5

Guiding Principles for Selecting Reference Values for Nutrition Labeling

The principal task for the Committee on Use of Dietary Reference Intakes in Nutrition Labeling was to provide guidance in translating the science in the Dietary Reference Intake (DRI) reports to reference values that could be used for the next revision of nutrition labeling regulations. The previous chapters have provided an overview of the task, history, and present status of nutrition labeling—in essence the context within which the committee conducted its deliberations. This chapter provides ten principles the committee has developed to guide the establishment of updated reference values for nutrition labeling.

The committee's approach to how the DRIs would be used as reference values for nutrition labeling was defined within the sponsors' contract language. In particular, this language specified that the purposes of reference values on food labeling are to enable consumers to compare the nutrient content of different food products and to determine the relative contributions of a food to an overall health-promoting diet. The information in nutrition labeling is not intended to be used to plan individual diets. The committee was to identify general guiding principles for use in setting nutrient reference values for nutrition labeling in consideration of the stated purposes. It was to do this by assessing the objectives, rationale, and recommendations for the methodology to select reference values for the nutritive value of food to appear in the Nutrition Facts box. The committee therefore has developed its recommendations using as its main reference materials the nutrient-specific DRI reports (IOM, 1997, 1998, 2000b, 2001, 2002a), the DRI derivative reports

on applications in dietary assessment (IOM, 2000a) and in planning (IOM, 2003), and the preambles, text, and other background materials of appropriate labeling regulations from the United States and Canada. The committee presents its recommendations as guiding principles—it does not provide nutrient values. Any numbers in the text related to the guiding principles are illustrative only. It is not the committee's responsibility, or its intent, to make regulatory recommendations. Rather the guiding principles provided in this report were developed as science-based recommendations for the sponsors to accept or reject as appropriate to their own activities.

GUIDANCE ON DEVELOPING REFERENCE VALUES

Using the Percent Daily Value

GUIDING PRINCIPLE 1. Nutrition information in the Nutrition Facts box should continue to be expressed as percent Daily Value (% DV).

Section 2(b)(1)(A) of the Nutrition Labeling and Education Act of 1990 (NLEA) (104 Stat. 2353, 2356) requires that nutrition labeling be designed so that it ". . . enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." The Food and Drug Administration (FDA) developed the percent Daily Value (% DV) concept to meet this requirement. The % DV was modeled on the "percentage of the U.S. Recommended Daily Allowance," an approach used in the 1973 version of nutrition labeling to help consumers understand and compare the relative amount of protein, vitamins, and minerals in food. Studies in the United States and Canada do, in fact, support this (see FDA, 1993a; NIN, 1999), although increased educational efforts are needed to optimize its potential use as a consumer tool (Levy et al., 2000). The % DV was selected after careful study, including consumer research and review of public comments (FDA, 1993c). The committee found the rationale for the use of % DV compelling and offers no alternative approaches to the DV concept. The committee recommends that the nutrient content per serving of a food be expressed as a % DV whenever it is possible to establish this value for a nutrient. The committee notes that when it refers to the DV throughout this report, it recognizes

that the DV is a single term that refers to Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs), which have distinctly different derivations and scientific bases.[1]

Defining the Population

DRIs have been established for 22 distinct life stage and gender groups. These groups were created because the available data indicated that each group has a unique set of nutrient needs that differentiates it from the others (see "Life Stage Groups" in Chapter 4). When using the DRI reports to generate reference values for nutrition labeling of the food supply, the population base needs to better represent the general population through a combination of the distributions represented by these life stage and gender groups. The committee therefore recommends using a base population of individuals 4 years of age and older, excluding pregnant and lactating women, to represent the general population. By the time active children reach 4 years of age, their energy requirements are similar to the energy needs of small, less-active adults (IOM, 2002a). Also, in an earlier review, FDA reported that by 4 years of age children's food-consumption patterns are similar to those of adults (FDA, 1993c). The committee considered whether current scientific information indicates that children in North America are assuming adult eating patterns at a younger age. However it did not find evidence from food-intake studies to support moving this age division for the general population (Birch, 1999; Milner and Allison, 1999; Nicklas et al., 1991). The committee did identify four distinctive life stage groups that should be considered for nutrition labeling; they are defined in Guiding Principle 8.

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[1]The RDI ". . . denote(s) those nutrients whose label reference values have been derived from the National Academy of Sciences (NAS) Recommended Dietary Allowances (RDAs) and Estimated Safe and Adequate Daily Dietary Intakes" (FDA 1993c, p. 2208). DRVs are label reference values originally established for eight nutrients for which there were no NAS RDAs at the time. Based on a body of scientific literature linking diet and the risk of chronic disease, FDA established DRVs as label reference values for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein based on a 2,000 calorie diet (FDA, 1993c).

Using a Population-Weighted Reference Value

GUIDING PRINCIPLE 2. The Daily Values (DVs) should be based on a population-weighted reference value.

As noted above, a single reference value is most appropriate for the Nutrition Facts box, but this value must be designed to be meaningful for a base population that is 4 years of age and older. Even this smaller base population is comprised of 13 separate life stage groups in the DRI reports, excluding pregnancy and lactation. These groups are: all children ages 4 to 8 years and for males and females, separate groups based on the following age breaks: 9 to 13 years, 14 to 18 years, 19 to 30 years, 31 to 50 years, 51 to 70 years, and older than 70 years. Although the DRIs can differ for these groups, for many nutrients multiple groups have the same values. Because it is not practical to provide a DV for nutrition labeling for each of the 13 life stage groups, it is necessary to combine the DRIs for the groups to produce a single DV for the general population.

The committee considered a variety of ways to compute the DV and concluded that the most scientifically valid approach was to apply weighting based on census data and the proportions of each life stage and gender group in the overall national population. A DV defined in this way will represent a central value of the requirement for the base population, with individual requirements varying around this value. The details are slightly different for nutrients with an Estimated Average Requirement (EAR), where the distribution of the requirements has been defined; for nutrients with an Adequate Intake (AI), where the distribution of requirements could not be defined; and for nutrients with an Acceptable Macronutrient Distribution Range (AMDR), where the reference values are expressed as a range. The rationale, however, is the same regardless of which DRI is provided: because the groups are represented in the base population in different proportions, the DRIs of the groups should be represented in the DV of the base population in the same proportions.

Developing Reference Values Based on the Estimated Average Requirement

GUIDING PRINCIPLE 3. A population-weighted Estimated Average Requirement (EAR) should be the basis for Daily Values (DVs) for those nutrients for which EARs have been identified.

The committee recommends that the DVs be based on population-weighted values of the EARs for the different life stage and gender groups. This is because the EAR represents the most accurate reflection of the true contribution of a particular food to total nutrient needs in the general population. A fundamental assumption underlying the committee's recommendation is that the DV (expressed as % DV) is intended not only to help individuals compare different products within a food type, but also to help them understand nutrition information about foods ". . . in the context of a total daily diet" (NLEA, P.L. 101-535). To fulfill this function, the DV must take into account that nutrient requirements differ not only by life stage and gender group, but also within any single life stage and gender group. The best point of comparison for the nutrient contribution of a particular food to an individual's total nutrient needs is the individual's nutrient requirement, which is almost never known, but can be represented by the median of the requirement distribution (EAR). The logic is described in the following paragraphs.

The recommendation that DVs be based on population-weighted EARs arose from the examination of two questions. First, given a distribution of requirements, how should a single numerical characterization be obtained? Second, given a collection of distributions of requirements corresponding to different subpopulations, how should these be combined to produce a single, meaningful DV?

The true requirement of any one individual is almost never known, but it can be estimated from the DRIs. For nutrients for which the distributions of nutrient requirements for particular life stage and gender groups have been characterized, the best estimate of an individual's requirement is the EAR for the life stage and gender group to which he or she belongs. This is because levels of intake above or below the EAR will have a greater likelihood of systematically over- or underestimating an individual's needs. Mathematically, the most appropriate single numerical characterization of a distribution of requirements is typically the median. For symmetrical distributions, the median is equal to the mean. By definition the EAR is the median of the estimated distribution of requirements for a particular life stage and gender group (IOM, 1997); therefore the EAR represents the best estimate of the nutrient requirement for individuals within a specific life stage and gender group. The probability that any individual in the group has a nutrient requirement above the EAR is 0.5. This probability declines as requirement levels rise above the EAR, falling to 0.025 at the Recommended Dietary Allowance (RDA). The RDA overstates the needs for 97.5 percent of the population in terms of a specific

criterion of nutrient adequacy. Since the RDA is defined to be 2 standard deviations above the mean, a consequence of the normality assumption is that the RDA is 1.2 times the EAR. This distribution relationship is illustrated in Figure 5-1. For a nutrient with a normal (Gaussian) distribution of requirements and a 10 percent coefficient of variation (CV), the requirements of 95 percent of the population will be within 20 percent (2 standard deviations) of the EAR. Thus the EAR is clearly a better single numerical representation of the requirements for the vast majority of the individuals in the subpopulation than is the RDA.

The second issue in calculating DVs based on the EAR is identifying the best approach for combining subpopulation distributions. Intake levels beyond an individual's requirement have no demonstrable benefit. This argument, applied to the population as a whole, suggests that the DV should be the median of the population distribution of requirements. However in the DRI reports, the requirement distributions are given for subpopulations, not for the total population.

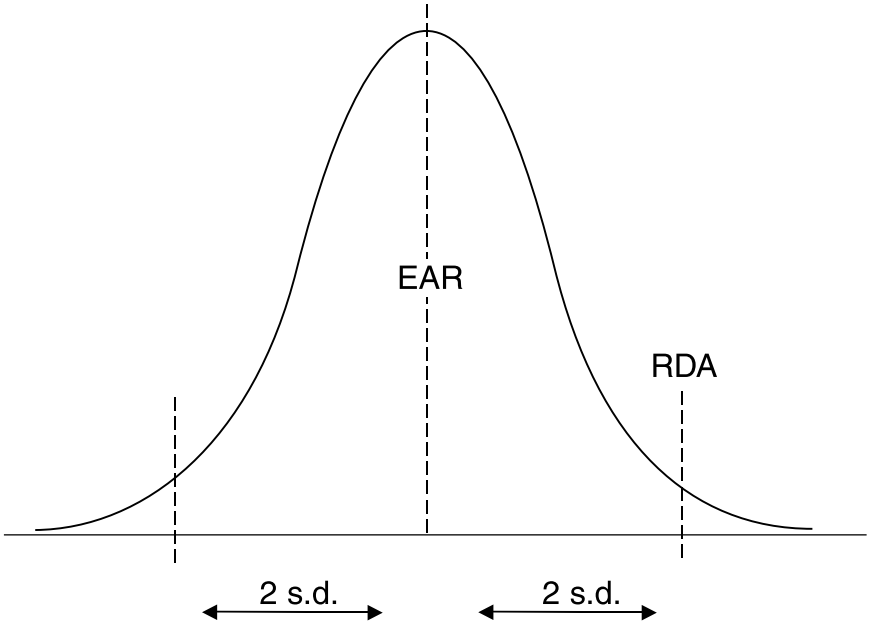


FIGURE 5-1 Relationship of the distribution of the population requirements between the Estimated Average Requirement (EAR) and Recommended Dietary Allowance (RDA) for a hypothetical nutrient. Note that 95 percent of the population is within 20 percent of the EAR where 2 standard deviations (s.d.) = 20 percent. The coefficient of variation = 10 percent.

