Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification

Committee on Use of Dietary Reference Intakes in Nutrition Labeling

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DIETARY REFERENCE INTAKES

Guiding Principles for Nutrition Labeling and Fortification

Committee on Use of Dietary Reference Intakes in Nutrition Labeling
Food and Nutrition Board

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OF THE NATIONAL ACADEMIES

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Richard Black, International Life Sciences Institute, North America; Susan Borra, International Food and Information Council; Robert O. Earl, National Food Processors Association; John W. Erdman, University of Illinois; Nancy D. Ernst, Ernst Nutrition Consulting; Kenneth Fisher, KD Consultants; Cutberto Garza, Cornell University; Katherine Gray-Donald, McGill University; Peter Barton Hutt, Covington & Burling; Gilbert Leveille, Cargill, Inc.; Ian C. Munro, Cantox Health Sciences International; Suzanne P. Murphy, University of Hawaii; Lynn Parker, Food Research and Action Center; Donna Porter, Congressional Research Service; George F. Sheldon, The University of North Carolina at Chapel Hill; John Vanderveen, San Antonio, Texas; and Kathryn L. Wiemer, General Mills.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by Maldon C. Nesheim, Cornell University, and Enriqueta Bond, Burroughs Wellcome Fund. Appointed by the Institute of Medicine and the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

The task for the Committee on Use of Dietary Reference Intakes in Nutrition Labeling, which I was privileged to chair, was to provide guidance to the U.S. Department of Health and Human Services' Food and Drug Administration (FDA), the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), and Health Canada on how to use the Dietary Reference Intakes (DRIs) to update the nutrient reference values used in nutrition labeling. The committee was also asked to produce guidance on how to use the DRIs when making decisions about the discretionary fortification of food.

The evolution of the current seven plus DRI volumes from a single-volume book of Recommended Dietary Allowances (RDAs) in the United States and from Recommended Nutrient Intakes (RNIs) in Canada reflects the tremendous surge in the scientific understanding of basic nutrition and the relationships between diet and health in the 8 years between the publication of the last RDA and RNI books and the first volume of the DRIs. The DRIs are definitely *not* your mother's RDAs or RNIs! They include four reference values: the RDA, the Estimated Average Requirement (EAR), the Adequate Intake (AI), and the Tolerable Upper Intake Level (UL). (An overview of the DRIs and their derivation is provided in Chapter 4.)

The report before you represents the result of six meetings, numerous phone conferences, and much writing by the scientists on this committee who volunteered their time to work with the complexity of these issues. First and foremost, I want to acknowledge them for their dedication and perseverance in working through the

diversity of issues and bringing to the discussion their depth of expertise in the diverse areas necessary for a report such as this. Second, I want to thank Linda Meyers, study director, for her leadership in helping all of us stay focused on the task at hand and for providing support to our endeavor in so many ways. I especially thank our expert consultant, Bernadette Marriott, for her vital contributions that were essential and critical to the completion of the report. The committee appreciates the assistance of the Food and Nutrition Board (FNB) staff in developing this report, particularly that of Romy Gunther-Nathan for her contributions as the original co-study director, Harleen Sethi for making our meetings and conference calls run so smoothly, Tazima Davis for her research assistance, Shannon Ruddy for assisting in the completion of the report, and Gail Spears for her technical editing. We wish to thank Allison Yates, former FNB Director, for her thoughtful interactions and discussions with the committee on some of the more difficult issues. The committee also benefited greatly from the statistical and computer skills of Craig Johnson. The committee held two workshops to broaden its knowledge of the issues and to hear from interested groups. The committee acknowledges the following individuals for their insightful comments at these workshops: Susan Borra, Margaret Cheney, Brenda Derby, Annette Dickinson, Robert Earl, Constance Geiger, Nancy Green, Suzie Harris, Regina Hildwine, Clifford L. Johnson, Allison Kretser, Bonnie Liebman, Alanna Moshfegh, Ian Munro, Robert Post, Leila Saldanha, Christine Taylor, and Kathryn Wiemer. In particular, the committee thanks Margaret Cheney, Robert Post, and Virginia Wilkening and their colleagues for assisting its research into the history and status of food labeling and fortification.

This report is a derivative of the DRI reports and as such reflects the work of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its panels and subcommittees. The multipart committee-panel structure that comprises the DRI process has led to a series of reports involving over 100 expert scientists who have rigorously maintained a consistent approach and understanding of the basic DRI definitions and derivations. While this report is outside of the framework of review for the DRI reports, its essence has benefited from the diligent work of those scientists.

In this report the Committee on Use of Dietary Reference Intakes in Nutrition Labeling presents its recommendations as a series of guiding principles to assist the regulatory agencies that oversee food labeling and fortification in the United States and Canada. Although the committee members have varying levels of past experience with food regulations in our respective countries, over the course of this

study we have gained a deeper appreciation for the difficulty and complexity of the steps necessary to develop a nutrition label and the policies of discretionary fortification that are truly helpful for the broad population of consumers in our two countries. We provide this guidance to FDA, FSIS, and Health Canada with the hope that it will assist them in moving the process forward so that the significant science base in the DRIs can rapidly be used to benefit the health of our nations.

Irwin H. Rosenberg, *Chair*
Committee on Use of Dietary Reference Intakes
in Nutrition Labeling

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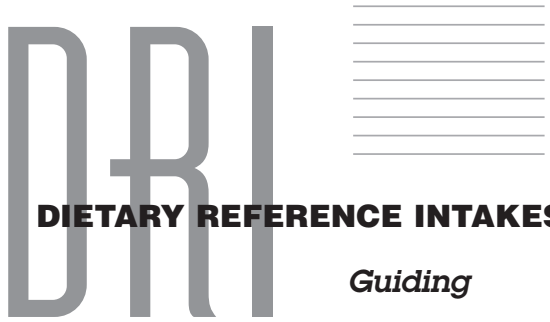


DIETARY REFERENCE INTAKES

Guiding Principles for Nutrition Labeling and Fortification

Executive Summary

OVERVIEW

An old adage warns "You Are What You Eat!" In order for individuals to test this adage, they must understand what they are eating. The Food and Drug Administration (FDA) first required nutrition information as part of food and dietary supplement labeling in 1941. As early as the 1950s, reports were published that informed consumers about the links between diet and health, specifically dietary fat, cholesterol, and heart disease. The 1969 White House Conference on Food, Nutrition, and Health set the stage for the 1973 promulgation by FDA of the first comprehensive regulations for nutrition labeling. This was followed by the release of a number of major government and professional association reports in the 1970s on diet and health, including *Dietary Goals for the United States* (Senate Select Committee on Nutrition and Human Needs, 1977). In the late 1980s, with the publication of *The Surgeon General's Report on Nutrition and Health* (DHHS, 1988) and *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a), the increasing scientific evidence on the links between diet and chronic disease risk came to the forefront and brought even greater credence to the old adage. In the early 1990s these two reports, along with *Nutrition Labeling: Issues and Directions for the 1990s* (IOM, 1990) and other key events, such as the Nutrition Labeling and Education Act of 1990, led to changes in the nutrition information included on food labels. Specifically, FDA published new food labeling regulations that required the Nutrition Facts box to be included on almost all food (FDA,

1993a, 1993b, 1993c). The Nutrition Facts box and other mandated label changes strengthened the label's ability to serve as an important resource for helping consumers select food that could contribute to a healthful diet.

The current percent Daily Values (% DVs) that appear in the Nutrition Facts box in the United States are based in part on recommended reference values for nutrients from the 1968 Recommended Dietary Allowances (RDAs) (NRC, 1968). In Canada the nutrient information that appears on the label is based on the 1983 Recommended Nutrient Intakes (RNIs) (Canada, 1983b).

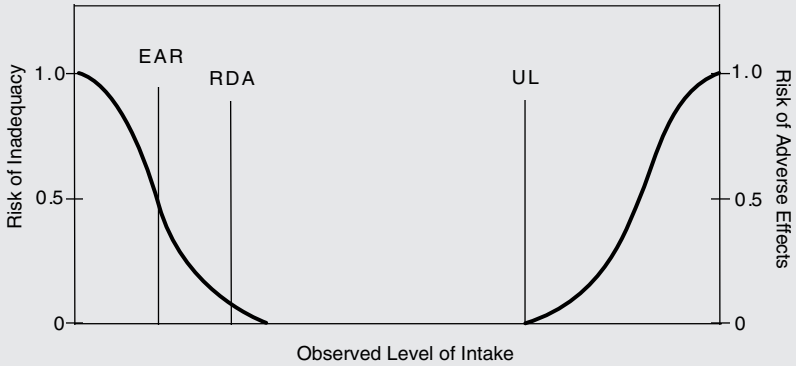
Since 1997 the Institute of Medicine has issued a series of nutrient reference values that are collectively termed Dietary Reference Intakes (DRIs) (IOM, 1997, 1998, 2000b, 2001, 2002a), which include four categories: the Estimated Average Requirement (EAR), the Adequate Intake (AI), the RDA, and the Tolerable Upper Intake Level (UL) (see Box ES-1). These reference values are replacements for the former RDAs in the United States and the RNIs in Canada and as such represent a harmonization of the nutrient recommendations of the two countries. In addition to the DRIs, an Acceptable Macronutrient Distribution Range (AMDR) was developed for macronutrients.[1]

As a result of the change in the concept for setting reference values for nutrients, the Committee on Use of Dietary Reference Intakes in Nutrition Labeling was convened to address a number of questions, including: Is the one reference value represented by % DV the most helpful approach for nutrition labeling for consumers? Is it best to derive one new reference value for nutrition labeling for each nutrient or a set of values that address the diversity of needs for various life stage and gender groups? Which of the four categories of DRIs must be incorporated into the basis for the new food reference values? What approach should be taken to integrate the new DRIs into the concept of discretionary fortification of food? Is the same reference value approach used for labeling also the best scientific approach for discretionary fortification?

This report focuses on how the DRIs, and the science for each nutrient in the DRI reports, can be used to develop appropriate reference values for nutrition labeling. The primary scientific resources for this report are therefore the DRI reports (IOM, 1997,

[1]An AMDR is a range of intakes for a particular energy source that is associated with reduced risk of chronic disease but also provides adequate intakes of essential nutrients.

BOX ES-1 Dietary Reference Intakes



Recommended Dietary Allowance (RDA): the average daily dietary nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

Adequate Intake (AI): the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate—used when an RDA cannot be determined.

Tolerable Upper Intake Level (UL): the highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.

Estimated Average Requirement (EAR): the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group.[a]

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[a]In the case of energy, an Estimated Energy Requirement (EER) is provided; it is the average 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 and lactating women, the EER is taken to include the needs associated with the deposition of tissues or the secretion of milk at rates consistent with good health.

SOURCE: IOM (2002a).

1998, 2000a, 2000b, 2001, 2002a, 2003). The overarching goal is to have updated nutrition labeling that consumers can use to compare products and make informed food choices. The task of the committee was to aid this effort by providing recommendations to the sponsoring agencies, in the form of guiding principles, on how best to use the new DRIs and their underlying science in nutrition labeling. In addition, the committee was requested to provide guidance on incorporating the DRIs into approaches for discretionary fortification. In the United States mandatory fortification (usually called enrichment) refers to the situation where a food product is labeled in a manner that purports to conform to the standard of identity for the enriched version of the food. Discretionary fortification refers to all other forms of the addition of nutrients to food, including unenriched versions of products for which an enrichment standard has been promulgated by FDA. In Canada the Food and Drug Regulations specify the foods to which micronutrients may be added and the level at which they may be added. Throughout this report the general term "fortification" refers to the addition of nutrients to food. The sponsors and primary audience for this study are the U.S. Department of Health and Human Services' FDA, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), and Health Canada.[2]

GUIDING PRINCIPLES AND RECOMMENDATIONS

Guiding Principles for Nutrition Labeling

The committee focused its analysis on the existing DRIs, the purpose of nutrition labeling, current labeling and fortification policies, and the limited information on consumer use of food labels. The committee's main recommendations are presented in the form of guiding principles for how to use the DRIs in nutrition labeling and discretionary fortification. Boxes ES-2 and ES-3 list the 16 guiding principles.

In the first guiding principle the committee recommends that nutrition information continue to be presented as percent Daily

[2]Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. In partnership with provincial and territorial governments, Health Canada provides national leadership to develop health policy, enforce health regulations, promote disease prevention, and enhance healthy living for all Canadians (Health Canada, 2003).

BOX ES-2 Guiding Principles for Nutrition Labeling

1. Nutrition information in the Nutrition Facts box should continue to be expressed as percent Daily Value (% DV).
2. The Daily Values (DVs) should be based on a population-weighted reference value.
3. A population-weighted Estimated Average Requirement (EAR) should be the basis for DVs for those nutrients for which EARs have been identified.
4. If no EAR has been set for a nutrient, then a population-weighted Adequate Intake (AI) should be used as the basis for the DV.
5. The Acceptable Macronutrient Distribution Ranges (AMDRs) should be the basis for the DVs for the macronutrients protein, total carbohydrate, and total fat.
6. Two thousand calories (2,000 kcal) should be used, when needed, as the basis for expressing energy intake when developing DVs.
7. The DVs for saturated fatty acids, *trans* fatty acids, and cholesterol should be set at a level that is as low as possible in keeping with an achievable health-promoting diet.
8. While the general population is best identified as all individuals 4 years of age and older, the committee recognized 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 DVs for these groups should be guided by the following principles:

   Infants (<1 y): one set of DVs based on the EARs or 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 Dietary Reference Intake (DRI) pregnancy groups.
   Lactation: one set of DVs based on the population-weighted EARs or AIs for all DRI lactation groups.

9. The Supplement Facts box should use the same DVs as the Nutrition Facts box.
10. Absolute amounts should be included in the Nutrition Facts and Supplement Facts boxes for all nutrients.

BOX ES-3 Guiding Principles for Discretionary Fortification

11. The scientific justification for discretionary fortification of food should be based on documented public health needs, particularly on dietary inadequacy that is determined by assessing the prevalence of nutrient inadequacy in the population. Regulatory agencies should develop criteria for determining when the evidence of dietary inadequacy indicates a documented public health need for the increased availability of nutrients in the food supply.
12. In situations where discretionary fortification is scientifically justified, intake data should be used with the Tolerable Upper Intake Level (UL) to provide evidence, using a careful modeling approach, to explain how current exposure to the nutrient in question would be altered by discretionary fortification.
13. Currently there is limited research on the impact of discretionary fortification on the distribution of usual intakes in the population. Consideration should be given to fortification with nutrients up to the amount for products to meet the criteria as "good" or "excellent" sources of the nutrients, consistent with the modeling approach described in Guiding Principle 12.
14. Potential changes to certain long-standing discretionary fortification practices should be carefully reviewed because they may be central to the maintenance of nutrient adequacy in the population.
15. The severity of the adverse effect on which the UL is based should be reviewed when considering discretionary fortification with a nutrient using the conceptual decision approach presented in Figure ES-1.
16. Where discretionary fortification is scientifically justified for special-use products, the intended use of the targeted food should be the standard against which the nutrient content is assessed.

Value (% DV). Guiding Principles 2 through 10 are grounded in developing reference values based on a population-weighted EAR, where available, as the foundation for the % DV. If there has been no EAR set for a nutrient, the committee describes the use of the other reference values, specifically a population-weighted AI or an AMDR (see Chapter 5).

The Nutrition Facts box has limited space and cannot accommodate a large table of values, nor would such complexity be helpful for the consumer. Population-weighting is needed because the committee recommends defining individuals 4 years of age and older as

the general population. The DRI reports, however, include separate life stage and gender groups for which reference values often differ. The most scientifically valid approach to combining these life stage and gender group values to obtain one number for nutrition labeling is to apply weighting based on population census data.

An important component of the DRI concept is how each reference value has been derived and the relevance of the derivation for different applications. For the purposes of nutrition labeling, the committee's task was to provide guidance for the development of reference values that could be used by an individual to compare the nutrient content of food items within food types and to make 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 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 the 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. For those nutrients for which the distributions of nutrient requirements for particular life stage and gender groups have been characterized, then the best, most representative estimate of an individual's requirement or need is the EAR for the group to which he or she belongs. A level of intake above or below the EAR will have a greater likelihood of systematically over- or underestimating an individual's needs. 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 as the basis for the DV when an EAR has been set for a nutrient. This approach should provide the most accurate reference value for the majority of the population.

EARs have not been set for some nutrients included in nutrition labeling. For these nutrients the committee recommends using a population-weighted AI as the reference value for the DV. AIs were set for nutrients only when there was insufficient scientific evidence to calculate an EAR. AIs were derived using a diversity of methods based on the best scientific information available. As a result, until more research is completed that allows calculation of the mean and

distribution of requirements for these nutrients, and therefore AI estimates are replaced with EARs, the nutrition label may need to use different DRI reference values as the basis for the DVs. Since the science base is the same for nutrients in food and in dietary supplements, the committee recommends that the guiding principles should apply to both nutrient vehicles. To aid consumers who are attempting to follow healthy eating guidelines that identify specific quantitative intake goals (e.g., calcium intake recommendations for older individuals), and for improved consistency between the Nutrition Facts and Supplement Facts boxes, the committee also recommends including absolute amounts for all nutrients in nutrition labeling.

Guiding Principles for Discretionary Fortification

Outside of fortification practices used to replace nutrients lost due to the preparation and storage of food components, the committee states in Guiding Principle 11 that the foremost scientific justification for discretionary fortification should be a documented public health need, particularly dietary inadequacy in a segment of the population. Clearly the promotion of the health of the population can play an important role. As a first step in identifying whether there is a public health need that might provide a scientific justification for discretionary fortification, federal agencies should estimate the level of dietary inadequacy in life stage and gender subgroups of the population for any nutrient of concern. The DRIs can be used to assess the proportion of a group that has a usual intake of a nutrient that is less than the requirement. In addition to assessing nutrient intakes, assessment of the health and nutritional status of groups or individuals needs to include biochemical, clinical, and anthropometric indicators as indicated in the DRI report on dietary assessment (IOM, 2000a). Guiding Principles 12 through 16 (Box ES-3) present the committee's additional recommendations for discretionary fortification, as described below.

Once the prevalence of inadequacy for a particular nutrient has been assessed in a nationally representative sample of individuals, further review is required to determine whether there is sufficient evidence of public health need to scientifically justify the addition of a nutrient to the food supply through discretionary fortification. There is currently little published research on the impact of discretionary fortification practices on nutrient intakes or on the prevalence of nutrient inadequacy or excess. Although there is a growing body of literature on the effect of fortification (e.g., the addition of

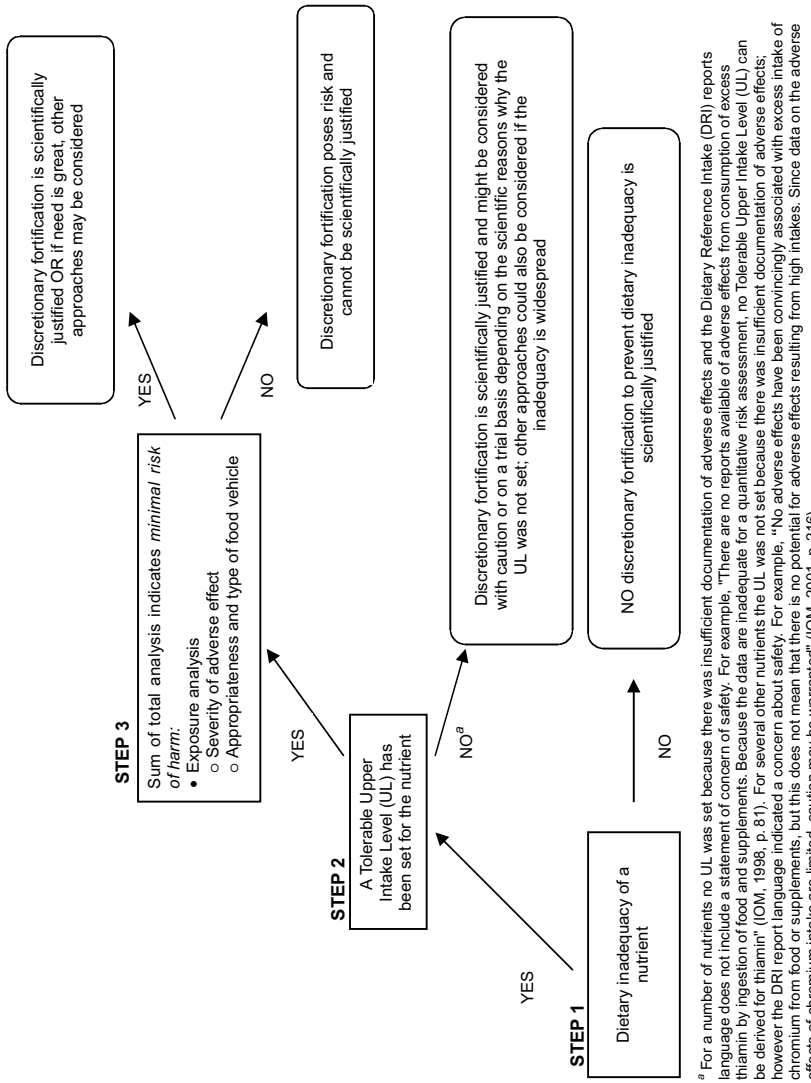
folic acid to standardized cereal and grain products) (Bailey et al., 2003; Mills et al., 2003; Quinlivan and Gregory, 2003; Ray et al., 2002a, 2002b, 2003), it would be premature to draw inferences about all fortification from these studies.

The committee cannot recommend guidelines that may affect the impact of discretionary fortification on nutrient inadequacy and the distribution of inadequate intakes in the population without empirical data on discretionary fortification. Instead the committee presents four key issues that should be considered as regulatory agencies appraise the public health need for discretionary fortification: the magnitude of the estimated prevalence of the nutrient inadequacy, the reliability and validity of the prevalence estimate, the health risks associated with the determined inadequacy, and the indications that the inadequacy can possibly be ameliorated by increasing the availability of the nutrient in the food supply.

Discretionary Fortification Decision Making

The diversity of the severity of the adverse effects that form the basis for the ULs, the current discretionary fortification practices in the United States that may result in fortification of greater than 100 percent of the DV, and the widespread consumer use of dietary supplements led the committee to believe that it was not prudent to base discretionary fortification on a single reference standard as is recommended for nutrition labeling. Data from the DRI reports indicate that such an approach has the potential to increase the risk of overconsumption of specific nutrients.

In addition, the scientific justification for discretionary fortification would most likely be comprised of several steps, and optimally the responsibility for these steps could fall to different groups: regulatory agencies, food manufacturers, federal research institutions, and university scientists. The committee therefore recommends increased communication among these groups to share consumer intake data and potential effects on health. To implement the guidance on discretionary fortification in Guiding Principles 11 through 16, the committee recommends that agencies involved in the regulation of fortification adopt the step-wise decision approach (Figure ES-1) to evaluate whether fortification will meet a public health need. This decision approach provides a way to evaluate whether fortification is scientifically justified and incorporates systematic reviews of data using two DRI reference values: the EAR and the UL. In this three-step approach the agencies would first determine the presence of inadequacy in the population. Next, in cases where



[a] For a number of nutrients no UL was set because there was insufficient documentation of adverse effects and the Dietary Reference Intake (DRI) reports language does not include a statement of concern of safety. For example, "There are no reports available of adverse effects from consumption of excess thiamin by ingestion of food and supplements. Because the data are inadequate for a quantitative risk assessment, no Tolerable Upper Intake Level (UL) can be derived for thiamin" (IOM, 1998, p. 81). For several other nutrients the UL was not set because there was insufficient documentation of adverse effects; however the DRI report language indicated a concern about safety. For example, "No adverse effects have been convincingly associated with excess intake of chromium from food or supplements, but this does not mean that there is no potential for adverse effects resulting from high intakes. Since data on the adverse effects of chromium intake are limited, caution may be warranted" (IOM, 2001, p. 216).

FIGURE ES-1 Flow diagram for decisions about discretionary food fortification.

a UL has been identified for the nutrient additions, the totality of scientific evidence amassed through modeling of exposure analysis, the severity of the adverse effects associated with the UL, the degree of risk of adverse effects to any segment of the population, and the appropriate nature of the food vehicle would all be considered when determining the potential for public health benefit from fortification. However it is imperative that the contribution of existing fortification practices and dietary supplements to current intakes be understood before regulations are introduced that would dramatically alter these practices. Given this situation, the agencies may decide that it important to support the continuation of certain longstanding discretionary fortification practices for the general nutritional well-being of the population. The guiding principles for discretionary fortification, in combination with this decision-making approach, provide a method for determining whether discretionary fortification is scientifically justified.

Research and Data Support Recommendations

During its deliberations the committee identified five areas where additional research and data support would benefit nutrition labeling and discretionary fortification. These areas are:

- Determination of requirements for those nutrients for which EARs could not be developed
- More data of high quality on adverse effects and dose relationships to permit definition of the biological endpoints, no-observed-adverse-effect levels, and lowest-observed-adverse-effect levels underlying the ULs
- Empirical research to ascertain the impact of discretionary fortification practices
- Enhanced data collection and food composition and dietary supplement databases
- Changes in nutrition labeling and consumer research on its use

A particular problem that the committee faced was the paucity of published data on consumer use of nutrition labeling. The committee puts forward this report in the anticipation that FDA, FSIS, and Health Canada will use the guiding principles in a systematic process to revise the scientific basis for nutrition labeling and for discretionary fortification. As part of this process, the committee also recommends a general review of the Nutrition Facts box, as well as significant consumer-based research on labeling of conventional food and supplements.

The committee believes that its recommendations will result in changes to the nutrition labeling on food and supplements that will enable consumers to more readily compare products and make informed purchase decisions. The desired long-term outcome of this report is the demonstration, through future research, that North Americans are effectively using nutrition labeling to make more informed food choices and to become a healthier population.

1
Introduction

Most people in the United States have difficulty remembering a time when they could not check the food label for the calorie or fat content of a food. At least a generation of young people does not realize that packaged food ever existed without nutrition labeling. Americans and Canadians have long been assisted in making informed food choices through regulations that control food labeling. In the United States, there have been three eras of nutrition labeling during which different reference values were used on the label: from 1941 to 1972, Minimum Daily Requirements were used; from 1973 to 1993, U.S. Recommended Daily Allowances (US RDAs) were used; and since 1993, Daily Values (DVs) have been used. The Nutrition Facts box that currently appears on virtually all food labels includes the DV and is a critical tool for consumers to use in making informed food choices. In January 2003 the Canadian government published new food labeling regulations that manufacturers can begin to implement immediately (Canada, 2003). With these new labeling regulations, Canadians will join Americans in receiving additional assistance in food selection through consistent, controlled Nutrition Facts information on food labels.

It has never been more important for consumers to make healthy food choices. Diet-related chronic diseases are a leading cause of preventable deaths in the United States and Canada (DHHS, 2001). In fact, because of the sharp rise in obesity and the decline in cigarette smoking, some public health researchers predict that if current trends continue, obesity will soon surpass smoking as the primary preventable cause of death (Allison et al., 1999b; Manson

and Bassuk, 2003). The current Nutrition Facts box that appears on food labels was conceived as an important public health tool to reduce diet-related disease. Since 1941 nutrition labeling in the United States has reflected the current scientific knowledge on the relationship between diet and health. For example, the changes reflected in nutrition labeling regulations promulgated by the Food and Drug Administration (FDA) in 1973 required that both positive and negative aspects of the nutrient content of food appear on the label to emphasize the relationship between diet and health (Hutt, 1981). The Nutrition Facts box and the related nutrition information on the label continued this effort to encourage healthier food choices. To achieve this health goal, the 1993 version of nutrition labeling included a new tool—the percent Daily Value (% DV)—that enables consumers to rapidly and efficiently understand how a particular food fits in the context of a healthy diet (FDA, 1993a).

The science underlying the % DVs in the Nutrition Facts box in the United States and Canada is not the most current. As explained further in Chapter 2, in the United States the majority of the nutrient reference values are based on the 1968 Recommended Dietary Allowances (RDAs) (NRC, 1968); for the reference values for which there were no RDAs at the time, FDA developed Daily Reference Values, which were based on the then current scientific information on reduction in risk of chronic diseases (FDA, 1993c). The new Canadian label values are based on the 1983 Recommended Nutrient Intakes (RNIs) (Canada, 1983b). In the United States and Canada, the Institute of Medicine's (IOM) Dietary Reference Intakes (DRIs), which have replaced the former RDAs and RNIs as quantitative estimates of required nutrient intakes, were developed to be used as reference values for planning and assessing diets and for many other purposes, including serving as the basis for nutrition labeling (IOM, 1997). The DRIs include the RDA and three additional reference values—the Estimated Average Requirement, the Adequate Intake, and the Tolerable Upper Intake Level (UL)—that need to be considered when establishing the basis for reference values for nutrition labeling. To enable consumers to use the nutrition label in making informed dietary choices, the science underlying the Nutrition Facts box must be up-to-date. Thus the U.S. Department of Health and Human Services' FDA, the U.S. Department of Agriculture's Food Safety and Inspection Service, and Health Canada asked IOM to undertake a study of the use of the DRIs in nutrition labeling and fortification.

COMMITTEE CHARGE AND STUDY PROCESS

Committee Charge

Following the National Academies committee process, the Committee on Use of Dietary Reference Intakes in Nutrition Labeling was appointed. The committee was to assess the objectives, rationale, and recommendations for the methodology to select reference values for labeling the nutritive value of food based on the DRIs and for the discretionary fortification of food, including meat and poultry products. The committee was to identify general guiding principles for use in setting reference values for nutrients on the food label, recognizing that the approach may need to be modified for special situations or for physiological needs related to each nutrient. These modifications were to be outlined and their rationale described. As a result of identifying approaches to use the DRIs as the basis for food label reference values, the committee was to determine principles for discretionary fortification and the suitability of using reference values for the food label for discretionary nutrient additions. In its consideration of nutrition labeling reference values, the committee was to take into consideration:

- the development of food label reference values and discretionary fortification practices in the United States and Canada;
- the purpose of reference values on food labels, specifically that consumers are expected to use the reference values to compare different food products and to determine the relative contributions of a food product to an overall health-promoting diet;
- the scientific basis for principles to be used to guide the selection of values for different nutrients, possibly using examples from various classes of nutrients;
- whether the resulting reference value for nutrition labeling should be a single set of reference values or if different sets of values for various life stage and gender groups are needed; and
- how reference values should be expressed.

In its determination of principles for discretionary fortification, the committee was to consider the 1980 FDA fortification policy (21 C.F.R. 104.20) and, given the new DRI concept of ULs, whether the discretionary addition of nutrients to food when based on labeling reference values alone may have the potential to increase risk due to overconsumption. This was to be done with special attention to vulnerable population groups, such as children for whom the RDA

for adults meets or exceeds the UL for children (as is the case for vitamin A, zinc, niacin, and folate) or young women who may become pregnant (and thus have a lower UL for vitamin A). The committee was also to consider the extent to which the discretionary addition of nutrients to food when based on labeling reference values alone may have the potential to increase risk due to overconsumption. The committee was not to address the format of the Nutrition Facts box, labeling claims, or fortification practices other than in relation to discretionary fortification.

After its review of these items the committee was to produce a report that provided the rationale and recommendations for the selection of reference values for nutrition labeling based on the DRIs. The report was to include a description of the purpose of reference values in nutrition labeling and to identify guiding principles for the selection of reference values for different nutrients. Based on the development of the reference value approach for nutrition labeling, the committee was to provide guiding principles for the discretionary fortification of food, including meat and poultry products.

Study Process

The committee met six times between March 2002 and April 2003 to consider its scope of work, review scientific evidence, and develop its recommendations and guiding principles. At these meetings the committee focused its analysis on the history of nutrition labeling and fortification, current labeling and fortification policies, the existing DRIs, and the limited information on consumer use of nutrition labeling. It held two open workshops to gather information from invited experts, government scientists, representatives of the food industry, and related groups on issues related to the nutrition labeling of food and dietary supplements and discretionary fortification.

