



Council for Responsible Nutrition

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RE: Vitamins and Minerals and Key Nutrients Including Folate, Choline, Iodine, Iron and Vitamin B12.

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).

CRN supports the notion espoused by the 2015 Dietary Guidelines Advisory Committee (DGAC) that the Dietary Guidelines for Americans (DGA) should provide food-based guidance for obtaining nutrients needed for health and wellness across the lifespan (*Part D. Ch.1, page 7, lines 246-248*). However, several conclusions and implications statements in the Advisory Report¹ pertaining to nutrient intakes and nutrients of concern suggest Americans can benefit from the use of dietary supplements including a multivitamin/mineral (MVM) to achieve nutrient adequacy.

Most Americans are not meeting nutrient intake recommendations. The DGAC identified several nutrients that are underconsumed relative to the Estimated Average Requirement (EAR) or Adequate Intake (AI) levels set by the Institute of Medicine (IOM) and characterized these as shortfall nutrients: vitamin A, vitamin D, vitamin E, vitamin C, folate, calcium, magnesium, fiber, and potassium (*Part D. Ch.1, page 10, lines 336-342*). In some cases, intakes of shortfall nutrients are lower in those with low income status compared to those with high income status (*Part D. Ch.1, page 12, lines 445-447*). The DGAC also found that in comparison to recommended amounts in the USDA Food Patterns, the majority of the U.S. population, across all age groups, has low intakes of key food groups, including vegetables, fruits, whole grains, and dairy, which are important sources of shortfall nutrients. Furthermore, the majority of the U.S. population exceeds recommended intakes for refined grains and added sugars (*Part D. Ch.1, page 26, lines 973-977*). Indeed, it is imperative that Americans “increase intake of underconsumed food groups and nutrient-dense foods, while maintaining energy balance, and without increasing saturated fat, sodium, and added sugars,” as the DGAC stated (*Part D. Ch.1, page 27, lines 987-988*). MVMs offer a safe and assessable way to fill nutrient gaps when recommended nutrient intakes are not met through food alone, without increasing the total calories of the diet.

Dietary supplements are mainstream, with about half of the U.S. population using them; and the MVM is the most popular dietary supplement². MVMs can contribute to a healthful diet by supporting adequate nutrient intake, but should not be used to replace a healthy diet. According to a recent CRN survey³ that measured consumer attitudes and the role of multivitamins, calcium and/or vitamin D supplements and other supplements in improving dietary intakes, nearly 90% of U.S. adults agree that multivitamins and minerals can help to meet

nutrient needs when these needs cannot be met through food alone. Over 80% of U.S. adults agree that multivitamins and minerals should not be used to replace healthful dietary lifestyle habits. Other surveys show that consumers understand that dietary supplements are just one part of a healthy lifestyle, reporting “for overall health and wellness” and “to fill nutrient gaps” as the top two reasons consumers use supplements⁴. Furthermore, supplement users generally have healthy habits; they are more likely than non-supplement users to try to eat a healthy diet, engage in regular physical activity, maintain a normal weight, try to see a doctor regularly and not smoke⁵. A recommendation to use a MVM to help meet nutrient adequacy may benefit Americans without taking away from the message that they should make healthy food choices. According to CRN’s survey, the statement “*To ensure nutrient adequacy, people may consider taking a multivitamin and mineral supplement when recommended vitamin and mineral intake cannot be met through food alone*” was considered easy to understand by nearly 85% of U.S. adults and a relevant and an important reminder for health by nearly 75% of U.S. adults.

Like healthy foods, MVMs are safe. Intakes of nutrients above the tolerable upper intake level (UL) from food and supplements are low in the U.S. adult population⁶. Further, intakes of vitamins and/or minerals do not exceed the UL toward adverse effects. In fact, the Physicians’ Health Study II, the largest, long-term randomized trial of over 14,000 men 50 years and older testing a daily multivitamin, found no serious adverse effects among users of MVMs⁷. In addition, the evidence shows that supplementation with a MVM does not increase cardiovascular disease (CVD)-related mortality, total mortality, chronic diseases, or cancer⁸⁻¹⁰.

Dietary supplements or fortification of certain foods may be advantageous in specific situations to increase intake of a specific vitamin or mineral. CRN generally agrees with the DGAC’s statement: “The public may safely use dietary supplements containing RDA level of nutrients, so long as total intake from diet plus supplements does not exceed the UL. Use of products with high doses of nutrients, such that total intake exceeds the UL, should be discussed with a Registered Dietitian or other qualified health care provider. Supplement users should seek guidance about factors such as whether the amount of nutrients in supplements exceeds the UL for those nutrients. Monitoring of dietary patterns in supplement users should continue to be done, with attention paid to the highest risk groups, such as children and women who are pregnant” (*Part D. Ch.1, page 18, lines 670-678*).

