

# 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	<i>Dietary Goals for the United States</i> <sup>a</sup>
1979	<i>Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention</i> <sup>b</sup>
1980	<i>Dietary Guidelines for Americans (First Edition)</i> <sup>c</sup>
1988	<i>The Surgeon General's Report on Nutrition and Health</i> <sup>d</sup>
1989	<i>Diet and Health: Implications for Reducing Chronic Disease Risk</i> <sup>e</sup>
1989	<i>Recommended Dietary Allowances (Tenth Edition)</i> <sup>f</sup>
1990	<i>Nutrition Labeling: Issues and Directions for the 1990s</i> <sup>g</sup>
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 <i>trans</i> fatty acids to the Nutrition Facts box, final rule

<sup>a</sup>Senate Select Committee on Nutrition and Human Needs (1977).

<sup>b</sup>DHEW (1979).

<sup>c</sup>USDA/DHEW (1980).

<sup>d</sup>DHHS (1988).

<sup>e</sup>NRC (1989a).

<sup>f</sup>NRC (1989b).

<sup>g</sup>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<sub>6</sub>, folic acid, vitamin B<sub>12</sub>, 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<sup>1</sup> 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

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<sup>1</sup>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

<b>Nutrition Facts</b>	
Serving Size 1 cup (228g)	
Servings Per Container 2	
<b>Amount Per Serving</b>	
<b>Calories</b> 260	Calories from Fat 120
<b>% Daily Value*</b>	
<b>Total Fat</b> 13g	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<i>Trans</i> Fat 2g	
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 660mg	<b>28%</b>
<b>Total Carbohydrate</b> 31g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein</b> 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<sup>2</sup> 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<sup>3</sup> on a food package is a statement of a scientifically demonstrated relationship between a food substance (defined by

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<sup>2</sup>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.

<sup>3</sup>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<sup>4</sup> 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<sup>5</sup> 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.<sup>6</sup> Proprietary blends may be listed by weight of the total blend,

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<sup>4</sup>Pearson v. Shalala 164 F.3d 650 (D.C. Cir. 1999).

<sup>5</sup>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)).

<sup>6</sup>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

<b>Supplement Facts</b>		
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 <sub>6</sub> (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B <sub>12</sub> (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).

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).<sup>7</sup>

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

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<sup>7</sup>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<sub>6</sub>, folacin, vitamin B<sub>12</sub>, 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

<b>Nutrition Facts</b>	
<b>Valeur nutritive</b>	
Per 125 mL (87 g) / par 125 mL (87 g)	
Amount Teneur	% Daily Value % valeur quotidienne
<b>Calories / Calories 80</b>	
<b>Fat / Lipides 0.5 g</b>	<b>1 %</b>
Saturated / saturés 0 g + Trans / trans 0 g	<b>0 %</b>
<b>Cholesterol / Cholestérol 0 mg</b>	
<b>Sodium / Sodium 0 mg</b>	<b>0 %</b>
<b>Carbohydrate / Glucides 18 g</b>	<b>6 %</b>
Fibre / Fibres 2 g	<b>8 %</b>
Sugars / Sucres 2 g	
<b>Protein / Protéines 3 g</b>	
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 <sup>a</sup>	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

<sup>a</sup>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.