During the committee process the Canadian government issued several consultation documents on the development of new policies on food fortification (Health Canada, 2002) and published new regulations for food labeling (Canada, 2003). Also during this time IOM released a report on the DRIs for macronutrients (IOM, 2002a) and a report on using the DRIs in dietary planning (IOM, 2003). The committee included these documents in its deliberations. A report on DRIs for electrolytes and water was not sufficiently finalized to be included in the committee's deliberations. The committee was cognizant of the timing of its recommendations while

the DRI reports were continuing to be published, and it developed the principles in this report not only to reflect published DRI reference values, but also to provide guidance on approaches that can be used as the science base evolves and new DRIs are established. This report addresses the aspects of nutrition labeling of food and dietary supplements that are currently included in laws regarding nutrition labeling in the United States and Canada. The committee includes a discussion of dietary supplement labeling because the same scientific principles apply to the derivation of the DRIs for conventional food and for dietary supplements. Consideration of the discretionary fortification of food focused on the DRIs, with special attention to the ULs in regard to vulnerable population groups.

REPORT ORGANIZATION

The first four chapters in this report include the committee's task, overviews of nutrition labeling and fortification in the United States and Canada, and a brief review of the history and concepts of the DRIs. It is within this context that the committee undertook its task of providing guidance on the best approach to develop reference standards for nutrition labeling of conventional food and supplements and for discretionary fortification based on the DRIs. Chapters 5 through 8 present the committee's findings and recommended guiding principles, recommendations for data support and research, and supporting references. Appendix A provides brief biosketches of the committee members. Appendixes B and C, respectively, include illustrative examples of application of a population-weighted approach as discussed in Chapter 5 and reference tables. Appendix D provides the agendas of the two information-gathering workshops convened by the committee.

2

Overview of Nutrition Labeling in the United States and Canada

The overview of nutrition labeling in the beginning of this chapter provides the historical context for the issues addressed by the Committee on Use of Dietary Reference Intakes in Nutrition Labeling in developing its recommendations on nutrient reference values. Key milestones are listed in Box 2-1; a more comprehensive discussion of the history of food labeling may be found elsewhere (e.g., Hutt, 1984, 1995; IOM, 1990). At the end of this chapter, information on consumer understanding of the label elements and the impacts of label content on consumer food purchases are briefly described.

REFERENCE VALUES AND NUTRITION LABELING IN THE UNITED STATES

The Early Years and Minimum Daily Requirements, 1906–1973

The federal government has had an essential and evolving role in assuring the integrity of the food supply. Government regulatory interest in the food supply began with a focus on preventing fraud in the marketplace, expanded into preventing the sale of unsafe food and, with the development of the science of nutrition, has assumed the role of protecting the integrity of the food supply (Hutt, 1984). The Food and Drugs Act of 1906 (21 U.S.C. §1) was the first federal statute that broadly prohibited the misbranding or adulteration of food (Hutt, 1984). While it upgraded the safety and integrity of the entire food supply in the United States, the law lacked authority to establish standards of identity for particular food

BOX 2-1 Selected Milestones in Nutrition Labeling in the United States

1906	Food and Drugs Act and Federal Meat Inspection Act
1938	Federal Food, Drug and Cosmetic Act
1941	Special Dietary Food Regulations, including Minimum Daily Requirements
1957	Poultry Products Inspection Act
1969	White House Conference on Food, Nutrition, and Health
1970	Egg Products Inspection Act
1973	Nutrition Labeling Regulations, including U.S. Recommended Daily Allowances (US RDAs)
1977	*Dietary Goals for the United States*[a]
1979	*Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention*[b]
1980	*Dietary Guidelines for Americans (First Edition)*[c]
1988	*The Surgeon General's Report on Nutrition and Health*[d]
1989	*Diet and Health: Implications for Reducing Chronic Disease Risk*[e]
1989	*Recommended Dietary Allowances (Tenth Edition)*[f]
1990	*Nutrition Labeling: Issues and Directions for the 1990s*[g]
1990	Reference Daily Intakes and Daily Reference Values, proposed rule
1990	Nutrition Labeling and Education Act (NLEA)
1991	Reference Daily Intakes and Daily Reference Values, proposed rule to implement NLEA
1992	Dietary Supplement Act
1993	Reference Daily Intakes and Daily Reference Values, final rule
1994	Dietary Supplement Health and Education Act
1997	Dietary Supplement Labeling Regulations
1997	Food and Drug Administration Modernization Act
2003	Addition of *trans* fatty acids to the Nutrition Facts box, final rule

[a]Senate Select Committee on Nutrition and Human Needs (1977).
[b]DHEW (1979).
[c]USDA/DHEW (1980).
[d]DHHS (1988).
[e]NRC (1989a).
[f]NRC (1989b).
[g]IOM (1990).

products and to require affirmative label declaration of information about the nutrition content of food products (Hutt, 1984, 1995). The Federal Meat Inspection Act (21 U.S.C. §601), enacted on the same day as the Food and Drugs Act of 1906, also originated from concerns about adulteration, as well as unsanitary conditions.

The Federal Food, Drug and Cosmetic (FD&C) Act of 1938 (21 U.S.C. §301) replaced the Food and Drugs Act of 1906. The FD&C Act broadened the Food and Drug Administration's (FDA) authority with regard to the nutrient content of food (Hutt, 1995), and it strengthened the prohibition against economic adulteration of food and authorized FDA to establish mandatory food standards. With regard to labeling, it prohibited false or misleading statements in food labeling, required any imitation food to be labeled as such, required affirmative labeling of food with particular information specified in the statute (name and address of the manufacturer, net quantity of contents, name of the food, and statement of ingredients), authorized FDA to require additional label information for special dietary food, and required that food labels affirmatively reveal all facts material in light of any other representations made for the product (Hutt, 1984, 1995).

Following enactment of the FD&C Act, FDA worked to implement a provision that authorized additional label information for food for special dietary use (Hutt, 1995; IOM, 1990), and in 1941 it issued regulations governing the labeling of fortified food, vitamin and mineral supplements, and other explicit food categories (e.g., infant formulas and hypoallergenic food) (IOM, 1990). These new regulations specified how the manufacturer should list ingredients if it chose to do so, but the regulations did not restrict the type or quantity of nutrients in a food that could be included, nor did they limit other claims that could be made (IOM, 1990). For example, the regulations governing dietary supplements and fortified food required that the label include a declaration of the percent of the "minimum daily requirements" for a vitamin or mineral for which a specific representation was made when consumed in a specified quantity during a period of 1 day (Hutt, 1995). The Poultry Products Inspection Act of 1957 (21 U.S.C. §451) and the Egg Products Inspection Act of 1970 (81 U.S.C. §1620) provided regulatory authority for poultry products and processed egg products to the U.S. Department of Agriculture (USDA). While misbranding and adulteration provisions were similar for meat, poultry, and egg products, the inspection and compliance framework differed. The Wholesome Meat Act of 1967 (21 U.S.C. §601) and the Wholesome Poultry Products Act of 1968 (21 U.S.C. §467a) incorporated additional provisions against adulteration and misbranding with greater enforcement authority for USDA.

U.S. Recommended Daily Intakes, 1970–1990

Early labeling policies were concerned primarily with maintaining the composition of basic food products and discouraging the sale of processed substitutes on the assumption that traditionally formulated food and meals prepared in the home would ensure healthy diets (IOM, 1990). The White House Conference on Food, Nutrition, and Health, convened by President Nixon in 1969, moved labeling policies to another plane. The conference focused on previously unrecognized malnutrition in Americans and included in its final report criticism of the manner in which FDA was regulating food labeling and the need for improved label information to help Americans make informed dietary choices to enhance nutrition (WHC, 1970).

By 1973 FDA had adopted several amendments to its regulations in follow-up to the White House Conference recommendations. Most important was its adoption of regulations governing nutrition labeling for packaged food (IOM, 1990; Wodicka, 1973). The regulations applied to retail packaged food other than meat and poultry products. Nutrition labeling was required in a specified format and place on the food label if the manufacturer of a food added a nutrient or made a nutrition claim for the product (IOM, 1990). The regulations required the same nutrition information if a manufacturer voluntarily chose to use nutrition labeling. It has been estimated that about half the food supply contained nutrition information under these requirements. These and other issues pertinent to the history of nutrition labeling in the 1970s through 1990 are well described by Hutt (1995) and in *Nutrition Labeling: Issues and Directions for the 1990s* (IOM, 1990).

In keeping with the concern about undernourishment in the United States, FDA officials wanted to ensure that consumers had sufficient information to enable them to select a diet that was adequate in vitamins, minerals, and protein, while also curbing excessive consumption of these nutrients (IOM, 1990). Under the overall heading of "Nutrition Information," vitamins and minerals were described in terms of a percentage of a single set of nutrient reference values called U.S. Recommended Daily Allowances (US RDAs) per standard size serving (FDA, 1973). US RDAs were established for 12 vitamins (vitamin A, vitamin C, thiamin, riboflavin, niacin, vitamin D, vitamin E, vitamin B_6, folic acid, vitamin B_{12}, biotin, and pantothenic acid), 7 minerals (calcium, iron, phosphorus, iodine, magnesium, zinc, and copper), and protein (FDA, 1990b; IOM, 1990). Macronutrients were described in terms of weight and provided no

percentage information (Hutt, 1995). US RDAs were derived from the highest of the National Research Council's 1968 Recommended Dietary Allowances (RDAs) (NRC, 1968) for persons 4 years of age and older, excluding pregnant and lactating women. The exceptions were calcium and phosphorus, for which the highest values were not selected. Instead, the labeling values were based on the human requirements of approximately 1 g for calcium and on an equimolar basis for phosphorus. Other exceptions were the US RDAs for copper, biotin, and pantothenic acid. Although the scientific community recognized that these nutrients were essential for health, no RDAs had been established for them at that time.

The use of the highest values of the RDAs for most US RDAs grew out of concern about nutrient deficiencies in some segments of the population. Differences among the highest RDAs for the various age and gender groups were considered minor. The values for 19- to 35-year-old men were the highest and therefore were used for the reference values, with the exception of iron, where the RDA for women was selected. For food targeted for children less than 4 years of age, the RDA for that age group was selected.

In the 1970s evidence emerged that suggested a role for nutrition in reducing the risk for several chronic diseases. In 1977 the Senate Select Committee on Nutrition and Human Needs published *Dietary Goals for the United States* (Senate Select Committee on Nutrition and Human Needs, 1977), which provided dietary recommendations to assist in maintaining health and reducing risk for chronic diseases, especially cardiovascular disease. In response, in 1979 the Surgeon General issued a report on health promotion and disease prevention (DHEW, 1979), and in 1980 USDA and the Department of Health, Education, and Welfare issued the first edition of *Dietary Guidelines for Americans* (USDA/DHEW, 1980).

The final impetus for major changes in nutrition labeling regulations, including nutrient reference values, occurred in the late 1980s. In 1988 then Surgeon General C. Everett Koop released *The Surgeon General's Report on Nutrition and Health* (DHHS, 1988). This report and the National Research Council (NRC) report *Diet and Health: Implications for Reducing Chronic Disease Risk* (NRC, 1989a) described significant links between dietary patterns and chronic diseases. Also in 1989 NRC issued the tenth edition of *Recommended Dietary Allowances* (NRC, 1989b). To address concerns about the currency of nutrient information in food labeling, the U.S. Department of Health and Human Services and USDA asked the National Academy of Sciences to undertake a review of nutrition labeling. The study resulted in a report, *Nutrition Labeling: Issues and Direc-*

tions for the 1990s, which included numerous specific recommendations on all aspects of nutrition labeling, including label format and nutrient content (IOM, 1990).

Throughout this period congressional and public concern increased as FDA actions on issues related to emerging new information on the relationship between diet and health lagged behind expectations (Hutt, 1995). Recommendations were made to expand nutrition labeling to include additional macronutrients, to establish clear definitions for widely used nutrient descriptors, and to provide for disease claims in nutrition labeling. In July 1990 FDA published proposed regulations related to mandatory nutrition labeling on packaged food, including a regulation that would establish new nutrient reference values for macronutrients, called Daily Reference Values (DRVs), and for vitamins and minerals, called Reference Daily Intakes (RDIs). The proposed RDIs were based on a population-average approach, that is, the adjusted mean of the RDAs weighted according to age groupings in the United States (FDA, 1990b). The use of reference values as part of nutrition labeling was intended to "assist consumers in interpreting information about the amount of a nutrient present in a food and in comparing the nutritional value of food products" and was part of FDA's efforts to "respond to changing nutrition information needs of consumers" (FDA, 1990b). In the proposed regulations FDA acknowledged questions about its authority to require nutrition labeling and tentatively concluded that the nutritional content of a food is a material fact and that a food label is misleading if it fails to have nutrition information that would be required under the proposal. On November 18, 1990, the Nutrition Labeling and Education Act (NLEA) (21 U.S.C. §343) was signed into law by President George H.W. Bush (Hutt, 1995). The passage of NLEA also served to confirm the authority of FDA to require nutrition labeling (FDA, 1991).

Reference Daily Intakes and Daily Reference Values, 1990 and Beyond

The passage of NLEA began the current era of nutrition labeling. NLEA called for all packaged food under FDA's jurisdiction to bear nutrition labeling. It also covered dietary supplements and included a strict timeline. The proposed regulations were to be released by November 8, 1991, and the final regulations were to be implemented by November 8, 1992 (Hutt, 1995).

As part of the implementation of NLEA, in November 1991 FDA republished the 1990 proposal on RDIs and DRVs (FDA, 1991).

The 1991 proposal also addressed issues related to the mandatory status of nutrition labeling and nutrient content revision, with some modifications of the 1990 proposed regulation (FDA, 1991). Also in 1991 USDA's Food Safety and Inspection Service (FSIS) announced its commitment to improving harmonization with FDA on nutrition labeling (FSIS, 1991).

FDA again proposed to replace the 1973 US RDAs with RDIs and to establish DRVs. The proposal included reference values for five life stage and gender groups that were to be used for nutrition labeling based on the increasingly complex RDAs (FDA, 1990a, 1991). The five groups were: infants (0–12 months), children less than 4 years of age (13–47 months), children and adults 4 or more years of age (excluding pregnant women and lactating women), pregnant women, and lactating women. FDA proposed that the reference values for these groups be used in nutrition labeling for food targeted to these groups. Because children 4 or more years of age and adults were thought to generally eat the same food, FDA grouped them together to establish one set of reference values to define the general population (FDA, 1990b). This approach thereby simplified nutrition labeling since it resulted in the listing of one column of nutrients on most food.

The proposal called for RDIs for protein and 26 vitamins and minerals for all five age groups. FDA also outlined the establishment of eight new DRVs for food components of increasing concern for Americans but for which there were no established RDAs: total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein (FDA, 1990b).

The DRVs were based on discussions, recommendations, and guidelines presented in *Diet and Health* (NRC, 1989a) and *The Surgeon General's Report on Nutrition and Health* (DHHS, 1988). The proposal also indicated that the tenth edition of the *Recommended Dietary Allowances* (NRC, 1989b) provided a basis for reexamining current nutrient standards. Additionally, FDA's proposal cited a range of reports (Butrum et al., 1988; DHHS, 1988, 1989; Expert Panel on Population Strategies for Blood Cholesterol Reduction, 1990; LSRO, 1987; NRC, 1989a; USDA/DHHS, 1985) that provided a basis for expanding the required information on nutrition labeling to include information on nutrients and food components that were associated with risk of chronic disease (FDA, 1990b).

FDA also proposed to calculate RDIs by using a population-adjusted mean of the relevant RDAs rather than the highest-of-the-high, population-coverage approach that was used to establish the US RDAs (FDA, 1990b, 1991). FDA proposed this new approach for

several reasons. First, the use of a population average was thought to more appropriately meet the stated purpose of the RDIs, which was to serve as a general nutrition labeling reference value. Second, it seemed logical not to use maximum values as the basis for reference values given the decreasing public health concern with nutritional deficiencies. Third, FDA hoped that the selection of lower reference values would foster more prudent fortification and formulation of food consistent with its fortification policy (FDA, 1990b).

FDA also suggested that the reference values should be listed under a single new term and proposed "Daily Value" (DV) for two reasons: (1) consistency with the NLEA direction that information in nutrition labeling be presented in a manner that enabled consumers to understand the significance of the information presented in the context of a total daily diet, and (2) consumer research on the DV that indicated that the term was interpreted correctly (FDA, 1991).

Although there was support for continued use of the RDAs as the basis for reference values, use of the population-adjusted mean met with resistance. The most frequently expressed concern about the approach was that it resulted in a value that was too low for at least half of the population and as such would lead to suboptimal nutrient intakes. The concern was partly expressed by passage of the Dietary Supplement Act of 1992 (DSA) (P.L. 102-571) that established a 1-year moratorium on implementation of NLEA with regard to dietary supplements and prohibited until November 1993 any nutrition labeling regulations that used recommended daily allowances or intake values for vitamins and minerals other than those currently in effect (Commission on Dietary Supplement Labels, 1997). It also prohibited FDA from promulgating regulations based on the RDAs any earlier than November 1993 (other than those specified in 21 C.F.R. 101.9 (c)(7)(iv), i.e., the US RDAs) and prohibited implementation of NLEA for dietary supplements earlier than December 15, 1993 (21 U.S.C. §301).

In January 1993 FDA published its final regulations on nutrition labeling for conventional food. Because of the moratorium in the DSA, the regulations retained the use of the highest value approach and the 1968 RDAs as nutrient reference values for vitamins and minerals for the age categories proposed (FDA, 1993c). In the preamble to the regulations, FDA indicated that it had planned to return to the population-coverage approach, acknowledging that the proposed approach lowered reference values for vitamins and minerals by an average of about 14 percent compared with those that would have been derived using the population-adjusted mean.

The remaining differences were attributed to differences between the 1968 and 1989 RDAs (FDA, 1993c). The final regulations did change the name of the US RDAs to RDIs for vitamins and minerals and established DRVs for sodium, potassium, and macronutrients. Once the moratorium was no longer in effect, FDA proposed RDIs for nutrients that had not been included in the 1968 RDAs but were in the 1989 edition (FDA, 1994). This led to final regulations in 1995 that established RDIs for vitamin K, selenium, manganese, chromium, molybdenum, and chloride (FDA, 1995). (See Appendix Table C-9 for the list of reference values.)

With regard to the use and representation of a unified reference value for nutrition labeling, FDA explained that a unified reference value on the label was in response to the directive in the legislation that the information be conveyed to the public in a manner that enabled the public "to readily observe such information and comprehend its relative significance in the context of a total daily diet" (FDA, 1993a).

The preamble to the 1993 regulations explained that FDA had also conducted focus group research with adults (Lewis and Yetley, 1992), called for additional suggestions, and reviewed new consumer research and comments regarding a term for the overall label reference value. FDA had earlier proposed using DVs, and it decided to retain the term and to use the percent DV (% DV) as the best representation for consumers: "FDA has carefully considered the arguments regarding percent displays but finds no basis not to conclude that consumers will be able to use percent DV declarations more effectively than they would any other format tested" (FDA, 1993a). Health claims, nutrient content claims, and structure/function claims were also addressed in implementing the NLEA regulations.

Current Status of Nutrition Labeling

FDA and FSIS have regulatory oversight for ensuring that food labeling in the United States is accurate and not misleading. Each agency has responsibility for the labeling of different food products in the food supply. FDA has jurisdiction over all food except that which contains 2 percent or more cooked or 3 percent or more raw meat (i.e., from livestock-cattle, sheep, swine, goats, and equine) or poultry (i.e., from domestic birds: chicken, turkey, ducks, geese, guineas, ratites, and squabs), and processed egg products, all of which are under the jurisdiction of FSIS. Although the products they regulate are subject to different laws, these agencies have coordinated their approach to nutrition labeling in order to maintain consistency.

Nutrition Labeling on FDA-Regulated Products

Under NLEA all packaged food except those excepted in the Act[1] must have nutrition labeling. NLEA also provides for voluntary nutrition information for fresh produce and seafood (21 U.S.C. §201). Specific nutrient content "facts" in a mandatory order are required in the Nutrition Facts box, as are specific label design elements (see Box 2-2). The product content of other nutrients specified by FDA may be voluntarily included in the box at the discretion of the manufacturer, but the order of the nutrients on the label must be maintained. If a manufacturer chooses to fortify a product with nutrients, then the content of those nutrients also must be included in the box. This is also true for nutrients about which manufacturers make health or nutrient content claims. The mandatory nutrient components in the Nutrition Facts box include those that scientists and health practitioners believed were important to the health of the American people based on the science available at the time NLEA was implemented.

FDA specifies that the Nutrition Facts box include all nutrients presented as % DVs (with the exception of sugars, monounsaturated fatty acids, polyunsaturated fatty acids, and soluble and insoluble fiber for which DVs have not been established) with the amount in grams or milligrams also included for specific nutrients. The % DV for protein is required only if a protein claim is made for the product or when the product is intended for infants or children under 4 years of age. On most larger food packages the box also must include a footnote that states that the % DVs are based on a 2,000-calorie diet. In addition it may include a statement of the calories provided per gram for fat, carbohydrate, and protein. Serving sizes, calculation of % DVs, and Nutrition Facts box format modifications are regulated by FDA and FSIS in a consistent manner. (For additional information about nutrition labeling, see CFSAN, 2003b; FDA, 1993a, 1999b; OPPD, 2003a.)

In 1999 FDA proposed to amend its regulations to require that the Nutrition Facts box include information about *trans* fatty acids

[1]The food products specified by NLEA as exempt from food labeling include: food served for immediate consumption, ready-to-eat food not for immediate consumption that can be eaten when carried away, bulk-shipped food not for sale to consumers, medical food, food of no nutritional significance, food produced by small businesses (annual sales of not more than $500,000 if food is offered for sale or sales of food less than $50,000), and low-volume food products (fewer than 100,000 units of a product sold annually in the United States and less than 100 full-time equivalent employees of the firm).

BOX 2-2 Sample U.S. Nutrition Facts Box

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20**%
Saturated Fat 5g	**25**%
Trans Fat 2g	
Cholesterol 30mg	**10**%
Sodium 660mg	**28**%
Total Carbohydrate 31g	**10**%
Dietary Fiber 0g	**0**%
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

SOURCE: ONPLDS (2003a).

in a food (FDA, 1999a). In July 2003 FDA published final regulations with this mandate (FDA, 2003b). The regulations also apply to dietary supplement labeling. The regulations specify that the gram amount of *trans* fatty acids be listed in the box immediately below the line for saturated fatty acids. Particularly pertinent to this report,

the regulations specify that the new line does not require a % DV for *trans* fatty acids and withdrew the earlier proposal (FDA, 1999a) that the *trans* fatty acid line have a footnote stating "Intake of *trans* fat should be as low as possible." The regulations, effective January 1, 2006, are a result of research and public comments reviewed by FDA that documented the link between consuming diets high in *trans* fatty acids and increased serum low-density lipoprotein cholesterol, a risk factor for coronary heart disease.

Other FDA-Regulated Label Elements Related to or Dependent on DVs

Other nutrition information, such as ingredient lists, structure/function claims, nutrient content claims, and health claims, that is found on food labels outside the Nutrition Facts box also is relevant to a discussion of reference nutrient values. Food products that contain more than one ingredient must list these ingredients on the package. FDA has provided manufacturers with regulations about how the ingredient list must appear on the package and which ingredients must be listed (21 C.F.R. 101.4). Ingredient lists are important label elements because they enable consumers to identify sources of the nutrients, and they can be used to compare products for the presence or absence of ingredients. Claims about the structure and function of a nutrient have historically appeared on labels of conventional food and dietary supplements, as well as on drug labels. (For more information on structure/function claims, see ONPLDS, 2003b.)

Nutrient content claims[2] are FDA-regulated statements on food packages that characterize the level of a nutrient in a food, such as "free," "high," and "low." These claims are based on the amounts of the nutrient in the food item, and FDA specifies the package wording and allowable synonyms (FDA, 1993b). With few exceptions, a nutrient content claim can be made only if there is a DV identified for that nutrient and if FDA has established, by regulation, the criteria a food must meet to list the claim.

A health claim[3] on a food package is a statement of a scientifically demonstrated relationship between a food substance (defined by

[2]NLEA permits the use of label claims that characterize the level of a nutrient in a food made in accordance with FDA's authorizing regulations.

[3]According to NLEA, it describes "the relationship between a nutrient of the type required in the label or labeling of a food . . . and a disease or health related condition and the significance of each such nutrient in affecting such disease or health related condition" (21 U.S.C. § 343(r)(3)(B)(ii)).

law as a specific food or component of food) and a disease or health-related condition. Some of the criteria for health claims are dependent on reference values for nutrition labeling because a food must meet the criteria for a certain nutrient content level based on the DV in order to be eligible for the health claim. For example, the food needs to contain, without fortification, 10 percent or more of the DV for at least one of six nutrients (dietary supplements excepted): vitamin A, vitamin C, iron, calcium, protein, and fiber.

The wording of health claims is carefully delineated by FDA and requires that the relationship between the food component and the risk of a disease or health-related condition is stated in a way that does not imply direct causation. FDA has approved 14 health claims that may be used on packaging, and new claims may be added to the list. (For more information on current claims, see CFSAN, 2003a.)

Health claims must be authorized by FDA prior to their use in food labeling. There are several methods for obtaining authorization. First, FDA reviews scientific evidence supporting a proposed health claim in response to a health claim petition. When FDA finds that the evidence satisfies the significant scientific agreement validity standard prescribed under NLEA, the agency issues a regulation authorizing use of the health claim. Second, under the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), if a scientific body of the U.S. government or the National Academies has published an authoritative statement about the relationship between a nutrient and a disease or health-related condition, that statement may serve as the basis for authorizing the use of a health claim. In such a situation, a manufacturer submits to FDA a notification of its intent to use a health claim based on the authoritative statement. Barring an objection by FDA, claims based on authoritative statements become authorized 120 days after submission of the notification. Third, when FDA's evaluation of scientific evidence supporting a petitioned health claim concludes that the available evidence does not meet the significant scientific agreement standard, but that there is some credible evidence in support of the health claim, FDA will consider permitting a "qualified" health claim that includes appropriate qualifying language to explain the level of scientific proof that the claim is truthful. In approving a qualified health claim, FDA issues a letter stating that it will consider its "exercise of enforcement discretion" in permitting a qualified claim under prescribed conditions although the health claim has not been authorized by a regulation. FDA first considered permitting the use of qualified health claims for dietary supplements and conventional

food in response to a court decision[4] that was based on First Amendment commercial free speech considerations for dietary supplement labeling.

More recently FDA issued guidance on the review process for qualified health claims as part of its initiative on Consumer Health Information for Better Nutrition. The guidance included an interim method to systematically evaluate and rank the scientific evidence for qualified health claims (FDA, 2003c). While health claims are not addressed in this report, the committee's recommendations may inform the process of developing health claims in so far as they relate to reference nutrient values.

Dietary Supplement[5] Labeling

NLEA covered dietary supplements, but as described earlier, DSA prohibited implementation of NLEA for dietary supplements earlier than December 15, 1993. Thus the 1993 nutrition labeling regulations did not address labeling of dietary supplements. However, as part of the implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA) (21 U.S.C. §401(q)(5)), in 1997 FDA issued final regulations requiring that a Supplement Facts box appear on all dietary supplements effective in 1999 (FDA, 1997). The Supplement Facts box (see Box 2-3) is modeled after the Nutrition Fact box and is similarly regulated in content and format. It must include amounts and % DV of the same nutrients that are required on nutrition labeling of conventional food if the nutrients are present in the supplement and the amounts of other dietary ingredients included. These other dietary ingredients must be identified by their common or usual name and, in some cases for botanicals, by their Latin binomial name and specific plant part, if applicable.[6] Proprietary blends may be listed by weight of the total blend,

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[4]Pearson v. Shalala 164 F.3d 650 (D.C. Cir. 1999).

[5]Dietary supplements, as defined by DSHEA, include products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical; an amino acid; a dietary substance used to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above. A dietary supplement must be intended for ingestion in the form of a capsule, powder, soft gel, or gel cap, or, if not in one of those forms, is not represented as a conventional food or as a sole item of a meal or the diet (21 U.S.C. §321(ff).

[6]In a direct final rule FDA (2003a) amended its regulation on botanical ingredients in dietary supplements to incorporate the use of the latest (year 2000) editions

BOX 2-3 Sample U.S. Supplement Facts Box

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

SOURCE: 21 C.F.R. 101.36, subpart C.

and the serving size must be clearly stated within the box. Nutrients for which there are established DVs must be listed first, followed by a horizontal line that separates these nutrients from nutrients and other ingredients for which there are no DVs (e.g., botanicals).

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of two books that serve as references for botanical nomenclature. The current regulation cites by reference *Herbs of Commerce* (Foster, 1992) and the *International Code of Botanical Nomenclature (Tokyo Code)* (Grueter et al., 1994). This rule also includes statutory changes in the definition of ginseng and other changes with regard to labeling botanicals. This final rule is effective January 1, 2006, if FDA receives no significant adverse comments during the comment period.

The box must state that % DVs have not been established for these latter ingredients and must indicate these ingredients clearly with an asterisk. The ingredients used in the manufacturing process (e.g., excipients, fillers, binders, flavors), a clear statement of identity, the net quantity of the contents, the manufacturer contact information, and any label claims must be located outside the Supplement Facts box. Source ingredients (e.g., calcium carbonate as the source of calcium) may be listed parenthetically within the Supplement Facts box following the dietary ingredient or in the ingredient list that appears outside and below the box.

Dietary supplements may include three categories of claims on the label outside the Supplement Facts box. Under the same regulations that apply to conventional food labels, dietary supplement labels may include nutrient content claims and health claims. Dietary supplements also may contain statements of nutritional support, including structure/function claims (21 U.S.C. §343(r)(6)). This category of label statement may claim or describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body or its general well-being. As with structure/function claims for conventional food, the manufacturer is responsible for the accuracy and truthfulness of structure/function claims for dietary supplements. FDA has statutory authority to take action against any false or misleading claims. FDA, by law, does not require prior approval of the wording of the claim. As a result of DSHEA, dietary supplement manufacturers notify FDA within 30 days after the first use of a structure/function claim (referred to also as a nutritional support statement). All structure/function claims used on a dietary supplement label must be accompanied by the disclaimer that FDA has not evaluated the claim and that the ingredient or product is not intended to "diagnose, treat, cure, or prevent any disease." (For additional information on structure/function claims, see FDA, 2000.)

Nutrition Labeling of FSIS-Regulated Products

NLEA required that FDA implement regulations for food labeling, but it did not address the labeling of meat and poultry products under FSIS jurisdiction. FSIS, however, coordinated efforts with FDA and issued regulations that were based on its existing statutes and were designed to be as consistent as possible with FDA regulations (FSIS, 1993a, 1993b; Keystone Center, 1996). FSIS requires that meat and poultry products bear eight required labeling features: (1) common or usual name of the food, (2) if fabricated

from two or more ingredients, a statement of ingredients listed, by common or usual name, in descending order of predominance by weight, (3) an accurate statement of the quantity of contents, (4) the name and place of business of the manufacturer, packer, or distributor, (5) an inspection legend with the establishment number for the establishment where the product was made, (6) nutrition labeling unless an exemption exists, (7) a handling statement if the product is not shelf stable, and (8) safe handling instructions if the meat or poultry component of the product is not ready to eat (9 C.F.R. 317.2 9, 381 subpart N).

Under the Federal Meat Inspection Act (21 U.S.C. §601), the Poultry Products Inspection Act (21 U.S.C. §451), and the Egg Products Inspection Act (81 U.S.C. §1620), FSIS conducts a "prior label approval system" for meat, poultry, and egg products. These Acts and their implementing regulations provide for certain exemption from USDA jurisdiction (e.g., products prepared for human consumption that contain meat or poultry ingredients in relatively small proportions or are not considered by consumers to be products of the meat or poultry industry).[7]

FSIS has over 80 food standards of identity for the meat and poultry products it regulates. For example, specific definitions exist that underlie what can be identified as "ham with natural juices" or "ham with water added." FSIS also regulates the new use and labeling of food ingredients as they relate to FSIS standards of identity. Additionally, FSIS regulates claims and special statements on labeling, including animal production claims (e.g., "no added hormones"), processing statements (e.g., "treated for pathogen control"), and descriptive terms (e.g., "fresh"). FDA also has regulations governing use of the term "fresh."

