

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.

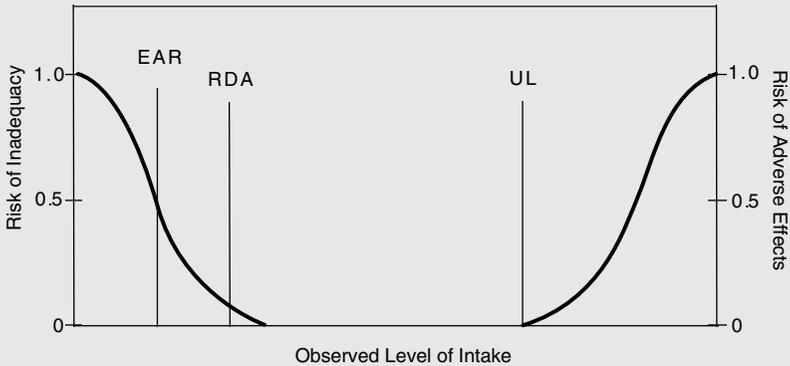
The current percent Daily Values (% DVs) that appear in the Nutrition Facts box in the United States are based in part on recommended reference values for nutrients from the 1968 Recommended Dietary Allowances (RDAs) (NRC, 1968). In Canada the nutrient information that appears on the label is based on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

¹An 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

^aIn 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

²Health 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

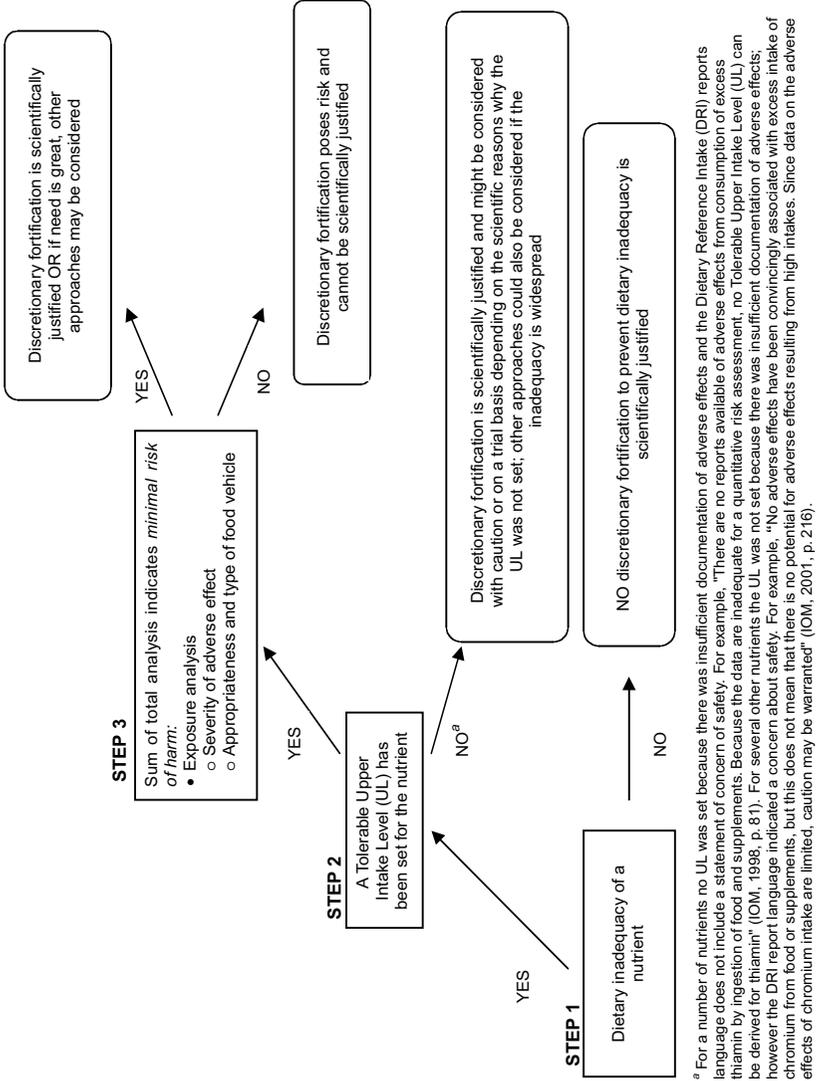


FIGURE ES-1 Flow diagram for decisions about discretionary food fortification.

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 long-standing 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.