CRN recognizes the importance of discussing dietary supplement use with healthcare providers, especially when higher amounts are being used. However, it is important to note that the UL is not a strict cut point at which known toxicity will occur if exceeded. Instead, it is defined as the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. In some cases, it has been recognized that data used to establish ULs are limited and that several ULs for nutrients should be reviewed⁶.

In summary, the DGAC identified several nutrients that are being underconsumed by Americans, some of which were classified as nutrients of public health concern. Use of a MVM is an accessible, no calorie and safe way to help Americans achieve nutrient adequacy when this need is not met through food alone, especially in light of evidence that Americans do not meet recommended intakes of key food groups that are good sources of shortfall nutrients. It is for these reasons that CRN believes the 2015 Dietary Guidelines should make the following recommendation:

Americans should consider taking a multivitamin and mineral supplement when recommended vitamin and mineral intake cannot be met through food alone.

The agencies may consider language such as: “Americans are encouraged to consume vitamins and minerals through adequate intakes of vegetables, fruits, whole grains, low- or non-fat dairy, lean proteins, and nuts and seeds; however, when nutrient intakes cannot be met through food sources alone, a multivitamin and mineral supplement should be considered to fill nutrient gaps.” CRN believes such a recommendation aligns with the DGAC’s overarching call for action “to achieve a population-wide ‘culture of health’ through which healthy lifestyle choices are easy, accessible, and normative” (*Part B. Ch.2, page 4, lines 134-136*).

Folic Acid, Choline, Iodine, and Iron

Dietary supplements, including MVMs, are also useful for women of child bearing age to help achieve adequacy in key nutrients known to play important roles during pregnancy, including folate, choline and iodine, and iron. The Dietary Guidelines should make specific

recommendations regarding these nutrients to ensure that women capable of pregnancy achieve adequate intakes for healthy pregnancies and healthy babies.

CRN supports the DGAC's recommendation for folic acid supplementation. The DGAC also noted the following implication based on conclusions drawn from the research review of the relationship between dietary patterns and risk of congenital anomalies: Women of reproductive age should consume folic acid in the form of a supplement or through fortified foods in the range recommended by the U.S. Preventive Services Task Force (400 to 800 micrograms) in addition to consuming a diet rich in vegetables, fruits, and grains; lower in red and processed meats; and low in sweets (*Part D. Ch.2, page 34, lines 1285-1288*). In addition to folic acid supplements, CRN suggests the Dietary Guidelines include MVMs that provides 100% of the Daily Value for folic acid as options that can help meet requirements.

Choline is a key building block in the biosynthesis of phosphatidylcholine, acetylcholine, and betaine, which are important for diverse functions in the human body. Choline is essential to early stages of human development as it contributes to the maintenance of normal cognitive, cardiovascular, and hepatic function. Studies have shown that choline intake is important for pregnancy and lactation¹¹⁻¹⁴. The DGAC did not classify choline as a nutrient that is underconsumed based on 2007-2010 NHANES/WWEIA data (*Part D. Ch.1, page 10, lines 340-342*). This interpretation is in conflict with a recent study that examined NHANES data up to 2010 and found that 92% of the population fails to consume the AI for choline¹⁵. Moreover, the DGAC identified choline as one of the nutrients for which adequate goals are not met in almost all USDA Food Patterns (*Part D. Ch.1, page 22, lines 827-828*). The data demonstrate that choline is a shortfall nutrient and should be included in the Dietary Guidelines recommendations as a nutrient for which intakes should be increased.

Iodine is a dietary mineral required for the production of thyroid hormones, which are necessary for brain development *in utero* and during early childhood. Iodine deficiency during pregnancy results in irreversible brain damage and other neurological abnormalities. Intake data demonstrates that pregnant and lactating women in the U.S. may be at risk of insufficient iodine intake¹⁶. In fact, the Office of Dietary Supplements (ODS) began its Iodine Initiative in response to concerns that some pregnant women may have inadequate intakes of this nutrient at a time of high physiologic demand. ODS analyzed NHANES data from 1999-2006 and determined that

although 80% of pregnant women were advised by their physician to take supplements containing iodine, only 20 % used iodine containing supplements, reinforcing concerns that iodine intake may be inadequate in this population¹⁷. Sharing similar concerns, The American Thyroid Association, Endocrine Society, and American Pediatric Association recommend that all pregnant and lactating women receive a multivitamin that contains 150 µg iodine. CRN supports this recommendation and encourages HHS and USDA to include a recommendation in the Dietary Guidelines to help reinforce the message that women capable of pregnancy should make sure they achieve adequate iodine intake. A daily MVM containing recommended amounts of iodine is an efficient way to ensure adequate intake.