FSIS has promulgated regulations for the labeling of nutrient content claims on meat and poultry products (9 C.F.R. 317 subpart B, 381 subpart Y). These regulations are similar to those issued by FDA. FSIS has no regulations for the labeling of health claims, but

[7]Generally, FSIS has determined by policy that the "relatively small proportions" of livestock ingredients are: 3 percent or less raw meat; less than 2 percent cooked meat or other portions of the carcass; or 30 percent or less fat, tallow or meat extract, alone or in combination. In the case of poultry, the relatively small proportions are: less than 2 percent cooked poultry meat; less than 10 percent cooked poultry skins, giblets, or fat, separately; or less than 10 percent cooked poultry skins, giblets, fat, and poultry meat (limited to less than 2 percent) in any combination (9 C.F.R. Part 381.15(a)). These percentages are computed on the basis of the moist cooked chicken in the ready-to-serve product when prepared according to the directions on the consumer package.

it permits the voluntary labeling of health claims on meat, poultry, and egg products provided the claims are labeled in accordance with FDA's regulations. Thus, the committee's guiding principles and recommendations will equally apply to FSIS-regulated food. (See OPPD, 2003b, for information about the prior approval of product labels and labeling terminology for meat, poultry, and egg products as regulated by FSIS.)

REFERENCE VALUES AND NUTRITION LABELING IN CANADA

Historical Overview

In Canada the Food and Drugs Act (R.S. 1985, c. F27) is the principal federal statute governing the labeling of food. The Act applies to all food sold in Canada at all levels of commerce. Regulations made under the Act cover ingredient listing, nutrition labeling, and all types of claims.

Until 1988 when nutrition labeling guidelines were introduced, regulations pertaining to the declaration of nutrients in food were largely intended to control claims. They were put in place over a 40-year period, and for the purposes of labeling they distinguished between added and naturally occurring vitamins and minerals. Amounts of added vitamins and minerals were required to be declared in absolute amounts per 100 g of food whenever one or more was added to a food. For the most part, the labeling of absolute amounts of naturally occurring vitamins and minerals was not permitted; a food containing minimum levels of one or more of nine nutrients in a reasonable daily intake could only be described as a "good" or "excellent" source of the nutrient. With few exceptions, declaration of the energy value and of single nutrients other than naturally occurring vitamins and minerals was permitted. Declaration of protein was permitted if it was grouped with a declaration of carbohydrate and fat content and all were expressed in grams per 100 g. Sodium and potassium had to be declared together in milligrams per 100 g. Nutrition labeling was only required for food for special dietary uses and for food containing intense (artificial) sweeteners. Energy value, protein, carbohydrate, and fat, each expressed both per 100 g and per unit of ready-to-serve food, were required to be listed (Canada, 1988a).

Nutrition labeling guidelines were introduced in Canada in 1988, along with amendments to the Food and Drug Regulations, concluding a process that was started in 1983. The system was voluntary,

with a few exceptions. *The Guidelines on Nutrition Labelling* (Canada, 1989) governed format, nutrient content information (core list and optional nutrients), and a declaration of serving size. Once applied, the nutrient declaration had to comply with the amended regulations (Canada, 1988b), which stipulated nomenclature, units of measurement, and expression on a per serving basis. Under the overall heading of "Nutrition Information," amounts of vitamins and minerals were required to be expressed in terms of a percentage of a single set of nutrient reference values, Recommended Daily Intakes, per serving of stated size (Canada, 1986). Amounts of macronutrients were expressed in terms of weight; no percentage information was provided.

The process begun in 1983 had proposed criteria for rating the nutrient content of food based on two reference standards: a nutrient density index (NDI) and the percentage of a composite Recommended Nutrient Intake (RNI) derived from the Recommended Nutrient Intakes for Canadians (Canada, 1983a, 1983b). A reference set of RNIs expressed per megajoule (RNI/MJ) was derived by dividing the RNI for each age and gender group by the average energy requirements of that group. When the RNIs were not based on energy and the nutrient to energy ratios were not constant among groups (e.g., iron and vitamin C), the highest RNI/MJ was selected. The NDI was the amount of the nutrient per MJ in the food divided by the RNI/MJ. To arrive at the composite RNI, a demographic average energy intake was determined and the RNI/MJ was multiplied by this number. Minimum levels for both the NDI and the composite RNI were required for claims. Relating all the RNIs to energy was criticized and the proposal was not pursued.

In 1986 Health Canada decided to set Recommended Daily Intakes for nutrition labeling using the highest RNI from 1983 for each nutrient for each age and gender group, omitting supplemental needs for pregnancy and lactation (Canada, 1986). Thus the values chosen were those for 19- to 24-year-old males (except for iron, for which the value was that of women of childbearing age). Recommended Daily Intakes were established for 11 vitamins (vitamin A, vitamin D, vitamin E, vitamin C, thiamin, riboflavin, niacin, vitamin B_6, folacin, vitamin B_{12}, and pantothenic acid) and 6 minerals (calcium, iron, phosphorus, iodide, magnesium, and zinc). The *Guidelines on Nutrition Labelling* (Canada, 1989) specified the minimum nutrient content information, the label format, and the serving size information that would constitute nutrition labeling for food sold in Canada.

In 1996 Canada published its national action plan on nutrition, *Nutrition for Health: An Agenda for Action* (Joint Steering Committee,

1996). This report identified important strategies for Canadians to reduce health risks and supported the need for improving the usefulness of nutrition labeling, increasing its availability, and broadening public education on its use. In June 2001 Health Canada undertook a final consultation on proposals to improve nutrition information on prepackaged food labels, including nutrition labeling. On December 12, 2002, the Canadian government issued "Regulations Amending the Food and Drug Regulations (Nutrition Labeling, Nutrient Content Claims and Health Claims" (Canada, 2003). The new regulations mandate nutrition labeling on most prepackaged food, update and consolidate permitted nutrient content claims, and introduce a new regulatory framework and process for diet-related health claims. While companies marketing food in Canada may begin to follow the new regulations immediately, they have until December 12, 2005, to bring their labels into compliance with the new regulations. Small businesses, defined as having less than $1 million in sales, will not have to be in compliance until December 2007 (Canada, 2003).

Current Status of Nutrition Labeling

Health Canada and the Canadian Food Inspection Agency (CFIA) oversee the regulatory process of food labeling in Canada. Health Canada is responsible for setting health and safety standards and for developing food labeling policies related to health and nutrition under the Food and Drugs Act. CFIA is responsible for administering other food labeling policies and enforcing all food labeling regulations.

The new regulations require a Nutrition Facts table that is modeled after the Nutrition Facts box used in the United States (see Box 2-4). Similar to the United States, the Canadian Nutrition Facts table will be a requirement on most packaged food, but some food products are exempted (e.g., fresh fruits and vegetables; raw, single-ingredient meat and poultry, except when ground; fish and seafood; food prepared in retail establishments and individual portions prepared for immediate consumption; and alcoholic beverages).

The Canadian Nutrition Facts table includes calories and 13 nutrients in a specified order (see Box 2-4). Recommendations from and discussions with Canadian consumers, scientists, and health professionals led to the selection of the 13 nutrients (Canada, 2003). The required nutrients in the Nutrition Facts table are identical to those required in the United States, including a statement on *trans* fat, with the exception that the new Canadian table does not require a

BOX 2-4 Sample of Canada's Nutrition Facts Table

Nutrition Facts
Valeur nutritive
Per 125 mL (87 g) / par 125 mL (87 g)

Amount Teneur	% Daily Value % valeur quotidienne
Calories / Calories 80	
Fat / Lipides 0.5 g	**1** %
Saturated / saturés 0 g + Trans / trans 0 g	**0** %
Cholesterol / Cholestérol 0 mg	
Sodium / Sodium 0 mg	**0** %
Carbohydrate / Glucides 18 g	**6** %
Fibre / Fibres 2 g	**8** %
Sugars / Sucres 2 g	
Protein / Protéines 3 g	
Vitamin A / Vitamine A	2 %
Vitamin C / Vitamine C	10 %
Calcium / Calcium	0 %
Iron / Fer	2 %

SOURCE: Canada (2003).

listing for "calories from fat." Other nutrients from a permitted list may be included in the table at the discretion of the manufacturer, but the specified order of the nutrients must be maintained. Nutrient information with the exception of that for cholesterol must be expressed in terms of % DV, and, in the case of macronutrients, sodium, and potassium, in grams and milligrams based on a serving of stated size. The % DVs for fat, cholesterol, carbohydrate, fiber, sodium, and potassium are based on Reference Standards that are identical to the DRVs used in the United States. Since the RDIs for vitamins and minerals used in the United States are based largely on the 1968 RDAs, it was decided to retain the Canadian Recommended Daily Intakes, which are based on the 1983 RNIs, until further guidance is received from the Institute of Medicine on the establishment of reference values for nutrition labeling.

The Canadian regulations require *trans* fat to be incorporated with saturated fat in the same % DV, with the % DV for the sum of saturated and *trans* fats being 20 g based on 10 percent of energy with a 2,000-calorie dietary energy reference value. Expression of a % DV was considered important to assist consumers in understanding the relative significance of the amount of these nutrients in a food. The % DV for cholesterol is optional. There is no % DV for protein because protein intakes in Canada were not considered to be a public health concern. Explanatory footnotes related to the DV are similar to those used in the United States and may be included in the Nutrition Facts table. The graphic elements of the Nutrition Facts table are tightly regulated to ensure the use of a consistent and legible format. The Canadian regulations, unlike those of the United States, do not include specific regulations to define the serving size except in the case of single-serving containers. Guidelines for establishing serving sizes are provided in CFIA's *Guide to Food Labelling and Advertising* (CFIA, 2001). Reference Amounts, a specific quantity of a type of food usually eaten by an individual at one sitting, serve as the basis for composition criteria for claims and are regulated.

Only nutrition labeling that complies with the regulations may appear on food labels in Canada, and the information must be presented in both English and French like other mandatory labeling information. Because other countries' nutrition labeling does not meet the Canadian requirements, they cannot be used on food sold in Canada.

The new regulations permit specifically defined nutrient content claims that are similar to, but have slightly different definitions than, those allowed in the United States. Prior to passage of the new regulations, health claims were not permitted on food labels in Canada. Now claims associated with four diet and health relationships are permitted: sodium and potassium and their association with blood pressure, calcium and vitamin D and their association with osteoporosis, saturated fat and *trans* fat and their association with heart disease, and vegetables and fruit and their association with some types of cancer. The regulations stipulate the prescribed wording for the permitted claims. One criterion for health claims is based on another reference value, the Weighted Recommended Nutrient Intake (WRNI). WRNI became part of the regulations in 1996 (Canada, 1996). A food must contain at least 10 percent of the WRNI for one vitamin or mineral per reference amount and per serving of stated size in order to be eligible for claims related to blood pressure and heart disease. The WRNIs are the demographic

averages of RNIs published in 1990 (Canada, 1990) and are considered to represent the nutritional needs of the total population because they are weighted according to the age and gender distribution of the Canadian population.

CONSUMER UNDERSTANDING AND USE OF NUTRITION LABELING

Consumer Research on Nutrition Labeling in the United States

The history of consumer research on nutrition labeling of food parallels the evolution of food labeling legislation in the United States, with the temporal pattern of research focused around significant proposed changes in label format or content. For example, FDA undertook extensive research in the 1970s, which contributed to the current concepts about nutrition labeling, including the use of percent US RDA (FDA, 1972), and there was research conducted just before and after the 1993 regulations implementing NLEA (FDA, 1993a). Overall however, research to track the continuing evolution of consumer-use patterns of food labeling has been limited.

The Context of Research on Current Nutrition Labeling

The implementing regulations for NLEA explained that nutrition information on the label was to assist consumers in maintaining healthy dietary practices and was to be conveyed in a manner that enabled the public "to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet" (FDA, 1993a). Thus it was designed to serve as a tool to allow consumers to compare similar products and to understand the contribution of an individual food to the diet—not for planning the overall structure of the diet (FDA, 1991, 1993a).

The development of a label to meet these objectives required extensive testing and included experimental studies, shopping mall-intercept interviews, and focus groups (FDA, 1993a; Geiger, 2001; Geiger et al., 1991; Levy et al., 1992; Lewis and Yetley, 1992). No single design consistently performed best as measured by correct interpretation of the information and consumer format preferences (Levy et al., 1992). Experimental studies found that the % DV helped consumers to make judgments about whether different food products were high or low in a particular nutrient and to put individual food products into the context of a total diet. Without the

% DV, consumers could not interpret metric values correctly and made inaccurate judgments about individual products (Geiger, 2002; Levy et al., 1996).

Trends in the Use and Understanding of the Nutrition Facts Box

Both FDA and the Food Marketing Institute (FMI) periodically track label use. FMI surveys indicate that in 1992, half of U.S. adult consumers said they used nutrition labeling when buying a food for the first time (FMI, 1993). The number rose to about 60 percent by 1995, and then dropped nearly to baseline (FMI, 1997). About half of consumers continue to report using nutrition labeling for first-time purchases (FMI, 2001). Estimates from the FDA Food Label Use and Nutrition Education Surveys (FLUNES) conducted in spring 1994 and fall 1995 indicated that about half of adult consumers reported using the food label to make a food product choice in the two weeks before the interview (Derby, 2002).

Data from FLUNES also showed that over 50 percent of consumers used the Nutrition Facts box to make a summary judgment of the overall nutritional quality of a food (Derby, 2002). The most notable increase in the way the new label was used was to determine how high or low a product was in a particular nutrient, especially fat (Derby, 2002). The percentage of consumers who checked fat information rose steadily from 1992 to a high of 83 percent in 1995 (Derby, 2002; FMI, 1992, 1995), but dropped back to 70 percent by 1997 (FMI, 1997). Overall, fat content was the factor that influenced purchase decisions in both directions, but the percentage of shoppers who identified fat as the factor that led them to choose a specific product declined (FMI, 1997).

The second most common use of the Nutrition Facts box was for information about the calorie content of food. In 1992, 51 percent of consumers said that they always or almost always checked calories (FMI, 1992). By 1997 however, that figure had dropped to 33 percent of label readers (FMI, 1997), but calories were still listed among the top three pieces of information sought by 80 percent of label readers.

Consumers use the Nutrition Facts box, and specifically the % DV, to confirm a claim on the front of a product and to make product-specific judgments (FDA, 1995; Geiger et al., 1991). In general consumers continue to report that they use nutrition labeling to make purchase decisions, more often to avoid, rather than to buy, a specific item (FMI, 1997).

Satisfaction with the Label

In the 1994 FMI survey (FMI, 1994), two-thirds of shoppers who had seen the new Nutrition Facts box said it was clearer and more understandable than the old box. Kristal and coworkers (1998) reported that significantly fewer people found the label to be confusing, burdensome, and difficult to read after the new format was introduced, but 70 percent of those studied, especially older and less well-educated individuals, still wanted the label to be easier to understand. The main barrier to use of nutrition labeling as reported by Kristal and coworkers (1998) was lack of interest. In a 1995–1996 study, Levy and coworkers (2000) found that the majority of subjects could not define % DV, did not find it useful for assessing the fat content of a product, and did not know how to use it appropriately to select a diet low in fat. Hrovat and colleagues (1994) also reported that 56 percent of 200 volunteers in a small pilot study did not correctly use the % DV, but the researchers acknowledged limitations in the study design.

The Impact of the Nutrition Facts Box on Diet Quality

Since 1973 the Nutrition Facts box or its equivalent has provided consumers with the reliable, objective nutrient composition of the product, the ability to compare products and, increasingly, the ability to place them in the context of a total daily diet. Several studies have attempted to address the larger question of whether the use of nutrition labeling information contributes to overall diet quality. Kreuter and colleagues (1997) found that label users had diets lower in fat and higher in fruits and vegetables than nonusers. In a population-based study in Washington State that was conducted between 1995 and 1996 and in which 80 percent of residents reported reading nutrition information on packaged food, there was a significant association between label reading and fat intake (Neuhouser et al., 1999). Levy and colleagues (2000), however, found a relationship between reported regular use of the label and fat consumption, but no association between understanding of the label and fat consumption. Regardless of an individual's income, Perez-Escamilla and Haldeman (2002) found label use to be associated with higher scores on the Healthy Eating Index, a measure of diet quality based on the Food Guide Pyramid (Kennedy et al., 1995). In this study those who were more affluent but did not use labels were as likely as less affluent nonusers to have a low Healthy Eating Index.

One study provided information about how label use predicted dietary intake. Kristal and coworkers (2001) compared data collected in Washington State in 1995–1996 and followed-up in 1997–1998. They found that fat intake decreased by approximately 2 percent of calories (from 32 percent to 30 percent) and was strongly associated with the use of food labels. Reductions were greater among women, older persons, persons who were well educated, and those in the later stages of eating a low-fat diet.

Several studies have explored the use of nutrition labeling information by women with type 2 diabetes mellitus (Miller and Brown, 1999; Miller et al., 1997, 1999). In one study, participants reported frequent use of the Nutrition Facts box, but comprehension of label information was poor (Miller and Brown, 1999). An intervention to teach a similar group of women to use the label resulted in a significant increase in their ability to use the food label as compared with the control group (Miller et al., 1999).

Consumer Research on Nutrition Labeling in Canada

In 1999 a study for Health Canada evaluated consumer attitudes and behaviors related to nutrition labeling prior to the policy review (Joint Steering Committee, 1996). A representative sample of 1,331 adults 18 years of age and older was drawn from all ten provinces and stratified for location (urban or rural), age, gender, and education. One subsample included persons who followed a special diet related to heart disease or diabetes or who shopped for a person on a special diet. Over 40 percent reported that nutrition-related information on the food label is "extremely" or "very" important in making purchase decisions; less than 10 percent regarded it as "not important at all." Women and persons with a university education or with the highest income level were more likely to be influenced by nutrition labeling. The information perceived as most useful was nutrient content, especially fat (46 percent). Over 80 percent reported that they understood the nutrition information on labels "fairly" or "very well."

Frequency of using the Nutrition Information Panel (NIP), in use at that time, also was assessed. Respondents who had previously indicated that they referred to the NIP "often" or "sometimes" were led through the possible uses of the NIP. Table 2-1 displays the total of "often" and "sometimes" responses to each choice. The results demonstrated few meaningful differences between groups by gender, age, education level, or income.

TABLE 2-1 Use of the Nutrition Information Panel in Canada

Categories of Answers Regarding the Use of Food Labels[a]	Percent Responding Often or Sometimes Used
To see how high or how low a food is in nutrients like fat or sodium	87
To see how high or low a food is in nutrients like fiber, vitamins, or minerals	83
To get a general idea of the calorie content of a food	78
To compare similar types of food with each other	76
To compare different types of food with each other	74
To see if something said in the advertising or on the package is true	65
To figure out how much of a food product you or your family should eat	54

[a] The question posed was: "You mentioned that you use the information on the Nutrition Information Panel. When you look at the Nutrition Information Panel on food packages, either in the store or at home, how often, if at all, do you use the information provided in the following ways?"
SOURCE: NIN (1999).

In this study various formats of nutrition labeling were presented. For macronutrients and micronutrients respondents preferred information presented as both actual amounts and % Recommended Daily Intake. However, less than half understood % Recommended Daily Intake before educational intervention. Over one-half of users said that nutrition labeling influenced their decision to buy a product; there were no age or gender differences.

Within the context of the history, current status, and use of nutrition labeling in the United States and Canada described in this chapter, the committee developed the guiding principles presented in Chapter 5. The next chapter provides an overview of fortification and provides the background for the guidance the committee presents in Chapter 6.

3

Overview of Food Fortification in the United States and Canada

The addition of nutrients to food, food constituents, or supplements, termed fortification, has a complex history in the United States and Canada. The purpose of this chapter is not to review the rationale for fortification, which remains debated in many circles, but to provide a brief overview of the history and current status of policies, guidelines, and regulations related to fortification. In the United States, mandatory fortification (usually called enrichment) refers to the situation when a product is formulated to conform to the standard of identity promulgated by the Food and Drug Administration (FDA) for the enriched version of the food. Discretionary fortification refers to all other forms of the addition of nutrients to food, including unenriched versions of products for which an enrichment standard has been promulgated by FDA. The addition of vitamins and minerals (micronutrients) to food in Canada is controlled under regulatory provisions first declared in 1964 (Part D Division 3 of the Food and Drug Regulations [FDRs]). These regulations list the food to which micronutrients may be added, which micronutrients may be added, and the levels to which they may be added (Health Canada, 2002).

HISTORY AND CURRENT STATUS OF U.S. FOOD FORTIFICATION POLICY

Early Fortification

In the United States, as in most parts of the world, fortification of food was initiated as a systematic approach to correct identified

nutrient deficiencies in the population. In 1924 iodine was first added to salt on a voluntary basis in an attempt to address the prevalent health problem of goiter in the United States. This program was begun only after a number of prominent national health organizations of the time, the American Public Health Association, the Council on Foods and Nutrition of the American Medical Association (AMA), and the Committee on Food and Nutrition of the National Academy of Sciences, recommended this step based on new research demonstrating that sodium iodide prevented goiter (Quick and Murphy, 1982). This initial fortification effort was followed in 1933 by the fortification of milk with vitamin D based on recommendations from similar groups. The addition of vitamin D to milk was originally accomplished by irradiating milk or by feeding the cows irradiated yeast. This technique was replaced in the 1940s by the simpler and more effective method of adding vitamin D concentrate to milk, as is currently practiced today (Quick and Murphy, 1982).

In the 1930s and 1940s specific deficiency disease syndromes were first identified and documented in the United States (Foltz et al., 1944; McLester, 1939; Williams et al., 1943). Based on this new science, in 1940 the Committee on Food and Nutrition (now the Food and Nutrition Board [FNB]) recommended the addition of thiamin, niacin, riboflavin, and iron to flour (NRC, 1974). About that time FDA first established a standard of identity for enriched flour that identified specific nutrients and amounts required for addition to any flour labeled as "enriched" in order to improve the nutritional status of the population (FDA, 1941). The approach of using a standard of identity, which establishes the specific type and level of fortification required for particular staple food to be labeled as enriched, has remained a key aspect of fortification regulations and policy in the United States. These standards have been amended over the years, but they continue as the basis for the addition of thiamin, niacin, riboflavin, folic acid, and iron to enriched flour, with the addition of calcium as optional.

Concurrent with these activities, the nutritional status of Americans was being questioned as a result of the poor nutritional status of young men enlisting for service during World War II. These concerns led to the National Nutrition Conference for Defense in May 1941, convened by President Roosevelt. An outcome of this conference was the recommendation for flour and bread enrichment using the existing standards developed by FDA (Quick and Murphy, 1982).

Although the original FDA standard was not amended to include bread for several years, the enrichment of bread began in 1941 as a

result of discussions among FNB, AMA, FDA, and the American Bakers Association. The voluntary cooperation of bakery-associated industries led to 75 percent of the white bread in the United States being fortified by the middle of 1942 (Quick and Murphy 1982). The first War Food Order, enacted in 1943, stated that all flour sold for interstate commerce would be enriched according to FDA standards. This order was later repealed in 1946, but was followed in 1952 with official standards of identity for enriched bread (FDA, 1952a, 1952b). Under this new regulation, fortification of flour and bread products was not mandatory, but if a product was labeled as "enriched" it was required to meet the standards of identity described in the regulation.

FDA made a decision in the 1940s that it would not require mandatory fortification for any food product; this policy is still in place. For every standard of identity for which there is an enriched version of a food, there is a corresponding standard of identify for an unenriched version. Prior to 1990 individual states could enact laws that addressed fortification of products sold within their boundaries. For example, by the time the enriched bread standard was finally promulgated by FDA in 1952, the enrichment of flour and bread was mandatory in 26 states (Hutt, 1984). The National Labeling Education Act of 1990 provided for federal preemption of standards of identity, however, thus nullifying these state laws.

Since the 1950s standards of identify have been issued for the fortification of food, such as oleomargarine and rice and other cereal grains, and have been proposed for formulated meal replacements. The most recent standard of identity change for these products was the regulation, effective in January 1998, regarding folate. To meet the standard of identify for most breads, flours, corn meals, rice, noodles, macaroni, and other grain products labeled as enriched, folic acid is to be added at the level of 0.43 mg to 1.4 mg/lb of product. This decision reflects an overall approach within the United States that incorporates six underlying principles first presented in a joint statement of FNB and the Council on Foods and Nutrition of AMA (NRC/AMA, 1968):

- The intake of the nutrient, in the absence of fortification, is below the desirable level in the diets of a significant number of people.
- The food from which the nutrient is to be derived is likely to be consumed in quantities that will make a significant contribution to the diet of the population in need.
- The addition of the nutrient is unlikely to create an imbalance of essential nutrients.

- The nutrient added is stable under proper conditions of storage and use.
- The nutrient is physiologically available from the food to which it will be added.
- There is a reasonable assurance against intake sufficiently in excess to be toxic.

Fortification Policies and Regulations Since the 1960s

In the 1960s FDA proposed a more restrictive regulatory approach in response to increased fortification of food that it feared might lead to overfortification. These were the first major regulatory changes related to food fortification that had been proposed since 1941. In 1962 FDA proposed to limit fortification to only nutrients essential to human health and appropriate for supplementation. The agency listed 12 essential nutrients with a suitable range for their supplementation and 11 nutrients that were considered essential but not appropriate for supplementation because signs of deficiency only occurred under experimental situations (Hutt, 1980, 1984). The previous year FDA had brought legal action against New Dextra Brand Fortified Cane Sugar claiming in part that the sugar's labeling was misleading because its 19 added nutrients inherently claimed that it was more nutritious than other sugars and that the nutrients were present in sufficient amounts to significantly improve the diet. Another element of the legal action claimed that sugar was an inappropriate vehicle for fortification. FDA's "misbranding" approach was not upheld in the U.S. District Court, and the U.S. Court of Appeals agreed.[1] The court held that FDA had no legal authority to prohibit food fortification unless it can be shown to be unsafe. The United States District Court concluded (as upheld by the United States Court of Appeals):

> The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the marketplace simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug, and Cosmetic Act did not vest in the Food and Drug Administration or any other federal agency the power to determine what foods should be included in the American diet; this is the function of the marketplace. . . .[1]

[1]United States v. 119 Cases . . . "New Dextra Brand Fortified Sugar," 231 F. Supp. 551 (D. Fla. 1963), aff'd per curiam, 334 F 2d 238 (5th Cir. 1964).

Still attempting to reduce indiscriminant food fortification and dietary supplement products, in 1966 the FDA proposed to limit the number of food products that could be fortified to eight classes and to specify the nutrients that could be used with each class. This proposed regulation was worded in the context of two new standards of identity: one for vitamin and mineral dietary supplements and the other for a limited number of food products (FDA, 1966). FDA convened public hearings on these proposed regulations in 1968 and 1969 (Hutt, 1980). This proposed regulation and a subsequent proposal in 1974 of general rules governing the addition of nutrients to food, along with provisions to enforce the rules (FDA, 1974), were eventually abandoned due to objections and comments in public hearings and due to other events.

Two events in particular changed the course of FDA's regulatory approach in the 1960s and 1970s: President Nixon's White House Conference on Food, Nutrition and Health in 1969 and Congress's enactment of the new Section 411 of the Food, Drug, and Cosmetic Act (FD&C) in 1976. The White House Conference issued a report that recommended fortification of existing and new food products to reduce malnutrition, which was in many ways the opposite of the 1966 FDA proposed regulation (Hutt, 1980; WHC, 1970). After FDA published regulations based on its 1968 and 1969 hearings, Congress was persuaded in 1976 to amend the FD&C Act to limit FDA's authority over vitamin and mineral supplements. This amendment explicitly prohibited FDA from imposing maximum limits on the potency of any vitamin or mineral in a dietary supplement in tablet, capsule, or small measured liquid form except for safety reasons. The 1976 statute also prohibited FDA from limiting the combination or number of safe nutrients in a dietary supplement (21 U.S.C. §350). The FDA Modernization Act of 1997 extended this to include dietary supplements in food form (P.L. 105-115). When FDA attempted to limit the amount of vitamin A and vitamin D fortification by declaring any level higher than 150 percent of the U.S. Recommended Daily Allowances (US RDAs) to be a prescription drug, this approach was also struck down by the courts.[2]

Current Fortification Policies

In 1943, due to the heightened interest in fortified food, FDA issued a policy statement (which has never been withdrawn) on the

[2]National Nutritional Foods Association v. Mathews, 557 F.2d 325 (2d Cir. 1977).

addition of nutritive ingredients to food. In this policy FDA stated that implicit in fortification is the promise to consumers that the fortified food, through its fortificants, contributes substantially to the nutritional well being of the individual who consumes usual amounts of the food. This aspect of the policy was rejected by the courts in the New Dextra Sugar case and by the 1976 vitamin-mineral amendments to the FD&C Act. The FDA policy also said that the specific nutrient deficiencies in the diet of the general population and population subgroups, the overall place of the food item in the diet of this population, and the effectiveness and suitability of the food vehicle should determine the type and amount of nutrients to be added to food. This policy further affirmed the importance of natural food in the diet, endorsed the restoration of nutrients lost during food processing, and indicated that it was appropriate, in some instances, to fortify processed food above restoration amounts and to fortify unprocessed food in order to correct deficiencies if the food in question is a particularly effective vehicle for fortification (Hutt, 1980, 1984).

In 1974 FDA proposed regulations that moved beyond the standard of identity approach and included a more comprehensive viewpoint of the addition of nutrients to food (FDA, 1974). In 1980 these views were published not as regulations, but as a policy statement that manufacturers ". . . are urged to follow if they elect to add nutrients to a manufactured or processed food" (FDA, 1980, p. 6314). The policy was codified in 21 C.F.R. 104.20 (FDA, 1980). This policy is the current statement of the agency regarding fortification. It is important to note that this statement, as a policy, it is not enforceable.

Of key relevance to this report, the codified policy includes situations and conditions in which the fortification of food with the nutrients listed in the policy is considered appropriate:

> 1) . . . to correct a dietary insufficiency that is recognized by the scientific community to exist and known to result in nutrient deficiency disease . . . ; 2) . . . to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling and processing . . . ; 3) . . . in proportion to the total caloric content of the food, to balance the vitamin, mineral, and protein content . . .; and 4) . . . that replaces traditional food in the diet to avoid nutritional inferiority . . . (FDA, 1980, p. 6323)

In the codified policy there are a number of qualifications listed with each condition of fortification. For example, the policy recom-

mends that vitamins, minerals, and protein be added in proportion to the total caloric content of the food for which the stated caloric reference value is ". . . per 100 kilocalories based on a 2,000-kilocalorie total intake as a daily standard . . ." (FDA, 1980). This section includes a listing of the nutrients the policy recommends as appropriate to add as fortificants and cites the US RDAs as the reference standards for amounts of nutrients to be added per 100 kilocalories.[3] The FDA fortification policy thus recommends using the same reference standards for fortification that are used for the nutrition labeling of food.

The policy includes statements that nutrients added to food should be stable, physiologically available, present at a level that will not led to excess intake, suitable for fortification purposes, and acceptable in terms of food safety regulations. The policy concludes with links to food labeling in that it specifies that claims and statements on the label cannot be false or misleading. Another point mentioned in the fortification policy is that FDA "does not consider it appropriate to fortify" fresh produce, meat, poultry, or fish products, sugars, or snack foods (e.g., candies and carbonated beverages).

