D, magnesium, phosphorous, and fluoride in 1997. I also was a member of the U.S. Dietary Guidelines committee charged with making recommendations for the 2005 Dietary Guidelines. As chair of the Nutrition Adequacy subcommittee, I led the effort for creating food guidance to meet the DRIs. In October of 2003, NIH sponsored a conference on vitamin D. I was asked to give the talk on vitamin D requirements – present and future. The proceedings paper is in press with the American Journal of Clinical Nutrition. My research focus for the last 20 years has been calcium nutrition and bone health. Because of vitamin D's role in calcium metabolism, and consequently, bone health, my laboratory has been involved indirectly in vitamin D research as well.

Of all the nutrients considered by the Dietary Guidelines committee, we were most uncomfortable with the current DRIs for vitamin D. Considerable new data have been published since the 1997 DRIs were released that suggest that the current Adequate Intakes are too low to achieve optimal health and that safety of vitamin D intakes is much higher than the current Upper Level. Several safety trials have demonstrated that vitamin D intakes would have to greatly exceed the current Upper Level of 2000 IU/day to create toxic symptoms (1,2).

In both my W.O. Atwater Memorial Lecture invited publication (3) and the proceedings from the NIH Conference (4) I argue that we now have better data to set vitamin D requirements based on functional end points of optimal calcium absorption and suppressed parathyroid hormone levels compared to the basis for the 1997 requirements which were based on reference ranges for serum 25-hydroxyvitamin D, the best indicator of vitamin D status. Similar arguments have been made by Dr. Robert Heaney in his E.V. McCollum Award lecture publication (5) and Dr. Michael Holick in his Robert H. Herman Memorial Award lecture publication (6). These vitamin D experts suggest that vitamin D requirements be raised to 1000 IU/day. The conclusive statement of vitamin D by the Dietary Guidelines Advisory Committee is "The elderly, persons with dark skin, and persons exposed to insufficient radiation are at risk of being unable to maintain vitamin D status. Persons in these high-risk groups may need substantially more than the 1997 AI for vitamin D from vitamin D-fortified foods and/or vitamin D supplements" (7).

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Attaining optimal vitamin D status occurs through ingestion of adequate vitamin D and cutaneous synthesis. The Dietary Guidelines Advisory Committee identified high risk individuals who could not be assured of cutaneous production of vitamin D in the conclusive statement above. Even at the current Adequate Intakes (AI) given in 1997, now considered inadequate for these subpopulations, it is difficult to obtain the recommended intakes with the current food supply. Considering that fortified milk is one of the few concentrated sources of vitamin D at 100 IU/cup, a younger adult would have to consume 4 cups of milk to achieve their AI of 400 IU/day and an older adult would have to consume 6 cups of milk. These levels are only approached by the 90th percentile consumers in the scenario described in the petition when a variety of vitamin D foods including juice and cheese are consumed. The new Dietary Guidelines suggest 3 cups of milk and that is greater than current consumption. Natural sources of vitamin D are restricted to certain fatty fish, a food not commonly consumed by the U.S. population in amounts approaching vitamin D adequacy. Other foods fortified with vitamin D are variable and typically at much lower levels than milk.

For individuals who do not consume the recommended amounts of fluid milk, it is vital to have the logical substitute, i.e., other dairy foods, to also be fortified with vitamin D. The amount proposed in petition, 81 IU/30 g serving, approaches the amount of vitamin D in a serving of milk. Many of the subpopulations identified as high risk individuals, i.e. dark skinned and elderly, are the every groups more likely to substitute cheese and cheese products for milk. Without providing more vitamin D choices in the food supply, we will be forcing many Americans to consider vitamin D supplements.

In summary, I endorse vitamin D fortification of all dairy products as a safe and practical means for helping to ensure vitamin D adequacy of the U.S. population.

Sincerely,



Connie M. Weaver, Ph.D.
Distinguished Professor
Department Head

CMW:deh

cc: Robert E. Brackett, Ph.D. (HFS-001, Rm 4B064)
Garfield N. Biddle, Ph.D. (HFS-265, VERB-1229)
Ms. Judith L. Kidwell (HFS-22, Rm. 4B022)

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