Iron is classified by the DGAC as a shortfall nutrient of public health concern for adolescent females and adult females who are premenopausal due to the increased risk of iron-deficiency in these groups (*Part D. Ch.1, page 16, lines 607-608*). In review of the evidence, the DGAC found that in adults of all ages, a small proportion of iron supplement users have intakes above the UL. Concerns related both to cardiovascular health and oxidant damage exist, but are not well-defined. Iron supplementation is very common during early childhood and pregnancy, but is unlikely to pose a health risk (*Part D. Ch.1, page 19, lines 707-710*). CRN recommends that the 2015 DGA adopt the 2010 DGA language on iron supplementation: Women who are pregnant are advised to take an iron supplement as recommended by an obstetrician or other health care provider. Additionally, CRN recommends dietary guidance including a daily MVM containing recommended amounts of iron for adolescent females and adult females who are premenopausal.

Vitamin B12

The 2015 DGAC did not assess vitamin B12 status in older populations comparable to the 2010 DGAC. Based on NHANES data, the 2010 DGAC concluded that individuals older than age 50 years are consuming adequate intakes of vitamin B12, including naturally occurring vitamin B12 found in foods and crystalline vitamin B12 consumed in fortified foods. Nonetheless, a substantial proportion of individuals older than age 50 years may have reduced ability to absorb naturally occurring vitamin B12 but not the crystalline form¹⁷. Therefore, the

2010 DGAC provided the following implication in its Scientific Report:

Although individuals older than age 50 years appear to be meeting their need for vitamin B12, they should be encouraged to consume foods fortified with B12, such as fortified cereals, or the crystalline form of B12 supplements, when necessary. Practitioners should assess vitamin B12 status in those older than age 65 years, using a low serum vitamin B12 value of less than 300 pg/mL, high serum methylmalonic acid value of greater than 0.4 $\mu\text{mol/L}$, and serum total homocysteine level of greater than 15.0 $\mu\text{mol/L}$ as evidence of vitamin B12 deficiency.

The 2015 DGAC did not find that vitamin B12 was underconsumed in the U.S. and did not list it as a nutrient of concern for certain populations as did the 2010 DGAC. The 2015 DGAC also did not consider clinical evaluations of vitamin B12 status, the ability of certain populations to adequately absorb vitamin B12 from food, and consequently, potentially low vitamin B12 status in certain populations. Subcommittee 1 utilized NHANES 2007-2010 data to quantify mean intake and percentiles of usual intake of vitamin B12 from food and beverages by Dietary Reference Intake age-gender groups in the United States. Less than 3% of males 50 and older and 7% of females 50 and older were found to have intakes below the EAR (*Appendix E-2.1, page 28*). Further, the USDA Food Patterns provide 275-450% of the target levels for vitamin B12 for all age/gender groups (*Part D. Ch.1, page 134, Figure D1.8*), but do not take into account the older population's decreased ability to absorb naturally occurring vitamin B12 and therefore low vitamin B12 status. Although vitamin B12 intakes from food and beverages do not appear to be at critically low levels, and USDA Food Patterns provide sufficient vitamin B12, the scientific evidence¹⁷ suggests that even if older people are consuming enough vitamin B12 through the diet, they may not be absorbing the vitamin sufficiently to have adequate vitamin B12 status.

CRN recommends that HHS and USDA address the potential for low vitamin B12 status in the older population due to reduced ability to absorb naturally occurring vitamin B12. HHS and USDA should maintain vitamin B12 as a nutrient of concern for older populations and carry forward the vitamin B12 recommendations from the 2010 DGA, including a recommendation for

older individuals to have their vitamin B12 status checked by a healthcare professional. A daily MVM with 100% of the Daily Value for vitamin B12 provides the vitamin in the well absorbed crystalline form and can help individuals 50 years of age and older meet their needs for this nutrient.

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.
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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 "Haiyuen Nguyen", with a long, sweeping flourish at the end.

Haiyuen Nguyen
Associate Director, Scientific & Regulatory Affairs

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