Historically the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has followed an unwritten policy prohibiting indiscriminant fortification of the products it regulates (Post, 2002). In 1980 it adopted FDA's policy guidelines on the addition of nutrients to food (21 C.F.R.104.20). In 1982 an FSIS review of the policy concluded that the food it regulated would continue to follow FDA policy guidelines (Quick and Murphy, 1982). Meat and poultry regulations do, however, permit some limited addition of nutrients for specific purposes, such as the addition of ascorbic acid (vitamin C) to accelerate the curing process and the addition of thiamin hydrochloride for flavoring. With the exception of margarine, there are no FSIS food standards that permit or require the addition of nutrients (Post, 2002). The diversity of food products in the marketplace that fall under FSIS regulation has grown, and FSIS has found that products may contain label claims for fortification that are not addressed by the 1980 guidelines (Post, 2002). FSIS has made some accommodation for these food products by allowing label statements about nutrients contributed by fortified ingredients approved by FDA (e.g., calcium-enriched egg noodles) (Post, 2002).

[3]The US RDA reference standards were updated on January 6, 1993 (FDA, 1993c) to use FDA's Recommended Daily Intakes and Daily Reference Values.

HISTORY AND CURRENT STATUS OF CANADIAN FOOD FORTIFICATION POLICY

Canada has a long history of fortification that is based, as in the United States, on previous conditions of nutrient deficiency in the population. The diversity of climate, sunlight exposure, soil biogeochemistry, food commerce, and population size across the country led to significant regional differences in the need and demand for fortification of the food supply within Canada.

Nutrition Issues

In the early 1900s there were occasional observations of illness, such as beriberi and blindness, in segments of the population in Newfoundland and Labrador that were attributed to nutrient deficiencies (Aykroyd, 1928; Little, 1912). A survey of the clinical and biochemical nutritional status of 868 people in St. John's and several outposts of Newfoundland was carried out in 1944 (Adamson et al., 1945). Clinical and biochemical signs of deficiencies of vitamin A, B vitamins, and ascorbic acid were prevalent in the group examined.

The first comprehensive nutrition surveys that were conducted in British Columbia and Saskatchewan in 1946 indicated that about 21 percent of children had a least one sign of clinical vitamin A deficiency and about 50 percent of school children had evidence of past rickets (Pett and Hanley, 1947). Newfoundland, not part of Canada at that time, promulgated the mandatory addition of nutrients to food to reduce nutrient deficiencies in the population, including adding calcium (as bone meal), iron, and B vitamins to flour and vitamin A to margarine (Lotfi, 2002).

The first comprehensive national nutrition survey, Nutrition Canada, was conducted in 1970–1972 and involved approximately 13,000 people. Many segments of the population had dietary intake inadequacies based on a 24-hour dietary recall, particularly of iron, calcium, vitamin D, and protein. Biochemical indicators confirmed iron deficiency among all groups in the population and low serum vitamin A levels in children and adolescents, but no clinical evidence of vitamin A deficiency or rickets (Canada, 1973). The survey also revealed that approximately 50 percent of the population was overweight (Canada, 1973, as cited in Lotfi, 2002).

Fortification Policies

The addition of vitamins and minerals to food is strictly controlled under the FDRs. The FDRs list the foods to which micronutrients

may be added, which micronutrients may be added, and the level to which they may be added. This is an example of a "positive listing" approach. These regulations apply to all food sold in Canada.

When vitamins became available for addition to food, no regulatory controls were in place. Concern about fraudulent practices in the addition of vitamins to food led the government to set minimum levels for this addition in 1942, followed in 1949 with maximum levels (Cheney and Lee, 1994). Newfoundland had required the enrichment of flour since 1944, and following the entry of Newfoundland into the Canadian Confederation, the standard for flour was amended to permit the same nutrient enrichment (Health Canada, 1999).

The Canadian government has used mandatory fortification to address documented deficiencies. Iodinization of salt, which became mandatory in 1949, virtually eliminated goiter throughout the country; a highly targeted approach to vitamin D fortification turned around a widespread problem with rickets (Cheney and Lee, 1994; Health Canada, 1999). In particular, Canada's experience with a high incidence of severe rickets and death from vitamin D deficiency is cited as an example of how thoughtful, full-coverage fortification of a targeted food category can address a widespread deficiency. In the 1940s and 1950s all unstandardized food could be fortified within the specified minimum and maximum levels of vitamin D. While rickets continued to be documented in infants and young children, one survey indicated that some of the young children in Ontario were consuming very high levels of vitamin D from supplements and food (Broadfoot et al., 1966). Nationwide food-intake surveys had not been conducted at that time, but concern about the apparent contradictions related to vitamin D status (very high intakes at the same time as a continuing problem of rickets) led in 1964 to the present controls on the addition of vitamins and minerals to food (Cheney and Lee, 1994). Although the addition of vitamin D to evaporated and dried milks had been permitted since 1950, the change in the regulations in 1964, which led to cessation of vitamin D fortification of many food products, resulted in an increase in rickets (Cheney and Lee, 1994; Health Canada, 1999). Health Canada attributes this rise to its overlooking "a fundamental principle of food fortification—the selection of an appropriate vehicle to reach the target population" (Health Canada, 1999, p. 6). In the case of vitamin D, while evaporated and powdered milk was fortified, fluid milk was not. The regulations were amended in 1965 to include fluid milk, and rickets cases began to decline. Educational campaigns in the late 1960s, coupled with a further broadening of the

regulations to include fortification of all milks in 1975, eliminated rickets as a public health problem beginning in the late 1970s (Cheney and Lee, 1994).

The "positive list" approach to fortification was initiated with the 1964 regulations. The inclusion of a list of food that may be fortified, as well as the specific micronutrients and maximum levels to which they may be added, is viewed by Health Canada as a successful fortification program that addresses inadequacies and protects the population from excesses of fortificants (Cheney, 2000; Health Canada, 1999). Extensions to food fortification are guided by policies first enunciated in 1971 (Canada, 1971) and later in accordance with the general principles for the addition of essential nutrients to foods of the Codex Alimentarius Commission[4] (1994).

Fortification of food in Canada is also permitted to maintain nutritional equivalence for substitute food, to restore nutrients lost during manufacturing, and to ensure the nutrient composition of a special-purpose food in a carefully regulated fashion. The principles in the Codex Alimentarius Commission's (1994) general principles include definitions and approaches for fortification that cover issues such as ". . . safety, nutrient interactions, bioavailability, technical feasibility, and choice of food vehicle . . . " (Health Canada, 1999, p. 29).

Canadian regulations apply to all food sold in Canada, regardless of where it is produced. Canada permits discretionary fortification with defined limits, and therefore it does not have a reference standard for levels of nutrient addition.

In 1998 Health Canada began a policy review of the addition of vitamins and minerals to food through an iterative consultation process that resulted in the 1999 publication of new proposed policy recommendations (Health Canada, 1999). This proposal includes five recommendations that continue to support the existing fortification policies. One important change, however, is the proposal for discretionary fortification, as indicated in Recommendation 1c, which states:

[4]"The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations" (Codex Alimentarius Commission, 2003).

> It is recommended that fortification programs be expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes (p. 14).

This recommendation is a result of the view of a variety of groups in Canada that the current food fortification policies are too restrictive. If the proposal is adopted, it should provide the opportunity for more choices of fortified food, a wider distribution of nutrients in the food supply, and greater flexibility in the regulatory framework.

SUMMARY

The United States and Canada have current policies and regulations regarding fortification that differ in many ways. In the United States FDA has maintained its decision to not require mandatory fortification of any food product, and it has parallel standards of identity for versions of food products that are enriched and those that are not. FDA currently has a policy statement that identifies fortification practices that manufacturers are encouraged to follow. However, this policy cannot be enforced, and FDA employs labeling requirements rather than rigid standards for nutrient composition to assist consumers. In Canada the situation with food fortification is changing. For many years food fortification has been tightly regulated. The policy currently being crafted will likely result in expanded options for food fortification, particularly in the area of discretionary fortification.

4

A Brief Review of the History and Concepts of the Dietary Reference Intakes[1]

The Dietary Reference Intakes (DRIs) are a set of reference values for specific nutrients, each category of which has special uses. The development of the DRIs replaces the reports on Recommended Dietary Allowances (RDAs), issued periodically from 1941 to 1989 by the National Academy of Sciences, and Recommended Nutrient Intakes (RNIs), published by the Canadian government (Canada, 1990). Seven reports have resulted from the comprehensive effort undertaken by the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes (DRI Standing Committee) of the Food and Nutrition Board (FNB), Institute of Medicine, the National Academies, and its panels and subcommittees (IOM, 1997, 1998, 2000a, 2000b, 2001, 2002a, 2003). This report on nutrition labeling and discretionary fortification is a derivative report that is separate from the DRI committee oversight process, yet is based entirely in the science and outcomes of the DRI reports. This chapter provides a brief description of the overall origin of the DRIs, the basic DRI concepts, and several issues from the DRI reports that are particularly relevant to nutrition labeling.

ORIGIN

The DRI initiative began in June 1993, when FNB organized a symposium and public hearing entitled "Should the Recommended

[1]This chapter is derived from the description of the DRIs in the macronutrient report (IOM, 2002a).

Dietary Allowances Be Revised?" Shortly thereafter, to continue its collaboration with the larger nutrition community on the future of the Recommended Dietary Allowances (RDAs), FNB prepared, published, and disseminated the concept paper "How Should the Recommended Dietary Allowances Be Revised?" (IOM, 1994), which invited comments regarding the proposed concept, and it held several symposia at nutrition-focused professional meetings to discuss its tentative plans and to receive responses to the concept paper. Many aspects of the conceptual framework of the DRIs came from the United Kingdom's report *Dietary Reference Values for Food Energy and Nutrients in the United Kingdom* (COMA, 1991).

The five general conclusions presented in FNB's concept paper were:

1. Sufficient new information has accumulated to support a reassessment of the RDAs.
2. Where sufficient data for efficacy and safety exist, reduction in the risk of chronic degenerative diseases is a concept that should be included in the formulation of future recommendations.
3. Upper levels of intake should be established where data exist regarding risk of toxicity.
4. Components of food that may benefit health, although not meeting the traditional concept of a nutrient, should be reviewed, and if adequate data exist, reference intakes should be established for them.
5. Serious consideration must be given to developing a new format for presenting future recommendations.

Subsequent to the symposium and the release of the concept paper, FNB held workshops at which invited experts discussed many issues related to the development of nutrient-based reference values. In addition, FNB gave attention to the international uses of the earlier RDAs and the expectation that the scientific review of nutrient requirements should be similar for comparable populations.

Concurrently, Health Canada and Canadian scientists were reviewing the need for revision of the RNIs (Canada, 1990). Consensus following a symposium for Canadian scientists, cosponsored by the Canadian National Institute of Nutrition and Health Canada in April 1995, was that the Canadian government should pursue the extent to which involvement with the developing FNB process would benefit both Canada and the United States by leading toward harmonization.

Based on extensive input and deliberations, FNB initiated action to provide a framework for the development and possible inter-

national harmonization of nutrient-based recommendations that would serve, where warranted, for all of North America. To this end, in December 1995, FNB began a close collaboration with the government of Canada and took action to establish the DRI Standing Committee.

RATIONALE FOR THE FRAMEWORK

The 1993 symposium and subsequent activities provided substantial evidence that a comprehensive, coordinated approach to developing DRIs was needed for diet planning, nutritional assessment, and nutrition policy development. The current framework is based on the following four assumptions:

1. Since the publication of the tenth edition of *Recommended Dietary Allowances* (NRC, 1989b) in the United States and the RNIs in Canada (Canada, 1990), there has been a significant expansion and evolution of the research base toward defining functional endpoints that are relevant to the understanding of nutrient requirements and food constituents and their relationship to a number of aspects of human health.
2. These advances allow the refinement of the conceptual framework for quantitatively defining nutrient requirements, as well as a clearer determination of the legitimate uses of nutrient requirement estimates and their derivatives in the interpretation and use of dietary intake data. Such uses might broadly be categorized according to whether they are: (a) prescriptive or planning applications, where suitable levels of nutrient intake by individuals and population groups are established, or (b) diagnostic or assessment applications, where determinations are made about the likely nutritional adequacy of the observed intake when considered in relation to appropriate nutrient requirement data. Major differences in the types of information required about nutrient needs and relevant nutrient intake data are fundamental to appropriately focusing on the individual or on a defined population group (Beaton, 1994).
3. Neither the RDAs nor the RNIs have been applied appropriately in many settings. The availability of only a single type of reference value in the face of various needs has led to inappropriate applications. Moreover, inconsistent methods and criteria for deriving certain RDAs and RNIs and insufficient documentation of methods and criteria have also contributed to inappropriate applications.
4. In these times of extensive international collaboration, agricultural and food exchange, and global nutrition-related health prob-

lems, harmonization of nutrient-based dietary standards between Canada and the United States is viewed as a first step, with the expectation that Mexico will be able to join in the future. Such harmonization within the North American continent would further global development of similar efforts. Although the same general approaches have been used by most countries in developing recommended nutrient intakes (e.g., RDAs in the United States, RNIs in Canada, and Dietary Reference Values in Great Britain), and physiological requirements for nutrients are expected to be similar across healthy population groups, many of the quantitative values that have emerged from the different national expert groups are quite divergent, largely reflecting differences in the interpretation and use of scientific data and often based on different food habits and indigenous diets. A mechanism is needed to determine the commonality of the bases on which recommendations are made and to use scientific data to indicate differences in requirements among apparently similar population groups in different geographic locations.

In 1995 the DRI Standing Committee was appointed to oversee and conduct the establishment of DRIs. It devised a plan involving the work of seven or more expert nutrient-group panels and two overarching subcommittees (Figure 4-1). The nutrient-group panels, composed of experts on those nutrients, were responsible for: (1) reviewing the scientific literature concerning specific nutrients under study for each stage of the lifespan, (2) considering the roles of nutrients in decreasing the risk of chronic and other diseases and conditions, and (3) interpreting the current data on nutrient intakes of North American population groups. The panels were charged with analyzing the literature, evaluating possible criteria or indicators of adequacy, and providing substantive rationales for their choices of each criterion. Using the criterion or criteria chosen for each stage of the lifespan, the panels estimated the average requirement for each nutrient or food component reviewed, assuming that adequate data were available. As the panel members reviewed data on requirements, they also interacted with two subcommittees regarding their group of nutrients. The Subcommittee on Upper Reference Levels was charged with reviewing possible risk assessment models for estimating levels of nutrients that may increase risk of toxicity or adverse effects and then assisting the panel to apply the model to each nutrient or food component reviewed. Similarly, the Subcommittee on the Interpretation and Uses of DRIs assisted the panels and the DRI Standing Committee in developing practi-

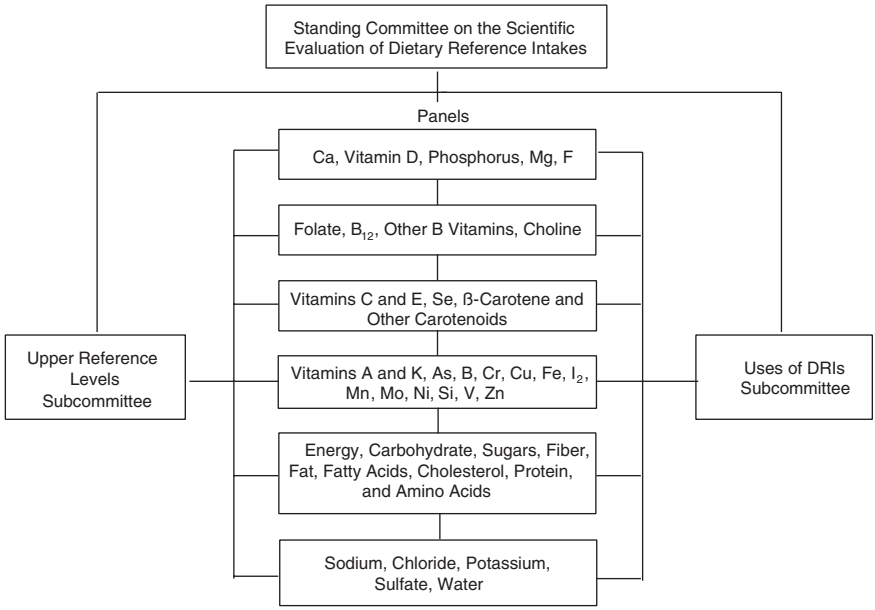

FIGURE 4-1 Dietary Reference Intakes Standing Committee, Subcommittee, and Panel Structure.

cal information and guidance on using DRIs appropriately. Based on interaction with and information provided by the panels and subcommittees, the DRI Standing Committee determined the DRI values to be included in the reports (IOM, 1997).

WHAT ARE DIETARY REFERENCE INTAKES?

The DRIs include the Estimated Average Requirement (EAR), the RDA, the Adequate Intake (AI), and the Tolerable Upper Intake Level (UL). Establishment of these reference values requires that a criterion be carefully chosen for each nutrient and that the population for whom these values apply be carefully defined. For the DRIs a requirement is defined as the lowest continuing intake level of a nutrient that, for a specific indicator of adequacy, will maintain a defined level of nutriture in an individual (IOM, 1997). The chosen criterion or indicator of nutritional adequacy upon which the EARs and AIs are based is identified for each nutrient. The criterion may differ for individuals at different life stages. Particular attention is

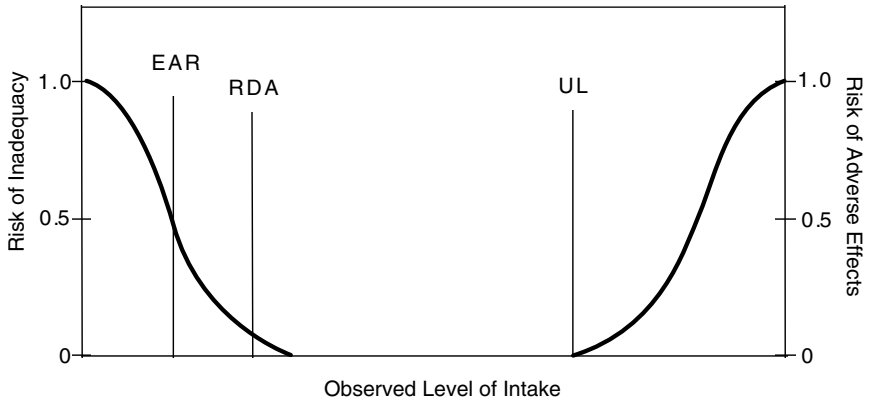

FIGURE 4-2 Dietary reference intakes. This figure shows that the Estimated Average Requirement (EAR) is the intake at which the risk of inadequacy is estimated to be 0.5 (50 percent) to an individual. The Recommended Dietary Allowance (RDA) is the intake at which the risk of inadequacy would be very small—only 0.02 to 0.03 (2 to 3 percent). At intakes between the RDA and the Tolerable Upper Intake Level (UL), the risks of inadequacy and of excess are both estimated to be close to 0. At intakes above the UL, the potential risk of adverse effects may increase. SOURCE: IOM (2002a).

given in each DRI report to the choice and justification of the criterion used to establish requirement values and the intake levels beyond which the potential for increased risk of adverse effects may occur.

CATEGORIES OF DIETARY REFERENCE INTAKES

Estimated Average Requirement

The *Estimated Average Requirement*[2] (EAR) is the daily intake value that is estimated to meet the requirement, as defined by the specified indicator or criterion of adequacy, in half of the apparently healthy individuals in a life stage or gender group (see Figure 4-2).

[2]The definition of the EAR implies a median as opposed to a mean, or average. The median and average would be the same if the distribution of requirements followed a symmetrical distribution and would diverge as a distribution became skewed.

(A normal or symmetrical distribution [median and mean are similar] is usually assumed for nutrient requirements.) This use follows the precedent set by others that have used the term "Estimated Average Requirement" for reference values similarly derived, but meant to be applied to population intakes (COMA, 1991).

The EAR's usefulness as a predictor of an individual's requirement depends on the appropriateness of the choice of the nutritional status indicator or criterion and the type and amount of data available. The general method used to set the EAR is the same for all nutrients. The specific approaches differ since each nutrient has its own indicator(s) of adequacy, and different amounts and types of data are available for each. Thus, coupled with an estimate of the variance in requirements, the EAR has served three major functions: as the basis for the RDA, as the primary reference point for assessing the adequacy of estimated nutrient intakes of groups (IOM, 2000a), and, together with estimates of the variance of intake, in planning for the intake of groups (IOM, 2003).

Recommended Dietary Allowance

The *Recommended Dietary Allowance* (RDA) is an estimate of the minimum daily average dietary intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group (see Figure 4-2). The RDA is intended to be used as a goal for daily intake by individuals as this value estimates an intake level that has a high probability of meeting the requirement of a randomly chosen individual (about 97.5 percent). However the RDA is not an appropriate value to use to assess the adequacy of intakes. The process for setting the RDA is described below; it depends on being able to set an EAR and estimating the variance of the requirement itself. Note that if an EAR cannot be set due to limitations of the data available, no RDA will be set.

This approach differs somewhat from that used by the World Health Organization, Food and Agriculture Organization of the United Nations, and International Atomic Energy Agency (WHO/FAO/IAEA) Expert Consultation on *Trace Elements in Human Nutrition and Health* (WHO, 1996). That publication uses the term basal requirement to indicate the level of intake needed to prevent pathologically relevant and clinically detectable signs of dietary inadequacy. The term normative requirement indicates the level of intake suffi-

cient to maintain a desirable body store or reserve. In developing an RDA (and AI, see below), emphasis is placed instead on the reasons underlying the choice of the criterion of nutritional adequacy used to establish the requirement. It is not designated as basal or normative.

Method for Setting the RDA When Nutrient Requirements Are Normally Distributed

When the distribution of a requirement for a nutrient among individuals in a group can be assumed to be approximately normal (or symmetrical) and a standard deviation (SD) of requirement ($SD_{requirement}$) can be determined, the EAR can be used to set the RDA as follows:

$$RDA = EAR + 2 \times SD_{requirement}$$

If data about variability in requirements are insufficient to calculate an $SD_{requirement}$ for that specific nutrient in that population group, but normality or symmetry can be assumed, then a coefficient of variation (CV) of 10 percent is assumed and the calculation becomes:

$$RDA = EAR + 2\ (0.1 \times EAR) = 1.2 \times EAR$$

The assumption of a 10 percent CV is based on extensive data on the variation in basal metabolic rate (FAO/WHO/UNA, 1985; Garby and Lammert, 1984) and the CV of 12.5 percent estimated for the protein requirements in adults (FAO/WHO/UNA, 1985). If there is evidence of greater variation, a larger CV is used. In all cases, the method used to derive the RDA from the EAR is stated in the DRI reports.

Since it is derived from the EAR, the RDA's usefulness as a goal depends on the choice of nutritional status indicator or criterion and the type and amount of data available. Its applicability also depends on the accuracy of the form of the requirement distribution and the estimate of the variance of requirements for the nutrient in the population subgroup for which it is developed. For many of the nutrients there are few direct data on the requirements of children and the elderly. In the case of children, EARs and RDAs are based on extrapolations from adult values.

Method for Setting the RDA When Nutrient Requirements Are Not Normally Distributed

For most of the nutrients for which EARs have been established, the required assumption of distribution of requirements is that of symmetry about the mean. In the case of iron, a nutrient of concern in many subgroups in the population in the United States, Canada, and other areas, requirements are known to follow a non-normal distribution. Thus a different method was needed to determine the intake of iron at which half of the individuals would be expected to be inadequate in the criterion used to establish adequacy (the EAR) and also to construct an intake level at which only a small percentage of the population would be inadequate (the RDA).

If the requirement of a nutrient is not normally distributed but can be transformed to normality, its EAR and RDA can be estimated by transforming the data, calculating the 50th and 97.5th percentiles, and transforming these percentiles back into the original units. In this case the difference between the EAR and the RDA cannot be used to obtain an estimate of the SD of the CV because skewing is usually present.

When factorial modeling is used to estimate the distribution of requirement from the distributions of the individual components of requirement, as was done in the case of iron recommendations (IOM, 2001) and for the maintenance and growth components of the recommendations for children for protein and amino acids (IOM, 2002a), it is necessary to add the individual distributions (convolutions). This is easy to do given that the average requirement is simply the sum of the averages of the individual component distributions, and an SD of the combined distribution can be estimated by standard statistical techniques. The 97.5th percentile can then be estimated.[3] If normality cannot be assumed for all of the components of requirement, then Monte Carlo simulation is used for the summation of the components. This approach models the distributions of the individual distributions and randomly assigns values to a large simulated population. The total requirement is then calculated for each individual and the median and the 97.5th percentile are calculated directly. As was the case for iron (IOM, 2001), the underlying joint distribution is approximated and a large

[3]For further elaboration of this method, see Chapter 9 and Appendix I of *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (IOM, 2001).

number of individuals (100,000) are randomly generated. Information about the distribution of values for the requirement components is modeled on the basis of known physiology. Monte Carlo approaches may be used in the simulation of the distribution of components; where large data sets exist for similar populations (e.g., growth rates in infants), estimates of relative variability may be transferred to the component in the simulated population (Gentle, 1998). At each step the goal is to achieve distribution values for the component that not only reflect known physiology or known direct observations, but also can be transformed into a distribution that can be modeled and used in selecting random members to contribute to the final requirement distribution. When the final distribution representing the convolution of components has been derived, then the median and 97.5th percentiles of the distribution can be directly estimated. It is recognized that in its simplest form the Monte Carlo approach ignores possible correlation among components. In the case of iron, however, expected correlation is built into the modeling of requirement where components are linked to a common variable (e.g., growth rate) so that not all sources of correlation are neglected.

Adequate Intake

If sufficient scientific evidence is not available to calculate an EAR, a reference intake called an *Adequate Intake* (AI) is provided instead of an RDA. The AI is a value based on experimentally determined approximations or estimates of observed median nutrient intakes by a group (or groups) of healthy people. In the judgment of the DRI Standing Committee, the AI is expected to meet or exceed the amount needed to maintain a defined nutritional state or criterion of adequacy in essentially all members of a specific, apparently healthy population. Examples of defined nutritional states include normal growth, maintenance of normal circulating nutrient values, or other aspects of nutritional well-being or general health.

For young infants for whom human milk is the recommended sole source of food for most nutrients for the first 4 to 6 months of life, the AI is based on the daily mean nutrient intake supplied by human milk for healthy, full-term infants who are exclusively fed human milk. The goal may be different for infants consuming infant formula for which the bioavailability of a nutrient may be different from that in human milk. For adults the AI may be based on data from a single experiment, on estimated dietary intakes in apparently healthy population groups, or on a review of data from different

approaches that, when considered alone, do not permit a reasonably confident estimate of an EAR.

Comparison of Recommended Dietary Allowances and Adequate Intakes

There is much less certainty about an AI value than about an RDA value. Because AIs depend on a greater degree of judgment than is applied in estimating an EAR and subsequently an RDA, an AI may deviate significantly from, and be numerically higher than, an RDA. For this reason AIs must be used with greater care than is the case for RDAs. Also, an RDA is usually calculated from an EAR by using a formula that takes into account the expected variation in the requirement for the nutrient.

Both the AI and the RDA are to be used as goals for individual intake. In general the values are intended to cover the needs of nearly all apparently healthy persons in a life stage group. (For infants the AI is the mean intake when infants in the age group are consuming human milk. Larger infants may have greater needs, which they meet by consuming more milk.) The AI for a nutrient is expected to exceed the RDA for that nutrient, and thus it should cover the needs of more than 97 to 98 percent of individuals in the life stage group. The degree to which the AI exceeds the RDA is likely to differ among nutrients and population groups. As with RDAs, AIs for children and adolescents may be extrapolated from adult values if no other usable data are available.

For people who have diseases that increase specific nutrient requirements or who have other special health needs, the RDA and AI each may serve as the basis for adjusting individual recommendations. Qualified health professionals should adapt the recommended intake to cover higher or lower needs.

Tolerable Upper Intake Level

The *Tolerable Upper Intake Level* (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the specified life stage group (see Figure 4-2). As intake increases above the UL, there is the potential for an increased risk of adverse effects. The term *tolerable* was chosen to avoid implying a possible beneficial effect. Instead the term is intended to connote a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake as there is no established benefit for healthy

individuals if they consume a nutrient in amounts exceeding the recommended intake (the RDA or AI).

The UL is based on an evaluation conducted by using the methodology for the risk assessment of nutrients. The need for ULs has arisen because high consumption levels of some nutrients have resulted from the increased nutrient fortification of conventional foods and the increasing use of dietary supplements. The UL applies to chronic daily use and is usually based on the total intake of a nutrient from food, water, and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from one or both of those sources only rather than on total intake. As in the case of applying AIs, professionals should avoid very rigid application of the ULs and should first assess the characteristics of the individual or group of concern (e.g., the source of nutrient, the physiological state of the individual, and the length of sustained high intakes).

For some nutrients data may not be sufficient to develop a UL. This indicates the need for caution in consuming amounts greater than the recommended intake; it does not mean that high intake poses no potential for risk of adverse effects.

The safety of routine, long-term intake above the UL is not well documented. Although the general population should be advised not to routinely exceed the UL, intake above the UL may be appropriate for investigation within well-controlled clinical trials. Clinical trials of doses above the UL should not be discouraged as long as participants have signed informed consent documents regarding possible toxicity and they are appropriately monitored. Because the DRI concept is relatively new, there are few published reports that have examined population-based intake levels in the context of the UL. Recent dietary intake studies, which take into account nutrients from conventional food and dietary supplements, have demonstrated total intake levels that regularly approach and sometimes exceed the ULs (Allen and Haskell, 2002; O'Brien et al., 2001). Long-term intake of nutrients at levels above the UL places individuals at risk for adverse effects, but only continued longitudinal research will be able to demonstrate the level of potential harm.

Life Stage Groups

The life stage groups described below were chosen as part of the initial DRI process (IOM, 1997) while keeping in mind all the nutrients to be reviewed. If data were too sparse to distinguish differences

in requirements by life stage or gender group, the analysis provided in establishing the DRI for any given nutrient may have been presented for a larger grouping.

Infancy

Infancy covers the period from birth through 12 months of age and is divided into two 6-month intervals. Except for energy in the macronutrient report, the first 6-month interval was not subdivided further because intake is relatively constant during this time. That is, as infants grow, they ingest more food; however, on a body-weight basis, their intake remains nearly the same. Growth velocity slows during the second 6 months of life, and thus daily nutrient needs on a body-weight basis may be less than needs during the first 6 months of life.

The average intake of nutrients by full-term infants who are born to healthy, well-nourished mothers and who are exclusively fed human milk has been adopted as the primary basis for deriving the AI during the first 6 months of life. The DRI values established are thus not EARs. The extent to which the intake of human milk may result in exceeding the actual requirements of the infant is not known, and ethics of human experimentation preclude testing the levels known to be potentially inadequate. Therefore, the AIs, while determined from the average composition of an average volume of milk consumed by this age group, are not EARs in which only half of the group would be expected to have their needs met.

Using the infant fed human milk as a model is in keeping with the basis for estimating nutrient allowances of infants developed in the last revisions of the RDA (NRC, 1989b) and the RNI (Canada, 1990) reports. It also supports the recommendation that exclusive breastfeeding is the preferred method of feeding for normal, full-term infants for the first 4 to 6 months of life. This recommendation has also been made by the Canadian Paediatric Society (Canada, 1990), the American Academy of Pediatrics (AAP, 1997), and in the FNB report *Nutrition During Lactation* (IOM, 1991).

In general special consideration was not given to possible variations in physiological need during the first month after birth or to the variations in intake of nutrients from human milk that result from differences in milk volume and nutrient concentration during early lactation. Specific DRIs to meet the needs of formula-fed infants have not been proposed in the DRI reports. The previously published RDAs and RNIs for infants have led to much misinterpre-

tation of the adequacy of human milk because of a lack of understanding about their derivation for young infants. Although they were based on human-milk composition and volume of intake, the previous RDA and RNI values allowed for the lower bioavailability of nutrients from nonhuman milk. However, where warranted, information on specific changes in the bioavailability or the source of nutrients for use in developing formulations is included in the DRI reports.

