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Nutrition Labeling

A Look at FDA's Proposed Requirements

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On Nov. 2, 2007, the Food and Drug Administration (FDA) published an Advance Notice of Proposed Rulemaking (ANPR) to revise nutrition labeling requirements for foods and dietary supplements. FDA requested public comments on which nutrients should be listed in Nutrition Facts and Supplement Facts labels, what new reference values should be used to determine percent daily values (DVs) and which factors should be considered in calculating DVs, as well as several specific issues regarding calories, fats, cholesterol, carbohydrate, protein, dietary fibers, sugar alcohols, sodium, chloride, vitamins and minerals. FDA's ANPR commences perhaps the most sweeping food labeling modification effort since 1993, when FDA issued the nutrition labeling rules mandated by the Nutrition Labeling and Education Act (NLEA) of 1990.[1]

The first nutrition labeling regulations were created in 1974 when FDA and the U.S. Department of Agriculture (USDA) established voluntary nutrition labeling and required mandatory labeling of products containing added nutrients or bearing nutrition claims. The early regulations were amended in 1984 to add sodium as a mandatory nutrient and potassium as a voluntary nutrient to be listed in voluntary nutrition labeling,[2] but otherwise remained essentially unchanged.

Published in response to NLEA, the 1993 regulations required nutrition labels to include information on calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, dietary fiber, total protein, vitamin A, vitamin C, calcium and iron.[3] FDA established Reference Daily Intakes (RDIs) for vitamin K and selenium in 1995[4] and added *trans* fats to the nutrition label in 2003.[5] In 1997, FDA required that dietary supplements include a Supplements Facts label.[6] Food and supplement labels must include the percentage of the applicable reference value for each nutrient with an established Daily Reference Value (DRV)

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or RDI, identified as the "% DV" or "% Daily Value" on the label.[7] If the food label makes a specific health claim about a particular nutrient, information on that nutrient must also be included on the nutrition label.[8] With certain exceptions, a food or dietary supplement is deemed misbranded "unless its label or labeling bears nutrition information."[9]

Based on health and nutrition information available at that time, FDA's 1993 regulations established the RDIs for essential vitamins and minerals,[10] and the DRVs for other particular food components.[11] The RDIs were based on the 1968 Recommended Daily Allowances (RDAs) and nutrition data collected in 1989, and the DRVs were based on the National Academy of Sciences (NAS) Diet and Health Report, the 1990 Dietary Guidelines for Americans and the Surgeon General's Report on Nutrition and Health (for dietary fiber).[12] In 1995, FDA established RDIs for vitamin K, selenium, chromium, molybdenum and chloride, again based on 1989 nutrition data.[13] The RDI and DRV reference values were based on a 2,000 calorie diet, which FDA considered the best amount to cover the greatest portion of the population and an easy number for consumers to remember.[14] To be eligible for an FDA-approved nutrient content claim, there must be an FDA-established DRV or RDI for the nutrient.[15]

Developments in Nutrition Since NLEA

A tremendous amount of new nutrition data and information was generated in the 17 years following NLEA. Of particular significance are the 2005 Dietary Guidelines for Americans,[16] and the Institute of Medicine's (IOM's) series of reports on the Dietary Reference Intakes (DRIs) for vitamins and other micronutrients,[17] minerals,[18] dietary antioxidants and related compounds,[19] and energy and macronutrients[20] published from 1997 to 2004. In addition, the IOM released a 2003 report, "Guiding Principles for Nutrition Labeling and Fortification," on recommended use of its DRIs in nutrition labeling.[21]

The DRIs are nutrient intake standards established by IOM for healthy individuals and include the Estimated Average Requirements (EARs), the RDAs, the Adequate Intakes (AIs), Tolerable Upper Intake Levels (ULs), and Acceptable Macronutrient Distribution Ranges (AMDRs).[22] The EAR is the "average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group."[23] The AI is the "recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently health people that are assumed to be adequate; used when an RDA cannot be determined."[24] The UL is the "highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population."[25] The AMDR is "the range of intakes of an energy source that is associated with a reduced risk of chronic disease yet can provide adequate amounts of essential nutrients."[26]

IOM Recommendations For Change

The IOM DRI reports revised existing RDAs for some nutrients (e.g., iron), converted existing RDAs to AIs for other nutrients (e.g., calcium), established new RDAs and AIs for certain nutrients (e.g., copper and fluoride), and set AMDRs for carbohydrates, total fat, omega-3 and omega-6 fatty acids, and protein.[27] IOM's 2003 report offered several recommendations for incorporation of the new DRIs in updated nutrition labeling. IOM recommended that nutrition information continue to be expressed in terms of percent DV, but suggests that DVs be based on a population-weighted method rather than the current method of population-coverage. The population-coverage method applies the highest recommended intake level for all gender and age groups, whereas the population-weighted method relies on a central value of need.[28] FDA proposed use of the population-weighted method to establish RDIs in 1990, but faced with considerable and uniform support for continued use of the population-coverage method, chose not to do so.[29] Use of a population-weighted approach would likely decrease the percent DV values for most nutrients.