Because it is impractical to provide DVs on the nutrition label for each subpopulation, it is necessary to compute a single number that will summarize the distribution of requirements in the total population. The logic described above argues in favor of choosing a central value of the distribution as the DV. For symmetrical distributions, such as the normal distribution, the mean and the median are identical. However the distribution of requirements for the population, derived from the distributions for the subpopulations, in general will not be symmetrical (see Chapter 4). Therefore the median, with 50 percent of the requirements above and 50 percent below, is preferred to the mean, which is sensitive to extreme values of requirements. In summary, the DV should be defined as the median of the population distribution of requirements. This is represented by the population-weighted EAR for nutrients where the distribution of requirements is known. Derivation of this value takes into account the relative proportions of the population in each of the 13 life stage and gender groups that comprise the target population for the Nutrition Facts box and the EAR and the CV of the requirement distributions for each group.

To compute the population distribution of requirements for the DV, the subpopulation distributions are combined using weights obtained from census data. The DV is the median of this resulting distribution. This procedure is easily adapted for different demographic profiles, such as for the Canadian population or for different projected future populations (see Appendix B).

Specifically, to calculate the population-weighted EAR for each subpopulation defined by life stage and gender, the requirement for each nutrient is assumed to have a distribution. For nutrients having an EAR, this distribution is assumed to be normal with the median equal to the EAR and a CV of 10 percent. Two exceptions are vitamin A and niacin, which have assumed CVs of 20 percent and 15 percent, respectively. The following text illustrates how the weighting could be approached for nutrients with CVs equal to 10 percent. Slight modifications are required for the two exceptions.

Calculation Examples

As an example, let the population of interest be females and males ages 4 years and older (excluding pregnant and lactating females) in the United States. As stated earlier there are 13 subpopulations with EARs in this population: all children ages 4 to 8 years, and for males and females, separate groups based on the following age breaks: 9 to 13 years, 14 to 18 years, 19 to 30 years, 31 to 50 years, 51

to 70 years, and older than 70 years. To calculate the population distribution of requirements, use (a) the distribution of requirements for each subpopulation, and (b) the proportions of each subpopulation in the population. The DRIs provide the distributions of requirements for the subpopulations. The subpopulation proportions are available from U.S. census data (Population Projections Program, 2000). The distribution of requirements for the population is called a *mixture* of the distributions for the subpopulations. There are 13 subpopulations; the index i with values 1 to 13 is used to distinguish them. Let π_i denote the proportion of the population in subpopulation i and let $\Phi_i(x)$ denote the cumulative distribution function (CDF) for the requirements in subpopulation i. The quantity $\Phi_i(x)$ gives the proportion of the subpopulation with requirements less than or equal to x. The population CDF is thus:

$$\Phi(x) = \sum_{i=1}^{13} \pi_i \Phi_i(x)$$

The median of the population requirement distribution is the value of x where $\Phi(x) = 0.5$. There is no simple formula for this median. However, it is a simple task to calculate $\Phi(x)$ for a very large number of values of x. From these results the value of the median can be determined to any arbitrary number of significant digits.

The probability distribution function (PDF) provides an alternative view of a distribution. To denote PDFs, $\varphi(x)$ is used. The relationship between the population PDF and the subpopulation PDFs is similar to that for CDFs:

$$\varphi(x) = \sum_{i=1}^{13} \pi_i \varphi_i(x)$$

As examples, the CDF and the PDF for vitamin E are depicted in Figure 5-2, and similar plots for riboflavin are depicted in Figure 5-3.

Just as the EAR is the best estimate of an individual's nutrient requirement, there is no single value that would be a better representation of the nutrient requirements of individuals in the population than the population-weighted EAR. The relevance of the population-weighted EAR in relation to the nutrient requirement of any one individual in the population is illustrated in Appendix Tables B-1 and B-2. Using U.S. population predictions for 2005, 54 to 85 percent of the entire population will have requirements that

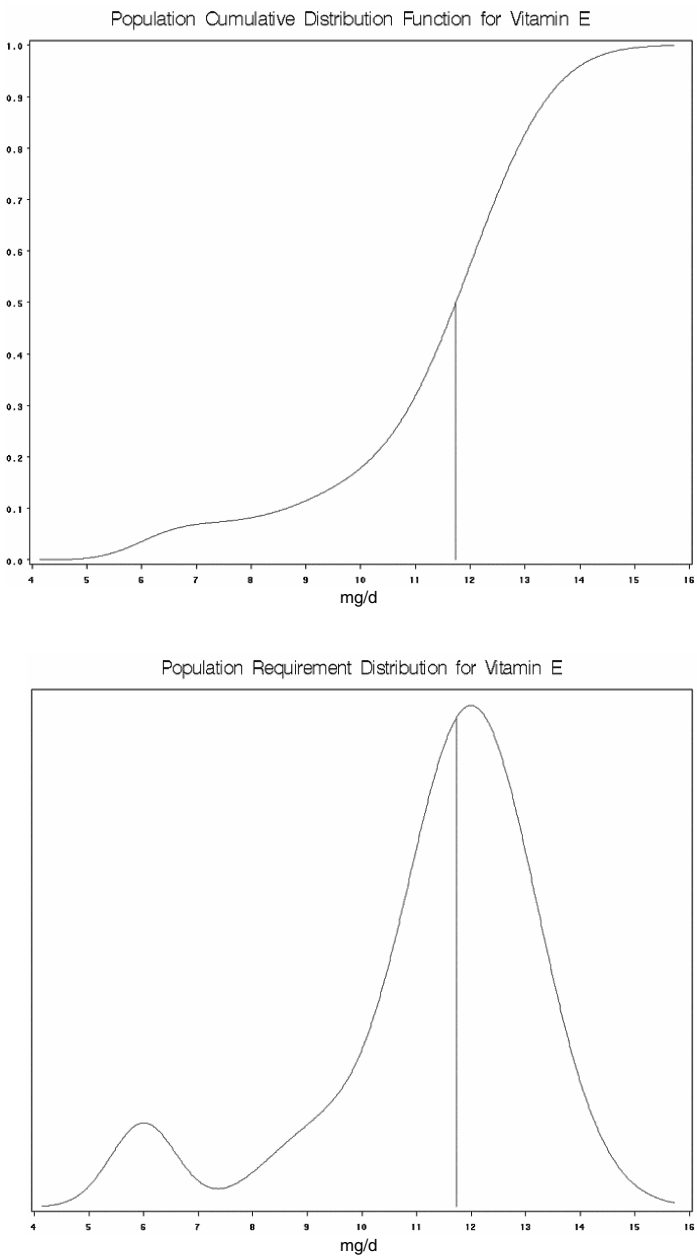
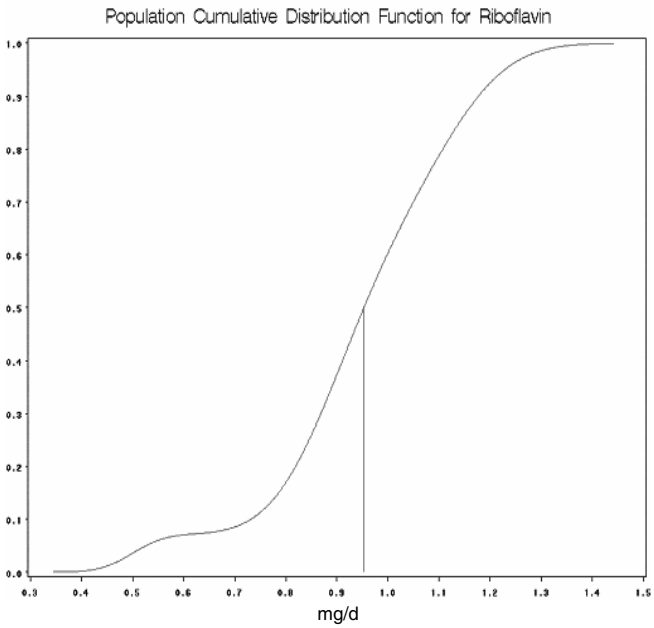


FIGURE 5-2 Population cumulative distribution function and probability distribution function for the vitamin E requirement distribution. The vertical line represents the median.



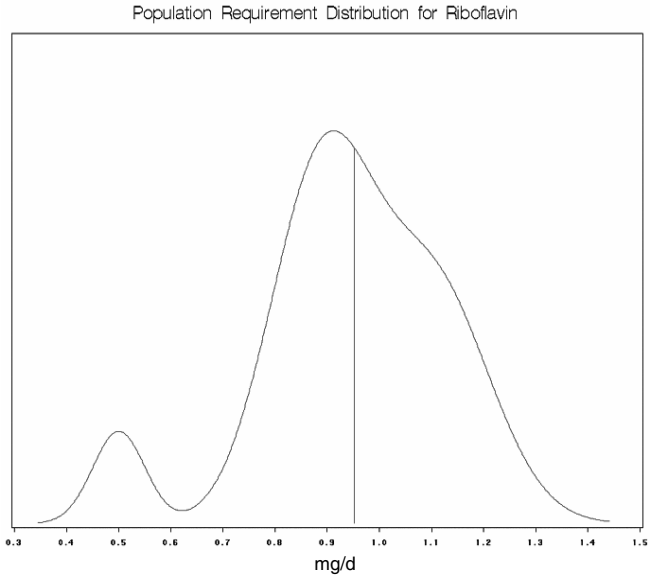


FIGURE 5-3 Population cumulative distribution function and probability distribution function for the riboflavin requirement distribution. The vertical line represents the median.

are within 20 percent of the population-weighted EAR, and 72 to 95 percent will have requirements that fall within 30 percent of this value for the list of nutrients examined. Using Canadian 2006 population predictions, 55 to 86 percent will be within 20 percent and 73 to 96 percent will be within 30 percent of the population-weighted EAR. The observed ranges highlight two important differences among nutrients: (a) the variation in requirements within the life stage and groups, represented by the CV of the requirement distribution, differs among the nutrients, and (b) the requirements for some nutrients differ more markedly among life stage and gender groups than do others. For nutrients with considerable variation in requirements within and among gender and life stage groups (e.g., vitamin A), the "spread" around the population-weighted EAR is greater than for those nutrients that have requirements that are less variable (e.g., iodine). Nevertheless the modeling in Tables B-1 and B-2 confirms that a population-weighted EAR is relevant to the vast majority of individuals in the target population. Thus it provides a reasonable basis for a DV that individuals can use to evaluate the nutrient contributions of a particular food to the total diet.