Ages 0 through 6 Months. To determine the AI value for infants ages 0 through 6 months, the mean intake of a nutrient was calculated by multiplying the average concentration of the nutrient in human milk produced during the second through sixth month of lactation (derived from consensus values from several reported studies [Atkinson et al., 1995]) by the average volume of milk intake of 0.78 L/day (as reported from studies of full-term infants by test weighing [Butte et al., 1984; Chandra, 1984; Hofvander et al., 1982; Neville et al., 1988]). Because there is variation in both of these measures, the computed value represents the mean. It was assumed that infants have adequate access to human milk and that they consume increased volumes as needed to meet their requirements for maintenance and growth.

Ages 7 through 12 Months. EARs were developed for these older infants for iron, zinc, and protein (IOM, 2001, 2002a). The reference body-weight method was used in the DRI reports to extrapolate the AI for infants 0 through 6 months of age to an AI for older infants in the absence of direct data on older infants (IOM, 1997). The extrapolation method was not deemed appropriate for dietary fats or carbohydrate in the macronutrient report (IOM, 2002a). This is because the amount of energy required on a body-weight basis is significantly lower during the second 6 months of life, due largely to the slower rate of weight gain per kilogram of body weight. Therefore the basis of the AI values derived for this age category for dietary fats and carbohydrate was the sum of the specific nutrients provided by 0.6 L/day of human milk (the average intake of infants in this age group [Heinig et al., 1993]) and that which was provided by their usual intake of complementary weaning foods (Specker et al., 1997). This approach is in keeping with the recommendations of the Canadian Paediatric Society (Canada, 1990), the American Academy of Pediatrics (AAP, 1997), and *Nutrition During Lactation* (IOM, 1991) for continued feeding of human milk to infants through 9 to 12 months of age with the appropriate introduction of solid foods.

Toddlers: Ages 1 through 3 Years

Two points were primary in dividing early childhood into two groups. First, the greater velocity of growth in height for children ages 1 through 3 years of age compared with those 4 through 5 years of age provides a biological basis for dividing this period of life. Second, because children in the United States and Canada begin to enter the public school system starting at age 4 years, ending this life stage prior to age 4 years seemed appropriate so that food and nutrition policy planners have appropriate targets and cutoffs for use in program planning.

Data are sparse for indicators of nutrient adequacy on which to derive DRIs for these early years of life. In these cases, extrapolation from data on 0- to 6-month-old infants has been employed (IOM, 1997, 1998, 2000b, 2001, 2002a).

Early Childhood: Ages 4 through 8 Years

Major biological changes in the velocity of growth and changing endocrine status occur in children 4 through 8 or 9 years of age (the latter depending on onset of puberty in each gender); therefore, the category of 4 through 8 years is appropriate. For many nutrients, a reasonable amount of data is available on nutrient intake and on various criteria for adequacy (e.g., nutrient balance measured in children 5 through 7 years of age) that can be used as the basis for the EARs and AIs for this life stage group.

Puberty/Adolescence: Ages 9 through 13 Years and 14 through 18 Years

Because current data support younger ages for pubertal development, it was determined that the adolescent age group should begin at 9 years. The mean age of onset of breast development (Tanner Stage 2) for white girls in the United States is 10.0 ± 1.8 years (SD); this is a physical marker for the beginning of increased estrogen secretion (Herman-Giddens et al., 1997). In African-American girls, the onset of breast development is earlier (mean 8.9 ± 1.9 years). The reason for the observed racial differences in the age at which girls enter puberty is unknown. The onset of the growth spurt in girls begins before the onset of breast development (Tanner, 1990); the age group of 9 through 13 years allows for the early growth spurt of African-American girls.

For boys the mean age of initiation of testicular development is 10.5 to 11 years, and their growth spurt begins 2 years later (Tanner,

1990). Thus, to begin the second age category at 14 years and to have different EARs and AIs for girls and boys for some nutrients at this age seems biologically appropriate. All children continue to grow to some extent until as late as age 20 years; therefore, having these two age categories span the period 9 through 18 years of age seems justified.

Young Adulthood and Middle Ages: Ages 19 through 30 Years and 31 through 50 Years

The recognition of the possible value of higher nutrient intakes during early adulthood on achieving optimal genetic potential for peak bone mass was the reason for dividing adulthood into ages 19 through 30 years and 31 through 50 years. Moreover, mean energy expenditure decreases during this 30-year period, and needs for nutrients related to energy metabolism may also decrease. For some nutrients, the DRIs may be the same for the two age groups. However, for other nutrients, especially those related to energy metabolism, EARs (and RDAs) are likely to differ for these two groups.

Adulthood and Older Adults: Ages 51 through 70 Years and Over 70 Years

The age period of 51 through 70 years spans the active work years for most adults. After age 70, people of the same age increasingly display variability in physiological functioning and physical activity. A comparison of people over age 70 who are the same chronological age may demonstrate as much as a 15- to 20-year age-related difference in their level of reserve capacity and functioning. This is demonstrated by age-related declines in nutrient absorption and renal function. Because of the high variability in the functional capacity of older adults, the EARs and AIs for this age group may reflect a greater variability in requirements for the older age categories. This variability may be most applicable to nutrients for which requirements are related to energy expenditure.

Pregnancy and Lactation

Recommendations for pregnancy and lactation may be subdivided because of the many physiological changes and changes in nutrient need that occur during these life stages. In setting EARs and AIs for these life stages however, consideration was given to adaptations to increased nutrient demand, such as the increased absorption and

greater conservation of many nutrients. Moreover, nutrients may undergo net losses due to physiological mechanisms regardless of the nutrient intake. Thus, for some nutrients there may not be a basis for EAR values that are different from those for nonpregnant or nonlactating women of comparable age.

Reference Heights and Weights

Use of Reference Heights and Weights

Reference heights and weights are useful when more specificity about body size and nutrient requirements are needed than that provided by life stage categories. For example, while the EAR may be developed for the 4- to 8-year-old age group, a small 4-year-old child may be assumed to require less than the EAR for that age group, whereas a large 8-year-old child may require more than the EAR. Based on the model for establishing RDAs however, the RDA (and for that matter, an AI) should meet the needs of both.

In cases where data regarding nutrient requirements are reported on a body-weight basis, it is necessary to have reference heights and weights to transform the data for comparison purposes. Frequently, where data regarding adult requirements represent the only available data (e.g., on adverse effects of chronic high intakes for establishing ULs), extrapolating on the basis of body weight or size becomes a possible option to estimate ULs for other age groups. Thus when data are not available, the EAR or UL for children or pregnant women may be established by extrapolation from adult values on the basis of body weight.

Reference Heights and Weights Used in the Early DRI Reports

The most up-to-date data providing heights and weights of individuals in the United States and Canada when the DRI process was initiated in 1995 were limited to anthropometric data from the 1988–1994 Third National Health and Nutrition Examination Survey (NHANES III) in the United States and older data from Canada. Reference values derived from the NHANES III data and used in early DRI reports are given in Table 4-1.

These earlier values were obtained as follows: the median heights for the life stage and gender groups through age 30 years were identified, and the median weights for these heights were based on reported median body mass indexes (BMIs) for the same individuals. Since there is no evidence that weight should change as adults age

TABLE 4-1 Reference Heights and Weights for Children and Adults in the United States Used in the Vitamin and Element Dietary Reference Intake Reports

Sex	Age	Median Body Mass Index, kg/m^2	Reference Height, cm (in)	Reference Weight[a], kg (lb)
Male, female	2–6 mo	—	64 (25)	7 (16)
	7–12 mo	—	72 (28)	9 (20)
	1–3 y	—	91 (36)	13 (29)
	4–8 y	15.8	118 (46)	22 (48)
Male	9–13 y	18.5	147 (58)	40 (88)
	14–18 y	21.3	174 (68)	64 (142)
	19–30 y	24.4	176 (69)	76 (166)
Female	9–13 y	18.3	148 (58)	40 (88)
	14–18 y	21.3	163 (64)	57 (125)
	19–30 y	22.8	163 (64)	61 (133)

[a] Calculated from body mass index and height for ages 4 through 8 years and older.
SOURCE: IOM (1997, 1998, 2000a, 2000b, 2001). Adapted from the Third National Health and Nutrition Examination Survey, 1988–1994.

if activity is maintained, the reference weights for adults ages 19 through 30 years were applied to all adult age groups.

The most recent nationally representative data available for Canadians at the time (from the l970–1972 Nutrition Canada Survey [Demirjian, 1980]) were also reviewed. In general median heights of children from 1 year of age in the United States were greater by 3 to 8 cm (1 to 2.5 in) than those of children of the same age in Canada measured two decades earlier (Demirjian, 1980). This difference could be partly explained by approximations necessary to compare the two data sets, but more likely by a continuation of the secular trend of increased heights for age noted in the Nutrition Canada Survey when it compared data from the 1970–1972 survey with a 1953 national Canadian survey (Pett and Ogilvie, 1956).

Similarly, median weights beyond age 1 year derived from the then most recent survey in the United States (NHANES III, 1988–1994) were also greater than those obtained from the older Canadian survey (Demirjian, 1980). Differences were greatest during adolescence, ranging from 10 to 17 percent higher. The differences probably reflect the secular trend of earlier onset of puberty (Herman-Giddens et al., 1997) rather than differences in populations. Calculations of BMI for young adults (e.g., a median of 22.6 for

Canadian women compared with 22.8 for U.S. women) resulted in similar values, thus indicating greater concordance between the two surveys by adulthood. The reference weights used in the earlier DRI reports (IOM, 1997, 1998, 2000a, 2000b, 2001) were thus based on the most recent data set available from either country, with recognition that earlier surveys conducted in Canada indicated shorter stature and lower weights during adolescence than did surveys conducted in the United States.

New Reference Heights and Weights

Given the increasing prevalence of overweight and obesity in both adults and children, the use of population data, as was done with the earlier DRI reports, is of concern. With the recent publication of new U.S.-based growth charts for infants and children and the introduction of BMI recommendations for adults (Kuczmarski et al., 2000), reference heights and weights for children and adults have been updated. These data have allowed the development of new reference heights and weights for the most recent DRI report, the macronutrient report (IOM, 2002a). Besides being more current, these new reference heights and weights are more representative of the U.S. population, which should more closely approximate ideal weights based on low risk of chronic disease and adequate growth for children. However, while these data are the best available data, it is recognized that information on older individuals is still seriously lacking. Table 4-2 provides the updated values.

DIETARY REFERENCE INTAKE ISSUES ESPECIALLY RELEVANT TO NUTRITION LABELING AND DISCRETIONARY FORTIFICATION

Determination of Adequacy

In the derivation of EARs or AIs, close attention has been paid to the determination of the most appropriate indicators of adequacy. A key question is, Adequate for what? In many cases a continuum of benefits may be ascribed to various levels of intake of the same nutrient. One criterion may be deemed the most appropriate to determine the risk that an individual will become deficient in the nutrient, whereas another may relate to reducing the risk of a chronic degenerative disease, such as certain neurodegenerative diseases, cardiovascular disease, cancer, diabetes mellitus, or age-related macular degeneration.

TABLE 4-2 New Reference Heights and Weights for Children and Adults in the United States

Sex	Age	Previous Median Body Mass Index[a], kg/m^2	New Median Body Mass Index[b], kg/m^2	New Median Reference Height[b], cm (in)	New Reference Weight[c], kg (lb)
Male, female	2–6 mo	—	—	62 (24)	6 (13)
	7–12 mo	—	—	71 (28)	9 (20)
	1–3 y	—	—	86 (34)	12 (27)
	4–8 y	15.8	15.3	115 (45)	20 (44)
Male	9–13 y	18.5	17.2	144 (57)	36 (79)
	14–18 y	21.3	20.5	174 (68)	61 (134)
	19–30 y	24.4	22.5	177 (70)	70 (154)
Female	9–13 y	18.3	17.4	144 (57)	37 (81)
	14–18 y	21.3	20.4	163 (64)	54 (119)
	19–30 y	22.8	21.5	163 (64)	57 (126)

[a] Taken from male and female median body mass index and height-for-age data from the Third National Health and Nutrition Examination Survey, 1988–1994; used in earlier Dietary Reference Intake reports (IOM, 1997, 1998, 2000a, 2000b, 2001).
[b] Taken from new data on male and female median body mass index and height-for-age data from the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) Growth Charts (Kuczmarski et al., 2000).
[c] Calculated from CDC/NCHS Growth Charts (Kuczmarski et al., 2000), median body mass index, and median height for ages 4 through 19 years.

Each EAR and AI in the DRI report series is described in terms of the selected criterion or indicator of adequacy. The potential role of the nutrients in the reduction of disease risk was considered in developing the EARs. With the acquisition of additional data relating intake more directly to chronic disease or disability, more sensitive and reliable indicators or criteria may be validated and thus the criterion for setting the EAR may change.

The DRI process is iterative in nature; with each set of nutrients the DRI concept evolves slightly, but with future science the DRI concept may change significantly. In terms of nutrition labeling, when the Food and Drug Administration devised the U.S. Recommended Daily Allowances in the early 1970s there was national concern about the quality of the food supply and the RDAs were set as reference values to prevent deficiency disease. In the DRIs a requirement is defined as the lowest continuing intake level of a nutrient that will maintain a defined level of nutriture in an individual. This

intake level is dependent on the specific indicator of adequacy identified in the DRI report for that nutrient. Depending on the nutrient, the indicator of adequacy may incorporate not only research on deficiency diseases, but also evidence for risk reduction for chronic diseases and amounts to maintain health. Scientific data have not identified an optimum level for any nutrient for any life stage or gender group, and the DRIs are not presented as such. Therefore for this study, key elements that the committee considered were the various criteria for adequacy and how these were related to developing a reference value for nutrition labeling and discretionary fortification

Special Issues for Macronutrients

Unlike other nutrients, energy-yielding macronutrients can be used somewhat interchangeably (up to a point) to meet energy requirements of an individual. In the DRI report on macronutrients (IOM, 2002a) EARs or AIs were provided for specific macronutrients or components of the classes of macronutrients where the data were adequate to establish a causal relationship between intake and a specific function or chosen criterion of adequacy. However, for the general classes of nutrients and some of their subunits, this was not always possible; the data did not support a single number, but rather trends between intake and chronic disease identified a range. Given that energy needs vary with individuals, a specific number was not deemed appropriate to serve as the basis for developing diets that would be considered to decrease risk of disease, including chronic diseases, to the fullest extent possible. Thus Acceptable Macronutrient Distribution Ranges (AMDRs) were established for macronutrients and components as percentages of total energy intake. These are ranges of macronutrient intakes that are associated with reduced risk of chronic disease while providing recommended intakes of other essential nutrients.

Because much of this evidence is based on clinical endpoints (e.g., coronary heart disease, diabetes, cancer, obesity) that point to trends rather than distinct endpoints, and because there may be factors other than diet that may contribute to chronic disease, it is not possible to determine a defined level of intake at which chronic disease may be prevented or may develop. Therefore, an AMDR is not considered to be a DRI that provides a defined intake level. An AMDR is provided to give guidance in dietary planning by taking into account the trends related to decreased risk of disease identified in epidemiological and clinical studies.

AMDRs are expressed as percentages of total energy intake because their requirements, in a classical sense, are *not* independent of each other or of the total energy requirement of the individual. Each must be expressed in terms relative to the others. A key feature of each AMDR is that it has a lower and upper boundary, some of which are determined mainly by the lowest or highest value judged to have an expected impact on health. Above or below these boundaries, there is a potential for increasing the risk of chronic diseases.

Nutrient Intakes

Each type of DRI refers to the average daily nutrient intake of individuals over time. The amount consumed may vary substantially from day to day without ill effect in most cases. Moreover, unless otherwise stated, all values given for EARs, RDAs, AIs, and AMDRs represent the quantity of the nutrient or food component to be supplied by foods from diets similar to those consumed in the United States and Canada. Healthy subgroups of the population often have different requirements, so special attention has been given to the differences due to gender and age, and often separate reference intakes are estimated for specified subgroups.

For some nutrients (e.g., trace elements) a higher intake may be needed for healthy people if the degree of absorption of the nutrient is unusually low on a chronic basis (e.g., because of very high fiber intake). If the primary source of a nutrient is a supplement, a higher or lower percentage of the nutrient may be absorbed, so a smaller or greater intake may be required. In addition, an adverse effect may be demonstrated at a lower level of intake when the source of the nutrient is from a supplement rather than from a food. When issues such as these arise, they are discussed in each DRI report.

The DRIs apply to the apparently healthy population and while the RDAs and AIs are levels of intake recommended for individuals, meeting these levels would not necessarily be sufficient for individuals who are already malnourished. People with diseases that result in malabsorption syndrome or who are undergoing certain treatments, such as hemo- or peritoneal dialysis, may have increased requirements for some nutrients. Special guidance should be provided for those with greatly increased or decreased needs (e.g., decreased energy due to disability or decreased mobility). Although the RDA or AI may serve as the basis for such guidance, qualified health care personnel should make necessary adaptations for specific situations.

GENERAL ISSUES FOR NUTRITION LABELING AND DISCRETIONARY FORTIFICATION

The new DRIs are more complex and differ considerably from the earlier RDAs and RNIs. They also represent a much broader conceptual approach from the earlier RDAs and RNIs, and they employ very specific modeling and statistical designs:

> Where specific data on safety and a role in health exist, reduction in the risk of chronic degenerative disease or developmental abnormality, rather than just the absence of signs of deficiency, is included in the formulation of recommendations. The concepts of probability and risk underpin the determination of the EAR, RDA, and UL, and inform their application in assessment and planning. (IOM, 2003, p. 17)

An important change in DRIs from a public health perspective is the inclusion of the UL. As intake increases above the UL, there is the potential for an increased risk of adverse effects. This is the first time a reference value that deals with toxicity has been ascribed to nutrients. The DRI Standing Committee cited the potential for the overconsumption of specific nutrients due to high levels of discretionary fortification (sometimes over 100 percent of the Daily Value), coupled with the widespread use of dietary supplements, as rationales for developing the UL (IOM, 1997). In the DRIs, the ULs for children for some nutrients overlap with new recommended intakes for adults (for children ages 1–3 years: vitamin A, zinc, manganese, folate, and niacin; for children ages 4–8 years: vitamin A, niacin, and folate). The committee was charged with considering the best way to use the UL in developing reference values for nutrition labeling given this overlap and the resulting implications for discretionary food fortification. The challenge of these charges in the context of appropriate values for nutrition labeling is addressed in the next two chapters.

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.

[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.

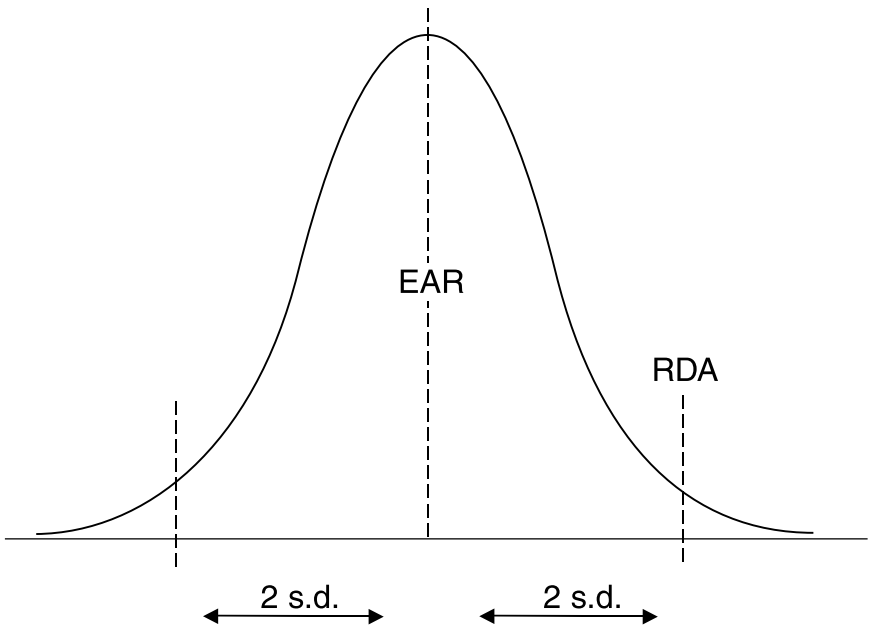

FIGURE 5-1 Relationship of the distribution of the population requirements between the Estimated Average Requirement (EAR) and Recommended Dietary Allowance (RDA) for a hypothetical nutrient. Note that 95 percent of the population is within 20 percent of the EAR where 2 standard deviations (s.d.) = 20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

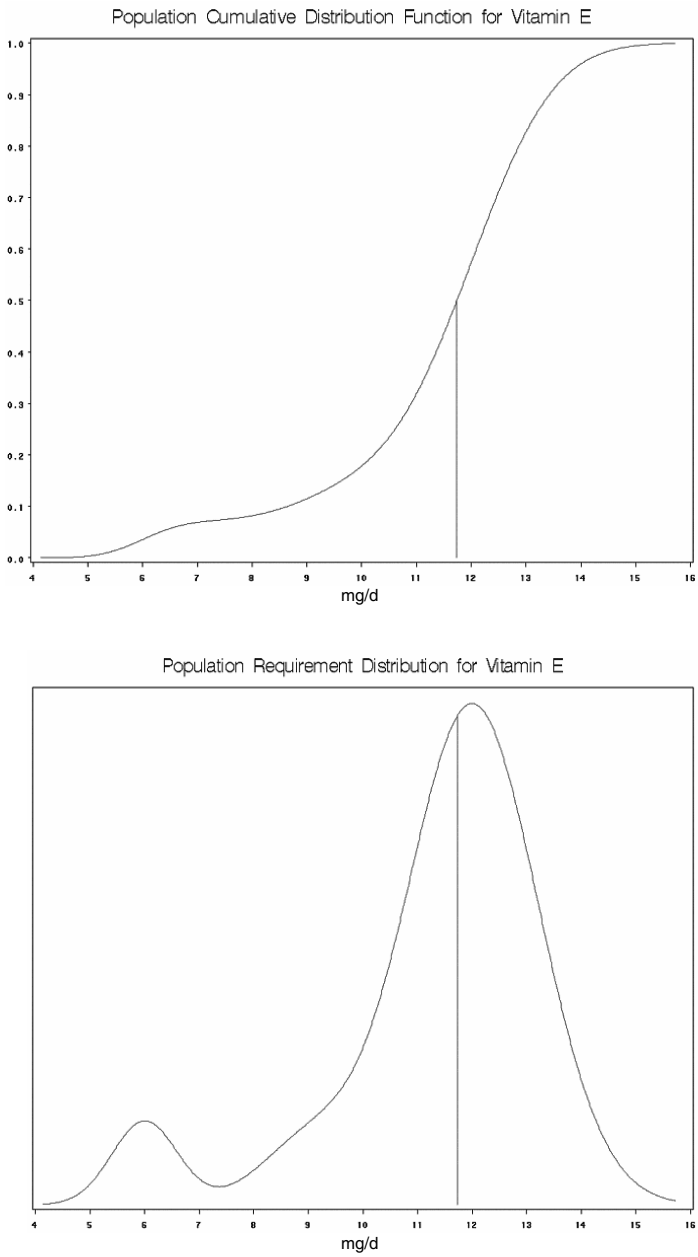

FIGURE 5-2 Population cumulative distribution function and probability distribution function for the vitamin E requirement distribution. The vertical line represents the median.

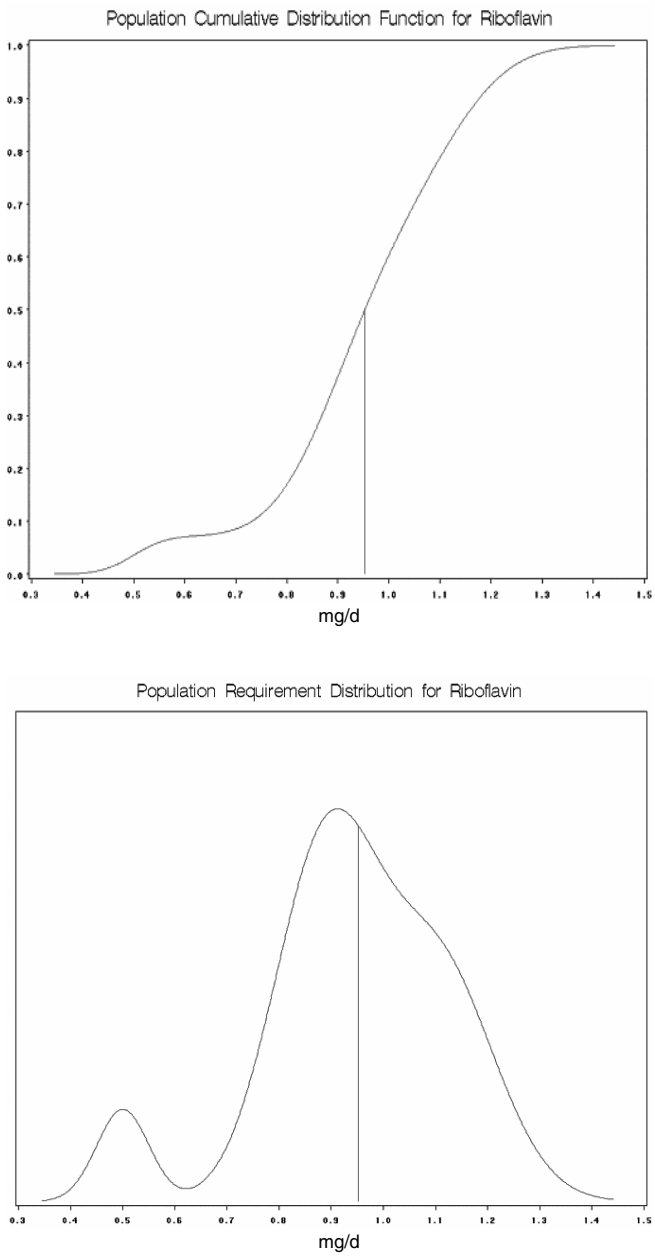

FIGURE 5-3 Population cumulative distribution function and probability distribution function for the riboflavin requirement distribution. The vertical line represents the median.

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.

6

Guiding Principles for the Discretionary Addition of Nutrients to Food

As discussed in Chapter 3, fortification practices in the United States differ from those in Canada. The United States permits the discretionary fortification of food (with the exception of fresh produce, meats, poultry, and egg products) following Food and Drug Administration (FDA) guidelines (FDA, 1980; 21 C.F.R. 104.20). Canada has a more controlled approach.

The Dietary Reference Intake (DRI) reports clearly indicate that the potential exists for over- or underexposure to some nutrients for specific population groups or subgroups. The various reference values that comprise the DRIs were developed in part to provide benchmarks and comparison points that could be used by government agencies in the United States and Canada to set policies to improve the general health of their populations. The Tolerable Upper Intake Levels (ULs), in particular, were developed in partial response to concerns about the risks of overconsumption of nutrients in these two countries where nutrient deficiency diseases have significantly declined in the general population (IOM, 1997). With the decline in deficiency diseases, the relationship of nutrient and food intake to long-term health and the reduction in risk of chronic diseases has become an area of emphasis in nutrition programs and policies in the United States and Canada. A particular recent focus has been on those conditions related to the growing problem of overweight and obesity in the population (Joint Steering Committee, 1996; USDA/DHHS, 2000).

Some populations throughout North America, however, are still at risk for specific nutrient inadequacy in their diets because they

consume an insufficient amount of food to meet energy needs, they consume food with low nutrient density, or they omit one or more food groups. Historically, enrichment or fortification[1] of food targeted to specific populations has been used to reduce these types of inadequacies. Through fortification the specific nutrient content in food products can be minimally enhanced to restore naturally occurring nutrients lost during processing or it can be increased above the level found in comparable food to serve as a significant source of the specific nutrient.

The committee has approached discretionary fortification of food within the parameters of its limited charge from the study sponsors. This charge states:

> As a result of identifying approaches to using the DRIs as the basis for reference values for the food label, [the committee is to] determine principles for discretionary fortification or addition of nutrients to foods as well as the suitability of using reference values for the food label for discretionary fortification.

Thus the committee focused its deliberations on the suitability of applying the DRIs and the guiding principles recommended in Chapter 5 to the issues surrounding discretionary fortification. In doing so, the committee focused on the DRIs and, as also requested by the sponsors, considered FDA's 1980 fortification policy and specific vulnerable groups in the population. This chapter presents six principles, based on the scientific information contained in the DRI reports, that are intended to guide future discretionary fortification practices. The committee's approach has not been to review individual types of food, but rather to develop principles that would be applicable for all food, including meat and poultry products.

The committee has also approached its task on discretionary fortification with the assumption that the resulting guiding principles are scientific criteria that the sponsoring agencies would review and apply as they deem appropriate to identify situations where fortification is justified. While the historic and current approaches to fortification in the United States and in Canada differ, the committee has developed these principles with the anticipation they will serve as guidance to facilitate compatibility of discretionary fortification practices between the two countries.

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[1]Throughout this chapter the term "fortification" refers to the addition of nutrients to food.

SCIENTIFIC JUSTIFICATION AND CRITERIA

GUIDING PRINCIPLE 11. The scientific justification for discretionary fortification of food should be based on documented public health needs, particularly on dietary inadequacy that is determined by assessing the prevalence of nutrient inadequacy in the population. Regulatory agencies should develop criteria for determining when the evidence of dietary inadequacy indicates a documented public health need for the increased availability of nutrients in the food supply.

The committee recommends that discretionary fortification be based on public health need. The committee realizes the importance of fortification and its impact on disease prevention and the potential for problems if there are no policies that govern the fortification levels for nutrients. The fortification policies of the United States (21 C.F.R. 104.20) and the proposed policies of Canada (Health Canada, 1999, 2002) warn of over- or underfortification and the potential for nutrient imbalances that may occur as a result of random and excessive fortification of food.

The committee discussed what defines a "need" that can be met through discretionary fortification. This situation might occur when the nutrient content of the general diet does not meet the needs of all segments of the population or when the need might be less widespread. Within these broad situations of public health need, clearly the promotion of the health of the population can play an important role.

As a first step in identifying whether there is a public health need that might provide scientific justification for discretionary fortification, federal agencies should estimate the level of dietary inadequacy in life stage and gender subgroups of the population for any nutrient of concern. The DRIs can be used to assess the proportion of a group that has a usual intake of a nutrient that is less than the requirement. In addition, the health and nutritional status of groups or individuals need to be assessed through use of biochemical, clinical, and anthropometric indicators (IOM, 2000a). The appropriate method for assessing the prevalence of nutrient inadequacy for groups using the DRIs is presented in Section III of *Dietary Reference Intakes: Applications in Dietary Assessment* (IOM, 2000a). As discussed in that report, assessment is a two-step process. First, the distribution of usual nutrient intakes in the population from both food and supplements must be estimated using appropriate dietary intake assessment methods to determine actual intakes (i.e., 24-hour dietary intake recalls or food records). Then, by applying standard

statistical procedures, the effect of day-to-day variation can be discounted and an estimated distribution of usual intakes can be derived. For most nutrients the Estimated Average Requirement (EAR) cut-point method[2] can be applied to estimate the proportion of the population with usual intakes that are insufficient to meet their nutrient requirements. A probability approach is required for iron and protein, however, because the requirement distributions of these nutrients are not symmetrical. These assessment methods are outlined in the DRI reports for these nutrients (IOM, 2001, 2002a).

As noted in the DRI assessment report (IOM, 2000a), it is not possible to estimate the population prevalence of inadequacy for a nutrient for which there is an Adequate Intake (AI) and no EAR. Since AIs have been determined using different methodologies and assumptions, consideration must first be given to how the AI was established. Only when the AI was set as the median intake of the nutrient by a healthy population (i.e., for pantothenic acid, vitamin K, chromium, manganese, and *n*-6 and *n*-3 polyunsaturated fatty acids) can any degree of inadequacy be determined, and then only in a very limited way. Groups with mean intakes at or above the AI can generally be assumed to have a low prevalence of inadequate intakes. When mean intakes are below the AI, assumptions about adequacy cannot be made unless intakes approach zero. For all other AIs no quantitative measure of adequacy can be made. However other evidence, such as a direct measure of inadequacy with biological tests and measures of long-term health benefits with other biomarkers, should be used to validate intake data and as the basis for assessing adequacy in the absence of other information.