IOM further recommends adoption of a population-weighted EAR as the basis for the DVs rather than an RDA. The RDAs are set at the highest level of need as a way of ensuring that most Americans will get the nutrients they need. However, IOM concluded that the RDAs are "so high that they are essentially irrelevant for most of the population."[30] While using a population-weighted EAR to establish the DVs would lower the DVs, IOM believes it is a more accurate representation of actual need for the majority of Americans and would not lead to nutritional deficiencies. If a nutrient does not have an EAR, IOM recommends using a population-weighted AI.[31]

The IOM further recommended that AMDRs be relied upon for the DVs for protein, total carbohydrate and total fat, which would change the currently recommended amounts slightly.[32] FDA has received nine citizen petitions requesting changes to the total carbohydrate declaration requirements.[33] IOM has urged FDA to set the DVs for saturated fat, *trans* fat and cholesterol as low as possible, while

continuing to use a 2,000 calorie diet for expressing energy intake.[34] IOM advocated development of DVs for infants (ages one year or less), toddlers (ages one to three), pregnancy and lactation.[35] Finally, the IOM suggested that supplements use the same DVs as food, and that the actual amounts of nutrients be included in the Nutrition Facts and Supplement Facts labels.[36]

IOM's Recommended Dietary Fiber Definition

Another IOM recommendation is related to the definition of dietary fiber. Currently there is no formal definition of fiber in the Federal Food, Drug, and Cosmetic Act, nor in the FDA regulations. A 2001 IOM report on dietary fiber recommended three new definitions: "dietary fiber," "added fiber" and "total fiber." IOM proposed to define dietary fiber as "nondigestible carbohydrates and lignin that are intrinsic and intact in plants,"[37] and "added fiber" as "isolated, nondigestible carbohydrates that have beneficial physiological effects in humans."[38] The sum of "dietary fiber" and "added fiber" would constitute "total fiber."[39]

IOM also concluded that the terms "soluble fiber" and "insoluble fiber" should be phased out, since scientific research shows that the benefits of fiber are linked not to solubility but to its two physicochemical properties—viscosity and fermentability.[40] IOM acknowledged that adopting its proposed fiber definitions will require "major developments and modifications … in the area of fiber analysis and additional research into physiological actions of many fibers," but reasoned that ultimately such developments would lead to significant improvements over existing methods and enhance current understanding of fiber's physiological effects.[41]

Finally, the 2005 Dietary Guidelines for Americans provides several recommendations considered by FDA in formulation of the ANPR. The Dietary Guidelines support the current recommendation that saturated fat intake be kept to less than 10 percent of Calories and cholesterol intake be less than 300 mg/day. The Dietary Guidelines also recommend that sodium intake be less than the UL of 2,300 mg/day, and identified key nutrients of concern based on dietary intake data and evidence of health problems, including calcium, fiber, and vitamins A, C and E.[42]

Stakeholders' Input Sought

FDA's ANPR requests public comments on numerous aspects of the recommendations by IOM, the Surgeon General, the agency's Obesity Working Group and others for updating nutrition labels. First, FDA seeks input on the proposed changes to the DVs as well as the appropriate method for setting the DVs and which populations to target. For nutrients with an established EAR, FDA asks whether the DVs should be based on the EAR, and if so whether the EAR calculation method should be population-weighted or population-coverage. FDA alternatively asks whether AIs should be used to establish the DVs and if so, whether a population-coverage AI or population-weighted AI should be used.[43]

FDA requests comments on whether the DVs should be intended for specific populations. The current system applies the DVs for all people ages four and older, but does not set separate DVs for infants, toddlers, and women who are pregnant or lactating. FDA asks whether DVs should be set for any or all of these groups, and if so, what method should be used to set the DVs.[44]

In addition, FDA solicits comments about labeling requirements for energy and specific nutrients. FDA is interested in whether or not it should continue to use a 2,000 Calorie diet as a reference energy intake or use Estimated Energy Requirements (EERs) as reference intakes. If EERs are used, FDA seeks comments on how they should be set.[45] FDA asks whether the method of calculating grams of carbohydrates should be changed and if so, what method should be used. Specifically, FDA asks whether types of carbohydrates (such as starch) should be classified on the nutrition label and whether carbohydrates should be classified based on their physiologic effect. Further, FDA requests information relating to consumer interpretation of the "Calories from fat" listing on nutrition labels.[46]

With regard to specific nutrients, FDA wants comments on recommendations for cholesterol, sodium, chloride, vitamin K, vitamin D, calcium, pantothenic acid and biotin. If comments suggest changing the current recommendations, FDA would like feedback on how the new recommendations should be set.[47] FDA also asks several questions relating to dietary fat, including whether the recommended intake of total fat, saturated fat and *trans* fat should be changed and if so, what method should be used to calculate recommended intake. FDA asks whether it should require polyunsaturated and monounsaturated fat labeling and how to establish a DV for polyunsaturated fat.[48] FDA seeks input on whether declaration of sugar alcohols should be made mandatory and if so, what method should be used to calculate caloric values for sugar alcohols.[49]