The Population-Weighted EAR and the RDA

The committee's recommendation to use population-weighted EARs as the basis for the DVs represents a move beyond past practice in light of new scientific evidence. Past practice based DVs on the highest of the RDAs or Recommended Nutrient Intakes for all individuals in the population. The logic behind this choice was to set a value that was high enough to cover the needs of almost every individual in the population. Because the RDA was set to include a margin of safety, it was considered a prudent choice for nutritional advice for the general public. Furthermore, when the existing DVs were set, the EAR concept had not been developed, and the only quantification of requirements was in the form of RDAs.

In many cases using the highest RDA yields DVs that are so high that they are essentially irrelevant for most of the population. On the other hand, a rationale that has been given in support of using the highest RDA is that there should be some special attention given to the most vulnerable group, which is defined to be the group with the highest requirements, thought by some to be young children. Examination of the DRIs reveals, however, that the group with the highest requirements (with the exception of iron for women of childbearing age) is typically males, including young males. These high intake requirements are based on the rapid growth of this age

group. However this group generally has little problem achieving needed nutrient intake (LSRO, 1989, 1995).

Another issue is whether a DV based on a population-weighted EAR would facilitate a more meaningful comparison of food vis-à-vis total nutrient needs than would a DV set at the highest EAR, the highest RDA, or a population-weighted RDA. For the purpose of making nutritional comparisons among food products, any reference value would be sufficient, and the concept of a margin of safety or total population coverage is not necessary. However, for the purpose of positioning a food within the context of a total daily diet, basing calculations on a value that includes a margin of safety or covers the entire population would actually distort the overall information. As noted above, within any single life stage or gender group the EAR provides the best estimate of total daily nutrient needs. The RDA overstates these needs for 97 to 98 percent of the population. Thus a guiding principle for a DV based on the highest RDA for a nutrient would provide an exaggerated impression of total daily needs for most people and would systematically underrepresent the true contribution of an individual food to these needs. Using a population-weighted RDA for a nutrient would result in a somewhat lower level than would use of the highest RDA (at least for some nutrients), but it would still be an overestimate of the requirement of most people and an underestimate of the contribution of an individual nutrient to this need. Observations about the implications of the population-weighted approach for nutrient content claims, health claims, food formulation, and overages are included later in this chapter.

It is emphasized that this application of the DRIs is subtly different from the recommended applications for planning diets for individuals. Use of the EAR rather than the RDA is appropriate because the former value provides a better estimate of an individual's true requirement for a nutrient. As such, the EAR provides a better basis against which to appraise the relative significance of a particular food within the context of a total daily diet—which is the goal of the DV. In contrast the RDA is recommended as a goal for planning the diets of individuals. When used as a basis to appraise the nutrient contributions of an individual food to one's total nutrient needs, however, the RDA—by definition—would present an overestimate of needs for most (97.5 percent) of the population. Thus while meeting the RDA may be a prudent goal for an individual's diet plan, the RDA is not the most appropriate measure of need for the population overall.

In summary, an important component of the DRI concept is how

each reference value has been derived and its relevance for different applications. For the purposes of nutrition labeling, the committee's task was to provide guidance for the development of a reference number that could be used by an individual to compare the nutrient content of food items within a food type and to place purchase decisions in the context of the food's contribution to his or her total daily diet. The best point of comparison for the nutrient contribution of a particular food to an individual's total nutrient *needs* is the individual's nutrient requirement. It is almost impossible to know the true requirement of any one individual, but a reasonable estimate can be found in the median of the distribution of requirements, or EAR. The EAR is a daily intake value defined by carefully selected measures of adequacy based on biochemical, functional, or other markers or indicators. As such the EAR represents the best current scientific estimate of a reference value for nutrient intake based on experimental and clinical studies that have defined nutrient deficiency, health promotion, and disease prevention requirements. The EAR, as its name implies, is an estimate of the average of a *distribution of the requirements* for the nutrient in question. For those nutrients for which the distributions of nutrient requirements for particular life stage and gender groups have been characterized, the best, most representative estimate of an individual's requirement is the EAR for the life stage and gender group to which he or she belongs. Levels of intake above or below the EAR will have a greater likelihood of systematically over- or underestimating an individual's requirement. The RDA is derived from the EAR and is defined to be 2 standard deviations above the EAR on the nutrient requirement distribution curve. Therefore the RDA is not the best estimate of an individual's nutrient requirement. For these reasons the committee recommends the use of a population-weighted EAR, when an EAR has been set for a nutrient, as the basis for the DV. This approach should provide the most accurate reference value for the majority of the population.

Developing Reference Values Not Based on the Estimated Average Requirement

The DRIs are a set of reference values that vary with each nutrient depending upon the scientific information available at the time the DRIs were developed for that particular nutrient (see Chapter 4). If there was insufficient scientific evidence to develop an EAR for a nutrient for all life stage and gender groups, an AI, an AMDR, both an EAR or AI and an AMDR, or no reference values were devel-

oped. For nutrients for which an EAR could not be derived, the committee recommends several different approaches to developing the DVs.

The committee recognizes that the AIs and AMDRs reflect their names in that they do not describe the distribution of intake *requirements* for a nutrient, but rather represent the best approach scientifically available to describe an acceptable intake level or range. Because EARs could not be set for all nutrients, there will have to be a heterogeneity of reference values for the DVs until such time that the science base permits the replacement of AI estimates with EARs. The committee notes however, with the exception of calcium and vitamin D, that EAR values have been set for almost all of the micronutrients that are currently included or are optional in the Nutrition Facts box.

Using Adequate Intakes When There Are No EARs

GUIDING PRINCIPLE 4. If no Estimated Average Requirement (EAR) has been set for a nutrient, then a population-weighted Adequate Intake (AI) should be used as the basis for the Daily Value (DV).

Despite the heterogeneous derivation of the AIs, the committee recommends the use of a population-weighted AI for the DV for nutrients for which no EAR exists. Nutrients for which AIs have been set fall into several groups based on the approach used for their derivation: AIs specially derived for infants; AIs based on experimental data (calcium, vitamin D, choline, biotin, fluoride) (IOM, 1997, 1998); AIs set using the median intake of the nutrient where no deficiency was observed (pantothenic acid, vitamin K, chromium, manganese, *n*-3 and *n*-6 polyunsaturated fatty acids) (IOM, 1998, 2001, 2002a); and an AI based on the level observed to protect against coronary heart disease (fiber) (IOM, 2002a). The AI for fiber is expressed as an amount per 1,000 kcal.

The AIs for infants, which are set for one or both of two life stage groups (i.e., for younger infants ages 0 through 6 months and older infants ages 7 through 12 months), bear brief mention because they were set for specific age categories. For the younger infants the AI is defined as the amount of the nutrient provided in the usual daily intake of human milk; for the older infants the AI is defined as the amount of the nutrient provided by the usual daily intake of human milk and solid food typical for the age group.

The AI was provided for a nutrient if there was not enough scien-

tific evidence available to calculate an EAR. The AI was developed using a "greater degree of judgment than is applied in estimating an EAR" and accordingly there ". . . is much less certainty about an AI value" (IOM, 2002a, pp. 1–5). These points, along with the heterogeneity of its derivation, make the AI a less desirable replacement for the EAR as a reference value for the DVs. Specifically, the fact that AI estimates do not describe the distribution of requirements for a particular nutrient means that DVs based on population-weighted AIs will not have the same meaning as those based on population-weighted EARs. Insofar as an AI exceeds the mean requirement, a DV based on this value will underestimate the relative contribution of particular foods to total daily nutrient needs. Because the precise relationship between an AI and the true distribution of nutrient requirements is unknown, it is impossible to quantify or adjust for this distortion. The committee has made its best effort to use the current DRIs for labeling purposes. The lack of an EAR for some nutrients underscores the need for more research in this area to provide the best scientific estimates of nutrient requirements and therefore the best sources of reference values for nutrition labeling. As the study of requirements for nutrients with AIs continues to evolve, it is anticipated that AIs will be replaced with EARs and RDAs. It will be important to then revise the DVs so that they will all be based on population-weighted EARs and will provide consumers with a consistent standard against which to evaluate the nutrient contributions of a food.

Protein, Total Carbohydrate, and Total Fat

GUIDING PRINCIPLE 5. The Acceptable Macronutrient Distribution Ranges (AMDRs) should be the basis for the Daily Values (DVs) for the macronutrients protein, total carbohydrate, and total fat.

An AMDR is not a DRI, but was created to provide guidance for recommended intakes of macronutrients to reduce chronic disease risk. The DRI report on macronutrients (IOM, 2002a) established the AMDR and defined it as:

> . . . a range of intakes for a particular energy source that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients. The AMDR is expressed as a percentage of total energy intake because its requirement, in a classical sense, is not independent of other energy fuel sources or of the total energy requirement of the individual. (p. S-5)

The AMDRs were set because, in the case of some macronutrients or their components, it was not possible to identify a numerical amount where there was a causal relationship between intake and function or criterion of adequacy. Rather, the data better supported a range of intakes that also reflected varying energy needs in the population.

Since there were sufficient data, both an EAR and an AMDR were set for protein and total carbohydrate. Only an AMDR was developed for total fat. The committee recommends using the AMDR to derive the DV for protein, total carbohydrate, and total fat in order to provide a consistent approach that has its basis in risk reduction of chronic disease and healthful dietary practices.

EARs for protein were established for adult males and females based on a rigorous analysis of available nitrogen balance studies. An EAR for protein was established for children ages 1 through 13 years based on a factorial method that adds the amount of protein needed for maintenance based on body weight to the amount needed for protein deposition (IOM, 2002a). The maintenance requirements of adults and the estimates of protein deposition were used to establish the EAR for males and females ages 14 through 18 years. The EARs for protein are expressed in terms of gram per kilogram of body weight and are based on good quality or "complete" protein (IOM, 2002a). Assumptions about body weight would be needed to convert the EAR for protein into grams per day in order to set a reference value for nutrition labeling based on a population-weighted EAR. Deriving a label reference value for protein based on the new reference weights included in the DRI macronutrient report (IOM, 2002a) may not be representative of the requirements of the North American population, which has a high percentage of overweight individuals (see "New Reference Heights and Weights" in Chapter 4). Also, a label reference value for protein derived in this manner would likely be below the AMDR of 10 to 35 percent of energy for adults and 10 to 30 percent of energy for older children.

An EAR for total carbohydrate of 100 g/day was set for boys, girls, men, and women of all age groups. The EAR was based on the average minimum amount of glucose utilized by the brain. This level of intake, however, is typically exceeded to meet total energy needs while consuming acceptable levels of fat and protein. Thus using the EAR for total carbohydrate would result in a very low label reference value (e.g., 20 percent of calories for a 2,000-calorie diet), which also would be below the AMDR of 45 to 65 percent of energy for carbohydrate.

An EAR was not set for total fat because there were insufficient

data to determine a defined level of fat intake at which no risk of inadequacy or prevention of chronic disease occurs. "AMDRs were estimated for total fat based on evidence indicating a risk for coronary heart disease (CHD) at low intakes of fat and high intakes of carbohydrate, and based on evidence for increased risk for obesity and its complications, including CHD, with high intakes of fat" (IOM, 2002a). The AMDRs for fat were estimated for children (25 to 35 percent of energy for ages 4 to 18 years) primarily based on a transition from the high-fat intakes that occur during infancy to the adult AMDR for fat (20 to 35 percent of energy).