Once the prevalence of inadequacy for a particular nutrient has been assessed in a nationally representative sample of individuals, further review is required to determine whether there is sufficient evidence of public health need to scientifically justify the addition of a nutrient to the food supply through discretionary fortification. There is little published research on the impact of discretionary fortification practices on nutrient intakes or on the prevalence of nutrient inadequacy or excess. Although there is a growing body of literature on the effect of mandatory fortification (enrichment) (e.g., the addition of folic acid to standardized cereal and grain products) (Bailey et al., 2003; Mills et al., 2003; Quinlivan and Gregory,

[2]"With this method, the population prevalence of inadequate intakes is simply the proportion of the population with intakes below the median requirement (EAR)" (IOM, 2000a, p. 81).

2003; Ray et al., 2002a, 2002b, 2003), it would be premature to draw inferences about all discretionary fortification from these studies.

The committee cannot recommend guidelines about the impact of discretionary fortification on nutrient inadequacy and the distribution of inadequate intakes in the population without empirical data on discretionary fortification. Instead, the committee presents four key issues that should be considered as regulatory agencies appraise the public health need for discretionary fortification: the magnitude of the estimated prevalence of inadequacy, the reliability and validity of the prevalence estimate, the health risks associated with the determined inadequacy, and the indications that the nutrient inadequacy can possibly be ameliorated by increasing the availability of the nutrient in the food supply.

Magnitude of the Estimated Prevalence of Inadequacy

Regulatory agencies need to develop criteria to assess the public health importance of prevalence estimates in the context of concerns about discretionary fortification. For example, if the population prevalence of inadequacy for a nutrient is estimated to be 5 percent, questions can be raised about whether this prevalence level is sufficient to justify discretionary fortification. Although 5 percent of the population is a significant number of individuals, unless there is adequate information about this 5 percent of the population that enables fortified food products to be targeted to them, it is unlikely that discretionary fortification would have a discernible impact on the usual nutrient intakes. With a higher prevalence of inadequacy in clearly defined target groups, discretionary fortification might be a more viable strategy. Before considering this option, however, it would be necessary to examine data on the potential impact this discretionary fortification would have on nutrient intake levels in the population. Such prevalence information would need to be determined on the basis of total nutrient intake from food and dietary supplements.

Reliability and Validity of the Prevalence Estimate

There is imprecision associated with all prevalence estimates, but estimates may also be biased by particular methodological problems. In appraising the estimated prevalence of inadequacy for a particular nutrient in the population, the direction and magnitude of measurement errors in the assessment of dietary inadequacy need to be considered. The problems of measurement error associated

with dietary intake assessment have been discussed at length in the DRI assessment and planning reports (IOM, 2000a, 2003). Briefly, errors can arise in the estimation of usual food and nutrient intakes because of random and systematic errors in self-reporting of intakes (particularly systematic underreporting of intakes), estimation of usual intake levels from observed intakes, and determination of the nutrient content of a particular food (because of incomplete or erroneous food composition data).

Although knowledge of these measurement errors continues to grow and methods have been proposed to assess the accuracy of self-reported dietary intakes, there are limited tools with which to identify and correct such errors in population survey data. Because the determination of dietary inadequacy rests on an evaluation of the adequacy of usual nutrient intake levels in the population, errors in the measurement of usual intake levels pose a serious threat to this process. The prevalence of nutrient inadequacy could be grossly overestimated if there are high levels of underreporting in the dietary intake data or if the food composition database includes incomplete or erroneous data on the levels of a particular nutrient in food. Errors also are introduced into measurements of dietary supplement intake because formulations change frequently, and individuals who participate in surveys often have difficulty identifying the exact supplement brand or formulation they used, as well as the duration and regularity of use. Such problems need to be addressed before dietary intake assessments alone are used as a basis for discretionary fortification.

Given the limitations of dietary intake data, evidence of nutrient inadequacy from dietary intake assessments should be verified whenever possible by comparisons with other biochemical or clinical evidence of nutrient inadequacies at the population level. Congruence between dietary and biochemical indices of nutrient inadequacy is particularly valuable in establishing that problems of dietary inadequacy identified through dietary assessments are indeed of public health importance. Conversely, conflicting evidence of dietary insufficiencies need to be carefully reviewed before discretionary fortification could be scientifically justified as providing a potential public health benefit.

Health Risks Associated with Nutrient Inadequacy

Evidence of dietary inadequacy also needs to be weighed against the criteria used to determine the requirements for a particular nutrient. A prevalence of nutrient inadequacy based on nutrient

requirements as defined in the DRIs does not necessarily indicate a prevalence of nutrient deficiency. For example, two different indicators for estimating an average requirement were identified for vitamin A. One was the reversal of night blindness. The other, for which an EAR was calculated, was the minimum acceptable liver vitamin A reserve. A 10 to 15 percent prevalence of usual intakes below the calculated value required to prevent night blindness would indicate a more serious public health problem than a similar prevalence of intakes below the value required to maintain liver stores in healthy individuals. Vitamin A is the only nutrient for which there are two approaches for establishing requirements to address two different endpoints. This nutrient, however, highlights the importance of considering the severity of the consequences of not meeting requirements for particular nutrients when interpreting prevalence estimates to justify the need for discretionary fortification. In addition, based on such factors as geographic location, access to food, patterns of intake, and demographics, not meeting the requirements for one nutrient (e.g., vitamin D) in a given population may pose more of a health risk than not meeting the requirements of another nutrient. Depending on the prevalence of inadequacy and the severity of the health consequences associated with inadequate intakes of a particular nutrient, regulatory agencies may wish to encourage discretionary fortification or to consider population-level interventions (similar to the approach taken with folate) rather to address identified problems.

Selecting the Most Effective Strategy to Address Nutrient Inadequacy

Before an observed prevalence of nutrient inadequacy can be interpreted to scientifically justify the need for increased availability of the nutrient in the food supply, some analysis of the dietary correlates and sociodemographic characteristics associated with inadequate intakes in the population is required. Since discretionary fortification is first and foremost a strategy to increase nutrient density, it is important not to embark on this intervention without some indication that increased nutrient density might help to ameliorate the identified nutrient inadequacy. For example, if inadequate nutrient intakes are observed in the context of inadequate energy intakes, strategies to increase total food intake may be more important than strategies to increase the nutrient levels in food. An association between inadequate energy and nutrient intakes might also be indicative of an underreporting problem in the dietary intake data,

particularly if there is no corroborating evidence of energy inadequacy in the population.

A CONCEPTUAL MODEL

Use of the Tolerable Upper Intake Levels

When the UL was first introduced in the DRI report on calcium and related nutrients, one rationale for its development was concern about ". . . the increased fortification of foods with nutrients and the use of dietary supplements by more people and in larger doses" (IOM, 1997, p. 26). As mentioned in the original description of the model for the ULs (IOM, 1997), nutrients can be viewed like other chemical agents as having the potential to produce adverse health effects from excessive ingestion via the various sources available: conventional food, dietary supplements, and drugs. The UL is specifically defined as ". . . the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the specified life stage group" (IOM, 2002a). After discussing several possible approaches, the DRI Subcommittee on Upper Reference Levels of Nutrients determined that the science bases for nutrients and toxicology at the time best lent itself to a risk assessment framework for deriving ULs. The term "tolerable" was included as part of the name for this reference value because it connotes a level of intake that can be biologically tolerated, yet with regular intake above the UL there is the potential for increased risk of adverse health effects. The definition of an adverse effect underlying the ULs is broad. This breadth has led to significant diversity in the severity of the adverse effects, the typical ingestion sources (e.g., food, supplements, pharmaceutical preparations), and the rationale for intake (e.g., nourishment, treatment regime, prevention) that have been used as the basis for the ULs. These factors, as well as the specific details of the derivation of the UL, must be taken into account when considering discretionary fortification.

Discretionary Fortification Decision Making

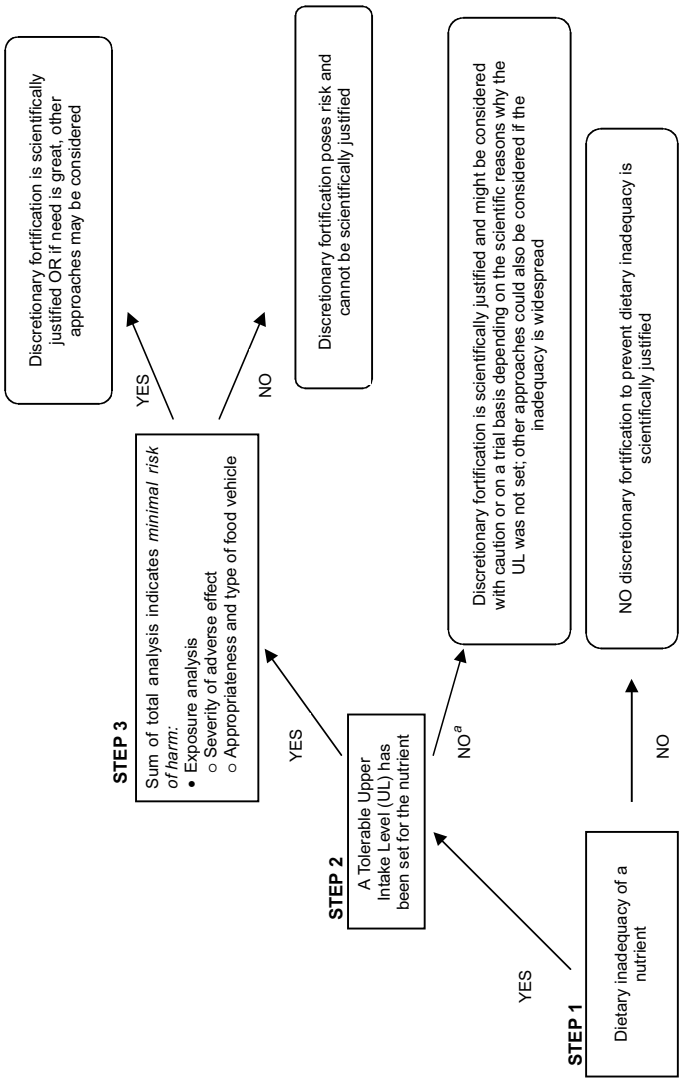
Guiding Principle 11 implies that existing food- and supplement-intake databases should be used to determine exposure of population groups to the nutrient proposed for fortification, and that the EAR should be used as a basis for this determination. The committee also made the following assumptions:

- Regardless of how the data are accumulated, decisions about the presence of dietary inadequacy and the level of public health need should reside with the regulatory agencies.
- If it is determined that there is no dietary inadequacy or that the inadequacy is at such a level that it does not constitute a public health risk, discretionary fortification would not be scientifically justified.
- If it is determined that there is dietary inadequacy of a nutrient in the population, discretionary fortification with that nutrient would be scientifically justified but, depending on the level of the public health need, the agencies may wish to consider other approaches to address the inadequacy. The scientific justification for discretionary fortification would most likely be composed of several steps, and optimally different groups (e.g., regulatory agencies, food manufacturers, federal research institutions, and university scientists) would have responsibility for these steps. The committee therefore recommends increased communication among these groups to share information about dietary and supplement intake and their potential effects on health.

GUIDING PRINCIPLE 12. In situations where discretionary fortification is scientifically justified, intake data should be used with the Tolerable Upper Intake Level (UL) to provide evidence, using a careful modeling approach, to explain how current exposure to the nutrient in question would be altered by discretionary fortification.

The committee recommends that intake data and the UL be used to model how exposure to potential fortification with a nutrient would alter the population's exposure to that nutrient. This modeling would use the amount of the nutrient under consideration for fortification to be provided to the population as a whole, to be provided to the population groups targeted by the food, and to be provided to the population groups at potential risk for overexposure to the nutrient.

To provide a documented public health justification for discretionary fortification, the committee recommends the three-step conceptual approach to decision making as illustrated in the flow diagram in Figure 6-1. This approach indicates how scientific information, including the DRIs, might justify four different outcome decisions with regard to discretionary fortification: no documented scientific justification for the discretionary fortification of food, fortification poses a significant safety risk and therefore cannot be scientifically



[a] For a number of nutrients no UL was set because there was insufficient documentation of adverse effects and the Dietary Reference Intake (DRI) reports language does not include a statement of concern of safety. For example, "There are no reports available of adverse effects from consumption of excess thiamin by ingestion of food and supplements. Because the data are inadequate for a quantitative risk assessment, no Tolerable Upper Intake Level (UL) can be derived for thiamin" (IOM, 1998, p. 81). For several other nutrients the UL was not set because there was insufficient documentation of adverse effects; however the DRI report language indicated a concern about safety. For example, "No adverse effects have been convincingly associated with excess intake of chromium from food or supplements, but this does not mean that there is no potential for adverse effects resulting from high intakes. Since data on the adverse effects of chromium intake are limited, caution may be warranted" (IOM, 2001, p. 216).

FIGURE 6-1 Flow diagram for decisions about discretionary food fortification.

justified, discretionary fortification needs additional scientific study or proceeds on a trial basis while more information is gathered, or discretionary fortification is scientifically justified. If the public health need is sufficient, agencies may consider approaches other than discretionary fortification as a means to increase a nutrient in the food supply, including the use of supplements.

Step One. Determine whether a dietary inadequacy of a specific nutrient has been documented scientifically in at least one segment of the population and if there is sufficient public health need. If *no* dietary inadequacy of a specific nutrient has been documented scientifically in at least one segment of the population, there is no demonstrated public health need for increased availability of the nutrient, and no discretionary fortification is justified. However, if there is a documented inadequacy and sufficient need, the next step is consideration of the UL.

Step Two. If a UL has not been set by the DRI reports for the nutrient being considered for discretionary fortification because there are no reports of adverse effects,[3] then discretionary fortification to address the inadequacy would be scientifically justified. Different approaches might be taken depending upon the language in the DRI reports.

For a number of nutrients no UL was set because there was insufficient documentation of adverse effects and the DRI report language does not include a statement that indicates a concern about safety. For example, "There are no reports available of adverse effects from consumption of excess thiamin by ingestion of food and supplements. Because the data are inadequate for a quantitative risk assessment, no Tolerable Upper Intake Level (UL) can be derived for thiamin" (IOM, 1998, p. 81). For several other nutrients the UL was not set because there was insufficient documentation of adverse effects; however the DRI report language indicated a concern about safety. For example, "No adverse effects have been convincingly associated with excess intake of chromium from food or supplements, but this does not mean that there is no potential for adverse effects resulting from high intakes. Since data on the adverse effects of chromium intake are limited, caution may be warranted"

[3]A UL was not set for the following nutrients for the population 4 years of age and older: vitamin K, thiamin, riboflavin, vitamin B_{12}, pantothenic acid, carotenoids, arsenic, chromium, silicon, and vanadium.

(IOM, 2001, p. 216). When there is no cautionary language in the DRI report, discretionary fortification might be considered. When caution is expressed as part of the UL discussion for the nutrient in a DRI report, then according to the decision model discretionary fortification would be considered only after more detailed scientific review and modeling or, on a trial basis while more data are collected, similar to the temporary marketing authorization used in Canada (Health Canada, 1999) and the temporary marketing permits used for variation from standardized food in the United States (21 C.F.R. 130.17). If sufficient public heath need is demonstrated, the regulatory agencies may consider other approaches to increase the availability of the nutrient. If the nutrient has a UL, then the next step is to proceed with modeling of the impact of fortification on the appropriate populations.

Step Three. An exposure analysis would be prepared using the appropriate populations. The analysis would include an evaluation of the severity of the adverse effect and whether the effect is observed with food, fortified food, supplements, or dosages designed for pharmacological purposes. If the totality of evidence from the exposure analysis indicates that fortification of a food item poses a *significant risk* of adverse effects to at least one segment of the population, then discretionary fortification at the proposed level would not be scientifically justified. If the exposure analysis indicates a *minimal risk of harm* and/or the effects are not noted at the levels proposed to be provided in food and supplements, discretionary fortification might be scientifically justified. In all cases appropriate records of the analyses should be maintained in the event adverse effects occur. If sufficient public health need is demonstrated, other approaches may be considered to increase the availability of the nutrient to the population.

Selected Nutrient Examples Using the Discretionary Fortification Decision Approach

Use of the decision flow diagram presented in Figure 6-1 is necessarily dependent upon many factors, such as the food that is being considered for fortification, the form of the food, the form and amount of the nutrient to be included in the food, and the exposure/modeling data. Below are four hypothetical examples that illustrate how the approach might be used. These examples are highly abstract because the necessary data specifics are not included.

Iron

The need for iron varies greatly among life stage and gender groups. Some groups, such as adult men and postmenopausal women, meet their relatively low needs for iron very easily. For example, men in a study conducted on Prince Edward Island, Canada, had a prevalence of inadequacy for iron of less than 1 percent (Taylor et al., 2002). In contrast, women of childbearing age and young children show vulnerability to iron deficiency. Women ages 19 to 50 years in the same Prince Edward Island study had a prevalence of inadequacy for iron of 29 percent (Taylor et al., 2002). Discretionary fortification with iron requires selection of the appropriate food vehicles that will be consumed preferentially by those in need of enhanced iron intake. A further complication is that many dietary assessment programs calculate total dietary iron, but not bioavailable iron. Finally, the needs of one group (e.g., women of child-bearing age) must be balanced against the risk of exceeding the UL for other groups (e.g., individuals with iron storage disease). According to the decision flow diagram in Figure 6-1, under these circumstances there might be sufficient scientific information to justify discretionary fortification with iron or to consider other approaches to supply iron to the specific subgroups that are iron deficient.

Vitamin D

Since publication of the DRIs for vitamin D (IOM, 1997), studies have shown that the current recommended intake levels are inadequate to maintain nutrient status in the absence of substantial cutaneous production (Heaney et al., 2003). Other recent studies demonstrated that the levels of vitamin D already added to food are not high enough or are not found in enough different food products to prevent vitamin D inadequacy (Looker et al., 2002; Nesby-O'Dell et al., 2002; Rucker et al., 2002; Tangpricha et al., 2002; Vieth et al., 2001). Since the DRI value established for vitamin D is an AI, calculation of the prevalence of inadequacy using this reference value is not possible. The studies cited above used biological indicators of vitamin D status to demonstrate that current dietary intakes are not adequate. According to the decision flow diagram in Figure 6-1, vitamin D might be another example of a nutrient for which discretionary fortification might be scientifically justified. At the same time, while the UL for vitamin D for the general population is 50 μg/day, a number of studies have documented vitamin D toxicosis in elderly individuals consuming a healthful diet and multiple sup-

plements (Marriott, 1997). Therefore, depending on the most current information regarding risk to specific populations, it might be decided that the scientific justification for discretionary fortification necessitated a more in-depth scientific review process or was more congruent with a trial period of fortification while more data was collected.

Vitamin A

The UL for vitamin A (as retinol) is 3,000 μg for pregnant women 19 to 50 years of age and 2,800 μg for pregnant women 18 years of age and younger. These values are approximately four times the Recommended Dietary Allowance (RDA). Some foods are highly concentrated sources of preformed vitamin A (e.g., liver). Other common food products, such as fortified low-fat milk, butter, or margarine, can provide additional preformed vitamin A. Thus preformed vitamin A may pose a significant risk of adverse effects to women of childbearing age who may become pregnant. According to the decision flow diagram in Figure 6-1, vitamin A could possibly be an example when discretionary fortification would not be scientifically justified or would necessitate careful study.

Alternatively fortification could be considered using provitamin A carotenoids, such as β-carotene, rather than retinol to increase vitamin A content. Provitamin A carotenoids are converted to retinol at an estimated rate of 12 μg as β-carotene or 24 μg as other provitamin A carotenoids (e.g., α-carotene and β-cryptoxanthin) to 1 retinol activity equivalent (RAE) (IOM, 2001). These conversation rates, however, assume that the carotene is bound in a fruit or vegetable matrix, so food fortified with carotenes may provide more RAEs than corresponding endogenous carotenes. Carotenes have no known level of toxicity and no UL, and there is no cautionary language about them in the DRI report (IOM, 2000b). Therefore, assuming that a public health need has been demonstrated, fortification might be scientifically justified.

Vitamin C

Vitamin C is a nutrient that is added to food not only for fortification purposes, but also for its in vitro antioxidant effects. Vitamin C has a UL of 2,000 g for adults. This value decreases to 650 mg for children ages 4 to 8 years. In considering the risk of harm based on the decision flow diagram in Figure 6-1, two factors emerge as important in assessing the scientific justification about fortification

with vitamin C: the severity of the adverse effects and a complete exposure analysis. Many potential risks of excess vitamin C have been identified. In the DRI report (IOM, 2000b) the relatively mild adverse effect, osmotic diarrhea, was chosen as the endpoint for the UL for vitamin C. The DRI report explained "[the] effects are generally not serious and are self-limiting." However the ULs for children for vitamin C were extrapolated based on body weight differences and therefore the risk of harm for children may warrant additional consideration.

The other important factor is that an exposure analysis would be needed that estimated vitamin C inclusion in food under all circumstances. For example, attention should be paid to the potential for vitamin C to increase iron absorption in instances where this effect is not desired, that is, when iron intakes are not inadequate or limited. While healthy people do not increase iron absorption in response to high doses of vitamin C, it is not known whether individuals with hereditary hemochromatosis could be adversely affected by the long-term ingestion of vitamin C (IOM, 2000b). Therefore, depending on the most current information regarding risk to specific populations, it might be decided that the scientific justification for discretionary fortification necessitated a more in-depth scientific review process or was more congruent with a trial period of fortification while more data were collected.

ISSUES IN IMPLEMENTING A LEVEL OF DISCRETIONARY FORTIFICATION

Role of Existing Practices in Maintaining Adequacy

GUIDING PRINCIPLE 13. Currently there is limited research on the impact of discretionary fortification on the distribution of usual intakes in the population. Consideration should be given to fortification with nutrients up to the amount for products to meet the criteria as "good" or "excellent" sources of the nutrients,[4] consistent with the modeling approach described in Guiding Principle 12.

[4]In the United States, for a food to qualify to serve as a "good source" of a nutrient, it must contain 10 to 19 percent of the Daily Value (DV) per reference amount customarily consumed. An "excellent" or "high" food source must contain at least 20 percent of the DV.

There is currently an absence of empirical data on the impact of discretionary fortification on the distribution of usual nutrient intakes in the population. This lack of data makes it difficult to estimate the amount of a nutrient that must be added to food to have the desired effect on an identified nutrient inadequacy. As a temporary alternative, fortification levels could be matched to the criteria for meeting nutrient content claims as "good" or "excellent" sources of nutrients, consistent with the modeling approach recommended in Guiding Principle 12. Recognizing that the defining conditions for these claims may change in the future, the committee recommends using these criteria with outcome modeling as a potentially effective approach to increasing the availability of selected nutrients in the food supply and facilitating communication of this benefit to consumers. The committee recommends using these criteria as a scientifically sound approach, even if the defining criteria for claims should change.

GUIDING PRINCIPLE 14. Potential changes to certain long-standing discretionary fortification practices should be carefully reviewed because they may be central to the maintenance of nutrient adequacy in the population.

Discretionary fortification of the food supply has evolved over time in the United States. This evolution has created a dynamic relationship between the micronutrient content of the food supply and the dietary adequacy and nutritional status of population groups. For example, in the United States many breakfast cereals have been fortified with vitamins and minerals at about 15 to 25 percent of the DV per serving since the 1970s. Since the 1980s some orange juice products have been fortified with calcium at 30 percent of the DV per 8 fl oz, an amount equivalent to that contained in 8 oz of milk. Regular use of these products could contribute meaningfully to nutrient intake in many segments of the population. Berner and colleagues (2001) demonstrated that discretionary fortification of some food products moved the ". . . median or the 25th percentile intakes from below to above the RDA . . ." for a number of different nutrients.

As indicated previously the committee recommends the use of existing food composition and dietary supplement databases to assess the level of dietary adequacy in selected population groups. It is the committee's understanding that individual food items that have been fortified under discretionary fortification policies in the United States cannot be readily identified as such in the current U.S.

Department of Agriculture food composition databases (Moshfegh, 2002). Thus it is presently difficult to analyze the impact of current discretionary fortification on usual nutrient intakes in the population. However, it is imperative that the contribution of existing fortification practices and dietary supplements to current intakes be understood before regulations are introduced that would dramatically alter these practices Given this situation, the agencies may decide that it important to support the continuation of certain longstanding discretionary fortification practices for the general nutritional well-being of the population.

Severity of the Adverse Effect

GUIDING PRINCIPLE 15. The severity of the adverse effect on which the Tolerable Upper Intake Level (UL) is based should be reviewed when considering discretionary fortification with a nutrient using the conceptual decision approach presented in Figure 6-1.

An important consideration in using the ULs is the heterogeneity of the severity of the adverse effects on which they are based. The definition of a UL includes the phrase ". . . is likely to pose no risk of adverse health effects . . ." (IOM, 1997, 1998, 2000b, 2001, 2002a). The DRI reports define the term adverse effect as ". . . any significant alteration in the structure or function of the human organism (Klaassen et al., 1986) or any impairment of a physiologically important function that could lead to a health effect that is adverse."[5] This definition provides wide latitude in identifying adverse effects. Often the effect identified for a nutrient is the first effect noted, regardless of its severity, which may not be evidenced from the consumption of food, but only from the consumption of nonfood sources or highly fortified food sources. Selected examples of the diversity of adverse effects identified as the basis for ULs for several nutrients are included in Box 6-1. The committee acknowledges that the paucity of direct data and diversity of adverse effects are limitations to the UL concept.

Therefore in evaluating the potential for overexposure to a specific nutrient, it is necessary to carefully consider the basis for esti-

[5]This definition is ". . . in accordance with the definition set by the joint World Health Organization, Food and Agriculture Organization of the United Nations, and International Atomic Energy Agency (WHO/FAO/IAEA) Expert Consultation on *Trace Elements in Human Nutrition and Health* (WHO, 1996)" (IOM, 1997, p. 52).

BOX 6-1 Examples of the Diversity of Adverse Effects as the Basis for Tolerable Upper Intake Levels (ULs) of Nutrients

Magnesium:

Magnesium, when ingested as a naturally occurring substance in foods, has not been demonstrated to exert any adverse effects. However, adverse effects of excess magnesium intake have been observed with intakes from nonfood sources such as various magnesium salts used for pharmacological purposes. Thus, a Tolerable Upper Intake Level (UL) cannot be based on magnesium obtained from foods. . . . The primary initial manifestation of excessive magnesium intake from nonfood sources is *diarrhea* (Mordes and Wacker, 1978; Rude and Singer, 1980). (IOM, 1997, p. 242)

Niacin:

Flushing is the adverse effect first observed after excess niacin intake and is generally observed at lower doses than are other effects. Flushing that results in patients deciding to change the pattern of niacin intake (i.e., reduce the amount taken at a time or withdraw from treatment) was selected as the most appropriate endpoint on which to base a UL. Although nicotinamide appears not to be associated with flushing effects, a UL for nicotinic acid that is based on flushing is considered protective against potential adverse effects of nicotinamide. The data on hepatotoxicity are considered less relevant to the general population because they involve large doses taken for long periods of time for the treatment of a medical condition. (IOM, 1998, p. 142)

Vitamin A:

Based on considerations of causality, quality, and completeness of the database, *teratogenicity* was selected as the critical adverse effect on which to base a UL for women of childbearing age. For all other adults, liver abnormalities were the critical adverse effects. Abnormal liver pathology, characteristic of vitamin A intoxication (or grossly elevated hepatic vitamin A levels), was selected rather than elevated liver enzymes because of the uncertainties regarding other possible causes such as concurrent use of hepatotoxic drugs, alcohol intake, and hepatitis B and C. Bone changes were not used because of the conflicting findings and the lack of other data confirming the findings of Melhus et al. (1998). (IOM, 2001, pp. 132–133)

Vitamin D:

Hypervitaminosis D is characterized by a *considerable increase in plasma 25(OH)D* concentration to a level of approximately 400 to 1,250 nmol/liter (160 to 500 ng/ml) (Jacobus et al., 1992; Stamp et al., 1977). Because changes

continued

BOX 6-1 Continued

in circulating levels of $1,25(OH)_2D$ are generally small and unreliable, the elevated levels of 25(OH)D are considered the indicator of toxicity. . . . The adverse effects of hypervitaminosis D are probably largely mediated via hypercalcemia, but limited evidence suggests that direct effects of high concentrations of vitamin D may be expressed in various organ systems, including kidney, bone, central nervous system, and cardiovascular system (Holmes and Kummerow, 1983). (IOM, 1997, p. 278)

NOTE: Words in *italics* are the adverse effects that form the basis for the UL for the nutrient.

mating the UL for that nutrient. In many instances the ULs are based on the intake of a nutrient from food, fortified food, and supplements. By definition, the ULs apply to chronic or usual intake levels. Assessments of overexposure thus need to be based on distributions of usual intake, and in cases where the UL applies to the total intake of a nutrient from food and supplements, the estimate of usual intake must incorporate intake from both sources.

Exposure Analysis of Dietary Supplements

Dietary supplements contribute substantially to the nutrient intake of large segments of the North American population (Balluz et al., 2000; Radimer et al., 2000; Vitolins et al., 2000). These contributions must be captured in the assessment of the total intake exposure of populations. While a number of studies have shown minimal to significant improvements in nutritional status with supplements targeted to at-risk groups in Western countries (Fiatarone Singh et al., 2000; Kiely et al., 2001; Stang et al., 2000; Stratton and Elia, 2000), emerging research demonstrates possible risks. This research indicates that the amounts of certain nutrients in some dietary supplements, coupled with adequate dietary intake, may result in total intake levels that approach and sometimes exceed the ULs (Allen and Haskell, 2002; O'Brien et al., 2001). The committee recognizes that FDA is prohibited by statutory provision from limiting the composition of the levels at which a specific nutrient is included in a dietary supplement other than for safety reasons. Because it is necessary

to know total nutrient intake in the diet relative to the UL, exposure estimates analogous to those for conventional foods need to be developed for dietary supplements.

Modifications for Special Purposes

GUIDING PRINCIPLE 16. Where discretionary fortification is scientifically justified for special-use products, the intended use of the targeted food should be the standard against which the nutrient content is assessed.

The committee's discussion of food marketed for special purposes focused on three types: those specially formulated for targeted populations at risk, meal replacements, and food designed as alternative sources of nutrients. In the United States some small children require relatively high amounts of nutrients that are inadequate in their diets. In this situation foods are formulated to ameliorate the nutrient inadequacy. For example, the Special Supplemental Nutrition Program for Women, Infants and Children has used cereals highly fortified with iron as a cornerstone of its efforts to decrease anemia among at-risk children. These special cases may require the use of higher amounts of discretionary fortification than might be suitable for more general-purpose food products.

Meal replacements are single foods—in bar, powdered mixes for reconstitution, or ready-to-drink form—that are intended to replace one or more meals or to serve as a sole source of nourishment. These products are marketed to or "represented for use" by a variety of individuals, such as those seeking a convenient meal or snack, those trying to manage their weight, and those at nutritional risk due to involuntary weight loss or recovery from illness or surgery.

In the United States FDA does not regulate the nutrient composition of meal replacements, but how a product is represented for use plays an important role in determining appropriate fortification goals for these products. FDA's current general fortification policy (FDA, 1980; 21 C.F.R. 104.20) states that nutrients must be added to food in proportion to caloric content. FDA recognizes that this policy may not be appropriate if a food is represented for use as a substitute for one made to resemble a traditional food. For example, a product represented to be used in a weight-reduction program is more appropriately fortified to replace the vitamins and minerals normally provided by a traditional meal that contains more calories.

In Canada "special purpose foods," which include meal replacements and nutritional supplements, are handled separately from

other foods in order that the food is appropriate for its intended purpose. Health Canada has recommended that manufacturers be given "the flexibility to develop new products targeted to groups or individuals with special needs" (Health Canada, 1999, p. 24). The manufacturer, however, would be required to provide the scientific rationale for both the target group and the nutrient composition. In Canada the composition of meal replacements is regulated under the Food and Drug Regulations to provide nutrients in accordance with the Recommended Nutrient Intakes (RNIs) and the *Nutrition Recommendations* (Canada, 1990). Meal replacements must contain approximately 25 percent of the RNIs of 12 vitamins and 10 minerals in a serving, and the quantity and quality of protein and the quantity of fat and essential fatty acids are controlled.