FDA further asks a number of questions relating to the IOM dietary fiber recommendations. First, FDA solicits comments on whether it should adopt the IOM proposed definition for dietary fiber, whether declaration of soluble and insoluble fiber should be made mandatory, and whether "soluble fiber" and "insoluble

fiber" should be described instead as "viscous fiber" and "nonviscous fiber."[50]

Finally, FDA asks for consumer data "[t]o help determine which regulatory options might address problems associated with food package labels reflecting current DVs." Specifically, FDA seeks consumer perception data on how and the extent to which consumers use percent DV, whether consumers find percent DV helpful, and whether there are any particular nutrients for which consumers would like percent DVs. FDA also asks for data and information to help evaluate how the proposed changes would impact consumers.[51]

The November 2007 announcement is only an ANPR, the very early initial step in the rulemaking process. The deadline for submission of public comments in response to the ANPR is Jan. 31, 2008, but the deadline is likely to be extended, possibly more than once. If there is one certainty about the ANPR, it is that the nutrition labeling issues generate significant debate among FDA, consumer and industry groups. If history provides any precedent, we can expect the rulemaking process to require at least three years if not longer.

1 Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343 et. seq. (2000)).
2 49 Fed. Reg. 15510 (April 18, 1984); *see also* Paula Kurtzweil. *Good Reading for Good Eating. Available at* http://www.fda.gov/fdac/special/foodlabel/goodread.html. Accessed on November 11, 2007.
3 21 C.F.R. § 101.9(c) (1994).
4 60 Fed. Reg. 67164 (Dec. 28, 1995).
5 68 Fed. Reg. 41434 (July 11, 2003).
6 62 Fed. Reg. 49826 (Sept. 23, 1997).
7 21 C.F.R. § 101.9(d)(7)(ii).
8 *Id.* § 101.9(c)(8)(iii).
9 21 U.S.C. 343(q)(1).
10 21 C.F.R. § 101.9(c)(8)(iv) (1994).
11 *Id.* § 101.9(c)(9).
12 58 Fed. Reg. 2206 (Jan. 6, 1993).
13 60 Fed. Reg. 67164 (Dec. 28, 1995).
14 *Id.* at 2217.
15 21 C.F.R. § 101.13(b)(1).
16 U.S. Dep't of Health and Human Services and U.S. Dep't of Agriculture, "Dietary Guidelines for Americans, 2005," 6th ed., Washington, DC: U.S. Government Printing Office, 2005. Available at http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf
17 IOM, Executive Summary. (1998). *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline,* Washington, DC: National Academy Press., 1-16; IOM, Executive Summary. (2001). *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc,* Washington, DC: National Academy Press, 1-28.
18 IOM, Executive Summary. (1997). *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride,* Washington, DC: National Academy Press, 1-20. IOM, Executive Summary. (2004). *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate,* Washington, DC: National Academies Press, 11-20.
19 IOM, Executive Summary. (2000). *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids* Washington, DC: National Academy Press, 1-20.
20 IOM, Executive Summary. (2004). *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids,* Washington, DC: National Academies Press, 1-20.
21 IOM. (2003). *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification,* Washington, DC: National Academies Press.
22 DRI Values: Definitions. *Available at* http://www.iom.edu/CMS/3788/4574/45105.aspx.
23 *Id.*
24 *Id.*
25 *Id.*
26 *Id.*
27 72 Fed. Reg. at 62153.
28 IOM. (2003). *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification,* Washington, DC: National Academies Press at 80-82.
29 72 Fed. Reg. at 62150.
30 IOM. (2003). *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification,* Washington, DC: National Academies Press at 89.
31 *Id.* at 89-91.
32 *Id.* at 93.
33 72 Fed. Reg. at 62168.
34 IOM. (2003). *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification,* Washington, DC: National Academies Press, at 97-99.
35 *Id.* at 102.
36 *Id.* at 108, 111.
37 IOM, Expert Panel. (2001). *Dietary Reference Intakes: Proposed Definitions of Dietary Fiber,* Washington, DC, National Academy Press at 22.
38 *Id.* FDA refers to "added fiber" as "functional fiber" in its notice. 72 Fed. Reg. at 62166.
39 *Dietary Reference Intakes: Proposed Definitions of Dietary Fiber* at 22.
40 *Id.* at 25.
41 *Id.* at 26.
42 72 Fed. Reg. at 62168.
43 *Id.*
44 *Id.*
45 *Id.* at 62168-62169.
46 *Id.* at 62169.
47 *Id.*
48 *Id.*
49 *Id.* at 62170.
50 *Id.*
51 *Id.* at 62170-62171.