To promote healthful dietary practices and nutritionally adequate diets and to provide consistency for setting label reference values for protein, total carbohydrate, and total fat, the committee believes that an approach based on the AMDR is most appropriate. Because the AMDR for each macronutrient is expressed as percent of energy in terms relative to each other, the approach for setting their label reference values should ensure that their sum totals to 100 percent. The committee recommends using the midpoint of the AMDR for total carbohydrate (since the AMDR for carbohydrate is 45 to 65 percent of energy for all reference groups) and a population-weighted midpoint of the AMDR for total fat (using the midpoint of the range of 20 to 35 percent of energy for adults and 25 to 35 percent of energy for children 4 to 18 years of age). A reference value for protein could then be based on the difference needed for the sum of the macronutrients to equal 100 percent of energy. Using the midpoint of the AMDR as the basis for label reference values avoids extreme values (i.e., lower- or upper-boundary levels) and is an approach that focuses on moderation.

Sugars and Added Sugars

Naturally occurring and added sugars are chemically identical and analytically indistinguishable by current techniques. Naturally occurring sugars (also called intrinsic sugars) are primarily found in fruits, milk, and dairy products that also contain other essential nutrients (IOM, 2002a). Added sugars are defined as sugars and syrups that are added to food during processing and preparation.[2]

[2]"Specifically, added sugars include white sugar, brown sugar, raw sugar, corn syrup, corn-syrup solids, high-fructose corn syrup, malt sugar, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, anhydrous dextrose, and crystal dextrose. Added sugars do not include naturally occurring sugars such as lactose in milk or fructose in fruits" (IOM, 2002a, p. 6-2).

The total amount of sugars (in grams) is currently listed in the Nutrition Facts box under the general heading of Total Carbohydrate.

The DRI report on macronutrients established an EAR and an RDA for total carbohydrate; no values were set for either total or added sugars. The discussions of adverse effects of overconsumption and hazard identification in the DRI macronutrient report included a complete review of the literature and concluded that the data were not in sufficient agreement to develop a Tolerable Upper Intake Level (UL) for total or added sugars:

> Published reports disagree about whether a direct link exists between the trend toward increased intakes of sugars and increased rates of obesity. The lack of association in some studies may be partially due to the pervasive problem of underreporting food intake, which is known to occur with dietary surveys (Johnson, 2000). Underreporting is more prevalent and severe by obese adolescents and adults than by their lean counterparts (Johnson, 2000). In addition, foods high in added sugar are selectively underreported (Krebs-Smith et al., 2000). Thus, it can be difficult to make conclusions about associations between sugars intake and BMI [body mass index] using self-reported data.
>
> Based on the above data, it appears that the effects of increased intakes of total sugars on energy intake are mixed and increased intakes of added sugar are most often associated with increased energy intake. There is no clear and consistent association between increased intake of added sugars and BMI. Therefore, the above data cannot be used to set a UL for either added or total sugars. (IOM, 2002a, p. 6–37)

The nutrition labeling committee did consider the suggestion in the DRI report about maximal intake of added sugars:

> Based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a UL for total or added sugars. Although a UL is not set for sugars, a maximal intake level of 25 percent or less of energy from added sugars is suggested based on the decreased intake of some micronutrients of American subpopulations exceeding this level. (IOM, 2002a, p. 6–42)

However it was clear to the committee that the maximal intake level of 25 percent of energy from added sugars, as suggested in the DRI report, would be an inappropriate reference value for nutri-

tion labeling. Such a reference value could be misinterpreted as a desirable intake.

In North America a large and increasing number of adults, adolescents, and children are overweight or obese. The Nutrition Facts box already includes leading information on total calories and total calories from fat. Consumers need guidance about major sources of calories in food, including sugars.

Guidelines for healthy eating, including U.S. government consumer guidelines, often caution consumers to moderate their intake of sugars in general and to sparingly use beverages and food containing added sugars (USDA, 1996; USDA/DHHS, 2000). The major Canadian consumer guidelines are under revision, but a recent fact sheet for educators and communicators that interprets the existing guidelines defines simple sugars and states that "all added sugars, including honey and molasses, contribute primarily energy and taste and have no other significant nutrition advantages" (Health Canada, 2002). In the United States there is no line item in the Nutrition Facts box for added sugars, and there is no DV for sugars to place this source of energy in the context of the total daily diet.

The nutrition labeling committee considered that consumers attempting to follow dietary advice on added sugars might benefit from nutrition labeling that enables them to easily assess the relative amount and caloric contribution of natural and added sugars in food and supplements. However, without appropriate reference values for total, natural, or added sugars in the macronutrient report, the committee is unable to recommend an approach for developing a reference value for sugars or added sugars for nutrition labeling based on the DRIs. Moreover, it is unclear whether a % DV is the most appropriate means for providing information to consumers about sugars or added sugars in the context of a total daily diet. The committee does, however, recognize that consumers need guidance by which to place this important source of calories in labeled food in the context of the total diet. Provision of this guidance should be an urgent consideration of the cognizant regulatory bodies.

Reference Values Requiring a Reference Energy Level

Calorie Reference Level

GUIDING PRINCIPLE 6. Two thousand calories (2,000 kcal) should be used, when needed, as the basis for expressing energy intake when developing Daily Values (DVs).

The current DVs for protein, total carbohydrate, total fat, and saturated fat are based on a 2,000-calorie reference level (FDA, 1993c). The new Canadian labeling regulations also use this reference level (Canada, 2003). When the U.S. nutrition label was revised in the early 1990s, a 2,350-calorie reference level was proposed (FDA, 1993c). However the 2,000-calorie reference level was selected because it was thought that a rounded value would be easier for consumers to use and that 2,000 calories was less likely to suggest an inappropriate level of precision. In addition, the use of a lower calorie value was consistent with the public health goals of NLEA (FDA, 1993c). In the United States an estimated 64 percent of adults and 15 percent of children and adolescents are obese or overweight (Flegal et al., 2002; Ogden et al., 2002); in Canada it is estimated that 57 percent of men, 35 percent of women, 33 percent of boys, and 27 percent of girls are obese or overweight (Tremblay et al., 2002). Presenting a DV that might further encourage the overconsumption of calories would not benefit the public health of North Americans.

The committee considered whether there was a basis in the recently established Estimated Energy Requirements (EERs)[3] for developing a calorie reference level for macronutrients in nutrition labeling. The committee recognized that using the EER to derive a calorie reference level would require making assumptions about height, weight, and physical activity level. However, the prediction equations used to calculate the EERs were based on normal-weight individuals, but both the American and the Canadian populations have a high prevalence of overweight and obesity. Thus the committee found that the North American data necessary to use the EER concept as the basis for a calorie reference level for nutrition labeling are incomplete and it cannot recommend this approach.

The committee concluded that retaining the current 2,000-calorie reference level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy. A 2,000-calorie reference level should not be presented in such a manner that consumers construe it to be a mandatory daily intake level for good health. The committee also

[3]The EER is defined in the macronutrient report as ". . . the dietary energy intake that is predicted to maintain energy balance in a healthy adult of a defined age, gender, weight, height, and level of physical activity consistent with good health. In children and pregnant or lactating women, the EER includes the needs associated with deposition of tissues or the secretion of milk at rates consistent with good health" (IOM, 2002a, p. S-3).

notes that young children and very sedentary individuals, including the elderly, have energy requirements below 2,000 calories, which underscores the importance of nutrient density in the food consumed by these individuals.

Saturated Fatty Acids, Trans *Fatty Acids, and Cholesterol*

GUIDING PRINCIPLE 7. The Daily Values (DVs) for saturated fatty acids (SFA),* trans *fatty acids (TFA), and cholesterol should be set at a level that is as low as possible in keeping with an achievable health-promoting diet.

The macronutrient report (IOM, 2002a) recommends that saturated fatty acids (SFA), *trans* fatty acids (TFA), and cholesterol intakes should be as low as possible "while consuming a nutritionally adequate diet" (pp. 8-1, 8-2, 9-1). In support of this approach the macronutrient report cites research indicating that SFA, TFA, and cholesterol are not required in the diet. The macronutrient report also presents results of regression analyses of various studies that indicate that any incremental increase in intake of these fats correspondingly increases blood total and low-density lipoprotein (LDL) cholesterol and the risk of coronary heart disease (IOM, 2002a). The committee recommends the application of the DV approach for SFA, TFA, and cholesterol. Use of % DVs for these food components would provide a meaningful perspective about their presence in food so that individuals can compare products and make food choices that are consistent with the guidance in the macronutrient report and with the public health goals of NLEA. Inclusion of these food components in the Nutrition Facts box is based on the reduction in risk of chronic disease, and thus for the current nutrition labeling, the reference values for SFA and cholesterol are DRVs.

The committee considered how best to recommend translating the scientific information on SFA, TFA, and cholesterol contained in the DRI report into reference values for the Nutrition Facts box. Since the DRI report did not establish an EAR, an AI, or an AMDR for SFA, TFA, or cholesterol because their presence in the diet meets no known nutritional need, there are no DRI values that can be readily used as the basis for the DVs. Therefore, to establish DVs for these chronic disease-related food components, the committee recommends the use of food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consis-

tent with nutritionally adequate and health-promoting diets for diverse populations.

Fats are mixtures of fatty acids and all fats contain some SFA. To meet the AMDR for total fat (20–35 percent of energy for adults and 25–35 percent of energy for children ages 4–18 years), some SFA will be present in diets. The question then becomes how much SFA will be present in an achievable health-promoting diet. For example, using menu modeling, diets can be planned that have 3 to 5 percent of calories from SFA (IOM, 2002a; Kris-Etherton et al., 2000). These menu-modeling estimates fall within the recommendations of a report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (2002) of less than 7 percent of calories that were developed for a Therapeutic Lifestyle Change diet.

Similarly, diets can be planned that provide less than 1 percent of calories from TFA provided that the only sources of TFA are naturally occurring (i.e., in meats, poultry, and dairy products). A recent study that used data from the Continuing Survey of Food Intakes by Individuals reported that the average intake of TFA was 2.6 percent of energy, of which approximately 25 to 26 percent was from naturally occurring sources (Allison et al., 1999a). A TFA-free diet is not possible if animal-based food is consumed.

For SFA and TFA the committee's challenge was to recommend the best manner in which to use the scientific information in the macronutrient report that would lead to a useful % DV. The committee recommends that SFA and TFA amounts be listed on separate lines, but that one % DV be included in the Nutrient Facts box for these two nutrients together. The committee recognizes that SFA and TFA are chemically distinct and acknowledges that the macronutrient report identified research that demonstrated physiological effects that differed among the fatty acids (IOM, 2002a). However both SFA and TFA raise total and LDL cholesterol levels and therefore are potential contributors to CHD risk. Since consumer research has shown that the % DV is a helpful tool for comparing different food products (FDA, 1993c; NIN, 1999) that could be optimized further (Levy et al., 2000), the committee recommends that the % DV be included for both SFA and TFA. By listing SFA and TFA and their gram amounts on separate lines and by providing a combined % DV for them, the consumer can be further educated about the unique differences between these fatty acids yet recognize that neither is desirable in terms of CHD risk. As stated

earlier one of the main purposes of the Nutrition Facts box is to help consumers compare food products and determine their relative significance and contributions to an overall healthful diet, and providing a % DV has been shown to enhance this consumer ability. Further, Health Canada has included this approach in its recent regulations on nutrition labeling (Canada, 2003).

