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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: [Docket No. 2006N-0168] Food Labeling: Revision of Reference Values and Mandatory Nutrients; Advance Notice of Proposed Rulemaking 72 FR 62149 (November 2, 2007).

To whom it may concern,

The Council for Responsible Nutrition (CRN) appreciates the opportunity to comment on this important regulation, the result of which has potential for significant public health implications. We recognize and support the need for updating the scientific basis of Daily Values (DV) to make it commensurate with the current scientific knowledge of nutrition. We and our member companies are committed to promoting the health and well-being of the American public, and we believe our comments reflect the best approach to the issues listed in the ANPRM. The following comments are organized in a general manner and cover only the major questions of relevance.

As a matter of principle, CRN strongly believes that the only logical basis for the DV, for those nutrients which have been assigned such a value, is the highest Recommended Dietary Allowance (RDA) or Adequate Intake (AI) established by the Institute of Medicine's (IOM) DRI process. The food label is an important tool consumers use not only to compare the relative nutrient content between foods, but also to assess the nutrient contribution of a given food in the context of the overall diet. Accordingly, use of an RDA (or AI)-based and population-coverage approach, not a population-weighted average for DVs on the food label will provide the best available targets for nutrient intake and ensure consistency with other nutrition policy initiatives (such as the USDA Dietary Guidelines for Americans and the Food Guide Pyramid).

Estimated Average Requirement (EAR) vs. Recommended Dietary Allowance (RDA)

CRN believes that the DV should not be based on an Estimated Average Requirement (EAR). Changing the basis of the DV from the presently used RDA to the EAR would lower the DV for many important nutrients, in some cases dramatically, by establishing target intake values that are the lower bound of acceptable intakes and would meet the needs of only 50 percent of the population. Nutrients such as iron would be dramatically impacted by such a shift in approach (Table 1). If implemented, this approach could have detrimental effects on the nutritional health of the American public.

Much of the support for basing the DV on the EAR is built on misconceptions of the purpose and use by consumers of the DV on food labels. In its Labeling Report, the IOM states (1) that DVs serve two purposes: "to enable the consumer to compare the nutrient contents of different food products and to determine the relative contributions of a food to an overall health-promoting diet." Obviously, the first purpose could be served by a simple quantitative measure such as milligrams per kilogram or per serving of food, without any reference to nutrient requirements or recommendations. The second purpose requires addressing nutrient needs or recommendations, and this clearly implies that the individuals reading food labels are expected to have their choices of foods and overall diets influenced by and evaluated in relation to the DV. In apparent self-contradiction, the IOM further states that "the information in nutrition labeling is not intended to be used to plan individual diets" (1). It seems that the IOM is contradicting itself by recognizing that the DV will influence individual diets but at the same time cautioning that this is not to be done. These mutually exclusive positions on the uses of the DV are found in subsequent papers that advocate the EAR as the basis for the DV (2, 3). The implication of the recognized impact on actual intakes by the DV as stated by the IOM, is ignored in statements such as the IOM "did not include any suggestion that the DV should be promoted as the target intake for individuals" (2).

Regardless of the intent of policymakers and regulatory officials, survey results suggest that DVs on food labels are actually used by many consumers as guidance for their individual

desirable intakes (4-11). Such use is implicitly acknowledged by the IOM (1), European Commission (12), and others (2) through their assertion that the DV will influence an individual's nutrient intake level. Nonetheless, the assertion is still frequently made that DVs are not to be used as advice to individuals (1, 2, 12).

How the DV should or is intended to be used or promoted is irrelevant in this context. What is relevant is how consumers actually use the DV, which in our opinion (and many others), is as a means to determine how a food contributes to their individual nutrient goals. If FDA were to follow the IOM recommendation (and by default the rationale behind it), then the Agency would be compelled to ensure that consumers use the DV on the food label as the IOM intended. This would leave FDA with the seemingly insurmountable task of altering consumer behavior to ensure that individual consumers not use the food label to help plan their diet.

