Dietary Reference Intakes and Nutrition Labeling: Updating the Daily Values for Vitamins and Minerals and the Implications for Industry and Consumers

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Understanding that our knowledge of nutrition science has almost completely transformed since 1968, the FDA and Health Canada requested specific guidance from the Institute of Medicine (IOM) on the appropriate use of Dietary Reference Intakes (DRIs) in nutrition and supplement labeling in 2002. In 2003, the IOM issued the report, Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification[1], which recommended three important changes to food and supplement labels:

1. The Nutrition Facts Panel should contain both the actual amount of a nutrient by weight and percentage Daily Value (%DV) (mimicking the Supplement Facts Panel).
2. The %DV should be based on the estimated average requirement (EAR) as opposed to the traditionally

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used Recommended Daily Allowance (RDA).

3. The EAR used should be a population-weighted mean of EARs, rather than selecting the highest value of an EAR for any age and/or gender group.

In 2007, FDA announced its plans to update the daily values (DVs) in response to the IOM's recommendations to reflect the current DRI values for nutrients.[2] Since that time, a debate within the scientific and nutrition communities has emerged and various stakeholders have weighed in regarding the appropriate methodology that FDA should adopt: a population coverage approach using the RDA, or a population-weighted approach using the EAR.

RDA vs. EAR

The IOM sets individual DRI values (i.e., the RDA and EAR) for subpopulations based on their gender and age. For example, the DRI values for iron are higher for menstruating women than for adolescent boys. Recall basic calculus principles and the normal distribution, or "bell", curve. The EAR is the mean or number at which half the subpopulation, assuming normality, meets the target for a nutrient. Because the EAR is the mean value, it is the closest estimate of what any one individual in a normal population would require to prevent deficiency (i.e., 50% will require more and 50% will require less). The RDA is the value at which 97.5% of the population is sufficient for a nutrient (2 standard deviations above the EAR or mean).

DVs are currently calculated by selecting the highest RDA among all the subpopulations excluding pregnant and/or lactating women. For example, the DV for iron reflects the RDA for women 19-30 and 31-50 years of age. This is known as a population coverage approach because all subpopulations and 97.5% of the subpopulation requiring the greatest amount of a given nutrient are covered. In comparison, a population-weighted approach is the average of all subpopulations. A population-weighted EAR would thus reflect the mean value for the entire population (i.e., all subpopulations combined), whereby half the population would still require a greater amount to successfully meet their target intake.

Implications for Industry and Consumers

Newly published data supports the position that FDA should continue to utilize the highest RDA in nutrition labeling vs. a population-weighted EAR approach.[3] The EAR approach is also likely to have significant implications for product labeling, consumer education, and public health. For nearly 40 years, consumers and healthcare professionals have become accustomed to the DV reflecting the population weighted RDA. There is no question or debate that nutrition labeling should be updated to reflect actual amounts in addition to the %DV and the current science surrounding DRI values. Healthcare professionals and consumers have traditionally utilized the DV on the Nutrition and Supplement Facts Panels as a goal for an individual. To support the position that FDA should continue to utilize the population coverage RDA in nutrition labeling, actual population-weighted EAR and RDA values were calculated using the current IOM's method, the current DRI values, and the 2010 U.S. Census data. These values indicate that large portions of the population that would have a greater requirement for each nutrient should FDA move to the population-weighted EAR model.

Adoption of the EAR model would have important implications for food and supplement labeling claims. As authorized by the Nutrition Labeling and Education Act of 1990[4], nutrient content claims can be used to characterize or describe the level of a nutrient or dietary substance in a product, using terms such as *free*, *high*, and *low,* or terms such as *more*, *reduced*, and *lite* when comparing the level of a nutrient in a food to that of another food. Nutrient content claims are linked to reference values on the label and determine whether a food or dietary supplement is eligible to bear such a claim. Any change to the current reference value amounts will require FDA to reevaluate its current approach to nutrient content claims. However, if FDA adopts the EAR model, there is a greater risk that the amount of a nutrient required for a food to be considered a "good" or "excellent" source would be significantly lower, resulting in less nutritious foods using nutrient content claims.

In addition, some manufacturers may choose to reformulate products by reducing nutrient levels in order to meet the new reference standards. A de-fortification of foods and supplements could have a detrimental impact on public health given that fortified foods and dietary supplements contribute significantly to micronutrient intakes, with an even greater impact on subpopulations with special dietary needs. Studies confirm that a significant percentage of the population still does not meet the EAR for essential nutrients.[5] Using the EAR effectively lowers the DV for many important nutrients by establishing target intake values that meet the needs of only 50%

of the population – further contributing to this problem.

From an individual consumer standpoint, population coverage values using RDA are necessary because many consumers use label values as their personal target intakes, rather than a midpoint of the population. Labels assist consumers in comparing the nutrient content between foods and assessing the nutrient contribution of a given food within their overall diet, e.g., a product that contains 100% DV for vitamin C would provide 100% of that nutrient. Consumers have the most familiarity with the RDA as their reference value, and FDA would be tasked with a considerable amount of consumer education if the agency shifts its nutrient value calculations to the EAR.

FDA received nearly 700 comments to its 2007 Advanced Notice of Proposed Rulemaking[6] on the revision of reference values and mandatory nutrients. In its 2012 Semiannual Regulatory Agenda[7], the agency had announced its intention to publish a Notice of Proposed Rulemaking for comment by December 2012, which is now expected by Q1 of 2013. As FDA continues to evaluate its approach to updating the daily values, any changes to the current nutrition labeling scheme should not only be scientifically valid, but also help consumers easily and accurately meet their nutritional targets. The updated labeling system should also be consistent with other public health recommendations and nutrition policy initiatives, such as the Dietary Guidelines for Americans[8] and MyPlate.[9]

1. Food and Nutrition Board. Institute of Medicine: "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification." Washington, DC: National Academy Press, 2003.
2. Food Labeling: Revision of Reference Values and Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007).
3. Wallace TC. Dietary reference intakes and nutrition labeling: updating the daily values for vitamins and minerals. J Amer Coll Nutr 2013 (accepted; in press).
4. Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (1990).
5. Fulgoni VL, Keast DR, Bailey RL et al. Foods, fortificants and supplements: where do American's get their nutrients? J Nutr. 2011;141:1847-1854.
6. Food Labeling: Revision of Reference Values and Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007).
7. Department of Health and Human Services Semiannual Regulatory Agenda, 77 Fed. Reg. 7945, 7947 (Feb. 13, 2012).
8. U.S. Department of Agriculture and U.S. Department of Health and Human Services, Dietary Guidelines for Americans, available at: http://www.cnpp.usda.gov/dietaryguidelines.htm (last accessed on January 9, 2013).
9. U.S. Department of Agriculture, MyPlate, available at: http://www.cnpp.usda.gov/MyPlate.htm (last accessed on January 9, 2013).