Providing a % DV for combined SFA and TFA on nutrition labeling serves several other purposes. For example, this approach does not promote one type of fat as being more unhealthful than the other. Also, such an approach provides a target and flexible goal for food manufacturers to utilize when combining SFA and TFA in product formulations in order to achieve functional objectives in the sensory appeal and structure of food. Considering SFA and TFA together thus creates an incentive for the food industry to lower both components as much as possible.

With regard to cholesterol the committee noted that a cholesterol-free diet is possible if all animal-based foods are eliminated from the diet; however this is not a realistic dietary pattern for North Americans. An average daily cholesterol intake of 200 mg is attainable if a diet contains two 2-oz servings of lean meats (about 120 mg of cholesterol), 2 to 3 servings of skim milk or fat-free dairy products (about 8–12 mg of cholesterol), and 2 eggs per week (60 mg of cholesterol/day) as the only major cholesterol sources. Including nonfat-free dairy products (i.e., low-fat, reduced-fat, or whole-fat products), a larger serving of lean meat (e.g., 3 oz), or a third egg per week would contribute additional cholesterol.

The committee recognizes that the dearth of experimental data on acceptable diets that contain minimal levels of these food components makes it difficult to establish DVs for them without further research. The committee recommends that in developing DVs, examples of minimal intake levels of SFA, TFA, and cholesterol estimated through menu modeling should be evaluated against achievable health-promoting diets (identified in dietary survey data) that may be more realistic for a diverse population. While menu modeling provides a basis for evaluating the potential lowest amounts of these fats in a healthy diet, the resulting menus might be well outside the norm for most North Americans. Using dietary survey data will allow these hypothetical menus to be placed in perspective and will allow adjustments to be made that should result in recommendations for meaningful approaches to the intake of SFA, TFA, and cholesterol for the general population.

Distinctive Life Stage Groups

GUIDING PRINCIPLE 8. While the general population is best identified as all individuals 4 years of age and older, the committee recognized the existence of four distinctive life stages during which individuals' nutrient needs are physiologically different from the main population. These are: infancy, toddlers ages 1 to 3 years, pregnancy, and lactation. Development of Daily Values (DVs) for these groups should be guided by the following principles:

Infancy (< 1 y): ***one set of DVs based on the Estimated Average Requirements (EARs) or Adequate Intakes (AIs) of older infants (7–12 mo).***

Toddlers (1–3 y): ***one set of DVs based on the EARs or AIs.***

Pregnancy: ***one set of DVs based on the population-weighted EARs or AIs for all DRI pregnancy groups.***

Lactation: ***one set of DVs based on the population-weighted EARs or AIs for all DRI lactation groups.***

A DV based on a population-weighted value of the EAR or AI for all life stage and gender groups will reflect the actual contribution of a particular food to the total nutrient needs of the general population. However, individuals in the life stages listed in Guiding Principle 8, have nutrient needs that are physiologically different from those of the general population. A DV based on a population-weighted EAR or AI for the population of people 4 years of age and older would overestimate the nutrient contribution of a food for infants and toddlers and underestimate the contribution for pregnant and lactating women. Therefore the committee recommends separate DVs for food made for these four life stage groups.

Children Less Than 4 Years of Age

Infants (< 1 y) and Toddlers (1–3 y) in the United States. In the United States FDA has established substantially different labeling regulations for food manufactured for children under 4 years of age than that manufactured for populations 4 years of age and older. The younger age group is separated into those who are "persons not more than 12 months of age" and those who are 1 to 3 years of age (specifically 13–47 months) (21 C.F.R. 107.30, 107.100). In this report, these groups are referred to as "infant" and "toddler," respectively.

Current dietary recommendations are that human milk should be the sole food source for infants until about 6 months of age and

should be continued as a milk source until at least 12 months of age. Infants who are not fed human milk, who are weaned before 12 months of age, or who are provided supplemental milk sources before 12 months of age should be fed iron-fortified infant formula. Iron-enriched solid foods are recommended for introduction to the diet for most infants at 6 months of age (AAP, 1997). In the United States infant formulas are labeled under the implementing regulations (21 C.F.R. 107.100) of the Infant Formula Act of 1980 (21 U.S.C. §350a). Infant formulas are thus covered under separate regulations and do not use nutrition labeling that conforms to what is required for other food.

The final regulation on RDIs and DRVs (FDA, 1993c) provides details of the DVs to be used for infants and toddlers. This rule basically uses the highest 1968 RDA (NRC, 1968) for each nutrient listed. Therefore the current infant DVs are the RDAs for infants 7 through 12 months of age. Although indicated as being for infants, the listed RDA actually reflects older infants who receive a mixed diet rather than the exclusively human milk-fed or formula-fed younger infant.

There are several other important differences between nutrition labeling for infants and toddlers and that for the general population. First, protein is listed as a percent of the RDA in nutrition labeling for infants and toddlers, which is not the practice for the general population. Second, saturated fat and cholesterol are not listed in the Nutrition Facts box on food for infants and toddlers. Third, total fat, calories from fat, fiber, total carbohydrate, sodium, and potassium are not given as a % DV, but only as a weight of the component. Fourth, the footnotes[4] that appear in nutrition labeling for the general population do not appear on the infant or toddler label. These differences are designed to ensure that consumers do not improperly focus on the fat content of infant and toddler food and that the diets chosen do not appear to reflect adult caloric density or nutrient distribution requirements. For protein a special

[4]These include an asterisk at the end of the total fat line and its quantitative amount that provides more detail at the bottom of the label about the specific amount of nutrients in the mix. For example, "A serving of cereal plus skim milk provides 1 g total fat, less than 5 mg cholesterol," and so on. Another footnote to the heading % Daily Value must include a specifically worded statement that % DVs are based on a 2,000-calorie diet with a table illustrating the contribution of specified nutrients to diets that are 2,000 and 2,500 calories. This latter footnote may include calorie conversion information: a listing of calories per gram of fat, carbohydrate, and protein (FDA, 1999b).

rule requires that the protein digestibility-corrected amino acid score for toddlers must be at least 40 percent for the % DV to be included in the Nutrition Facts box, otherwise the box must include a statement that the food is "not a significant source of protein" (21 C.F.R. 101.9(c)(7)). In the United States many foods designed for infants and toddlers list both the infant and the toddler values as % DV for protein and micronutrients.

Children in Canada. The new Canadian food labeling regulations include different label specifications for children less than 2 years of age (Canada, 2003). The Nutrition Facts table for food intended solely for children under 2 years of age is specifically not to include: the % DV for total fat (or the sum of SFA and TFA), cholesterol, sodium, potassium, carbohydrate, or fiber and the energy values from fat or fatty acids. The Nutrition Facts table must contain the amount of calories and gram amounts per serving of a stated size for total fat, sodium, carbohydrate, fiber, sugars, and protein, with % DVs for vitamin A, vitamin C, calcium, and iron.

General guidance for infant feeding has been provided in Canada through a statement of a joint working group comprised of the Canadian Paediatric Society, the Dietitians of Canada, and Health Canada: *Nutrition for Healthy Term Infants* (Canadian Paediatric Society Nutrition Committee et al., 1998). The statement recommends breastfeeding for at least the first 4 months of life and, for formula-fed infants, cow's milk-based, iron-fortified formulas until 9 to 12 months of age. Labeling, composition, and related packaging and processing of infant formulas are regulated under the Canadian Food and Drug Regulations (Canada, 1988a). Under this law and its amendments, infants are defined as "a person who is under the age of one year," and the nutrient content and composition of infant formulas are tightly regulated. The food label must include:

> (i) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre, . . . (ii) the energy value expressed in calories . . . (iii) the quantity of all the vitamins and mineral nutrients set out in Table II[5] . . . (iv) the quantity of choline and of any added nutritive substances . . . (all as) contained in the human milk substitute portion of the food, expressed in grams per 100 grams or per 100 millilitres . . . or in International Units for table II nutrients . . . of the human milk substitute portion of the food

[5]Table II includes biotin, folic acid, niacin, pantothenic acid, riboflavin, thiamin, alpha-tocopherol, vitamins A, B_6, B_{12}, C, D, K, calcium, chloride, copper, iodine, iron, magnesium, manganese, phosphorus, potassium, sodium, and zinc.

> as offered for sale . . . or in a stated quantity of the food when ready-to-serve food. . . . (Canada, 1988a)

The regulations further state that the % DV of fat, SFA, TFA, sodium, potassium, carbohydrate, fiber, and cholesterol or the number of calories from fat or SFA and TFA cannot be included on the infant formula label.

Recommendations for Nutrition Labeling for Children Less Than 4 Years of Age. Tables 5-1 and 5-2 provide a comparison of the reference values for nutrients that are used for toddler and infant product labels in the United States. An EAR for toddlers (Table 5-1) exists for the major nutrients (except for calcium and vitamin D). Because there is a single age and gender group for toddlers, there is no need to use population weighting. Therefore, for nutrients with an EAR for toddlers, the committee recommends that the EAR be used as the basis for the DV; for nutrients where there is no EAR, the committee recommends that the AI be used for the DV.

The situation is more complex for infants (Table 5-2) as a result of the age split at 7 months, which reflects the change from a virtually exclusively human milk- or formula-based diet to one that includes age-appropriate solid food. An AI was established for most nutrients based on the nutrient intake of infants fed human milk. EARs that were established for some nutrients were specifically for 7- through 12-month-old infants. At this age, weaning food may provide most of the ingested nutrients (e.g., iron and zinc). For calcium, although only an AI based on the human milk-fed infant is included in the

TABLE 5-1 Comparison of Nutrient Reference Values for Toddlers Ages 1 to 3 Years

Nutrient	1968 RDA	1989 RDA	EAR	AI
Iron	15 mg	10 mg	3 mg	N/A
Zinc	N/A	10 mg	2.5 mg	N/A
Calcium	800 mg	800 mg	N/A	500 mg
Magnesium	150 mg	80 mg	65 mg	N/A
Vitamin A	~500 µg RAE	~500 µg RAE	210 µg RAE	N/A
Vitamin D	10 µg	10 µg	N/A	5 µg
Vitamin C	40 mg	40 mg	13 mg	N/A
Protein	15 g	16 g	13 g	N/A

NOTE: RDA = Recommended Dietary Allowance, EAR = Estimated Average Requirement, AI = Adequate Intake, N/A = not applicable, RAE = retinol activity equivalents.
SOURCE: IOM (1997, 2000b, 2001, 2002a); NRC (1968, 1989b).