Justification for using the EAR and not the RDA as the basis of the DV is often done by misleading characterizations of the RDA, although these descriptions may be accurate in isolation. For example, the IOM report (1) states that "the RDA is not the best estimate of an individual's nutrient requirement," or equivalent statements (2, 13). Such statements are true in isolation because the RDA is defined as the level of intake two standard deviations above the EAR (the "best estimate" of the requirement) (14), but become false in the context of identifying desirable (i.e. "target") intakes for persons (almost everyone) who do not know their individual nutrient requirements.

Thus, the RDA (or AI in the absence of an RDA) is the most appropriate value on which the DV should be based. RDAs and AIs represent targets for individuals' nutrient intake, whereas the EAR represents the average requirement for the population. The recurring debate about whether a reference value is appropriate for application to individuals or populations (1, 2, 13) is not directly pertinent to the DV. Individuals, not populations, read and rely on the nutrition label for the purposes of comparing products *and* to evaluate the contribution of those products to their own diet. It therefore follows, that the DV be based on an appropriate target value for individuals, i.e. the RDA.

The RDA-based approach will ensure that the information provided in nutrition labeling is consistent with the guidance provided in other public health initiatives. Recommendations from the Dietary Guidelines for Americans and the Food Guide Pyramid (15) are based on the notion that it is important that diets achieve recommended nutrient intake levels for essential nutrients, i.e. RDAs or AIs. Using an approach that renders the nutrition label inconsistent with other public health recommendations, would at best lead to confusion among consumers and health care professionals, and worse, pose public health problems by placing large segments of the population at risk for nutrient inadequacy.

Population weighted vs. Population coverage

Equally important to the RDA-based approach, is that the DV be based on a population coverage RDA, i.e. the highest age-gender group RDA for those nutrients for which an RDA has been established. Such an approach would cover the needs of virtually all of the population. In contrast, a population-weighted approach would average out the needs of the population by including together the needs of various segments. Inclusion of segments with lower needs (such as children or elderly) with those of segments with higher needs (such as adolescents and adults) would average out the needs of the population and could be accompanied by a higher risk of inadequacy among some segments.

Implicit in the recommendation made in the IOM Report (1) are unfounded concerns that Americans are "over-nutrified," i.e. that nutrient intake levels are approaching the tolerable upper intake level (UL). The IOM and others (e.g., Beaton 2007 (2)) express concern that lower label values are needed to reduce the risk of over-consumption of many nutrients, and that using a population-weighted EAR as the basis of the DV on the nutrition label will somehow address these concerns. With the exception of a few specific nutrients and subsets of the population, there is little evidence supporting this rationale. In contrast, the NHANES surveys consistently show that on average, many Americans fail to achieve the recommended intakes for many nutrients, including vitamins C and E, calcium and magnesium (16). Not only is "Americans are over-nutrified" an unsound argument on which to base the recommendation for a population-

weighted EAR, but it also acknowledges that in fact, individual consumers rely on the nutrition label to assess the contribution of a food product to their diet, i.e. that the DV can influence individuals' nutrient intakes.

If a substantial number of consumers use the DV as surrogates for their specific age-gender group RDA (if they are even aware that there are age-gender specific differences), the DV needs to be a population-coverage value so that consumers with the highest requirements will be more likely to achieve adequate intake. Clearly, the population-coverage value is the highest of the RDAs. Again, as noted earlier, the IOM and other advocates of the population-weighted EAR basis for the DV acknowledge that label values are likely to influence actual intakes by consumers.

On a practical basis, the choice of population-weighted values versus the highest age-gender group values makes a very large difference for iron and substantial differences for several other nutrients, although the impact is relatively small (only 10-20 percent, or the difference between EAR and RDA) for some nutrients that have similar values (considering either EAR or RDA) across different age-gender groups. For iron, with many consumers using the DV as surrogates for their specific RDA, a population-weighted EAR as the basis of the DV for iron could produce adverse decreases in the iron intake of young women. (See Table 1).