Meal replacements represent a special situation with respect to fortification, be it discretionary as in the United States, or regulated as in Canada. The important consideration is that a meal replacement be fortified with a defined variety of nutrients in quantities appropriate for the meal it replaces.

Another type of special-purpose food, sometimes called a substitute food, is a food product designed specifically to provide an alternative source of a nutrient. Examples include orange juice or soy- and rice-based beverages intended to provide a milligram equivalent amount of calcium per reference serving for persons with lactose intolerance or food allergy, for vegetarians, or for personal choice to meet calcium needs. When discretionary fortification is used for special purposes, the intended use of the targeted food should determine the amount of the proposed nutrient addition.

7

Data Support and Research Recommendations

The committee has proposed principles to guide the use of Dietary Reference Intakes (DRIs) in selecting reference values for nutrition labeling and principles for the use of DRIs in discretionary food fortification. To measure the impact of the implementation of the guiding principles, it is necessary to design and conduct studies to better understand consumers' use of nutrition labeling with regard to dietary intakes and purchase decisions in the United States and Canada, as well as the impact that fortified foods have on nutrient intake. Without this information it is difficult to judge either the effects of nutrition labeling in instituting healthy changes in the diet or the need to fortify the food supply with additional nutrients. These efforts will require the expertise and collaboration of academia, industry, and government. Because food and dietary supplement composition and consumption in both countries continually change, these studies need to be ongoing.

The committee identified five specific areas where this additional research and data support would be of benefit: studies that would lead to the determination of requirements for those nutrients for which Estimated Average Requirements (EARs) could not be developed; more data of high quality on adverse effects and dose relationships to permit definition of the biological endpoints, no-observed-adverse-effect levels (NOAELs), and lowest-observed-adverse-effect levels (LOAELs) underlying the Tolerable Upper Intake Levels (ULs); empirical research to ascertain the impact of discretionary fortification practices; regular collection of food and dietary supplement intake information and enhancement of current food composition

and dietary supplement databases; changes in nutrition labeling and consumer research on its use.

RESEARCH IN SUPPORT OF DETERMINING NUTRIENT REQUIREMENTS

The DRI reports identified a set of research priorities for each nutrient (IOM, 1997, 1998, 2000b, 2001, 2002a). One priority was the need to establish EARs for nutrients where data were insufficient to set them at the time (e.g., vitamin D) (IOM, 1997). EARs have multiple uses. As mentioned in Chapter 6, without an EAR it is not possible to estimate the population prevalence of inadequacy for a nutrient following the approach used in the DRI assessment report (IOM, 2000a). The committee recommends that the U.S. Department of Health and Human Services (DHHS), the U.S. Department of Agriculture (USDA), and Health Canada promote and support basic research that will lead to the development of EARs that were not established by the DRI panels, especially for those nutrients that are deemed important for public health or for special populations. Nutrients currently without EARs include vitamin D, vitamin K, pantothenic acid, biotin, choline, calcium, chromium, fluoride, manganese, total fiber, linoleic acid, and α-linolenic acid.

The research needs are described in detail in the DRI volumes for each nutrient. In general, these research needs include studies to provide the basic data to construct risk and benefit curves across graded exposures to food- and supplement-based intake of a nutrient while monitoring a combination of response indices. They also point to the need for subpopulation-specific information even for those nutrients with EARs. For example, for vitamin C, vitamin, E, selenium, and β-carotene and other carotenoids, useful data are seriously lacking for setting requirements for adolescents, pregnant and lactating women, and the elderly (IOM, 2000b).

BIOLOGICAL ENDPOINTS UNDERLYING THE TOLERABLE UPPER INTAKE LEVELS AND INFORMATION ON ADVERSE EFFECTS

For many nutrients the DRI panels were unable to set ULs because data were not available on adverse effects that had been associated with high intakes of the nutrient from food sources (see Appendix C). Some nutrients clearly had adverse effects associated with doses of the nutrient either consumed as a dietary supplement or for treatment purposes, such as the development of neuropathy with high

doses of pyridoxine to treat carpal tunnel and premenstrual syndromes (Schaumburg et al., 1983, as cited in IOM, 1998). With the neuropathy related to high-dose treatments of pyridoxine, there was sufficient scientific documentation for the panel to identify a NOAEL and a LOAEL to derive a UL for adults and to address specific issues based on limited data related to the life stage groups of those under 19 years of age, pregnancy, and lactation (IOM, 1998). Because pyridoxine had been used as a single-treatment modality at high doses, the relationship could be identified. With other nutrients, more often the case was that the data were too limited to clearly demonstrate a relationship between the biological endpoint and the dose or duration of treatment. With pyridoxine, a dose-response relationship and the development of neuropathology had been well described in animal studies prior to the first reports in humans (Phillips et al., 1978, as cited in IOM, 1998). While the LOAEL and NOAEL for pyridoxine were identified based on human studies, the animal data served to confirm the dose cut-points.

The ability to set a UL for a nutrient is particularly important for discretionary fortification. For most nutrients there is limited indication that the UL could be reached through the intake of nutrients from conventional food marketed for the general population 4 years of age and older. The risk may be greater for food marketed to specific life stage and gender groups and through the prolonged use of high doses of dietary supplements either as part of the overall diet or for treatment purposes. The committee recommends that support for research on adverse effects become a high priority for those nutrients for which no UL could be established and for which initial data indicate that the general population or particular life stage and gender groups may be at risk from high intakes.

In addition, the committee recommends that the Food and Drug Administration and Health Canada expand their educational efforts to help consumers and health care professionals clearly understand the breadth of possible adverse effects, the information needed to identify a relationship between a food or dietary supplement and an adverse effect, and the best process for accurately reporting this information.

EMPIRICAL RESEARCH TO ASCERTAIN THE IMPACT OF DISCRETIONARY FORTIFICATION

There is an urgent need for empirical research to determine the impact of discretionary fortification practices on the distribution of usual nutrient intakes and on the prevalence of nutrient inadequacy

and nutrient excess in the population. The USDA food composition database is not designed to facilitate the tracking of discretionarily fortified food products in intake surveys. The committee understands that USDA is currently working to address this issue and encourages continuation of that effort. Such research is needed to form a sound scientific basis for future nutrition labeling and discretionary fortification policies. This research would require cooperation between industry and government agencies such as was done on a smaller scale by Berner and colleagues (2001). Only those fortified products consumed by a significant percentage of the population should be considered for this research and related database expansions unless a particular product is consumed almost exclusively by a specific ethnic or economic population subgroup. In this way the sociodemographic and behavioral characteristics of the population subgroups whose usual intakes are most likely to be affected by discretionary fortification may be determined. Research is also required to determine the optimal levels for discretionary fortification and the selection criteria for food vehicles that are likely to have the greatest impact on the lower or upper ends of the intake distribution.

FOOD COMPOSITION AND DIETARY SUPPLEMENT DATABASES

Specific data are necessary for a complete and accurate assessment of nutrient adequacy and excess. In particular there is a vital need to maintain current and representative databases for food and supplements that can be used to effectively assess nutrient intakes. Complete databases that reflect current fortification practices are critical to accurately assess the nutrient content of the food supply, population food intakes, and the effects of dietary intake on health outcomes. To do this, the databases must be up-to-date to ensure there are no missing values and that the nutrient data within the databases are current. As mentioned in Chapter 6, the prevalence of nutrient inadequacy could be grossly overestimated if there are high levels of underreporting in the dietary intake data or if the food composition databases include incomplete or erroneous data on the levels of a particular nutrient in food. With the new DRIs the quantifying units of measure also may need to be updated in the databases. In those instances where computerized nutrient databases serve as data sources for nutrition labeling, care should be taken to ensure that those databases are the same ones used with dietary surveys of the United States and Canadian populations. This

may require harmonization or cross-verification of databases. The application of bioinformatics (classification, manipulation, and retrieval of data) in support of food and supplement databases in both countries would contribute substantially to the accuracy and the ease of use of these databases.

Research on methodologies for the sampling and analysis of food and its constituents is warranted. Consideration must be given to the food matrix, not just the chemical constituent under analysis, as there is impetus from the DRI macronutrient report (IOM, 2002a) to consider fiber and sugar sources as natural or added to food or supplements. The development of valid analytical techniques for differentiating dietary fiber from functional fiber and added sugars from naturally occurring sugars in food and dietary supplements is essential. Other important parameters for this research include how added sugars might contribute to appetite regulation, total energy intake, and nutrient density.

CHANGES IN NUTRITION LABELING AND CONSUMER RESEARCH ON ITS USE

A problem faced by the committee was the paucity of data on consumer use of nutrition labeling, especially on the reference nutrient values. The committee expects that the regulatory agencies will use the guidelines and recommendations in this report in a systematic process to revise the scientific basis for nutrition labeling and for discretionary fortification. As part of this process the committee also recommends a general review of nutrition labeling, as well as significant consumer-based research on the understanding and use of nutrition labeling found on conventional food and supplements.

Nutrition Labeling

As the rules are modified to accommodate changes in the reference values, other changes should be considered. First, the committee recommends that the original intent of the Nutrition Facts box should be reevaluated to determine whether and how it should be modified. Second, a number of elements of nutrition labeling warrant review: the order in which nutrients are listed on the label, which nutrients should be included, the relative emphasis on macro- and micronutrients, the emphasis within macronutrients, the way in which the label may contribute to positive behaviors that address the increase of overweight and obesity in North America, the importance of the position and size of the Nutrition Facts box on the

food label, and harmonization of the serving sizes on the Nutrition Facts box and other dietary recommendations such as the Food Guide Pyramid. Third, the committee encourages the regulatory agencies to assess the potential impact of changing the Nutrition Facts box on the response of food manufacturers with respect to the composition of products and the development of new products, including the use of biotechnology. Finally, the committee encourages that advance planning for nutrition labeling is put into place by the regulatory agencies to ensure that the process from proposals to final rules is timely.

Research on the Use of Nutrition Labeling to Inform Consumer Decisions

The Nutrition Facts box has been in the marketplace for nearly a decade, and it is likely that the way in which consumers use the information it provides has changed over time. The committee found a paucity of current research on all aspects of consumer use and understanding of the Nutrition Facts box. In the United States, research primarily was conducted around the times of regulatory change in the early 1970s and in the early 1990s.

Data from more recent studies (Kreuter et al., 1997; Neuhouser et al., 1999; Perez-Escamilla and Haldeman, 2002) suggest that the Nutrition Facts box has had a positive effect on the quality of the diets of some population groups, but information has been limited since the beginning of nutrition labeling in the 1970s. Further, the committee has been unable to identify studies that provide a comprehensive view of current usage patterns. One recent web-based, nationally representative sample survey of primary household shoppers 18 years of age and older found that when consumers use the current Nutrition Facts box to evaluate the nutritional quality of a product, they tend to rely on a variety of components, such as calories, total fat, sodium, and saturated fat. However this study was designed for the specific purpose of assessing the impact of *trans* fat label information on consumer food choices (Cogent Research, 2003). Some studies suggest that it is important to proceed cautiously in making modifications to nutrition labeling (IOM, 2002b) since consumers may focus on new information when making purchasing decisions and ignore basic information that may be equally important. This behavior was confirmed in the recent *trans* fat label information study (Cogent Research, 2003). It would seem relevant to understand how different segments of the population are using nutrition labels and, in particular, the extent to which the percent

Daily Values (% DV), rather than absolute amounts, contribute to consumers' purchase decisions and their overall diet quality.

Even less consumer research has been conducted on the Supplement Facts box. Therefore research also is needed to understand how consumers use this information. In addition, studies that compare the relative consumer use and understanding of both the Nutrition and the Supplement Facts boxes would enhance the ability of the agencies to revise both labels to better meet consumer needs.

The committee has identified 14 questions that could frame development of much-needed consumer research on nutrition labeling:

- To what extent do consumers use the Nutrition Facts box?
- How does use of nutrition labeling differ by ethnic, life stage, and gender groups?
- How does use of nutrition labeling differ with first-time purchases and with increased label use?
- To what extent do consumers understand the concept of the Daily Value (DV) and do they use it to make purchase decisions?
- Do consumers understand the difference between nutrients (e.g., calcium) for which the % DV is on the label to help them reach a positive goal for intake, and other nutrients (e.g., cholesterol) for which the % DV is on the label to help them reduce their risk of chronic disease?
- To what extent do consumers use the information in the Nutrition Facts box to confirm information they read on the front of the package, including nutrient content and health claims?
- Is the current format of the Nutrition Facts box the most effective manner to convey the information that consumers state that they use, as well as to convey the information that health professionals indicate is important clinically, such as absolute amounts?
- Is there a need to modify the Nutrition Facts box for food and supplements marketed to special populations, such as the elderly?
- Would changes in levels of the DVs based on EARs impact food choices, especially in high-risk groups, such as children participating in the Special Supplemental Nutrition Program for Women, Infants and Children?
- Would the repercussions to changing the current format, such as consumer confusion, outweigh the positive communication benefits of a revised label format?
- Specifically in Canada, what will be the effects of introducing a new label format into the marketplace and of any additional changes that may be necessitated as a result of incorporation of new DVs into the label?

- What are the influences of and the roles for the Nutrition Facts box on overall diet quality?
- What is the role of the Nutrition Facts box in the larger context of nutrition education to affect consumer behavior?
- Are there novel ways that can be identified for using the Nutrition Facts box to teach consumers about nutrition?

Addressing such questions will require a comprehensive approach that includes both quantitative and qualitative methods as commonly employed in market research. This research should provide information about different population groups stratified by traditional factors, such as age, gender, and educational level, and it also should examine how individuals who either have diet-related diseases or are at high risk for developing them use nutrition labeling to inform their purchases. Understanding how consumers use labeling information to inform purchase decisions will require the use of traditional survey techniques, accepted methods of qualitative research, and innovative techniques, such as the verbal protocol analysis described by Higginson and colleagues (2002).

The information obtained from this research should guide the development of a comprehensive food label communication plan that includes the Nutrition Facts box, other information provided on the label (including the ingredients list and health claims) and that integrates this information to help consumers choose more healthful diets. Such a communication plan should include increased broad consumer education on the use of the label, and it should have specified behavioral outcomes that may differ for the various populations of interest. In this manner new and emerging science and data from consumer research may provide the opportunity for a more comprehensive government-based communication and consumer education approach for using the Nutrition Facts box to improve food selection.

8
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A

Biographical Sketches of the Committee

IRWIN H. ROSENBERG, M.D. (*chair*), is an internationally recognized leader in nutrition science. Dr. Rosenberg is a senior scientist at the Jean Mayer USDA Human Nutrition Research Center on Aging and dean of the Friedman School of Nutrition Science and Policy at Tufts University. He served for 15 years as the director of the Human Nutrition Research Center, which studies the interaction of aging and nutritional/dietary factors, as well as the way in which diet, nutrition, and physical activity can modulate or prevent degenerative diseases of aging. The focus of his research has been on vitamin metabolism, especially folate and cardiovascular disease, as well as stroke and cognitive decline. He receives research support from the National Institutes of Health, the U.S. Department of Agriculture, and the Foundation for Nutritional Advancement. As dean and professor, Dr. Rosenberg has been involved in nutrition and food policy issues ranging from dietary guidelines and reference intakes to international nutrition recommendations for the elderly. Prior to joining Tufts, Dr. Rosenberg held faculty positions at the Harvard Medical School and at the University of Chicago, where he served as the first director of the Clinical Nutrition Research Center and helped develop a nutritional focus within the field of gastroenterology. He has served on the Food and Drug Administration Food Advisory Committee's Subcommittee on Folic Acid and on the Institute of Medicine (IOM) Subcommittee on Upper Reference Levels of Nutrients. He is a past chair of the Food and Nutrition Board. Among his many honors are the Josiah Macy Faculty Award, the Robert H. Herman Memorial Award of the American Society

for Clinical Nutrition, and the Bristol Myers Squibb/Mead Johnson Award for Distinguished Achievement in Nutrition Research. He was elected to the IOM in 1994 and became a university professor at Tufts in 2001. He was chair of a March 2003 World Health Organization Consultation on Guidelines for Food Fortification.

STEVEN A. ABRAMS, M.D., is a professor of pediatrics at Baylor College of Medicine at the USDA/ARS Children's Nutrition Research Center. He received a B.S. in biology from the Massachusetts Institute of Technology and an M.D. from the Ohio State University College of Medicine. Dr. Abrams' research centers on the metabolism of nutritionally important minerals, including calcium, magnesium, zinc, and iron. He is a member of numerous professional associations, including the American Society for Bone and Mineral Research, the American Society for Clinical Nutrition, the American Society for Nutritional Sciences, and the Society for Pediatric Research, and he is a fellow of the American Academy of Pediatrics. Dr. Abrams served on the Dietary Reference Intakes Panel on Calcium and Related Nutrients and the Subcommittee on Upper Reference Levels of Nutrients.

GARY R. BEECHER, Ph.D., recently retired as a research chemist of the Food Composition Laboratory at USDA's Beltsville Human Nutrition Research Center. He has over 30 years of professional research experience in the response of biological systems to dietary alterations and in the analytical chemistry of biological and food systems. Dr. Beecher's recent work has been on the absorption and metabolism of dietary carotenoids. His group has also developed analytical techniques for food carotenoids and flavonoids, analyzed a wide variety of foods for these constituents, and compiled data into food composition databases for use by professionals and the public. Dr. Beecher was cochair of the Symposium on Healthy Diets and Food Trade: The Role of Food Composition Data at the International Congress of Nutrition in July 1997. He also served on the Dietary Reference Intakes Panel on Dietary Antioxidants and Related Compounds.

CATHERINE M. CHAMPAGNE, Ph.D., R.D., is a professor-research and chief of Nutritional Epidemiology/Dietary Assessment and Counseling at the Pennington Biomedical Research Center at Louisiana State University in Baton Rouge. She is also the coordinator of the Women's Nutrition Research Program at Pennington. Dr. Champagne's research includes the Delta Nutrition Intervention Research

Initiative, dietary assessment and nutrient databases, nutritional changes promoting weight loss and improvement in chronic disease risk, intake of soldiers both during U.S. Army basic training and in field environments, and nutrient composition of domestic and foreign foods. She receives research support through the Pennington Center, primarily through the National Institutes of Health, the U.S. Department of Agriculture, the Department of Defense, and other funding sources. Dr. Champagne is a fellow of the American Dietetic Association. She is also a member of the Institute of Food Technologists, the American Society for Nutritional Sciences, the American College of Sports Medicine, the American Heart Association, and the North American Association for the Study of Obesity. She has been an invited speaker at numerous workshops and other professional meetings.

FERGUS M. CLYDESDALE, Ph.D., is a distinguished professor and chair of the Department of Food Science and Nutrition at the University of Massachusetts-Amherst. His current research interests include physical-chemical changes in food processing, mineral-fiber interactions in foods, and technological optimization of physiological and functional properties and color-sensory interactions in foods. He receives research support from the U.S. Department of Agriculture. Dr. Clydesdale has served on numerous committees, including the Keystone National Policy Dialogue on Food, Nutrition, and Health; the Food and Drug Administration Food Advisory Committee; and the Institute of Medicine's Food and Nutrition Board (FNB); and is past chair of the FNB Food Forum. Dr. Clydesdale is a fellow of the Institute of Food Technologists (IFT) and the American College of Nutrition. He is the recipient of many distinguished awards, including IFT's highest honor, the Nicholas Appert Award; the University of Massachusetts Distinguished Teaching Award; and the Center for Applied Science Technology's Charles A. Black Award for scientific communication.

JEANNE P. GOLDBERG, Ph.D., R.D., is a professor of nutrition and director of the Center on Nutrition Communication and the Graduate Program in Nutrition Communication at the Tufts University Friedman School of Nutrition Science and Policy. Her research interests include communications strategies, health promotion, theory-based program interventions, mass media, and effective nutrition communication. Dr. Goldberg served as principal investigator on the study that led to the selection of the Food Guide Pyramid by the U.S. Department of Agriculture and the U.S. Department of

Health and Human Services. She is currently the coprincipal investigator on a 5-year program intervention that promotes healthy lifestyles in early elementary school children in diverse communities, with support from the National Institute of Child Health and Human Development. She is also coinvestigator on a 3-year intervention to prevent obesity in elementary school children with support from the Centers for Disease Control and Prevention. Dr. Goldberg is a well-known consultant to the food industry and government on consumer issues. She receives some research support from Kraft, Ross Laboratories, Novartis Foundation, National Cattlemen's Beef Association, and the Centers for Disease Control and Prevention for communication/website related projects. She served as a member of the Food and Drug Administration Food Advisory Committee from 1992 to 1996, is a trustee of the International Food Information Council Foundation, and is a member of the Advisory Board to the National Institute of Diabetes and Digestive and Kidney Disorders Weight Information Network. For over 20 years she coauthored a biweekly newspaper column on nutrition, nationally syndicated by the Washington Post Writer's Group. She also coauthored Dr. Jean Mayer's *Diet and Nutrition Guide*. Dr. Goldberg received her Ph.D. from Tufts University.

PENNY M. KRIS-ETHERTON, Ph.D., R.D., is distinguished professor of nutrition and ADA Plan V program director at the Pennsylvania State University. Her expertise is in the areas of diet and coronary heart disease risk factors and the nutritional regulation of lipoprotein and cholesterol metabolism. Dr. Kris-Etherton was a member of the Food and Nutrition Board Panel on Dietary Reference Intakes for Macronutrients. She is also a member of the American Dietetic Association (ADA); the American Society for Nutritional Sciences, where she serves as treasurer-elect; and the Society for Nutrition Education. She has served as the ADA representative to WOMENHEART and to the Nutrition Committee of the American Heart Association. Dr. Kris-Etherton is a recipient of the Lederle Award for Human Nutrition Research from the American Society for Nutritional Sciences and the Foundation Award for Excellence in Research from ADA. She is also the recipient of many substantial research support grants.

JEROLD R. MANDE, M.P.H., is associate director for policy at the Yale Cancer Center. Prior to that he was director of policy programs at Yale University School of Medicine. He has also served as senior vice president for Strategy, Health Dialog, Inc. Between 1991 and

2000, Mr. Mande served in several executive branch senior positions, including Deputy Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor; senior adviser in the Office of Science and Technology Policy, Executive Office of the President; senior adviser and executive assistant to the Commissioner of the Food and Drug Administration (FDA); and acting associate commissioner for legislative affairs at FDA. Prior to that he was the health and environment legislative assistant to Representative and then Senator Al Gore. Mr. Mande has received a number of awards for his work, including the Presidential Award for Design Excellence, in recognition of his lead role in designing the Nutrition Facts food label; the American Heart Association's National Public Affairs Special Recognition Award for his work on FDA's tobacco rule; and the FDA Commissioner's Special Citation for his work on priority initiatives, including the food label, food safety, and the tobacco rule. Mr. Mande was a founding steering committee member of the National Dialogue on Cancer and cochaired its Leadership Forum on Obesity. Mr. Mande received his M.P.H. in nutrition and epidemiology from the University of North Carolina at Chapel Hill.

GEORGE P. McCABE, Ph.D., is a professor of statistics and head of statistical consulting in the Department of Statistics at Purdue University. His current research interests include applied statistics (most recently related to vitamin A and iron nutriture), statistical computing, and statistics and the law. He is a fellow of the American Statistical Association and a member of the Institute of Mathematical Statistics, the American Society for Quality, the New York Academy of Sciences, and the American Association for the Advancement of Science. He is the coauthor of a widely used introductory statistical text and over 125 publications, ranging from statistical theory to a meta analysis comparing daily and weekly iron supplementation.

FRANCES H. SELIGSON, Ph.D., R.D., is a consultant on food and nutrition issues and also serves as an adjunct associate professor with the Department of Nutritional Sciences, the Pennsylvania State University. She recently retired as associate director, Nutrition, at Hershey Foods Corporation. During her tenure at Hershey Foods, she also held positions of senior manager, Nutrition and Food Safety; manager, Nutrition and Food Safety; and manager, Nutrition Affairs. She earlier worked for the Procter and Gamble Company and was an assistant professor of nutrition at the University of North Carolina, Chapel Hill. Dr. Seligson's professional memberships include the American Society for Nutritional Sciences and the

American Dietetic Association. She has also held leadership positions on many committees and activities at such associations as the American Society for Nutritional Sciences, the International Food Information Council, the International Life Sciences Institute, and the National Food Processors Association. Dr. Seligson has published extensively in the areas of nutrition and food consumption. She is currently a consultant on scientific issues to Hershey Foods, and as such represents Hershey Foods on International Life Sciences Institute technical committees on dietary lipids, carbohydrates, energy, and life styles and weight management. She received her Ph.D. from the University of California, Berkeley.

VALERIE TARASUK, Ph.D., is an associate professor of the Faculty of Medicine at the University of Toronto's Department of Nutrition Sciences and Public Health Sciences. Her primary research interests are in domestic food insecurity and hunger and in dietary assessment. Her specialties within these areas are in social and economic determinates of health and nutrition, population-level indicators of risk, evaluation of public policies in response to food insecurity, and the statistical analysis of dietary intake data at the individual and population levels. In 2003 she received funding from the Canadian Institute of Health Research, the Nova Scotia Health Research Foundation, and the Dairy Farmers of Canada. Dr. Tarasuk has served on a number of committees and advisory groups, including Health Canada's Expert Advisory Committee on Dietary Reference Intakes, the Nutrition Expert Advisory Group of the Canadian Community Health Survey, the External Advisory Panel for Food Directorate Review of Policies on the Addition of Vitamins and Minerals to Foods, and the Expert Scientific Workshop to Evaluate the Integrated National Food and Nutrition Survey. She chaired the Data Review Panels for the Prince Edward Island and Saskatchewan Nutrition Surveys. Dr. Tarasuk was a member of the Food and Nutrition Board Subcommittee on Interpretation and Uses of Dietary Reference Intakes.

SUSAN WHITING, Ph.D., is a professor of nutrition at the College of Pharmacy and Nutrition, University of Saskatchewan. She taught nutrition at Mount Saint Vincent University in Halifax prior to moving to the University of Saskatchewan, where she has taught in the Nutrition and Dietetics Program for 14 years. Dr. Whiting's areas of expertise involve the safety and effectiveness of calcium supplements, the role of nutrition in the prevention and treatment of osteoporosis, how nutrition affects bone development in children

and young adults, dietary assessment methodology, and food policy with emphasis on socioeconomic factors and agricultural biotechnology. She receives research support from the Canadian Institutes of Health Research, as well as from the private recipes grant-in-aid, Bioriginal Foods Inc., and the Dairy Farmers of Canada. She is a member of the Canadian Society for Nutritional Sciences and is serving as its president from 2002 to 2004. She is also a member of the American Society for Nutritional Sciences. Dr. Whiting holds membership in several other professional organizations, including the Dietitians of Canada and the American Society for Bone and Mineral Research.

B

Selected Illustrative Calculations Using a Population-Weighted Approach

The tables included in this appendix are not recommended values for either the U.S. or the Canadian population. They were developed using the formulas and methodology described in Chapter 5 to illustrate how a population-weighted approach could be applied to generating Daily Values. The development of actual numerical values would necessitate careful discussion and decisions regarding the selection of the best representative numbers to use for each variable in the formulas. In addition, decisions regarding such factors as numerical rounding and certain aspects of the calculations would need to be made. The population base chosen for these examples is indicated within each table. For details of other variables see the methodological description in Chapter 5.

TABLE B-1 Illustrative Calculations of Population-Weighted Estimated Average Requirements (EARs) for Persons 4 Years of Age and Older Using 2005 U.S. Population Figures and of the Highest EAR for Each Nutrient (Nonweighted)

Nutrient[a]	Median Weighted EAR	Percent Within 20%[b]	Percent Within 30%[c]	Highest EAR[d]	Percent Within 20%[e]	Percent Within 30%[f]
Vitamin A (μg RAE)	529	54	72	630	51	71
Vitamin C (mg)	63	65	79	75	60	80
Vitamin E (mg α-tocopherol)	12	83	91	12	84	91
Thiamin (mg)	0.9	80	90	1.0	78	89
Riboflavin (mg)	1.0	73	88	1.1	67	87
Niacin (mg)	11	70	86	12	71	86
Vitamin B_6 (mg)	1.1	69	83	1.4	51	77
Folate (μg DFE)	314	84	92	330	84	91
Vitamin B_{12} (μg)	2.0	83	91	2.0	84	91
Copper (μg)	684	84	92	700	84	91
Iodine (μg)	93	85	95	95	85	94
Iron (mg)	6.1	59	77	8.1	39	64
Magnesium (mg)	286	60	79	350	53	75
Molybdenum (μg)	33	84	92	34	84	91
Phosphorus (mg)	588	75	81	1,055	14	15
Selenium (μg)	44	84	92	45	85	92
Zinc (mg)	7.5	61	79	9.4	48	75

NOTE: Population subgroup proportions for this table were computed using the U.S. Census Bureau middle series of the national population projections (Population Projections Program, 2000). The source data, which give the age distribution for each age and gender, were aggregated in concordance with the Dietary Reference Intakes age and gender categories.

[a] RAE = retinol activity equivalents, DFE = dietary folate equivalents.

[b] Estimated percentage of the population with a requirement within 20% of the population-weighted EAR.

[c] Estimated proportion of the population with a requirement within 30% of the population-weighted EAR.

[d] Excludes EARs for pregnant and lactating women.

[e] Estimated proportion of the population with a requirement within 20% of the highest EAR.

[f] Estimated proportion of the population with a requirement within 30% of the highest EAR.

TABLE B-2 Illustrative Calculations of Population-Weighted Estimated Average Requirements (EARs) for Persons 4 Years of Age and Older Using 2006 Canadian Population Figures and of the Highest EAR for Each Nutrient (Nonweighted)

Nutrient[a]	Median Weighted EAR	Percent Within 20%[b]	Percent Within 30%[c]	Highest EAR[d]	Percent Within 20%[e]	Percent Within 30%[f]
Vitamin A (μg RAE)	533	55	73	630	52	72
Vitamin C (mg)	64	67	82	75	61	82
Vitamin E (mg α-tocopherol)	12	85	92	12	85	92
Thiamin (mg)	0.9	81	92	1.0	80	90
Riboflavin (mg)	1.0	75	90	1.1	68	88
Niacin (mg)	11	72	87	12	72	87
Vitamin B_6 (mg)	1.1	70	85	1.4	53	79
Folate (μg DFE)	315	86	93	330	85	92
Vitamin B_{12} (μg)	2.0	85	92	2.0	85	92
Copper (μg)	686	86	93	700	86	93
Iodine (μg)	93	86	96	95	86	95
Iron (mg)	6.1	61	78	8.1	38	63
Magnesium (mg)	288	62	81	350	54	77
Molybdenum (μg)	33	85	93	34	86	93
Phosphorus (mg)	587	77	83	1,055	13	14
Selenium (μg)	44	86	93	45	86	93
Zinc (mg)	7.5	62	80	9.4	49	76

NOTE: Population subgroup proportions for this table were computed using the Statistics Canada national population projections (Statistics Canada, 2003). The source data are aggregated; group definitions differ slightly from the EAR guidelines.

[a] RAE = retinol activity equivalents, DFE = dietary folate equivalents.

[b] Estimated proportion of the population with a requirement within 20% of the population-weighted EAR.

[c] Estimated proportion of the population with a requirement within 30% of the population-weighted EAR.

[d] Excludes EARs for pregnant and lactating women.

[e] Estimated proportion of the population with a requirement within 20% of the highest EAR.

[f] Estimated proportion of the population with a requirement within 30% of the highest EAR.