TABLE 5-2 Comparison of Nutrient Reference Values for Infants Ages 7 through 12 Months

Nutrient	1968 RDA	1989 RDA	EAR	AI
Iron	15 mg	10 mg	6.9 mg	N/A
Zinc	N/A	5 mg	2.5 mg	N/A
Calcium	600 mg	600 mg	N/A	270 mg (human milk-fed) 335 mg (formula-fed)
Magnesium	70 mg	60 mg	N/A	75 mg
Vitamin A	~375 µg RAE	375 µg RAE	N/A	500 µg RAE
Vitamin D	10 µg	10 µg	N/A	5 µg
Vitamin C	35 mg	35 mg	N/A	50 mg
Protein	16 g	18 g	9.9 g	N/A

NOTE: RDA = Recommended Dietary Allowance, EAR = Estimated Average Requirement, AI = Adequate Intake, N/A = not applicable, RAE = retinol activity equivalents.
SOURCE: IOM (1997, 2000b, 2001, 2002a); NRC (1968, 1989b).

tables of AI values, the DRI text (IOM, 1997) includes different values for formula-fed infants. This is due to the presumed lower bioavailability of calcium in infant formulas relative to human milk.

For infants, as for toddlers, the committee recommends that EARs be used as the basis for DVs for nutrition labeling and that the AIs be used when no EARs have been set. The DRIs include two age groups for infants less than 1 year of age, but no separate values based on gender. Only three nutrients have EARs for infants (protein, iron and zinc), and these were set for the 7- through 12-month life stage group. While there in no need for population weighting of the EAR values for infants because they were set for this single life stage group, the AIs for many of the nutrients differ for the two infant age groups. Values for infants ages 7 through 12 months of age serve as the basis for formula and food labeling. The committee recommends that the infant food label continue to be used and to *only* represent the needs of 7- through 12-month-old infants. During the first 6 months of life, virtually all nutrition is supplied by human milk or infant formulas, and infant formulas are labeled based on the Infant Formula Act and its regulations (21 C.F.R. 107.100).

Although AIs are used as the basis for many of the infant DVs, it should be noted that the AIs reflect the intake from the whole diet and are not limited to intake from solid food. The committee therefore encourages continuing educational efforts to ensure that parents understand that human milk or infant formula should be the principal source of most nutrients throughout the first year of life.

It is also important to note that for infants during the first 6 months of life, there are no specific requirements that have been identified for most nutrients beyond that provided by human milk or infant formula. Two exceptions are vitamin D and iron. The American Academy of Pediatrics has recommended that 5 µg of vitamin D (the AI level) be provided to human milk-fed infants beginning in the first two months of life (Gartner and Greer, 2003). Beyond that provided by human milk, most infants may not require iron until 6 months of age. However, a substantial number of at-risk infants, such as those born small for their gestational age, may require iron at an earlier age. Therefore although the nutrition label recommendations use the values derived for infants 7 through 12 months of age, they reflect the requirements of younger infants for some nutrients. It is important to note that infants born prematurely or those with special health issues may not have their nutrient needs met by the standard DVs on the infant nutrition label. These issues underscore the importance of the role of the pediatrician, in partnership with the family, in monitoring the early nutritional health and growth of infants (AAP, 1997). The committee notes that while the historic and current approaches to nutrition labeling for infants and toddlers in the United States and Canada differ, it has developed these recommendations with the anticipation that it will facilitate harmonizing nutrition labeling regulations between the two countries.

Pregnancy and Lactation

During pregnancy and lactation, women have elevated requirements for some nutrients. For example, the requirement for pantothenic acid for pregnant women is 20 percent higher than that for nonpregnant women and for iron it is 172 percent higher (see Appendix Table C-1). Pregnant and lactating women are in three DRI age groups: 14 through 18 years, 19 through 30 years, and 31 through 50 years. The EARs and AIs for pregnant teenagers (ages 14–18 years) are higher for several nutrients and slightly lower for others compared with older pregnant females (ages 19–50 years). In general, the difference between these age groups are less than 20 percent and range from –17 percent for vitamin K for both pregnancy and lactation, to +16 and +13 percent for pregnancy and lactation, respectively, for magnesium. The only exceptions are phosphorus and calcium, where the EARs for both pregnancy and lactation for phosphorus and the AI for calcium are above 20 percent for teens (82 percent for phosphorus and 30 percent for calcium).

The committee considered creating an additional pregnancy category for teenagers and concluded it was not necessary because of recent statistics that show that birth rates for teenagers in the United States have been on the decline since 1990 (Ventura et al., 2003). For birth statistics, teenagers are divided into three age categories: 10 to 14 years, 15 to 17 years, and 17 to 19 years (Ventura et al., 2003). In 2002 birth rates for teenagers overall were 28 percent lower than in 1990. The decrease in birth rates reported among the middle-teenage category is more dramatic than the older teens, with a decline of 38 percent compared with 18 percent from 1990 to 2002. In 2002 the youngest age group showed the lowest birth rate in 40 years, with only 7,318 births. Further, the relatively small percentage of teenage pregnancies (10.7 percent of total pregnancies in 2002) does not merit a separate DV. If teenage pregnancy trends begin to increase in the future, then the creation of an additional group DV for pregnant or lactating teenagers might need consideration.

Dietary Supplements

GUIDING PRINCIPLE 9. The Supplement Facts box should use the same Daily Values (DVs) as the Nutrition Facts box.

The Dietary Supplement Health and Education Act (21 U.S.C. §321 (ff)) defined a dietary supplement as:

> . . . a product other than tobacco intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

The Supplement Facts box must include the nutrients (if they are present) that are required to appear on conventional food labels, any botanicals (including the specific plant part), and proprietary blends by weight. The serving size must be clearly stated on the box. Ingredients for which there are established DVs must be listed first on the box, followed by a horizontal line that separates those nutrient ingredients from ingredients for which there is no DV, such as botanicals. The box must state that DVs have not been established for these latter ingredients, which must be clearly marked with an asterisk.

The committee recognizes that a significant proportion of the population at all socioeconomic levels in both the United States and Canada uses dietary supplements, particularly nutrient supplements, as an important part of their total dietary intake (Balluz et al., 2000; Hoggatt et al., 2002; Radimer et al., 2000; Troppmann et al., 2002; Vitolins et al., 2000). In reviewing the background material and developing its approach to the use of the DRIs for DVs, the committee considered the relevance of the guiding principles for conventional food when considering recommendations for the Supplement Facts box. Since the Supplement Facts box requires the inclusion of the % DVs for the nutrients that are mandated for conventional food, the committee recommends that the DVs for dietary supplement labeling should be based on the population-weighted EAR or AI for each nutrient as defined for the Nutrition Facts box. In addition, all other guiding principles for nutrition labeling of conventional food should apply to dietary supplement labeling. For supplement products that are marketed to specific life stage and gender groups, Guiding Principle 8, which describes four distinctive life stage groups (infancy, toddlers, pregnancy, and lactation), is appropriate for nutrition labeling of dietary supplements.

USE OF TOLERABLE UPPER INTAKE LEVELS

The committee discussed various possibilities for ensuring that the UL (see Chapter 4) was considered in nutrition labeling. These discussions included the possible use, in the Nutrition Facts box, of the nutrient's ULs and/or the percentage of the UL that is represented in the product. However the committee agreed that the direct use of the UL in the Nutrition Facts box could be subject to misinterpretation, including the possibility that consumers might view the UL as an optimum or, conversely, a toxic amount. Hence the committee does not recommend including the ULs, their representation, or a statement mentioning them in the Nutrition Facts box for conventional food.

The committee noted that—in addition to being the most scientifically justifiable approach—the population-weighted EAR has the added advantage of providing the widest margin of safety relative to the lowest ULs across all life stage and gender groups. In fact reference values based on the population-weighted EAR would be lower than the ULs for all of the life stage and gender groups used to compute this EAR (i.e., individuals 4 years of age and older, excluding pregnant and lactating women), with the exception of magnesium. The population-weighted EAR may be close to the UL for

children ages 1 to 3 years for preformed vitamin A, niacin, and folate from fortified food and supplements and zinc from all sources. The significance of this proximity will need to be evaluated on a case-by-case basis.

Magnesium is one nutrient for which the population-weighted EAR would not be lower than the UL for all life stage and gender groups. However, the UL for magnesium is based on *only nonfood sources that are consumed acutely,* and the criterion used to establish the UL is diarrhea from nonfood sources (IOM, 1997). Magnesium has never been demonstrated to exert any adverse effect when consumed in food.

Supplements, however, differ from whole food in that they are highly concentrated, bioavailable sources of nutrients. While it is nearly impossible to consume levels of nutrients that approach the UL from nutrients that are naturally occurring in conventional food (Turner et al., 2003), there are a few studies that demonstrate ingestion at the UL of certain nutrients from combinations of conventional food and supplements or diets that contain highly fortified food and supplements (Allen and Haskell, 2002; Johnson-Down et al., 2003; O'Brien et al., 2001). In the DRI reports the ULs are predicated on the concern that total nutrient intake should not reach a harmful level. The committee recognizes that dietary supplements provide a substantial portion of total nutrient intake in some segments of the population and contribute to intakes well above the DV and RDA in other segments. The committee is concerned about emerging data, which for the first time are combining nutrient intake from food and supplements and indicate intake levels for some nutrients that closely approach or exceed the UL. To help the consumer place nutrients from supplements into the context of the total daily diet, the committee recommends that the regulatory agencies consider how best to include information about the UL on the supplement label.

ADDITIONAL ISSUES

During its consideration of the application of DRIs to nutrient reference values, the committee discussed other issues relevant to these values. These issues are: the inclusion of absolute amounts for micronutrients in the Nutrition Facts box, the use of standardized units of quantity in all aspects of nutrition labeling, and the selection and presentation of required nutrients in nutrition labeling that convey a *positive* public health message and have the greatest public health benefit.

Absolute Amounts for Micronutrients

GUIDING PRINCIPLE 10. Absolute amounts should be included in the Nutrition Facts and Supplement Facts boxes for all nutrients.

When FDA issued regulations to implement NLEA, it continued a long-standing policy of not including the absolute amount of micronutrients per serving within the Nutrition Facts box. Food products could, however, include the absolute amounts of micronutrients elsewhere in the food label. The regulations require that micronutrients be declared within the Nutrition Facts box as a % DV. FDA chose this approach for several reasons. First, previous research demonstrated that % DVs better enabled consumers to understand the relative amount of a micronutrient in a food than did the absolute amount (FDA, 1993a; NIN, 1999). Second, the Nutrition Facts box was designed to be easy to read, and adding the absolute amounts of micronutrients would make the label more complex (FDA, 1993a). Third, the 1973 nutrition labeling did not provide absolute amounts because FDA determined that many consumers did not understand the metric system, and there was no formally voiced dissatisfaction with this approach (FDA, 1993a). The new labeling rules in Canada also state that proposed nutrition labels will not include absolute amounts of micronutrients, although absolute amounts will be allowed for the macronutrients in the core group (Canada, 2003). The committee considered a number of potential benefits and drawbacks for including absolute amounts in nutrition labeling.