Use of Adequate Intake (AI) in the absence of an RDA

CRN believes that for those vitamins and minerals without an RDA, the AI should be used as the basis for the DV. The AI is intended as a substitute for the RDA for nutrients without appropriate data to set EAR and calculate RDA (17). That is, the AI, like the RDA, is a target intake for most individuals in the population. Like the RDA, the AI is not an estimate of the average nutrient need (the best estimate of the need of an individual with unknown specific needs, i.e., the vast majority of the population). And further, this best estimate of an individual's needs is never an appropriate target intake unless the individual's needs (i.e., the specific requirements) are individually known—and that is a very rare circumstance. Indeed, the RDA

and AI are identical in principle, in that both values represent targets or goals for adequate nutrient intake well above the average requirement. It is also important to have a consistent approach. In the absence of RDAs, AIs should be used as the basis of the DV. A regulation that bases some DVs on EARs and others on AIs would make no sense by using target intakes for some nutrients and average requirements for others. Further, doing so would be confusing and misleading to consumers and health professionals.

Furthermore, CRN believes that all AIs should be used, regardless of how they were derived. IOM established AIs for those nutrients which lacked sufficient quantitative data to establish EARs (and therefore calculate RDAs). Presumably, the intent of IOM is to replace the AIs with EARs and RDAs where the data warrant such a change. However, it is unclear when IOM may provide such updates and FDA should not wait for these changes to revise the basis of the DVs, which are already extremely outdated.

As in the case with RDAs, where a population coverage approach is advocated, for DVs based on AIs, the highest of the age-gender group values should also be used. The reasons and rationale are identical to those presented above in the EAR-RDA discussion. The need is for population-coverage values because many consumers use label values as their individual target intakes.

Dietary Fiber

CRN will provide here a brief set of general comments pertaining to dietary fiber. As a matter of principle, CRN believes that FDA should adopt for the purposes of food and dietary supplement labeling, a more open and inclusive system for identifying the presence and/or functional characteristics of fiber or fiber-containing products. FDA should not limit the definition of dietary fiber to include only certain fiber types. As there is as yet no consensus for defining dietary fiber by either analytical or functional means, FDA should allow for flexibility in the definition. The term “fiber” as it is presently used in the marketplace represents many different constituents, synthesized chemically or extracted from natural sources which are responsible for a variety of health benefits. Given the lack of consensus around the choice of

methodological or functional definitions, we propose that FDA allow companies that make functional or compositional claims pertaining to fiber to bear the burden of substantiation of such claims. FDA should not restrict the identification of fiber on the label to only "functional fiber" or fiber quantified by one analytical method, or to only total fiber, or soluble and insoluble fiber. These terms do not adequately reflect the type and scope of fiber products present in the marketplace for which there are adequate data supporting their use and function. As long as companies can support and substantiate their fiber claims using a scientifically valid and defensible approach, they should be allowed to make functional and content fiber claims.

Sincerely,

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Table 1. Comparison of Daily Values[@] (DV) for certain nutrients

Nutrient	**Current DVs**	**CRN position* (based on new DRIs)**	**IOM recommendation[†] (based on new DRIs)**
Vitamin A	5000 IU (1500 mcg)	3000 IU (900 mcg)	1800 IU (529 mcg)
Vitamin D	400 IU (10 mcg)	600 IU (15 mcg)	280 IU (7 mcg)
Niacin	20 mg	16 mg	11 mg
Vitamin B-6	2 mg	1.7 mg	1.1 mg
Iron	18 mg	18 mg	6.1 mg
Phosphorus	1000 mg	1250 mg	588 mg
Magnesium	400 mg	420 mg	286 mg
Zinc	15 mg	11 mg	7.5 mg

[@]Values listed represent 100% of the DV

*DV based on a population-coverage RDA (highest RDA)

[†]DV based on a population-weighted EAR

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