TABLE B-3 Illustrative Calculations of Population-Weighted Adequate Intakes (AIs) Based on U.S. Census Bureau Data from 2001 and 2005

Nutrient	Toddlers[a]	General Population[b]	Pregnant Women[c]	Lactating Women[d]
Biotin (µg)	8	28	30	35
Calcium (mg)	500	1,091	1,011	1,011
Choline (mg)	200	460	450	550
Chromium (µg)	11	27	30	45
Fluoride (mg)	0.7	3	3	3
Linoleic Acid (g)	7	13	13	13
α-Linoleic Acid (g)	0.7	1.3	1.4	1.3
Manganese (mg)	1.2	2.0	2.0	2.6
Pantothenic acid (mg)	2.0	5	6	7
Vitamin D (µg)	5	7	5	5
Vitamin K (µg)	30	95	89	89

[a] AIs for toddlers ages 1–3 y in the United States (IOM, 2002a). No weighting was done for this group.
[b] Based on U.S. Census Bureau estimates of the general population of the United States in 2005 ages 4 y and above (Population Projections Program, 2000).
[c] Based on U.S. Census Bureau estimates of the population of pregnant women in the United States in 2001 (Population Projections Program, 2000).
[d] In the absence of specific data on the ages of lactating women, these values are based on National Vital Statistics System estimates of the population of pregnant women in the United States in 2001 (Ventura et al., 2003).

TABLE B-4 Acceptable Macronutrient Distribution Ranges (AMDRs) for the General Population 4 Years of Age and Older

	Range (% of energy)		
Macronutrient	Low	Average	High
Fat[a]	21	28	35
Linoleic acid	5.0	7.5	10.0
α-Linolenic acid	0.6	0.9	1.2
Carbohydrate[b]	45	55	65

[a] The AMDR for total fat is comprised of population-weighted values that were computed based on U.S. Census Bureau estimates of the U.S. population in 2005 (Population Projections Program, 2000).
[b] No weighting was done for this group.

TABLE B-5 Illustrative Calculations of Population-Weighted Estimated Average Requirements (EARs) and of the Highest EAR for Nutrients for Pregnant Women in the United States

Nutrient[a]	Median Weighted EAR	Percent Within 20%[b]	Percent Within 30%[c]	Highest EAR	Percent Within 20%[d]	Percent Within 30%[e]
Vitamin A (μg RAE)	549	68	87	550	68	87
Vitamin C (mg)	70	95	99.7	70	95	99.7
Vitamin E (mg α-tocopherol)	12	95	99.7	12	95	99.7
Thiamin (mg)	1.2	95	99.7	1.2	95	99.7
Riboflavin (mg)	1.2	95	99.7	1.2	95	99.7
Niacin (mg)	14	82	95	14	82	95
Vitamin B_6 (mg)	1.6	95	100	1.6	95	100
Folate (μg DFE)	520	95	99.7	520	95	99.7
Vitamin B_{12} (μg)	2.2	95	99.7	2.2	95	99.7
Copper (μg)	799	95	99.7	800	95	99.7
Iodine (μg)	160	95	99.7	160	95	99.7
Iron (mg)	22	95	99.7	23	94	99.6
Magnesium (mg)	295	94	99	335	81	98
Molybdenum (μg)	40	95	99.7	40	95	99.7
Phosphorus (mg)	583	92	96	1,055	3.6	4.1
Selenium (μg)	49	95	99.7	49	95	99.7
Zinc (mg)	9.5	95	99.6	10.5	88	99

NOTE: Computations are based on 2001 estimates (Ventura et al., 2003) of the number of pregnant women comprised of three age groups: 18 y, 19–30 y, 31–50 y.

[a] RAE = retinol activity equivalents, DFE = dietary folate equivalents.

[b] Estimated proportion of the population with a requirement within 20% of the population-weighted EAR.

[c] Estimated proportion of the population with a requirement within 30% of the population-weighted EAR.

[d] Estimated proportion of the population with a requirement within 20% of the highest EAR.

[e] Estimated proportion of the population with a requirement within 30% of the highest EAR.

TABLE B-6 Illustrative Calculations of Population-Weighted Estimated Average Requirements (EARs) and of Highest EAR for Nutrients for Lactating Women in the United States

Nutrient[a]	Median Weighted EAR	Percent Within 20%[b]	Percent Within 30%[c]	Highest EAR	Percent Within 20%[d]	Percent Within 30%[e]
Vitamin A (µg RAE)	899	68	87	900	68	87
Vitamin C (mg)	100	95	99.7	100	95	99.7
Vitamin E (mg α-tocopherol)	16	95	99.7	16	95	99.7
Thiamin (mg)	1.2	95	99.7	1.2	95	99.7
Riboflavin (mg)	1.3	95	99.7	1.3	95	99.7
Niacin (mg)	13	82	95	13	82	95
Vitamin B_6 (mg)	1.7	95	100	1.7	95	100
Folate (µg DFE)	450	95	99.7	450	95	99.7
Vitamin B_{12} (µg)	2.4	95	99.7	2.4	95	99.7
Copper (µg)	999	95	99.7	1,000	95	99.7
Iodine (µg)	209	95	99.7	209	95	99.7
Iron (mg)	6.5	95	99.7	7.0	92	99
Magnesium (mg)	260	94	99	300	77	97
Molybdenum (µg)	36	95	99.7	36	95	99.7
Phosphorus (mg)	583	92	96	1,055	3.6	4.1
Selenium (µg)	59	95	99.7	59	95	99.7
Zinc (mg)	10.4	95	99.7	10.9	94	99.6

NOTE: Computations are based on approximation. Proportion of lactating women for each age group was assumed to be the same as the proportion of pregnant women (proportion of births stratified by mother's age in three age groups: 18 y, 19–30 y, 31–50 y) using data from Ventura and colleagues (2003).

[a] RAE = retinol activity equivalents, DFE = dietary folate equivalents.

[b] Estimated proportion of the population with a requirement within 20% of the population-weighted EAR.

[c] Estimated proportion of the population with a requirement within 30% of the population-weighted EAR.

[d] Estimated proportion of the population with a requirement within 20% of the highest EAR.

[e] Estimated proportion of the population with a requirement within 30% of the highest EAR.

C
Reference Tables

TABLE C-1 Dietary Reference Intakes: Estimated Average Requirements

Life Stage Group	Vitamin A (μg/d)[a]	Vitamin C (mg/d)	Vitamin E (mg/d)[b]	Thiamin (mg/d)	Riboflavin (mg/d)	Niacin (mg/d)[c]	Vitamin B_6 (mg/d)	Folate (μg/d)[d]
Infants								
7–12 mo								
Children								
1–3 y	210	13	5	0.4	0.4	5	0.4	120
4–8 y	275	22	6	0.5	0.5	6	0.5	160
Males								
9–13 y	445	39	9	0.7	0.8	9	0.8	250
14–18 y	630	63	12	1.0	1.1	12	1.1	330
19–30 y	625	75	12	1.0	1.1	12	1.1	320
31–50 y	625	75	12	1.0	1.1	12	1.1	320
51–70 y	625	75	12	1.0	1.1	12	1.4	320
> 70 y	625	75	12	1.0	1.1	12	1.4	320
Females								
9–13 y	420	39	9	0.7	0.8	9	0.8	250
14–18 y	485	56	12	0.9	0.9	11	1.0	330
19–30 y	500	60	12	0.9	0.9	11	1.1	320
31–50 y	500	60	12	0.9	0.9	11	1.1	320
51–70 y	500	60	12	0.9	0.9	11	1.3	320
> 70 y	500	60	12	0.9	0.9	11	1.3	320
Pregnancy								
14–18 y	530	66	12	1.2	1.2	14	1.6	520
19–30 y	550	70	12	1.2	1.2	14	1.6	520
31–50 y	550	70	12	1.2	1.2	14	1.6	520
Lactation								
14–18 y	880	96	16	1.2	1.3	13	1.7	450
19–30 y	900	100	16	1.2	1.3	13	1.7	450
31–50 y	900	100	16	1.2	1.3	13	1.7	450

NOTE: This table presents EARs, which serve two purposes: for assessing adequacy of population intakes and as the basis for calculating Recommended Dietary Allowances (RDAs) for individuals for those nutrients. EARs have not been established for vitamin D, vitamin K, pantothenic acid, biotin, choline, calcium, chromium, fluoride, manganese, or other nutrients not yet evaluated via the DRI process.

[a] 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.

[b] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of

Vitamin B_{12} (µg/d)	Copper (µg/d)	Iodine (µg/d)	Iron (mg/d)	Magnesium (mg/d)	Molybdenum (µg/d)	Phosphorus (mg/d)	Selenium (µg/d)	Zinc (mg/d)
			6.9					2.5
0.7	260	65	3.0	65	13	380	17	2.5
1.0	340	65	4.1	110	17	405	23	4.0
1.5	540	73	5.9	200	26	1,055	35	7.0
2.0	685	95	7.7	340	33	1,055	45	8.5
2.0	700	95	6	330	34	580	45	9.4
2.0	700	95	6	350	34	580	45	9.4
2.0	700	95	6	350	34	580	45	9.4
2.0	700	95	6	350	34	580	45	9.4
1.5	540	73	5.7	200	26	1,055	35	7.0
2.0	685	95	7.9	300	33	1,055	45	7.3
2.0	700	95	8.1	255	34	580	45	6.8
2.0	700	95	8.1	265	34	580	45	6.8
2.0	700	95	5	265	34	580	45	6.8
2.0	700	95	5	265	34	580	45	6.8
2.2	785	160	23	335	40	1,055	49	10.5
2.2	800	160	22	290	40	580	49	9.5
2.2	800	160	22	300	40	580	49	9.5
2.4	985	209	7	300	35	1,055	59	10.9
2.4	1,000	209	6.5	255	36	580	59	10.4
2.4	1,000	209	6.5	265	36	580	59	10.4

α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of 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.

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

[d] 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.

SOURCE: IOM (1997, 1998, 2000b, 2001).

TABLE C-2 Dietary Reference Intakes: Recommended Intakes for Individuals, Vitamins

Life Stage Group	Vitamin A (μg/d)[a]	Vitamin C (mg/d)	Vitamin D (μg/d)[b,c]	Vitamin E (mg/d)[d]	Vitamin K (μg/d)	Thiamin (mg/d)
Infants						
0–6 mo	400*	40*	5*	4*	2.0*	0.2*
7–12 mo	500*	50*	5*	5*	2.5*	0.3*
Children						
1–3 y	**300**	**15**	5*	**6**	30*	**0.5**
4–8 y	**400**	**25**	5*	**7**	55*	**0.6**
Males						
9–13 y	**600**	**45**	5*	**11**	60*	**0.9**
14–18 y	**900**	**75**	5*	**15**	75*	**1.2**
19–30 y	**900**	**90**	5*	**15**	120*	**1.2**
31–50 y	**900**	**90**	5*	**15**	120*	**1.2**
51–70 y	**900**	**90**	10*	**15**	120*	**1.2**
> 70 y	**900**	**90**	15*	**15**	120*	**1.2**
Females						
9–13 y	**600**	**45**	5*	**11**	60*	**0.9**
14–18 y	**700**	**65**	5*	**15**	75*	**1.0**
19–30 y	**700**	**75**	5*	**15**	90*	**1.1**
31–50 y	**700**	**75**	5*	**15**	90*	**1.1**
51–70 y	**700**	**75**	10*	**15**	90*	**1.1**
> 70 y	**700**	**75**	15*	**15**	90*	**1.1**
Pregnancy						
14–18 y	**750**	**80**	5*	**15**	75*	**1.4**
19–30 y	**770**	**85**	5*	**15**	90*	**1.4**
31–50 y	**770**	**85**	5*	**15**	90*	**1.4**
Lactation						
14–18 y	**1,200**	**115**	5*	**19**	75*	**1.4**
19–30 y	**1,300**	**120**	5*	**19**	90*	**1.4**
31–50 y	**1,300**	**120**	5*	**19**	90*	**1.4**

NOTE: This table (taken from the DRI reports, see www.nap.edu) presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevents being able to specify with confidence the percentage of individuals covered by this intake.

[a] As retinol activity equivalents (RAEs). 1 RAE = 1 μg retinol, 12 μg β-carotene, 24 μg α-carotene, or 24 μg β-cryptoxanthin. To calculate RAEs from REs of provitamin A carotenoids in foods, divide the REs by 2. For preformed vitamin A in foods or supplements and for provitamin A carotenoids in supplements, 1 RE = 1 RAE.
[b] As calciferol. 1 μg calciferol = 40 IU vitamin D.
[c] In the absence of adequate exposure to sunlight.
[d] As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of

Riboflavin (mg/d)	Niacin (mg/d)[e]	Vitamin B_6 (mg/d)	Folate (μg/d)[f]	Vitamin B_{12} (μg/d)	Pantothenic Acid (mg/d)	Biotin (μg/d)	Choline (mg/d)[g]
0.3*	2*	0.1*	65*	0.4*	1.7*	5*	125*
0.4*	4*	0.3*	80*	0.5*	1.8*	6*	150*
0.5	**6**	**0.5**	**150**	**0.9**	2*	8*	200*
0.6	**8**	**0.6**	**200**	**1.2**	3*	12*	250*
0.9	**12**	**1.0**	**300**	**1.8**	4*	20*	375*
1.3	**16**	**1.3**	**400**	**2.4**	5*	25*	550*
1.3	**16**	**1.3**	**400**	**2.4**	5*	30*	550*
1.3	**16**	**1.3**	**400**	**2.4**	5*	30*	550*
1.3	**16**	**1.7**	**400**	**2.4**[h]	5*	30*	550*
1.3	**16**	**1.7**	**400**	**2.4**[h]	5*	30*	550*
0.9	**12**	**1.0**	**300**	**1.8**	4*	20*	375*
1.0	**14**	**1.2**	**400**[i]	**2.4**	5*	25*	400*
1.1	**14**	**1.3**	**400**[i]	**2.4**	5*	30*	425*
1.1	**14**	**1.3**	**400**[i]	**2.4**	5*	30*	425*
1.1	**14**	**1.5**	**400**	**2.4**[h]	5*	30*	425*
1.1	**14**	**1.5**	**400**	**2.4**[h]	5*	30*	425*
1.4	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
1.4	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
1.4	**18**	**1.9**	**600**[j]	**2.6**	6*	30*	450*
1.6	**17**	**2.0**	**500**	**2.8**	7*	35*	550*
1.6	**17**	**2.0**	**500**	**2.8**	7*	35*	550*
1.6	**17**	**2.0**	**500**	**2.8**	7*	35*	550*

α-tocopherol that occurs naturally in foods, and the *2R*-stereoisomeric forms of 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.

[e] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan; 0–6 months = preformed niacin (not NE).

[f] 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.

[g] Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of the life cycle, and it may be that the choline requirement can be met by endogenous synthesis at some of these stages.

Table C-2 footnotes continue

TABLE C-3 Dietary Reference Intakes: Recommended Intakes for Individuals, Elements

Life Stage Group	Calcium (mg/d)	Chromium (µg/d)	Copper (µg/d)	Fluoride (mg/d)	Iodine (µg/d)	Iron (mg/d)
Infants						
0–6 mo	210*	0.2*	200*	0.01*	110*	0.27*
7–12 mo	270*	5.5*	220*	0.5*	130*	**11**
Children						
1–3 y	500*	11*	**340**	0.7*	**90**	**7**
4–8 y	800*	15*	**440**	1*	**90**	**10**
Males						
9–13 y	1,300*	25*	**700**	2*	**120**	**8**
14–18 y	1,300*	35*	**890**	3*	**150**	**11**
19–30 y	1,000*	35*	**900**	4*	**150**	**8**
31–50 y	1,000*	35*	**900**	4*	**150**	**8**
51–70 y	1,200*	30*	**900**	4*	**150**	**8**
> 70 y	1,200*	30*	**900**	4*	**150**	**8**
Females						
9–13 y	1,300*	21*	**700**	2*	**120**	**8**
14–18 y	1,300*	24*	**890**	3*	**150**	**15**
19–30 y	1,000*	25*	**900**	3*	**150**	**18**
31–50 y	1,000*	25*	**900**	3*	**150**	**18**
51–70 y	1,200*	20*	**900**	3*	**150**	**8**
> 70 y	1,200*	20*	**900**	3*	**150**	**8**
Pregnancy						
14–18 y	1,300*	29*	**1,000**	3*	**220**	**27**
19–30 y	1,000*	30*	**1,000**	3*	**220**	**27**
31–50 y	1,000*	30*	**1,000**	3*	**220**	**27**
Lactation						
14–18 y	1,300*	44*	**1,300**	3*	**290**	**10**
19–30 y	1,000*	45*	**1,300**	3*	**290**	**9**
31–50 y	1,000*	45*	**1,300**	3*	**290**	**9**

NOTE: This table presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy infants fed human milk, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover

Table C-2 footnotes continued

[h] Because 10 to 30 percent of older people may malabsorb food-bound B_{12}, it is advisable for those older than 50 years to meet their RDA mainly by consuming foods fortified with B_{12} or a supplement containing B_{12}.

[i] In view of evidence linking folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 µg

Magnesium (mg/d)	Manganese (mg/d)	Molybdenum (µg/d)	Phosphorus (mg/d)	Selenium (µg/d)	Zinc (mg/d)
30*	0.003*	2*	100*	15*	2*
75*	0.6*	3*	275*	20*	**3**
80	1.2*	**17**	**460**	**20**	**3**
130	1.5*	**22**	**500**	**30**	**5**
240	1.9*	**34**	**1,250**	**40**	**8**
410	2.2*	**43**	**1,250**	**55**	**11**
400	2.3*	**45**	**700**	**55**	**11**
420	2.3*	**45**	**700**	**55**	**11**
420	2.3*	**45**	**700**	**55**	**11**
420	2.3*	**45**	**700**	**55**	**11**
240	1.6*	**34**	**1,250**	**40**	**8**
360	1.6*	**43**	**1,250**	**55**	**9**
310	1.8*	**45**	**700**	**55**	**8**
320	1.8*	**45**	**700**	**55**	**8**
320	1.8*	**45**	**700**	**55**	**8**
320	1.8*	**45**	**700**	**55**	**8**
400	2.0*	**50**	**1,250**	**60**	**12**
350	2.0*	**50**	**700**	**60**	**11**
360	2.0*	**50**	**700**	**60**	**11**
360	2.6*	**50**	**1,250**	**70**	**13**
310	2.6*	**50**	**700**	**70**	**12**
320	2.6*	**50**	**700**	**70**	**12**

needs of all individuals in the group, but lack of data or uncertainty in the data prevents being able to specify with confidence the percentage of individuals covered by this intake.
SOURCE: IOM (1997, 2000b, 2001).

from supplements or fortified foods in addition to intake of food folate from a varied diet.
[j] It is assumed that women will continue consuming 400 µg from supplements or fortified food until their pregnancy is confirmed and they enter prenatal care, which ordinarily occurs after the end of the periconceptional period—the critical time for formation of the neural tube.
SOURCE: IOM (1997, 1998, 2000b, 2001).

TABLE C-4 Dietary Reference Intakes: Recommended Intakes for Individuals, Macronutrients

Life Stage Group	Carbohydrate (g/d)	Total Fiber (g/d)	Fat (g/d)	Linoleic Acid (g/d)	α-Linolenic Acid (g/d)	Protein[a] (g/d)
Infants						
0–6 mo	60*	ND	31*	4.4*	0.5*	9.1*
7–12 mo	95*	ND	30*	4.6*	0.5*	**13.5**
Children						
1–3 y	**130**	19*	ND	7*	0.7*	**13**
4–8 y	**130**	25*	ND	10*	0.9*	**19**
Males						
9–13 y	**130**	26*	ND	12*	1.2*	**34**
14–18 y	**130**	38*	ND	16*	1.6*	**52**
19–30 y	**130**	38*	ND	17*	1.6*	**56**
31–50 y	**130**	38*	ND	17*	1.6*	**56**
51–70 y	**130**	30*	ND	14*	1.6*	**56**
> 70 y	**130**	30*	ND	14*	1.6*	**56**
Females						
9–13 y	**130**	31*	ND	10*	1.0*	**34**
14–18 y	**130**	26*	ND	11*	1.1*	**46**
19–30 y	**130**	25*	ND	12*	1.1*	**46**
31–50 y	**130**	25*	ND	12*	1.1*	**46**
51–70 y	**130**	21*	ND	11*	1.1*	**46**
> 70 y	**130**	21*	ND	11*	1.1*	**46**
Pregnancy						
14–18 y	**175**	28*	ND	13*	1.4*	**71**
19–30 y	**175**	28*	ND	13*	1.4*	**71**
31–50 y	**175**	28*	ND	13*	1.4*	**71**
Lactation						
14–18 y	**210**	29*	ND	13*	1.3*	**71**
19–30 y	**210**	29*	ND	13*	1.3*	**71**
31–50 y	**210**	29*	ND	13*	1.3*	**71**

NOTE: This table presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may both be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy infants fed human milk, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevents being able to specify with confidence the percentage of individuals covered by this intake.

[a] Based on 0.8 g protein/kg body weight for reference body weight.

SOURCE: IOM (2002a).

TABLE C-5 Acceptable Macronutrient Distribution Ranges

	Range (% of energy)		
Macronutrient	Children, 1–3 y	Children, 4–18 y	Adults
Fat	30–40	25–35	20–35
n-6 polyunsaturated fats (linoleic acid)	5–10	5–10	5–10
n-3 polyunsaturated fats[a] (α-linolenic acid)	0.6–1.2	0.6–1.2	0.6–1.2
Carbohydrate	45–65	45–65	45–65
Protein	5–20	10–30	10–35

[a] Approximately 10% of the total can come from longer-chain *n*-3 fatty acids.
SOURCE: IOM (2002a).

TABLE C-6 Dietary Reference Intakes: Tolerable Upper Intake Levels (UL[a]), Vitamins

Life Stage Group	Vitamin A (μg/d)[b]	Vitamin C (mg/d)	Vitamin D (μg/d)	Vitamin E (mg/d)[c,d]	Vitamin K	Thiamin
Infants						
0–6 mo	600	ND[f]	25	ND	ND	ND
7–12 mo	600	ND	25	ND	ND	ND
Children						
1–3 y	600	400	50	200	ND	ND
4–8 y	900	650	50	300	ND	ND
Males, Females						
9–13 y	1,700	1,200	50	600	ND	ND
14–18 y	2,800	1,800	50	800	ND	ND
19–70 y	3,000	2,000	50	1,000	ND	ND
> 70 y	3,000	2,000	50	1,000	ND	ND
Pregnancy						
14–18 y	2,800	1,800	50	800	ND	ND
19–50 y	3,000	2,000	50	1,000	ND	ND
Lactation						
14–18 y	2,800	1,800	50	800	ND	ND
19–50 y	3,000	2,000	50	1,000	ND	ND

[a] UL = The maximum level of daily nutrient intake that is likely to pose no risk of adverse effects. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for vitamin K, thiamin, riboflavin, vitamin B_{12}, pantothenic acid, biotin, or carotenoids. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes.

[b] As preformed vitamin A only.

[c] As α-tocopherol; applies to any form of supplemental α-tocopherol.

Riboflavin	Niacin (mg/d)[d]	Vitamin B_6 (mg/d)	Folate (µg/d)[d]	Vitamin B_{12}	Pantothenic Acid	Biotin	Choline (g/d)	Carotenoids[e]
ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	10	30	300	ND	ND	ND	1.0	ND
ND	15	40	400	ND	ND	ND	1.0	ND
ND	20	60	600	ND	ND	ND	2.0	ND
ND	30	80	800	ND	ND	ND	3.0	ND
ND	35	100	1,000	ND	ND	ND	3.5	ND
ND	35	100	1,000	ND	ND	ND	3.5	ND
ND	30	80	800	ND	ND	ND	3.0	ND
ND	35	100	1,000	ND	ND	ND	3.5	ND
ND	30	80	800	ND	ND	ND	3.0	ND
ND	35	100	1,000	ND	ND	ND	3.5	ND

[d] The ULs for vitamin E, niacin, and folate apply to synthetic forms obtained from supplements, fortified foods, or a combination of the two.

[e] β-Carotene supplements are advised only to serve as a provitamin A source for individuals at risk of vitamin A deficiency.

[f] ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

SOURCE: IOM (1997, 1998, 2000b, 2001).

TABLE C-7 Dietary Reference Intakes: Tolerable Upper Intake Levels (UL[a]), Elements

Life Stage Group	Arsenic[b]	Boron (mg/d)	Calcium (g/d)	Chromium	Copper (µg/d)	Fluoride (mg/d)	Iodine (µg/d)	Iron (mg/d)
Infants								
0–6 mo	ND[f]	ND	ND	ND	ND	0.7	ND	40
7–12 mo	ND	ND	ND	ND	ND	0.9	ND	40
Children								
1–3 y	ND	3	2.5	ND	1,000	1.3	200	40
4–8 y	ND	6	2.5	ND	3,000	2.2	300	40
Males, Females								
9–13 y	ND	11	2.5	ND	5,000	10	600	40
14–18 y	ND	17	2.5	ND	8,000	10	900	45
19–70 y	ND	20	2.5	ND	10,000	10	1,100	45
> 70 y	ND	20	2.5	ND	10,000	10	1,100	45
Pregnancy								
14–18 y	ND	17	2.5	ND	8,000	10	900	45
19–50 y	ND	20	2.5	ND	10,000	10	1,100	45
Lactation								
14–18 y	ND	17	2.5	ND	8,000	10	900	45
19–50 y	ND	20	2.5	ND	10,000	10	1,100	45

[a] UL = The maximum level of daily nutrient intake that is likely to pose no risk of adverse effects. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for arsenic, chromium, and silicon. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes.

[b] Although the UL was not determined for arsenic, there is no justification for adding arsenic to food or supplements.

[c] The ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water.

[d] Although silicon has not been shown to cause adverse effects in humans, there is no

Magnesium (mg/d)[c]	Manganese (mg/d)	Molybdenum (µg/d)	Nickel (mg/d)	Phosphorus (g/d)	Selenium (µg/d)	Silicon[d]	Vanadium (mg/d)[e]	Zinc (mg/d)
ND	ND	ND	ND	ND	45	ND	ND	4
ND	ND	ND	ND	ND	60	ND	ND	5
65	2	300	0.2	3	90	ND	ND	7
110	3	600	0.3	3	150	ND	ND	12
350	6	1,100	0.6	4	280	ND	ND	23
350	9	1,700	1.0	4	400	ND	ND	34
350	11	2,000	1.0	4	400	ND	1.8	40
350	11	2,000	1.0	3	400	ND	1.8	40
350	9	1,700	1.0	3.5	400	ND	ND	34
350	11	2,000	1.0	3.5	400	ND	ND	40
350	9	1,700	1.0	4	400	ND	ND	34
350	11	2,000	1.0	4	400	ND	ND	40

justification for adding silicon to supplements.

[e] Although vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents.

[f] ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

SOURCE: IOM (1997, 2000b, 2001).

TABLE C-8 Additional Macronutrient Recommendations

Macronutrient	Recommendation
Dietary cholesterol	As low as possible while consuming a nutritionally adequate diet
Trans fatty acids	As low as possible while consuming a nutritionally adequate diet
Saturated fatty acids	As low as possible while consuming a nutritionally adequate diet
Added sugars	Limit to no more than 25% of total energy

SOURCE: IOM (2002a).

TABLE C-9 Reference Values for Nutrition Labeling, Based on a 2,000-Calorie Intake, for Adults and Children 4 or More Years of Age

Nutrient	Unit of Measure	Daily Value
Total fat	Grams (g)	65
Saturated fatty acids	Grams (g)	20
Cholesterol	Milligrams (mg)	300
Sodium	Milligrams (mg)	2,400
Potassium	Milligrams (mg)	3,500
Total carbohydrate	Grams (g)	300
Fiber	Grams (g)	25
Protein	Grams (g)	50
Vitamin A	International Unit (IU)	5,000
Vitamin C	Milligrams (mg)	60
Calcium	Milligrams (mg)	1,000
Iron	Milligrams (mg)	18
Vitamin D	International Unit (IU)	400
Vitamin E	International Unit (IU)	30
Vitamin K	Micrograms (µg)	80
Thiamin	Milligrams (mg)	1.5
Riboflavin	Milligrams (mg)	1.7
Niacin	Milligrams (mg)	20
Vitamin B_6	Milligrams (mg)	2.0
Folate	Micrograms (µg)	400
Vitamin B_{12}	Micrograms (µg)	6.0
Biotin	Micrograms (µg)	300
Pantothenic acid	Milligrams (mg)	10
Phosphorus	Milligrams (mg)	1,000
Iodine	Micrograms (µg)	150
Magnesium	Milligrams (mg)	400
Zinc	Milligrams (mg)	15
Selenium	Micrograms (µg)	70
Copper	Milligrams (mg)	2.0
Manganese	Milligrams (mg)	2.0
Chromium	Micrograms (µg)	120
Molybdenum	Micrograms (µg)	75
Chloride	Milligrams (mg)	3,400

NOTE: Based on reference caloric intake of 2,000 calories.
SOURCE: CFSAN (1999).

D

Workshop Programs

USE OF DIETARY REFERENCE INTAKES IN NUTRITION LABELING

Workshop Sponsored by

Committee on Use of Dietary Reference Intakes in Nutrition Labeling
Food and Nutrition Board, Institute of Medicine

Ida and Cecil Green Building, Room GR 104
2001 Wisconsin Ave., NW
Washington, DC

May 23, 2002

PROGRAM

8:30 am	**Welcome and Introduction** *Romy Gunter-Nathan/Linda Meyers,* Co-Study Directors *Irwin Rosenberg,* Committee Chair
8:40 am	**Historical Perspective on Nutrition Labeling and Daily Values in the United States** *Christine Taylor,* Food and Drug Administration
9:20 am	**Historical Perspective on Nutrition Labeling in Canada** *Margaret Cheney,* Health Canada
10:00 am	**Break**

10:15 am **Consumer Understanding of Nutrition Labels and Use of Daily Values**
Brenda Derby, Food and Drug Administration
Constance Geiger, Geiger and Associates
Susan Borra, International Food Information Council

12:00 pm **Lunch**

1:15 pm **Implications of Using Dietary Reference Intakes for Nutrition Labeling**:
(10 minute comments followed by questions from the committee)
Bonnie Liebman, Center for Science in the Public Interest
Leila Saldanha, Consumer Healthcare Products Association
Annette Dickinson, Council for Responsible Nutrition
Regina Hildwine, National Food Processors Association
Robert O. Earl, American Dietetic Association
Suzanne Harris, International Life Sciences Institute

3:00 pm **Break**

3:15 pm **Open Forum**
Interested individuals and organizations are invited to present their views during this part of the workshop. To be considered for a brief (5 minute) presentation to the panel, an abstract with references must be submitted to FNB no later than May 21, 2002. Interested parties should fax requests to 202-334-2316.

4:00 pm **Adjourn**

DIETARY REFERENCE INTAKES
AND DISCRETIONARY FORTIFICATION
Workshop Sponsored by
Committee on Use of Dietary Reference Intakes in Nutrition Labeling
Food and Nutrition Board, Institute of Medicine

National Academy of Sciences Building, Lecture Room
2101 Constitution Ave., NW
Washington, DC

November 21, 2002

PROGRAM

1:00 pm **Welcome and Introductions**
Irwin Rosenberg, Committee Chair

1:10 pm	**Tolerable Upper Intake Levels (ULs): Overview and Issues** *Ian Munro,* CANTOX Health Sciences International
1:30 pm	**Regulatory Perspectives on DRIs and Discretionary Fortification** *Robert Post,* U.S. Department of Agriculture *Christine Taylor,* Food and Drug Administration *Margaret Cheney,* Health Canada
2:30 pm	**Trends in Nutrient Intake and Status** *Alanna Moshfegh,* U.S. Department of Agriculture *Clifford L. Johnson,* Centers for Disease Control and Prevention
3:30 pm	**Break**
3:45 pm	**Application of DRIs in Discretionary Fortification** *Kathryn Wiemer,* General Mills Bell Institute of Health and Nutrition *Nancy Green,* Tropicana Products, Inc.
4:30 pm	**Open Forum** Interested individuals and organizations are invited to present their views during this part of the workshop. [Presenters were Robert O. Earl and Allison Kretser.]
5:30 pm	**Adjourn**

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