Benefits to Adding Absolute Amounts to the Nutrition Facts Box

Adding absolute amounts for micronutrients to the Nutrition Facts box could provide several benefits. First, public health advice is often given in absolute amounts and not as a % DV. For example, advice on calcium intake by health educators and health professionals, national health associations, and government consumer information is given in milligrams. As a result, consumers are not able to easily determine the amount of calcium in a food by reading the Nutrition Facts box since it is listed as % DV. By adding absolute amounts, consumers would know the amount of calcium in a food product, yet still be able to use the % DV for quick comparison with other products.

Second, including absolute amounts would assist consumers who want nutrient information yet are unable to understand the % DVs

(NIN, 1999). In addition, some consumers state that they want both pieces of information—the % DVs and the absolute amounts—because they seek different information depending upon the nutrient and the food item (NIN, 1999).

Third, the food label would be a more useful teaching tool for nutrition and health professionals, especially for teaching persons on special diets. This information would be particularly useful if the food label declared not only the absolute amount of micronutrients and % DV per serving, but also the % DV for a special group if a food also is being targeted to that group. Nutrition educators contend that the presence of absolute amounts for micronutrients on food labels would make it easier to educate consumers about nutrient needs that are unique to a particular life stage and gender group (Osteoporosis Society of Canada, 2003).

Fourth, absolute amounts and % DVs (when they exist) for macronutrients already are required in the Nutrition Facts box. Adding absolute amounts for micronutrients on food labels would make the label more internally consistent in the way information is provided to consumers.

Fifth, absolute amounts and % DVs (when they exist) already are required on the Supplement Facts box. Adding absolute amounts for micronutrients in the Nutrition Facts box would make the consumer information for conventional food and dietary supplements consistent.

Finally, one problem in communicating information on food labels is the inconsistency of the terminology used to describe nutrient levels in food. On the front panel, where nutrient information may be provided with a nutrient content or health claim, the level of the particular nutrient is expressed qualitatively or in a relative sense, for example, "good" or "excellent" source or "reduced/less." In the Nutrition Facts box, however, nutrient information for vitamins and minerals is expressed as a % DV.

Potential Drawbacks to Adding Absolute Amounts to the Nutrition Facts Box

Adding absolute amounts for micronutrients to the Nutrition Facts box has potential drawbacks. First, adding absolute amounts would require more label space, making the label visually more complex and requiring companies to devote more product package space to the nutrition label or to reduce type size.

Second, the additional information on the label might make it more difficult for consumers to use the label to make healthy food

choices. For example, studies conducted by FDA during the design of the Nutrition Facts box found that while consumers preferred to have both % DVs and absolute amounts on the label, they did a better job using the label that contained % DVs alone (NIN, 1999). In addition, studies have repeatedly shown that when some consumers see large numbers next to a nutrient, they conclude that there is a large quantity of that nutrient in the food, regardless of the units of measure or the relative amount compared to the DV (FDA, 1993a).

However the overall conclusions that have been drawn based on earlier research typically reflect consumers' use of nutrition labeling without experience, education, training, or guidance. Recent studies have focused on the education of special populations. Training programs and studies with children and adults with diabetes (Baylor College of Medicine and Texas Children's Hospital, 2001; Kessler and Wunderlich, 1999; Miller and Brown, 1999; Miller et al., 2002), patients with chronic heart failure (Neily et al., 2002), and clinically obese patients seriously striving for weight loss (Fishman, 1996) have demonstrated success in teaching patients to use the Nutrition Facts box to make appropriate food choices. With diabetes education in particular, the focus of training sessions, in priority order, is on: (1) serving size, (2) grams of total carbohydrate, and (3) grams of fat. For those diabetic patients who are trained to count carbohydrate grams, there is an added emphasis on grams of dietary fiber in nutrition labeling. For diabetic patients with renal complications, the training also includes a focus on grams of protein, total calories, and milligrams of sodium. In the United States most diabetic training, especially with children, does not use the % DV, but rather has the absolute amount as its focus (Personal communication, B. Schreiner, Baylor College of Medicine and Texas Children's Hospital, 2003).

The decision to add absolute amounts of micronutrients to the Nutrition Facts box should be based primarily on the information that will enable consumers to make healthy food choices. If making healthy food choices is the primary goal of the Nutrition Facts box, then adding absolute amounts should help achieve that goal. Therefore, the committee recommends that absolute amounts of micronutrients be added to the Nutrition Facts box because this addition has significant potential health value to the consumer.

Units of Quantity

Over time the scientific understanding of micronutrients has grown and the units of measure for expressing micronutrient quan-

tities have changed. In Table 5-3 proposed units for expressing DVs are provided for every nutrient that has an EAR or an AI. The following guidelines were used in deciding what the proposed units should be:

- The unit of quantity for nutrition labeling should be consistent with the EAR or AI. Thus the units for vitamin A, vitamin D, vitamin E, folate, and copper should be changed to reflect the new DRIs.
- Where the current unit is appropriate and consistent with the unit in the DRI report, it should be retained.
- For nutrients where there are no DRI values because the report has not been released (electrolytes), the current units should be retained.

Implications of Changes to the Label Reference Values

In response to the study task and perspectives presented at the workshops, the committee considered several implications of using the population-weighted EAR or AI or making other changes to reference values for food labeling. In particular the committee discussed nutrient content claims, saturated fat and cholesterol claims, health claims, food formulation, and overages. The committee does not intend for this section to reflect an in-depth review of these issues, but rather to highlight several areas where it recommends careful consideration of the impact of potential changes. The tables included in this section were developed using the formulas and methodology described earlier in this chapter and the illustrative examples of population-weighted values and population estimates from the tables in Appendix B. The resulting numerical values are *illustrative only* because the development of actual numerical values would necessitate discussions and decisions about the selection of the best representative numbers for each variable in the formulas. In addition, decisions about issues such as units, numerical rounding, population estimates, and certain aspects of the calculations would need to be made before calculations could be done to generate the actual numbers.

While outside the direct task of the committee, nutrient content and health claims in the United States are dependent on the DVs. The workshop presentations helped to make it clear to the committee that manufacturers were concerned about the impact of changes in the DVs on the criteria for making nutrient content and health claims.

TABLE 5-3 Proposed Units of Quantity for Nutrients

Nutrient	Current Unit	Proposed Unit	Comment
Change needed			
Vitamin A	IU	μg RAE	DRI unit is RAE; carotenes will provide the sole source of vitamin A for vegans (show RAE in footnote)
Vitamin D	IU	μg	DRI unit is μg
Vitamin E	IU	mg	DRI unit is mg; the amount shown should be α-tocopherol
Folate	mg	μg DFE	Because fortified foods contain folic acid, this form should be converted to food folate using DFE calculation (show DFE in footnote)
Choline		mg	AI unit is mg, but UL unit is g
Copper	mg	μg	DRI unit is μg
No change needed			
Vitamin K	mg		
Thiamin	mg		
Riboflavin	mg		
Niacin	mg		Although NE is the DRI unit, the label should only refer to preformed niacin
Vitamin B_6	mg		
Vitamin B_{12}	mg		
Biotin	mg		
Pantothenic acid	mg		Shorten name to pantothenate
Vitamin C	mg		
Calcium	mg		
Magnesium	mg		
Phosphorus	mg		
Fluoride	mg		
Chromium	mg		
Iodine	mg		
Iron	mg		
Manganese	mg		
Molybdenum	mg		
Zinc	mg		
Potential change unknown			
Sodium	mg		Units may change pending release of the DRI report on electrolytes
Potassium	mg		Units may change pending release of the DRI report on electrolytes
Chloride	mg		Units may change pending release of the DRI report on electrolytes

NOTE: IU = international units, RAE = retinol activity equivalents, DRI = Dietary Reference Intake, DFE = dietary folate equivalents, AI = Adequate Intake, UL = Tolerable Upper Intake Level, NE = niacin equivalents.

New labeling regulations also make the following discussion of the proposed changes more relevant in Canada. Nutrient content claims have been permitted in Canada for food for special dietary use since 1974 and for all food meeting the compositional criteria for specified claims since 1988. For the first time, amendments to the Canadian *Food and Drug Regulations* (Canada, 2003) permit five health claims on food, including a claim for dental caries on the labels of certain chewing gums, candies, and breath-fresheners that contain a specified amount of fermentable carbohydrate.

Nutrient Content Claims

For a food to qualify to serve as a "good" source of a nutrient, it must contain 10 to 19 percent of the DV per reference amount customarily consumed (RACC). An "excellent" or "high" food source must contain at least 20 percent of the DV per RACC (21 C.F.R. 101.54(b), (c), (e). As shown in Table 5-4, the amount of nutrient per RACC for a food to qualify for a good or excellent/high claim would be lower in most cases if the DVs were based on the population-weighted EAR or AI than if they were based on the current DVs. The example population-weighted EAR is similar to the current DV for vitamin C and lower for most other nutrients—by 22 (folate) to 66 percent (vitamin B_{12}, copper, and iron). Because the units of measure for the DV and population-weighted EAR differ for vitamins A and E, it is not readily apparent how the qualifying amounts for these label claims might potentially differ. Population-weighted AIs for calcium, vitamin K, and fiber may be slightly higher by approximately 10 to 20 percent than the current DVs; the population-weighted AI would most likely be lower than the current DV for vitamin D (~30 percent), pantothenic acid (~52 percent), and biotin (~91 percent).

Currently protein content expressed as a % DV and the criteria for protein content claims are based on the amount of protein in a food after protein digestibility-corrected amino acid scores (PCDAAs) are applied. The committee recommends that the reference value for protein be based on the difference between the sum of the reference values for carbohydrate (based on the midpoint of the AMDR for carbohydrate) and fat (based on the midpoint of the population-weighted midpoint of the AMDR for fat for children and adults).

If a protein DV based on an AMDR of greater than 10 percent of energy was adopted, consideration would need to be given to the criteria for expressing protein content as a % DV, as well as to the

criteria for protein content claims. The committee discussed some of the implications—both with and without PDCAAs—of a 75-g DV on protein label declarations and criteria for protein content claims. Under the current regulations a good source of protein contains at least 10 percent of the DV per RACC. Therefore a good source of protein based on a DV of 75 g would require 7.5 g of protein per RACC. By way of comparison, a large egg contains 6 g of protein per RACC (50 g), peanut butter contains 8.1 g (2 tbs), and canned navy beans contain 9.7 g (130 g). With or without adjustment for PDCAAs, the egg would not qualify as a good source. Peanut butter would qualify as a good source if not adjusted for PDCAAs, but it would not qualify if adjusted (4.7 g/RACC by the Food and Agriculture Organization/World Health Organization pattern and 5.4 g/RACC by the Food and Nutrition Board/Institute of Medicine pattern). Canned navy beans would qualify as a good source whether or not PDCAAs were adjusted (7.8 g by both patterns).

In a mixed diet that contains ample protein, the correction factors probably are not important. However the factors would become important when evaluating an individual food's contribution to protein intake—especially in circumstances where the diet lacks variety and is relatively low in energy content (e.g., when meal replacement drinks and bars are used in supplemental feeding or weight-management programs). Because of the complexities associated with evaluating the contribution of protein to a health-promoting diet, the committee suggests a thorough evaluation of the regulatory and nutritional implications of the use of PDCAAs in this context.

Saturated Fat and Cholesterol Content Claims

In general, the criterion for a "free" content claim is the lower limit of analytical accuracy for a given nutrient, the criterion for a "low" content claim is about 5 percent of the DV, and the criterion for a "reduced" content claim is at least 25 percent less than the reference food. A lower DV for saturated fat and cholesterol may reduce the amounts per RACC required to meet the criteria for free and low claims, perhaps making it more difficult to make these claims about food. It is therefore important to take into consideration that the ability to meet current criteria for reduced cholesterol claims also may be affected by a lower DV for saturated fat.

Health Claims

Specific Nutrient Requirements. Each health claim has specific nutri-

TABLE 5-4 Illustrative Comparison of the U.S. Daily Value (DV) and a Possible DV Calculated Using a Population-Weighted Approach

Nutrient	DV	Good	Excellent
Nutrients that have a Population-Weighted EAR			
Vitamin A	5,000 IU	500	1,000
Vitamin C	60 mg	6	12
Vitamin E	30 IU	3	6
Thiamin	1.5 mg	0.15	0.30
Riboflavin	1.7 mg	0.17	0.34
Niacin	20 mg	2	4
Folate	400 μg	40	80
Vitamin B_{12}	6 μg	0.6	1.2
Copper	2 mg	0.2	0.4
Iodine	150 μg	15	30
Iron	18 mg	1.8	3.6
Magnesium	400 mg	40	80
Molybdenum	75 μg	7.5	15
Phosphorus	1,000 mg	100	200
Selenium	70 μg	7	14
Zinc	15 mg	1.5	3
Nutrients that have a Population-Weighted AI			
Biotin	300 μg	30	60
Calcium	1,000 mg	100	200
Choline	—[f]		
Chromium	120 μg	12	24
Fluoride	—[f]		
Manganese	2 mg	0.2	0.4
Pantothenic acid	10 mg	1	2
Vitamin D[g]	400 IU	40	80
	(10 μg)	(1)	(2)
Vitamin K	80 μg	8	16
Fiber	25 g	2.5	5

NOTE: Good source and excellent source refer to nutrient content claims. Under current regulations, a food must contain 10 to 19 percent of the DV to serve as a good source of a nutrient. An excellent (or high) source must contain at least 20 percent of the DV.

[a] EAR = Estimated Average Requirement, AI = Adequate Intake.

[b] As retinol activity equivalents (RAE). 1 RAE = 1 μg retinol, 12 μg β-carotene, 24 μg α-carotene, or 24 μg β-cryptoxanthin. The RAE for dietary provitamin A carotenoids is twofold greater than retinol equivalents (RE), whereas the RAE for preformed vitamin A is the same as RE.

[c] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of

Population-Weighted EAR or AI[a]	Good	Excellent
529 μg RAE[b]	53	106
63 mg	6	13
12 mg α-tocopherol[c]	1	2
0.92 mg	0.09	0.18
0.95 mg	0.10	0.19
11.1 mg NE[d]	1.1	2.2
314 DFE[e]	31	63
2.0 μg	0.2	0.4
684 μg	68	137
93 μg	9	19
6.1 mg	0.6	1.2
286 mg	29	57
33 μg	3	7
588 mg	59	118
44 μg	4	9
7.5 mg	0.75	1.5
28 μg	2.8	5.6
1,091 mg	109	218
460 mg	46	92
27 μg	2.7	5.4
3.2 mg	0.32	0.64
2 mg	0.2	0.4
4.8 mg	0.48	0.96
6.9 μg	0.69	1.38
95 μg	9.5	19
28 g[h]	2.8	5.6

α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements.

[d] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan.

[e] As dietary folate equivalents (DFE). 1 DFE = 1 μg food folate = 0.6 μg of folic acid from fortified food or as a supplement consumed with food = 0.5 μg of a supplement taken on an empty stomach.

[f] No DV established.

[g] For vitamin D, IU is the current unit of expression for nutrition labeling; μg is the unit of expression for the Dietary Reference Intakes.

[h] Based on an AI of 14 g/1,000 kcal and 2,000 kcal reference calorie level.

ent criteria, among other criteria, for determining the eligibility of a food to make the claim. Generally a food must be a good or excellent/high source of nutrients associated with risk reduction and a low source of nutrients associated with increased risk (see Table 5-4) (FDA, 1993d). Table 5-5 summarizes selected nutrient requirements for health claims that may be affected by changes in the DV. Determination of possible effects on the criteria for sodium- and potassium-related claims is pending the DRI report on water and electrolytes.

General Nutrient Criteria for Health Claims. In addition to meeting specific nutrient requirements to qualify for a health claim, a food must contain 10 percent or more of the DV, without fortification, for one of the following six nutrients: vitamin A, vitamin C, iron,

TABLE 5-5 Current Nutrient Requirements for Health Claims

Claim[a]	Nutrient Requirements[b]
Calcium and osteoporosis	High in calcium
Sodium and hypertension	Low sodium
Dietary SFA and cholesterol and CHD risk	Low SFA Low cholesterol
Fiber products, fruits, and vegetables and cancer	Good source of fiber
Fruits, vegetables, grains, and soluble fiber and CHD risk	Low SFA Low cholesterol 0.6 g soluble fiber/RACC
Fruits and vegetables and cancer	Good source (without fortification) of one or more of vitamin A, C, or dietary fiber
Folate and neural tube defects	Good source of folate
Soluble fiber from certain food and CHD risk	Low SFA Low cholesterol Soluble fiber/RACC on nutrition label
Soy protein and CHD risk	Low SFA Low cholesterol
Plant sterol/stanol esters and CHD risk	Low SFA Low cholesterol
Potassium and risk of high blood pressure and stroke	Good source of potassium Low sodium Low SFA Low cholesterol

[a] SFA = saturated fatty acid, CHD = coronary heart disease.
[b] List includes only those possibly affected by a change in Daily Value. RACC = reference amount customarily consumed.

calcium, protein, and fiber. In those cases where the population-weighted EAR or AI is less than the current DV, more food products may qualify for a health claim. A higher DV for fiber, based on the AI for a 2,000-calorie reference value, however, may disqualify some food products from bearing a health claim.

Disqualifying Nutrients. Food that contains more than a specified level of fat, saturated fat, cholesterol, or sodium are disqualified from making a health claim, even though all other criteria might be met. The disqualifying amount is typically 20 percent of the DV. Lowering the DV for saturated fat and cholesterol might make it more difficult for a food to qualify for certain health claims. DVs based on a population-weighted EAR or AI concept or other recommended principles may have mixed implications for claims in nutrition labeling under current regulatory criteria. Regardless, the committee believes that the principles presented in this report provide the most accurate scientific approach to using the DRIs to determine reference values for nutrition labeling.

Effects of Nutrition Labeling on Food Formulation

While discussions about the Nutrition Facts box typically revolve around its impact as a tool to help consumers make more healthful food selections, it must be recognized that the regulations governing the Nutrition Facts box and the associated nutrient content claims also influence the formulation of products. Manufacturers often adjust the quantities of particular ingredients or discretionary fortificants so that their products can be shown in the Nutrition Facts box to have a higher percent DV for some nutrients and a lower percent DV for others, thereby meeting the criteria for particular content claims. Thus any changes to the DV or to the list of nutrients included in the Nutrition Facts box can be expected to have some effect on the nutrient profiles of processed food. Furthermore, implementation of the recommended principles for discretionary fortification is expected to affect the inclusion of nutrients and their amounts suitable for fortification.

Overages

In the United States, for the purpose of determining compliance with nutrition labeling regulations, nutrients added to fortified or fabricated food (e.g., vitamins and minerals) are classified as Class I (21 C.F.R. 101.9(g)). A food containing a Class I nutrient is deemed to be misbranded if the amount of the nutrient in a composite

sample (collected and analyzed in accordance with regulations) is not at least equal to the value declared on the label. This requirement differs from that for Class II nutrients, which are those that naturally occur (i.e., are indigenous) in food. The nutrient content of a composite sample containing a Class II nutrient must be equal to at least 80 percent of the value declared on the label.

In order to ensure compliance with label declarations, fortified nutrients are often added in excess (an overage). The amount of overage to ensure compliance depends on several factors, including the chemical stability of the nutrient itself, the manufacturing process (e.g., where in the process a vitamin or mineral is added; how well the vitamin or mineral is incorporated into the product; the conditions of time, temperature, pressure, and moisture), and the conditions used to simulate abusive handling throughout the distribution and retail chain (because manufacturers cannot control conditions after a product leaves their factories and distribution centers). In the United States reasonable excesses of vitamins and minerals over labeled amounts are acceptable within current good manufacturing practices.

In attempting to comply with the regulation for Class I nutrients, some manufacturing practices may result in unnecessary, excessive overages. Excessive overages would be of concern for those nutrients with a low margin between the DV and the lowest UL and for which a serious adverse effect is the basis for the UL. Even in the absence of the potential for an adverse effect, excessive overages, which may not be captured in food composition databases, complicate the evaluations of nutrient intakes and nutritional status.

Positive Health Message and Public Health Benefit in Nutrition Labeling

The tone of the message conveyed by the elements in the Nutrition Facts box merits careful consideration because the box serves as an important public health communication tool. When the Nutrition Facts box is revised, the committee suggests that thought be given to the selection, organization, and display of nutrients as these elements may impact the tone of the public health message. The Nutrition Facts box currently can be construed as presenting a negative message because many of the required nutrients that appear in bold print on the top of the Nutrition Facts box (e.g., cholesterol, fat, and sodium) are those that consumers are expected to restrict in order to reduce their risk of chronic disease. There is no similar

emphasis made by grouping, format, or letter size of those nutrients for which consumers are encouraged to increase their intake (e.g., calcium). The priorities of required nutrient selection, label design, and other factors need to be reviewed in light of the potential positive message tone and educational value that could be presented for nutrients included on the label.

In 1973 the selection of nutrients and food components to be included on nutrition labeling was primarily based on ameliorating nutritional deficiencies and on illustrating the positive and negative nutrient content of food. In 1990 FDA critically reviewed these nutrients, modified the list, and placed more emphasis on food components associated with chronic diseases and less emphasis on nutrient-deficiency diseases. In particular the revision placed emphasis on those nutrients that reflected the primary public health objective of a reduction in the risk of cardiovascular disease and the secondary objective of a reduction in the risk of cancer.

Periodic reviews of the key scientific issues of public health significance and whether these issues are being addressed by nutrition labeling will help to maintain the scientific currency of the information provided to consumers. These reviews should include discussions with scientific experts to ascertain if the nutrients listed in the Nutrition Facts box reflect the most current scientific understanding of the nutrition, health, and disease relationships important for public health. Appropriate revisions to nutrition labeling should be considered based on these discussions. While changes in the nutrients required in the Nutrition Facts box can have significant ramifications for food manufacturers, the representation of public health issues and positive health messages only can be accomplished by these periodic reviews and, if necessary, revisions to the list of nutrients required in the Nutrition Facts box.